



COLORADO CLINICAL AND TRANSLATIONAL SCIENCES INSTITUTE (CCTSI)

COLORADO CTSA HUB

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SPECIFIC AIMS

Funded by NIH since 2008, the **Colorado Clinical and Translational Sciences Institute (CCTSI)** has made substantial progress in advancing translational science by catalyzing innovations in biomedical research, partnering with communities and stakeholders, and developing a strong, resilient workforce in the Colorado region. The CCTSI **vision** is to further accelerate the translation of discoveries into improved, equitable patient care and public health for all. The CCTSI is headquartered at the University of Colorado (CU) Anschutz Medical Campus and is an active partnership between CU Denver, CU Boulder, Colorado State University (CSU), 5 hospitals and 20 community organizations serving minority and rural communities throughout the state. All Partnering Institutions have faculty who lead or administer CCTSI programs and participate in educational and funding opportunities. Partnering Institutions share best practices and provide input and collaboration to improve CCTSI programs and provide new innovations across the CTSA consortium. The CCTSI educates a diverse workforce of professional research staff and investigators, creates a collaborative environment that supports local and multi-site research, partners with communities through its unique PACT-centered community engagement program, creates methodologies that support research in special populations, and enhances health informatics and data science and sharing capabilities. CCTSI infrastructure and professional staff played a critical role in the Colorado response to the COVID-19 pandemic that led to new innovations in research processes and implementation, while at the same time recognizing the overt health inequities exposed by the pandemic. Despite our successes, **there remain many challenges to overcoming inefficiencies and roadblocks in clinical translational science (CTS) processes and to reducing health disparities among rural, minority and underserved populations.** To meet these challenges, we plan to strategically improve the efficiency of research processes, integrations and coordination with Partnering Institutions and across the CTSA Consortium, reinforce our extensive community partnerships, create innovative informatics solutions, and develop a diverse professional translational workforce. This UM1 will be tightly coordinated with our other 6 CTSA grant applications, to accomplish the following **6 Overall Strategic Goals**:

Goal 1: Advance CTS by developing, demonstrating, and disseminating innovative programs to improve the efficiency and impact of translation across the entire T0.5 to T4 spectrum.

Goal 2: Promote collaboration, team and data science, and partnerships to accelerate CTR locally, regionally and nationally.

Goal 3: Partner locally, regionally and nationally with institutions, stakeholders and communities to develop innovative research programs that address health inequities and disparities.

Goal 4: Develop operational efficiencies to increase the quality, safety, efficiency, effectiveness and informativeness of clinical research.

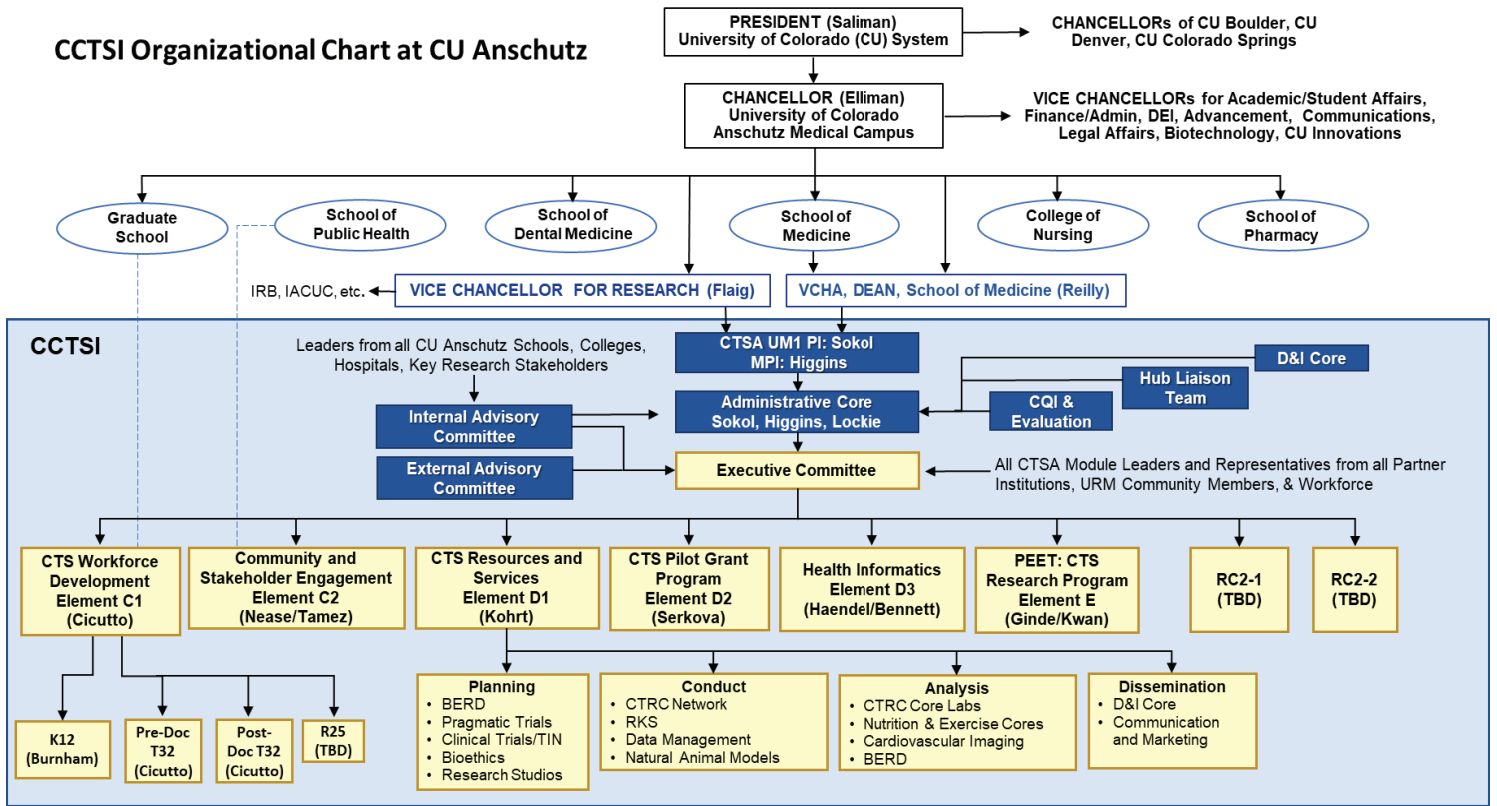
Goal 5: Promote a safe and nimble research environment that can rapidly respond to urgent public health needs.

Goal 6: Develop and disseminate CTS training programs that educate and sustain a resilient, diverse team of clinical research professionals.

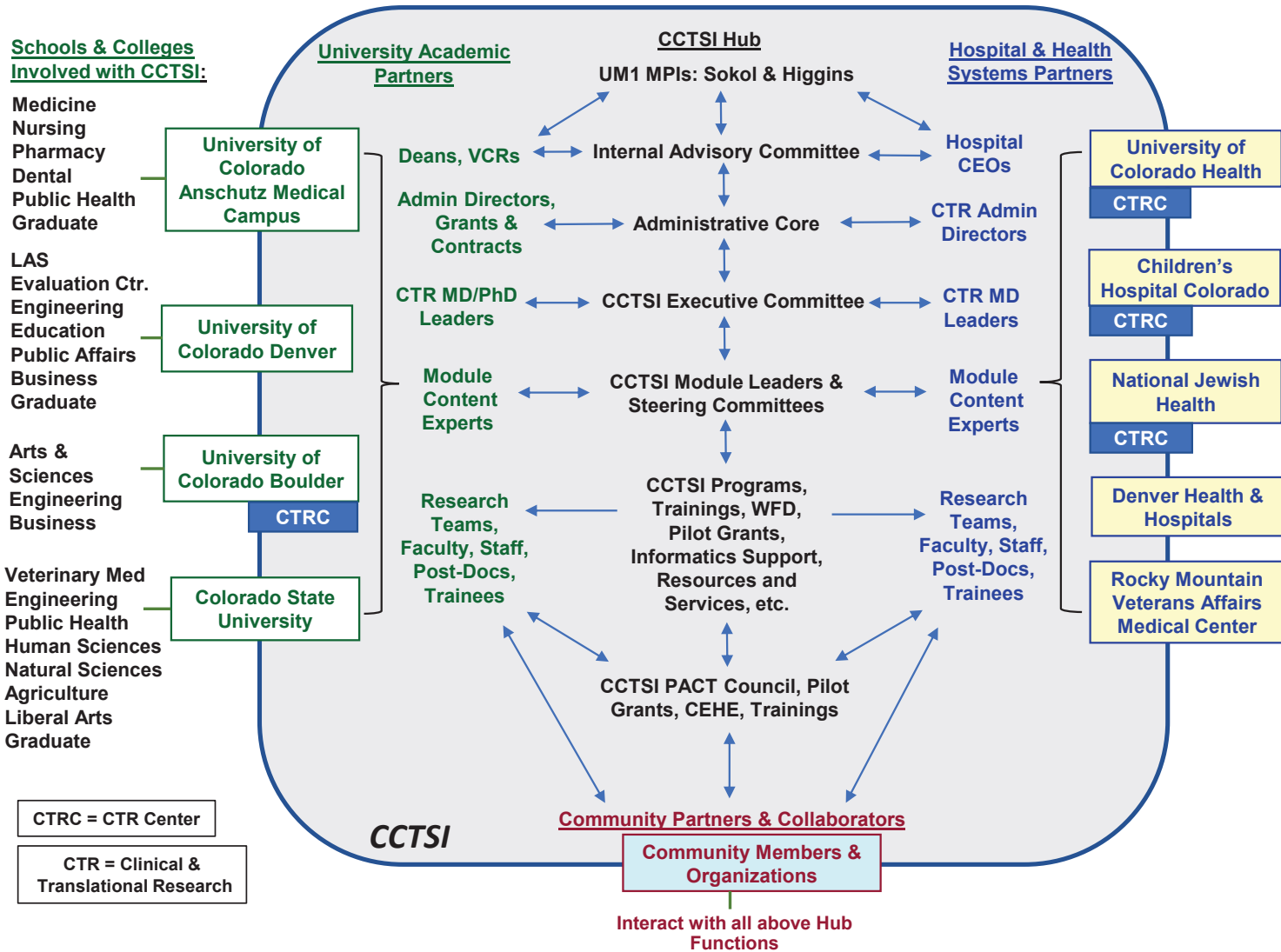
COMMON ABBREVIATIONS USED IN THIS APPLICATION					
ACCORDS	Adult and Child Consortium for Health Outcomes Research and Delivery Science	CTMS	Clinical Trial Management System	I-Corps	Innovation Corps
BERD	Biostatistics, Epidemiology and Research Design	CTRC	Clinical and Translational Research Center (clinical research unit)	QPIP	Quality and Process Improvement Program
CBC	Colorado Biostatistics Consortium	CTR	Clinical and Translational Research	REDCap	Research Electronic Data Capture
CCTSI	Colorado Clinical & Translational Sciences Institute	CTS	Clinical and Translational Science	RKS	Regulatory Knowledge and Support
CE&R	Community Engagement & Research	CU Anschutz	University of Colorado Anschutz Medical Campus	SARC	Scientific Advisory & Review Committee
CHCO	Children's Hospital Colorado	CU Boulder	University of Colorado Boulder	SOD	School of Dentistry
CLSC	Clinical Sciences Graduate Program	CU Denver	University of Colorado Denver	SOM	School of Medicine
CIDA	Center for Innovative Design & Analysis	DH	Denver Health & Hospital Authority	SOP	School of Pharmacy and Pharmaceutical Sciences
COHA	CTSA One Health Alliance	EHR	Electronic Health Record	TIN	Trial Innovation Network
COMIRB	Colorado Multiple Institutional Review Board	HDC	Health Data Compass	TL1, T32	Pre-doctoral Research Training Program
CON	College of Nursing	KL2, K12	Mentored Career Development Program	UCH	University of Colorado Hospital
CO-Pilot	Colorado Translational Pilot Grant Program	KTR	K to R Transition Program	UCHealth	University of Colorado Health System
CSPH	Colorado School of Public Health	MCH	Maternal and Child Health	VCHA	Vice Chancellor for Health Affairs
CSU	Colorado State University	NJH	National Jewish Health	VAMC	Veterans Affairs Medical Center
CTO	Clinical Trials Office	OGC	Office of Grants and Contracts	VCR	Vice Chancellor for Research
CRAO	Clinical Research Administration Office	PACT	Partnership of Academicians and Communities for Translation	WD	Workforce Development

Hub Institution Organization

CCTSI Organizational Chart at CU Anschutz



Working Relationships Between CCTSI Hub and Partnering Institutions



RESEARCH PLAN: Colorado Clinical and Translational Sciences Institute (CCTSI)

ELEMENT A: OVERVIEW

A. SIGNIFICANCE OF CCTSI “HUB AND SPOKE” MODEL

One of medicine's greatest challenges today is the efficient, seamless and safe translation of biomedical research discoveries into clinical applications that can be disseminated and implemented to improve the health of all patients and communities. Significant barriers, social determinants and roadblocks continue to confound our ability to achieve these outcomes, as demonstrated vividly during the COVID-19 pandemic. Moreover, community members from historically underserved minorities and rural locations may be hesitant to partner with academic researchers due to historic distrust, unaddressed cultural differences, poor access to clinical services, and limited experience with mutually beneficial, bi-directional¹, academic-community collaborations. In Colorado we witness these challenges every day in our rural, frontier and tribal communities, racial and ethnic minority groups, and other vulnerable and underserved populations.

To address these challenges, overcome these barriers and accelerate the pace of translating science into improved health in communities throughout our state, the **Colorado Clinical and Translational Sciences Institute (CCTSI)** Hub was created and funded by an NIH CTSA award in 2008, and refunded in 2013 and 2018. The CCTSI is now an established ongoing Hub and Spoke partnership of the 4 major biomedical research university campuses in Colorado, 5 academic hospital systems with strong historic associations with our universities, and community organizations and programs as well as practice-based research networks throughout our state, with collaboration of several state agencies. The CCTSI Hub is headquartered at the **CU Anschutz Medical Campus** just east of Denver, the physical home to the 6 CU health professions schools, including the *only medical (CU SOM), pharmacy, dental and public health schools in the state*, and the location of 3 of our health system partners. Importantly, the Hub is integrated within and extends deeply (Spokes) into our long-standing CCTSI Partner Institutions: two other CU campuses (CU Denver downtown campus and CU Boulder), Colorado State University (**CSU**) in Ft. Collins, and 5 health systems that extend across our state: University of Colorado Health system (**UCHealth**), Children's Hospital Colorado Health system (**CHCO**), Denver Health and Hospitals (**DH**), National Jewish Health (**NJH**), and the Rocky Mountain Regional VA Medical Center (**VAMC**) (see *Hub Institution Organization, Working Relationships Between CCTSI Hub and Partnering Institutions*, and *Coordination and Integration Plan attachments*). Each hospital system brings specific populations served, translational researchers with CU faculty appointments, clinical and unique research expertise and geographic reach extending across our state to enhance the CCTSI statewide impact.

These CCTSI Partnerships were built on the preceding many decades of strong relationships and collaborations between these institutions and our CU SOM with CU faculty, clinicians, residents, fellows and students located within or rotating through each hospital system, all of whom now have access to CCTSI services, training programs and funding opportunities. It should be stressed that faculty at each institution are encouraged to collaborate and be co-investigators in NIH funded research programs across these institutions, creating a uniquely collaborative research environment in our state, which is the basis for the success of the CCTSI structure. Now with over 7,000 members spread across the Partner Institutions (online membership is required to access CCTSI resources), the CCTSI is viewed by leadership, faculty and stakeholders at each institution as integral to their biomedical research enterprise (see *LOS from each Partner Institution Leader*). Importantly, over 20 community organizations across our state participate as CCTSI collaborators through our Community Engagement and Health Equity (**CEHE**) Core and our Pilot Grant and Workforce Development programs, among others. In the proposed suite of 7 planned CTSA grant applications (UM1, K12, Pre and Post-Doc T32, two RC2, and R25), we will strengthen our coordination with our CCTSI Partners and stakeholders and across the CTSA Consortium to accelerate the clinical study life cycle, enrich meaningful bidirectional community partnerships and address health disparities, develop innovative informatics and technology solutions to advance clinical and translational science (**CTS**), and educate a diverse professional workforce for the future, emphasizing diversity, equity and inclusion at all levels. In these and other ways described below, the CCTSI demonstrates all of the Essential Characteristics of Successful CTSA Hubs, as defined in FOA PAR-21-293. **NOTE: Our CCTSI organizational structure will be described in depth in Element B (Elmt 1B.2), and in attachments “Hub Institution Organization” and “Hub Partners and Collaborators”.**

B. VISION, STRATEGIC GOALS AND EXPECTED ACCOMPLISHMENTS AND IMPACT

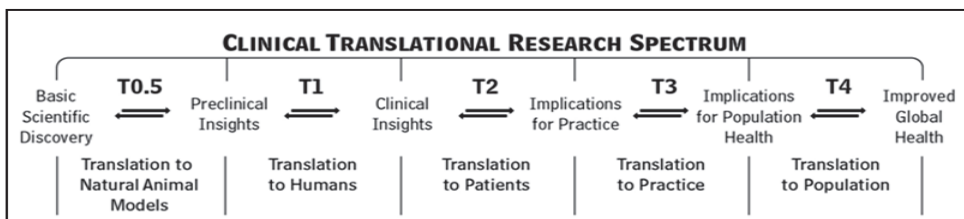
The **Vision of the CCTSI** is to accelerate and catalyze the translation of innovative science into improved, equitable health and patient care for all. We will aspire to this vision through the following **6 CCTSI Strategic**

Goals, which align with the 6 NCATS Goals for the CTSA Program (PAR-21-293). Here, we provide a brief description of the **Approaches** to address each goal and **Expected Accomplishments and Impact**.

Goal 1: Advance CTS by developing, demonstrating, and disseminating innovative programs to improve the efficiency and impact of translation across the entire T0.5 to T4 spectrum.

The CCTSI supports the full spectrum of translational research (**Figure A1**) across medicine, nursing, dentistry, pharmaceutical sciences and public health, and incorporates the expertise of many colleges and schools at CU Anschutz, CU Boulder, CSU and our Partnering Hospital systems and community stakeholders. This broad spectrum of research capacity was instrumental in our response to the COVID-pandemic, in which our investigator teams, institutions and community partners collaborated to better understand the virology and animal reservoirs of SARS-CoV-2; develop and implement best practices in clinical care; develop and lead the N3C national effort (Drs. Haendel and Bennett); develop diagnostics and vaccines; efficiently enroll and retain diverse cohorts in numerous clinical trials of vaccines and therapeutics; engage and address

Figure A1. Spectrum of Clinical and Translational Research



disparities and needs of communities with underserved populations across the state; and provide accurate information and messaging about COVID-19 to minority groups that have historically distrusted the medical establishment through Colorado Community Engagement Alliance Against COVID-19 Disparities (CO-CEAL). We will use these lessons learned (see **Elmts B, C and D**) to: **1)** advance CTS processes and improve our efficiency in study design and accelerate study approval and start-up; **2)** further build our community and stakeholder engagement, communication and support network; **3)** disseminate best practices to other CTSA hubs; **4)** focus on health equity and disparities among Colorado populations of color and geographical isolation; and **5)** further expand use of N3C infrastructure to improve public health. Through our Evaluation Core and our Continuous Quality Improvement (**CQI**) program, we will process map roadblocks to efficiency, measure metrics of impact for each module, and implement bottleneck solutions (**Elmt B**). We will also measure Impact of our research programs through application of the Translational Science Benefits Model from Washington University². To accelerate and support NIH-funded multi-site clinical studies and trials, we will employ our Hub Liaison Team (**HLT; Elmt B**) and significant clinical research Resources and Services (**Elmt D**), including our 4 CCTSI-operated clinical research units (**CTRCs**) integrated into Partnering Institutions. Our renewed campus-wide efforts to bolster data science and health informatics capabilities, including creation of the Chief Research Informatics Officer (**CRIO**) position and the new Dept. of Biomedical Informatics at CU Anschutz, and the expansion our Google-cloud data warehouse and investigator friendly software to enhance data analysis, will accelerate our impact (**Elmt D3**). Many other innovations will be implemented as outlined in the Approach sections of Modules in **Elmts B to E**.

Goal 2: Promote collaboration, team and data science, and partnerships to accelerate CTR locally, regionally and nationally.

The CCTSI has a strong track record of promoting and incentivizing collaboration, partnerships, and team science with our Partnering Institution and across the CTSA consortium. In the next grant period, we will continue to strengthen the relationships among our Partnering Institutions and our inter-disciplinary research collaborations across institutions, take action to ensure diversity in the make-up of research teams (including gender/racial/ethnic diversity), and educate investigators in the science and application of team science. We will continue to emphasize collaboration as a key review criterion in our Pilot Grant programs, including our CU-CSU collaborative Pilot award (**Elmt D2**). We will initiate and evaluate a transformative new program in which we will integrate both leadership and team training into a trans-institutional unified program called "**Leading and Teaming**", designed to improve effectiveness and success of team-oriented research locally and then to disseminate across the CTSA consortium (**Elmt C1**). The results of these new programs will be carefully and thoroughly evaluated for metrics and impact by our Evaluation Core (**Elmt B**). With the considerable investments made at CU Anschutz in data science and informatics over the past three years (>\$50 million), we will also expand our Health Informatics (**Elmt D3**) program and data warehouse (Health Data Compass) to improve accessibility and interoperability of regional and national data sharing and analytics. These will be essential for national partnerships in data science, as demonstrated by the transformative National COVID Cohort

Collaborative (N3C), led by our Health Informatics Co-Lead, Melissa Haendel, PhD, and our current involvement within NIH/NHLBI funded programs addressing long COVID (**RECOVER**) and CEAL initiatives (**CO-CEAL**).

Goal 3: Partner locally, regionally and nationally with institutions, stakeholders and communities to develop innovative research programs that will address health inequities and disparities.

Community Engagement & Research (**CE&R**), with meaningful bi-directional participation of community members and other stakeholders in our research and training programs as well as in leadership committees, has been a priority throughout the 14-year lifespan of the CCTSI. We will continue to engage and build trust with patients and communities as **active partners** in the full spectrum of CTR to address priorities and health inequities identified by community members, co-design studies in a culturally-sensitive and participant-friendly structure, implement and disseminate findings into the community, and enhance public trust in research. Our many CE&R programs (**Elmt C2**) and CE Pilot grants (**Elmt D2**) are conceptually joined as a pipeline of resources to serve and educate investigators and community stakeholders as partners seeking to identify, address and reduce health inequities and ultimately improve community health. In **Elmt C2** of this application we describe in detail our strategy for achieving our CE&R goals over the next 7 years and our metrics to measure impact. We will expand existing successful programs, create new initiatives and disseminate those that prove to be successful and generalizable. The benefits of these new interactions will be evaluated by the Evaluation Core.

Goal 4: Further develop operational efficiencies to increase the quality, safety, efficiency, effectiveness and informativeness of clinical research.

This goal is to continuously innovate and streamline our operational and regulatory processes and methods to ensure that **1)** research performed at our Universities and Partnering Institutions is of the highest quality, **2)** barriers to recruitment, enrollment and operations are identified and overcome, **3)** we accelerate study protocol approval, start-up, implementation and completion, **4)** we maximize efficiency in our operations and the conduct of clinical research and trials, and **5)** the safety of human research participants remains our highest priority. We will also expand efforts to build trust in communities (**Elmt C2**) that have been historically underserved in order to provide equitable research participation opportunities that matter to the communities. **Elmt D1 (Resources and Services)** outlines operational innovations that will accelerate study start-up, ensure quality and safety, support complex clinical research studies, and enhance recruitment and retention, with focused efforts on rural and underserved populations. **Elmt B, Goal 2** outlines how we will evaluate research programs for outcomes and translational impact/informativeness and continuously improve programs through our Quality and Continuous Process Improvement Program (**QPIP**). Finally, our established HLT in collaboration with the Trial Innovation Network will ensure that highest quality and best practices are employed in multi-site studies that originate from CCTSI investigators (**Elmt B**).

Goal 5: Promote a safe and nimble research environment that can rapidly respond to urgent public health needs.

The COVID pandemic taught us how important it is for our institutions to respond quickly and effectively to a national health emergency. Not only did our clinical care require dramatic changes, but our research environment was dramatically altered in ways previously unimaginable. The CCTSI, in coordination with the VCR office and leadership of Partnering Hospitals, rapidly developed and instituted many new policies and procedures that will ensure our ability to conduct critical research in an accelerated fashion if needed in a future emergency. Lessons learned in 2020-2022 have been published and archived. Critical to our ability to rapidly shift to research priorities during an emergency is the fact that the CCTSI manages clinical research units (CTRCs) and staff at CU Anschutz, two Partnering Hospitals and CU Boulder. We now have the know-how to quickly re-categorize human research studies into those that should or should not be paused during an emergency, rapidly obtain regulatory approvals and execute contracts for urgently needed new research (e.g., COVID vaccine trials), redeploy research personnel to critical research studies/trials, and rapidly pivot our research units to patient care, if needed, among other critical operational responses. We now have the ability for staff to work remotely when needed, have adequate PPE in stock, have adopted tele-research methods, and have executed advanced infection control measures as needed. More details re: Emergency Plans are in **Elmt B** and **Elmt D1, Goal 4**.

Goal 6: Develop and disseminate CTS training programs that educate and sustain a resilient, diverse team of clinical research professionals

Ensuring a diverse, superbly trained translational research workforce is a critical objective of the CCTSI. To accomplish this, we will: **1)** focus our training and career development initiatives to support pipeline programs to

expand diversity within our professional workforce and to enhance feedback from the workforce. **2)** We obtained a **CTSA Diversity KL2 supplement** this current cycle (Dr. Demetria McNeal) and will continue to apply for these supplements. **3)** We will weave our value that “Diversity Accelerates Research and Translation” into all workforce development (**WD**) programming. **4)** We will work with **CU Anschutz Health Profession Schools and our Partnering Institutions, all of which have programs strongly committed to increasing the diversity of faculty, students, workforce & leadership (see Letters from CEOs and Deans)** and have established offices or Vice Chancellors of DEI. **5)** We will provide training opportunities in Teaming and Leading, mentoring, grant reviews, and Communicating Research to the Public. **6)** We will ensure the entire CCTSI workforce receives training in DEI, Good Clinical Practice, Responsible Conduct of Research, research ethics, and regulatory compliance. Major efforts to retain our research staff will also be prioritized. Details for this Goal are in **Elmt C1, Facilities and Other Resources**, and the accompanying **Pre- and Post-Doc T32 and K12 grant** applications.

C. THE ASSEMBLED CCTSI LEADERSHIP TEAM

In this section, we focus on the **Leadership Team** assembled to execute the goals of the CCTSI and NCATS (see also **Hub’s Senior Leadership** attachment). A full description of the organizational structure, integration of components, and qualifications and unique attributes of the CCTSI Partner Institutions will be provided in **Elmt B (1B.2.1 and 2.2)** and the **Hub Institution Organization** and **Coordination & Integration Plan** attachments.

Administrative Core and Executive Committee: The CCTSI Hub is governed by an Administrative Core and Executive Committee (EC) composed of investigator and administrative leaders from each Partnering Institution with extensive experience in oversight of complex organizations and programs and long-standing expertise in the conduct and facilitation of CTS and CTR. The Administrative (Admin) Core will oversee financial and administrative activities and the EC (meeting virtually or in person twice per month) will be the decision-making, strategic planning, and integrative body. The EC includes the MPIs, research leaders from each Partnering university and hospital system, two community representatives, and Element and Module leaders. *Please see Biosketches and Budget Justification for academic and professional achievements of each individual below.*

Admin. Core Leadership includes:

- **Ronald J. Sokol, MD, UM1 Contact MPI**, Distinguished Professor of Pediatrics, Strategic Management Module Leader and Director of the CCTSI (responsibilities described in **Elmt B.1**) since the CCTSI inception in 2008. Dr. Sokol will be responsible for all aspects of the implementation and functions of the CCTSI. He will be involved in and ensure integration of all Elements of the UM1 grant and the programs funded by the K12, Pre- and Post-Doc T32, the two RC2 and the R25 grant applications. He will oversee all of the Element and Module Leaders, Chair the CCTSI EC and the Administrative Core, and will communicate with leaders of Partnering Institutions. He has a long basic science and clinical investigative career focusing on mechanisms underlying childhood liver diseases, clinical trials and health outcomes. He is chair of several national studies and trials funded by NIDDK and has been PI on NIH funded basic, clinical and translational research grants for >35 years.
- **Janine Higgins, PhD, MPI** and Professor and Vice Chair for Research, Department of Medicine, will work with Dr. Sokol to lead and manage integration and collaboration across all Elements of the UM1 and RC2 programs. Dr. Higgins has been CCTSI Director of Operations for 8 years and will continue to oversee the day-to-day workflows in all CCTSI programs and ensure that resources are being used efficiently. Dr. Higgins will Co-Chair the CCTSI EC with Dr. Sokol and will work as a key member of the Administrative Core. Dr. Higgins will work to inform and implement initiatives from the CPI Program across resources. Dr. Higgins has over 20 years of experience in pre-clinical and clinical nutrition research, including design and delivery of dietary intervention studies for single- and multi-center trials and key roles in NIH multi-center consortia. Dr. Higgins is known for her work developing novel methods to measure dietary intake using wearable sensors.
- **Tim Lockie, MS, MBA, Director of Finance and Administration (DFA)** has functioned in this position since 2008. Mr. Lockie has a scientific background (MS in Medical Genetics) and finance background (MBA) as well as years of operational, grants management, human resource, clinical research infrastructure development, and fiscal management experience at CU Anschutz. Mr. Lockie has forged strong relationships with senior administrative and finance leaders of CU Denver and each of its schools and all of the CCTSI Partnering Universities and Hospitals.

Module Leaders. The CCTSI Leadership Team will include the following 8 CCTSI Module Leaders who will be responsible for directing the operations and functions, implementation, and oversight of each Module, and are all voting members of the CCTSI EC (see **Hub Institution Organization Attachment**).

- **Lisa Cicutto, RN, MSc, ACNP (cert), PhD**, Module Leader for Workforce Development (WD; Elmt C.1), current PI of TL1 NRSA Training grant and Associate Director of CCTSI KL2 Career Development, is an

accomplished researcher in lung health and has sustained uninterrupted extramural funding since 1998. Dr. Cicutto will be responsible for directing and coordinating the overall activities of the Education and WD programs and participate on the national CTSA WD Enterprise Committee. She will also serve as the PI for the CCTSI Pre- and Post-Doctoral T32 grants and sit on the CCTSI EC. Dr. Cicutto is a faculty member in CO School of Public Health and the College of Nursing and is based at NJH, a CCTSI Partner.

- **Donald Nease Jr., MD, MPH**, Module Leader for Community & Stakeholder Engagement Research (Elmt C.2), is Professor and Vice Chair for Community Research in the Department of Family Medicine at CU SOM. Dr. Nease also directs the Colorado SNOCAP (State Networks of Collaborating Ambulatory Practices and Partners) practice-based research network collaborative, which is based at CU. Dr. Nease has over 25 years of experience in practice and community-based research in topics that include mental health care, cancer prevention and control and health information technology. Dr. Nease will sit on the CCTSI EC.

- **Wendy M Kohrt, PhD**, Module Leader for CTS Resources and Services (Elmt D.1), is a Distinguished Professor of Medicine (Division of Geriatric Medicine) at CU-SOM. Dr. Kohrt is an NIH-supported clinical investigator, continuously funded for more than 30 years, whose research focuses on lifestyle and pharmacologic interventions to mitigate metabolic and functional declines with advancing age. Dr. Kohrt is the Director of the Energy Balance Core Laboratory for the NIH-sponsored Nutrition and Obesity Research Center, and current Director of the Hub Research Capacity Core of the CCTSI for the past 5 years. Dr. Kohrt will oversee the extensive Resources and Services Module and sit on the EC.

- **Natalie Serkova, PhD**, Module Leader for CTS Pilot Module (Elmt D.2) since 2020, is Professor of Radiology at CU Anschutz. Dr. Serkova will develop the annual RFAs for each Pilot Grant program, oversee the application process, including scientific advice and support to the applicants, the review process and selection of awardees. She will also track progress and outcomes of the awardees. Dr. Serkova will facilitate dissemination of our REDCap peer-review process platform to other CTSA hubs. Dr. Serkova will sit on the EC.

- **Tellen Bennett, MD, MS**, Module Co-Leader for Health Informatics (Elmt D.3), Associate Professor of Pediatric Critical Care and Biomedical Informatics, currently is Informatics Director for the CCTSI and has developed translational informatics infrastructure and services across the CCTSI Partner campuses. He is an expert on EHR data use in research, data security and data sharing and has played a major national role in the National COVID Cohort Collaborative (**N3C**) as Co-Lead of the Clinical Scenarios and Analytics team. He will oversee implementation of Health Informatics Goals 1 and 3 and will sit on the EC.

- **Melissa Haendel, PhD**, Module Co-Leader for Health Informatics (Elmt D.3), Professor and Chief Research Informatics Officer (CRIO) at CU Anschutz, is nationally known in the health informatics community, being one of the creators of N3C and other national data sharing and computational collaboratives (include CD2H and the Monarch initiative). She has been a member of the CTSA Consortium Steering Committee, and relocated to Colorado in 2020 where she coordinates CCTSI informatics services with Dr. Bennett. Dr. Haendel will lead implementation of Health Informatics Goals 2 and 4, and will sit on the CCTSI EC.

- **Adit Ginde, MD, MPH**, Module Co-Leader for Elmt E: Pragmatic EHR-embedded Trials Research Program, Professor of Emergency Medicine, has been the Director of the CCTSI Trial Innovation Network HLT and has been actively involved in NIH-funded clinical trials in the acute and emergency setting, including numerous COVID-19 trials. He has held national leadership positions in the NHLBI PETAL and CONNECTS networks and ACTIV-3. He is director of a large NCATS-funded real-world evidence (RWE) trial of monoclonal antibodies for COVID-19 being conducted through the CCTSI and UHealth in Colorado. Dr. Ginde brings his extensive expertise and experience in clinical trials to co-lead the new CTS Research Program (Elmt E) using pragmatic trial approaches in EHR-embedded clinical trials. He will be a member of the CCTSI EC.

- **Bethany Kwan, PhD, MSPH**, Module Co-Leader for Elmt E, Associate Professor of Emergency Medicine, is the lead for the CCTSI D&I Core and is nationally known for her expertise in dissemination and implementation (**D&I**) science and pragmatic research. She is a co-investigator with Dr. Ginde and lead for D&I aims on the monoclonal antibody RWE study. As PI for an AHRQ R13 on pragmatic research methods and a PCORI multi-site pragmatic trial, Dr. Kwan brings her extensive expertise in pragmatic trial conduct and stakeholder engagement in designing for dissemination and implementation. Dr. Kwan will be a member of the EC.

D. CONTRIBUTIONS OF THE APPLICANT AND PARTNERING INSTITUTIONS TO CTS RESEARCH

The CCTSI Hub and Partnering Institutions share a rich history of collaborating to advance human health and patient care. Highlights of representative major accomplishments over the past 5 years are described in the attachment Tables **CTS Track Record** and **Clinical Trial Experience**. The following examples will illustrate **several notable high-impact, innovative CCTSI contributions** that have advanced research towards better methods, processes and ultimately human health:

- **I-Corps@CCTSI:** I-Corps is a team-based immersive innovation learning program taught by faculty with an entrepreneurial background, which prepares teams to compete for SBIR/STTR funding. I-Corps@CCTSI launched in 2016 at CU Anschutz and has continued to expand to include our Partners at CU Denver Downtown, CSU and Hospitals during this past 5 years. To date we have trained 81 teams representing a spectrum of T1 to T4 translation, each with a product for commercialization. Utilizing what we call a 'warm hand-off,' I-Corps participants are provided direct access to resources and individuals who can facilitate next steps in product development following I-Corps. The I-Corps@CCTSI program has become immensely popular, necessitating the addition of a third training cohort for each year. CU Anschutz is now ranked as the #5 academic institution globally by the Nature Patent Influence Metric.
- **Clinical Science Graduate Program (CLSC):** One of the first of its kind in the nation, the CLSC is the CU Anschutz degree-granting (Masters and PhD) program for advanced training in CTS and CTR. The CLSC has expanded over the past 5 years to now be the second largest graduate program at CU Anschutz. This program strongly promotes team science, enhancing diversity of our researchers, and places a strong emphasis on mentorship and understanding the needs of Colorado's rural, minority and underserved populations. Over 78% of CLSC alumni hold grant support and 87% are persistent in translational research careers.
- **Colorado Community Engagement Alliance Against COVID-19 Disparities (CO-CEAL),** funded by NHLBI, conducted innovative work since 2020 promoting **Health Equity** in 5 urban and rural racial and ethnic communities in Colorado, leveraging our CCTSI infrastructure to reach racial/ethnic underserved communities that have been disproportionately impacted by COVID-19. We utilized community members as the key individuals responsible for the work of CO-CEAL as they have the expertise in their communities' needs and have the trusted relationships. We created two new roles: *Community Connectors*, who have the primary responsibility of overseeing the work in their community through recruitment of Community Translation participants, and recruitment and oversight of *Community Data Collectors*, the second new role, who have engaged and recruited members of their community to respond to serial surveys about COVID-19 misinformation, trusted sources of information and vaccine hesitancy (see **Elmt C2** for details).
- **COVIDome.** Leveraging a number of CCTSI resources, Dr. Joaquin Espinosa and colleagues evaluated blood specimens from COVID positive and negative patients at UCH during the first months of the COVID pandemic. Multi-omics and immunophenotyping were performed creating multi-dimensional datasets integrated with clinical data, that were made accessible to the international community through an online research portal, the *COVIDome Explorer*. This project was designed to enable the development of better prevention, diagnostic, and therapeutic tools for the clinical management of COVID-19 through open science collaboration. New insights into the roles of specialized interferons in COVID pathogenesis using these data were recently published in PNAS.³ The COVIDome was highlighted as an open science innovation on the NCATS website in 2021.
- **Health Data Compass (HDC) Research Data Warehouse:** Established in 2017, HDC is the world's first integrated large-scale clinical, administrative, genomic, and population-based research data warehouse *on the Google Cloud Platform*. We established governance and secure data integration pipelines to HDC including: hospital EHR data, Colorado death registry, vaccination, and all-payer claims databases, state and national environmental data sources, Colorado Center for Personalized Medicine genomic Biobank resources (currently ~200,000 patients and growing) and made those data available to investigators for high-impact linked analyses. Data are surfaced to investigators for cohort discovery using a variety of technologies including Leaf (in beta testing) and external applications such as TriNetX, i2b2, and Tableau. HDC also continues to be leveraged for national initiatives, such as N3C and others. We are sharing the cloud-based technology with other CTSA Hubs.
- **COVID-19 Monoclonal Antibody (mAb) Therapy Real World Evidence and Dissemination and Implementation Study.** Leveraging many of the innovations developed by the CCTSI over the past several years, Drs. Adit Ginde and Ronald Sokol obtained a CTSA supplement (~\$8 million) in 2021 to conduct a study to design and evaluate strategies to enhance dissemination and equitable access to mAbs, and to gather Real World data in the UC Health and Denver Health systems for prevention of hospitalization and death in COVID positive patients receiving mAb therapies propensity matched to those not receiving mAb therapy. This study demonstrated mAb real world effectiveness during the alpha and delta waves of COVID, and that the original mAb therapies were ineffective against the omicron variant. These data were used to inform federal agencies on effectiveness of mAbs in real-time and resulted in several published^{1,4-8} and submitted manuscripts. Collaboration between the CCTSI CTRCs, D&I Core, CEHE Core, CU Denver, UCHHealth, DH, Colorado Department of Public Health & Environment, and others was essential for the success of this project, which may be a forerunner to a national program for COVID treatment effectiveness surveillance.

ELEMENT B. STRATEGIC MANAGEMENT

A. STRATEGIC GOALS

The Colorado Clinical and Translational Sciences Institute (CCTSI) leadership proposes the following 3 *Strategic Goals* for Strategic Management of the Institute over the 7-year UM1 grant period, with Dr. Ronald J. Sokol as the Strategic Management Module Leader:

Goal 1. Provide an integrated **Overall Management Plan** and **Organizational Governance Structure** that engages Partnering Institutions and constituencies and garners feedback to achieve the vision of the CCTSI.

Goal 2. Promote a **Continuous Quality Improvement (CQI) and Evaluation Program** to ensure system-wide monitoring, analysis and actions that will result in the highest quality, efficiency and safety of CCTSI programs.

Goal 3. Establish **Internal and External Advisory Committees** to annually review CCTSI progress and make recommendations for improvement.

B. RESEARCH PLAN

GOAL 1. OVERALL MANAGEMENT PLAN: Provide an integrated Overall Management Plan and Organizational Governance Structure that engages Partnering Institutions and constituencies to achieve the vision of the CCTSI.

1A. SIGNIFICANCE. The CCTSI, created in 2008, is a CU institute with the authority and broad reach to forge relationships within the CU system and establish partnerships and collaborations with outside universities, hospital systems, community stakeholders, and industry. The Director and Contact MPI of the CCTSI, Dr. Ronald J. Sokol has programmatic authority and autonomy to implement the programs and functions of the Institute, manage the space assigned to CCTSI, and hire and fire personnel within the Institute. Strong buy-in has been obtained from CU Anschutz, CU Denver, CU Boulder and CSU leadership, the Deans of each CU health profession school, CEOs of the 5 Partnering Hospital and Health Care Organizations, multiple community organizations (see **Letters of Support**), corporate leaders, officials at each campus, and most importantly, faculty, investigators, trainees and research staff. The CCTSI is actively involved in identifying and solving roadblocks and barriers to effective translational science; providing essential resources and services to the translational science community; expanding data science and sharing capabilities; engaging with community stakeholders to address health inequities and DEI; and establishing and advancing a multitude of innovative training and educational programs to ensure a diverse, nimble workforce that conducts high quality ethical research and at the ready for any national health-related emergency. In these and many other ways, the CCTSI has transformed the translational science landscape in Colorado and its relationship to communities throughout the state. For this Goal, we describe our leadership, organizational structure and communication plans, strengths of Partnering Institutions, efforts to ensure diversity and inclusion in leadership and staff, readiness for national health emergencies, planning and coordination of research activities/funds, management plan for competing institutional perspectives, structure and functions, and Dissemination and Implementation strategies.

1B. APPROACH

1B.1. LEADERSHIP PLAN

1B.1.1. OVERALL ORGANIZATIONAL STRUCTURE, LEADERSHIP, AND GOVERNANCE. The CCTSI has been a formal CU Institute since 2008 headquartered at the CU Anschutz campus and governed by a highly collaborative Executive Committee (EC) chaired by Ronald J. Sokol, MD, the Director and Contact PI in the current application. The Director reports to the CU Anschutz Vice Chancellor for Research (VCR), Thomas Flaig, MD, and the Vice Chancellor for Health Affairs (VCHA), John Reilly, Jr. MD, the Dean of the School of Medicine, who in turn report to the CU Anschutz Chancellor, Donald Elliman, Jr., who oversees the entire campus and all of its Schools and programs including the Deans of all health sciences schools (Medicine, Nursing, Pharmacy, Dentistry, Public Health, Graduate School), and who reports to the President of the CU System (see **Hub Institution Organization**). The VCR and VCHA work closely to integrate and support educational, research and clinical programs at CU Anschutz, thus the dual reporting of the CCTSI Director to both of these individuals ensures campus-wide integration of CCTSI programs. The CCTSI sits within the VCR office, along with central administration research support including the basic science support team, clinical research operations team, laboratory animal resources, regulatory and compliance administration, and Chief Research Informatics Officer (CRIO) office. *Although the CCTSI Hub administratively is based at CU Anschutz, its programs extend deep into the Partnering Universities and Hospital systems with each Partner being represented in the CCTSI leadership*

team and with subcontracts established from the Hub to each Partner (Hub and Spoke; see 1B.2). The MPIs, Drs. Sokol and Higgins, will meet monthly (or more often as needed) with the VCR and every 2 months with the VCHA to review CCTSI progress and challenges. The Internal Advisory Committee (see below) further ensures strong communication and integration of CCTSI programs within Partner Institutions. The VCR, Dr. Flaig, attends CCTSI EC Meetings (see below) to ensure alignment of CCTSI programs with other programs on the campus.

The **Directors/MPIs** (Ronald Sokol, MD and Janine Higgins, PhD) will have institutional responsibility and authority for all aspects of the CCTSI including: **1)** oversight of all administrative, strategic, academic, operational, programmatic and financial functions, **2)** control over assignment of space and allocation of resources assigned to the CCTSI, **3)** relationships with the Partnering Institutions, **4)** collaboration with other CTSA through the National CTSA Consortium, **5)** interactions with NIH/NCATS Program Officer, and **6)** maintenance of career development opportunities to encourage new investigators in clinical and translational sciences. The MPIs will work with Department Chairs throughout the Health Profession Schools at CU Anschutz and Partner Hospitals, and the Vice Chancellors of Research and appropriate departments at CU Boulder, CU Denver and CSU, to recruit translational investigators and ensure their protected time for research and ensure promotion of investigators. (Note: The CCTSI does not have authority to directly hire faculty, who must have an appointment in a department within a school or college). The MPIs are viewed as campus and hospital leaders in clinical and translational science, research and training and sit on important committees at CU Anschutz, including the Executive Committee of the School of Medicine (SOM), the Clinical and Translational Research Advisory Committee to the VCR and VCHA, the Enterprise Data Warehouse planning committee, the Research Advisory Forum at University of Colorado Hospital (UCH), and Research Institute Scientific Committee at Children's Hospital Colorado (CHCO) among others. The MPIs are established scientists who are recognized academic leaders with funded research programs, excellent administrative, fiduciary and communication skills, and highly regarded by the Partnering Institutions and community organizations (see **LOS** and **Multiple PI Plan**).

The CCTSI **Director of Finance and Administration** (DFA), Tim Lockie, MS, MBA, will work closely with the MPIs to prepare and administer the budget for each year; oversee the program income system; oversee day to day fiscal management and monitor expenses; ensure compliance with institutional and federal grant management policies; manage subcontracts with Partnering Institutions; generate fiscal and other required reports; direct CCTSI human resources; manage the administrative, financial and operational teams; work closely with Human Resources to annually survey engagement from Admin Core personnel and address their needs; attend monthly Department/Division/Centers Administrator meetings; coordinate the preparation of the annual RPPRs; participate as a member of the CTSA National Consortium Administrators Enterprise Committee and attend annual meetings; and direct the Administrative Core.

The CCTSI functional units will be organized into an **Administrative Core, Executive Committee** and **11 Core Programs** which have been aligned to match the Module Functions outlined in PAR-21-293 (see **Hub Institution Organization**) and additional CTSA grant applications that we will be submit in response to separate FOAs (K12, Pre and Post-Doc T32, RC2x2 and R25) and which will remain seamlessly incorporated into the CCTSI governance structure as they are now. Each of the UM1 Modules will be overseen and managed by a CCTSI Module Leader or Co-Leaders (see **Hub's Senior Leadership**) who report to Drs. Sokol and Higgins, and is/are responsible for the functions, implementation, and oversight of their Module/Program. Each Module may contain several Cores to address specific functions. Each Module Program will have a Steering Committee chaired by the Module Leader which will meet monthly or bimonthly; administrative staff will be assigned to each Module Program to ensure operational and fiscal effectiveness. Each Module leader will sit on the Executive Committee to ensure communication and integration among the CCTSI programs.

The **CCTSI Executive Committee (EC)**, the governing body of the CCTSI, chaired by Dr. Sokol (and Dr. Higgins in his absence), will meet twice monthly for 90 minutes to **1)** review progress of CCTSI programs (including UM1, K12, T32s, RC2s and R25 programs); **2)** integrate activities and operations across Partnering Institutions; **3)** approve pilot grant funding; **4)** review stakeholder engagement issues and translational obstacles and develop solutions, **5)** discuss evaluation and CQI of the Program; **6)** review the annual Workforce Personnel Engagement Survey; **7)** work with the Evaluation and CQI programs to implement process improvement and efficiency measures, and **8)** review progress made toward the DEI goals for leadership and programs and implement change as necessary to achieve the goals. The EC will include the MPIs, 8 Module Leaders and other Core leaders, the directors of the K12, two T32, RC2 and R25 programs, two Community representatives from PACT, the Hub Liaison Team director, the CQI director, the Evaluation Core director, one research leadership representative from CSU, CU Boulder, UCH, DH, NJH, VAMC, CHCO, and the DFA. The EC in this configuration will function as an integrated cross-institutional team, *as they have during the past 14 years*, and will serve as

ambassadors of the CCTSI on and off campus. **The presence of leadership of each of the main CCTSI functional units and Partners at EC meetings promotes effective communication, integration and collaboration.** Meetings are held in person with virtual access available to ensure participation by all. The MPIs and DFA also hold a separate weekly meeting to set agendas for EC meetings and review operations.

1B.1.2. LEADERSHIP SUCCESSION PLAN: It is essential that the MPIs/Program Directors and Module Leads undergo a rigorous annual evaluation with input from stakeholders, and that replacement be considered if performance does not meet expectations. The Directors will undergo an annual performance review by the VCR and VCHA based on 1) annual self-review, 2) information gathered by the VCR and VCHA, and 3) a written evaluation by the CCTSI External Advisory Committee (**EAC**, see **3B.2**). The MPIs will evaluate performance of the Module Leads, using objectives and specific criteria. Replacement of Directors or Module Leaders will be considered if they have not capably carried out their job responsibilities, if they are unable to perform all of their duties because of other responsibilities, or if they leave the institution or resign from their position. The VCR and VCHA will make the final decision on replacing the MPIs/Directors and the Directors will decide on the Module Leads. If replacement of either of the MPIs is required, the remaining PI will assume both roles until the VCR and VCHA assign an interim co-Director from the EC. Many members of the EC are now familiar with the workings of the CCTSI to be able to step into that role. The VCR will be the signatory for the Program Directors in their absences. The Search Committee for a new PI/Director will be chaired by the VCR and VCHA, and will include Deans of the 6 health science schools (or designees), CEOs (or designees) from the 5 affiliated Hospitals, high-ranking representatives from CU Boulder, CU Denver, CSU, and 5 faculty involved in translational research. The Search Committee will forward ranked names to the VCR and VCHA for final decision. For replacement of a Module Lead, the Directors will consider replacements after consulting with the EC, Internal Advisory Committee (**IAC**, see **3B.1**), and Deans of the 6 health science schools, with final sign-off by the VCR and VCHA. In the unlikely situation where the VCR and VCHA cannot come to a mutual agreement, the Chancellor will make final decisions.

1B.2. PARTNERING INSTITUTIONS AND STAKEHOLDERS

The CCTSI, based at CU Anschutz, has evolved over the past 14 years into the academic home for clinical and translational investigators and sciences at the CCTSI Partnering Institutions, including 4 public research university campuses, 5 academic hospitals and health systems, and over 20 community organizations and PBRNs (see **Hub Institution Organization, Working Relationships Between Hub and Partners, Coordination & Integration Plan**). The academic institutions and hospitals are located primarily in the Denver metropolitan area, Boulder (30 miles away) and Ft. Collins (65 miles away) with the **health systems and community organizations extending across much of Colorado**. CSU, several community partners, and UHealth facilities are located in northern Colorado, closer to Cheyenne, Wyoming, than Denver, facilitating broad reach to diverse populations throughout the state and beyond. These institutions and communities have collaboratively achieved success over the past 40 years in promoting excellence in education and training in all health care professional fields and in cutting-edge research programs. The first 14 years of the CCTSI program has helped to solidify the academic and educational partnerships among these institutions, with numerous programs (and NIH grants) spanning across multiple institutions (see **1B.2.1** and **.2**). Each university has extensive health related academic programs with substantial research funding, and they have collaborated together on NIH Center grants, program projects, T32 grants, and other research programs (e.g., Comprehensive Cancer Center, NORC, RECOVER & BIRCWH). Basic statistics and NIH grant funding in 2021 for the University partners are found in **Table B1**. Here, we provide a brief description of our

University or School	Location	# Faculty	# Students	FY-22 NIH Funding (Total Cost)	FY-22 Total Funding
CU Anschutz	Aurora	5,499	4,571	\$326.4M	\$691.6M
<i>Medicine</i>	Aurora	4,913	1,716	\$284.1M	\$577.2M
<i>Nursing</i>	Aurora	186	1,244	\$1.7M	\$8.8M
<i>Pharmacy</i>	Aurora	111	564	\$7.9M	\$15.5M
<i>Dentistry</i>	Aurora	132	324	\$4.7M	\$4.4M
<i>Public Health</i>	Aurora	157	723	\$22.7M	\$52.7M
CU Denver	Denver	1,127	14,884	\$7.5M	\$18.9M
CU Boulder	Boulder	4,150	35,897	\$55.9M	\$630.1M
Colorado State	Ft. Collins	1,872	32,908	\$48.3M	\$391.7M
TOTAL		12,648	88,260	\$438.1M	\$1,732.3M

Partnering Institutions and stakeholders. *Additional description of each Institution and their important roles in the CCTSI is provided in **Hub Partners and Collaborators** and **Facilities and Other Resources**.*

1B.2.1. CU DENVER AND PARTNERING RESEARCH UNIVERSITIES

(see **Hub Partners and Collaborators** and **Facilities and Other Resources** for details)

- **University of Colorado Denver (CU Denver)**, in 2021 designated as a Hispanic Serving Institution and Asian American Native American Pacific Islander Serving Institution (AANAPISI) by the U.S. Dept. of Education,

is a comprehensive University with a Downtown Denver Campus and the Anschutz Medical Campus 9 miles east in Aurora, CO. With more than 12 schools and colleges, CU Denver awards more than 3,400 degrees each year and more graduate degrees than any other institution in Colorado. The **Downtown Denver Campus** is the *most ethnically diverse college campus* in Colorado and offers bachelor to doctoral degrees in the full spectrum of liberal arts and professional fields, with many programs to support students from minority and underserved populations to participate in biomedical and translational research and pursue careers in health science related fields. **382 Downtown Denver faculty and trainees are registered as CCTSI Members.** The CCTSI Evaluation Core is housed at the CU Denver School of Education and Human Development.

- **CU Anschutz (a CU Denver campus)**, is the central headquarters of the CCTSI and is home to the 6 CU Health Profession Schools (see below), including the only medical, pharmacy and dental schools in the state. CU Denver research and training *grant awards were \$691 million in FY 2022 with \$326 million received from NIH (Table B1).* Over **4,950 faculty, staff, and trainees** on this campus are registered CCTSI Members. The Chancellor and the Deans of each CU Health Profession School have provided **Letters of Support.**

CU Anschutz is home to the **CU School of Medicine (SOM)**, one of the outstanding public medical schools and research institutions in the United States. SOM houses the NIH-funded CU Comprehensive Cancer Center, which is a partnership with CU Boulder and CSU. SOM faculty and trainees are involved in all CCTSI programs. The **CU College of Nursing (CON)** is the premier nursing school in the Rocky Mountain West and is best known as the birthplace of the nurse practitioner program, and for research in community outcomes, informatics, and human caring. CON trainees and faculty have major involvement in the Clinical Science PhD graduate program, Health Informatics and the Community Engagement and Research activities of the CCTSI. The **CU Skaggs School of Pharmacy and Pharmaceutical Sciences (SOP)** is consistently ranked among the top pharmacy graduate programs and ranked 12th in NIH funding in 2021. The school has developed a cutting-edge Medicinal and Translational Pharmacology Program. The **CU School of Dentistry (SOD)** is the preeminent dental school within the Rocky Mountain West. The School pioneers research in oral cancer, Native American oral health, salivary gland disease, neurobiology, pain control and tissue engineering. The **Colorado School of Public Health (CSPH)**, created in 2007, is a partnership between CU Denver, CSU and University of Northern Colorado. The CSPH plays a major role in the Clinical Sciences, K12 and T32 training programs and T3 and T4 translational research programs within the CCTSI and houses the CCTSI Biostatistics (BERD) Core. **CU Denver Graduate School** offers 21 PhD graduate programs and five Master's Programs and is where the CCTSI CLSC PhD program of our Workforce Development program is housed.

- **CU Boulder** is a premier research university, including 8 schools and colleges and 44 doctoral degree programs. With 5 Nobel Laureates on faculty, there is a rich history of innovation leading to human applications in fields of biotechnology, medical research, biochemistry, biology, and engineering. *Grant awards exceeded \$630 million in FY 2022 with > \$56 million received from NIH.* Interdisciplinary collaboration between CU Boulder and CU Anschutz investigators has led to major discoveries in bioengineering, tissue engineering, congestive heart failure, congenital heart disease, the microbiome, circadian misalignment, pharmaceutical biotechnology, and molecular biology. **386 CU Boulder faculty, staff, and trainees** are CCTSI Members. Partnership is evidenced by the CCTSI-directed CTRC (clinical research unit) located at CU Boulder and the many CO-Pilot grants awarded to CU Boulder faculty. A major CCTSI goal will be to expand collaborative research and training programs between CU Boulder and CU Anschutz. *The Provost of CU Boulder has provided a Letter of support.*

- **Colorado State University (CSU)** is a public land grant institution located in Fort Collins, one hour north of Denver. CSU includes 8 colleges and over 30,000 students, including the renowned College of Veterinary Medicine and Biomedical Sciences, ranked #2 in NIH grants in 2021. CSU is a leading research university in animal sciences, atmospheric science, infectious diseases, and environmental science, with *total federal research awards exceeding \$284 million in FY 2022 including >\$48 million in NIH support.* Collaborative research and education programs have taken place for decades among CSU faculty, CU Anschutz and CU Boulder faculty. CSU is a partner in the CU Comprehensive Cancer Center, the Nutrition and Obesity Research Center (NORC, NIDDK), and the CSPH, with major CU Anschutz research collaborations in infectious disease, cancer, exercise physiology, HIV/AIDS research, vaccine development, COVID, and community engagement and research. Partnership in the CCTSI is further evidenced by the Natural Animal Models of Human Diseases core, the "Teaming and Leading" program directed by CSU faculty, and the **568 CSU faculty and trainees registered as CCTSI Members** who benefit from CCTSI programs. *The VP of Research has provided a Letter of support.*

1B.2.2. HOSPITAL AND HEALTH SYSTEM PARTNERING INSTITUTIONS (see also **Hub Partners and Collaborators** and **Facilities and Other Resources**). The following Partnering Institutions have played

essential roles in the CCTSI since its formation in 2008, and for decades before that related to the CU SOM. A research leader from each hospital is a member of the CCTSI EC and participates in the twice monthly meetings to facilitate frequent communication, integration of programs and participation in decision-making of the EC. Hospital Leadership are also members of the IAC which meets bi-yearly to provide input and advice to CCTSI leadership. In addition, the MPIs meet at least annually with leadership of each Partnering Hospital to update on stewardship of resources and alignment of strategic directions in translational science and research. NOTE: *All researchers at the following hospitals have primary or secondary faculty appointments at a health profession school at CU Anschutz.*

- **University of Colorado Hospital (UCH)**, located on CU Anschutz campus adjacent to research and education buildings, is a private, not-for-profit hospital (not owned by CU) for adults and is one of the primary teaching hospitals for SOM. UCH is consistently ranked among the top hospitals in the country by *US News and World Report*. Facilities include a 665-bed hospital, the Anschutz Outpatient Pavilion (> 550,000 visits annually), and the Anschutz Cancer Center. UCH is dedicated to research and quality improvement in clinical care. CCTSI CTSCs are located at UCH and UM1 Elements C, D and E will use UCH facilities and resources. UCH EHR data are integrated into the Enterprise Data Warehouse (Health Data Compass; HDC). **1,932 CCTSI Members** list UCH as their primary clinical affiliation. Tom Gronow, UCH President, gives his full support and partnership with the CCTSI and CTSCs (see **CEO Letter of Support**).
- **University of Colorado Health System (UCHealth)**. Created in 2011, the *largest health system across Colorado* combines UCH with 11 other hospitals in Colorado and Wyoming, totaling over 1,800 hospital beds and >1.5 million annual outpatient visits. All facilities use a single EHR (Epic) leading to unprecedented opportunities for performing clinical trials, personalized medicine and community-based research. The CCTSI will play a major role in developing and integrating clinical research infrastructure, data sharing and training across UCHealth. UCHealth EHR data from all of its hospitals and facilities are integrated into HDC. UCHealth will be instrumental in the operations of Elements C, D, and E in this application.
- **Children's Hospital Colorado (CHCO)**, one of the preeminent academic pediatric healthcare institutions in the nation, is a private, not-for-profit independent hospital with a strong affiliation with CU Anschutz and commitment to clinical and translational research. Consistently ranked in the top 10 Children's Hospitals by *US News and World Report*, its 1.4 million ft² facility on the Anschutz Medical Campus is in close proximity to the health science schools, UCH, and the CU Denver training and research facilities. EHR (Epic) data are integrated into HDC. Total beds are 444 and there are >600,000 outpatient visits annually. The CHCO CCTSI CTSC is one of the most active in the nation. CHCO will be instrumental in the operations of Elements C and D, K12, and T32 programs of the CCTSI. **1,385 CCTSI Members** list CHCO as their primary clinical affiliation. Dr. Sokol, MPI, is also Chief Scientific Officer at CHCO. Jena Hausmann, President and CEO of CHCO, has pledged her partnership and full support to the CCTSI (see **CEO Letter of Support**).
- **National Jewish Health (NJH)** is known world-wide for ground-breaking basic and translational research and treatment of respiratory, immune, and allergic disorders. NJH is a non-sectarian, not-for-profit academic hospital which has been ranked in top 2 in respiratory diseases for >20 consecutive years by *US News and World Report*. NJH faculty have appointments in the CU SOM, mentor trainees and junior faculty in the SOM and collaborate on many shared NIH grant programs. A CCTSI CTSC unit and Core Lab facilities are housed at NJH (for the past 26 years). **123 CCTSI Members** list NJH as their primary clinical affiliation. Michael Salem, MD, President and CEO of NJH, has pledged ongoing partnership and support to the CCTSI (see **CEO LOS**).
- **Denver Health and Hospitals (DH)** is a premier safety net hospital for underserved urban diverse minorities, providing healthcare for over 25% of all residents in the City of Denver. DH is a comprehensive, integrated health care organization, including a 477-bed hospital, the Denver Public Health Department, an 11-site network of school-based health centers, correctional care, and a 9-clinic network of family health centers throughout Denver. DH SOM faculty are active in training of SOM investigators and have been international leaders in community translational research and informatics technology, trauma and surgical research, health disparities and outcomes research, and HIV prevention and treatment. **176 CCTSI Members** list DH as their primary clinical affiliation. Plans are for DH EHR data to be incorporated into HDC in the next grant period. Donna Lynne, President and CEO of DH, has committed partnership and support for the CCTSI (see **CEO Letter of Support**).
- **Rocky Mountain Regional Veteran's Affairs Medical Center (VAMC)**, adjacent to the CU Anschutz campus, is a training site for CU SOM residents in all adult specialties and has a highly diverse patient population. The VAMC is a 182-bed, 1.1 million ft² facility. Supported by >\$25 million of grant funding, the VAMC conducts

major clinical and translational research in cardiovascular epidemiology, health disparities, gastrointestinal cancer, chronic hepatitis, mental health, neurodegenerative diseases, diabetes, substance abuse and geriatrics, many in collaboration with SOM. VAMC faculty (e.g., Jane Reusch, MD) hold leadership positions within the CCTSI. **126 CCTSI Members** list VAMC as their primary clinical affiliation. Robert Keith, Director of VAMC, has pledged continued CCTSI partnership (see **Letter of Support**).

1B.2.3. COMMUNITY IMPACT - ORGANIZATIONS AND PARTNERSHIPS. Through the CCTSI Community Engagement and Health Equity (CEHE) research program, sustained relationships with over 20 community organizations from historically underserved communities spread across Colorado have been established over the last decade. The Partnership of Academicians & Communities for Translation (PACT) is the governing body of the CEHE program and is a statewide collaborative of academic researchers, community-based organizations, practice-based research networks (PBRNs) and healthcare provider networks working together to provide a platform for innovation in CEHE research (see **Elmt C2 & Facilities and Other Resources**). The PACT is governed by a 16-member Council, meeting quarterly, with equal representation from communities and academic institutions. PACT oversees our Community Engagement Pilot Award program. Among the PACT members is the Shared Network of Colorado Ambulatory Practices & Partners (SNOCAP), which includes 7 large PBRNs which cover the state of Colorado and have performed over 80 research studies. PACT and SNOCAP organizations cover nearly 300 physician practices, 30 hospitals and one million individuals, representing rural, frontier, underserved, LGBTQ+ and minority populations across Colorado.

1B.2.4. COMMUNICATION PLAN, COLLABORATION, AND INTEGRATION OF PARTNERING INSTITUTIONS IN THE CCTSI HUB. Theoretically, one might anticipate major differences in institutional culture among the CCTSI Partner Institutions that would create competing institutional perspectives and would be a challenge for implementing a CTSA Hub across 4 university campuses and 5 academic hospitals. However, in reality, **these institutions have worked collaboratively for decades** and are well aligned in missions and actions. For example, all research and most clinical faculty in each of the 5 hospitals are faculty in the CU SOM, Pharmacy, Public Health, Dentistry or Nursing, as CU Anschutz campus is the location **of the only health profession schools for >500 miles in any direction**. Thus, translational scientists interested in research have sought and received appointments at CU, regardless of their hospital affiliation, for >40 years. The establishment over 20 years ago of a central IRB (COMIRB) on record for 5 of the institutions further illustrates the willingness of the organizations to work together to achieve efficiency and best practices. In a state with poor governmental support of higher education, it is essential that the major public universities (CU Denver, CU Boulder and CSU) collaborate and share core facilities and other resources to be successful, and this is certainly the case in Colorado. Leadership at each of the 5 hospitals are also committed to the CCTSI mission and the CU Health Profession Schools in order to achieve their own missions. Thus, the VCHA of CU Anschutz meets regularly with hospital Presidents and CEOs of all the Partner Institutions, further ensuring open communication channels for collaboration. It should be emphasized that faculty at CU Boulder, CU Denver and CSU collaborate on hundreds of projects each year across institutions, co-mentor graduate students, publish together and are co-investigators on major grants, illustrating the collegial relationships between the academic institutions themselves. Leaders of each Partnering Institution are members of the CCTSI IAC, providing another opportunity for communication and collaboration. Finally, the many CCTSI training and education programs are available to trainees and faculty at all Partner Institutions. Thus, the national reputation of our institution as a highly collaborative environment permeates through the CCTSI programs & partnerships. (See **Coordination and Integration Plan** attachment.)

Contributions to CCTSI (see also **Hub Partners and Collaborators**): Each university and academic hospital will contribute to the CCTSI scientific collaborations, provide faculty and mentors for training programs, faculty for administrative CCTSI positions, facilities and participants for clinical studies and trials, clinical research space, core facilities, EHR data for HDC (UCH, CHCO, and DH in future), and will include active Members of the CCTSI. **CCTSI Membership** is available to faculty, trainees, public or private companies experienced or interested in CTS, and interested community members and requires an online application – there are currently **over 7,000 CCTSI individual members**. CSU has unique attributes in veterinary sciences including Natural Animal Models of human disease, CU Boulder has outstanding strengths in engineering, biochemistry and integrative physiology, NJH in immune and allergic disorders, DH to a diverse patient population and research in health disparities (e.g., collaborator in COVID mAb and RECOVER studies), and CU Anschutz is home to all health profession schools in the state. These institutions are **justified** to be partnering with the CCTSI as they expand the diversity of faculty, trainees, research staff and patient populations that might participate in research, provide needed clinical trial capacity (especially during a public health emergency), bring unique scientific and clinical strengths, extend the geographic reach and access to research across the state of Colorado, and have

strong track records in research in health disparities and inequities. In addition, there is a long and successful history for partnerships in education and research. Thus, there is a bi-directional reciprocity between the CCTSI and its Partnering Institutions that has worked exceptionally well for decades.

Decision-making and input: The CCTSI EC, the decision-making body, will include leaders from each Partnering University and Hospital, Module and Core leaders, and Community stakeholders who will be voting members in decision-making and strategy. Representation on the CCTSI IAC (which meets biannually) includes high ranking leadership from each Institution, as well as the health profession school Deans. Drs. Sokol and Higgins will conduct town hall meetings at least annually at each partner institution to provide information and receive input from faculty and staff. Input from trainees and from R&S users (PIs, staff, administrators, and managers) is provided via surveys performed by the Evaluation Core at least annually. Research staff input will be provided both directly, through reports from the CRSP Development Program Directors, and indirectly from the Research Operations and Strategic Integration (ROSI) service's User Advisory Boards (UABs) comprised of all stakeholders (PIs, coordinators, budget specialists, statisticians) and hospital administration representatives. These groups guide and prioritize CTSC QPI projects at local and network levels.

COMMUNICATION PLAN: Drs. Sokol and Higgins will maintain ongoing communication with leadership, Members and staff by facilitating: **a)** monthly meetings with VCR and VCHA, **b)** biannual IAC meetings in which leaders from all Partnering Institutions will participate, **c)** Town Hall meetings for faculty and staff for CCTSI updates at each Partnering Institution at least annually, and **d)** EC bimonthly meetings for direct input from all Partners for decision making and strategy planning. Dr. Sokol meets annually with each Hospital Leadership to provide resource stewardship updates. The CCTSI emails weekly announcements and a quarterly e-newsletter ("Found in Translation") to all >7,000 Members. The CCTSI website (>6,000 visits per month) is an important vehicle for communication. In addition, CCTSI employs an outstanding Communications Director, Ms. Wendy Meyer, who provides announcements, outreach and marketing of CCTSI programs to all Partnering Institutions and their Member constituents and is part of the national CTSA Consortium communication working group.

1B.2.5. PLANS TO PROMOTE DIVERSITY AND INCLUSION IN LEADERSHIP AND STAFF. The CCTSI and CU Denver value principles of fairness, diversity, equity and social justice in relation to, and across, intersections of race, age, color, disability, faith, national origin, citizenship, sex, sexual orientation, ethnicity, gender identity and gender expression. The CCTSI is committed to ongoing examination of our organizational policies and practices to ensure that we are in alignment with these values and to work in partnership with our leaders, faculty, staff, trainees and community partners to create an inclusive culture of equity and one that identifies and removes structural racism elements. We believe that a diverse faculty and research staff will foster innovation and creativity, emphasize research that matters to community members, contribute to the learning environment, improve the quality of the research, advance the likelihood that underserved or health disparity populations will participate in, and benefit from, health related research, and build public trust and community partners in the research enterprise. Moreover, the CU SOM believes that a diverse student body enhances excellence in medical education and practice and its students **are the pipeline for future CTS investigative teams**. A primary goal of CU SOM is to increase the matriculation of students from backgrounds underrepresented in medicine (URM). CCTSI and CU Denver have taken considerable efforts over the last 4 years to **identify barriers for and create solutions in this regard**, which have increased the diversity of students, faculty, staff and other members of the CTS workforce at our institution. E.g, 30% of CU medical students are now from URM backgrounds.

The CCTSI has successfully increased the **gender diversity** of CCTSI leadership, EC membership, and in our staff, such that the majority of our EC members, Module Leads and Core Directors in this application are female, our MPI is female, and our EC (our decision-making body) includes community members of Hispanic and African American heritage. In 2021, we instituted a CCTSI **DEI and Social Justice Committee** and **1)** have active diversity and anti-racism educational trainings required of all staff employed by the CCTSI, **2)** have instituted new hiring practices to ensure inclusive candidates are interviewed and considered for all positions, **3)** are integrating health equity and social determinants of health considerations into the planning, conduct and dissemination of research across the CTS spectrum, **4)** are detecting and mitigating algorithmic bias in artificial intelligence (AI) systems and machine learning, **5)** are examining and cleansing our hiring and recruiting practices for any structural racism that may be exposed, **6)** have successfully obtained a KL2 Diversity Supplement during the current cycle and will continue to submit applications for additional supplements, and **7)** In the next funding cycle, we will methodically address and implement local solutions for the **DEI recommendations by Boulware et al. for the CTSA programs** that originated from the NCATS 2020 Annual Meeting^{9,10}. We are committed to increasing further the diversity and broad representation of our CCTSI Leadership Team and be held accountable to these initiatives, as described on our CCTSI public website. Our

campus now has a VC of DEI and Community Engagement, Regina Richards, PhD, MSW, who we work with closely in developing and implementing our DEI programs, plans and solutions.

1B.2.6. PLAN FOR PUBLIC HEALTH EMERGENCY. During 2020-2022 in the COVID-19 pandemic, the CCTSI, in coordination with the VCR and Chancellor's offices, rapidly developed and instituted many new policies and procedures to ensure that we could continue to conduct critical research of high impact while ensuring the safety of our research participants and staff, and **we now have a plan in place to deploy these strategies for any future public health emergency.** We now have the full capability of rapidly switching to a remote and virtual leadership and staff meeting structure, as well as for our educational and training programs, using Zoom or a similar platform, a pivot that has served us extremely well in 2020-2022. All leaders and staff are provided the required remote equipment for their home and in their offices for this virtual communication mechanism. We can rapidly realign activities in order to respond. In the pandemic, we quickly learned how to efficiently assess each research study to determine those that needed to be shut down temporarily, switch to tele-research formats (which we have developed extensively over the past 3 years), or continue (such as COVID clinical trials) out of necessity for public health. We learned how to rapidly redirect our human and other resources to the most urgent clinical trials and research (e.g., COVID vaccine trials, mAb and antiviral clinical trials, acute care and ICU clinical care trials, etc.) and these learnings will be adapted to a future pandemic or other health emergency. We learned how to rapidly conduct IRB review and execute contracts, assess and approve much needed urgent clinical studies/trials while protecting participant and staff safety, with initial review to study start-up happening in as little as 10 days. Our budgeting and contracting offices worked at warp speed, and it was all hands-on deck for months. We also redeployed much of our research nursing staff to assist with staffing clinical care units when there were staff shortages, since our research units were temporarily closed. Our inpatient CTSC unit (and staff) was converted to a patient care area when UCH was overwhelmed with COVID inpatients. There were many more lessons learned, including rapidly establishing a single entry "research restart" portal and policies for all research protocols at CU Anschutz, UCH, and CHCO, novel research pharmacy operations, adapting CTSC Scheduler to ensure that only research approved to continue could conduct study visits, institutional policies restricting access to research and campus buildings, and new safety measures. A new system was developed that tiered research studies based on risk, allowing for systematic, fair and transparent restart of clinical research operations across all CU Anschutz Partners, again demonstrating our willingness and effectiveness to work collaboratively to achieve optimal outcomes^{11, 12}. Finally, the CCTSI created a new Pilot Grant program in March 2020 for clinical research in COVID diagnostics or therapeutics that went from grant application to study start-up in 12 days, a fraction of our usual turn-around time. CCTSI staff and leadership were intimately involved in developing and implementing all of these new campus policies and procedures and will play a critical role in implementing new policies and procedures in any future public health emergency.

1B.2.7. PLANNING AND COORDINATION OF RESEARCH ACTIVITIES AND CONFLICT RESOLUTION. The CCTSI leadership and EC, which includes leaders across CCTSI programs and Partnering institutions sitting at the same table, have had an outstanding collaborative working relationship for the past 14 years with strong communication and engagement of all involved parties. For decisions resting with the EC, we anticipate that a collegial consensus will continue to be the mode of decision making. If critical issues arise that cannot be decided through consensus, the Program Directors/PIs will discuss them with VCR and VCHA and come to a final decision. The CCTSI IAC will be an additional venue for open discussion of issues that cut across institutional boundaries, with high level institutional representation present for meetings. We have several principles that we will enact: e.g., CCTSI resources will be prioritized for NIH-funded or other federally-funded investigators, trainees and investigator-initiated research projects. After funding source is considered, allocation to Member investigators and trainees will be based on merit and need, and not on their location or academic affiliation. Specific resources (e.g., Pilot funds) will be set aside to ensure inclusion and diversity. The decision-making processes for allocation will be transparent and fair. If conflicts arise between the major CCTSI institutions that cannot be resolved at the PI/Director level, CU Anschutz highest leadership (Chancellor, VCR and VCHA) will become involved. We do not anticipate such situations to arise given the collegial, collaborative and respectful relationship between all CCTSI stakeholders and our long history of collaboration.

At times **resource allocation** may require difficult choices given our flat NIH budget in the face of considerable cost inflation, but it will be handled in a fair and transparent manner. Data collected by Module Leaders, study tracking systems and Evaluation Core data will be submitted to the Administrative Core nearing the end of each annual UM1 funding period. Specifically, the Evaluation Core triangulates data from needs assessments, utilization surveys, and monitoring of metrics for each Core/Program which will be used to assist making resource allocation decisions. Using these data as performance measures, the MPIs/PDs and DFA will determine

appropriate budget and resource allocation for each program for the upcoming year. Actions taken may include increased support for a component, re-allocation of resources to a more utilized component, instituting strategies to increase utilization, or termination of a program or component Leader. Factors under consideration for allocation of resources will include 1) the value of the Program/Core to the mission of the CCTSI, 2) utilization of the resources and the performance measurement for the prior year, 3) potential negative impacts if the function were to be scaled back or eliminated, 4) the proposed budget for the next year, 5) the availability of funds either from the NIH grant, program income or institutional support, and 6) national CTSA Consortium and NCATS strategies and priorities. The final decision on distribution of resources and the budget will be made by the MPIs.

Finally, **synergy among our UM1, K12, T32s, RC2s and R25 programs** will be built into our EC structure, with the PDs/PIs for each of these programs being active members of the CCTSI EC. With all of the Module and Core directors attending our EC meetings twice monthly, we have built the structure to ensure optimal communication and integration of these programs within our Hub. The CCTSI Evaluation Core will review and discuss the evaluation of each of these programs with the EC annually.

1B.2.8. HUB LIAISON TEAM AND PARTICIPATION IN THE NATIONAL CTSA CONSORTIUM. The CCTSI Hub Liaison Team (HLT) led by Dr. Adit Ginde, has functioned as an interface with the Trial Innovation Network (TIN) for the past 5 years, facilitating local investigators in accessing TIN resources for multi-site studies and identifying Colorado investigators to participate in multi-site TIN studies proposed from other Hubs. The CCTSI is now positioned to expand our HLT with individuals that will interface with other national collaborative activities of the CTSA Program, including innovative approaches to collection, analysis, use and sharing of various types of data and digital health research; support for workgroup, scientific and training activities of the CTSA Consortium; participating in clinical trials supported by NCATS and the CTSA program; dissemination of innovations in clinical trials (e.g., our infrastructure for the NCATS-funded CTSA supplement Real World Evidence trial of monoclonal antibodies being conducted at UHealth by Adit Ginde, MD, MPH); and interfaces with the collaborative informatics community (e.g., our Hub efforts leading CD2H and N3C). Dr. Ginde will continue to function as our HLT Director with other HLT members continuing their roles based on national consortium activities that will be active when our UM1 grant cycle begins in 2023.

1B.2.9. DISSEMINATION AND IMPLEMENTATION (D&I) CORE AND ACTIVITIES. The CCTSI D&I Core, which has been an essential component of the CCTSI for the past 5 years and is directed by Bethany Kwan, PhD, MSPH, will expand its services to **integrate D&I systems, methods, and principles across all CCTSI components and support and build capacity for use of D&I science methods for all CCTSI members and Partners.** We will build upon the Core's national reputation for advancement of "designing for dissemination and sustainability" (D4DS) and pragmatic approaches for CTS¹³. Such approaches consider multi-level context and stakeholder and community involvement in design, conduct, and active dissemination of research to ensure the products of research will "fit the context" of intended use¹⁴ improving the speed at which research products will scale up. D&I activities will be guided by a process framework (the F2C Framework for D4DS)¹³, a determinants framework (diffusion of innovation [DOI] theory)^{15,16}, a CTS product framework (Translational Science Benefits Model; TSBM)^{2,17}, and an outcome evaluation framework (RE-AIM¹⁷). The F2C Framework informs the process of D4DS by grounding CTS in four phases: 1) conceptualization (determining evidentiary support and stakeholder demand for an innovation), 2) design (context and situation analysis; product development, proof of concept, and messaging, and distribution that fits the context for intended use – i.e., the product is acceptable, feasible, and sustainable for decision makers), 3) dissemination (enactment of dissemination strategies), and 4) impact (assessing adoption, sustainment, and equity impacts). D&I will inform context and situation analysis and dissemination planning (e.g., understanding systems of communication/influence are critical factors to consider in dissemination planning); the TSBM Benefits Checklist will inform the types of CTS products (i.e., "translational sciences benefits") to be distributed at the clinical, community, economic and policy levels; RE-AIM will inform evaluation of the Reach, Effectiveness, Adoption, Implementation, and Maintenance outcomes of CTS products.

The D&I core¹⁸ leaders will participate in all CCTSI EC meetings to identify strategic opportunities for integration of D&I across all Hub activities. We will prioritize 1-2 major opportunities per year for new collaboration, synergies, and/or incorporation of D&I science methods in local implementation and consortium-wide dissemination of CCTSI scientific and operational innovations. An example of successful D&I Core integration with other CCTSI components is the real-world evidence COVID mAb project described on last page of Element A^{4-8,18-20}. In year 1 we will collaborate with the Evaluation, CEHE, and Health Informatics Cores to establish novel data systems for assessing impact of CTS at scale based on the TSBM Checklist and priority outcomes for communities and stakeholders (**see Element D. Resources and Services, D&I**). We will be readily accessible for D&I consultation for all CCTSI core teams and activities and will serve as D&I experts on major

CCTSI-affiliated research and infrastructure-building initiatives. We will offer several services and resources to CCTSI member investigators and staff to provide D&I and pragmatic research training and team science opportunities.²¹⁻²³ This includes the pragmatic trials navigation service, D&I science education, mentoring, and consultation services, and the CCTSI Dissemination Service. We will continue to serve as faculty for the D&I graduate certificate program courses and COPRH Con. We will lead and participate in National CTSA Consortium D&I working groups and cross-CTSA grants, papers, and projects. A priority need for cross-CTSA collaboration is the development of a common and generalizable system of conceptualization, design, distribution, and impact assessment of CTS innovations across the CTSA consortium and other networks. We will seek funding to collaborate with other CTSA to design, test, and scale-up a sustainable model for CTSA innovation dissemination systems.

Successful achievement of these objectives over the course of the 7-year award will benefit from enhanced systems, infrastructure, and partnerships for conducting D&I research, including the use of investigator self-guided D4DS tools and resources.²⁴⁻²⁷ **In year 1** of the new funding period, we will systematically explore opportunities for new partnership building for D&I research by holding a series of D&I research roundtables with existing and emerging stakeholder groups. We will start with roundtable discussions with specific research groups (e.g., Centers for American Indian and Alaska Native Health (CAIANH); the VA's Seattle-Denver Center for Center of Innovation; the Colorado Health Institute) and use snowball and consensus methods (nominal group technique²⁸) to identify other stakeholder groups across statewide and national sectors with D&I training and research partnership potential. We will subsequently engage priority partners in D&I training, demonstration, and/or research grant proposals.

The CCTSI D&I Core, part of the Admin Core (see **Hub Institution Organization**), will be directed by **Bethany Kwan, PhD, MSPH**, who has led the core since 2019 and will attend all CCTSI EC meetings. CCTSI D&I priorities and resource allocation will be determined by Dr. Kwan, Dr. Higgins and Dr. Sokol and informed by the CCTSI EC and EAC on an annual basis. **Dr. Heather Gilmartin, PhD, NP**, Clinical Assistant Professor, will be the Associate Director and Co-I for CCTSI D&I.

GOAL 2. CONTINUOUS QUALITY IMPROVEMENT AND EVALUATION: Promote a Continuous Quality Improvement (CQI) and Evaluation Program to ensure system-wide monitoring, analysis and actions that will result in the highest Quality, Efficiency and Safety of CCTSI programs.

2A. SIGNIFICANCE AND INNOVATION. The CCTSI has robust efforts related to tracking, evaluation, CQI and impact of the CCTSI which are being conducted by the CCTSI Evaluation Core based at The Evaluation Center, CU Denver Downtown Denver Campus, in coordination with our established Quality and Process Improvement Program (QPIP; the CCTSI CQI program) at CU Anschutz. The Evaluation team is comprised of Ph.D.-credentialed evaluation professionals (led by Goldie Komaie, PhD) who, with senior-level staff support, collectively bring more than 6 decades of experience with conducting large-scale evaluations for NIH, NSF, CDC and the U.S. Department of Education. The team includes evaluators with specialized quantitative and qualitative expertise who have applied their skills to develop and implement evaluations that are rigorous, robust and data-driven, and support broad-based organizational change and capacity-building initiatives. The QPIP team is led by Leah Emerick, BS, a Lean-trained Senior Continuous Improvement Specialist with the Office of the Vice Chancellor for Research at CU Denver. A rigorous, external tracking, assessment and evaluation program, coupled with a formal, internal quality and process improvement program, will ensure the most efficient, cost-effective, and innovative use of resources. As the external evaluator, the Evaluation Core will in the next grant cycle to collect metrics that examine and document the impact of the CCTSI through **four Objectives: 1) Establish specific metrics to demonstrate local CTSA impact through rigorous program evaluation; 2) Disseminate research results and best practices broadly; 3) Integrate QPIP activities to continuously improve programs and impact; and 4) Participate in national-level efforts to develop and metrics to measure the impact of the CTSA program.** The results of the Evaluation Core's work will inform the CCTSI MPs and EC on priorities for process improvements to be conducted by QPIP. In this section, evaluation plans related to assessing CCTSI's local impact on CTS as well as using the TSBM to demonstrate real-world impact are described.

2B. APPROACH

2B.1. Objectives 1-2: Establish and disseminate specific metrics to demonstrate local CTSA impact. The Evaluation Core will develop pragmatic and rapid approaches to measurement of key metrics and evaluation of implementation, process, adoption, and sustainability of each of our CCTSI programs. For this new grant cycle,

our evaluators will now implement use of the novel TSBM² to establish evidence for **impact of our programs** focusing on real-world impact. The TSBM model includes 30 indicators that demonstrate impact in four domains relevant to CTR and CTS: clinical and medical benefits, community and public health benefits, economic benefits, and policy and legislative benefits. **As an example**, our Evaluation Core has applied the TSBM checklist to the CD2H/N3C program evaluation and disseminated a one-page Impact Profile that demonstrates the clinical, community, economic cost savings, and policy benefits that CD2H has had on the CTSA consortium and broader informatics community. Working closely with our D&I Core, the Evaluation Core will apply the TSBM model to CCTSI programs to develop exemplar case studies to disseminate to local stakeholders and to the CTSA consortium. *Examples of specific Metrics are listed at the end of Modules in Elements C through E.*

2B.2. Objective 3: Integrate CQI and QPIP activities to continuously improve programs and impact.

Recognizing that improving quality, decreasing waste, and establishing efficient and transparent processes are characteristics of successful CTSA Hubs, the CCTSI transformed its organizational structure in 2012 by incorporating QPIP. QPIP (the CCTSI CQI program) is made up of seasoned quality and Lean-trained process improvement medical professionals, directed by Leah Emerick, and integrated with the Process Improvement team in the VCR office. The QPIP team will apply its expertise to improve processes that are considered critical to a successful and efficient CTS enterprise. QPIP assessments have already led to re-engineering of the CCTSI BERD core, our CTCRC participant scheduling process, personnel deployment in our CTCRCs and other operational improvements. QPIP will work to: **1) Identify and remove obstacles to efficiency and process improvement in priority areas, 2) Form clearly identified and empowered process improvement teams, 3) Link with the Evaluation Core to ensure results of efforts are monitored and evaluated, and 4) Integrate CQI into CCTSI governance and decision-making structures.** QPIP will identify several roadblocks each year in our translational research processes (e.g., participant visit scheduling at CHCO CTCRC and study start-up delays for new trials), process map these, and use Lean and Six-Sigma approaches to improve efficiencies. **For example**, their team is currently working on improving processes to reduce time to clinical trial start-up at CU Anschutz, including our Cancer Center trials; working on a review of data security in our data warehouse, Health Data Compass; and working with our CU Anschutz Biobanking Core to improve its processes. In this way, through interactions with the Admin Core and the EC, we will integrate the work of our Evaluation Core and the QPIP team to identify critical bottlenecks, institute CQI and then measure impact of these changes.

2B.3. Objective 4: Participate in national-level efforts to develop and collect Consortium-wide metrics to measure the impact of the CTSA program.

Although there will be a transition to an as yet-to-be defined mechanism by which CTSA Consortium metrics and impact will be collected nationally, we will comply with the future mechanism and report our results to the CTSA consortium in accordance with required timelines. We will convene key member meetings with individuals representing our CCTSI leadership and administration of each of the evaluated programs to discuss trends in the metrics, important context needed to interpret each metric, any action steps necessary for addressing the metric, and base these action steps in literature and best practices. Finally, we will maintain strong partnerships with local owners of institutional data, such as the CU Office of Grants and Contracts, COMIRB, the CTMS (OnCore) and the Graduate School, to supplement primary source data collection, the goal being to ensure the accuracy and completeness of metrics reported by the CCTSI.

2B.3.1. Needs Assessment Surveys. The Evaluation Core will administer comprehensive needs assessment surveys each 3 years to CCTSI members at all CCTSI-Partnering Institutions, as well as all investigators and research support staff at CU Anschutz, as has been done in 2011, 2014, 2016, and 2021. The Core then will present the results and its recommendations to the EC. This assessment will determine the resources/services that investigators prioritize and the extent to which these needs are effectively met. Results of the 2016 and 2021 needs assessments guided a number of new initiatives undertaken during the current grant cycle. The **Evaluation Core** also reviews CCTSI progress annually and submits an official report to the MPIs. The EC leadership and QPIP will utilize these data, as well as the financial reporting generated by the program income system, in annual data-informed decision making and resource allocation.

2B.3.2. Development of Local Indicators of Success and Metrics. During the first year of the new grant cycle, the Evaluation Core and QPIP will work closely with each CCTSI program to *finalize logic models and associated immediate, intermediate and long-term outcome Metrics*. These models will inform the detailed evaluation matrices, organized by key evaluation questions and domains of interest, which will lead to development of local indicators of success, metrics and methods/data sources. **Study Life Cycle metrics:** Specific metrics have been developed for Protocol Tracking, which will be monitored at least annually by the MPIs and EC in coordination with the Evaluation Core. Implementation milestones and timelines will be developed and tracked for each program, as during the past 14 years.

GOAL 3. INTERNAL and EXTERNAL ADVISORY COMMITTEES

3B.1. INTERNAL ADVISORY COMMITTEE (IAC).

The IAC will provide for Communication among Key Leadership from each of the Universities and Partnering Institutions and other stakeholders through meaningful discussions of CCTSI strategy, priorities and programs at meetings held each 6-months. The MPIs will provide the IAC with updates on CCTSI opportunities, collaborations, accomplishments, milestone achievements and major plans for the next year, which will inform and facilitate IAC input to the CCTSI leadership about strategy and future collaborations. The IAC membership will consist of Deans (or their representatives) of each of the 6 CU-Anschutz health science Schools, a high-ranking research official from CU Boulder and the Downtown Denver Campus of CU Denver, and from CSU (e.g., VP for Research), CEOs (or their representatives) of each of the 5 Partnering Hospitals, the Director of CU Innovations, 2 members from the local biotechnology community, a representative from several major research units at CU Anschutz (e.g., Barbara Davis Center and CU Comprehensive Cancer Center), and 2 community representatives. Meetings will be held virtually to allow for participation by all of these very busy individuals. This committee will be chaired by the contact PI; the CU Anschutz VCR and VCHA will be ex officio members. The IAC will be the vehicle to assure strategic discussions and partnership among the major Universities, Schools, campuses, Partnering Hospitals, biotech industry and communities impacted by the CCTSI.

3B.2. EXTERNAL ADVISORY COMMITTEE (EAC).

CCTSI has an established EAC which has been in place for the last 3 cycles of the CCTSI and which has been extremely helpful in providing guidance and evaluation of CCTSI programs. The EAC will meet annually at CU Anschutz (or virtually) to provide an annual written review of CCTSI program progress, provide guidance to challenges that have arisen and make recommendations to the MPIs. For the new grant cycle, current members of the EAC will be reappointed (**see Letters of Support**) in recognition of their excellent service to the CCTSI in recent years. EAC appointments are approved by the VCR and VCHA under recommendation of the PI and Executive Committee. The multidisciplinary diverse EAC will consist of 6-8 nationally renowned CTS scientists and CTSA PIs with individual expertise and extensive personal experience in the spectrum of T1-T4 translational sciences relevant to the CCTSI mission, up to 1-2 biotechnology industry representatives, and 1-2 community stakeholders. **Members of the EAC will include:** 1) EAC Chair: Steven Dubinett, MD, PI of the UCLA CTSA and Assoc. Vice Chancellor of Research UCLA, a T1-T2 pulmonary scientist, 2) Tesheia Johnson, MBA, MHS, Deputy Director and Chief Operating Officer of Yale University's CTSA program, 3) Alexander Kirst MD, MPH, Director of Community-Engaged Research at the Wright Center for CTR, Family Medicine Professor at Virginia Commonwealth University, 4) Cynthia Morris, PhD, MPH, Associate Director, Oregon CTRI, Professor of Informatics and Epidemiology, OHSU, 5) Dan Cooper, MD, Associate Vice Chancellor for CTS and PI for CTSA program at UC Irvine, Professor of Pediatrics, 6) Jareen Meinzen-Derr, PhD, MPH, PI and Director of University of Cincinnati CTSA program, Director of Biostatistics, Epidemiology and Research Design, University of Cincinnati and 7) Peter Embi, MD, MS, Chair, Dept. of Biomedical Informatics, and Senior VP for Research and Innovation, Vanderbilt University. In the proposed grant cycle, we will add a Community Organization leader (TBN) and Biotech Industry representative (TBN). The EAC will meet in person (or virtually) each January for 2 days, meet with CCTSI EC leadership and K/T scholars, listen to presentations of our major programs and new initiatives, and provide feedback verbally followed by a written report to CCTSI leadership. This report will be reviewed by Drs. Sokol and Higgins with the VCR and VCHA, and with the EC and included in our annual RPPR.

The EAC has been instrumental in **providing recommendations** which have produced major transformational changes at our institution. For example, the EAC identified for several years that translational and health informatics and data science had no academic home or centralized organizational structure on our campus. Upon these recommendations, Dr. Sokol and Informatics Director at the time, Dr. Michael Kahn, led a major effort that culminated with a new Department of Biomedical Informatics (BMI) in the SOM. In July 2022, the new Dept. of BMI in the SOM was launched with Casey Greene, PhD the inaugural Chair. The Chancellor and SOM have invested heavily in this new Dept. which will expand our academic footprint in data science. Furthermore, a new position, Chief Research Informatics Officer (CRIO) for CU Anschutz, was created in 2021 and Melissa Haendel, PhD, was appointed as inaugural CRIO. Not only will Dr. Haendel help to transform our data science ecosystem among our Hospital Partnering Institutions on the CU Anschutz campus, but she also brings her extensive experience in national data sharing, genetics research and analytic platforms, e.g., the N3C initiative. Dr. Haendel will also co-direct our CCTSI Informatics Core (with Dr. Tell Bennett). Thus EAC recommendations have promoted transformational change at our institution in biomedical informatics and data science.

ELEMENT C: TRAINING AND OUTREACH

MODULE C1. WORKFORCE DEVELOPMENT (WD): CLINICAL RESEARCH STAFF PROFESSIONALS (CRSP) and SCIENTISTS

Table C1: METRICS OF SUCCESS for Workforce Development Programs

Workforce Diversity (last 5 years): 127% increase in URM participation in TL1 program; 30% increase in URM and 100% increase in Clinical Research Professional Staff (CRSP) participation; 38.5% of WD leaders are from URM or disadvantaged backgrounds
CO-Mentor: Mentors and mentees demonstrated growth in confidence for all mentorship-related skills , such as developing/reviewing individual career development plans, managing work environment, etc. (P=.001). Trained > 600 mentors and mentees.
Clinical Science Program: Offers >40 courses . Past 5 years graduated 89 MSCS and 46 PhD degrees. Alumni published 9,501 peer reviewed publications and secured 836 federal and 1238 non-federal grants . 88% persistent in translational research.
Grant Review and Mock Study Sections: Pre-K program reviews 38 grants/yr, 68% submit to agency with 39% funded the first time and 52% with re-submission (31% national rate) . K to R program reviews 22 grants/yr, 70% submit to agency with 31% success rates for initial and resubmissions compared to national levels of 16% and 31%, respectively.
Teaming for CTR: 380 attendees/year. Satisfaction was high for all 6 workshops (mean 4.5/5). Improved confidence (P<0.02); for ability to apply situational leadership, collaborative knowledge and shared language, build trust, collaborative writing principles.

A. SIGNIFICANCE, GOALS and INNOVATION

CCTSI's vision of accelerating and catalyzing the translation of innovative science into improved equitable health and patient care for all can only be realized with a well-trained, engaged and diverse clinical research workforce. The CCTSI is building a comprehensive and integrated portfolio of Workforce Development (WD) programs to attract, train, and retain a highly competent diverse workforce, including our T32 and K12 proposed programs. We will work with our CU and CSU Partners and their "**Pathway Programs**" designed to enhance diversity of our workforce by attracting, recruiting and preparing high school, community college and undergraduate students from URM and disadvantaged backgrounds in local schools for a career in healthcare, STEM and research. **We will integrate with URM recruiting and mentoring initiatives described in our CTSA K12 and T32 grant proposals.** Conducting rigorous and efficient clinical trials and translational research has become increasingly complex, mandating continuous learning of the workforce. Thus, our **WD Web of Learning (Figure C1)** will emphasize a culture of team science that is rigorous, reproducible and efficient, adheres to ethics and regulatory requirements, and is supported through effective mentorship, communication, and leadership. Anchoring threads of our Web include regulatory, operational, scientific, relationships and communication. Complementing these programs, our RKS Core (**Module D1**) provides weekly virtual training sessions for study coordinators and other research staff focused on clinical research/trials basics, writing protocols, use of our CTMS, IRB training, and problem solving.

The purpose of this Module is to **develop, deliver, demonstrate and disseminate flexible, evidence-informed²⁹⁻³⁵ clinical and translational science and research (CTSR) WD programs (for all clinical research staff professionals [CRSP] and scientists, including T32 and K12 CTSA programs)** to prepare and retain a highly qualified inter-disciplinary team-oriented workforce which embraces diversity, inclusion, and health equity (**DIHE**). **Our Goals** are:

Goal 1. Weave our value, **Diversity Accelerates Research and Translation**, into all WD programming.

Goal 2. **Support tailored learning to address needs of CRSP and scientists** for their ability to conduct rigorous and efficient cutting-edge clinical trials and CTR by providing comprehensive educational programming (regulatory, operational and scientific) across the translational spectrum and project life cycle.

Goal 3. Enhance the CCTSI's workforce effectiveness by providing **career development training** in Teaming and Leading, Mentoring, and Communicating Research.

Overview of CTSA Goals Addressed by this Element

Goal 1: Efficiency and impact of CTS

Goal 2: Collaboration, team, data science, partnerships

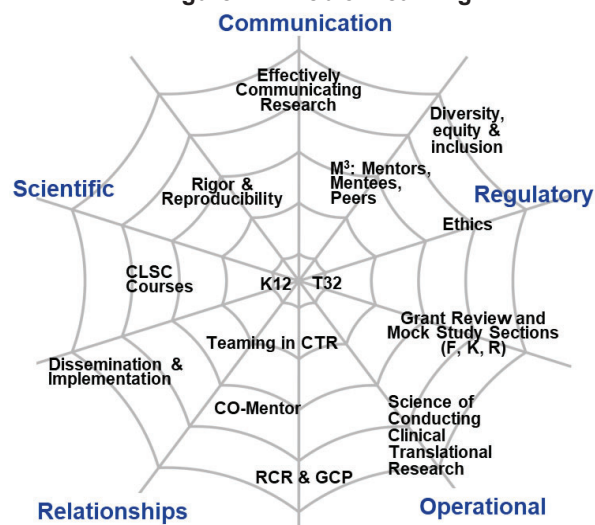
Goal 3: Community partnerships, health inequities, disparities

Goal 4: Operational efficiencies

Goal 5: Rapid response to public health emergencies

Goal 6: CTS training for all research professionals

Figure C1. Web of Learning.



Goal 4. Ensure the entire CCTSI workforce receives **comprehensive training** in Diversity, Inclusion and Health Equity in Research, Good Clinical Practice, Responsible Conduct of Research, research ethics, and regulatory compliance.

Goal 5. Achieve **beneficial impact of WD programming** using established metrics that are monitored and reviewed per program at least annually, by engaging with and listening to feedback from the Workforce, and by making necessary modifications for effective programming.

INNOVATION

CO-Mentor and Leadership in Innovative Team Science (LITeS) programs are emblematic of our ability to innovate, develop, demonstrate, and disseminate. CCTSI's **developed** programs, CO Mentor³⁵ and LITeS³¹, were **disseminated this past grant cycle** to other CTSA in Florida and Minnesota. In addition to accelerating translation of science at our CTSA, our faculty worked with collaborating universities to **innovate** train-the-trainer models that fit their contextual needs. Evaluations from learners **demonstrated** that new trainers were knowledgeable and confident in their ability to provide the program and that fidelity of benefits was maintained. For this renewal, we will leverage this work to disseminate our "*Leading and Teaming in CTSR*" program to other CTSA hubs and will publish learning/evaluative efforts for future adopters.

The pandemic was a stressor that demanded innovative responses. Our ATLAS^{ti} program **shifted from an in-person format to self-paced 24/7 web** modules that permitted pre-post assessments, asynchronous dialogue, and easy access to instructors. Evaluation demonstrated that the CU e-learning platform was easy to access, permitted data collection for evaluation, tracked program completion, and was acceptable to learners. Based on this success and the sustained need/desire for online learning, we will expand our use of CU e-learning to permit the application of a flipped classroom strategy, which has learners complete instructional sessions (CU e-learning modules) followed by skill application in live workshops. Programs to use this approach includes *Science of Efficient Clinical Research, Effectively Communicating Research; CRSP Staff Development, Atlas, Clinical Trials Training; Table C2*). Didactic elements will be developed into web-based modules allowing **self-completion on the learner's terms** prior to attending in-person sessions involving skill application. Resources and programs will be posted for use by others on the CTSA WD clearinghouse (previously CLIC).

B. PRELIMINARY DATA

CCTSI Needs Assessments and CCTSI Evaluation Core learner evaluations identified needs for teaming, mentoring, communicating research to the public, and management topics such as budgeting, contract negotiations, coordinating multi-center studies, and achieving inclusion of underrepresented groups, all of which will be instituted in the next funding cycle. **Table C1** highlights some Key Metrics of Success.

C. APPROACH

Ensuring that our CRSP and clinical investigators acquire and maintain required competencies, we have developed our Workforce Development Program Portfolio (**Table C2**), **which will support all workforce members**, including CRSP, K12 and T32 awardees, clinical investigators, faculty, and trainees at all Partnering Institutions (CU Denver, CU Boulder, Colorado Springs, CSU, NJH, DH, VAMC).

Goal 1. Weave our value that Diversity Accelerates Research and Translation (DART) into all WD programming.

Diversity is instrumental for the workforce to advance discovery, achieve health equity and improve patient-centered outcomes in the quest for better health³⁶. Our WD's value and philosophy is **DART**. A sustainable way to achieve diversity in the workforce is through learning together as a whole community and emphasizing diversity and inclusion in all aspects of the fabric of research - from the research team to study participants to design, measurement and analyses – and ensuring inclusion of individuals from historically underrepresented and underserved backgrounds in all research team roles. Several **strategies** will be used to achieve our imperative goal: **1)** Amira del Pino-Jones MD will serve as the CCTSI **WD Director for Diversity, Inclusion and Health Equity** (DIHE) and lead strategic initiatives to integrate DART into all WD efforts including CTSA K12 and T32s. She served a similar role in our TL1 program with great success and thus her role will be expanded to include all WD programs. **2)** Use consistent co-developed DIHE messaging and processes for all WD webpages, recruitment requirement materials, selection processes and hiring into leadership positions. **3)** Provide **training to all CCTSI staff** in DIHE such as power, systemic racism in health and research, cultural

humility, and minority/health equity principles. **4) Pathway Programs:** We will work with the CU-Anschutz Office of Educational Outreach and Pathway Initiatives in the VC for DEI and Community Engagement office, whose goal is to provide comprehensive programming to increase numbers of URMs participating in translational sciences, STEM, health care and research professions. Dr. Dominic Martinez directs the program and is a member of our WD Leadership Advisory Council (LAC). The Office uses a holistic support system to assist underrepresented individuals including access and transition, financial aid, health care and mental health, faculty/academic leadership, and campus climate. The Office will serve as the hub for all high school, community college, undergraduate and graduate Pathway Programs, many of which are funded by NIH and other federal agencies, to unify efforts, provide common infrastructure and support (admission, mentoring, trainings, immersion experiences) and identify core elements for data collection and evaluation. We will work with these Pathway Programs to reach students across Colorado and provide trainings, immersion experiences and mentors, and support program evaluation. For example, CCTSI supports a shared program with Diné College (Navajo Tribal College) in AZ that provides a summer undergraduate program for translational science and research. WD will provide faculty for trainings and immersion experiences in this program. **5) Partner with Dr. Kady Nearing's NIH grant "Workforce Development Engages Diverse Older Adults to Catalyze Innovative Approaches for Enhanced Recruitment and Retention".** Specifically, WD will assist by providing training, CTSR immersion experiences, and integrating the role of diverse community recruiters into WD DIHE trainings (**Table C2**). **6) Metrics:** Apply the Accountability Framework of the national **CTSA Consortium DEI Taskforce** to monitor metrics for attracting and serving diverse learners, including diversity of applications and participation rates of URMs in all research team roles. These data will be critical to confirm our goal of **increasing participation by 15% of URM individuals across programs by 2027.**

Goal 2. Support tailored learning to address needs of CRSPs and scientists for their ability to conduct rigorous & efficient trials and CTSR by providing comprehensive educational programming (regulatory, operational and scientific) across the translational spectrum and project life cycle.

Tailoring education to meet individual learning needs recognizes that the interdisciplinary and team-based nature of CTSR means team members have varying learning needs. The CCTSI **Clinical Science Graduate Program** (CLSC) will provide foundational education in clinical trials and CTSR to prepare clinical research staff to conduct high quality, rigorous and efficient CTSR. The CLSC awards certificates and masters and doctoral degrees. Students/learners have included CRSP, F, T & K awardees (CCTSI and non-CCTSI), faculty, community organization leaders and those from industry. We offer >40 courses to develop scientific, regulatory, and operational competencies, examples include *Conducting Clinical Trials for Investigators*, *Conduct, Design and Analyses of Clinical Trials*, *Critical Appraisal*, and *Measuring and Data Management of Patient Centered Outcomes*. In response to our Biennial Needs Assessment, two new courses will be offered, *Science of Efficient Clinical Research: Regulatory and Operational* and *Designing and Conducting Successful Rare Disease Clinical Trials*. Skill development in grant preparation will be achieved by CLSC Grant Writing courses (CLSC 7101, 7102) and participation in three grant review and mock study sections that focus on pre- and post-doctoral awards (F-awards), K/career development awards and R-type grants. New to our portfolio is the F-Award Grant Review and Mock Study Section.

An entirely new and innovative program to ensure engagement and competencies of CRSP is the **CRSP Development Program** that will be led by two senior CRSP, Hailey Steinert and Patricia Gesualdo, who have over 22 years of collective clinical research coordination and management experience at CU Anschutz. The program will be directed by Ben Echaliier MS, MBA, CCRP, Associate Director, Regulatory and Trials Operations and TIN HLT Director. Serving as the nexus for all CRSP career development programming and clinical trial education, this program will include multiple initiatives (**Table C2**) that follow the recommendations of the CTSA Joint Task Force for Clinical Trial Competency.³⁷ In the first year of this award (2023), the program will kick off with a **campus-wide survey** to assess areas of need specific to CRSP, followed by a series of listening tours and focus groups to inform development of a full curricula of trainings and resources to support CRSP career development. Yearly CRSP engagement surveys will be conducted by Evaluation Core and CRSP Development Program leaders will present results to WD Leadership Advisory Council and CCTSI EC. **These forums provide a direct pathway for CRSP to provide feedback to CCTSI leadership of advances and opportunities for further innovation, as well as prioritization for planned new initiatives.**

Further recognition of the essential roles of CRSP in the CTSR enterprise is the creation of a new **Career Ladder structure** for CRSPs at CU in 2022 to provide ongoing career path opportunities designed to retain highly skilled professional staff. This important update has moved CRSPs from a total of two possible steps on the career

ladder to five. Each step has defined criteria and the pay scale at each step incentivizes retention by providing higher salary for those with more years of experience.

Goal 3. Enhance the CCTSI’s workforce effectiveness by providing career development training in Teaming & Leading, Mentoring, and Communicating Research.

CTSR is most successful as a collaborative endeavor that requires multi-disciplinary approaches to solving problems. For the next grant cycle, LITeS (described above) will be integrated into a new program. Our Needs Assessment identified that several larger campus leadership training programs were initiated after LITeS brought attention to the need for leadership training, resulting in the evolution of LITeS. We will pivot to focus on leading within research teams through the new **Leading and Teaming for CTSR** program. Based on evaluation and CQI approaches, the new program’s target audience will be broadened to include early-mid career faculty, all CRSP, and pre- and post-doctoral trainees, and will integrate skill development in both leading and teaming. This will involve a self-assessment and self-paced web module followed by six, two-hour workshops involving small group activities. Topics will include building diverse teams, trust, accountability, change management, conflict resolution, negotiation, leadership, collaborative knowledge creation, meeting management, building a shared language, and inclusion of diverse voices. **CO-Mentor** will be completed by mentor-mentee dyads and prioritizes new faculty and all K awardees. CCTSI K12 awardees are required to complete this program. It consists of 4, half-day sessions and focuses on (1) developing skills and behaviors consistent with effective mentoring; (2) enhancing the individual mentor-mentee relationship; and (3) building a network of mentors and mentees. **Mentoring³: Mentee, Mentor, Peer** will be a new 12-hour program for pre- and post- doctoral trainees and their mentors across all CCTSI Partners and will be a class requirement for CCTSI T32 programs. The program will be based on our CO-Mentor³⁵ and Wisconsin’s CIMER³⁸ programs and will involve workshops that are attended by mentees and mentors separately as well as in dyads. Mentoring³ will be directed by Bruce Mandt PhD, Assistant Dean-Graduate School and Director of the Career Development Office. He has completed CIMER (including Entering Mentor Facilitator Training) and CO-Mentor programs and has extensive experience developing and facilitating workshops on mentoring relationships. Both CO-Mentor and Mentoring³ will build comfort and competency for mentoring across differences and will include activities for mentors, mentees, and dyads. **Effectively Communicating Your Science to the Public** will be a new program offered in response to the need to provide the public with accurate information about science, as demonstrated in the pandemic. It will involve three, 90-minute workshops and serve the entire workforce. Most workshop time will be for facilitated interactive group work that involves practicing skills and providing feedback to peers. This program will use the flipped classroom with learners reviewing web modules on the CU e-learning platform prior to workshops that focus on skill application with feedback. Topics include knowing the audience, identifying key messages, building and telling a story, interviews and answering questions (TV, radio, news), social media 101, building your brand, delivering your research elevator pitch, and disseminating research through video-based assets.

Table C2: Workforce Development (WD) Program Portfolio

Program (Lead & Timeframe)	Description of Program
For all Clinical Research Staff Professionals (CRSP), Researchers, Trainees and CCTSI T32 and K12 trainees	
Responsible Conduct of Research (RCR), Good Clinical Practice (GCP) (Lakin - ongoing) REQUIRED	Curriculum to develop competence for GCP, RCR, regulatory knowledge, rigor and reproducibility. Variety of training forums: seminars, courses, individual consults, online modules, webinars. Annual reach ≥1,600 attendees, 40 workshops and > 300 students/ year in graduate level ethics/RCR courses.
Diversity, Inclusion and Health Equity (DIHE) NEW , (Williamson/ Lakin - Start yr 1) REQUIRED	2-part workshop series provided by lay community members from URM and disadvantaged communities trained in clinical research, health navigation, ethics. Topics covered: diversity in research, trust, community engagement and marketing research, cultural humility and competent communication, and study recruitment and retention.
Clinical Trials Training (Williamson-ongoing)	Covers clinical trial conduct issues, budgeting, recruitment, FDA audits, harmonized informed consent/IRB, multiple site trials (web modules and lunchtime RKS series)
Clinical Science Graduate Program (CLSC; Cicutto-Ongoing) 2 NEW courses <i>Design & Conduct of Successful Rare Disease Clinical Trials</i> and <i>Science of Efficient Clinical Research</i> (Start yr 1)	Advanced CTSR training. > 40 courses: study designs, study/grant operations and conduct, ethics/RCR/GCP, grant writing, rigor & reproducibility. Enrollment: 101 degree-seeking students-including 20% CRSP staff, 77% clinicians. >150 non-degree students take courses/year; 40-50% are CRSP. New courses: <i>Design and Conduct of Successful Rare Disease Clinical Trials (Taylor, MD PhD)</i> & <i>Science of Efficient Clinical Research: Regulatory and Operational (Hammack PhD)</i> . Topics will include trial designs (N of 1, pragmatic, RCT and others) and analyses; DEI, ethics and equity, multi-site coordination; GCP; regulatory; recruitment/retention; and data sharing.
Dissemination and Implementation (D&I) Certificate in CLSC NEW-2022	Prepares graduates with D&I skills to design & conduct rigorous & innovative translational research. 12 credit hours completed through synchronous online learning. 3 new courses developed. Pilot started in 2021. 15-20 students/cohort.

Effectively Communicating Research to the Public NEW (Sasson; Start yr 1)	Three-part 1.5 hr workshop series provides an overview of how to engage the public - everyone from TV reporters to neighbors - and the world on social media. Each workshop will include hands-on practice and accompanying web module. (Pilot started 2022)
Leading and Teaming in Clinical Translational Science and Research NEW ; (Cross; Start yr 1)	14-hour program designed to build capacity to participate in and lead effective, interdisciplinary and translational teams. Topics: building relationships, diversity on teams and harnessing its power, conflict resolution, negotiation, leadership for all team members, collaborative knowledge creation, setting expectations, meeting management.
For Clinical Research Staff Professionals (CRSP)	
CTSA Clinical Training Program - ongoing	Ongoing training in competencies tailored to CRSP needs. Two to four lunchtime modules are offered per mo. - each topic is repeated 3-4 times/yr: responsible conduct of research, informed consent, COMIRB beginner training, introduction to INfoEd (CU IRB portal), measurement of vitals and anthropometrics, recruitment and retention of study participants. New modules will be added based on needs assessments from the new Clinical Research Staff Development Program
Clinical Research Staff Professional Development Program NEW (Echalier, Steinert, and Gesualdo, all CCRP prepared and CRSP (Phased implementation over 2 years)	Multi-faceted career development hub for <u>ALL</u> CRSP that includes <u>Clinical Research Connections</u> : Monthly meetings to review new regulations, standards, resources such as template forms, SOPs and checklists that can be adapted to meet needs. <u>Career Ladder training</u> (online and face to face) to support competency-based matrix for career advancement and acquisition of new skills aligned with the new 2022 CU career ladder. <u>Mentor-mentee match program</u> with mentoring training. <u>Quality Improvement (QI) in Clinical Trials</u> for QI team to provide consultations and support to research teams. <u>QI pilot grants made</u> to validate innovative approaches. <u>Monitor, Track, Report</u> : Conduct annual needs assessment to identify CRSP needs, hub satisfaction, training evaluations, monitoring CRSP career ladder progression, and data informed improvements to hub services. <u>CTSA Engagement</u> to increase CRSP relationships with other CTSA hubs to share resources/best practices and evaluate and adopt/adapt other's efforts.
For Researchers and Trainees (Required elements for CCTSI T32 and K12 trainees)	
CO-Mentor- CCTSI K12, K awardees, early stage faculty & their mentoring faculty (Austin and Libby - ongoing)	20 hours of training for mentor-mentee dyads over a year. Attended by 60 mentors-mentees/year. Mentors and mentees make significant gains in coaching, identifying strengths and gaps in mentoring team, clarity of career development needs, connecting with future mentors, and mentor networks. ³⁵ Targets K awardees and new faculty.
Mentoring³: Mentee, Mentor and Peer NEW (Mandt, Pre-Post-docs, faculty mentoring, CCTSI T32 required; Start yr1)	12 hours of workshop supplemented by homework activities. Attended by mentees and mentors separately and as dyads. Based on CO-Mentor and Wisconsin's CIMER. Will build in a train the trainer component to build pool of trainers for program delivery. Mentoring across differences will be discussed and supported by WD DIHE Director.
Grant Review & Mock Study Sections- F NEW (Hooper-Start yr 1), Pre K & K to R (MacLean, Castillo-Mancilla, Shomaker, Yang, Wierman, Cree-Green, Bergman (ongoing))	3 programs to support development and submission of competitive grants for pre- and post-doctoral awards, career development awards and research grants. Each program runs 3 times/year corresponding with NIH deadlines and covers: 1) "How to prepare your grant" workshop; 2) Submit specific aims page reviewed by program faculty with applicant feedback; 3) Submit full grant; 4) Grant reviewed by 3 reviewers with written feedback; 5) attendance at mock study section to hear all reviews, discuss and pose questions; 6) Meet with faculty for feedback.
See attached Biosketches of all named WD program faculty. All new programs will be fully implemented by 2027	

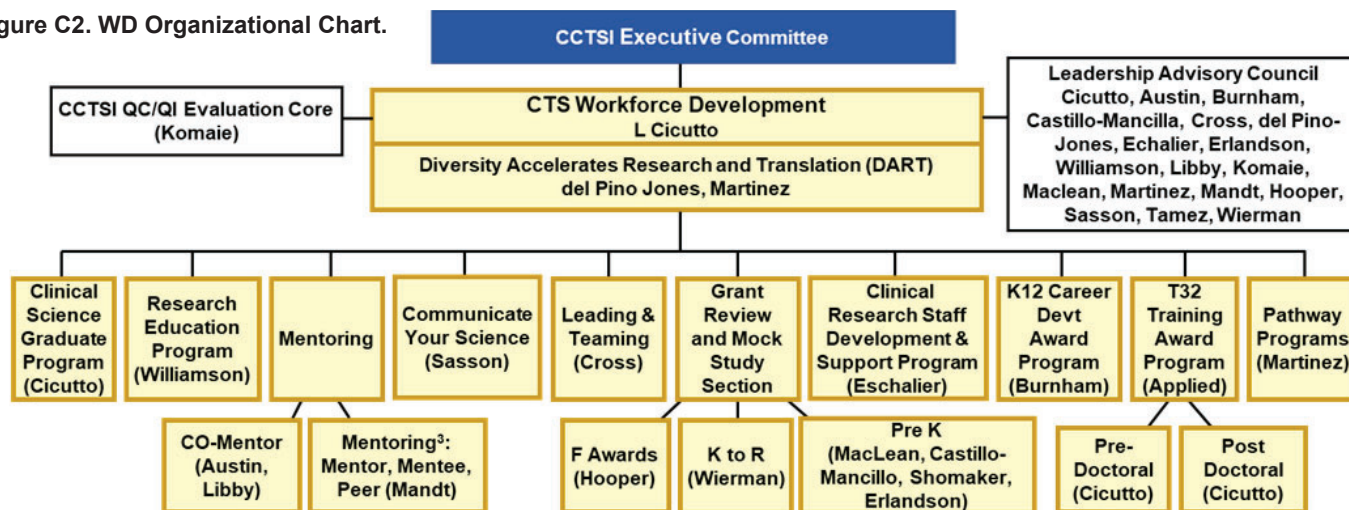
Goal 4: Require and ensure the entire CCTSI workforce receives comprehensive training in DIHE in research, Good Clinical Practice (GCP), Responsible Conduct of Research (RCR), research ethics, and regulatory compliance

A requirement of all personnel involved in any clinical translational research throughout our institutions is the completion of CITI online training modules for HIPAA, GCP, human subject protection, and RCR, in addition to attending live sessions of no less than 8 hours occurring no less than every 3 years. Training will be available in a variety of modalities that adhere to NIH curricular requirements (NOT-OD-10-019; OD-22-055) as follows: **1)** formal 15-week courses in the CLSC Program, **2)** lunch-hour workshops and short courses organized by the RKS Core, and **3)** online modules for self-paced instruction. New this funding period will be mandatory training in DIHE in Research which will be completed by CRSP, scientists, T32 and K trainees/scholars, and PhD students. Trainings will be led by lay members from historically underrepresented groups and communities, who received training in clinical research, ethics, and health navigation, and who will help prepare the CTSR workforce for future community engagement and inclusion. Topics will include engaging and promoting research in community, humility and culturally competent communication, and recruitment and retention. Through OnCore, our CTMS system, we will track mandatory training for CRSP, trainees, and researchers s to ensure compliance.

D. STRUCTURE, GOVERNANCE AND INTEGRATION

This core will be governed by an interdisciplinary (RN, CRP, MD, EDD, PhD, MPH, RD) and inter-organizational (NJH, DH, CSU, CU | Denver, CU|AMC, CHCO, UCH, DVAMC) partnership led by **Professor Lisa Cicutto RN, ACNP (cert), PhD** who is based at NJH. She will direct the CCTSI's WD, CLSC Program and CCTSI Pre- and Post-Doctoral T32 Programs (see **Hub Institution Organization** and **Figure C2**). Dr. Cicutto is a member of the

Figure C2. WD Organizational Chart.



CCTSI EC and will be involved in all decision making for CCTSI programs, both as education director and NJH representative. She has been CCTSI WD Director since 2016 and has directed the CLSC Program since 2008. She serves on the CTSA Consortium Workforce Development Enterprise (WDE) and TL1 committees and was recently elected to serve on the WDE Leadership Team. All CCTSI WD, T32 and K12 programs will be governed by the **Leadership Advisory Council** (LAC), which consists of directors and leaders of all WD programs (Figure C2 and Table C2) including: WD Director of DIHE, CCTSI K12 & T32 programs, other key CCTSI programs (e.g., Community Engagement and BERD), the Graduate School, Offices of Diversity, Equity, Inclusion and Educational Outreach and Pathway Programs. The Council will use shared decision making and meet monthly to review all programs’ activities, evaluation and feedback, metrics/outcomes, discuss integration across programs (WD, CCTSI, university, partners), need for revision and current events or issues. The LAC will ensure coordination, integration, synergy, and mutual reinforcement/ accountability, and will work with the Evaluation and CQI Core to evaluate all WD services and institute change as needed. The LAC has proved to be valuable as a communication vehicle between education leaders from different campuses, to provide the agility to collaborate/integrate, leverage resources, and avoid duplication. An example of a benefit was the creation of the Teaming Program, which was a partnership of the CCTSI, the Graduate School, School of Medicine, and CSU.

E. METRICS/ MILESTONES/ EVALUATION

Goal 5. - Achieve **beneficial impact of WD programming** using established metrics that are monitored and reviewed per program at least annually, by engaging with and listening to feedback from the Workforce, and by making necessary modifications for effective programming.

WD is outcomes focused, thus our programs continuously measure explicit metrics of success. Every WD offering is evaluated by attendees (CRSP, scientists, trainees). These data are reviewed by the Evaluation Core, program leaders and the LAC to inform the need for changes, additions, revisions and inform annual program plans. For example, we responded to stakeholder feedback from students in our Grant Review and Mock Study Section programs who identified a need for resources that create a timeline for writing a grant, templates for letters, budgeting, and more detailed written feedback. In response, requested resources were added to our website, reviewers were provided with guidelines and templates for detailed feedback, and program directors now review specific aims pages and counsel/coach applicants prior to the program’s full application deadline. These changes resulted in improved satisfaction, confidence in preparing grants, meeting grant deadlines, and submitting competitive grants by the trainees. In this way, we are applying the CQI Plan-Do-Study-Act Cycle. The **Collective Impact/Success Framework**³⁹ is applied for program evaluation and CQI, which involves shared measurement tools, such as our standard registration form collecting participant characteristics; participant pre/post program data for evaluating knowledge, confidence, and satisfaction using standardized questions permitting tracking over time; continuous review by program directors along with annual LAC review to identify areas of improvement and integration; and annual WD program revision plans. The Evaluation Core will collect **metrics** (Table C1) on former CCTSI T and K trainees including persistence in CTR, publications and H-indices, number and types of NIH awards, promotions and leadership positions to demonstrate impact of our programs on CCTSI-funded scholars. For this next grant cycle, our key outcome/indicator of success will be that each WD program will demonstrate **≥15% improvement in participation rates of URMs**. Diversity metrics will be reviewed for all WD programs to monitor progress towards our goal and inform strategies for improvement.

MODULE C2: COMMUNITY AND STAKEHOLDER ENGAGEMENT RESEARCH

Scientific advancements in medicine and healthcare do not equally benefit all communities, as evidenced by persistent inequities and poor health outcomes that often fall along racial, ethnic, gender, geographic and socio-economic lines. These inequities are rooted in centuries of oppression and systemic racism, including in our traditional academic and medical institutions. In the context of CTR, eliminating harmful disparities and advancing health equity requires an explicit commitment to ensuring that our institutional systems, structures, policies and practices are guided by values that seek to bridge divides between scientific innovation and societal impact and in which community members/stakeholders have a major voice in the development of solutions.

The CCTSI **Community Engagement and Health Equity (CEHE) Core** has a 14-year history as a foundational component of the Colorado research infrastructure, leading the development and implementation of innovative funding mechanisms and approaches to advance health equity, decrease health disparities and support the equitable and authentic bidirectional engagement of communities and stakeholders across the translational research spectrum. As our CEHE program looks toward the future, we seek to **advance health equity through translational science** by investing in capacity within our campus, Partnering Institutions, and community stakeholders, and ensuring that CTS is conducted in partnership with diverse populations. We will do this by building on the foundation of successful approaches that we have developed over the past 14 years.

STRATEGIC GOALS:

Goal 1. Develop the capacity of investigators and research professional staff to equitably engage diverse communities and stakeholders in clinical and translational research.

- a. Develop and provide training for research coordinators and staff in Diversity, Equity and Inclusion and Community Engagement.
- b. Expand the capacity of our existing program for training investigators in DEI and Community Engagement.
- c. Expand the reach of the Community Clinical Trials Advisory Board (CCTAB) beyond COVID-related trials.

Goal 2. Develop the capacity of communities and stakeholders to provide input and feedback and equitably engage with investigators and staff in clinical and translational research.

- a. Expand the development and implementation of programs to train Community Based Organizations in research fundamentals.
- b. Promote the development and implementation of programs to train individual community members to partner in the development and conduct of research in community settings.

Goal 3. Establish, build and maintain trust with communities and stakeholders through return of results, and interpretation and dissemination of results in partnership with communities and stakeholders.

Goal 4. Continuously evaluate and improve our capacity development activity on campus and in communities by measuring and monitoring our impacts on equitable engagement and involvement with diverse communities and stakeholders in clinical and translational research.

Through the realization of these strategic goals, we will **advance health equity through clinical and translational science** addressing the disproportionate impacts of health conditions on rural, minority and other underserved populations in the state of Colorado and beyond.

A. SIGNIFICANCE

The governing body of the CCTSI CEHE program is the Partnership of Academicians and Communities for Translation (**PACT**) Council, whose mission statement is: ***The PACT uses the principles of balanced responsibility and equitable power between community, clinicians, and researchers to improve the health of the people of Colorado and the Rocky Mountain Region.*** The make-up of the PACT reflects the mission of balancing responsibility and power through an equal membership of 7 community stakeholders (from underserved communities) and 7 academic members. The Chair of PACT alternates between a community member and an academician each 2 years. The community stakeholders on PACT each year lead a discussion of the most important health issues in their own communities and develop priorities for the Community Engagement Pilot Grant Program (**Module D2**) for the coming year. Through the 14 years of our work, the PACT Council's guidance has helped us develop and sustain a robust infrastructure to elevate patient-centered, practice-based, community-engaged research and training throughout the translational research spectrum (T0.5 to T4) and strengthen the bidirectional links between the academic medical center (CU Anschutz), Partnering

Institutions, healthcare providers, community organizations, government agencies and community stakeholders. The CEHE infrastructure has proven to be an invaluable resource in our state in addressing health disparities and equity issues during the COVID-19 pandemic, through programs such as the Colorado Community Engagement Alliance against COVID-19 Disparities (**CO-CEAL**).⁴⁰

B. INNOVATION AND PRELIMINARY DATA/ INSTITUTIONAL ASSETS

Throughout our current grant cycle, we have continued to innovate and expand our CEHE Programs, integrating and embedding them into the overall infrastructure of the CCTSI and our Partner Institutions. Our CEHE Director (Nease) and Deputy Director (Tamez) are both permanent members of the CCTSI EC, the governance and decision-making body of the CCTSI; importantly, during the current grant cycle we have brought **two community PACT Council members onto the CCTSI EC**. These community members were selected by the PACT Council and will serve non-overlapping two-year terms, **ensuring direct input and feedback from community stakeholders at the highest level of CCTSI leadership**. We also fund 13 Community Research Liaisons (CRLs) who are members of the diverse rural, ethnic, and LGBTQ communities around the state in which they

are embedded to act as direct bridges between our campuses and their communities. CRLs, being community members, regularly assess the “pulse” of their community’s health challenges and bring this information to the PACT council for discussion and planning. Our CEHE programs are strongly aligned with the CTSA Program Goals as outlined in Section 1, PAR-21-293 (**Table C3**). Below we highlight several of these programs that will be enriched in the next grant cycle.

TABLE C3. NCATS CTSA Program Goals	Corresponding CCTSI Community Engagement Activities
Develop, demonstrate, disseminate innovations that turn science into medicine faster	<ul style="list-style-type: none"> • Community (Boot Camp) Translation • Community Engagement Pilot Grant Program (CE Pilot) • SNOCAP’s 23 active practice-based research projects (\$23.7 million in funding)
Promote impactful partnerships and collaborations	<ul style="list-style-type: none"> • Partnership of Academicians and Communities for Translation (PACT Council) • Community Research Liaison Program • Trailhead Institute Partnership • Community Clinical Trials Advisory Board
Address health disparities	<ul style="list-style-type: none"> • Research Readiness; CE Pilot Grants addressing health disparities • Older Adult Research Specialist Training Collaboration • Mandatory DEI Trainings for CCTSI Staff
Provide a national resource for the rapid response to urgent public health needs	<ul style="list-style-type: none"> • Colorado Community Engagement Alliance Against COVID 19 Disparities • SNOCAP practice-based research networks’ COVID-19 sentinel surveys • Research Readiness • Community Research Liaison Training Framework
Promote training and career support	<ul style="list-style-type: none"> • Colorado Immersion Training in Community Engagement • Technical Assistance and Coaching for CE Pilot Awardees • Quarterly CU Campus Community Engagement Forums • Community (Boot Camp) Translation Facilitation Training • Community Engagement Training for Researchers • Community Engagement Consultation Service
Nurture field of translational science	<ul style="list-style-type: none"> • Community Engagement Pilot Grant Program (CE Pilot) • Participation in Team Science Competencies Workgroup

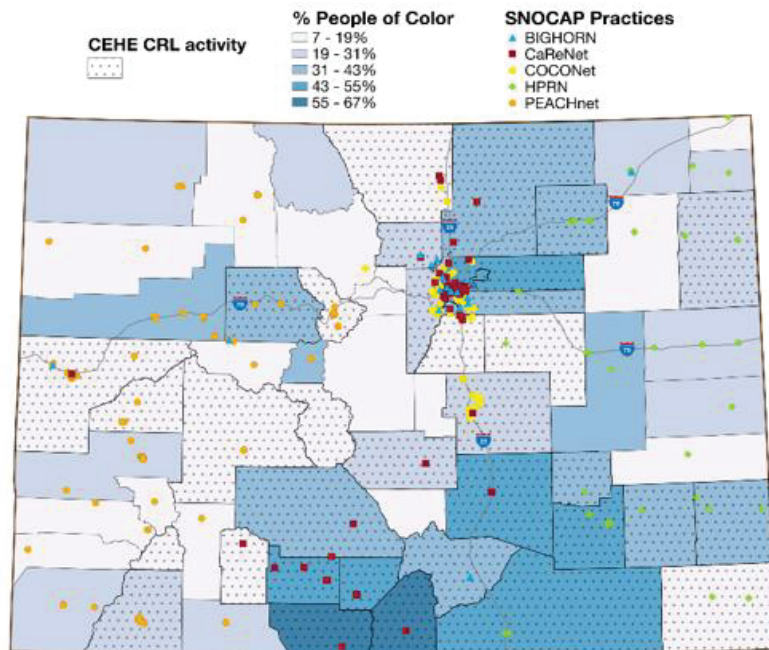
Our flagship workforce training program, **Colorado Immersion Training in Community Engagement (CIT)** continues to train investigators from all CU Anschutz schools and colleges and Partnering Institutions in the principles of community engagement and community-engaged research. Demonstrating the **impact** over the 10 years of the CIT program, 25 graduates have gone on to receive 33 Community Engagement Pilot awards which have led to \$8,723,000 in follow-on grant funding. We continue to disseminate and apply our innovative **Boot Camp/Community Translation (BCT)** methodology⁴¹ of developing culturally sensitive, community specific messaging about research and studies, by accelerating the time course of this methodology to the needs of communities during the COVID-19 pandemic. We disseminated BCT and conducted BCT virtual training at Wayne State University with Detroit area community partners during the early pandemic months. These partners then conducted a series of BCTs that developed materials and messages to address COVID-19 misinformation. Similarly, we adapted BCT to a rapid 8-week virtual format that has formed a foundational method for our NHLBI/NIH funded **Colorado Community Engagement Alliance Against COVID-19 Disparities (CO-CEAL)** work in 5 urban and rural racial and ethnic minority communities in Colorado. Through **CO-CEAL** we have leveraged our infrastructure to reach racial/ethnic underserved communities in both rural and urban areas disproportionately impacted by COVID-19. We have engaged and hired community members as the key individuals responsible for the work of CO-CEAL as they have the expertise in their communities’ needs and have trusted

relationships. Thus, we have created two new roles: *Community Connectors* and *Community Data Collectors* (see Goal 2b for details). These new models will be **expanded beyond COVID** in the next grant cycle.

Practice-based Research Networks (PBRNs):

The State Network of Collaborative Ambulatory Practices & Partners (SNOCAP) oversees 5 PBRNs and is supported by the CCTSI, SOM Department of Family Medicine, and ACCORDS. SNOCAP currently works with 282 primary care practices statewide (**51% rural/ frontier**) managing 23 projects with \$27.3 million in active funding. SNOCAP is led by Dr. Nease, CEHE Director. SNOCAP works closely with practices across the state to develop and answer research questions that are relevant to primary care clinicians and their patients in communities across the entire state. SNOCAP PBRNs overlap with CEHE CRLs (**Figure C3**, which also displays county level % people of color). At a staff level, several of our CCTSI CRLs are in shared roles with the regional PBRNs which helps to ensure integration of research efforts.

Figure C3: Locations of PBRN practices & CRL activity



C. APPROACH

The current CTSA FOA calls on our CEHE Module to address **translational roadblocks** through the following:

- Plans to collaborate with and engage stakeholders in all aspects of CTS research
- Plans to accelerate CTS research to address the significant burden of conditions that disproportionately affect rural, minority, and other underserved populations
- Plans to promote health equity
- Plans to promote participation of underserved populations and ensure that research participants are engaged as full collaborators early and often throughout the process

With our overarching goal to **advance health equity through CTS**, we have aligned our specific goals to address these points directly through the lens of capacity building on our campuses, in communities and with stakeholders. In order to address these goals, we will advance our programs and prior experience, utilizing the guidance of the PACT Council to ensure our implementation is faithful to our guiding principles.

Goal 1: Develop the capacity of investigators and research professional staff to equitably engage and involve diverse communities and stakeholders in clinical and translational research.

While our ongoing program of Community Research Liaisons that provides bridges to establish partnerships with communities and community-based organizations is vital, absent basic training in community engagement and DEI, investigators *and* staff often lack the knowledge and skills to make optimal use of our infrastructure. Therefore, we propose to advance our existing training programs to address this deficit in the following ways.

Goal 1a: Develop and provide training for research coordinators and other professional research staff in Diversity, Equity and Inclusion and Community Engagement.

Research coordinators, recruiters and other staff are often the primary face of research and trials to the public with respect to implementation of a study, especially involving participant recruitment. We propose to develop a training program in community engagement and DEI for these clinical research professionals that will be made available at least annually to all campus research staff. This training will cover aspects of health equity, historical structural racism with respect to research and basic skills in community engagement. The training will be led by CEHE staff and CRLs with guest community speakers who will share their experiences and expertise on how to equitably and authentically engage with diverse communities. We will work closely with the CCTSI WD program (**Module C1**) and the Clinical Research Support Center at CU Anschutz (**Module D1**) to develop and implement this curriculum.

Goal 1b: Expand the capacity of our existing program for training investigators in DEI and Community Engagement.

Our **Colorado Immersion Training (CIT) program** has been extremely successful in training investigators committed to community-engaged research over the past 10 years. CIT provides 6 months of training through structured readings and discussions held outside normal work hours and a one-week intensive immersion experience in one of our partner communities. CIT also qualifies for course credit in the Clinical Sciences Graduate Program. We run the program in tracks specific to each partner community with a limit of 4-5 participants per track, minimizing burdens on the community partners while maximizing the learning. Because investigators can complete the training without taking significant time away from their other academic and clinical work, the program is extremely popular and demand is high. As a result, we regularly turn away qualified and interested applicants due to our funding model, which has been entirely reliant on CCTSI UL1 grant funds.

In the next grant cycle, we will expand the capacity of CIT by charging tuition, asking applicants' Departments or Divisions to pay 80% of the cost of participation while providing scholarships to highly qualified applicants who are unable to access tuition funding. CCTSI K12 Scholars will be prioritized. This tuition model is similar to that of the CCTSI's Clinical Faculty Scholars Program. Through adoption of this model, we estimate being able to expand the program to up to 15-20 participants per year in 3-4 tracks. We will also explore our ability to offer CIT as a formal course within the Colorado School of Public Health and as part of the Latino/a Health Certificate program in partnership with the CU Latino/a Research and Policy Center.

Goal 1c: Expand the reach of the Community Clinical Trials Advisory Board (CCTAB) beyond COVID-19 related clinical trials.

We will promote and encourage investigators to make use of our CCTAB that was created through our CO-CEAL work to assist investigators proposing or implementing COVID-19 related clinical trials in a community setting. The CCTAB is a mix of community stakeholders and academic members who consult with investigators to assist them in ensuring that studies are taking the needs of the communities into account in a culturally sensitive manner. We will ensure that access to the CCTAB is expanded to any investigator conducting a clinical trial that holds meaning for underserved communities and addresses a clinical topic where diverse and inclusive enrollment is sought or required.

Goal 2: Develop the capacity of communities and stakeholders to provide input and feedback and equitably engage with investigators and staff in clinical and translational research.

Equitable engagement of communities and stakeholders in clinical and translational research requires more than trained investigators and staff, it also *requires knowledgeable and empowered community members and organizations* who can act as full partners in research, ensuring stakeholder input and feedback, and that community interests and needs are being sought, respected and addressed. We propose to address this important issue through training of *community-based organizations* and of *individual community members*.

Goal 2a: Expand the development and implementation of programs to train Community Based Organizations (CBOs) and their staff to design organizational strategies and policies related to research and to equitably partner with researchers in community settings.

The CEHE Core has developed a series of educational training activities to build capacity in community-academic research partnerships. These trainings are now being combined into a comprehensive "**Research Readiness**" training program to equip individual community members and stakeholders, CBOs, and their staff with the knowledge and tools to authentically and equitably partner with researchers in all phases of the research process, and to co-design organizational strategies and policies related to research.

In the spring of 2018, the CEHE Core completed more than 20 key informant interviews with academic investigators and CBOs to assess the need and potential value of formal "Research Readiness" training. The interviews revealed that academic researchers were enthusiastic about being able to access a network of formally trained CBOs that are ready and willing to partner on research projects. CBOs expressed a desire to establish a more strategic, intentional, and informed approach to participating as full partners and co-leaders in research efforts that align with their organizational priorities, as opposed to participating in one-off projects in which they are primarily engaged in data collection or participant recruitment but excluded from the rest of the research process. Our "**Research Readiness for CBOs**" program goes beyond the research fundamentals of the training program for individual community members (see Goal 2b) and includes education in the principles of Community Based Participatory Research (CBPR), partnership development, trust, equity, data use and ownership, and developing organizational plans, policies & procedures to guide strategic research efforts.

In our current grant cycle, we had proposed to develop and pilot this training program, however, due to the pandemic these activities were delayed, yet to date we have developed 90% of the program but have yet to pilot test it. In the next grant cycle, we will complete the development of Research Readiness for CBOs, pilot and evaluate it, revise and then disseminate it broadly to interested CBOs and community members within Colorado and beyond.

Goal 2b: Promote the development and implementation of programs to train individual community members to partner in the development and conduct of research in community settings.

The companion training to Research Readiness for CBOs is “**Research Readiness for Individuals**”. These modules are designed to introduce the community member to research fundamentals and prepare them to participate as community-based members of a research team. Participants will learn about what research is, the different types of research, how a study is designed and conducted, ethical considerations in recruitment, retention and compensation, the importance of informed consent and privacy. They will also learn the basic standards of data collection and management in research and the importance of engaging communities and other stakeholders in the research process. This ten-hour training will equip participants to contribute to the research process as a valued member of a study team with a basic understanding of recruitment, consent and data collection and management as well as formal human subjects research training.

We have pilot tested some of our Research Readiness trainings for Individuals through new positions created for our NHLBI funded CO-CEAL program. We have developed two new community partners roles: **Community Connectors** are part-time contract community member partners who have helped coordinate CO-CEAL activities in each of our five focus underserved communities. They have **1)** led the recruitment of participants in our CO-CEAL Community Translations; **2)** assisted with the recruitment, training and oversight of Community Data Collectors and data collection activities; and **3)** helped to organize community dissemination of educational materials and survey results. In each CO-CEAL community, the Community Connectors have provided a vital link between our core CO-CEAL staff and investigators and our partner communities. The **Community Data Collectors** have played a vital role as the faces of our community-based survey data collection. They have been able to reach community members that would have otherwise been impossible to reach for survey data collection to help us understand what misinformation exists about COVID-19, the degree of vaccine hesitancy, and the trusted sources of information for each community.

To train the Community Connectors and Community Data Collectors, we partnered with our CCTSI and University regulatory staff who created new human subjects research training specific for community members (**Module D1**; RKS). This training extended and deepened a process that we had previously developed for our SNOCAP practice-based research network community advisory boards.⁴² The training occurs over a half day and addresses key elements of the Belmont Report and other protection of human subjects issues including data security. **During the next grant cycle, we will expand the Community Connector and Community Data Collector training and process to other Colorado communities and train others using the Research Readiness curriculum.**

Goal 3: Establish, build and maintain trust with communities and stakeholders through return, interpretation, and dissemination of results in partnership with communities and stakeholders.

A core principle of Community Based Participatory Research^{43,44} and community engagement⁴⁵ is ensuring that results are equitably shared with communities that participate in the research and that communities participate in the interpretation and dissemination of the results. This builds and sustains trust, a core indicator in the recent National Academies of Medicine commentary on *Assessing Meaningful Community Engagement*.⁴⁶ Communities should also take ownership of dissemination of results that inform and impact their communities. This dissemination activity in partnership with communities is a key trust building activity. Within our CEHE program we will expand our efforts to partner with community stakeholders and organizations in order to interpret and disseminate research findings. As an example, in our CO-CEAL work we are returning survey results to communities through community events, making the data available to them and including our Community Connectors in efforts to disseminate the results both locally and nationally at conferences such as the Association of Clinical and Translational Science annual Translational Sciences meeting.

Goal 4: Continuously evaluate and improve our capacity development activity on campuses and in communities by measuring and monitoring our impacts on equitable engagement and involvement with diverse communities and stakeholders in clinical and translational research.

METRICS: Over the 7 years of the CCTSI UM1 grant cycle, we will ensure that our capacity development efforts are meeting the needs of the CU Anschutz campus, Partnering Institutions and community stakeholders by regularly holding key informant interviews to elicit feedback. We will partner closely with the CCTSI CQI/Evaluation Core in these efforts as we have in the past. The Evaluation Core will continue to collect and monitor **metrics**, for example, on the number and types of CRL research activities, number and nature of community partnerships, number and length of investigator immersion in Colorado communities, research productivity, return on investment of CE-Pilot grantees, and community partner satisfaction with the CIT program. The Evaluation Core will also examine the TSBM indicators (particularly Community and Public Health Benefits) and develop community case studies and Impact Profiles to demonstrate impact of the CTSA award on CBPR research in Colorado. In the past this CQI activity has led to significant improvements in our programs. A notable example is how we have improved our Community Engagement Pilot Grant Awards by incorporating active technical assistance and coaching for pilot award recipients. This has been especially helpful for Partnership Development recipients as they are learning to build relationships across academic/community boundaries.

In addition to continuous quality and process evaluation and improvement of our programs, it is critically important that we measure and monitor the **impacts of our training and CCTAB programs** on engagement and involvement. At a campus level we will partner with the CCTSI Study Monitoring Committee which tracks trial enrollment metrics on age, race and ethnicity via our OnCore CTMS. This will permit monitoring of the enrollment of diverse populations in clinical research studies and clinical trials. To evaluate the impact of our training, we will assess whether participants in clinical trials are more likely to match in their enrollment the demographics of Colorado or exceed representation of disproportionately impacted racial, ethnic and rural populations when their investigators and staff have participated in our trainings and their clinical trials address conditions where significant health disparities exist. For those research studies that have sought input from the CCTAB, partnership through our CRLs, Community Connectors or Community Data Collectors, we will specifically monitor and inquire about their recruitment rates and assess actively through feedback from the community regarding their engagement and partnership. To add to the enrollment data, we and the CQI/Evaluation Core will regularly conduct surveys & interviews regarding the impacts of the training and consultation with investigators & staff of these trials who have participated in our trainings.

By monitoring the outcomes of our capacity building efforts on clinical and translational research participation, we will address a major roadblock of clinical and translational science: *how to best build trusting relationships and ensure participation of diverse communities and stakeholders*. These quantitative and qualitative data will form a mixed methods study of the effectiveness of our programs to **advance health equity through clinical and translational science**. We will then share best practices with other CTSA Consortium Hubs.

D. STRUCTURE, GOVERNANCE AND INTEGRATION

The CCTSI's CEHE core is staffed by a Director (Donald Nease, MD; see **Biosketch**), Deputy Director (Montelle Tamez), 2 half-time staff for program coordination and implementation, and a full-time administrative staff member. The Core's work is governed by the PACT Council, which reports to the CCTSI EC. The Core also supports **13 Community Research Liaisons** (CRLs) who are community members embedded in their own underserved rural and urban communities across Colorado. The Core partners closely with the Trailhead Institute, an independent non-profit public health institute that assists with directing funding and providing technical assistance to CBOs which are building their own capacity as research partners. **INTEGRATION:** CEHE is tightly integrated into CCTSI's leadership and governance structure with our Director, Deputy Director and 2 community-based PACT Council members as members of the EC, the governing and decision-making body for the CCTSI. Our Community Engagement Pilot Grant Awards are an integrated part of our CCTSI Pilot Grant Program (**Module D2**) with application review conducted by PACT Council members. We also work closely with the WD core (**Module C1**), providing trainings and coursework in community-engaged research for many programs, including the CLSC program and the Pre- and Post-Doc T32 and K12 programs, and trainings for research staff professionals. Our CEHE programs extend to CCTSI members at CU Boulder, CU Denver, CSU, Partner Hospitals, the PBRNs and across the state through community organizations. Finally, we are integrated into activities of RKS Core (**Module D1**), providing input on how to best ensure that the interests of communities are well represented in human subjects reviews, and office of Vice Chancellor for DEI & Community Engagement

E. METRICS, TIMELINE AND MILESTONES

During grant years 1-3 we will implement all programs described in Strategic Goals 1 and 2. During grant years 3-7 we will implement Strategic Goals 3 and 4 with a focus on continuing to develop relationships with our partner communities and stakeholders while continuously monitoring and improving our processes and outcomes on enrollment in CTR studies. *Our plans for Metrics and Evaluation are described above under Strategic Goal 4.*

ELEMENT D. CLINICAL AND TRANSLATIONAL SCIENCE RESOURCES AND PILOTS

A. STRATEGIC GOALS (for all 3 Modules)

Overview of CTSA Goals Addressed by this Element

Goal 1: Efficiency and impact of CTS

Goal 2: Collaboration, team, data science, partnerships

Goal 3: Community partnerships, health inequities, disparities

Goal 4: Operational efficiencies

Goal 5: Rapid response to public health emergencies

Goal 6: CTS training for all research professionals

• **Module D1 – RESOURCES AND SERVICES (R&S)**

The overarching goal of the R&S Program is to *remove structural roadblocks and accelerate clinical and translational research (CTR)* that engages diverse communities in projects carried out by investigators across the multi-disciplinary T0.5-T4 translational science spectrum. R&S will be essential to support CTR from inception to completion and ensure the highest quality, efficiency, safety, and informativeness of the research portfolio through the **Strategic Goals**:

Goal 1. Provide **supervisory oversight of R&S operations** to facilitate equitable access and ensure that services enhance the efficiency, quality, and safety of CTR protocols.

Goal 2. Develop expertise and capacity to support the **design of Virtual and Real-World clinical trials**.

Goal 3. **Accelerate the start-up and completion** of CTR by addressing barriers that impede progress, building on lessons learned from the rapid implementation of COVID-19 protocols.

Goal 4. **Ensure that R&S operations can respond to urgent public health emergencies** by employing COVID innovations to pivot to meet new needs and overcome emerging roadblocks quickly and efficiently.

Goal 5. **Enhance recruitment and retention of diverse research participants** by utilizing new targeted recruitment tools and deploying novel models to encourage research participation across the lifespan.

• **Module D2 – CLINICAL AND TRANSLATIONAL SCIENCE PILOT PROGRAM (CTS-PILOTS)**

The major focus of CTS-Pilots program is to support the initial stages of innovative projects that address CTS barriers. CTS-Pilots provide one-year awards to develop new ideas, methods, and collaborations, customarily supporting junior CTS researchers through the **Strategic Goals**:

Goal 1. **Accelerate the REDCap-based Pilot Award application process** to provide valuable support to CTS researchers and address needs and barriers in planning, conducting, analyzing, and disseminating CTS studies

Goal 2. **Provide a rigorous peer-review process** for selection of the best CTS pilot applications using a unique REDCap-based database to match the scientific focus of the proposal with reviewer expertise.

Goal 3. **Conduct a comprehensive evaluation** to monitor productivity and efficiency of CTS-Pilots awards during their funding period, and to follow-up on the success of awardees and the impact of their projects

Goal 4. **Disseminate our REDCap peer-review process platform to CTSA Hubs** for implementing fast, efficient, and transparent Pilot Grant Management to facilitate CTS-Pilots nationally.

• **Module D3 – HEALTH INFORMATICS**

The goals of the Health Informatics program are to be the steward for research data, democratize access & sharing, maintain critical software applications, and advance informatics education through the **Strategic Goals**:

Goal 1. **Integrate clinical, biological, administrative, and public health data and deploy robust analytical environments.** We will support translational research locally and nationally by integrating and linking a variety of data types and sources and deploying scalable, HIPAA-compliant computational environments for research.

Goal 2. **Improve accessibility and interoperability of regional and national data sharing and analytics.** CCTSI Informatics has deep expertise in realizing FAIR (findable, accessible, interoperable, reusable) Guiding Principles to maximize the utility of our collective data.⁴⁷ We will ensure that local data are aligned with global standards and maximally useful in national and international programs.

Goal 3. **Develop, validate, and deploy clinical decision support (CDS) and clinical trial execution tools.** With our Hospital Partners, we will deploy patient- and provider-facing tools within the EHR, for CDS and clinical trials, which use common data structures, governance, and processes. For EHR-based interventions, CDS and treatment tools will be the “return leg” of a “complete loop” from development to implementation in practice.

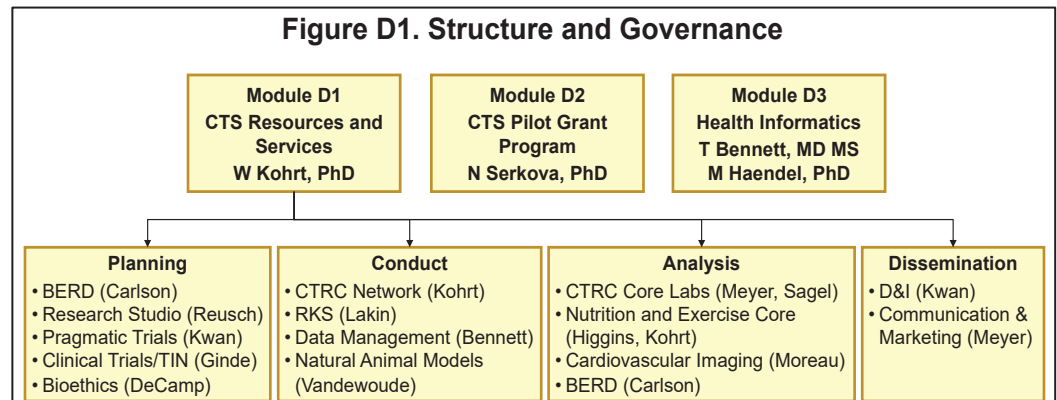
Goal 4. **Expand hands-on translational informatics education across career stages and disciplines.** We will extend CU graduate and clinical training programs, enrich REDCap training materials, and develop a pilot

informatics partnership program with community organizations in support of their data maturity.

B. STRUCTURE, GOVERNANCE, INTEGRATION

Figure D1 shows the structure and governance of Element D. **Module Leaders** (see *Biosketches* for qualifications) are: **R&S** - Wendy Kohrt, PhD, Distinguished Professor of Medicine; **CTS-Pilots** - Natalie Serkova, PhD, Professor of Radiology; and **Health Informatics** Co-Leaders are Tell Bennett, MD MS, Associate Professor of Pediatrics, and Melissa Haendel, PhD, Professor of Biochemistry. Dr. Bennett will lead Goals 1.2, 3, 4.1, and 4.2 and Dr. Haendel will lead Goals 1.1, 1.3, 2, and 4.3. All Module Leaders are standing members of the CCTSI Executive Committee (EC) and report to the PI Dr. Sokol (see **Element B**). Each oversees a team of scientists and administrators who enable efficient operation of the programs and facilitate integration with other CCTSI components and across the Partnering Universities and Hospitals and Community Stakeholders. To enhance efficient, compliant, impactful research, a broad array of R&S will be supported in the domains of Study Planning, Conduct, Analysis, and Dissemination, each resource led by an experienced faculty member (**Figure D1**).

Integration. EC meetings held every 2 weeks facilitate communication & integration of activities across the units in **Figure D1** and with other Elements of the CCTSI. This CTSA application builds on a long and successful history of support for CTR and innovation at CU Anschutz and Partnering Institutions, from CSU in Fort Collins to the PBRN sites across Colorado (**Figure C3**; page 517). All Partnering Institutions have faculty who lead, review, and participate in the R&S, Pilot Funding and Health Informatics programs described here. Users of these services include faculty, post-Docs, trainees, and research staff professionals at all Partnering Institutions. Partners share best practices and lessons learned to our EC to improve our programs and provide new innovations that can be disseminated to other CTSA.



MODULE D1 - RESOURCES AND SERVICES

a. SIGNIFICANCE AND PRELIMINARY DATA/ INSTITUTIONAL ASSETS

Many of our CTR resources and services have evolved during the course of CCTSI versions 1.0 to 3.0 and have been essential for facilitating impactful research that has changed clinical practice and health and allowed us to respond to the pandemic research needs quickly and rigorously. We have clustered these CTS R&S, **all of which will continue to be essential to clinical and translational research into the next funding period**, into study life cycle domains of **Planning, Conduct, Analysis, and Dissemination**.

PLANNING

R&S in this domain provide support for conceptualizing and designing impactful translational research.

The Biostatistics, Epidemiology, and Research Design (BERD) core fills a critical need by supporting a broadly accessible resource for design of high quality, scientifically sound, feasible, efficient, and impactful research studies, *particularly for early career investigators* (including KL2 scholars, **Module C1** and future **K12** Scholars) who have a critical need for, yet limited access to, such support. The BERD has evolved to meet the needs of investigators in addressing emerging advances in data science (e.g., high-throughput technologies, big data, machine learning, etc.). BERD is fully integrated within the campus-wide Center for Innovative Design and Analysis (**CIDA**). This integration includes shared leadership (Dr. Carlson directs both BERD and CIDA, Drs. Sammel and Kechris are Associate Directors of both), and 17 PhD faculty, 13 MS faculty, and 13 student research assistants in the BERD are CIDA members. The BERD supports **1)** consultation and collaboration formation for proposal development; **2)** drop-in office hours; **3)** delivery of short education courses, **4)** methodology development, and **5)** analysis support for cross-disciplinary projects in the CCTSI. In the last two

years, **BERD** averaged 260 collaborative proposals annually, held 790 project start-up/office hours consultations, conducted 226 projects analyses, and funded one methodology project per year. BERD faculty developed six new 6-week courses in data literacy and a big data seminar series (attendance ~50), launched a successful hack-a-thon with 60 attendees that developed software packages to analyze wearable device data, and hosted a CU Data Week with over 150 participants.

The Research Studio Program is designed to improve research quality using collaborative roundtable discussion. Sessions bring together research experts for a moderated discussion to assist investigators to address specific questions and/or barriers at various stages in the research development process (e.g., hypothesis generation, study design, etc.).⁴⁸ A summary report and audio recording are provided to the investigator. The **Research Studio** team conducted Studios for 96 investigators and engaged 300 panelists since 2014. Based on CCTSI Evaluation Core data, 94% of investigators would recommend the program to a colleague, 88% would participate in another Studio, and 92% would serve as an expert panelist. Studio participants in 2019-2020 believed the experience contributed to more than \$2M in subsequent grant funding.

Pragmatic research refers to research conducted in Real World settings using resources available under typical practice conditions, with participants broadly representative of those expected to benefit.^{49,50} Pragmatic trials minimize recruitment, consent, and data collection burden to participants and staff, make use of existing data sources (e.g., EHR), integrate into existing workflows, and require little to no additional training or fidelity monitoring.⁵¹⁻⁵³ The CCTSI and CU Anschutz have established multiple systems, partnerships, and tools that integrate into the **Pragmatic Trials Core** directed by Bethany Kwan, PhD: **a)** Adult & Child Center for Health Outcomes Research & Delivery Science (**ACCORDS**) provides training, education, and investigator support for pragmatic research and community engagement, **b)** CU NavLab provides support for data and informatics solutions for quality improvement-style pragmatic research within UCHHealth and CHCO, **c)** the Clinical Research Informatics and Innovation Unit (**CRIIU**) provides support for research that requires integration and modification with clinical informatics innovations. All of these programs operate in close collaboration with the CCTSI D&I, RKS, Health Informatics, BERD, and Community Engagement and Health Equity (**Module C2**) Cores.

The Clinical Trials Team, located in the office of the VCR, serves as part of our CTSA Trial Innovation Network (**TIN**) **Hub Liaison Team** with goals to develop, support, and promote multicenter clinical trials that are conducted efficiently, equitably, and with the highest quality and compliance. Our **Clinical Trials Team** integrates with multiple components of the CCTSI (e.g., Health Informatics, BERD, D&I, Community Engagement) and will expand the opportunities for investigators to both propose multicenter trials through the TIN and recruit patients locally for TIN-sponsored trials. Our clinical partners (UCHHealth, CHCO, DH, DVAMC, NJH) provide large, diverse patient populations for recruitment to studies. Since 2018, the **Clinical Trials Team** submitted 6 outgoing trials to the TIN and identified 19 local investigators to serve as site PIs for incoming trials.

The Bioethics Consult Service is available at no cost to CCTSI members including from Partner Institutions who seek advice about ethically complex aspects of their research. Consultations can also be triggered while a protocol is undergoing local scientific review or evaluation by the IRB. In the last year, the **Bioethics Service** provided consultations on the return of genomic findings, risks of publicly sharing data, withdrawal of deceased persons' samples from a biobank, requirement for research participant SSN for remuneration purposes, and securing informed consent in a study of deep brain stimulation for methamphetamine addiction. The Service also hosted its annual Research Ethics Conference (2022 topic: *The Ethics of Artificial Intelligence*) and delivered a hospital-wide grand rounds on *Diversity, Equity, and Inclusion in the Moderna National Vaccine Trial*.

CONDUCT

R&S in this domain facilitate and streamline the efficient performance of CTR studies and trials.

Clinical Translational Research Centers (CTRC; clinical research units) Network. Centralized facilities and personnel to support clinical research have been established for more than 60 years (originally GCRCs) and are integral to our culture of efficient, safe, and compliant human research. The **CTRC Network of 4 CTRC units, formalized in 2008**, supports clinical research and trials at CU Anschutz, UCH and CHCO (inpatient and outpatient facilities), and at NJH and CU Boulder (outpatient research facilities), by providing investigators access to state-of-the-art facilities, trained expert research nurses and other personnel, Core laboratories, and other services through a fee-for-service model. The availability of the CTRC units was critical for our robust response to the urgent national need for COVID-19 trials. The CTRC Network supports **~500 research protocols** each year (530 in 2018, 506 in 2019, 517 in 2020, 499 in 2021) for investigators from >40 departments/divisions; 30% are pediatric protocols. **Figure D2** illustrates the activity of outpatient and inpatient

CTRC units over the past 4 years. The high level of activity on the adult inpatient unit in 2021 reflects the use of that unit to respond to the public health emergency. When monoclonal antibody therapeutics for COVID-19 became available, UCHealth found it challenging to deliver treatment to patients because of limited space and personnel trained to administer infusions. The CCTSI made research space and personnel available to

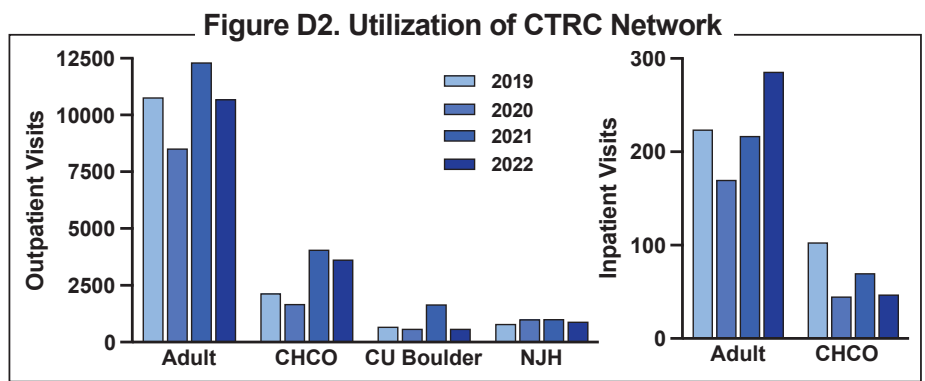
assist until UCHealth had adequate resources. This collaboration with UCH enhanced our ability to perform the *mAb Real World Evidence COVID-19* study funded by a UL1 NCATS supplement (see **Element A, page 496**).

CTRC Scheduler, based on freeware from the Harvard CTSA, is used for scheduling research participant study visits in the adult CTRC. A key advantage of this platform is that it enables study teams to schedule in real time the room, equipment, and personnel required for complex study visits, thereby optimizing the efficient use of CTRC units for the ~500 protocols supported annually.

Administrative Core. This Core helps R&S Core Leaders set up billing procedures and manage their accounts using the **iLab Solutions** platform. Because of its success in streamlining invoicing for core labs, iLab Solutions was transferred from a CCTSI resource to an institutional resource that resides in the Finance Office. All R&S Cores that provide services for research participant interactions (e.g., CTRC Network, all Analysis Cores) and Cores that provide other services for investigators operate under a fee-for-service model. Because early career investigators may be disadvantaged by the fee-for-service model, the CCTSI manages a **MicroGrants Program** that provides up to \$10,000 per year for up to 3 years for junior investigators to cover the costs of services provided through the CTRC Network. Grant funds do not support the *MicroGrants* awards but do support the administration of the program. CTSA grant funds used for each R&S Core are described in **Budget Justification**.

Regulatory Knowledge and Support (RKS) Core. This Core is directed by Dr. Alison Lakin, Associate VC for Regulatory Compliance, who is responsible for research compliance committees (e.g., COMIRB, Conflict of Interest, Radiation Safety, etc.) and compliance and safety of clinical research. Accordingly, the regulatory approval process is fully integrated with CCTSI Cores to ensure that research is operationalized in a compliant, efficient and effective manner. Among the many resources provided by RKS, four play a particularly critical role in supporting the CCTSI research enterprise: **1) The Clinical Research Support Center** provides a help desk, training classes, Clinical Trial Contracting team, CTMS support, and budget development. **2) COMIRB** has served as the single IRB of record for CU Anschutz, UCHealth, CHCO, DH, and VAMC since 1985. There is a **Single IRB (sIRB) Support Team** that assists investigators who need to rely on an external sIRB. COMIRB has also expanded capabilities to be a sIRB for multi-site studies, and, in collaboration with the CEHE CCTSI Core (**Module C2**), it addresses the challenges and concerns of practice-based researchers and serve as a sIRB for the CTSA consortium when needed. **3) Since 2018, there has been a single electronic Portal for IRB protocol submissions** for investigators from CU Anschutz, UCHealth, CHCO, and DH. The Portal provides a streamlined, single-entry point for review of CTR protocols. It enables compliance, feasibility, and scientific reviews to occur in parallel and is integrated with the approval processes of the Partnering hospitals. **4) The Scientific Advisory and Review Committee (SARC)** reviews all CTR protocols that have not undergone peer-review. Trainees from the MS and PhD Clinical Science Graduate programs (**Module C1**) conduct mentored reviews as part of their curriculum to learn about different study design limitations. SARC coordinates closely with the CCTSI Perinatal Research Facilitation Committee to combine reviews for pregnant women, placenta/cord samples, or neonates.

REDCap Data Management Service. The CCTSI provides a fully subsidized HIPAA-compliant REDCap Data Management service for members of the CCTSI that have received IRB-approval for their research projects. **Statewide reach:** We provide REDCap support for projects at CU Anschutz, CU Denver, CU Boulder, CU Colorado Springs, CSU in Fort Collins, UCH, CHCO, Rocky Mountain VAMC, NJH, Denver Health, and Kaiser Permanente Colorado. This has fostered collaborative research between CCTSI Partnering Institutions across the state and insured regulatory compliance by enabling investigators to follow best practices via no-cost access to secure, user-friendly data management services. Free training for investigators includes video tutorials (used worldwide) and 1:1 hands-on tutorials and consultations. REDCap currently supports >5,000 users and >16,000 projects. Our REDCap team is a national and international leader and regularly presents at REDCapCon.



The **Natural Animal Models Core**, headquartered at CSU, is a unique CCTSI resource which promotes collaboration between veterinary and human medical scientists to leverage naturally occurring diseases in dogs, cats, horses, and other species that mimic disease expression, biology and pathology in humans - a 'One Health' approach to translational medicine. More than a dozen collaborations have been strengthened by CCTSI support, including assessment of pathogenesis of inflammatory bowel disease in cats and people, canine models to assess cancer therapies (**Box D1**), clinical trials to evaluate stem cell and biological therapies in musculoskeletal diseases, and clinical trials to assess impacts of cannabidiol compounds on canine intractable epilepsy.⁵⁴ With CCTSI support, CSU has been a leader in developing a Clinical Review Board ('veterinary IRB') that has shown strong annual growth and currently evaluates more than 100 veterinary clinical protocols per year for research. CSU has been a leader in the CTSA One Health Alliance (**COHA**), a consortium of 15 CTSA affiliates with academic veterinary centers founded in 2014. This work aligns with NCATS Goal 1 (efficiency and impact of CTS) and Goal 8 (training all research professionals). CSU faculty have provided COHA leadership and have initiated programs in **1)** "One Health Datasets," promoting integration of veterinary and human EHR via a common data model,⁵⁵ and **2)** Interprofessional education for veterinary and medical students.

Box D1. Impact of Regional Lymph Node Irradiation on Anti-Tumor Immune Response for Advanced Head and Neck Cancer

- CSU-CU CO-Pilot study funded in 2019
- Co-PIs: Keara Boss, DVM PhD and Sana Karam, MD PhD
- Studies dogs as a model for human therapy
- K01 awarded to Dr. Boss based on this work

ANALYSIS

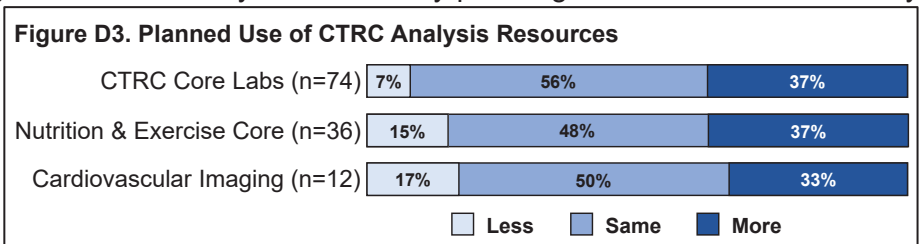
R&S in this domain meet the needs of CTR protocols that depend on availability of specialized facilities, sophisticated equipment for clinical phenotyping, unique expertise, and/or trained technicians.

Three **CTRC Core Labs**, co-located with the adult, pediatric, and NJH CTRCs, are CAP- and CLIA-accredited laboratories supporting >150 specialized assays for ~100 protocols annually, avoiding overlap among the labs.

The **Nutrition and Exercise Core** provides expert study design consultation for protocols that involve nutrition or exercise interventions or require assessment of body composition, fitness, physical activity, or energy balance (intake, expenditure). Services include: metabolic meal planning, preparation, and dispensation; measurement of dietary intake; assessment of hunger and satiety; dietary counseling; exercise stress tests; cardiopulmonary exercise tests; resting metabolic rate; body composition by dual-energy x-ray absorptiometry; and physical activity by triaxial accelerometry. Unique resources include: **1)** a state-of-the-art whole-room metabolic chamber that provides measurements of 24-hour energy expenditure and substrate utilization; and **2)** a 3,200 ft² research exercise training facility that supports many supervised exercise interventional trials, mostly NIH funded. The Nutrition Core provides services throughout Colorado by conducting study-specific dietary counseling via Zoom, virtual study design consultation, and using courier services for direct delivery of metabolic diets to those living in rural areas and studies at CSU.

The **Cardiovascular Imaging Core** uses vascular ultrasound and cardiac echocardiography to provide comprehensive measurements of cardiovascular health for research protocols. Services include: brachial artery endothelial function; arterial stiffness; intimal-medial thickness; cardiac function by real-time 3-D echo technology; and regional and global cardiac function by speckle tracking imaging.

Needs Assessment and Future Use: A Needs Assessment Survey conducted by the Evaluation Core in 2022 assessed recent and future use of CCTSI resources. Most CCTSI members who used CTRC Core resources in the last year predicted future use will be the same or increased (**Figure D3**). The results of this survey demonstrated the high need for these resources among CCTSI members. Through centralizing these resources and oversight by CCTSI personnel, we ensure quality, state-of-the-art interpretation of results, and low cost to investigators. The BERD Core, described in the PLANNING section, also provides important analysis services for CTR. Over the last 4 years the BERD established collaborative agreements (total \$1.8M) with 29 academic units for data analysis services. CTSA grant funds are only used for study planning and to offset cost for early career investigators and priority CCTSI collaborative initiatives. The Needs Assessment Survey related to BERD analytical services revealed that 21% of 183 respondents identified *General Study Design and Analysis* support as their highest priority need.



DISSEMINATION

R&S in this domain support the performance of Dissemination and Implementation activities and research.

Dissemination & Implementation: Support for D&I research is a formal component of the CTSA program and we are positioned to enhance capacity for training and application of D&I methods across the CTR spectrum. Building and expanding D&I capacity in CTSAAs has been recommended by NIH.⁵⁶ The **D&I Core**, in collaboration with the ACCORDS program, offers assistance with study design and application of D&I Science methods in CTR, by providing consultation, group mentoring, and collaboration in D&I methods for faculty, Post-Docs and trainees at all Partnering Institutions. In 2021, the **D&I Core** established the **Dissemination Consult Service**, which conducted 34 dissemination consults in 2022. In addition, the **D&I Core** offers several resources for self-guided application of D&I methods, such as the DICEmethods.org webtool,²⁵ an online tool for selecting engagement methods to inform planning, conduct, and/or dissemination of translational research. The CCTSI Dissemination Planning Workbook facilitates application of innovation and social marketing principles to create D&I plans. The CTSA Compendium of D&I Catalogs, developed by Dr. Kwan and national CTSA D&I Working Group collaborators, offers resources ranging from D&I training opportunities to catalogs of D&I frameworks.

The CCTSI **Communication and Marketing Core** (Wendy Meyer, director) will continue to disseminate information to investigators on the broad array of CCTSI R&S in **Figure D1**. Faculty, staff, trainees, and students across all four Partnering Academic and 5 Partnering Hospital systems, and stakeholders in community organizations receive weekly CCTSI email announcements as well as the quarterly newsletter (*Found in Translation*) and social media communications. Furthermore, in 2021, stories relating the impact of translational research written by Ms. Meyer or featuring the CCTSI were picked up 14 times by *CU Anschutz Today*, a campus-wide newsletter disseminated to 19,000 individuals, and 12 times by the CU systemwide newsletter distributed to 39,000 individuals, *CU Connections*, and have been featured on NCATS and CLIC websites.

b. **APPROACH AND INNOVATION**

Goal 1: Provide supervisory oversight of R&S operations

All of the essential R&S described above to support the Planning, Conduct, Analysis, and Dissemination of CTR (**Figure D1**) **will be advanced into the next funding cycle** under the experienced supervisory oversight of the CCTSI. The CCTSI oversight is critical to the functioning of these heavily utilized resources. For example, the **CTR Network** would not be feasible in the absence of the CTSA UM1 grant funding which provides administrative oversight support for each CTRC unit (e.g., nurse manager, medical director) to ensure that staff members are appropriately trained and maintain competencies, research protocols comply with regulatory requirements, and study visits are scheduled and conducted according to protocol. Other CCTSI resources, such as **BERD, which is a component of CIDA**, are integrated into other campus-wide services, however, CCTSI funding provides the support for early career and URM investigators to ensure that they have access to study design and analysis expertise. This will enable them to prepare competitive applications for extramural funding and advance their careers, whilst performing high quality, impactful research.

Our **Natural Animal Models Core leadership** (located at CSU), as part of COHA leadership, will develop national guidance for veterinary 'smart IACUC' for multi-center trials, best practices for veterinary bio-archive management, and promote advocacy, training, and communication efforts in One Health. CSU faculty provide leadership on several CTSA COHA subcommittees in clinical trials, clinician scientist education, biobanking, communication and collaboration and advocacy working groups. Guidance and best practice documents, training modules, and videos will be shared via websites, local and national meetings and workshops, and publication in peer-reviewed journals. The Natural Animal Models Core director will facilitate communications with CU Anschutz's IRB about veterinary clinical trials that intersect with human clinical trials and provide leadership to implement veterinary clinical trials best practices, training, and certification at CSU and nationally, and consult on veterinary Clinical Review Board protocols.

Disseminating Information about current and new R&S will be accomplished by the Communication and Marketing Core which will use the following tactics: weekly email announcements to CCTSI Members; CCTSI website content; *Found in Translation* newsletter (quarterly) for Members; *The Link* CCTSI staff newsletter (bimonthly); CCTSI events and trainings newsletter (monthly); stories and press releases on the CCTSI newsroom of the website; events calendar to promote programs and courses online; infographics; whiteboard videos; social media marketing; and events such as Town Hall meetings and conferences.

Goal 2: Develop expertise and capacity to support Virtual and Real-World (pragmatic) clinical trials

Exciting new innovations in three areas will address this goal and will be developed and adopted over the 7-year

period of the award. The following innovations will be developed in the first 3 years.

1. The **Pragmatic Trials Navigation Service** will leverage existing pragmatic research resources and services. The service will be primarily self-guided, with trainings and expert consultations offered as needed. Components include: **1) Annual cataloging of pragmatic research resources and services** at CU Anschutz and CCTSI Partner Institutions, including biostatistics and study design, technology integration, data and informatics tools, D&I science, qualitative and mixed methods, partnership development, and community and stakeholder engagement. The catalogue of offerings will be posted on the CCTSI website, promoted through CCTSI marketing channels, and highlighted in CCTSI pilot grant RFAs, training and degree programs, and the CO-Mentor program (**Module C1**); **2)** In collaboration with ACCORDS and CIDA, we will offer a twice-yearly **Pragmatic Trials Planning Workshop** that guides investigators through selection of methods, resources, partnerships, tools, and collaborations using our novel *Pragmatic Research Planning Workbook*; and **3) Expert consultation** made available through the existing CCTSI/ACCORDS research consult request systems.

2. A **Virtual Clinical Trials Core** will be established to address the lessons learned from the COVID-19 pandemic. The ability to conduct effective low-contact clinical trials is essential in an emergency setting and is also cost-effective in non-emergency situations, with the additional advantages of providing convenient, efficient, real-world data and being less burdensome for participants. CU Innovations, in collaboration with health device industry partners, has been testing products in the home to draw blood and monitor vital signs. Virtual regulatory support technology systems are already available on campus but have not yet been adapted for this type of research. For example, a convenient e-Consent tool is not easily accessible to all investigators. The goal of the Core will be to provide central access to these types of resources that will facilitate high quality, safe pragmatic clinical trials in either the home or hospital environment. **This Core will work closely with the projects in Element E (PEET) to develop electronic tools that can be broadly used in both EHR-embedded and traditional clinical trials.** Tools and resources developed will be disseminated to the CTSA consortium.

3. **D&I Research Core services** essential for real world clinical trials will be made available, including mentoring, collaboration, consultation, and graduate certificate program activities that build capacity for D&I science and practice across the CTR spectrum (described in **Element B, 1B2.9**). In 2023, the D&I Research Core will implement a fee-for-service model to provide investigators access to experts in dissemination and communication. In conjunction with the Community Engagement and Health Equity Research Core (**Element C2**), the i-Corps program, CU Innovations, the CLSC program (**Element C1**), CTS-Pilots, Research Studio, and Health Informatics, D&I consults and collaborations will help investigators identify communication channels, craft key messages tailored to specific audiences, program goals and objectives, envision product packaging (e.g., videos, infographics, policy briefs), and connect with contractors and resources for implementation. The D&I team also supports grant writing, budgeting, identifying commercialization or marketability opportunities (with CU Innovations and I-Corps), and archiving of materials for sustainable public access (with the CU Anschutz Digital Archives). D&I services **Metrics** include annual number of consults completed, number of hours of core services provided, and page views and downloads for the D&I core website and resources.

Goal 3: Accelerate start-up and completion of Clinical and Translational Research studies

Study Start-Up. R&S Cores will adopt changes in operating procedures that will accelerate the start-up and completion of CTR. Currently, **BERD, Research Studio, Pragmatic Trials, and Clinical Trials/TIN Cores** assist investigators to develop well-designed protocols and navigate through the regulatory approval process. To accelerate the study start-up, the **RKS Core** in coordination with the new **Chief Research Informatics Officer (CRIO; Melissa Haendel, PhD)** office will focus on using Broad Data Integration to evaluate new initiatives quickly and pivot based on data, metrics, and qualitative goals. The **CRIO** office is implementing a project planning software to track protocol start-up, effectiveness, and evaluate initiatives. The CRIO has data architects and dashboard developers to facilitate this implementation in collaboration with the Evaluation Core and CQI team. Given the institutional integrations across offices and the collaboration with the CCTSI Health Informatics and RKS Cores, these resources will be used to address a number of roadblocks to efficient and effective research across the CCTSI.

RKS Innovations to achieve this aim will include: **1) CTMS expansion:** Currently there are 8,836 active protocols in the CTMS (OnCore). Integration of the CTMS with Epic (funded by a NCATS UL1 Administrative Supplement) was implemented at UHealth in 2019 and is expected for CHCO in 2023. The next phase will be the **integration of data into a PI dashboard** so that research teams have real-time data to track, manage and respond to the challenges of clinical research in an efficient, consistent and integrated way. The **InSights**

OnCore module (purchased with funding from the UL1 Supplement) enables a dashboard for study start-up, enrollment, monitoring of demographic targets of enrollees, retention, and completion. The initial goal is to work with CCTSI Health Informatics and the CRIO office to establish a clinical research administration data warehouse that pulls data from the CTMS, InfoEd (administrative system for grants, COI and IRB), radiation safety, and biosafety. Once integrated, researchers can manage research portfolios, receive training renewal alerts, see accrual status, get safety alerts, etc. **2) Centralized IND/IDE support office:** CU Anschutz in partnership with the Partnering Institution hospitals has seen a steady increase in investigator-initiated IND studies and currently has 119 active such studies. The Clinical Research Support Center (**CRSC**) in collaboration with the CTRC Network provides regulatory and operational support for these studies. The goal is to consolidate resources into a centralized IND office and develop structured support for these studies to ensure quality, safe, efficient, and effective clinical research.

Many other new R&S Innovations will be implemented in the next grant cycle to to accelerate study start-up and completion. Innovations for the **CTRCs** in the next grant cycle include streamlining and aligning processes across **CTRCs**. Our **Research Operations and Strategic Integration (ROSI)** service, piloted successfully at the CHCO **CTRC**, will be made permanent and expanded to provide support across all **CTRC** locations. Separate **CTRC User Advisory Boards (UABs)**, comprised of all stakeholders (PIs, coordinators, budget specialists) and hospital administration representatives, will be formed at each **CTRC** site to address unique workflows and needs. **UABs** will guide and prioritize projects within their local site and across **CTRCs**. The **ROSI** will act as a conduit for the sharing of best practices and development of common SOPs and resources. Success of this initiative will be assessed by scores on annual CCTSI User Satisfaction surveys and increases in **CTRC** clinical research volumes due to increased efficiency. The **CCTSI Nutrition Core** will expand their expertise in the next grant cycle for assessment of energy intake from wearable electronic devices in free-living environments by comparing their analyses to doubly labeled water data to document discrepancies, perform iterative cycles of process improvement, and further improve methodology in this field. This will enhance our local expertise in data collection from wearable electronic devices that can be implemented across other Cores as these data become more commonplace in the design of clinical studies. The **Cardiovascular Imaging Core** will introduce Fibroscan liver elastography measurements, which are currently difficult to schedule using clinical resources at the hospitals. The **Exercise Core** will introduce HR-pQCT services for the first time. Directors will assist research teams with study design and interpretation, in addition to small start-up seed grant awards to initiate the first studies using this service. The **TIN** team plan to promote their multi-site study assistance by conducting leadership outreach, department-level meetings with faculty, announcements in the CCTSI and Vice Chancellor for Research newsletters, and highlighting the **TIN** during CCTSI Town Hall meetings and New Faculty Orientations as a resource able to address the operational needs of multicenter trials. In the next grant period, the **two CTRC Core labs** located at CU Anschutz will be integrated into a single entity to streamline processes across labs, maximize Core Lab staff efficiency, and halve the number of CAP audits and inspections. The time to prepare for and respond to CAP inspections decreases staff availability for CCTSI protocols so halving this time will boost productivity. Additionally, start-up times for protocols using both labs will be reduced by moving from two independent feasibility reviews to a single review.

Veterinary Clinical Trials Innovation. Partnerships among MD, DVM, and PhD scientists have been increasingly recognized as vital to accelerating the translational and discovery pathway.⁵⁷⁻⁵⁹ With strong evidence that SARS-CoV-2 emerged from animals, and irrefutable evidence that companion and wild animals are susceptible and may act as reservoir species⁶⁰⁻⁶³ or as agents of variant spillback,⁶⁴ *participation of DVM scientists in the translational pipeline has never been more urgent.* We identified the need for a **Veterinary Clinical Trials Coordinator** at CSU who will serve as a liaison for industry and academic partners to guide communication, identify DVM-MD partnerships and funding opportunities, support multi-institutional regional and national clinical trials, provide regulatory, budget, and logistical support, and implement veterinary 'smart IACUC' tools. Additionally, in partnership with CCTSI Health Informatics Core, CTSA COHA institutions, and others, data science initiatives will drive innovation by developing comparative data models.

Goal 4: Ensure that R&S operations can respond to urgent public health emergencies

A critical lesson learned during the COVID-19 pandemic was that the ability of the research enterprise to respond quickly to a public health emergency is dependent on having well-managed centralized research facilities and resources already in place that can pivot and redeploy rapidly when needed. Because of our existing **CTRC Network** at 4 locations and its use of **CTRC Scheduler** for scheduling study visits, the CCTSI was able to efficiently control which research protocols were shut down for COVID-19 and later approved to restart after the

shutdown. This also enabled the research units to prioritize the use of facilities and personnel for COVID-19-related prevention and treatment trials. The CTRC Network will continue to support the high quality, efficiency, and safety of CTR and respond to urgent/emergent needs by providing access to centralized research facilities for study visits and trained expert personnel (including research RNs) to assist with study procedures. Each CTRC unit is overseen by a Nurse Manager and a Medical Director, who ensure the appropriate training and credentials of staff and safety of unit operations. The Nurse Managers work closely with the Medical Directors and RKS to address safety concerns, particularly during a public health emergency, and maintain standard operating procedures. The **CTRC Network** will leverage support from the CRIO to restructure use of shared drives, REDCap surveys, Sharepoint, and productivity tracking tools to create a single CTRC IT governance plan, consolidate resources, and eliminate redundancy in IT architecture. Once a unified IT governance and architecture framework is adopted, we will use a standard monthly CTRC operations meeting to implement the integrated start-up documents and budget template across CTRC Cores and streamline all CTRC feasibility review processes and documents in partnership with the Continuous Quality Improvement (CQI) Team. In addition to these streamlining activities, the Core managers will work with hospital research entities to disseminate process changes and create user-friendly templates for hospital processes, such as the development of Epic Use Plans or Treatment plans. The CTRC Network accommodates some of the most complex research conducted within our Partner Hospitals, and providing guidance, especially for jr. investigators and new faculty, will expedite study start-up and completion, and ensure accurate data acquisition with maximal participant safety. These enhancements will enable the CTRC Network to respond quickly and efficiently to research needs provoked by public health emergencies.

Strategic Integration of Research Operations. The COVID-19 clinical research shut-down/re-start highlighted areas where CTRC Cores could enhance efficiency through integration of documentation, feasibility review, and elimination of redundancy. To facilitate CTRC Core integration, we piloted a new model at the CHCO CTRC, the **ROSI** service. We created a CHCO CTRC User Advisory Board (**UAB**) comprised of all stakeholders (PIs, coordinators, budget specialists, statisticians) and hospital administration representatives to guide and prioritize projects. In one year, the ROSI integrated the start-up documents across three CTRC Cores, created a single budget template for all CTRC services that enables simple grant budgeting over 5 or more years, and combined all CTRC feasibility review processes and documentation. These changes increased productivity for CTRC staff and it is expected they will result in enhanced user satisfaction in the next survey. Therefore, in the next grant cycle, we will utilize the ROSI model to integrate workflows across the entire CTRC network.

Goal 5: Enhance recruitment and retention of diverse research participants

To increase inclusion of older/elderly adults, which aligns with the NIH policy to include participants across the lifespan in research, we will implement and amplify the **Older Adult Research Specialist (OARS) model** developed by Dr. Kady Nearing in the RKS office at CU Anschutz. This model trains older adults, who have extensive life experience, professional skills, and connection to older adult communities, to facilitate the enrollment of older adults in clinical research. OARS complete 14 weeks of intensive education, preparing them to fulfill key roles as part of clinical research teams, so that they can facilitate informed consent and help participants complete studies by identifying potential barriers, finding solutions, and connecting participants to needed resources. The CCTSI will provide training components and resources for OARS (see **Module C1, Objective 1.1**) and amplify the reach of the program by disseminating and marketing the availability of OARS to research teams at all CCTSI Partner Institutions. OARS will also facilitate a free consultation service for CCTSI Members to develop comprehensive strategies for the inclusion of older adults in research.

To increase inclusion of minority and underserved populations, we will leverage newly developed research tools in the UHealth EHR for **patients who use the EHR patient portal**. New EHR features for targeted recruitment include a patient research preference profile, where users can denote their interest in research and select areas of highest interest, and, further, see targeted research fliers based on their interests and flag the research team by hitting the “I’m interested” button on a flier. Study teams can also send targeted recruitment messages based on a patient's research preference profile. Although these features will not capture individuals who do not use the EHR, it will provide access to a subset of under-represented populations across Colorado. The CEHE Community Clinical Trials Advisory Board (CCTAB) will be engaged to provide input on how to best reach these populations. **State-wide reach:** UHealth serves three large regions of Colorado (Northern Colorado, Metro Denver and Southern Colorado) that include 12 inpatient facilities and a broad geographically distributed population. Those with English as a secondary language can be identified by interpreter need denoted in the EHR and rural participant enrollment in research studies can be identified by participant zip code. Through

enhanced EHR research resources, study teams, with prior approval to protect individuals from overcommunication/multiple approaches for different studies, can send pre-approved research awareness and study information to those who are underrepresented in research or in their study specifically.

Strategies to recruit minority and underserved populations that **do not use the EHR patient portal** will include **1)** research partnership with PCPs within the statewide SNOCAP primary care practice-based research (PBRN) infrastructure which reaches rural and frontier areas of Colorado (**Module C2**), **2)** provision of interpreter services for research visits at CTRCs, **3)** access to certified interpreter services for consent form translation, **4)** provision of tablet devices during clinical visits for those who don't access the EHR at home or on their personal devices, **5)** training research personnel to equitably engage diverse communities and stakeholders (**Module C2, Goal 2**), and **6)** promoting the "research roadshows" run by Dr. Kady Nearing to educate communities on the value of research and how to participate, particularly in rural areas and communities with a high proportion of underserved residents. Partnering Institutions and PBRN sites are in areas with a high proportion of people of color, predominantly Hispanic and Native American, with lower proportion of African Americans, which is representative of Colorado (**Figure C2**). Sites are adjacent to multiple PACT community organizations who are skilled at working within communities to represent local interests and concerns. These partnerships, with the availability our CEHE boot camp translation, will help to develop specific recruitment strategies for different communities throughout the state, especially in rural areas, that will be available to study teams. This strategy has been highly successful in the ongoing NIH CO-CEAL initiative (**Module C2**).

The **RKS Core** will establish a new **CCTSI Recruitment & Marketing Center**, which will facilitate research team access to resources for the **design of participant recruitment materials** (e.g., social media material, literacy guidance) that are appropriate for traditional and real-world clinical trials. These will be developed in collaboration with the CEHE and the D&I CTSI Cores to ensure use of language that is meaningful to the specific community and the appropriate representation of minorities and older adults in CTR. The existing **Study Monitoring Committee** will, with the Evaluation Core (**Element B**), track improvement in diversity of enrollment over time.

C. METRICS AND EVALUATION

Needs Assessment. The Evaluation Core will conduct triennial Needs Assessment Surveys of members and nonmembers at CU Anschutz and all CCTSI Partnering Institutions. The purpose is to determine the resources and services that investigators consider essential and the extent to which these needs are met. Major CCTSI programs, such as RKS, BERD, Research Studios, are covered by this survey. Results of the 2024 and 2027 needs assessments will be reviewed by the IAC and EAC, and recommendations will be considered by the EC.

CTRC User Satisfaction & Enrollments. The Evaluation Core will conduct an annual survey of research teams that used any CTRC services in the last year to gauge satisfaction with CTRC facilities, staffing, and services. This survey is sent to all users of the CTRCs (adult, CHCO, CU Boulder, NJH), CTRC Core Laboratories, CCTSI Nutrition Core, Cardiovascular Bioimaging Core, and the Exercise and Body Composition Core. Respondents answer questions on a 5-point Likert scale and data are presented individually for each Core with comments for qualitative analysis. R&S leadership will work with the ROSI service, Core leaders, and the CCTSI QPI to respond to user needs. Once process improvements have taken place, the Evaluation Core will collect data and perform analysis of monitoring data to report back to Core Leaders and to the EC and MPIs. Metrics will also be collected on demographic distribution of study enrollees through OnCore and the SMC and Evaluation Core will track and report these numbers to the EC, as described above.

MODULE D2 – CLINICAL AND TRANSLATIONAL SCIENCE PILOTS

a. SIGNIFICANCE

The Clinical and Translational Science Pilot Grant Program (**CTS-Pilots**) accelerates translational and clinical science by providing a funding platform for new ideas, methods and collaborations among Members and Stakeholders from all CCTSI Partner Institutions. The projects will be focused on understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research. Following the NIH definition of a pilot study ("*A small-scale test of the methods and procedures to be used on a larger scale*"), the CTS-Pilots will support **a)** the development of new research methodology and/or new technologies/tools/resources that advance CTS and thus increase the efficiency and effectiveness of translation, **b)** early-stage development of new therapy/technology with generalizable application to an identified translational roadblock, **c)** demonstration in a particular use case(s) (i.e., research project) that the new methodology or technology advances translational science by successfully

making one or more steps of the translational process more effective or efficient, and **d)** feasibility and proof of concept studies to support future CTS projects. The major focus of CTS-Pilots is to support the initial stages of innovative projects with the ultimate goal to accelerate their clinical and translational application and to spark creative solutions to complex health problems. CTS-Pilots provides one-year awards to develop new ideas, methods, and collaborations that advance CTS, customarily supporting junior researchers at all CCTSI Partnering Institutions. A comprehensive administrative infrastructure is already in place to solicit and assist investigators in the application process, followed by a rigorous expert peer-reviewed process and evaluation metrics based on three well-defined goals (see Approach). The CTS-Pilots encompass 4 major Programs (**Table D1**) promoting new discoveries, networking, and inter-institutional research teams. A rapid, one-time only COVID-19-related (C2R2) pilot RFA was issued 4/2020 that funded 4 imperative pilot grant proposals and could be used again for future public health emergencies. To address the urgent and compelling need to expand diversity among CTS researchers, a new **Early Career Diversity Pilot Award** has been added to the Colorado (CO)-Pilot Program since 2021.

Pilot Program*	Awards	Projects with Follow-on Funding (%)	ROI
CO-Pilot	186	61%	28.7
CMH Pilot	88	57%	22.3
CE Pilot	124	52%	20.2
TM Pilot	54	67%	32.3
Total*	456	57%	21

followed by a rigorous expert peer-reviewed process and evaluation metrics based on three well-defined goals (see Approach). The CTS-Pilots encompass 4 major Programs (**Table D1**) promoting new discoveries, networking, and inter-institutional research teams. A rapid, one-time only COVID-19-related (C2R2) pilot RFA was issued 4/2020 that funded 4 imperative pilot grant proposals and could be used again for future public health emergencies. To address the urgent and compelling need to expand diversity among CTS researchers, a new **Early Career Diversity Pilot Award** has been added to the Colorado (CO)-Pilot Program since 2021.

b. INNOVATION

CTS-Pilots will focus on awarding early-stage highly innovative hypothesis-, technology- and community-driven projects that will accelerate the translational science process by addressing translational roadblocks applied to specific cases as feasibility or proof of concept projects. Leveraging the resources of our CCTSI Partnering Institutions (e.g., the CSU College of Veterinary Medicine), we will tailor the centralized CTS-Pilots infrastructure to broaden the reach of funding opportunities and to encourage integration across the entire T0.5-T4 spectrum of translational science. **REDCap Management Innovation:** The CTS-Pilots will continue to expand its novel REDCap Pilot Platform management system to streamline application, expert review, and continuous monitoring of applicant demographics, program impact, and return on investment (**ROI**). Importantly, we will disseminate this REDCap Pilot Platform to interested CTSA Hubs (see **Letters of support from Utah and Arkansas CTSA**s). **Diversity Pilot Awards:** To further promote diversity in research professionals, we will expand our Early Career Diversity Award Program during the next 7 years.

c. PRELIMINARY DATA, INSTITUTIONAL ASSETS

Existing Resources: Since its inception in 2009, the CTS-Pilots Program has received over 2,500 applications and issued 456 awards totaling >\$13.5M with funding from both NCATS and CCTSI Partnering Institutions. Awards have been given to investigators at CU Anschutz (65%), CSU (15%), CHCO (11%), CU Boulder (3%), DHHA (3%), DU (1%), CU Denver (1%), and NJH (1%). CCTSI implemented a customized REDCap submission platform in 2019 that, in April 2020, enabled us to introduce a new "rapid response" COVID-19 research pilot program in less than two weeks, from releasing the RFA on 3/31/2020 to announcing four awardees on 4/10/2020! This was followed by introducing a REDCap peer-review platform in 2021, expanding our CCTSI reviewer database from 420 to 990 experts in 2022. *This infrastructure can now be leveraged to award pilot grants rapidly to address future public health emergencies.*

Evaluation of Current Programs: Surveys from the CCTSI Evaluation Core showed that CTS-Pilots awardees received over \$280M in follow-on funding (2009-2021) to continue research related to their pilot award, resulting in **21-to-1** ROI across the program (**Table D1**). Based on the survey and a careful review of the NIH-Award database resources (RePORTER and Grantome, 2009-2021), 60% (2022) of our 435 awardees have received NIH funding following completion of their pilot project. A total of 343 peer-reviewed publications have resulted from CTS-Pilot projects since 2009. Over 80% of grantees report being satisfied or very satisfied with their experience with the CTS-Pilots Program. DEI factors have been carefully assessed within the CTS-Pilots. The 2022 CTS-applicant cohort was diverse with respect to sex (57% female), under-represented background (32%), low-income background (12%), challenging environment (8%), first generation college (16%), physical or mental disability (2%), ethnicity (11% Latino or Hispanic), and race (33% Asian or African-American).

d. APPROACH

CTS-Pilots will represent early-stage, preparatory, or feasibility studies to overcome roadblocks in the translational process that apply to new disease pathways, technologies, protocols, or participant recruitment strategies as stepping-stones toward a full, hypothesis-testing investigation. CTS-Pilots will provide support for

CTS studies and will serve as one of the vibrant mechanisms for investigators to obtain preliminary data needed to attract extramural grant funding. Projects that address an important question in translational science, and also provide insights that could be generalizable to other health-related areas, will be prioritized.

Goal 1: Implement a comprehensive CTS-Pilots Program to accelerate cutting-edge collaborative translational science and to address barriers in clinical research

Four programs in CTS-Pilots (**Table D2**) will be integrated across Discovery (T0.5-T2) and Community-Population (T3-T4) translation to fund the FOA-mandated maximum of 8 Pilot Awards per year:

1. Colorado (CO)-Pilots will support research across all disciplines, all disease areas, and at all CCTSI Partnering Institutions. A total of **\$140,000/yr** will be allocated to three categories:

- **Mentored Award** (\$40,000; 1/yr) for early-stage investigators (post-doc fellows, instructors, asst. professors) with mandatory multi-disciplinary mentorship and cross-disciplinary training.
- **Early Career Diversity Award** (\$40,000; 1/yr) for URM junior faculty (instructors, assistant professors). Mentorship is not required.
- **CU-CSU Collaborative Award** (\$60,000; 1/yr) for experienced investigators developing projects that require new cross-institutional (CSU-CU) collaboration. Projects that use natural animal models of human disease as well as other unique CSU resources to overcome existing roadblocks in translational science will be given priority. This award will require co-PIs from both CSU and CU.

Table D2. CTS-Pilot Program sub-categories (NCATS-supported over 7 years)

CTS Program	Annual Budget	1 st year # award	Total # award
Colorado Pilots	\$140,000	3	21
Mentored Pilot	\$40,000		
Early Career Diversity Pilot	\$40,000		
CU-CSU Collaborative Pilot	\$60,000*		
Child and Maternal Health Pilots	\$80,000	2	14
Mentored Pilot	\$40,000		
Junior Pilot	\$40,000		
Community Engagement Pilots	\$25,000	1	7
Joint Pilot	\$25,000		
Translational Methods Pilots	\$60,000	2	14
Innovation Pilot	\$30,000		
Bioinformatics/Biostatistics	\$30,000		
Total*	\$305,000	8	56

2. Child and Maternal Health (CMH) Pilots will address obstacles in performing cross-disciplinary and cross-institutional research in children, pregnant women, and mother/child pairs, which will improve child and maternal health and prevent diseases that begin in early life. A total of **\$80,000/yr** will be awarded in two categories:

- **Mentored Award** (\$40,000; 1/yr) for early-stage investigators to benefit from strong mentorship and cross-disciplinary training in clinical and translational research.
- **Junior Faculty Award** (\$40,000; 1/yr) for instructors and assistant professors. Mentorship is not required.

3. Community Engagement (CE) Pilots support projects that are a partnership between academic researchers and community organizations or individuals to address health disparities or inequities. **\$25,000/yr** will fund one *Joint Pilot Award* for a well-defined joint research project (community-academic co-PIs required) that addresses a community-based translational science problem while obtaining preliminary data for future grant applications.

4. Translational Methods (TM) Pilots will support innovative technology developments to address roadblocks and advance translational science. A total of **\$60,000/yr** will be allocated to two categories:

- **Innovation Award** (\$30,000; 1/yr) to develop novel cutting-edge methods, processes and technologies (devices, assays, digital, science of team science) to advance translational science.
- **Biostatistics/Bioinformatics Award** (\$30,000; 1/yr) to develop innovative statistical approaches, artificial intelligence algorithms, and bioinformatics software to address analysis of complex biomedical data sets.

Fiscal Management: A total of **\$305,000** in CTSA grant funds will be allocated to CTS-Pilots to support 8 projects per year (**Table D2**). Each awardee will have an account set up through the CCTSI Administrative Core. Personnel costs, consumables, Core services, and other expenses will be paid from these accounts, which will be monitored for compliance with all institutional and federal regulations. *In recognition of the value of the CTS-Pilots as a catalyst for new research, our institutions have agreed to provide support for additional meritorious applications (which could not be funded by the limited CTSA funds) through other funding mechanisms in the VCR's office, thus leveraging the CCTSI pilot review process.*

Goal 2: Conduct rigorous, transparent peer-review of CTS-Pilots applications to ensure the selection of the best translational science projects with the greatest potential impact

Solicitation of Applications: Solicitation for new applications will occur annually in July and be advertised on the CCTSI website and through email announcements from the Deans' offices, the CCTSI, CTS-Director townhalls, and email to all faculty and trainees at Partner institutions and affiliated community organizations. A Letter of Intent submitted by September is mandatory to allow the Administrative Team to assist individuals prior to submission of a full application in October and to choose appropriate reviewers using our REDCap Pilot Platform. To ensure compliance with federal and NIH policies, each applicant (as relevant) must describe inclusion of human participants, model organisms and animal welfare, genetic testing, and/or stem cell research and address the "scientific premise" and "scientific rigor" requirements outlined in NIH policies.

Review of Applications and Decision Process: CO-, CMH- and TM-Pilot applications will be subject to similar review criteria based on the standard NIH review template and scoring system. The REDCap Pilot Platform, with its comprehensive expert reviewer database, will ensure the optimal expertise match between the scientific focus of the proposal and two selected reviewers. Applications will be initially reviewed and scored by a primary and secondary reviewer, and scores averaged. A Study Section Panel will be held for each of the 4 Pilot Programs, operating in the NIH fashion, so the most meritorious applications receive discussion whereas applications deemed less meritorious will not be discussed. Each application will be scored and ranked by average impact score. Factors considered in the scoring include: innovation; scientific merit; translational science significance; relevance to the CCTSI mission; investigator and team credentials; environment and use of CCTSI resources; and community participation, if relevant. CE-Pilot applications have a unique focus and will be reviewed under a separate rubric: The PACT Pilot Grants Committee will review all CE-Pilot applications and identify those that have the greatest potential to improve community translation and potential to decrease health disparities. All applicants receive full written reviews from two reviewers.

Prioritization of Applications: The CCTSI EC will receive a formal report with recommendations for funding based on final impact scores. Applications with widely discrepant scores, virtual "ties," and applications that border the funding range will be discussed at length. The CCTSI EC provides final approval of funding. The CTS-Pilots Program **will not** fund "translational research projects" (which are focused only on crossing a particular step of the translational process for a particular target or disease) that do not also address a generalizable translational roadblock, in accordance with NCATS guidelines (PAR 21-293). Awarded projects will meet all institutional and NCATS Prior Approval requirements before award funds are released. Meritorious applications not selected for funding will be sent to the VCR office for potential institutional funding.

Goal 3: Establish and implement metrics to monitor the impact of the CTS-Pilots on scientific discoveries and clinical implementation

METRICS and Outcomes: Evaluation of projects will include: **1)** Timely completion of regulatory requirements by PIs; **2)** Interim (6-month) and close-out (12-month) progress reports; and **3)** annual follow-up for 5 years using Evaluation Core surveys, including assessment of ROI. Progress reports will describe study enrollment, limitations, analysis of data, and dissemination of results. **Metrics** will include dissemination and generalizability of solutions to translational science obstacles, publications, external funding, patents and novel innovations, initiation of novel clinical trials, and collaboration among awarded investigators. Novel methods developed by CTS TM-Pilots will be shared with I-Corps and CU Innovations for potential commercialization and dissemination across the CTSA consortium. Dissemination of the REDCap peer review infrastructure to the CTSA consortium will be tracked by the number of CTSA hubs who participate in virtual training and workshops, conducting surveys and interviews with participants, and sharing results with the CTSA consortium.

Triennial Needs Assessment Surveys of CCTSI members and non-members of CCTSI will assess benefits and obstacles encountered by CTS-Pilot applicants, and this feedback will be used to modify the program. Our Evaluation Core/CQI program will use these metrics to make recommendations to the EC for continuous QI.

Goal 4: Disseminate the REDCap peer-review process platform to other CTSA Hubs

We will disseminate our innovative REDCap infrastructure through peer-reviewed publications and presentations at the CTSA Program Annual Meetings, in collaboration with the CCTSI D&I Core. The REDCap Pilot Grant Management System will be offered through virtual training and workshops to interested CTSA Hubs for implementing fast, efficient, and transparent CTS-Pilots Infrastructure to facilitate and accelerate translational research locally, regionally and nationally (see **Letters of Support, Utah and Arkansas PIs**).

e. STRUCTURE, GOVERNANCE, INTEGRATION. The program will be led by the CTS-Pilots Steering Committee, chaired by Dr. Serkova (CTS-Pilots Director, TM-Pilots Director), and includes the 4 Co-Directors

(see *Biosketches*): Drs. VandeWoude (CO-Pilots), Nease (CE-Pilots), Zeitler and Baker (CMH-Pilots). The Co-Directors report to Dr. Serkova and oversee the specific type of pilot award including solicitation of applications, review, and prioritization. Dr. Serkova will sit on the CCTSI EC and report to Dr. Sokol, CCTSI MPI. The CTS-Pilots team will interact closely with the CTSC Network, BERD, Clinical Trials, Pragmatic Trials, Natural Animal Models, and D&I programs to ensure awardees benefit from these resources.

MODULE D3 – HEALTH INFORMATICS

a. BACKGROUND AND SIGNIFICANCE

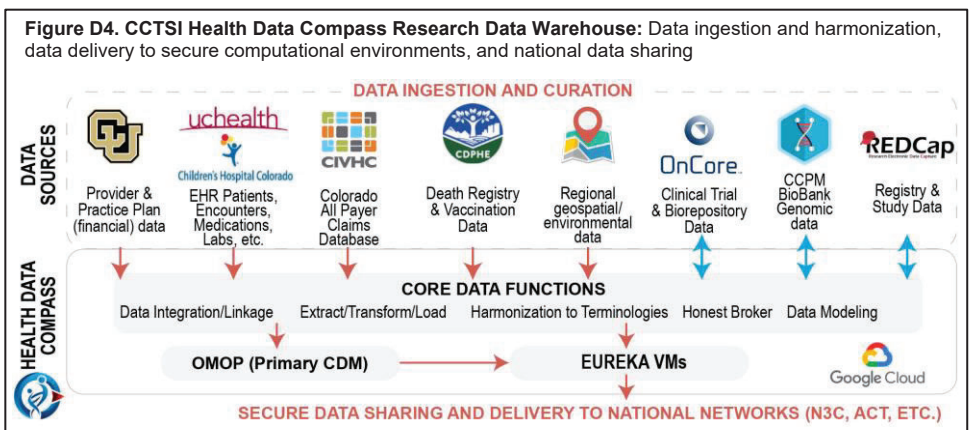
As a nation, we do not sufficiently leverage health informatics to improve healthcare. We have greatly benefitted from data science advances in recent years, but *clinical translation has not kept pace. This is a major roadblock that we must overcome.* It is challenging to incorporate clinical and translational data into informatics workflows while also safeguarding patient privacy and ensuring trust from our community members.⁶⁵ Therefore, tools, data, and analytical approaches remain siloed and bespoke. **The Health Informatics Core** provides a foundation of informatics excellence and innovation both locally and nationally. It identifies and implements innovative, scalable informatics solutions that improve the security, interoperability, and utility of data assets. Informatics plays a key role in the CCTSI culture of open science, data and resource sharing and reuse, and stakeholder engagement. We nurture and disseminate new knowledge, methods, tools, workflows, education, and approaches to a wide variety of stakeholders across the translational spectrum. We also work with the national informatics and translational research community to advance, extend, and disseminate innovations created by the CTSA Program and increase their impact.

b. INNOVATION

Our informatics innovation rests on our innovative cloud-based (Google Cloud) data warehouse, Health Data Compass (HDC), our mature and sophisticated REDCap instance, and close partnerships with health systems and national programs in which we played major roles (e.g., N3C). **During the next cycle**, we will continue to build on this innovation-enabling architecture by **1)** deploying analysis and ontology tools on the HDC Google Cloud, **2)** increasing integration of clinical image and signal data into HDC, **3)** expanding access to linked genomic and other biological data, and **4)** enhancing EUREKA by implementing machine learning tools such as TensorFlow. We will also **5)** implement and innovate REDCap-based tools and trainings for clinical research using Fast Healthcare Interoperability Resources (FHIR)-based connections to health system Epic EHR instances, and **6)** engage with national resources and programs such as N3C and the HL7 Vulcan Accelerator to contribute to improved access, interoperability, and integration of EHR data for translational research.

c. PRELIMINARY WORK, INSTITUTIONAL ASSETS

Health Data Compass (HDC): CU’s Multi-institutional Research Data Warehouse. Established in 2017, HDC is the world’s first integrated large-scale clinical, administrative, genomic, and population-based research data warehouse on the Google Cloud Platform (**Figure D4**). Our UHealth and CHCO Partners have hospitals and clinics across the state of Colorado, so EHR data in HDC has statewide reach. This reach is enhanced by secure integration of Colorado death registry, vaccination, and all-payer claims databases, environmental data sources, Colorado Center for Personalized Medicine genomic Biobank resources (~200,000 patients), and data are made available to investigators for high-impact linked analyses. To make full use of HDC, we implemented EUREKA, a system for powerful, scalable computational environments. EUREKA supports a variety of analytics, including reproducible computational phenotyping. HDC staff have academic and industry experience in computational infrastructure, data engineering, common data models, data quality and harmonization, terminologies and ontologies, regulatory and honest broker requirements, study design, and CTR. HDC uses OHDSI/OMOP as its primary Common Data Model (CDM), which includes national and international standardized terminologies, such as the CMS/ONC Meaningful Use terminologies. Data are surfaced to



investigators for cohort discovery using a variety of technologies including Leaf⁶⁶ and external applications such as TriNetX, i2b2, and Tableau. Custom data extracts are delivered to approved investigators that use REDCap.

CCTSI computing resources and REDCap data management. CCTSI Informatics maintains NIST SP 800-53 compliance for its on-premises virtualized server farm (**Table D3**). Our Information Security Officer establishes and monitors controls to maintain this level of compliance. The data center hosts a wide variety of systems and applications that directly support investigators and includes fault-tolerance, disaster recovery capabilities, and annual third-party audits and penetration testing. Details about our fully subsidized HIPAA-compliant REDCap data management service and computing resources available to investigators are in Module D1. CU Anschutz recently co-invested with CU Boulder and CSU in a new HPC cluster (Alpine, **Table D3**). The CCTSI Informatics team hosts the UHealth i2b2/ACT node and has technical experience with the PEDSnet/PCORnet CDM. We also contributed other technical innovations to the CTSA network (**Box D2**).

Institutional investments in informatics. In response to the strong recommendations of the CCTSI External Advisory Committee, CU Anschutz and the SOM recently made substantial investments in informatics (>\$50M). These investments provide much needed data and informatics infrastructure, a centralized academic home for informatics faculty, and significantly advance the capabilities and impact of the CCTSI HI program. In 2020, Casey Greene, PhD, a leading computational biologist, was recruited as the Director of a new multidisciplinary Center for Health Artificial Intelligence (**AI**) and founding Chair of a new Department of Biomedical Informatics launched in July 2022. In 2021, Melissa Haendel, PhD, an international leader in translational informatics, was recruited as the first campus Chief Research Informatics Officer (**CRIO**). Dr. Haendel is the contact PI of the NCATS-supported CTSA Network National Center for Data to Health (**CD2H**). CD2H co-leads the Informatics Enterprise Committee (**iEC**), and in collaboration with the iEC and CTSA community, has developed a variety of innovations, standards, and best practices relevant to the national CTSA program, including: co-designing cloud architecture at NCATS for deployment of shared methods and data, data harmonization strategies to bridge different common data models and terminologies, a living informatics best practices play book, informatics maturity models, and a CTSA-wide resource discovery platform.

National COVID Cohort Collaborative (N3C). Dr. Haendel and CD2H colleagues responded to the COVID-19 pandemic by establishing N3C, a secure research Data Enclave that includes HIPAA-limited EHR data from >16M patients at 76 sites across the U.S. (including UHealth and CHCO) as a partnership among NCATS-supported CTSA hubs and the Institutional Development Award for Clinical and Translational Research (IDeA-CTR). Colorado and Drs. Haendel and Bennett have played leading roles in numerous important COVID-19 efforts.⁶⁷⁻⁷⁰ Important examples include an R01 Supplement (Bennett) to build and maintain a pediatric COVID-19 dashboard using N3C data and a \$11+M contract (Haendel and Bennett MPIs) for N3C to serve as one of three EHR-based cohorts for the NIH Researching COVID to Enhance Recovery (RECOVER) Consortium.

CCTSI-led COVID-19 research. Other contributions by CCTSI Informatics include the COVID-19 BioBank and Data Mart led by the Vice Chancellor for Research, Tom Flaig, MD. Building the Data Mart in 2020 required close partnership among HDC, CHCO and UHealth, and the campus OnCore, REDCap, and CCTSI Informatics teams. The COVIDome generated multi-omics data for COVID-19 patients, paired it with clinical data, and made

Table D3. Impact of CCTSI Resources	
CCTSI Infrastructure	
Systems	3 physical ESXi Host servers, 110 Virtual servers, Multiple SQL Servers; Applications listed below plus SharePoint, ColdFusion Web Apps, FreezerWorks, EP Evaluator
Security Web	NIST SP 800-171 Rev. 2 security controls CCTSI web site: Monthly ~6,000 sessions, >10,000 page views
Applications for Clinical Research	Colorado Profiles, REDCap, Scheduler, Orchard Harvest LIS, SHRINE
Local Resources	
REDCap	Covers all CCTSI partners plus Denver VA; 2021 active: 5,936 users, 16,428 projects, 2,312 tutorial attendees; HIPAA-compliant, FISMA-compliance optional
CO Profiles	Covers four CU campuses, Colorado State, affiliated investigators; Monthly ~17,500 sessions, ~30,000 page views
Health Data Compass	Google Cloud-based Data Warehouse Data Sources: UHealth, CHCO, CU SOM, CU Medicine (practice plan), CDPHE, APCD; NIST SP 800-53 security controls
EUREKA	Google Cloud-based scalable VMs Each VM has GBQ, storage, compute; HIPAA-compliant; R, Python, etc.
OnCore	AMC-wide CTMS and biorepository linked to Health Data Compass
COVIDome	New in 2020; Linked clinical and multi-omics data; Publicly available
Regional Resources	
Alpine (Cluster)	New in 2022; with CU-Boulder, CSU initial AMC purchase 1088 CPU cores, >5TB RAM; Genomics-focused Previous HPC resource end-of-life
National Resources	
N3C	Lead site; OMOP; Separate CHCO and UHealth data feeds
PCORI PEDSnet NCATS ACT	CHCO a founding site; OMOP + PCORnet Separate CHCO and UHealth nodes; i2b2/SHRINE
TriNetX, OHDSI NCATS Data Translator	UHealth nodes Lead site; standards and reference implementation for consortium

Box D2. CCTSI Innovation

- **Data Sharing Networks:** Epic Caboodle/Clarity to OMOP, PEDSnet ETL, GBQ OMOP to i2b2 and TriNetX ETL
- **Novel Methods:** Privacy-Preserving Record Linkage, Data Sharing with R Data Packages
- **Software:** GBQ SQL for Informatics Common Metrics, GBQ implementation for N3C Phenotype, Scheduler Enhancements, i2b2/SHRINE Bugfixes

it publicly available in November 2020.^{71,72} The Data Mart was also the foundation for an \$8+M CTSA Supplement to study the Real-World Effectiveness of anti-SARS-CoV-2 monoclonal antibodies in outpatients (MPIs, Ginde, Sokol). Dr. Bennett leads informatics for this project, which integrates and curates data from HDC/UCHealth, the local safety net health system (Denver Health), state vaccination data, the state all-payer claims database (APCD), and prospectively collected survey data using REDCap. The project also involves the CCTSI BERD, D&I, TIN Hub Liaison and Clinical Research Support (**CReST**) teams.

EHR-REDCap integration using FHIR. Critical preliminary work for Goal 3 and foundational technology rests on the FHIR data standard. During the last grant period, both CHCO and UCHealth implemented the application programming interface (API) developed by the Vanderbilt CTSA that allows direct Epic to REDCap connection using FHIR. The CCTSI Informatics team developed experience using this interface and one multi-site clinical trial (SAVE-O2 BURN, site PI Adit Ginde; NCT04534972) already leverages it.

Translational Informatics Training. CU Anschutz has held an NLM-funded T15 to support the Computational Biosciences graduate program (CBP) since 2006. Current CBP faculty are based in several CU Anschutz schools and colleges (Medicine, Pharmacy, and Public Health), at CU Denver and CU Boulder (Colleges of Engineering - Computer Science), and at National Jewish Hospital, all CCTSI Partners. At CSU, the CCTSI will continue to support Mark Stenglein, PhD, in providing computational biology and genomics training to investigators. During 2021, he provided >200 1:1 consultations and taught courses in Computational Microbiology and Next-Generation Sequencing. The CCTSI publicly available REDCap training materials covering both basic and advanced functionality continue to have global impact: >2,300 views in 2021.

d. APPROACH

The goal of CCTSI Health Informatics is to manage and secure data, democratize access, maintain critical software applications, and advance informatics education. Our infrastructure and programs have matured significantly since our last funding period: at this inflection point it is both possible and vital to shift the focus toward data use and on the direct impact of our work for CTR. The Strategic Goals are as follows:

Goal 1: Integrate clinical, biological, administrative, and public health data and deploy robust analytical environments

We will support CTR locally and nationally by integrating and linking a variety of data types and sources and deploying scalable, HIPAA-compliant computational environments for research.

Goal 1.1. Improve data quality and usability. In partnership with HDC, CHCO, and UCHealth locally and N3C, OHDSI, and other data sharing networks nationally, we will continuously improve the quality of data resources available to CCTSI investigators. This will *overcome barriers* to translational research because the quality of EHR data has been insufficient to answer some questions. Indeed, centralized data quality benchmarking in the N3C Enclave revealed unique opportunities for *local* data quality improvement.⁷³ We will leverage our leadership in N3C and other data sharing partnerships to improve local data quality by increasing source reliance on EHR data fewer derivations away from the point of care (e.g. Epic Clarity rather than Caboodle).

Goal 1.2. Expand the number and types of data resources integrated within HDC. We will engineer data integration and access control infrastructure within HDC to enable improved access to Biobank data, clinical image data, physiological signal data, and incorporation of public health datasets to support Social Determinants of Health (**SDoH**) analytics (**Figure D4**). These additional data types, linked to EHR data, will *overcome barriers* to translational research by allowing investigators to probe biological, anatomic, and physiological biomarkers that are only represented in those data types. Supported by a CTSA Supplement, we have established secure pipelines to move the first raw clinical images (chest images) into HDC. Similarly, we are piloting ingestion of high-resolution physiological signals from continuous monitoring devices and ventilators at UCHealth. We will share non-proprietary and generalizable components of these pipelines with the CTSA consortium.

Goal 1.3. Advance our analytic environment. In collaboration with campus partners (CRIO, Center for Health AI, and CU Office of Information Technology), we will expand the capabilities and types of scalable and secure computational environments available to investigators. These platforms can be leveraged for data management, storage, organization, integration, mining, visualization, and advanced analytics. We will focus on EUREKA (project-specific Google Cloud-based VMs inside HDC security; **Table D3, Figure D4**) and Alpine (**Table D3**). Projects requiring HIPAA compliance will be directed to EUREKA. Projects not including protected health information (**PHI**) will be directed to Alpine. Because EUREKA instances can be made available to investigators from other institutions, they are also valuable platforms for collaboration. EUREKA is a significant advantage for

CCTSI members when competing for funding: recent funded projects that leverage EUREKA include the CTSA Supplement-supported SARS-CoV-2 monoclonal antibody project and an international effort to develop new criteria for pediatric sepsis. In the next funding period, we will enhance EUREKA growth by including Google-based tools for advanced analytics and machine learning such as TensorFlow.

Goal 2: Improve accessibility and interoperability of regional and national data sharing and analytics

CCTSI Informatics has deep expertise in realizing FAIR (Findable, accessible, interoperable, reusable) Guiding Principles to maximize the utility of our collective data.⁴⁷ Here, we ensure that local data are aligned with global standards and maximally useful in national and international programs.

Goal 2.1. Promulgate data harmonization and mapping best practices. The CCTSI Informatics team has technical expertise implementing all major CDMs, mapping data models and terminologies, and harmonizing CDEs and maintains a variety of tools for cohort discovery and data extraction (**Box D3**). Variability in EHR data within/across institutions limits the use of common tools and methods for data quality, discovery, phenotyping, and preparation for research. We provide robust management and provenance of mappings for local data to CDMs and their constituent terminologies and codesets, while supporting modeling and encoding new data and content types such as SDoH, signal data, exercise, sleep, rare disease, etc. (see **Aim 1**). We will publish mapping services and documentation for researchers to enable: **a**) alignment of data to CDMs such as OMOP and the FHIR standard and **b**) mappings to the United States Core Data for Interoperability (USCDI) terminologies and computational ontologies such as the OBO Foundry.⁷⁴ We will develop and enhance tools to assess data quality and publicly share mappings and their provenance, including our ongoing work on FHIR to OMOP and N3C.⁷⁰ We will explore use of FHIR to Clinical Data Integration Standards Consortium (CDISC) Standards for regulated trials. We will continue our leadership in the HL7 Vulcan accelerator and N3C and coordinate local practices with national and international activities.

Box D3. CCTSI Technologies for Data Sharing and Cohort Discovery

- **National Networks:** N3C, ACT, PEDSnet, TriNetX, CDC Vision
- **National Data Models:** OMOP, i2b2/ACT, PEDSnet, PCORnet, TriNetX
- **Cohort Discovery / Data Extraction Apps:** i2b2/SHRINE, TriNetX, Leaf, OHDSI Atlas

Goal 2.2. Share data responsibly. Downstream users of data are burdened by a lack of provenance, documentation, adherence to standards, data quality, and access. Data providers are burdened by a lack of direction in who should have access to data, for which purposes, for how long, and in what format. We will expand availability and utility of data by enhancing governance within CCTSI Partnering Hospital and state partnerships (**Figure D4**) and the newly established CU Anschutz CRIO Council. We will also support data sharing partnerships with national initiatives such as OHDSI, HL7, and N3C. HDC will continue to serve as an honest broker in regional and national data sharing activities and will support creation of privacy preserving record linkages (PPRL) between datasets within and across sites and data modalities. HDC will manage data sharing risks through robust access control, allowing multi-disciplinary and multi-institutional teams to collaborate on all aspects of data capture, harmonization, quality, and analytics. We will collaborate with the CTSA Consortium, the informatics community, and our CCTSI partners to develop and implement best practices to prevent codification of *racial and other biases in models and algorithms*.

Goal 2.3. Improve data lifecycle management and attribution. A vibrant informatics ecosystem requires technical and organizational engagement across the research data lifecycle. Having a secure, centralized platform (HDC) for managing the full lifecycle reduces barriers to tracking the diverse contributions of multiple stakeholders across various career stages and disciplines. In addition to storing artifacts (e.g., codesets and computable phenotypes), a proposed “knowledge library” will assign DOIs and track contributor ORCIDs; this will make it straightforward to attribute individuals and funding in collaborative contexts. We have demonstrated how such “transitive credit” can incentivize collaboration across disciplines and analytical contexts within the N3C. We will these values and technical architecture to the CCTSI community. This will allow researchers to push their artifacts to CCTSI Profiles and to national platforms and ensure that the CCTSI is an effective partner in national programs. The CCTSI D&I and Evaluation teams will analyze contributions and impact.

Goal 3: Develop, validate, and deploy clinical decision support and clinical trial execution tools

Deployment of clinical decision support (CDS) tools is a natural partner to the implementation of R&S clinical research tools. Deployment of patient- and provider-facing tools within an EHR, whether for CDS or research, uses common data structures, governance, and processes. For interventions intended to function within an EHR, CDS and treatment planning tools are the “return leg” of a “complete loop” from development to implementation.

Goal 3.1. Deploy CDS tools based on machine learning and other predictive analytic techniques. With

CHCO and UHealth health system partners and clinical domain experts, we will identify high-priority operational goals and scientific gaps for machine learning-based prediction model development and evaluation. We plan to deploy CDS tools targeting these. During the current grant period, both health systems licensed the Epic Cognitive Computing Platform (ECCP) and deployed models using that system. Examples include the partnership between CCTSI HI, UHealth, and others to rapidly deploy a mortality prediction tool to support pandemic decision-making⁷⁵ and tools being deployed at CHCO to predict sepsis.⁷⁶ Shared governance of CDS tool decision-making is critical to maintain mutual benefits between the University/CCTSI and the health systems. Dr. Bennett continues as a member of the UHealth Clinical Intelligence Steering Committee, the body charged with advising the health system as it chooses which tools to deploy. UHealth and the new Department of Biomedical Informatics are establishing a broad-based Clinical Intelligence Program in support of predictive analytic tool development and deployment. That Program, to be directed by Dr. Bennett, will perform end-to-end development including domain requirements gathering, data extraction, machine learning method development, model development and performance evaluation, partnership with the UHealth and Virtual Health Center for model deployment, clinical evaluation, and algorithmic monitoring.

Goal 3.2. Expand use of CDS tools in clinical trials. In partnership with CHCO, UHealth, the CCTSI TIN liaison team, and CU Anschutz Regulatory leadership, we will develop shared governance for and facilitate the use of informatics tools embedded in EHRs to support next generation clinical trials and clinical trial matching. Drs. Ginde and Bennett are partnering with Vanderbilt to expand the use of REDCap-based clinical trial tools and conduct a multi-center critical care-focused trial using them. This sub-aim will be most successful if conducted in partnership with other CTSA hubs. Dr. Bennett will be an active member of the recently formed Clinical Trials Management Ecosystem Maturity Working Group (**WG**) of the CTSA iEC, which will develop CTSA-wide best practices for development, maintenance, and innovation of clinical trial informatics.

Goal 4: Expand hands-on translational informatics education for various career stages and disciplines

Goal 4.1. Extend and integrate CU graduate and clinical training programs. We will enhance the existing cross-departmental programs at CU with new clinical and translational informatics content and courses. Anticipated topics for content integration into training programs include EHR data, data management and sharing, HIPAA compliance, computable phenotyping, and standard data science toolsets. We will leverage a Coursera multi-course “Specialization” developed by Drs. Laura Wiley and Michael Kahn titled Clinical Research Informatics and Analytics. A set of courses on translational standards, data integration, and data modeling is being planned to take advantage of local expertise in FHIR, OMOP, GA4GH, and semantic engineering. We will partner with other CTSA hubs to build the “Book of N3C,” a suite of training materials for performing EHR analytics at scale that can be incorporated into courses and workshops. As HDC data integration proceeds, we will offer coursework in integrative ‘omics and clinical data analytics within the extended EUREKA environment.

Goal 4.2. Enrich and innovate REDCap training materials. Functionality of our REDCap platform continues to expand, but investigators need to be trained in these advancements. We will expand our highly accessed REDCap training materials to cover emergent REDCap functionality and REDCap integration with other systems (including Epic) using APIs. The local community needs FHIR training in order to fully leverage that API. In addition to utilizing HL7-provided FHIR training, we will host training sessions for CCTSI and the CU community.

Goal 4.3. Develop and evaluate pilot informatics partnership program with community organizations. Community organizations are critical partners for CTR that addresses health disparities, but it can be challenging for them to meet their own data and informatics needs. We will *address this roadblock* by embedding informatics team members and trainees within our PACT community organizations for valuable diversified hands-on experience on time-limited projects. The first task will be to assess the organization’s informatics maturity using models developed by CD2H. The organization, HI team member, and program leadership will then identify an appropriately scope for the HI team member’s time with that organization, with the explicit goal of informatics maturity advancement and expanding the organizations’ opportunities for collaborative translational research. This innovative program will be jointly led by the CCTSI Community Engagement and Informatics teams.

e. EVALUATION and METRICS. The **Evaluation** Core will track Informatics activities using metrics including REDCap users and projects, HDC data deliveries, and EUREKA instances and associated publications and grants submitted/awarded as well as projects using new data types (Aim 1); data sharing locally and nationally (Aim 2); CDS tools developed and deployed and clinical trials conducted using novel CDS tools (Aim 3); students in and graduates of informatics training and certificate programs and users of REDCap training materials and organizations served by the informatics partnership program (Aim 4).

ELEMENT E. PRAGMATIC EHR EMBEDDED TRIALS (PEET) RESEARCH PROGRAM

A. STRATEGIC GOALS

The overarching goal of **Element E, the Pragmatic Electronic Health Record (EHR) Embedded Trials (PEET) Research Program**, is to expand infrastructure to support discrete research projects that will address **5 major roadblocks/barriers** in clinical & translational research⁷⁷: **1)** the high participant and provider burden associated with randomized, controlled clinical trials (RCTs), **2)** the current inability to harness an entire health system, such as University of Colorado Health (UCHealth), for research beyond the central academic hospital, **3)** limited stakeholder engagement and access to studies for those living outside of major urban areas, which limits participation by rural and minority populations and, thereby, limits broad translation of such research, **4)** the lack of clinical trial expertise within hospital IT departments, making it difficult to appropriately review and prioritize requests for EHR embedded trials; and **5)** the high cost and intense resource needs of RCTs. PEET will address these barriers through the following Goals:

Overview CTSA Goals Addressed by this Element
Goal 1: Efficiency & Impact of CTS
Goal 2: Collaboration, team, data science, partnerships
Goal 3: Community Partnerships and Health Inequities & Disparities
Goal 4: Operational Efficiencies
Goal 5: Rapid Response to Public Health Emergencies

Goal 1: To build the PEET Research Program infrastructure and governance needed for prioritization and support of proposed Pragmatic EHR-embedded Clinical Trials throughout the UCHealth system.

Goal 2: To engage stakeholders in co-design of user guidance materials and protocols for implementation of PEET infrastructure and “designing for dissemination” across the CTSA consortium.

Goal 3: To conduct a pragmatic EHR-embedded clinical trial and use lessons learned to inform user guidance for a broad range of subsequent EHR-embedded clinical trials (up to 2 ongoing per year) to be funded through this mechanism over the 7 years of the UM1 award.

By achieving these goals, the PEET Program will increase the availability of research studies to a broad population, whilst performing more efficient, cost-effective, broadly translatable clinical research. We hypothesize that remote delivery of research interventions through the EHR will leverage the established trusting relationship between patient and their provider, which may enhance the diversity of research participants.

B. STRUCTURE, GOVERNANCE, AND INTEGRATION

The PEET Research Program **Co-Leaders** are Dr. Adit Ginde (also Lead for Trial Innovation Network HLT) and Dr. Bethany Kwan (also Lead for D&I Core and Pragmatic Trials). As CCTSI Executive Committee (EC) members, they will inform the EC and Module Leaders of progress and collaborate with RKS and Health Informatics teams (Goal D5) to enhance recruitment and retention of diverse research participants. Drs. Ginde and Kwan will work with Dr. Thomas Flaig (PI of Goal E3 demonstration study), Dr. Tell Bennett (Co-Lead for Element D3), Dr. Donald Nease (Community Engagement and Health Equity (CEHE) Director) and Mr. Steve Hess (CIO for UCHealth) to establish the PEET infrastructure. PEET will be governed by the **PEET Steering Committee** (SC) that will review all future proposed PEET trials for scientific merit, feasibility, and impact. Prioritized applications will be sent to UCHealth IT leadership for feasibility review and implementation analysis. Future PEET Projects will be approved by the PEET SC followed by the CCTSI EC.

The PEET SC will be co-chaired by Drs Ginde and Kwan. Members include Dr. Thomas Campbell, Chief Clinical Research Officer for UCHealth; Dr. Ronald Sokol, CCTSI PI/Director; Dr. Tell Bennett, CCTSI Informatics Lead; Dr. Ian Brooks, Director for Health Data Compass (HDC); Matt Mimmall, UCHealth IT; Dr. Jodi Holtrop, pragmatic research methods; Dr. Ricardo Gonzalez-Fisher, CEHE; and Ms. Anita Walden, e-consent expert. The SC will meet monthly to: a) review progress towards Goals E1 and E2, b) review progress of demonstration studies (Goal E3); c) advise on operational improvements; and d) act as consultants for UCHealth and project teams during implementation to ensure resources are used efficiently. In year 1, the SC will develop a request for applications (RFA) and policies for future PEET-supported studies. All funded studies will receive an Element E start-up package consisting of dedicated UCHealth IT support, a CCTSI Community Engagement Consult to assist with plans for recruitment of rural and marginalized communities, the services of the Community Clinical Trials Advisory Board (CCTAB) to guide community engagement in study planning, conduct, and dissemination and a D&I consult to apply user guidance to the funded study. RFAs for additional studies will be released so that there are 1-2 ongoing projects (2-3 years/project) at any time. Total budget for the program will be \$300,000/year direct costs. Projects that expand PEET capabilities and add features (e.g., integration of patient-reported measures) will be prioritized such that, over the 7-year award period, we will develop a robust system capable of efficiently implementing numerous PEET studies across various fields. **Element E will not fund Phase 3 or 4 trials; only those up to Phase 2B will be considered.** We anticipate that most funded studies will be adaptable, pragmatic studies rather than research defined as clinical trials *per se*.

C. BACKGROUND, SIGNIFICANCE, AND PRELIMINARY DATA

RCTs remain the backbone of clinical discovery and evolution of medical standards of care⁷⁸. However, RCTs are resource and labor intensive, expensive, relatively limited to performance at urban medical centers with specialized research resources, utilize small, highly-defined participant populations that do not represent the larger community, and can be burdensome for participants^{79,80}, which challenges recruitment from racial/ethnic minority and rural communities, thereby limiting the generalizability of the resultant data.⁸¹ **Pragmatic clinical trials**, which utilize routine clinical workflows, personnel, and technology to recruit participants, collect data and, in some cases, deliver interventions^{82,83} have been proposed as a solution to many of these limitations. Pragmatic trials rely primarily on data collected during usual care visits and decrease participant burden.⁸⁴ We will conduct pragmatic trials employing the EHR (Epic) of a large health system (UCHealth) that spans across our state to facilitate interventions, using EHR-mediated eligibility screening, randomization, consent, and data collection^{85,86}.

Pragmatic EHR-embedded clinical trials have been employed successfully throughout the US to study medical and behavioral interventions across health conditions. The NIH Health Care Systems Research Collaboratory alone has facilitated 21 multicenter EHR-embedded clinical trials since 2012.⁸⁷ Successful completion of EHR embedded studies shows feasibility and revealed important technological factors for success:

a) **Establishing data warehouses across health systems.** The CCTSI and its partners have a well-established cloud-based data warehouse, Health Data Compass (HDC), which contains EHR data from the UCHealth and Children's Hospital Colorado health systems. HDC supports multiple ongoing clinical translational initiatives using both raw EHR data and data mapped to the Observational Medical Outcomes Partnership (OMOP) common data model, including the National COVID Cohort Collaborative (N3C).⁸⁸

b) **Engaged health system EHR IT expertise and effort dedicated to research.** For this program, we have the full support of the UCHealth Chief Information Officer, Steve Hess (see **Letter of Support**) and we have included salary support for a UCHealth IT team member to provide dedicated expertise and time for these projects.

c) **Leveraging standard EHR interfaces, workflows, and functions as much as possible.** Including a UCHealth IT EHR team member will facilitate understanding of standard Epic workflows, interfaces, and functions.

d) **Use of standardized fields and structured data.** The HDC and CCTSI Informatics teams will ensure that we use the most appropriate common language and/or application programming interface/s to standardize and structure data. These teams have extensive experience in data harmonization and consolidation (e.g., custom mapping to OMOP common data model).⁸⁹

e) **Ability to collect patient-centered data, such as questionnaires, in the EHR.** This is a future goal once the basic infrastructure for EHR embedded studies is implemented and tested.

Conducting pragmatic EHR-embedded trials requires both 1) an efficient and scalable technology infrastructure that produces high quality data, and 2) a feasible, acceptable, and usable interface and workflow for researchers, providers, and participants. Pragmatic EHR-embedded trials benefit from partnership with health systems, providers, researchers, and communities⁸⁷ to establish requisite infrastructure and governance and ensure equitable access among diverse populations. The proposed partnership-based governance for study approval and start-up will integrate multi-stakeholder perspectives on scientific importance, IT and workflow feasibility, prioritization of projects and resources, and feasibility, acceptability, and usability. Our PEET Co-Leaders and team have extensive experience in multi-center pragmatic clinical studies that rely on recruitment and consenting, intervention delivery, and data collection via usual systems and processes of care, including diverse participant engagement.^{20,90-99}

D. INNOVATION

The PEET Program employs clinical trial conduct innovations that will increase efficiency, reduce cost, and enhance diverse participation, providing more generalizable evidence to inform real-world care. This Research Program simultaneously addresses the **5 major clinical & translational research roadblocks** mentioned above in partnership with health systems, researchers, and patients to:

- Build, test, and disseminate an **innovative model for scalable, sustainable infrastructure and governance** for pragmatic EHR-embedded trial prioritization and conduct in the context of usual care processes and settings that will **reduce healthcare system and participant burden**
- Co-design and implement **patient-centered user guidance materials and protocols**, including recommended e-consent adaptations and alternatives, that will **enhance diversity in trial participation**.
- Develop an automated study dashboard directly from the EHR data to monitor accrual, demographics, balance of randomization, and special safety labs, to monitor **diversity in trial participation in real time**.

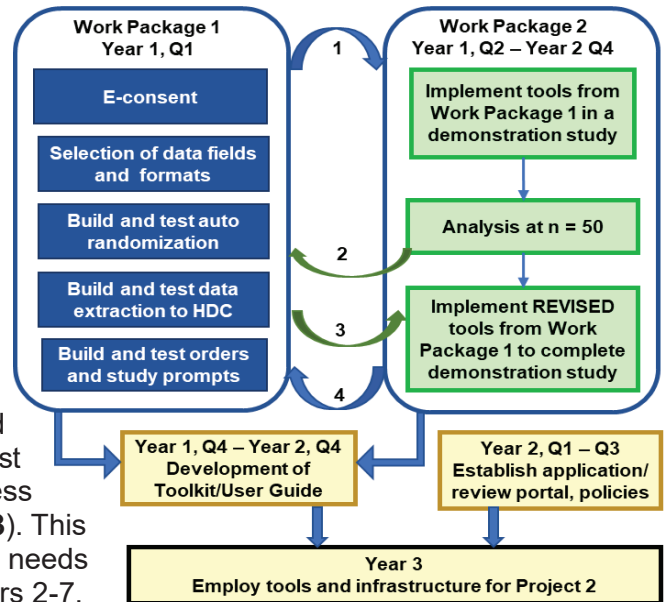
E. APPROACH

Goal 1: To build the Program infrastructure needed for prioritization and support of proposed Pragmatic EHR-embedded Trials conducted throughout the UCHealth system.

This Research Program will fund up to two concurrent separate PEET trials for 2-3 yrs per trial. After yr 1, study budgets can request up to \$150,000 direct costs per year.

Two work packages to build PEET infrastructure and governance will be finalized in yr 1; further refinement of tools to facilitate this type of research will be completed in yrs 1-2 (Figure E1). All work in these two packages will be pursued concurrently. The initial creation and testing of Epic and HDC workflows and programming will be initiated in the first quarter of yr 1. The PEET SC will meet monthly to establish policies and procedures for proposal RFAs, application processes, and review of subsequent trial proposals. The SC will meet quarterly to assess progress in the first trial (Goal E3) and adapt Work Package 1 (Figure E1) as needed. An analysis to assess completeness of enrollment and participant demographics will be performed using a trial specific dashboard developed in Epic after the first 50 participants are enrolled in the Goal E3 trial to assess demographics and implement changes as needed (see E3.3). This iterative process will build an infrastructure that will serve the needs of the subsequent trials funded through this mechanism in yrs 2-7.

Figure E1. Workflow and timeline for PEET Research Project



Goal 2: To engage stakeholders in co-design of user guidance materials and protocols for implementation of PEET infrastructure and designing for dissemination across the CTSA consortium.

A foundational principle for all pragmatic research is ensuring the conduct of research is aligned with usual systems and processes of care⁸². Such research should be patient-centered and feasible, acceptable, and appropriate to implement in real-world care settings with diverse communities^{77,100}. Collaborating with the CCTSI CEHE core, we will **engage patients, researchers, and other stakeholders** in the design of PEET user guidance materials and protocols to promote broad adoption among researchers and equitable participation among patient populations. Materials will include guidance on how to integrate community and stakeholder engagement in planning, conduct, and dissemination of findings from PEET studies; these materials will build upon the CCTSI CEHE core expertise and community relationships and the D&I core's webtools for selection of engagement methods and dissemination planning.²⁵

2.1. Design and Implementation. We will collaborate with CEHE and the **Community Clinical Trials Advisory Board (Element C1)** to recruit and establish a **Multi-Stakeholder Panel**, including researchers, providers, patients, and health system leaders. With CEHE, we will engage the panel in co-design of PEET user guidance materials and protocols using Community Engagement Studio (CE Studio) methods.^{101,102} We will conduct 2-3 CE Studios in yr 1 focused on promoting trust and equitable participation in PEET trials¹⁰³ among diverse patient populations (e.g., rural areas, underrepresented racial/ethnic groups, low digital literacy).¹⁰⁴ To address known ethical, legal, and social issues with use of e-consent (e.g., digital divide; user interface/user experience challenges),¹⁰⁵ at least one **CE studio will focus on recommendations for e-consent adaptation and alternative strategies**. In yr 1, we will conduct a customer discovery and value proposition design¹⁰⁶ process¹⁰⁷, focused on researcher perspectives, to propose a **messaging strategy about the value of PEET infrastructure and EHR-embedded trials**. The value proposition messaging will be incorporated into the RFA process to promote broad interest among CCTSI investigators. Prior to launch of the RFA in yr 2, we will test and refine the guidance materials to optimize perceived acceptability and usability^{108,109} among community members and researchers using the think aloud usability testing technique¹¹⁰; these materials will further be refined based on feedback from the first funded PEET trial (Goal E3). In subsequent years, the panel will prioritize other features relevant to patient-interfacing aspects of PEET infrastructure, such as recruitment or patient-reported measures. Finally, in collaboration with the D&I core and in alignment with Strategic Management goals, we will package and distribute PEET infrastructure and user guidance materials across the CTSA Consortium.

2.2. Evaluation & Equity. A major NCATS goal is to provide equitable access for participants in research studies that address clinical questions relevant to real-world settings. The plans for pragmatic EHR-embedded trials provide opportunity for self-selection by participants for research studies. The use of UCHealth's My Health

Connection patient portal for alerting patients who are eligible for the study and allowing them to *consent and enroll electronically*, minimizes selection bias that may occur with in-person consent. Also, remote intervention delivery to the participant through their existing health care provider leverages the trusting relationship that has been established between a patient and their provider; we hypothesize this will enhance the diversity of participants. To evaluate impact of PEET, we will track race, ethnicity, age, zip code and other variables of study enrollees to determine if this recruitment mechanism results in a cohort that resembles the population of Colorado. Additionally, as electronic questionnaires are incorporated into PEET trials, we will gather direct feedback from potential participants – both those who enroll in studies and those who are eligible but choose not to participate. This feedback will facilitate refinement of communication strategies with both patients and providers and influence our plans to ensure enrollment diversity (See E3.3 below).

Goal 3: To conduct a pragmatic EHR-embedded trial and use lessons learned to inform user guidance for a broad range of subsequent pragmatic EHR-embedded trials (up to 2 ongoing per yr) to be funded through this mechanism over the 7 years of the UM1 award.

3.1. Rationale: During yr 1 of the UM1 award, the PEET Program will support the initial demonstration study, “A Randomized, Pragmatic, Adaptive trial of Metformin for Glucose Intolerance or Increased Body Mass Index in Prostate Cancer Patients.” (see **Human Subjects and Clinical Trials** section for additional details). This vanguard pragmatic EHR-embedded trial has received IRB and hospital approval. Men with prostate cancer at risk for diabetes will be electronically randomized to metformin plus lifestyle education vs. lifestyle education alone and followed for up to 10 yrs. Dosing and continued use of metformin will be managed by the treating provider. A group of 25 medical oncologists, urologists, and radiation oncologists have been identified as study-associated providers for enrollment of patients across 3 broad regions of UCHealth (Colorado Springs, Metro Denver and Ft Collins) which encompass 12 inpatient facilities and a broad geographically distributed population in urban and rural areas. Best practice advisories (Epic popups) and enrollment information will be sent to these study-associated providers. The design and support for this trial will establish the infrastructure and provide generalizable innovations and insights that can be used in subsequent PEET studies.

Metformin, FDA approved for use in T2 diabetes treatment and prevention, was chosen as the intervention because retrospective data show an association with improved overall survival and reduced cancer-specific mortality with incidental use of metformin in men with prostate cancer.^{111,112} The mechanistic basis for metformin’s anti-cancer effect is not clear, but metformin-activated adenosine monophosphate–activated protein kinase (AMPK) is one possible mechanism.¹¹³ AMPK activation inhibits the mammalian target of rapamycin (mTOR) pathway, which has specific relevance in prostate cancer via the PI3K/AKT/mTOR pathway. Metformin has also been shown to inhibit mTOR independently of AMPK pathway, causing cell cycle arrest.¹¹⁴

3.2. Primary Objective: The primary objective of this trial will be to demonstrate that the use of PEET infrastructure developed in Goals E1 and E2 for conduct of a randomized, pragmatic, adaptive, interventional trial across the UCHealth network can enroll 200 patients in 2 yrs. This study will utilize an e-consent, electronic assessment of eligibility, electronic randomization in Epic, confirmation at a regular visit with one of the study investigators and allow for the majority of the data to be collected passively as part of standard of care via HDC.

Primary and Secondary Outcomes: The primary outcome is the rate of accrual. Secondary outcomes include demographic enrollment characteristics, time/effort needed to recruit 200 participants, and protocol adherence and retention of enrolled participants. These data will inform enhancements to the EHR and HDC resources to be implemented across time in this study and for subsequent PEET Program studies, and to inform revisions to the Goal E2 user guidance. The study team plans to explore the effectiveness of metformin for both oncologic and metabolic endpoints and safety of metformin using this pragmatic approach in an expanded follow-on study after the conclusion of this PEET demonstration study.

Enrollment criteria: Patients (≥ 18 years) with a prostate cancer diagnosis who have glucose intolerance (HbA1C 5.7-6.4%) and/or increased BMI (≥ 25 kg/m²) will be invited to enroll in a randomized pragmatic study of metformin plus lifestyle modification information versus lifestyle modification information only. Retrospective analysis shows that ~3,000 patients in the UCHealth system would qualify for this study.

3.3. Consenting, Enrollment and Randomization: Patients will be randomized 1:1 in Epic between 2 study arms (metformin plus lifestyle information or lifestyle information only). We will use a 2-step electronic consent approach to enroll patients (**Figure E2**) which was developed in discussions with the IRB and with support from the CCTSI D&I team. The initial *general consent* (Form 1) will invite patients to join a patient consortium to study prostate cancer and for additional trial opportunities under this mechanism. Those who consent to the initial project and are eligible for the trial will receive a *second electronic consent form* that is limited to the specific arm

to which the participant has been randomized. Thus, those in metformin arm will receive only the metformin + lifestyle information consent form (Form 2a), whereas those in lifestyle advice arm will receive the lifestyle information consent (Form 2b). After patient signs the second consent, the next study-associated provider to see the patient will receive an Epic best practice advisory (BPA), which will be transferred to the next study-associated provider visit, if needed, until consent is signed or declined by the patient. The provider will answer two basic questions to confirm key aspects of the electronic screening and consent, with the patient in the room, to activate the study and the pended metformin drug and/or lifestyle information order/s. In both arms, a BPA will remind providers about the need to follow good medical practice related to prostate cancer care and, for the metformin arm, obtaining annual BMP, HbA1C, and every other year vit. B12 levels. Electronic reminders will be sent to participating providers if these are not done in usual standard of care windows. Collection of data will be done primarily via HDC, and no data capture forms will be used. Clinical information generated during care and follow-up visits (e.g., disease course, lab data, mortality, diagnostic codes, drug/procedure information) is available via HDC, and will be harmonized with other study data in a study-specific data mart. We will use lessons learned from this study, in collaboration with study investigators and the CCTAB, to revise the Goal E2 user guidance.

Enrollment Diversity Concerns: This EHR-embedded approach has the potential to remove barriers for participant enrollment. However, not all patients actively use the EHR so we will take steps to ensure diversity and equity in accrual. Ample evidence suggests older patients have access to mobile technology, but we will pay particular attention to ensure technology barriers do not preclude enrollment. Demographic distribution of enrollees **will be monitored** throughout the trial and compared to the state cancer demographics to identify underrepresentation of rural populations and racial and ethnic minorities. **To proactively address technological, social, and/or cultural barriers** to e-consent, such as patient portal access or privacy concerns, the Goal E3 team will integrate Goal E2 recommendations for e-consent adaptations and alternatives. This may include providing hard copies of the step-by-step portal access instructions and/or an in-clinic tablet system so that patients can consent during standard of care visits with support of in-person staff. To further enhance enrollment by underrepresented populations, we will identify racial and ethnic minorities based on self-identification, Spanish-speaking patients based on whether an interpreter need is noted in the EHR, and rural patients based on zip code. The CU Cancer Center has the capacity to support efforts to enroll underrepresented populations in this trial through their office of Community Outreach and Engagement (COE). With the support of COE, we will contact Spanish-speaking patients with a bilingual coordinator who can assist with EHR portal use, and send individualized patient portal messages to raise awareness of the trial. To ensure an equitable distribution of urban and rural participants, enrollment will be monitored by health system region and zip codes. Additional outreach by phone or EHR messaging will be made to those in non-urban areas. Finally, we will work with the CCTAB and PEET MSP to culturally optimize our EHR messaging plan and for community engagement assistance as the trial progresses.

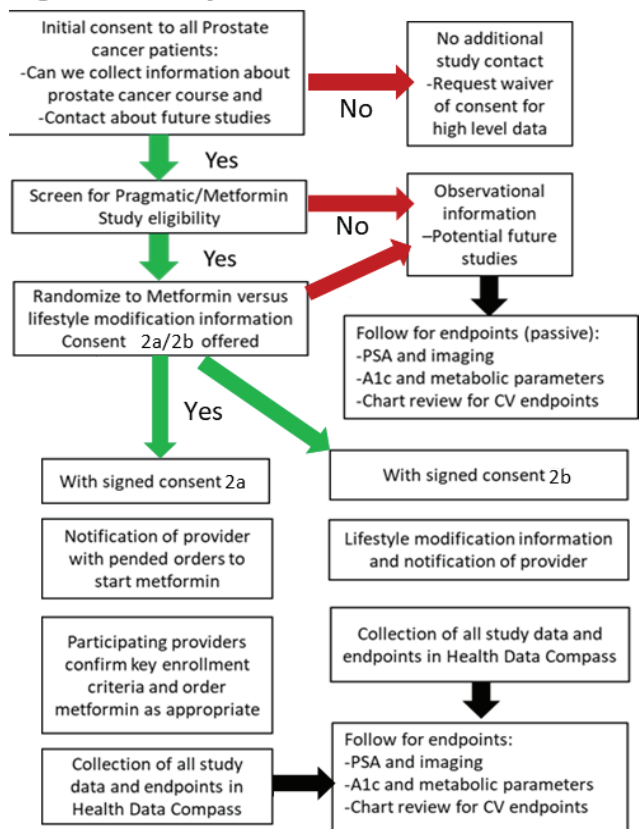
3.4. Intervention and Mode of Delivery

Metformin arm: 850 mg once daily for 2 weeks, then 850 mg twice daily (standard of care for glucose intolerance or overweight). Providers will be allowed to change doses for any clinical reason. Reminders for medication refill will be sent if refills have expired. Educational material, as for Lifestyle education arm, will also be provided.

Lifestyle education arm: Educational material on lifestyle modification to reduce the risk of diabetes, using American Diabetes Association materials, in the participant's primary language, will be sent via the EHR or email.

Safety data will be reviewed via a specific safety report developed by HDC. The PEET SC, whose members have appropriate medical and scientific expertise, will review trial safety data and accrual quarterly at standing

Figure E2. Study Schema.



SC meetings. Safety determinations made by SC will be referred to the CU Cancer Center Data Safety Monitoring Committee (as outlined in the IRB-approved protocol and **Human Subjects and Clinical Trials**).

3.4.2 Innovation. Innovation will include conducting a large randomized interventional trial without the extensive resources required to support a traditional RCT. The pragmatic approach will minimize disruption to both patients and physicians via integration with routine care. We postulate that this will increase the efficiency of translational research and provide generalizable innovations that can be utilized by other institutions. Streamlining engagement with participants and data collection will address multiple roadblocks due to systems and staffing and facilitate more inclusive research opportunities for patients. This study will serve as the inaugural model for the PEET Research Program. Approaches developed for this trial (e-consent, e-randomization, clinical nudges) will establish approaches to be applied to subsequent PEET-funded studies.

3.5. Data Analysis

After an initial analysis after enrollment of the first 50 participants to assess completeness and demographics of enrollment and data collection, we will implement corresponding study infrastructure changes. After 6 months of follow-up of the first 200 participants enrolled, a planned interim data analysis will be performed. Based on the findings of that analysis, a request to adapt the trial into a fully powered randomized trial may be submitted to the IRB. **It should be emphasized that only the initial demonstration portion of this study, examining accrual up to 200 participants, will be funded as the first project for Element E.** Analysis will include the primary outcome as the proportion of eligible patients who participated, rate of accrual and whether the accrued cohort is representative of the total pool of eligible patients and the demographics of the population of Colorado.

F. BENCHMARKS OF SUCCESS/METRICS

Benchmarks of success will be tailored to the phase of the PEET program (**Table E1**).

G. POTENTIAL PROBLEMS AND ALTERNATIVE STRATEGIES

Goal 1: Although not anticipated, it is possible that some planned improvements to the EHR or HDC cannot be executed due to technical limitations. We will implement revised elements of Work Package 1 as they become available, rather than as an amalgamated package, so that the project is not hindered if this occurs. We will reach out to other CTSA hubs with expertise in EHR embedded trials if we encounter technical barriers. We will document the frequency and types of these issues to include in lessons learned.

Goal 2: The Goal 2 user guide may be insufficient for adoption and use of PEET infrastructure in future EHR-embedded trials. If this is the case, we will add technical assistance as a complementary approach. The CCTAB may suggest features for PEET or the user guide that are not initially feasible. In this case, we will work to prioritize their suggestions in future iterations.

Goal 3: The primary outcome for success will be the feasibility of enrolling 200 participants in 2 yrs. Retrospective analysis shows over 3,000 in the UCHealth system would meet eligibility criteria, such that enrolling 100-125 patients/yr is a feasible target (see **Benchmarks of Success**). Enrollment through the EHR may exclude some underserved minorities because consent 1 (general consent) must be obtained before COE reaches out to assist individuals from underserved populations. We will address this by providing hard copies of the step-by-step portal access instructions and an in-clinic tablet system at all participating provider locations so that patients can consent during standard of care visits with support of in-person staff.

Table E1. Benchmarks	Deliverables/Metrics
Development of EHR & HDC infrastructure for PEET	Date of first PEET demonstration study launch
Iterative improvement to EHR and HDC resources	Launch date for each integrated change Number of changes/yr
Establishment of the Steering Committee	Date of first full meeting to work on Element E
Creation of the PEET application portal and policies	Policy ratification by CCTSI and UCHealth Date of portal activation
Development of PEET user guidance materials	PEET SC approval of each module and lessons learned
SC review of PEET applications	Number of protocols reviewed per year Number of protocols approved, sent to UCHealth Time from application to SC approval
Implementation of new PEET protocols	Number of new PEET studies launched per year
Ongoing additions/improvement to PEET resources	Number of changes recommended by SC/yr Number of changes launched per yr
Rate of patient enrollment	Enrollment of 200 patients in 2 yrs Patient demographics > state averages

H. RIGOR AND REPRODUCIBILITY AND FUTURE DIRECTIONS

To test the rigor and reproducibility of our created PEET infrastructure and resources, future approved projects in years 2-7 will include different subspecialties, investigating different disease states and outcome measures, and different practice locations. This will allow us to determine the robustness of our framework and adaptability of the infrastructure. Through iterative implementation of lessons learned and refinement of the infrastructure, we will position the CCTSI and our Partnering Institutions to be nimble and ready to lead and participate in multicenter EHR embedded clinical trials, including those responding to emergent public health crises.

A. Overall Structure, Coordination, and Integration

The CCTSI Hub is a highly integrated research and training program for clinical and translational science (CTS) based at the University of Colorado Anschutz Medical Campus (CU Anschutz) and with strong Partnerships with CU Denver, CU Boulder, Colorado State University (CSU), 5 hospitals, and multiple community organizations and stakeholders (see **Hub Institution Organization**). The CCTSI is applying for the next 7-year funding cycle through 7 grant applications in response to the 2021 CTSA grant FOAs: **1)** a **UM1 application** being resubmitted as an A1 application; **2)** a required **K12 application** that was reviewed in 2021 and received a score of 20; **3-4)** two optional **T32 (Pre-doctoral and Post-doctoral) applications** that received scores of 19 and 30; **5-6)** RC2 Specialized Innovative Projects under development; and **7)** an R25 application under development. The CCTSI UM1, K12, and optional T32 programs (and future RC2 and R25 programs) will function as a **single entity and partnership** similar to the current CCTSI structure. These programs will be integrated through coordinated, overarching governance and operations, including administration and finances, Executive Committee (EC) oversight and integration, strategic planning, coordination of resources and personnel, aligned goals across programs, and evaluation and continuous quality improvement. All CCTSI components share common goals of improving the efficiency and impact of the translational research enterprise in Colorado, partnering with communities and stakeholders, addressing health equity and disparities, and training a resilient professional research staff and the next generation of clinical and translational scientists. Since this unified collaborative CCTSI structure is the functional model that has been successful over the past 14 years, we expect a seamless transition to the new NCATS partnership model of multiple separately grant-funded programs integrated with the CTSA Hub. Here we outline coordination and integration of the proposed UM1, K12 and T32 programs.

B. Integration and Coordination of Central Governance Model

Administrative Core: The CCTSI Hub Administration Core, headquartered on the CU Anschutz campus, will oversee the Institute's execution of the goals laid out in the UM1, K12 and T32 applications (and future applications). The Administrative Core is directed by Tim Lockie, MBA, MS, the Director of Finance and Administration of the CCTSI, MPI Ronald Sokol, MD and MPI Janine Higgins, PhD. The Administrative Core oversees governance, operations and finances (**Element B**) with the goal to integrate, coordinate, track and improve all CCTSI programs and cores. The CCTSI resides in the office of the Vice Chancellor for Research (VCR) and the MPIs report to the VCR and the VC Health Affairs (Dean, SOM), who report to the Chancellor of CU Anschutz. The MPI positions and roles facilitate coordination, communication, integration and responsiveness across the broad University community. The Admin Core team will administer the UM1, K12 and T32s (and future RC2 and R25) CTSA grants including ongoing budgets, resources and personnel component of each program, and NIH RPPR preparation. This plan encourages sharing of personnel and resources across programs. The CCTSI headquarters include offices and meeting space for leaders and staff of the UM1, K12 and T32 programs (and future RC2 and R25 grants). This co-localization of leaders and team members promotes synergy, collaboration, and communication between components. Drs. Sokol, Higgins, Burnham (K12 PI) and Cicutto (Pre- and Post-doctoral T32 PI) have worked together over the last 10 years to coordinate the research and educational activities of the Hub within the current CCTSI governance, and will continue to do so in the next grant award period.

Executive Committee (EC): The EC is the integrated governing, coordinating and decision-making body of the CCTSI. Members of the EC include the MPIs of the UM1 (EC Chair), K12, and T32 programs (and future RC2 and R25 grants), all UM1 Module and Core leaders, two community representatives, and leaders from each Partner Institution. The EC meets twice monthly to promote seamless collaboration and integration among the various CCTSI programs; facilitate bidirectional feedback between leadership and key stakeholders/constituents; strategize and innovate by sharing ideas, metrics and other information on a regular basis; and ensure frequent communication and collaboration of modules, cores, and training programs with the Partnering Institutions (**Element B**). The Evaluation and Continuous Quality Improvement Teams provide regular reports for all **Element C, D, and E** programs to the EC as agents for change and innovation. Leaders from UM1 Modules, the K12 and T32 programs, and representatives from the research workforce provide annual reports to the EC to ensure communication and collaboration among Hub leaders. Based on this input from constituents, the EC makes recommendations for changes to programs/Cores, which are discussed and enacted in collaboration with the EC and other modules/Cores, and allocation of resources by the Administrative Core. This collaborative, bidirectional model of integration and governance through our central EC will promote the goals of NCATS and the CCTSI in the next grant cycle.

C. Overarching Goals and Integration of Components of the Multiple CTSA Grant Applications

The overarching goals of the CCTSI UM1, K12 and Pre- and Post-doctoral T32 grant applications are to advance the NCATS CTSA mission to improve health and reduce health disparities by developing, demonstrating and disseminating operational innovations that enhance the efficiency and effectiveness of translational research; promoting partnerships and bidirectional engagement with communities and patients equitably in research; training and retaining a diverse clinical research workforce and the next generation of translational scientists; and being prepared for future public health emergencies. Our 4 current CTSA grant applications will be coordinated at the administrative and operational levels with multiple **common integration points between the UM1 (all Elements and Modules [Mod.]), the K12, and two T32 programs**: **1)** all training programs, the K12 and two T32 programs, will have grant finances and HR administered through the CCTSI **Administrative Core (Elmnt B)**; **2)** the UM1 Workforce Development (WD) module (**Mod. C1**) will provide the funding, office space and administrative support for faculty leadership and programmatic needs of the K12 and T32 programs; **3)** multiple UM1 WD programs (Table C2; **Mod. C1**) will be leveraged to provide education and career development components of the K12 and T32 programs (details for each program below); and **4)** the PIs of the K12 and T32 programs are part of the CCTSI educational **Leadership Advisory Council (LAC**; UM1 Figure C2), chaired by Dr. Cicutto (T32 PI), which governs and integrates all CCTSI WD Programs (**Mod. C1**). Dr. Cicutto and Dr. Burnham (K12 PI) also sit on the CCTSI EC as full members to facilitate effective coordination and integration of K12 and T32 leadership into CCTSI Hub leadership. The LAC, composed of directors and leaders of all CCTSI WD programs, DEIA leads, Community Engagement (**Mod. C2**), BERD (**Mod. D1**) and Evaluation Core (**Elmnt B**) leaders, uses shared decision-making and meets monthly to review training program activities, evaluation and feedback, metrics/outcomes, and integration across programs (WD, CCTSI, Partners). Thus, the LAC ensures coordination, communication, synergy, and mutual accountability across all CCTSI educational and training programs. The LAC has proved to be extremely valuable to ensure that education/training leaders are aware of each other's services, have the agility to collaborate across programs, and can effectively leverage resources and avoid duplication of efforts. Dr. Cicutto presents LAC information to the EC for further integration of training opportunities into overall CCTSI functions. The LAC works with the CCTSI Hub Evaluation and CQI Cores (**Elmnt B**) for ongoing Program evaluation and CQI, in conjunction with EC recommendations, as needed.

K12 Scholar Program. The Goal of the CCTSI K12 Program is to provide opportunities and protected time and intensive mentored career development experiences for early-stage faculty that lead to independent extramural support and future leadership positions in academia, professional societies, and/or industry. Our K12 proposal will support career development for 6 early-stage faculty who hold a position at one of our Partnering Institutions.

The K12 Program is housed within the structure of the UM1 WD Program (see **Hub Institution Organization**). The UM1 programs that specifically support the education and career development objectives of K12 Scholars (**Mod. C1**) include: the CO-Mentor (mentor/mentee) program; mock study section review of K grant applications; the Clinical Sciences formal graduate program (Masters and PhD) in which many K12 Scholars enroll (includes coursework in grant writing, translational competencies, biostatistics, database design, etc.); responsible conduct in research training provided by the UM1 RKS Core (**Mod. D1**); DEIA principles training; and the new Leading & Teaming program. Many K12 Scholars also take advantage of the rich Resources & Services components (**Mod. D1**) of the UM1 to support conduct of patient-oriented clinical research and Phase 1-2b clinical trials. Highly utilized resources include inpatient and outpatient facilities and the research Nursing Core, Core Laboratories, BERD Core, Exercise Research Laboratory, and Nutrition Core. K12 Scholars pursuing careers in T2, T3, or T4 research will take advantage of programs of the UM1 Community and Stakeholder Engagement Core (**Mod. C2**), including Community Consults, Community Immersion training, CE Pilot Grants (**Mod. D2**), Community Research Liaisons, and the Clinical Faculty Scholars Program for health services research training. Our UM1 Health Informatics Module (**Mod. D3**) provides various data services (REDCap, Health Data Compass access, informatics training) for K12 Scholars.

Pre-doctoral T32 Program. The goal of the **Pre-doctoral T32 program**, directed by PI Lisa Cicutto PhD, RN, is to meet the needs of the translational science and research community by preparing diverse inter-disciplinary doctoral trainees to develop the skills necessary for successful careers in Clinical and Translational Science and Research (CTSR). We are requesting 8 trainee slots.

The Pre-Doc T32 is housed within the UM1 Workforce Development (**Mod. C1**) Core, which will provides many key educational elements to the T32 program. The CLSC graduate program provides foundational education in CTSR for trainees. The UM1 WD *Leading and Teaming in CTSR* educational program, *Mentoring3* program, the *F grant Review*, *DEIA training*, and *Communicating Research to the Public* will all be required training activities

for T32 appointees. From Resources and Services (**Mod. D1**), the BERD, RKS, and Bioethics Cores will provide seminars, one-on-one training, and workshops that support T32 trainees. Seminars on community engagement and health equity will be provided by leadership from the CEHE UM1 Core (**Mod. C2**) and immersion experiences will be identified for those trainees interested in community-based research. REDCap, Health Data Compass and other informatics needs of trainees will be supplied by the Health Informatics Core (**Mod. D3**). In summary, the Pre-doctoral T32 program will leverage numerous UM1 Cores and services to meet the goals of the program and the needs of the awardees. Feedback from awardees and T32 leaders is provided to the EC by the annual surveys and interviews conducted by the Evaluation Core.

Post-doctoral T32 Program. The goal of the **Post-doctoral T32 program**, directed by PI Lisa Cicutto PhD, RN, is to meet the needs of the research community by preparing diverse translational scientists, who have obtained their terminal degree, for successful CTSR careers. The CCTSI is requesting 4 post-doctoral T32 trainee slots for this program.

Many UM1 specific components directly support the Post-doctoral T32 program, which is housed within the Workforce Development (**Mod. C1**) Core. The WD CLSC graduate program provides education in CTSR for Post-doctoral T32 fellows pursuing a Master's in Clinical Sciences degree. The WD *Leading and Teaming in CTSR* educational program, *Mentoring3* program, *DEIA training*, *Communicating Research to the Public*, *Pre-K and K to R Grant Review Mock Study Sections* will be required training activities for Post-doctoral T32 awardees. From Resources and Services (**Mod. D1**), the BERD, RKS, and Bioethics Cores will provide seminars and workshops. Scholar applications to the CCTSI Pilot Grant Programs (**Mod. D2**) is encouraged and supported through the T32 program. Seminars on community engagement and health equity will be provided by leadership from the CEHE Core (**Mod. C2**). REDCap, Health Data Compass and other informatics needs of trainees will be supplied by the Health Informatics Core (**Mod. D3**). In summary, the Post-doctoral T32 program will heavily leverage numerous UM1 Cores and Services in order to meet the career goals of the trainees. Feedback from awardees and T32 leaders is provided to the EC by the Evaluation Core and LAC reports.

D. Integration of Components with Partnering Institutions

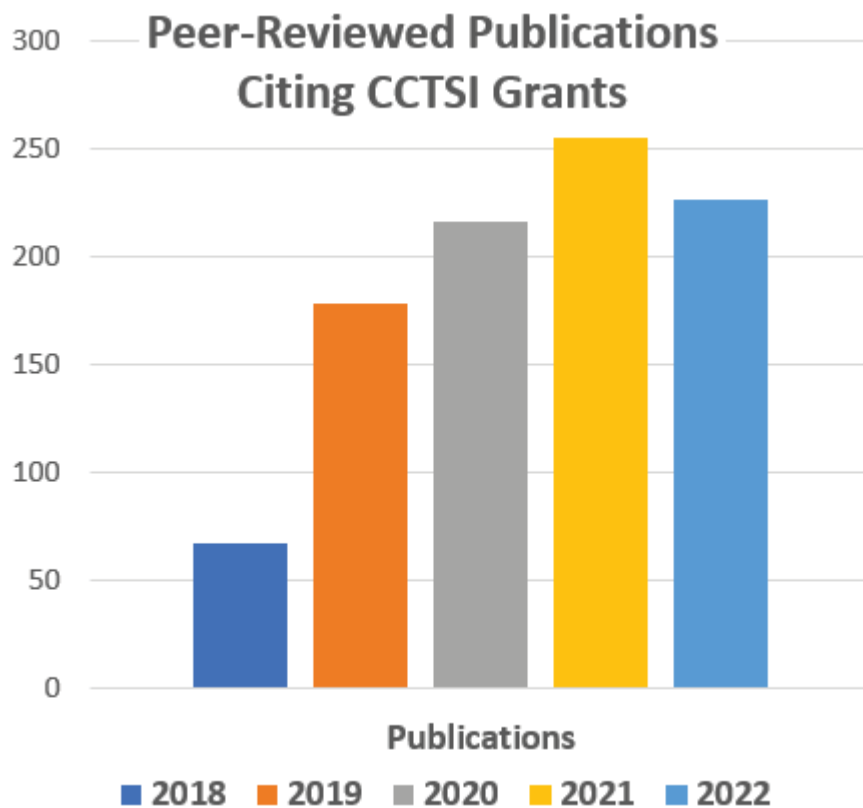
UM1 Partnering Institutions provide the faculty effort and expertise to lead many CCTSI Modules and Programs; mentor and teach trainees; facilities to conduct CTR; diverse patient populations throughout Colorado; facilitate access to CCTSI programs by a diverse and geographically distributed pool of students, staff and faculty; informatics and EHR data capabilities; and collaborations that make our CCTSI programs successful. Table C11 illustrates the integration of all CCTSI programs in the UM1, K12, and T32 applications (rows) with each Partnering Institution (columns). **A filled blue box** indicates that an institution's faculty/staff lead or deliver program services across sites and/or that an institution's faculty/trainees/staff participate in and benefit from the program.

TABLE C11. INTEGRATION OF PROGRAMS ACROSS PARTNERS	CU Anschutz	CU Boulder	CU Denver	CSU	UCH	CHCO	NJH	DH	VAMC	Community Reps & Organizations
B - Strategic Management										
Administrative Core										
Executive Committee										
Hub Liaison Team/TIN										
Continuous Process Improvement										
Evaluation Core										
Dissemination/Implementation										
Internal Advisory Board										
C1 - Workforce Development										
Research Staff Professionals										
CLSC										
CFSP										
PreK and K to R										
CO-Mentor										
Clinical Research Education Program										
C2 - Community & Stakeholder Engagement										
PBRNs										
PACT										
Bootcamp/Translation										
Community Immersion										
CE Pilot Program										
D1 - CTS Resources and Services										
BERD										
RKS										
Bioethics										
Data Management										
Research Studios										
CTRC Network (clin. research units)										
Pragmatic Trials										
Dissemination/Implementation										
Natural Animal Models Core										
Core Labs										
Nutrition and Exercise Cores										
D2 - Pilot Grant Program										
D3 - Health Informatics										
E - CTS Research Program										
Pre Doc T32										
Post Doc T32										
K12										

Facilities and Other Resources

Peer-Reviewed Publications Resource

The CCTSI infrastructure, Resources and Services, Community Engagement and Health Equity program, training and career development programs, informatics resources, pilot grant funding, and research facilities and personnel support hundreds of new and ongoing research studies and trials each year at CU Anschutz, CU Boulder, Colorado State University and our Partnering Hospitals and Health Care Systems as well as our Community Organization collaborations. The impact and dissemination of the results of this work is achieved through a number of channels, one of which is through peer-reviewed publications in the biomedical literature. The FOA for this UM1 grant application does not any longer require a list of publications derived from UL1 grant funding in the prior grant cycle. However, to illustrate the valuable research community resource provided by the productivity of the CCTSI Members in this context, the following figure demonstrates the number of PubMed peer-reviewed publications per year in the current CCTSI grant cycle (2018-2023) that cite our CTSA NCATS grant numbers. Following the year that the grant funding has commenced (2018) and after the bulk of



the research projects reach fruition (Year 2-3), there are approximately 200-250 peer reviewed publications per year derived from CCTSI support that appear in highly cited and impactful journals. Many more publications utilize some of the CCTSI resources (e.g., REDCap for database or survey management, BERD consultation) but do not cite the CCTSI grant support for these services.

Colorado Clinical and Translational Sciences Institute

The Colorado Clinical and Translational Sciences Institute (CCTSI) was established in 2008 with funding from the Clinical and Translational Science Award (CTSA) initiative of the National Institutes of Health (NIH) and substantial support from the involved institutions. It is a collaborative organization which aims to transform existing clinical and translational research and training efforts into a shared research enterprise. The **Vision of the CCTSI** is to accelerate and catalyze the translation of innovative science into improved health and patient care. To achieve this vision, the **Mission of the CCTSI** is to:

Goal 1: Advance CTS by developing, demonstrating, and disseminating innovative programs to improve the efficiency and impact of translation across the entire T0.5 to T4 spectrum.

Goal 2: Promote collaboration, team and data science, and partnerships to accelerate CTR locally, regionally and nationally.

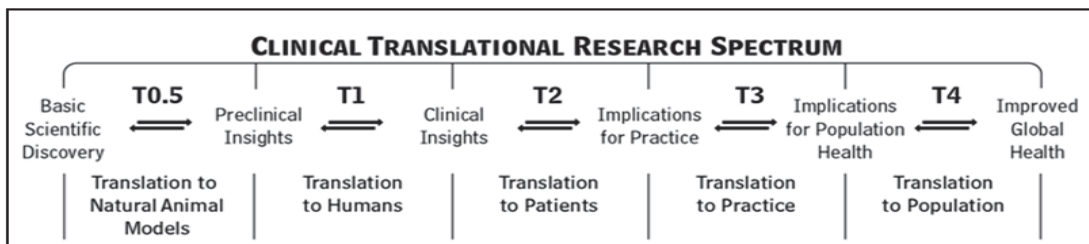
Goal 3: Partner locally, regionally and nationally with institutions, stakeholders and communities to develop innovative research programs that will address health inequities and disparities.

Goal 4: Further develop operational efficiencies to increase the quality, safety, efficiency, effectiveness and informativeness of clinical research.

Goal 5: Promote a safe and nimble research environment that can rapidly respond to urgent public health needs.

Goal 6: Develop and disseminate CTS training programs that educate and sustain a resilient, diverse team of clinical research professionals

Figure 1. Spectrum of Clinical and Translational research



The CCTSI is an Institute within the University of Colorado, based at the University of Colorado Anschutz Medical Campus. As such, CCTSI Program Directors and staff are generally housed within their home

department, according to faculty affiliation. The Institute’s resources, therefore, are distributed across the schools, campuses, and affiliated hospital that it serves. These include 5 Clinical Translational Research Centers (CTRCs) providing inpatient and outpatient clinical research resources at University of Colorado Hospital (UCH), Children’s Hospital Colorado (CHCO), National Jewish Health (NJH), and CU Boulder with an additional mobile perinatal CTRC; contact points at each hospital; and programs located across CU Anschutz, downtown campus, our affiliated institutions across Colorado, and the hospitals. The CCTSI provides office space for administrative staff in the Leprino Office Building, located on the CU Anschutz Medical Campus. This space also houses conference rooms and open workspaces that allow CCTSI Program Directors and staff to collaborate and work together.

An Executive Committee, chaired by the CCTSI Director and Contact Principal Investigator, Ronald J. Sokol, MD, oversees operations and decision making. Dr. Sokol reports to the Vice Chancellors for Research and the Vice Chancellor for Health Affairs (the Dean of the School of Medicine), who in turn report to the Chancellor at CU Anschutz. The CCTSI involves the six health professional schools and colleges located at CU Anschutz; the Schools of Engineering and Applied Science, Liberal Arts and Science, and Education and Human Development at CU Denver; the Colleges of Arts and Sciences and of Engineering and Applied Science at University of Colorado, Boulder; and the colleges of Veterinary Medicine and Biomedical Sciences, Liberal Arts, Health and Human Services, and Engineering at Colorado State University. Affiliated institutions include 5 local hospitals and health care organizations: University of Colorado Hospital (UCH), Children’s Hospital Colorado (CHCO), Denver Health (DH), National Jewish Health (NJH), and Rocky Mountain Veterans Affairs Medical Center (DVAMC). Faculty, trainees, and research staff at each of these institutions may become CCTSI members to access CCTSI resources. Through the CCTSI’s Partnership of Academicians and Communities for Translation (PACT), our community engagement and research program, it has 18 established Community-Academic partnerships throughout Colorado, involving diverse and underserved populations throughout the state. This collaborative network of universities, hospitals, and the communities they serve have successfully promoted excellence in health care professional training and cutting-edge research programs and innovation for the past 30 years.

Investigators from all areas of biomedical, biobehavioral and health services research use the CCTSI to access resources for innovative interdisciplinary research and clinical and translational sciences training. The CCTSI requires membership of faculty, research associates and post-Docs, trainees, community members, private companies, and public entities to use CCTSI resources, training programs or facilities. In May 2022, we have 6,762 members.

CU ANSCHUTZ PROGRAMS AND RESOURCES

University of Colorado Anschutz Medical Campus

The University of Colorado Anschutz Medical Campus (CU Anschutz) is the largest academic health center in the Rocky Mountain region which brings together on the same campus for the first time three hospitals and educational, administrative, and research facilities for all six health science schools. The 11.3 million ft² of state-of-the-art facilities has benefited from over \$4 billion of investments to date. The 230-acre campus provides adjacencies of clinical, educational, and research facilities all within walking distance of each other, building a new culture of collaboration among clinicians, investigators, and educators that invigorates research and innovation. An adjacent biotechnology park helps facilitate close collaboration between University investigators, industry, and the private sector.

CCTSI

Biostatistics, Epidemiology, and Research Design (BERD) Core

Expertise in biostatistics and research study design is a fundamental component of effective science and absolutely essential to the CCTSI. The cost of poor research design, inadequacies in the conduct of research, and bad practice in analysis and interpretation has been well documented in the biomedical literature and in the popular press. As such, the CCTSI has the BERD Core. It is a broadly accessible, yet discrete, study design and analysis resource that fills an otherwise unsupported need with a goal to advancing the efficiency and effectiveness of completing clinical or translational research projects. The CCTSI-BERD Core is fully integrated with the CU Anschutz's campus wide study design and data analysis infrastructure called the Center for Innovative Design and Analysis (CIDA), which is housed administratively in the Colorado School of Public Health with faculty appointments in the Department of Biostatistics and Informatics. This integration includes shared leadership (Dr. Carlson directs both BERD and CIDA and two BERD members Drs. Sammel and Kechris serve as Associate Directors of CIDA). 17 PhD faculty, 13 MS faculty, and 14 student research assistants comprise the faculty and staff of CIDA. Of those, 16 have some portion of effort towards BERD objectives. The BERD Core has four resource areas: 1) consultation and study design, 2) team formation, 3) new tool development (in the informatics section) and 3) education of clinical and translational scientists in biostatistics/study design principles and new to this application, education of BERD members in team science and collaboration skills. In addition, the Core co-develops larger projects to solve problems impacting clinical and translational science. This includes how to transform methods into usable products through R package development, tools for making consultation and analysis more reproducible, and new to this application, data driven strategic staffing and training.

We have a project funding and management system that continues to evolve to be responsive to both the CCTSI and broader CTSA objectives. Projects are funded and managed through three main mechanisms:

First hour free: The initial consult (either through office hours or project registration) is funded with BERD resources. The initial consult may necessitate a longer-term arrangement as outlined below.

Biostatistics Collaboration and Consultation: Guided by a simple scope of work (developed in the initial free 1-hour meeting). Consultations for analysis are fee-for-service or cost-shared using BERD funds for proposal development/study design for high priority investigators or for more extensive study design and analysis for compelling cases.

Long-term collaboration agreement: Agreements that are arranged and funded by individual departments or research units/centers. Collaboration agreements provide salary on a %FTE basis to support an individual biostatistician's collaborative work with investigators in that department, unit, or center.

Prioritization of projects: The project prioritization system is managed by the BERD Executive committee and evaluated at least annually. An initial prioritization could include prioritizing under-represented minorities, projects/proposals addressing an emergent public health issue, junior investigators/trainees from small units not covered under a collaborative agreement, proposals using new data sources or requiring innovative study design. Projects receiving BERD resources are already tracked weekly by each member in our smartsheet system and we will continue that approach for this proposal.

Computer

The CSPH at CU Anschutz Medical Campus is equipped with over 160 computers and workstations. CSPH faculty have computers, and laser printers for their use. University computing facilities provide access to email, Internet, and bibliographic databases. Information technology specialists are available through a SOM-IT contract. We partner with Health Data Compass and extensively use its cloud based Eureka system to conduct analyses requiring a HIPPA compliant computing environment. We also maintain a research computing environment for other large scale projects and methods development and simulation. The server is a Dell PowerEdge R740XD, with Intel Xeon Gold 6152 2.1G X (2) CPU, 44 cores, 1TB memory, 240 SSD X (2) mirrored disk operating system, and 14TB X (6) RAID 6 corresponding to ~50TB of usable disk storage. The operating system is CentOS 7.x, and common research software are available such as R, R Studio, MatLab, Python, and Java.

Office

BERD space is primarily located within the CSPH in the Fitzsimons Building with 25,410 square feet of state-of-the-art office space. In June of 2019 they moved into a newly renovated 4th floor office space with ~10,000 square feet of space shared with the Department of Biostatistics and Informatics. The school provides basic furniture, fax machines, copiers, and non-research related office supplies. In addition, the CSPH facility provides meeting and conference rooms, with video conferencing capabilities, that can be scheduled for project use as needed. The Center of Innovative Design and Analysis and the BERD have a combination of individual and shared offices and additional open office space in Fitzsimons all of its members members. The project managers in the BERD are housed in Fitzsimons adjacent to the Director.

Scientific Environment

In July 1, 2008, the newly established CSPH was the first and only school of public health in the Rocky Mountain Region, attracting top tier faculty and students from across the county, and providing a vital contribution toward ensuring our region's health and well-being. Collaboratively formed by the University of Colorado Denver, Colorado State University and the University of Northern Colorado, CSPH provides training, innovative research and community service to actively address public health issues, including chronic disease, access to health care, environmental threats, emerging infectious disease, and costly injuries.

The mission of the Colorado School of Public Health is to promote the physical, mental, social and environmental health of people and communities in the Rocky Mountain Region and globally. The mission will be accomplished through collaborations in education, population-based research, and community service that bring together institutions, agencies and diverse populations.

Department of Biostatistics and Informatics: This Department of Biostatistics and Informatics is housed in the Colorado School of Public Health. It offers three graduate training programs and provides the major service teaching for the master's of public health training programs. The Department has over 2-dozen research and tenure track faculty, a growing master's training based and more than a dozen research assistant training positions for students. The tenure track faculty maintain their own independent funding in diverse areas such as missing data, smoothing splines, health services research, Bayesian modeling, genetics/genomics, machine learning, causal modeling and imaging analysis of the brain and lung. The Department contributes to over 85M in collaborative research funding on the Anschutz Medical Campus along. It also leads and maintains substantial collaborations among the premier Centers on the Campus including the Colorado Clinical and Translational Science Institute and the Colorado Comprehensive Cancer Center and directs the campus wide collaboration and consultation center (CIDA described below).

Center of Innovative Design and Analysis (CIDA)

The CIDA is a campus wide resource for establishing and supporting collaborative and consulting relationships with clinical and health researchers, primarily at the CU Anschutz Medical Campus (cida.cuanschutz.edu). CIDA is a campus wide research and resource center for establishing and supporting collaborative and consulting relationships with clinical and health researchers. CIDA has four major businesses: 1) general consulting for short term projects, 2) in-depth collaboration and team formation, 3) external business partnerships and 4) primary analytic research, which includes a goal to establish data coordination units and grow our methodology funding. CIDA has a strong partnership with the BERD, Department of Biostatistics and Informatics of the CoSPH and SOM and has 17 PhD faculty, 14 MS faculty, and 14 graduate student research assistants. All have academic appointments in the Department of Biostatistics and Informatics and a subset of

the faculty and MS participate in the BERD. The range of expertise is substantial and varied. Some areas include: pragmatic trials, innovative study design, analysis of EHR data, Bayesian modeling, clinical trials, causal inference, SEM and mediation analyses, microbiome, 'omics (RNAseq, methylation, proteomics, metabolomics among others), along with more standard approaches of longitudinal analysis, survival analysis, joint modeling, and others. They maintain over 20 collaborative partnerships with campus units represented from every school. They also conduct primary research and have external funding to support research in lung CT imaging, multi-omics analysis, application of SEM methods, data visualization, and innovative clinical trial design.

Clinical Translational Research Centers (CTRCs)

Our network of four Clinical Translational Research Centers (CTRCs) are our clinical research units that provide inpatient and outpatient research facilities. The CTRCs have their original foundation in the enormously effective Adult and Pediatric GCRC facilities, which were continuously NIH-funded for 46 and 45 years, respectively, before the NIH transitioned the GCRC grant program to its CTSA initiative.

The CTRCs have been transformed since this transition and now provide resources for all phases of clinical trial development and conduct, critical care (adult and pediatric), and expanded multidisciplinary coordinated clinical research support. CTRC facilities are provided at University of Colorado Anschutz Medical Campus (UCH and CHCO), University of Colorado Boulder, and National Jewish Health. Available CTRC resources include dedicated inpatient and outpatient research space and equipment, expert research nursing, Core laboratories, and nutrition services. All CTRC services are available to investigators on a fee-for-service basis.

Adult CTRC

The adult CTRC provides the space, staff, and equipment necessary to conduct a broad range of specialized research procedures in primarily adults, including measurement of insulin sensitivity (insulin and glucose clamps, OGTT, IVGTT), body composition measurements, medication administration and infusions, bronchoscopies, fat and muscle biopsies, VO₂max and graded exercise tests, echocardiography for vascular and cardiac studies, sleep studies (acute and chronic) with polysomnography, measurement of total energy expenditure and rates of macronutrient utilization, conduct of short- and long-term exercise and dietary intervention studies, and specimen collection and processing. All procedures are supervised by highly-qualified and experienced personnel. All staff receive HIPAA and Good Clinical Practice training. Nurses are Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS), and ONS (Chemotherapy) certified. Health technicians are BLS certified.

The adult CTRC has 7,226 sq ft of inpatient space located on the 12th floor of UCH at CU Anschutz, has seven beds in five rooms, and a wet lab for sample processing. Additional unique resources include an inpatient whole room calorimeter for the measurement of 24-hour energy expenditure and substrate oxidation, and a sleep laboratory with adjacent monitoring space for polysomnography. Experienced research nursing and health technician support is available.

The adult outpatient CTRC moved to 7,700 sq ft of newly designed space in the Anschutz Health Sciences Building, which opened in April 2022. The adult CTRC outpatient research clinic houses an infusion room (5 chairs), phlebotomy room (4 stations), exercise testing room (3 stations), muscle function room (isokinetic dynamometer), body composition room (DXA, pQCT), secure medication storage room (approved for FDA controlled substances, including Schedule 1), sample processing room, two negative pressure rooms, two interview rooms, two extra-large procedure rooms with beds and private bathrooms (similar to an inpatient room) suitable for conducting neurology studies and hyperinsulinemic euglycemic clamps, four regular procedure rooms with beds (including one for RMR and one for echosonography), and 10 exam rooms with exam tables. There is a charting/work area with 9 computer work stations that can be used by research team members. An adjacent 3,500 sq ft state-of-the-art research exercise training facility is available for exercise intervention research. The CTRC clinical outpatient facility is generally open weekdays 7am – 4pm. During these hours, experienced physician assistant, research nursing, health technician, laboratory, and nutrition support is available.

The adult CTRC has 10.9 FTE of research nurses, 2.8 FTE of health technician support, a 1.0 FTE sonographer, 0.5 FTE physician assistant, and 0.3 FTE DXA technician. These research professionals have

extensive experience in conducting and documenting research for a diverse patient population from 12 to 90 years of age, both healthy and with a range of diseases such as diabetes, obesity, cardiovascular disease, renal disease, COPD, HIV and AIDS, chronic viral hepatitis, various forms of cancer, alcoholism, etc.

Equipment

- Portable indirect calorimetry (IC): True Max 2400 and TrueOne 2400 Metabolic Measurement Systems (Parvo Medics, Sandy UT), Ultima CPX 5530 (Medgraphics Corp, Saint Paul, MN)
- Maximal and submaximal exercise testing: Corival Ergometer and Lodebike 906900 (Lode Holding Company, Groningen The Netherlands), Velotron Pro exercise bike (RacerMate Inc, Seattle WA)
- Body composition measurement (Dual X-ray Absorptiometer): Discovery W (Hologic, Marlborough, MA)
- Stress Testing: Quinton Q-Stress Cardiac Stress Testing System with treadmill (Mortara, Milwaukee WI)
- CSMi Humac Norm isokinetic dynamometer (Computer Sports Medicine Inc, Stoughton, MA)
- Whole Room Calorimeter: CO₂ Analyzer AO2000 System (ABB Inc, Wickliffe OH), differential O₂ Analyzer Sable FC-2, Oxygen Analyzer (Sable Systems, Las Vegas, NV), Oxymat 6 Gas Analyzer (Siemens, Washington DC)
- *Peripheral Quantitative Computed Tomography (pQCT)*: Large Bore Scanner XCT 3000 (Orthometrix Inc, Naples FL)
- Cardiovascular Imaging: Ultrasound Vivid 7 and Vivid E9 (GE Healthcare, Pittsburgh PA)
- Cardiac Monitoring: M8004a Cardiac Monitoring System (Philips, Andover MA)
- Sample Processing: 3 x Algra 6r refrigerated centrifuges (Beckman Coulter, Brea CA)
- Bronchoscopes: 2 x Olympus Airway Mobile Scope MAF Type TM (Olympus America, Center Valley PA), and 2 x Pentax FB-18BS Bronchoscope (Montvale, NJ)

Pediatric CTRC at Children's Hospital Colorado (CHCO) **Facility**

The CHCO CTRC provides the space, staff, and equipment necessary to conduct a broad range of research procedures in children, including, but not limited to, measurement of insulin sensitivity (insulin and glucose clamps, OGTT, IVGTT), body composition measurements, medication administration and infusions, bronchoscopies, fat and muscle biopsies, maximal and submaximal exercise tests, echocardiography for vascular and cardiac studies, measurement of total energy expenditure and rates of macronutrient utilization, and conduct short- and long-term exercise and dietary intervention studies, as well as specimen collection and processing. All procedures are supervised by highly qualified and experienced personnel. All staff receive HIPAA and Good Clinical Practice training. CTRC Nurses are Pediatric (PALS), Advanced (ACLS), and Basic Life Support (BLS) certified.

The CHCO CTRC has up to four inpatient beds located on the 9th floor of CHCO at the CU Anschutz Medical Campus and an adjacent wet lab for sample processing. The CTRC utilizes this space as needed and, if patient rooms are not being utilized, they are released for hospital use. Experienced research nursing support is available 24h/d, 4d/wk.

The CHCO outpatient CTRC consists of 5,973 sq ft of space located on the 3rd floor of the outpatient pavilion at CHCO which houses four infusion rooms, six exam rooms, an extra-large procedure room with bed, one treatment room, two consult/consenting rooms, three staff workrooms, a secure medication room, and 2 wet labs for sample processing. A third wet lab is located on the fourth floor in the NICU. The body composition (DXA) laboratory is located in the Radiology Department on the 1st floor. The CTRC clinical outpatient facility is generally open weekdays 7am – 5:30pm. During these hours, experienced clinical research nursing, laboratory, and nutrition support is available.

The CHCO CTRC facility has 9 FTE of research nurses. This core of research professionals has extensive experience in conducting and documenting research for a diverse patient population from birth – 49 years of age, both healthy and with a range of diseases such as type 1 and type 2 diabetes, obesity, cystic fibrosis, cardiovascular disease, chronic hepatitis, rare genetic and metabolic diseases, gastrointestinal disease, cholestatic and fatty liver diseases, HIV, various forms of infectious diseases, etc.

Equipment

- Exercise equipment: Treadmill F85 (Sole, USA), and Ergomatic 828 E (Monark, Vansbro Sweden)

- Sample processing: Allegra X-22R Centrifuge (Beckman Coulter, Brea CA), Allegra X-22R Centrifuge (Beckman Coulter, Brea CA), Allegra X-30R centrifuge (Beckman Coulter, Brea CA), Multifuge 3L-R Centrifuge (Thermo Electron Corporation, Madison WI) Sorvall ST 16 R (Thermo Scientific Company, Hanover Park, IL)
- Sample storage: Forma 8600 Series -80 Freezer (Thermo Scientific, Hanover Park, IL), -20 Freezer, (Thermo Scientific, Hanover Park, IL), -20 Freezer (Whynter, Brea, CA), R134A Refrigerator, (Follet, Easton, PA) Refrigerator (U-Line), , Refrigerator/Freezer (Avanti Weston, FL)
- Cardiac monitoring: MAC 2000 ECG System (GE Medical Systems, Chicago, IL)
- Calorimetry: Vmax Encore 29N (Carefusion, Vyaire Medical, Yorba Linda, CA), Vmax Encore 29N (Carefusion, Vyaire Medical, Yorba Linda, CA)

CTRC Core Lab Facilities

CTRC Core Laboratories

Facilities

CTRC Core Laboratories are located adjacent to the adult, CHCO, and NJH CTCRCs. The adult Core Laboratory is 1,544 sq ft located within the UCH CTCRC outpatient space on the sixth floor of the new Anschutz Health Sciences Building. The CHCO Core Laboratory is 10,000 sq ft of space located in the basement of CHCO, adjacent to the hospital's clinical laboratory. The NJH Core Laboratory is 300 sq ft located in the Goodman Building. All laboratories are College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA)-accredited and provide trained personnel, reagents, equipment, and QC capabilities to conduct over 250 specialized assays for research (full list at <http://www.ucdenver.edu/research/CCTSI/programs-services/ctrc/lab-services/Pages/Lab-Assays-Pricing.aspx>). There is no redundancy in the services offered by the CCTSI Core Laboratory Network: the UCH Core lab specializes in hormone and metabolite assays (3.4FTE); CHCO Core Laboratory focuses on inflammation markers, fat-soluble vitamin measurement, specific protein and pulmonary fluid processing (5 FTE); and NJH Core lab specializes in flow cytometry, specialized cell culture, and DNA and RNA extraction (1.0 FTE).

Equipment

- Cold Sample Storage: Freezer Forma 923, Ultracold Forma 983, 4 x Ultracold Forma 995, 13 x Thermo Forma 8000 series , Thermo Electron, Forma 989 Dd , 2 x Panasonic -80C (Panasonic Healthcare Corporation of North America, Wood Dale IL), Forma Ultra 990, Undercounter 3.6°C Isotemp (ThermoFisher Scientific, Waltham MA); Ultra 500BX (Sanyo, San Diego CA); 4 x Thermo Scientific refrigerator FRLR/TAX (Thermo Scientific, Waltham, MA); VWR refrigerator (VWR, Radnor, PA)
- Centrifuges: 6 x Allegra 6r, Allegra X-15R, Avanti 30, Avanti J-20, Avanti J-E, Airfuge (Beckman Coulter, Brea CA); Sorvall Legend RT and RT6000D, RC3B Plus, J2-21 (ThermoFisher Scientific, Waltham MA); 2 x Eppendorf 5702R (Westbury, NY), 2 x Centra CL3R (Thermo IEC, Waltham, MA); 2 x Thermo Electron Heraeus Multifuge 3L-R (Waltham, MA); Fisher Accuspin Micro 17, Fisher Marathon 16KM, and Eppendorf 5415C; Shandon Cytospin 3
- HPLC: ICS-3000 (Dionex , Sunnyvale CA), Waters 2487 (Waters, Milford MA), Detector For Hplc ELSD2000 (Alltech, Lexington, KY), 1 x Waters Acquity UPLC with Detector (Waters, Milford MA)
- Real-time Whole Blood/Plasma Chemistry: 2 x 2300D Glucose Lactate Analyzer (Yellow Springs Instruments; YSI, Yellow Springs OH), 3 x Glucose Analyzer GM9 (Analox Technologies, Atlanta, GA); DCA Vantage Hemoglobin A1C analyzer (Siemens, Tarrytown, NY)
- Gamma Counter: Wizard 1470 (PerkinElmer, Waltham MA)
- Spectrophotometers/Plate Readers: Multiskan Spectrum Thermo Lab Sys 1500, Biotek EI-808, Biotek Synergy/HTX and ELx800 Plate Readers (Biotek, Winooski, Vermont), 2 x Beckman Coulter DU650 (Beckman Coulter, Brea CA), Nanodrop Tech ND-1000, Nanodrop One (ThermoFisher Scientific, Waltham MA), SpectraFluor Plus and infinite M200 PRO (Tecan US, Morrisville NC)
- Autosampling: Biolc AS (Dionex Corporation, Sunnyvale CA) Miniprep 60 Basic System, MP60 (Tecan US, Morrisville NC)
- Antek 9000 Series Elemental Nitrogen Analyzer (PAC, Houston TX)
- Chemistry Analyzers: Beckman AU480 and Access 2 (Beckman Coulter, Brea CA), 2 x Cobas Mira Plus (Roche, Indianapolis IN), Nephelometer Dade Behring (Siemens, Washington DC)

- Multiplex assays: Luminex FLEXMAP 3D, MagPix (Luminex Corporation, Austin TX), CiraScan planar multiplex instrument (Aushon BioSystems, Inc, Billerica, MA)
- Electrophoresis System: Capillary electrophoresis system (Waters, Milford MA)
- Microscopes: Nikon Optiphot and Nikon Eclipse E400 (Melville NY), 3 x Olympus (Olympus America, Center Valley PA)
- Immunoassays: Immulite 1000 Analyzer (Siemens, Washington DC); Liaison Chemiluminescence Analyzer (DiaSorin, Stillwater, MN), IDS iSYS Analyzer (Immunodiagnosics Systems, Scottsdale, AZ)
- PCR: Applied Biosys 7500, DNA Engine (BioRad)
- Automated Cell Counter: Invitrogen Countess (ThermoFisher Scientific, Waltham MA)

CCTSI Nutrition Core

Facilities

The CCTSI Nutrition Core consists of scientists and nutritionists with extensive experience in nutrition and metabolism research (3.0 FTE). All staff members are trained to prepare and distribute weighed, metabolic meals from our commercial research kitchen. The commercial kitchen is located at the Anschutz Health and Wellness Center (AHWC) on the CU Anschutz Medical Campus (1,273 sq ft). Smaller food preparation facilities are located in: 1) CTRC at UCH Health Inpatient Hospital (93 sq ft) 2) Anschutz Health and Science Building (AHSB) (287 sq ft) and 3) CTRC at Children's Hospital Colorado (CHCO) (84 sq ft). The kitchen and all staff designing and preparing diets are ServeSafe certified. Meals are prepared, stored and shipped to CTRC sites for distribution as needed, and are provided on a fee-for-service basis. The CCTSI provides all of the necessary computers, software, office space, and other resources for providing: dietary intake assessment, both traditional and novel, sensor-based methods; measurement of hunger and satiety; growth, body composition, and indirect calorimetry in pediatric populations (Energy Balance Lab provides this service for adults); protocol-specific dietary counseling and instruction; development of study-specific educational materials; consultation on study design and ways to achieve specific dietary intervention targets; design, preparation, measurement, and dispensation of study-specific meals and foods; and design and product development for novel foods and diets (e.g. foods to mimic Agrarian dietary intake that are palatable to Americans; specific allergen-free food items and allergen-added counterparts with equivalent taste, volume, and texture for blinded studies; formulation development for palatable high fiber foods for long-term dietary intervention studies).

Equipment

- Diet design software: ProNutra (Viocare Inc, Princeton NJ)
- Analysis of dietary intake: Nutrient data Systems for Research (NDS-R) software (Nutrition Coordinating Center, University of Minnesota)
- Portable indirect calorimetry (IC): Vmax Spectra-29N and Encore29 metabolic measurement systems (Sensormedics; Yorba Linda, CA)
- High Precision Balances (food weights and stable isotope additions): 5 x Ohaus Pro Scout SP4001, Ohaus Adventurer AX5202 (Ohaus Corporation; Parsippany, NJ), Mettler Toledo New Classic MF (Columbus, OH)
- Refrigeration/freezer storage at UCH inpatient CTRC and CHCO CTRC: T-35 double door refrigerator, T-46 double door refrigerator, T-23 single door freezer, and T-35F double door freezer (True Manufacturing Co; O'Fallon, MO), Manitowoc Freezer UD-140A (Manitowoc Refrigeration, Manitowoc, WI), UF21355 Freezer (Sunpentown International, City of Industry, CA)
- Diet preparation: full commercial kitchen including a walk-in freezer and refrigerator, a Vulcan Hart range, and Hobart commercial dishwasher.

Community Engagement and Research Program (CE&R)

The CCTSI has integrated community-based participatory research (CBPR) into programs that engage the wider community with research into the causes and remedies of health problems and disparities in underserved populations in Colorado and the nation. It has built on a rich history of practice-based and



community-based research in the state, which now includes 18 established community-academic partnerships. These partner communities include rural and urban populations, American Indian and Alaska Native, Hispanic and African American groups, providing a unique opportunity for culturally proficient research emphasizing health disparities. The innovative Partnership of Academicians and Communities for Translation (PACT) brings academic/community partnerships into a sustainable and collaborative balanced (equal numbers of community members and academicians) governance group for bidirectional exchange and fostering public trust in the research enterprise. PACT oversees a variety of activities, including 10 Community Research Liaisons, the Community Immersion Program, Bootcamp Translation program, CE Pilot Grants, training programs, community forums and other activities described more fully in the Community and Collaboration section of the grant application.

Child Maternal Health (CMH)

The overall goal of CMH is to support and promote clinical and translational research in children of all ages, pregnant women, and the mother-child dyad to improve child health and prevent diseases, with a focus on rare diseases, thus preempting adverse outcomes that increase disease burden and the cost of health care over the life span. CMH provides specific support for multidisciplinary, integrated, translational research focused on health problems that begin early in life and during childhood. The research initiative in CMH addresses the life trajectory of the mother and child, initiating new collaborations among basic, clinical, and translational scientists in multiple disciplines and for providing a streamlined infrastructure for development of novel methodologies and pipeline programs to accommodate lifespan research.

CMH promotes research of the highest scientific and ethical quality in special populations by pre-reviewing protocols for scientific merit and insuring that adequate participant protections are specified, and providing information and resources for families considering study participation.

The CMH Perinatal Research Advisory and Facilitation Committee is a group of experienced perinatal investigators, research nurses, and coordinators who assist investigators working with pregnant women, preterm infants, and newborns. This committee assesses the feasibility of each protocol, identifies potential overlap with existing studies and, if so, facilitates sample sharing, fosters collaboration between investigators working in similar areas, and assures that investigators are aware of existing data and biobank resources that could aid their research. This committee is vital to promote collaboration, insure maximal utilization of rare and/or small samples (e.g. from premature infants), and prevent competitive recruitment of vulnerable populations.)

Workforce Development (WFD) Program

The WFD program provides clinical-translational scientists, clinical research staff and trainees with education, training, and career development to become highly skilled for the design and conduct of effective and efficient clinical and translational research. WFD offerings span critical periods, from the beginning of research training

at the pre-doctoral level through senior faculty. The aim of the WFD is to create a robust local workforce and a national leadership pool for clinical-translational researchers who are interdisciplinary, innovative, highly motivated and successful. WFD leverages and integrates educational programs at CU-D and its partners to provide training in strategic areas. Programs are intended to promote innovation and team collaboration, leading to research with broad implications for public health. A cadre of faculty, educators, and administrative staff are dedicated to providing programs of the highest quality. The WFD provides a broad menu of training and career development opportunities for all roles involved in the life span of clinical and translational studies.

Programs

- TL1 Team Oriented Training across the Translational Sciences Spectrum (TOTTS) Training program (TOTTS): The goal of the TL1 Training Program is to build a diverse workforce of clinical and translational researchers (CTR) by enhancing capacity for team-based research training spanning the pre-clinical to population health spectrum. Three groups of future CTR investigators are targeted: a) biomedical PhD students, b) health professional trainees completing their doctorate (pre-doctoral) or post-doctoral medical residents, and c) veterinary post-doctoral trainees, which is a collaborative with Colorado State University Veterinary School. It involves 8 PhD students and 3 post-doctoral fellows each year with an emphasis on underrepresented minorities.
- K12 Career Development Program. This program provides protected time and opportunities for an intensive, mentored career development experience in CTS of up to 3 years that leads to independent extramural support and leadership positions in CTS and academia. K12 scholars are supported by two faculty mentors, one of whom must be a clinical researcher. This program supports six junior faculty at any one time.
- Clinical Science Graduate Program (CLSC). One of the first Clinical Science Graduate Programs in the country, this program awards MSCS and PhD degrees in 3 distinct specialty tracks: Clinical Investigation and Health Outcomes, Health Services Research (a collaborative program with the Colorado School of Public Health), and Health Information Technology. It also has a Dissemination and Implementation in Health Research Graduate Certificate program that is offered collaboratively with ACCORDS (Adult and Child Consortium for Health Outcomes Research and Delivery Science). The CLSC has 100-115 degree students at any given time and aims to train nationally competitive clinician/clinical translational scientists by providing a formal and structured educational and mentoring program. Graduates are trained to conduct rigorous and relevant patient-based research within stringent ethical and regulatory guidelines, and to translate the evidence for community application. In addition, more than 200 other non-degree students attend CSLC classes each year.
- Clinical Faculty Scholars Program focuses on developing junior faculty research independence. This program enrolls 4-5 learners per year and aims to help emerging investigators obtain a career development award (K08, K23 or foundation equivalent), or a first independent, extramural project award (R21, R01 or equivalent) through guided project development, educational seminars, grant writing classes, and mentorship. Each Faculty Scholar develops an individual career development plan and receives regular individual mentorship from four experienced senior researchers. This program acts as a pipeline of promising individuals into the KL2 program.
- Leadership for Innovative Team Science (LITeS) is a yearlong program to enhance leadership skills, foster team science by creating a network of colleagues who serve as resources for one another, expand opportunities for cross-disciplinary collaboration, and ensure that clinical and translational scientists have the skills for effective team leadership. To date, LITeS has trained over 300 participants including deans, associate deans, department chairs, vice-chairs, and section heads, as well as senior leadership from hospitals, major research centers, and training programs. This program competitively enrolls 20-30 participants per year to work on solutions to high-level issues chosen by UCD leadership.
- Mock study section and grant review programs (Pre K and K to R). Three separate programs support development and submission of competitive grants for pre and post-doctoral awards, career development awards and research operational grants. Each program runs three times/year corresponding with NIH deadlines and consists of six steps: 1) Attend/view "How to prepare your grant" workshop; 2) Submit specific aims page reviewed by program faculty with feedback to applicant; 3) Submit full grant; 4) Grant reviewed by 3 reviewers with written feedback; 5) Applicants attend mock study section to hear all reviews, discuss and pose questions; 6) Meet with faculty for feedback.
- Colorado Mentoring Training (CO-Mentor) a formal mentoring program for mentor-mentee dyads. CO-Mentor uses didactic, interactive and applied learning to develop skills related to teams, leadership,

managing conflict, and use of Individual Career Development Plans. Over four sessions, held about every 7 weeks, CO-Mentor: 1) develops skills and behaviors consistent with effective mentoring relationships; 2) enhances the mentor-mentee relationship; and 3) builds a network of trained mentors and mentees modeling these best practices for others, leading to a sustainable culture of mentoring.

- **Clinical Research Education Program**: A curriculum to improve regulatory knowledge and compliance, Good Clinical Practice and Responsible Conduct of Research application. Provides required regulatory courses (GCP, RCR, human subject protection including informed consent) for all people involved in Clinical and translational research. Topics include Authorship and Publication; Research Misconduct; Collaboration; Data Acquisition and Management; Conflicts of Interest; Peer Review; Mentor and Trainee Relationships; Industry-Academia Relationships, Industry Funded Research, and, Social Responsibility. A variety of training forums are used: seminars, graduate courses, individual consults, online and modules. Over 700 attendees annually.
- **ATLAS.ti**: TLAS.ti is qualitative data analysis software designed to help manage and analyze non-numerical data. The e-learning modules introduce learners to the foundational building blocks and tools of ATLAS.ti. Designed for learners investigators, trainees and clinical research staff.
- **Teaming for Early Career Investigators**: This curriculum is designed to build your capacity to participate in and lead effective interdisciplinary and translational scientific teams. It addresses the shift in science from an individual-based approach to a teamwork model of conducting clinical and translational research.
- **Researcher Management & Leadership Training**: A massive open online course on the global learning platform [Coursera](#). This course is targeted to early career researchers and mentors who believe that modern scientific careers require management skills and want to be research leaders—especially current and future principal investigators. The curriculum is designed to deliver skills to effectively implement funded projects, thereby enhancing research career success.

Innovators Ecosystem of Colorado

Innovation Corps (I-Corps™) uses proven customer-discovery methodologies for startups. It was developed for academic researchers by serial entrepreneurs working with the National Science Foundation. I-Corps@CCTSI is a team-based short course designed for faculty, staff and students. The program guides teams through the early stages of customer discovery where they can test the business model hypotheses for their technology or idea to accelerate the translation of innovations from the lab to clinical practice. I-Corps@CCTSI leverages and partners with other entities which promote innovation such as CU Innovations Technology Transfer Office, CU Boulder Ventures, CSU Ventures at Colorado State University. These partnerships facilitate collaboration, access to a large knowledge base and investor pool, access to proof-of-concept funds, and interdisciplinary expertise.

Resources planned for the upcoming RC2-SIP include the Research Triangle Institute's (RTI) iCanvas matrix, edited for regionally available programming and services to expand efforts throughout the CCTSI region to enhance collaboration and sharing of academic entrepreneurial and innovation-forward resources. Entrepreneurial Studios One and Two will provide expert mentoring and advising for early-stage to commercial launch Innovators regarding next steps required to achieve optimal patient impact through additional focused development and potential licensing, collaborative research with external companies, financial resources, and/or company development.

Two Affinity groups are under development. Affinity group one will focus on female entrepreneurs and Affinity group two will focus on underrepresented minorities. The groups are designed to provide support, as well as to focus on identifying solutions to overcome barriers specific to women and underrepresented minorities as they navigate the innovation pathway.

Ask the Expert is a monthly live interview that is recorded as a podcast for asynchronous viewing. Entrepreneurial experts from both industry and academia are invited to participate in a dialogue with an interviewer. Audience participation is encouraged and attendees are given ample time to ask the expert about their pathway to success.

In collaboration with the Chancellor's Office, a promotion and tenure review committee is launching that will work to develop, support and implement matrix criteria to enable innovation career paths and promotion for entrepreneurially-minded faculty, students and staff.

The PI, Dr. Bodine is housed in Bioscience III, an innovation hub recently opened in the CU-Anschutz adjacent Bioscience Tech Park with office space, computing resources, conference rooms and collaborator spaces with administrative support co-located in the reception area. Office space for faculty and administrative staff is also provided in the newly opened Anschutz Health Sciences Building on the CU Anschutz campus. This space houses conference rooms and open workspaces that allow SIP RC2 Program Directors and staff to collaborate and work together. CSU and CU Boulder partners are housed in their respective Technology Transfer Offices, and have office space, computing resources and other materials available on their campuses.

Regulatory Knowledge and Support Core (RKS) in collaboration with the Clinical Research Support Center (CRSC)

RKS helps CCTSI members navigate through regulatory requirements and provides training and consultation in the responsible conduct of research. The RKS and CRSC share 5,000 sq ft of office, conference room, and collaboration space on the ground floor of Fitzsimons Building at the CU Anschutz Medical Campus. This consists of 3 conference rooms, 27 cubicles, 4 offices, a storage room, a communal lunchroom, and collaborative spaces including open, communal printer/ copier and seating areas. This "google-style" space houses RKS staff as well as staff from CU Anschutz contracting, CCTSI Scientific and review Committee (SARC) and research education, the Trial Innovation network (TIN), CU Innovations, OnCore team members, and UCHHealth billing. This novel arrangement, housing parties within a functional cross-institutional team space rather than in space assigned by each staff member's employer spread over campus, facilitates collaboration and direct access to the knowledge and expertise necessary to assimilate information quickly, brainstorm and resolve problems in real time, and provide solutions, workflows, and training opportunities that are consistent across the CU Anschutz Medical Campus. In addition, RKS space is the same building as many entities essential for the safe and efficient conduct of translational research such as COMIRB, COI and other regulatory offices, and the Dean's Office, which provides further team building and collaboration opportunities.

The Trial Innovation Network (TIN) Hub Liaison Team

The Trial Innovation Network (TIN) Hub Liaison Team encourages, supports, and promotes multi-center investigations, and provides an environment where NIH-supported clinical trials are conducted efficiently, compliantly, and with the highest quality. The team consists of the Hub PI, Director, Medical Directors for both adult and pediatric studies, a project manager, central IRB liaison, contracting liaison, recruitment facilitator, research navigator and an honest broker for recruitment. The TIN team will build on the strong clinical research structure currently in place to support clinical trials within the CCTSI and expand the opportunity to both propose multi-center trials via the TIN and recruit patients locally for TIN-sponsored trials. The TIN team has members that are imbedded in the same space as the Regulatory Knowledge and Support Core and the CCTSI office space to facilitate collaboration, leverage existing expertise, and contribute to the overall goal of streamlining the startup and coordination of multi-site clinical trials.

Director – Adit Ginde, MD, MPH is Professor of Emergency Medicine and Anesthesiology at the University of Colorado School of Medicine. He is Vice Chair for Research in Emergency Medicine and Director of Clinical Research in Anesthesiology. In these leadership roles, he develops clinical research infrastructure, allocates resources, collaborates extensively with many other Departments/Divisions at CU Anschutz, and oversees implementation of all clinical research protocols for these Departments. Dr. Ginde also actively practices and teaches emergency medicine at UCHHealth University of Colorado Hospital. In his own research, Dr. Ginde has extensive experience with leading translational clinical trials in acute care research, funded by NIH (including NHLBI, NINDS, NIA, NCATS), DoD, CDC, foundation, and industry sponsors. Specifically, he has a strong track record in designing, overseeing, and implementing clinical trials in a variety of clinical environments including outpatient, emergency department, perioperative, and inpatient (including intensive care unit) settings, particularly in the areas of respiratory failure and sepsis/infection. He has been the lead investigator for 5 large multicenter clinical trials and participated in the design (as protocol committee member) and implementation (as site PI) of over a dozen other clinical trials. *He will be responsible for overall operations of the CCTSI TIN Hub, participation in conference calls and meetings, and communications with TICs and RICs and NCATS.*

Medical Director (Adult health) – Thomas Campbell, MD

Dr. Campbell is Professor of Medicine, Division of Infectious Diseases, and has also served as Medical Director of the UCH CTRC since 2008. His research focus is the use of antiretroviral agents to treat and prevent HIV infection and AIDS-related complications. He is Site Leader for the UCH Clinical Research Site in the NIAID AIDS Clinical Trials Group (ACTG) and a member of the ACTG Executive Committee. He led the design, implementation, and dissemination of 3 NIH-funded international clinical trials from 2002-2016. He has served as the local PI for 52 ACTG and HIV Vaccine Trials Network clinical trials and 33 pharmaceutical industry clinical trials. Dr. Campbell served as a liaison for the establishment of new ACTG clinical trials sites in Zimbabwe and South Africa from 2003-2008. *He will be responsible for operations and implementation of adult clinical trials of the TIN.*

Medical Director (Child health) – Jesse Davidson, MD, MPH, MSc

Dr. Davidson, Associate Professor of Pediatrics, is the Associate Medical Director for the Children's Hospital Research Institute and works with investigators to optimize clinical research operations at CHCO in this capacity. Clinically, Dr. Davidson is a pediatric cardiac intensivist and medical imager in the Children's Hospital Colorado Heart Institute. Dr. Davidson's NIH-funded research focuses on the metabolomic and proteomic response to pediatric congenital heart disease surgery and postoperative acute organ injury. *He will be responsible for operations and implementation of child health clinical trials of the TIN.*

TIN Project Manager – Aaron Mobley, PhD

Dr. Mobley is the Director of the Clinical Research Support Team (CReST) at CU Anschutz and has worked to support regulatory submissions, data entry and other general coordination for clinical trials in multiple specialties. He has over 5 years of experience managing clinical research teams in the academic research environment. He was most recently a Clinical Project Manager for a large Medical Device company responsible for oversight of multiple clinical trials and a Clinical Research Operations Manager at Children's Hospital Colorado responsible for overseeing startup and contracting activities for all studies conducted in the hospital. *He will be responsible for project management and implementation of TIN protocols at our site.*

Central IRB Liaison - Christy Williamson, CCRP

Ms. Williamson is the Senior Facilitation Manager with the Clinical Research Support Center at UC Denver and has a strong background in clinical research and regulatory and IRB coordination. She has been an Education Consultant in the same group and has extensive experience working with multiple IRBs, including with the central IRB mechanism, throughout her career. *Her responsibilities will be to ensure timely and compliant IRB reliance agreements, facilitate use of central IRBs, and streamline local IRB processes for TIN studies.*

Contracting Liaison – Deborah Barnard

Ms. Barnard has over 20 years of experience in research regulatory compliance with a demonstrated track record of excellence; an in-depth knowledge and understanding of complex regulations and international guidelines; a keen understanding of Good Clinical Practice guidelines, successful track record in working in and across very complex organizations. She has an ability to understand and interpret regulations and requirements translating these ideas into policies, procedures, and a sound operational system. She is exceptionally skilled at analyzing problems and providing appropriate yet practical solutions. *Her responsibilities will be to facilitate timely and complete execution of contracts related to TIN studies.*

Recruitment Facilitator - Barbara N. Hammack, Ph.D.

Dr. Hammack has been the Research Subject Advocate (RSA) for the CCTSI since 2008. She has taught regulatory science and research ethics and is the director for an investigator focused clinical trials course. She has close connections and has organized multiple recruitment resources at UC Denver and nationally that put her in a strong position to facilitate recruitment at our site. *Her responsibilities will be to develop, implement and facilitate research participant recruitment and retention strategies in coordination with the RICs.*

Honest Broker for recruitment – TBA

The Honest Broker will be a new position to facilitate the identification of subjects for clinical trials by working closely with the Health Data Compass team (our research data warehouse which includes patient data from

UCHealth, CHCO and CU Medicine. This Honest Broker will work closely with investigators to identify and contact potential participants with whom the investigators do not have a treatment relationship.

Clinical site operations coordinator

- CHCO – Erin Sandene, BSN, Director of Research Administration and Operations, CHCO Research Institute
- UCHealth – Laurie Blumberg-Romero, MA, CRA, Director of Research Administration for UCHealth

Health Informatics

CCTSI Informatics

The Informatics Program is a critical function of the CCTSI. The CCTSI Informatics team includes dedicated systems administration, information security, web development, software engineering, project management, and data management personnel. The team has deep experience with research computing using a wide variety of operating systems, database engines, regulatory and security environments, and software stacks. The team maintains 85+ virtual and physical servers running several applications, at the department and enterprise level, for data management needs across the CCTSI. In addition, the team manages backups, security, networking, access controls, and desktop support for the CCTSI administration core and CTCRCs, and CCTSI website development. CCTSI Informatics also supports Colorado Profiles, Scheduler, and the CCTSI research laboratory information system. CCTSI Informatics maintains NIST SP 800-53 compliance for its on-premises virtualized server farm. The CCTSI Informatics Information Security Officer establishes and monitors the necessary controls to maintain this level of compliance. The data center includes fault-tolerance and disaster recovery capabilities as well as annual third-party audits and penetration testing. COLORADO Profiles, a web-based searchable faculty biomedical research database for the entire University of Colorado system (<http://profiles.ucdenver.edu>), is managed by the CCTSI Informatics team. It receives over 30,000 page views per month.

REDCap

CCTSI Informatics has provided a fully subsidized HIPAA-compliant REDCap data management service since 2008. In doing so, we have fostered regulatory compliance and good data practices by enabling investigators to follow best-practices via no-cost access to secure user-friendly data management services. We provide free training including video tutorials (used worldwide) and 1:1 hands-on tutorials and consultations and currently support >5,000 active users and >16,000 active projects. Our REDCap team are national and international leaders and are regularly invited to present at REDCap Con and other community conferences.

CCTSI website

The CCTSI website (cctsi.cuanschutz.edu) is the online portal where faculty, trainees, research associates, university staff, and the public and private sector may access our services, resources, funding, and training opportunities. As of September 2021, the website receives an average of 9,634 page views per month and 5,769 sessions per month. CCTSI membership is required to utilize services and training programs, with membership exceeding 6,000 as of September 2021. Membership is available to faculty, trainees, research associates, community members and the private and public sectors and is obtained through an online registration form.

Health Data Compass (Compass)

Health Data Compass is a multi-institutional enterprise data warehouse funded by the University of Colorado Health System, Children's Hospital Colorado, CU Medicine (formerly UPI), and the University of Colorado School of Medicine. It is located on the Google Cloud Platform and all data that comes from UCHealth, CHCO, and CU Medicine contains PHI. No data are de-identified or scrubbed. Therefore, Compass can link additional data from sources outside of these institutions such as the Colorado All Payer's Claims Database (APCD) from the Center for Improving Value in Health Care (CIVHC). Thus, Compass is a vital source of multi-institutional integrated data and analytic services designed to transform data-driven processes into clinical research, operational excellence, molecular discovery, and personalized medicine. Compass is currently being integrated into the newly established Anschutz Medical Campus Research Informatics Office under the inaugural campus Chief Research Informatics Officer.

Established in 2017, Compass is the world's first integrated large-scale clinical, administrative, genomic, and population-based research data warehouse on the Google Cloud Platform (GCP). It is NIST 800-53 secure and HIPAA-compliant. It serves as the clinical and translational research data hub for the Anschutz Medical Campus. Compass is specifically designed to support data discovery and data science methodologies that integrate, harmonize, and link large-scale biological, clinical, administrative, regional, state and national data sets. Compass integrates patient clinical data from the separate EHRs at UHealth and Children's Hospital Colorado. HDC is able to link patient records from both institutions to create a longitudinal record that does not exist within either EHR alone. Governance and secure data integration pipelines are established to link EHR data with Colorado death registry, vaccination, and all-payer claims databases, state and national environmental data sources, Colorado Center for Personalized Medicine (CCPM) genomic Biobank resources (currently ~200,000 patients and growing), and to make those data available to investigators for high-impact linked analyses. Compass staff have academic and industry experience in computational infrastructure, data engineering, common data models (CDMs), data quality and harmonization, terminologies and ontologies, regulatory and honest broker requirements, study design, and clinical and translational research. Compass uses OHDSI/OMOP as its primary CDM. OMOP includes national and international standardized terminologies such as the CMS/ONC Meaningful Use terminologies. Compass data are surfaced to investigators for cohort discovery using a variety of technologies including Leaf (in beta) and external applications such as TriNetX, i2b2, and Tableau. Custom data extracts are delivered to approved investigators that use REDCap and other HIPAA-compliant tools. To date, Compass has delivered ~1500 datasets for research.

Eureka

Compass also provides the Eureka HIPAA-compliant cloud-based analytics platform to investigators. This innovative service deploys powerful cloud-VM (computational and storage) environments to service a variety of advanced analytics needs, from statistics and visualizations to bioinformatics processing and deep learning. Because Eureka users pay only for the time during which their virtual machines are in use, they can provision much more

power than could normally be afforded - all with the assurance of meeting health system and regulatory HIPAA security and compliance standards. Compass currently hosts ~200 users in Eureka environments.

CU Anschutz Computational Resources

Anschutz High Performance Computing Exchange (AHPCE)

The Translational Informatics and Computational Resource (TICR) is an integral component of the Colorado Center for Personalized Medicine (CCPM). This in-house, comprehensive, stand-alone biocomputing unit supports a multidisciplinary, robust computing resource to foster omics-based research using high-dimensionality data (e.g., genomics, transcriptomics, microbiomics, proteomics, metabolomics) and development and implementation of computational methods and tools for sequence analysis and systems biology approaches.

Computer Cluster

The Translational Informatics and Computational Resource (TICR) is an in-house, comprehensive, stand-alone biocomputing unit supports a multidisciplinary, robust computing resource to foster omics-based research using high-dimensionality data (e.g., genomics, transcriptomics, microbiomics, proteomics, metabolomics) and development and implementation of computational methods and tools for sequence analysis and systems biology approaches. The TICR computer cluster is designed with a minimum of 768 cores (Xeon E5-2680 v3 at 2.5Ghz), 4TB of RAM and 3.7 PB of useable storage. This cluster includes all necessary HPC components, including but not limited to a scheduler (SLURM), manager nodes, master nodes, login nodes, compute nodes, storage and cluster management software. The storage array is designed to provide a minimum of 3.7 PB of useable data storage for both home directories and scratch, using IBM General Parallel File System (GPFS). The processing network for the compute cluster consists of Infiniband switches, providing a low latency and high bandwidth interconnect for parallel computations and storage access. The compute cluster has redundant 10 gigabit Ethernet connectivity to OIT's current network core and management switches, and can easily expand both in terms of network, compute and storage capacity based on need. The HPC environment also includes an application cluster, which consists of six physical servers running VMware vSphere virtualization, plus a dedicated fibre channel SAN. The application cluster is designed for redundancy and high availability.

Each server has a minimum of 36 Xeon v3 cores at 2.3Ghz and 256GB of RAM. The fiber channel SAN is dedicated to the application cluster and includes 30TB of solid-state disk. This array is able to be easily expanded to support future storage growth. The application cluster has redundant 10 gigabit Ethernet connectivity to OIT's current network core and management switches, and can be easily expanded in terms of computation resources and storage. The TICC compute cluster currently includes one additional high memory compute node with 36 Xeon v4 cores and 1.5 TB RAM, to support high memory workloads such as experimental sequence alignment techniques.

Alpine

The Anschutz Medical Campus has recently co-invested with CU-Boulder and Colorado State University in a new high-performance computing (HPC) cluster (Alpine). This cluster will support investigator needs for genomics and computational biology computing on data that does not include PHI. The new cluster will be brought online during 2022 and will initially include 1,088 CPU cores, several graphics processing units (GPUs) optimized for deep learning, and >5 TB RAM, with planned future expansion. This multidisciplinary, robust computing resource is designed to foster omics-based research using high-dimensionality data (e.g., genomics, transcriptomics, microbiomics, proteomics, metabolomics) and development and implementation of computational methods and tools for sequence analysis and systems biology approaches.

Back-Up Solution

A file-level end-to-end back-up solution will be implemented with initial back-up requirements of 500 TB of protected data, with a design optimized for long term retention.

UNIVERSITY OF COLORADO DENVER (Downtown Campus)

Evaluation Center: The Evaluation Center is situated within the School of Education and Human Development at the University of Colorado Denver (CU - Denver). Since its inception in 2004, the Evaluation Center has provided program evaluation services to clients within and outside of the University functioning as an independent, self-supporting cost center with access to all campus research resources. The Evaluation Center has a staff of 23 full- and part-time evaluators who work across the Center's projects. The team is strong in quantitative, qualitative, and mixed methodologies and has experience implementing a wide range of evaluation theories, approaches, and dissemination methods. Located near CU Denver's downtown Auraria campus, the Center occupies over 3,000 square feet of office space in downtown Denver. The Evaluation Center has provided the evaluation components for all CCTSI program since the inception of the CCTSI in 2008.

Learning and Development Program: The Learning and Development Program is situated within Human Resources at the University of Colorado Denver and provides service to faculty and staff at the Anschutz Medical Campus and the Downtown Campus. Since its inception in 2018, the Learning and Development Team has provided a wide range of professional and organizational development services to staff and faculty. The Learning and Development Team has four full-time professionals who design, facilitate, and manage all aspects of our programs. In addition, the team provides organizational development services such as employee engagement surveys, team and individual coaching, and customized training based on gap analysis evaluations. The team is strong in curriculum design, data analytics, and eLearning technology.

CU BOULDER

CU Boulder hosts an outpatient clinical research unit that is part of the CCTSI's CTRC network. The CU Boulder CTRC is located within the translational biomedical research wing of the Ramaley Biology building on the CU Boulder campus. The unit occupies ~3,500 sq ft of discrete CTRC-dedicated space which houses a central nursing and charting/work area, nutrition core, phlebotomy stations, wet lab for sample processing, 4 large procedure rooms with beds, body composition room (DXA) and an Integrative Physiology Core Laboratory (IPCL). The IPCL provides research support in four general areas of investigation: 1) autonomic nervous system/cardiovascular physiology; 2) body composition; 3) exercise testing and intervention; and 4) indirect calorimetry.

Because the CU Boulder CTRC is located on an undergraduate campus and the majority of its investigators are PhD scientists, daily on-site physician and nursing coverage ensures that all protocols are performed

safely with optimal medical oversight. The CU Boulder CTRC facility has 1 on site physician, 2 research nurses, 1 medical technician, 1 nutritionist, 1 exercise physiologist, and 1 research subject advocate. Moreover, the CU Boulder CTRC has a comprehensive medical oversight plan and clinical staff is available 24/7 for medical consultation. An on-call physician service is available in the evenings 7 days/week to respond to participant needs/concerns. All staff receive HIPPA and Good Clinical Practice training and are Basic Life Support (BSL) and Advanced Cardiac Life Support (ACLS) certified. These clinical research professionals have extensive experience conducting and documenting research across the adult age-range involve both healthy individuals and those with disease such as obesity, prediabetes, cardiovascular disease, HIV-1 and chronic kidney disease. The CU Boulder CTRC is open weekdays 7am-4pm and the first and third Saturday (7am-12pm) of each month.

The UCB CTRC has a cooperative partnership with the Intermountain Neuroimaging Consortium involving the use of their fMRI machine. This partnership allows CTRC approved protocols involving the fMRI facility to receive full clinical support from the CU Boulder CTRC for the conduct of these studies.

The location of the UCB CTRC on an undergraduate campus provides a unique opportunity to facilitate training opportunities for undergraduate and graduate students to be involved in translational research. By providing opportunities for these students to be exposed to clinical/translational research and gain “hands-on” research experience, it is possible to establish an intellectual interest that will, at least for some, lead to a career as a clinical scientist. In this regard, undergraduate and graduate students involved with CTRC investigators and their approved CTRC protocols are eligible for academic credit through the campus Independent Study, Laboratory Rotations, and Research Projects course offerings. These mechanisms allow students to identify CTRC faculty investigators of interest, develop a mutually agreeable research training plan, and work with CTRC-supported investigators while obtaining up to 3 hours per semester of academic credit. Use of 2 or more of these mechanisms provide the student an opportunity to engage in a singular (or multiple) research effort(s) over a period of 2-3 years, which will greatly enhance the quality of their research experience.

Equipment

- SunTech 24/7 casual blood pressure monitors (Suntech Medical, Inc., Morrisville, NC);
- Cardiovascular Imaging: Xario XG multi-specialty ultrasound imaging system (Toshiba America Medical Systems, Inc., Tustin, CA) with high-resolution (7.5 and 12 MHz) linear array transducers;
- Vascular Imaging Acquisition and Analysis: Vascular Analysis Tools software version 5.10.9 (Medical Imaging Applications, LLC, Coralville, IA) equipped with Top Performance Analysis Integrated System with imager and frame grabber (DICOM, Rosslyn, VA), vascular ECG-gating module (University of Iowa, Iowa City, IA) and MIA Vascular Research Tools 5 analysis software;
- Forearm Cuff Occlusion: E20 Inflator AG101 Air Source, Rapid Version Cuffs (Hokanson, Inc., Bellevue, WA);
- Hokanson blood flow ptythesmography units (Hokanson, Inc., Bellevue, WA);
- Infusion pumps: Imed Gemini PC-2TX (Alaris Medical Systems, San Diego, CA);
- Body Composition Analysis: Lunar Prodigy Dual Energy X-ray Absorptiometry (DEXA) system and Encore 2008 analysis software version 12.20.023 (GE Medical Systems, Fairfield, CT);
- Nutrition Analysis: The Food Processor software version 8.2 (ESHA Research, Salem, OR), Nutrition Data System for Research (NDSR; Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN);
 - Ankle-Brachial Index: Transcutaneous Doppler flowmeters 810-A (Parks Medical, Aloha, OR);
 - Exercise Testing: Ultima gas analyzer module with ECG interface (MedGraphics, Saint Paul, MN), BreezeSuite ventilatory data collection software version 6.2C (MedGraphics, Saint Paul, MN), Trackmaster 425 Treadmill and 12-lead ECG-treadmill interface (Full Vision Inc., Newton KS);
- Parvo Machine (Salt Lake City, UT) to support resting metabolic rate studies
- Finapres to support continuous mean arterial pressure measurements
- Collins physiological monitors (Ohmeda, Madison, WI)
- Various centrifuges and freezers (for temporary sample storage)

CHILDREN'S HOSPITAL COLORADO (CHCO)

The Precision Diagnostics Laboratory at Children's Hospital Colorado established a scalable and expandable genomics testing infrastructure that supports the needs of patients and providers at Children's Colorado while enabling growth required to keep up with precision advancements and evidence-based changes to clinical practice, which evolves rapidly. The fully integrated genomics infrastructure includes a single ordering access point within the EHR, multimodal laboratory technologies, tailored bioinformatics solutions, data architecture that support FAIR data principles, integrated and transparent clinical interpretation processes and discreet data ingestion of genomics data into the EHR. The integrated system is well positioned to support development and validation of subsequent clinical decisions through research efforts. Since the operationalization of the infrastructure in 2020, the laboratory has resulted in close to 3,500 diagnostic tests. Leveraging the connectivity to the EHR and custom analytical processes the overall clinical utility of the current pediatric tests is over 60% with an average turnaround time of 10 days, reducing the time to a precise diagnosis and profoundly impacting clinical management of the patients. The laboratory has a range of high throughput sequencing equipment, namely three Miseqs, a Nextseq 550 and a NovaSeq 6000. Additionally to support the complex genomic operations the lab has 3 automated nucleic acid extractors and several liquid handlers.

The Precision Diagnostics Laboratory at Children's Colorado is a centralized clinical resource in the Department of Pathology and Laboratory Medicine which performs clinical and research genomic sequencing and analysis. The services of this group include development, validation and implementation of genomics-based technologies, consultation on experimental design, library preparation, and data analysis. The Scientific Director, Dr. Alisa Gaskell (NIH Biosketch included), oversees a team of 10 genomics experts and drives the design of necessary data systems and genomic tools to support the collection and use of genomic data within Children's Colorado and our partners. The Precision Diagnostics Laboratory is a fully integrated genomics infrastructure interfaced with the EHR. This bidirectional connectivity has ensured discreet resulting of genomics data as well as integration of clinical phenotypes into the genomics interpretive workflow. The Precision Diagnostics team has experience developing new laboratory and analytical methodologies, provides a range of genomic and metagenomic data assemblies and analysis services leveraging the state-of-the-art software pipelines.

COLORADO STATE UNIVERSITY (CSU)

CSU has several core facilities containing equipment that generate large datasets. These are available to faculty and students that are CCTSI members and provide training as well as access to equipment.

Human Performance Clinical Research Laboratory

The HPCRL is a designated CSU Program of Research and Scholarly Excellence, and serves as a center for interdisciplinary research, training, and outreach efforts that address the etiology, prevention, intervention and treatment of major chronic diseases including cardiovascular disease, diabetes, obesity and degenerative conditions associated with aging. The original HPCRL facility, which opened in May 2000, contained 6200 sq ft of research and clinical outreach space. In July 2008 an addition of 1100 sq ft of wet lab space was added; and, a new 4000 sq ft research addition opened in January 2010. In 2017 a \$2.5 million expansion of ~ 4500 sq ft was completed. Most recently, in 2021, an \$800,000 conversion of an underutilized space resulted in a 1570 sq ft open concept wet-lab multi-user space. With recent additions, the HPCRL now houses 17,400 sq ft of clinical administrative, and analytical research space.

Laurie Biela the Manager of Research Operations serves the Human Performance Research Laboratory as a whole by overseeing all shared resources, maintaining regulatory compliance, oversight of human participants, laboratory safety and training, and managing the clinical Resources for CSU Researchers and community Fee- For-Service programs. The MRO supervises 3 assistants (a total of 2.5 PTE) who perform quality control activities such as data verification, source document reconciliation, organization of site training binders, equipment maintenance and calibration, investigational product and reagent temperature monitoring, and fee based clinical research activities- such as exercise testing, phlebotomy, IV catheter placement, DEXA scans VO2 max testing and other services upon request.

Administrative core facilities:

- Reception Area and Lobbies: (reception area 344 sq ft, south lobby 92 sq ft, and north lobby 293 sq ft). The newly constructed reception area serves the clinical/outreach, teaching, and research needs of the HPCRL. This area serves as the check in point for research participants. The area also houses

computers, phone, fax, facilities scheduling services, and other administrative functions. In this area is a lobby that serves as a waiting room for research participants.

- Graduate Research Assistant Offices (combined 625 sq ft): Offices for masters and PhD students.
- Storage/Facilities Maintenance (combined 105 sq ft): Four small storage/plumbing/electrical closets are located in the administrative core.

Clinical core facilities:

Clinical Research Exercise Screening and Performance Flex Spaces (312 and 350 sq ft):

- Room 1: Space and equipment for multiple stress tests, with either treadmills or cycle ergometers, while capturing expired gases using metabolic carts and recording ECG traces.
- Room 2: Equipped for clinical stress testing using cycle ergometers (Velotron, Lode Bike or KickR), ECG and indirect calorimetry.

Clinical Research Procedural Flex Spaces (145 and 280 sq ft): These rooms contain a research bed, a sink, and storage cabinets. The space can be used for obtaining muscle and adipose tissue biopsies, blood samples for screening purposes, resting metabolic rate, and oral glucose tolerance data as well as other IRB approved research procedures. The room has the power requirements for a centrifuge to spin blood samples and for instrument sterilization equipment.

- Sleep and Metabolism Laboratory (SAM Lab) The SAM Lab of two specially built, sound-attenuated, light- and temperature-controlled sleep and circadian research suites, private bathroom and observation/instrument room and all necessary equipment for conducting rigorous sleep and circadian studies with a total space of 1000sqft.
- Sensorimotor Neuroimaging Laboratory: The primary laboratory for CO-PI Dr. Brett Fling's research consists of a 7922 ft laboratory, an attached electronics/fabrication shop (982 ft), an adjacent examination room for clinical evaluation (3062 ft), and office space for up to 5 personnel. The equipment available in the laboratory includes the following: MagVenture MagPro X100 Transcranial Magnetic Stimulator with angled, double-cone coil. Brainsight-2 NeuroNavigation system for navigated TMS: coil tracking hardware, integrated iMac computer with neuronavigation software, a positioning system that includes a full-body supportive reclining chair, head stabilization unit, and coil stabilization arm. An instrumented, split-belt treadmill with two Bertec force platforms (Model 4060-10, Bertec Corp, Columbus, OH) to record body kinetics. The instrumented treadmill is integrated with a high resolution 10-camera Vicon (Denver, CO), 3-dimensional motion analysis system linked with Nexus (Vers 2.3) to record body kinematics. A Magventure MagPro X100 transcranial magnetic stimulation system (Magventure Inc. Alpharetta, GA) synched with a 6-channel surface EMG system from Biopac (Biopac Systems, Inc. Goleta, CA) to assess muscle activity. Two 6- channel Opal wireless inertial sensor systems from APDM (APDM Portland, OR) to assess static and dynamic movement kinematics during over-ground walking and a NeuroCom Balance Master Clinical Research System (Natus Medical Inc. Pleasanton, CA) to assess balance.
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- Test Article Preparation and Nutritional Kitchen (360 sq ft): This room serves as a 'clean' room for test article dispensation, food preparation, and preparation of anything that is intended for human consumption. The room houses a refrigerator/freezer combo, a dish washer, a sink, locking cabinets for secure storage of test articles, and counter space.
- Clinical Exercise Outreach Testing lab (768 sq ft): The clinical exercise-testing lab. This room has three treadmill/ECG stations, three exam tables for participant prep, a medical "crash" cart, extensive storage, sink, and miscellaneous exercise testing equipment.
- Shower/Lavatories (combined 232 sq ft): The three shower lavatory facilities are available for research participants. Each room contains a shower, lavatory, sink, and lockers.
- Participant Interview Rooms (188 and 2-94 sq ft): Each room has a small conference table and four chairs for participant/client activities such as obtaining informed consent, screening, or follow up visits in a private room.
- DEXA Room (180 sq ft): Houses a dual-energy X-ray Absorptiometry (DEXA) unit used for body composition and bone densitometry analysis.
- BodPod Room (122 sq ft): Houses a Cosmed BodPod, scale, and weights for non-x-ray sources of body composition determination, along with cabinetry and a sink.
- Blood Draw Room (93 sq ft): Contains a phlebotomy chair, blood draw supplies for on-site blood analysis, and centrifuge.

Analytical core facilities

- Wet Laboratory 1 (1393 sq ft): A multiuser facility for molecular biology, biochemistry, and other analytic needs of multiple groups. The lab allows for the analysis of DNA, RNA, protein, lipid, carbohydrate, and other analytes from human rodent tissue, c. elegans and isolated cells (see equipment section for details of equipment).
 - Instrument Area (500 sq ft): Houses two GC-MS and GC-QQQ instruments, centrifuges, and upper metal case work for general supplies, and lower metal case work for acid and base storage.
 - The Microscopy/Imaging Laboratory (50 sq ft): Contains a shared fluorescence microscope/camera.
 - Cell Culture Room (180 sq ft): Contains 3 biosafety cabinets, clean bench, 3 incubators, centrifuges, water baths, and cell culture supplies.
 - Wet Laboratory 2 (1126 sq ft): An open concept multi-user lab space for biochemical/molecular analyses and short-term rodent studies. Contains 3 acid neutralizing fume hoods, vented chemical storage cabinets, 2 biosafety cabinets, 4 sinks with di-ionized water supply and eye wash station, safety shower, lab grade dishwasher, 7 work station benches with upper and lower metal cabinets and power and data along the length of the benches, 3 moveable benches with storage, accommodate up to ~20 work areas. Power requirements and space to add refrigeration/freezer units.
 - Animal Housing Area (132 sq ft): Intended for weekly short term housing for rodents also equipped with proper hourly air exchange rate and a biosafety cabinet.
 - Animal Behavioral Area (160 sq ft): Dedicated space to perform rodent studies using treadmills and other behavioral equipment. Also contains a sink and storage cabinets. Easily cleanable surfaces for disinfecting in between rodent studies.
 - Student Office Area (152 sq ft): Flex desk space/lounge for students performing work in the connect lab areas.
 - Storage for consumable lab supplies (400 sq ft)
 - Freezer Room (440 sq ft) Housing for 5 ultra low temperature freezers, -20C freezers, and fume capture hood for a speedvac. All freezers are equipped with remote temperature monitoring and connected to emergency back-up power.
 - Compressed Gas Tank Storage (133 sq ft): Area to secure various types compressed gas tanks ~50 full sized tanks.

- Biohazard Closet (26 sq ft): Biohazards storage area for pick-up and disposal by commercial contracted company.
- Capacity to house additional -80C freezers within the building as needed (**300 sq ft**).

Standard Equipment:

Fume hoods (6; 3 are acid neutralizing fume hoods); MilliQ ultrapure water system; ventilated chemical storage cabinets; BSL2 laminar flow biosafety cabinets (5); laminar flow cell fractionation/isolation work stations (2); refrigerated centrifuges and microfuges (6); autoclaves (2); CO2 incubators (3) including one with dual CO2/O2 control); RT-PCR (ABI) and thermocycler (ABI); Bio-Rad electrophoresis/immunoblotting stations (5) and rapid transfer station; NanoDrop spectrophotometer; agarose electrophoresis apparatus (2); chemiluminescent/UV imaging equipment and automated Wes capillary electrophoresis/immunoblotting unit (Protein Simple); plate readers (2, luminescence/ fluorescence/ absorbance; pH meters; stirring/heating plates; rockers; Rainin pipeter sets; analytical balances; refrigerators (4); -20°C freezers (4); -80°C freezers (8); sonicator; and equipment for 4 different approaches to tissue homogenization; Molecular Devices UV/VIS/fluorescence plate reader and ELX-808 Bio-Tek Instrument.

A specific set of standard equipment (centrifuge, analytical balance, Rainin pipeter sets, and a Molecular Devices UV/VIS/fluorescence plate reader) is designated for use with GxP research. All equipment is routinely calibrated and use is tracked with user sign-in.

Specialized Equipment:

For high resolution mitochondrial function: OROBOROS Oxygraph-2k instruments (2), one with a fluorescence module.

Isotope analyses/proteome maintenance assays: Glascol nitrogen concentrator (3); Fisher block heaters (3); Restek ion exchange manifold (2); speedvac; Waters Oasis HLB DNA cleanup manifold; 2 Agilent gas chromatography-mass spec instruments (Agilent 7890 GC and 5975 MS); Agilent gas chromatography-triple quad mass spec (Agilent 7890 GC and 7010 QQQ); Agilent HPLC 1200 series HPLC with multi-wave and fluorescent detector.

Measurement of extracellular vesicle abundance via nanoparticle tracking analysis: three-laser Manta/Horiba ViewSizer 3000 particle analyzer; Horiba Aqualog for comprehensive fluorescence characterization of bulk samples.

C. elegans research: TriTech research stereomicroscope for daily C. elegans maintenance; NemaLife semi-automated microfluidic system for C. elegans lifespan experiments; TriTech Research incubators for C. elegans maintenance (2).

Microscopic imaging: Invitrogen EVOS M7000 automated scanning microscope with four fluorescence channels, high-resolution 2-100x optics and Celleste digital deconvolution software; EVOS FL manual fluorescence microscope; Nikon TE2000 fluorescence microscope with a CoolSnap HQ camera and NIS Elements software); Olympus light microscope with digital color imaging; Nikon light microscope for daily cell imaging; Additionally, abundant access to the CSU Microscope Imaging Network (<https://www.research.colostate.edu/min/>) expands imaging instrumentation to include Keyence All-In-One Fluorescence Microscope; Nikon+Bruker atomic force and spinning disk confocal microscope; Nikon Eclipse Ti Total Internal Reflection Fluorescence (TIRF) microscope with N-STORM super resolution imaging capability; Nikon Inverted Epifluorescence Microscopes; Olympus inverted IX81 FV1000 confocal laser scanning microscope; Olympus inverted IX83 spinning disk confocal microscope; Zeiss LSM510 meta laser scanning confocal microscope; Zeiss LSM800 laser scanning confocal microscope.

Hypoxia research: Coy hypoxia glove box; walk-in environmental/hypoxia chamber.

Clinical Research Equipment:

All preparatory equipment and instrumentation for safe and sterile tissue collection including blood, adipose, and skeletal muscle sample collection are available.

Also available is equipment for insulin clamp procedures; multiple hospital beds (available in “flex spaces” as needed); 15 reusable Bergstrom biopsy needles; syringe pumps; autoclaves; refrigeration; 2 YSI glucose analyzers (2300 Stat Plus); Piccolo blood chemistry analyzer (Xpress Blood Analyzer).

Equipment for clinical and exercise testing includes a Hologic Horizon A DEXA scanner; digital and manual (balance) body mass scales; 3 stations equipped with treadmill and ECG for cardiac screening (Quinton TM65 and Quinton Q-Stress); 1e station with treadmill, ECG and indirect calorimetry (Parvo True Max); 2 cycle ergometers (Lode and Velotron) with indirect calorimetry (Parvo True Max) and ECG (Quinton Q- stress); pulmonary function testing (Medgraphics); a “crash cart”; multiple portable defibrillators.

Equipment Specific to the Sensorimotor Neuroimaging Laboratory:

The equipment available in the laboratory includes the following: MagVenture MagPro X100 Transcranial Magnetic Stimulator with angled, double-cone coil. Brainsight-2 NeuroNavigation system for navigated TMS: coil tracking hardware, integrated iMac computer with neuronavigation software, a positioning system that includes a full-body supportive reclining chair, head stabilization unit, and coil stabilization arm. An instrumented, split-belt treadmill with two Bertec force platforms (Model 4060-10, Bertec Corp, Columbus, OH) to record body kinetics. The instrumented treadmill is integrated with a high resolution 10-camera Vicon (Denver, CO), 3-dimensional motion analysis system linked with Nexus (Vers 2.3) to record body kinematics. A Magventure MagPro X100 transcranial magnetic stimulation system (Magventure Inc. Alpharetta, GA) synched with a 6-channel surface EMG system from Biopac (Biopac Systems, Inc. Goleta, CA) to assess muscle activity. Two 6- channel Opal wireless inertial sensor systems from APDM (APDM Portland, OR) to assess static and dynamic movement kinematics during over-ground walking and a NeuroCom Balance Master Clinical Research System (Natus Medical Inc. Pleasanton, CA) to assess balance.

CSU Core Equipment:

As necessary, we also have access to a variety of “omics,” imaging, and flow cytometry facilities located either on campus or in the surrounding area. The CCTSI Genomics Shared Resource provides Illumina Next Generation Sequencing (HiSeq 2500/4000, MiSeq), LifeTech IonPGM sequencing, Illumina BeadArrays, Agilent Microarrays, Affymetrix GeneChips® Microarray or Plate Arrays, SomaLogic SOMAScan (proteomics), and Fluidigm C1, BioMark HD, Juno, and AccessArray for Single Cell Genomics. The Rocky Mountain Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research includes a Genomics and Proteomics Core with instrumentation including an Agilent Q-TOF tandem mass spectrometer, Affymetrix Gene Chip 3000 microarray system, an Arcturus Autopix laser- capture microdissection unit, a Bruker MALDI/TOF mass spectrometer, and the SOLiDTM System are available to CSU personnel. The CSU Proteomics and Metabolomics Facility houses a Waters G2 TQ-S coupled with nanoUPLC, Bruker Ultraflex MALDI-TOF/TOF tandem mass spectrometer, and a Thermo LTQ ion trap mass spectrometer, and licenses for Mascot and other proteomics software. The CSU Central Instrument Facility, among many other capabilities, has Mass Spectrometry (GCMS, LCMS, LC-TOFMS, FTICRMS) and Magnetic resonance (NMR/EPR up to 600MHz). The Microscope Imaging Network has a JEOL 1400 and a JEOL 2000 Transmission Electron Microscopes, 2 Zeiss LSM510 meta laser scanning confocal microscopes, Olympus inverted IX81 FV1000 confocal laser scanning microscope, Olympus inverted IX81 spinning disk confocal microscope, Nikon Eclipse Ti Total Internal Reflection Fluorescence (TIRF) microscope with N-STORM super resolution imaging capability, 2 Nikon inverted epifluorescence microscopes. The CSU Flow Cytometry Core Facility has a wide variety of instrumentation for state-of-the- art flow cytometry and cell sorting, services, and expertise to support CSU research. Additionally, CSU has an excellent Glass Shop that is housed in the Department of Chemistry and machine shop services are available in the Department of Chemical and Biological Engineering and the College of Engineering.

Next Generation Sequencing Facility

The Department of Microbiology, Immunology, and Pathology (MIP) and OVPR operate a self-service facility that houses Illumina MiSeq and NextSeq next generation sequencers. The facility also provides an open access library preparation laboratory and other instruments required for sample processing, library prep, and library quantification and QC. Mark Stenglein, PhD is Director.

Services include:

- Training in the operation of the MiSeq and NextSeq instruments.
- Loading of libraries on MiSeq and NextSeq
- Pre-run library QC (qPCR-based library quantification and tape station analysis)

- Consumables useful for library prep and NGS
- Flow Cytometry Facility – This core provides cost effective access to state-of-the-art flow cytometry and cell sorting instrumentation, services, training and expertise for all researchers. Instrumentation includes:
 - BD FACSAria III
 - Cytex Aurora Spectral Cytometer
 - Beckman Coulter Gallios
 - HyperCyt Rapid Sampler for High Throughput Flow Cytometry
 - CyAn1-ADP 7 Color
 - CyAn1-ADP 9 Color

High Performance Computing

The \$3.55 million system was awarded under the auspices of the Rocky Mountain Advanced Computing Consortium (RMACC; www.rmacc.org). The Summit system architecture is comprised of general compute nodes, GPU compute nodes, high-memory compute nodes and Phi nodes. Compute time is allocated following review of applications.

Proteomics and Metabolomics Facility

The facility contains state of the art mass spectrometry instrumentation and can facilitate experiments in all aspects of protein and metabolite analysis including both non-targeted global profiling and targeted quantitative assays. Equipment includes:

- Waters G2 TQ-S Coupled with nanoUPLC
- Waters G2 TOF coupled with UPLC
- Waters G2 Q-TOF coupled with UPLC
- Elan DRC-ICP-MS
- Thermo Trace ISQ with liquid autosamplers
- Bruker Microflex LRF
- Thermo Orbitrap Velos MS coupled with nanoUPLC

Other cores include: Experimental Pathology Facility, Central Instrument Facility (mass-spec, NMR, X-ray diffraction, Optical Spectroscopy), Molecular Quantification Core (digital PCR and Typhoon Imaging), Lab Animal Resources, BSL3 Facilities, BioMARC cGMP Manufacturing, Protein Purification Facility.

All of these cores are available to CVMBS researchers. The Office of the VPR provides opportunities for Core Facilities to apply for funds to purchase additional equipment. Recent purchases include a Digital PCR System, and a Cytex Aurora 48 channel flow cytometer.

Animal Facilities

- a. Painter Center – This is the central animal facility with conventional, barrier and biocontainment animal housing, a surgical suite, the cage wash facility serving the entire university and offices for staff in the Department of Laboratory Animal Resources (LAR).
- b. Pathology Building – A conventional animal facility, located 30 yards from the Painter Center, is used by Pathology Department faculty.
- c. Physiology Building – A conventional animal facility located 75 yards from the Painter Center, has a surgical suite that can be used for small ruminants or rodents, one room for short-term post-surgical holding, and a hypo/hyperbaric chamber used for pulmonary and cardiovascular physiology research.
- d. Infectious Disease Research Center (IDRC) - The IDRC is composed of a series of several interconnected and one stand-alone buildings that includes approximately 175,000 sq. ft. of research space. These include the Biocontainment Research Building (BRB), the Rocky Mountain Regional Biocontainment Laboratory (RMRBL), and the Small Animal Research Annex (SARA). Within these facilities there are multiple isolated suites housing animals in ABSL3 conditions. The BRB contains three major animal housing areas: Immunology and Virology suites (BRB I), and Discovery suite (BRB II). The RMRBL adjoins the BRB, was completed in 2007, and was approved for select agent work in 2008. This facility was the first of the 13

RBLs to achieve this designation, and remains ABSL3 approved by both USDA and CDC. The RMRBL is a high containment facility for infectious disease research. It has both ABSL2 and ABSL3 animal holding rooms, procedure rooms, necropsy facilities and aerosolization rooms. The animal holding areas and supporting laboratories are divided into modules to allow separation of the agents under study. The SARA building is a stand-alone facility adjacent to the BRB and RBL facility that contains four large ABSL3 animal holding rooms. The building also contains an aerosol, necropsy and decontamination room, a staging area, and locker rooms. The Research Innovation Center (RIC) is a \$52M multi- functional project with 8,000 sq. ft. of research space. The RIC includes versatile ABLS2 animal space, 'incubator laboratories' for industrial partnerships, a GMP stand-alone facility, and an infectious disease-imaging core.

- e. Animal Disease Laboratory – A containment animal facility with design and construction features which allow for its use as a large animal biocontainment level II/III facility.
- f. Animal Reproduction and Biotechnology Laboratory (ARBL) – Contains a large animal surgical suite and indoor animal space currently used for rabbits, mice, chickens and sheep, a 1,500 sq. ft. stall barn for housing large animals, 5 acres of corrals for cattle, and an outdoor sheep facility

Veterinary Teaching Hospital Research Animal Facilities

- a. VTH Research Animal Facility – This is primarily a dog facility, in addition to space for conventional cat and rodent housing. There is also limited space for large research animal housing in stalls of the large animal barn and in outdoor paddocks (2.5 acres).
- b. Research Barn – This pole barn is used to house groups of sheep, primarily used in orthopedic research, in indoor pens with access to fenced outdoor pens. It is located 40 yards from the VTH.
- b. The VTH also houses complete advanced diagnostic facilities including imaging, clinical and histopathology laboratories, large animal surgery suites, microbiology and virology diagnostic laboratories, central supplies, and pharmacy. These facilities can be utilized for research animal diagnostics and procedures by arrangement. A 15,000 sq. ft. animal facility (Bay Facility) is currently in advanced planning phases to provide state of the art research animal housing at the CSU Veterinary Health Systems campus, with ground breaking planned for late 2019.

Graduate School Professional Development Series.

The Graduate School offers a series of free professional development events each fall and spring semester.

Graduate Center for Diversity and Access.

The Graduate Center for Diversity and Access (GCDA) is a comprehensive academic framework providing professional development and additional opportunities for graduate students of color to address systematic issues that may impede their progress in their graduate programs. It provides an opportunity to interact with diverse faculty and students, as well as professional development.

Resources for Disabled Students.

RDS provides support for students with both permanent and temporary limitations and chronic illness/health conditions (physical and mental health). Any student who is enrolled at Colorado State University and who self-identifies with RDS as having a disability or chronic health condition is eligible for support from RDS. Specific accommodations are determined individually for each student and must be supported by appropriate documentation and/or evaluation of needs consistent with a particular type of disability or health condition. Support services fall into three categories: accommodations, awareness, and advocacy. These three services areas relate to and complement one another to help lessen the negative effects that limitations or disabilities may have on students in an academic environment. Accommodations are designed to give students access to the programs offered by Colorado State University. Awareness activities are related to improving the climate on campus for students with disabilities. Advocacy efforts are to ensure the needs of students with disabilities or chronic health conditions are addressed both in individual situations as well as in policies and procedures of the university.

Student Diversity Programs and Services

Supports students in a variety of ways and provide opportunities to successfully participate in, and contribute to, the diverse campus environment. While each office listed may emphasize a specific segment of the student body, services and programs are available to benefit all students at CSU.

- The Asian Pacific American Cultural Center is committed to inclusion and interculturalism, the Asian Pacific American Cultural Center creates and supports opportunities for interaction among University and community constituencies to provide a learning environment that supports all students.
- The Black/African American Cultural Center promotes a diverse, inclusive campus environment and serves as a resource to the campus community as well as surrounding communities, through academic, professional, cultural and personal development programs that embrace Black and African American experiences.
- El Centro provides an inclusive learning environment that welcomes all students. El Centro supports and strengthens the academic and cultural experience of students by providing workshops, leadership opportunities and Latina/o cultural awareness programs that promote student success and retention.
- The Native American Cultural Center was established in 1979. The four primary advocacy and service areas include recruitment, retention, graduation and community outreach. The office embraces and encourages a supportive environment based on the traditions and cultures of Native American peoples.
- The GLBT Resource Center seeks to foster a campus free of prejudice, bigotry, harassment, and violence by providing a space for all members of CSU communities to explore and increase their understanding of aspects related to sexual orientation, gender identity and expression in an open and non-judgmental environment.
- Women and Gender Advocacy Center provides programs and resources focusing on all genders, social justice, and interpersonal violence prevention. Additionally, WGAC provides advocacy and support for victims of sexual violence, stalking, sexual harassment and relationship violence. Our purpose is to provide a safe and affirming space for the students we serve at Colorado State University, while supporting systemic change to end all forms of oppression within our community.

Colorado BioSciences Association & Colorado Bioscience Institute.

Colorado BioScience Association serves as the hub of Colorado's thriving bioscience sector by connecting innovators to funding, infrastructure, research and talent. From promising young companies to established corporations and institutions, they provide opportunities for networking, education and professional development. CBSA grows the bioscience workforce and lead business expansion policies to advance the industry in our state. CBSA represents more than 350-member organizations, including biotechnology, pharmaceutical, medical device, diagnostic, ag bio and mobile digital health companies, research and academic institutions and service providers. The Colorado BioScience Institute (the Institute) is a 501(c)3 non-profit that provides education, workforce and career development, innovation support and resources for life science professionals, companies, students and educators related to the bioscience industry in Colorado. Together these two agencies offer training opportunities and connections with local biotech industry for DVM/PhD student career development and networking.

DENVER HEALTH (DH)

Denver Health (DH) is an integrated academic health care system that serves as the primary safety net for the City and County of Denver, Colorado. DHHA has maintained an affiliate relationship with the University of Colorado's School of Medicine since 1947. DH-employed physicians/clinicians and doctoral researchers hold faculty appointments at the University, with rank commensurate to their experience and professional development.

Facility

DH has a 525-bed acute care hospital that is an academic Level 1 Adult and Pediatric Level II Trauma Center. Additionally, we run 11 federally qualified community health centers, 18 school-based clinics in the Denver public school system, a 100-bed non-medical detoxification facility, correctional care services for Denver's jails, the Rocky Mountain Poison and Drug Safety Center. Within the Denver Public Health department, which provides a variety of services, we provide many health services including the largest STD clinic in the state

with embedded primary care; innovative work in health informatics and public health research; innovative programs for health care delivery and cost containment; and educational services for a 17-state region.

DH served approximately 216,500 patients in 2018 (or 21% of the population in Denver County), and in its history, has provided billions of dollars in uncompensated care. A large proportion of DH patients are members of racial/ethnic minority groups (69% non-white Caucasian in 2018) and DH provides care to a large number of homeless patients each year.

DH has been an active collaborator in development and information sharing through a virtual data warehouse (VDW) model with multiple distributed research networks, including the CCTSI, and developing business intelligence tools for research activities in a broad array of health services and research domains. DH is making efforts to include patient-reported health status within the EHR as a means to provide care that is more patient-centered and availability of self-reported outcomes for research. DH's Coherent Research Platform focuses on opportunities that blend research with clinical and operational innovation to reduce health disparities, and advance quality of care and service excellence

Workforce Training and Development

The Investigator Development program, operated in partnership with University of Colorado Denver (UCD), fosters the skills and provides mentorship to emerging DH investigators to conduct research using scientifically rigorous methods that meet the methodological standards and philosophy of the Patient Centered Outcomes Research Institute (PCORI). To accommodate investigator and research growth at DH, we now support a pilot study program to provide funding for junior investigators.

Action Networks

DH is a collaborating organization within two of AHRQ's networks of provider organizations that conduct rapid-cycle field-based research. The ACTION IV network program is designed to promote innovation in health care delivery by accelerating the diffusion of research into practice. DH also is a member of a Center for Care Innovations (CCI) action network.

1. DH is a principal member of the network led by Intermountain Healthcare: "Health Care Delivery in ACTION IV." The other principal members are Mayo Clinic, Providence Health & Services, Baylor Health System, Dartmouth-Hitchcock, the Colorado Health Outcomes center (COHO), and the Veterans Affairs Medical Centers in Denver and Salt Lake City.
2. DH is a principal member of the network led by the University of Colorado: "Denver: Colorado ACTION Partnership." The other principal members are Avera Health, Children's Hospital Colorado, University of Colorado Health, and University of Oklahoma Physicians.
3. DH is a member of the network led by John Snow, Inc.: "Safety Net Partnership." The other healthcare organization members are AltaMed Health Services Corporation, Boston Medical Center, Keck Medicine of USC, Penobscot Community Health Center.

OnCore Clinical Trials Management System

DH has partnered with the CCTSI, University of Colorado School of Medicine, UHealth, and Children's Hospital of Colorado to use the OnCore Clinical Trials Management System. OnCore increases operational efficiency and directly benefits study teams by: providing transparency into start-up processes and financial management; improving invoicing; improving billing compliance; improving patient protection; centralizing study management; and allowing study teams to generate useful study metrics.

REDCap

DH has implemented Research Electronic Data Capture, (REDCap), a secure web application for building and managing online surveys and research databases. REDCap can be used to collect virtually any type of data in any environment, including compliance with 21 CFR Part 11, FISMA, HIPAA, and GDPR. REDCap is geared to support online and offline data capture for research studies and operations. The Office of Research has a dedicated team of REDCap Administrators that help maintain this specific instance, assist with research projects and data management across DH, and our presence in the larger REDCap network.

NJH hosts an outpatient clinical research unit and Core Laboratory that are part of the CCTSI's CTSC network. Note that the Core Laboratory equipment and services are listed under "CTSC Core Laboratories" due to central integration of management for all CTSC Core Labs. This change has reduced overall operating costs and increased efficiency of these operations across the CTSC network.

Facility

The NJH CTSC provides space, nursing services and core laboratory services for a broad range of research specializing in, but not limited to, pulmonary, asthma, immunology and allergy for adult and pediatric populations (including newborns). The unit consists of 4 patient care exam rooms and 2 negative air flow rooms. Two rooms are equipped with oxygen flow meters. There are 593 square feet of dedicated space for patient care use located on the third floor of the Goodman Building, plus the use of an exam room on the second floor by the pediatric care unit for oral food challenges. The unit is staffed by a nurse manager and 3 RN's, and is supported by a Nurse Practitioner and 0.8FTE of administration/regulatory support. There are 4 clinical research coordinators, including a registered dietician, available to support protocols as well. Consenting for studies, history and physical exams, skin biopsies, spirometry, skin testing, induced sputum, sweat testing, medication administration, 12 Lead EKG, standardized photography, are performed in the unit. The unit works with the Pharmacy for medication storage and distribution.

The unit also has 873 square feet for office space that houses nurses, study coordinators, and an administrative manager who assists in regulatory paperwork and protocol preparation. Computers are available for word processing, data collection and analyses. A CTSC funded statistician is available to support investigators with study design and statistical analyses.

Equipment

- EKG machine: ELI380 (Mortara Instrument, Inc., Milwaukee, WI) and MAC5500 CLR STD ENG NA AHA, (GE Medical Systems Information Technologies, Wauwatosa, WI)
- Spirometry: 2 x MCG Diagnostics (Breeze Suite version 8.1) (Medgraphics Corp, Saint Paul, MN)
- Sweat Testing equipment (MacroDuct)
- Vitals machines
- Stadiometer and scale
- Sputum induction equipment (Nouvag)
- Trans-Epidermal Water Loss (TEWL) machine: Biox Aqua Flux® AF200, STE, Inc., Towson, MD, USA)



PAR-21-338, “Limited Competition: Ruth L. Kirschstein National Research Service Award (NRSA) Postdoctoral Research Training Grant for the Clinical and Translational Science Awards (CTSA) Program (T32 Clinical Trial Not Allowed)”

CTSA Postdoctoral T32 at University of Colorado Denver

Principal Investigator:

Lisa Cicutto, PhD, MSc, RN, ACNP(cert)
Director, Translational Workforce Development
Director (PI) CCTSI T32 Pre- and Post-Doctoral Programs,
Colorado Clinical and Translational Sciences Institute
Director, Clinical Science Program
Adjunct Professor, College of Nursing
University of Colorado Anschutz Medical Campus

Professor of Medicine
Director of Community Outreach and Research
National Jewish Health

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Grant Number: T32TR004366

Performance Period: 09/18/2023 – 06/30/2028

Training Slots Funded: 4

TRAINING PROGRAM: PROGRAM PLAN

1. JUSTIFICATION

1a. Rationale. The Colorado Clinical and Translational Sciences Institute's (CCTSI) T32 Post-Doctoral Program aligns and supports the goals of NCATS to ensure that a diverse pool of highly trained scientists is available in adequate numbers and appropriate research areas to carry out the nation's clinical and translational science and research (CTSR) agenda. Clinician scientists, trained in translational science, clinical research, and clinical practice, play key roles in translating patient observations and experiences to the discovery bench, and in moving research findings into clinical and community practice, thereby contributing importantly to the improved health of populations. **By integrating discovery science with clinical practice and therapeutic intervention, clinician-scientists fulfil a unique role. However, their numbers are in decline, which is creating the need for flexible training and research opportunities to ensure their future.**¹⁻⁶ The CCTSI T32 Post-doctoral Program will address the need for highly qualified and competent translational research scientists by providing a responsive and evidence-informed program, outstanding mentorship, a stimulating environment with well-equipped facilities and a community of practice for translational scientists. We request support for **4 post-doctoral trainee slots** to be awarded to trainees for **two years each**, contingent on review of acceptable progress and productivity in year one.

1b. Novel and Responsive. Our program is novel in that it expands the translational spectrum by recognizing the importance of shared models of disease among animals and humans to push discovery, which we coin **T0.5**. Thus, our translational spectrum includes T0.5 to T4 and our program will involve both doctorally prepared clinicians (physicians (MD), pharmacists (PharmD), physical therapists (DPT), nurses (DPN) and others) at the University of Colorado Anschutz Medical Campus (**CU Anschutz**) who will complete the Master of Science in Clinical Science (**MSCS**) degree and veterinarians completing a PhD from Colorado State University (**CSU**), our partnering institution. For our application, we define clinician scientists as a professional (with a doctorate) who cares for patients (humans or animals), diagnosing or treating illness, and conducts research. Having clinical experience offers several advantages for CTSR.¹ A clinician scientist who deeply understands a disease, its inequities, its complications, implications, and interacts directly with the community of interest, can raise specific questions and develop focused research projects that can be more effectively translated into clinical benefits. They have the capability to transpose clinical observations into testable research hypotheses and translate research findings into medical and health care advances. Clinician scientists can promote bi-directional linkage of basic and clinical sciences and establish better links/relationships among researchers, clinicians and patients because they can better articulate the rationale and purposes of cross-disciplinary translational studies. The entity of a clinician scientist is in danger of vanishing. According to the NIH Physician Scientist Workforce report², physician scientists comprised only 1.5% of the total physician workforce in the US. As we approach an era of personalized disease management, prompted by a better understanding of disease mechanisms and the use of novel diagnostic and therapeutic approaches, there is demand for closer collaboration and teamwork among patients/families and research and clinical enterprises, and for clinician scientists who speak all three languages fluently.

Many organizations and studies have documented that an insufficient number of research veterinarians are being trained, particularly in fields such as emerging infectious disease and zoonoses, environmental health, laboratory animal/comparative medicine, and public health.³⁻⁶ It is increasingly clear that the confluence of increasing research costs, competition for research funding, and debt accumulation by veterinarians will make the research training necessary to produce physician and veterinarian clinician scientists impossible without post-professional preparation training grants. The number of veterinary scientists trained in biomedical and infectious disease research falls far below national needs. The capacity of veterinarians to fill this national need is severely limited due to insufficient opportunities for postdoctoral training in research as highlighted in several reports including the 2015 NIH Physician Scientist Workforce report, National Academy of Sciences analyses and the NIH ORIP One Health Workshop: Integrating the Veterinarian Scientist into the Biomedical Research Enterprise.³⁻⁶ These documents also stress the need for veterinarians to enhance translational research by consideration of the intersection of human, animal and environmental health (so-called One Health). The inclusion of veterinary clinicians in our CCTSI T32 Post-Doctoral Program is in response to national data showing that insufficient numbers of veterinarians are trained in translational biomedical research, despite the significant need for their expertise in comparative translational medicine to accelerate bench to bedside

discoveries for human health.³ Our training program addresses this national need by preparing veterinarians to become principal investigators in translational research.

One Health recognizes that the achievement of optimal human health is reliant on the interconnection between people, animals, and their shared environment and that research and its translation needs to occur through an interdisciplinary approach across eco-health system levels (local, regional, national and global). One Health acknowledges that population health is dependent on the interactions between animal and human diseases in a social and biological ecological environment. Humans and animals interact with greater frequency and intimacy in a globalized world. The One Health approach supports global health security by improving coordination, collaboration and communication at the human-animal-environment interface to address shared health threats such as zoonotic diseases, antimicrobial resistance, food safety and others. One Health is an approach to designing and conducting research and implementing programs, policies, and legislation in which teams from multiple sectors communicate and work together to achieve better public health outcomes. The One Health approach will be integrated into our interprofessional curriculum to realize synergies of participating CU Anschutz health professional and CSU veterinarian trainees. As a culminating exercise for the application of translational scientist competencies developed in the program and the team-oriented approach to science, a hackathon research design event will be held with the theme of antimicrobial resistance to bring together teams of our interdisciplinary trainees and faculty to develop a research agenda and program of projects within the One Health paradigm.

The **intent of the CCTSI T32 Post-Doctoral Training program** is that it represents a *targeted action in response to NCATS' call for highly trained scientists in adequate numbers and in appropriate research areas to carry out the nation's CTSR agenda, NIH Physician Scientist Workforce Working Group Report, National Academy of Sciences analyses and the NIH ORIP One Health Workshop: Integrating the Veterinarian Scientist into the Biomedical Research Enterprise.*¹⁻⁶ All of these national reports call for more translational scientists with training and credentials to ensure a heterogeneous workforce of clinical and translational scientists equipped with the knowledge, skills and abilities to advance diagnostics, therapeutics, clinical interventions, and behavioral modifications exists to improve health and fill the alarming gap in the research workforce that compromises our capacity to respond effectively to local and national public health threats. Future translational scientists must possess the competencies and fundamental characteristics of a translational scientist to conduct translational research and contribute to translational science. Gilliland⁷ and Austin⁸ identified these characteristics as Domain Expert, Rigorous Researcher, Boundary Crosser, Team Player, Systems Thinker, Skilled Communicator, and Process Innovator.

1c. Need for CCTSI T32 Post-Doctoral Program. The 30 existing federally funded postdoctoral programs for 168 slots at CU Anschutz and 6 federally funded training programs with 6 postdoctoral slots at CSU that provide vibrant training opportunities. When we look at CU Anschutz programs, only 4 programs with 20 slots are dedicated to preparing clinician scientists (3 for physician only trainees and 1 for physicians and psychologists) and zero are dedicated to preparing non-physician clinician scientists. The remaining 26

programs prepare both clinician (overwhelming majority MD) and non-clinician PhD prepared trainees with fluid proportions of clinician and PhD prepared trainees. **At CSU and CU, there are zero training slots available for truly multi-disciplinary training across the translational spectrum of T0.5-T4 research.** The proposed CCTSI T32 Post-Doctoral program will be the only program that emphasizes the development of knowledge and skills to be a boundary crosser, process innovator and systems thinker, in addition to domain expert and rigorous researcher with an orientation to team science. Our

Cohort	Women/total	Persists CTR (%)	Degree completion	Publication (#)	Grants
2021-22	1/3	100	Master Clinical Science; Completing PhD; Never in degree program	6	X 1 T32 X 1 Foundation X 1 Other (Co-I)
2020-21	2/3	100	3 In progress for PhD	16	X 3 T32
2019-20	3/3	100	PhD Clinical Science (x2), Microbiology (Defends June)	35	X 2 T32 X 2 Foundation X 1 Other X 1 RO1 (Co-I) X 4 Foundation (Co-I) X 5 Other (Co-I)
2018-19	2/3	100	PhD Zoonotic diseases, Never in degree program; Completing PhD	40	X 1 T32 X 1 Foundation X 1 Other X 3 RO1 (Co-I) X 1 Other (Co-I)

CCTSI TL1 program served as a catalyst and role model for other T32 programs. For instance, with our last renewal, we developed and required our CCTSI TL1 trainees to attend our team science program. After the first year of delivery, we were contacted by other T32 postdoctoral programs that wanted to participate. As a result, the program was opened to other T32 program trainees with representation from 17 of the 30 programs. We anticipate this also occurring with some of the new innovative programmatic elements we propose.

1d. Accomplishments. We will build on and extend our previous one-year TL1 combined pre- (8 slots) and post- (3 slots) doctoral program successes. Since the addition of postdoctoral trainees four years ago, **all 12 (100%) post-doctoral trainees completed the TL1 program and 100% are persistent in translational research (Table 1)**. Other indicators of program success include publications, grants and career progression. Our 12 trainees/alumni have published 97 peer-reviewed publications and secured 28 grants, 13 as Principal Investigator and 15 as Co-Investigator. Many alumni are currently holding academic faculty positions (25%), post-doctoral fellowships (17%), surgical fellowships (17%) and 33% are completing their PhD (**Table 2**). Shorter-term outcomes reveal that statistically significant improvements ($P < 0.01$) were noted in clinical research skills as measured by the validated CRAI (Clinical Research Appraisal Inventory⁹). Greatest improvements occurred for data analysis, sample size estimation, identifying collaborators outside of one's discipline, understanding the grant process and how to prepare a grant, and communicating with team members. **All (100%) alumni reported that the program greatly strengthened their commitment to conducting clinical translational research (100%), ability to be a contributing team member in conducting clinical and translational research (100%), access to mentorship and support for career development (100%)**

Table 2. Postdoctoral Alumni: Career Positions	
Cohort (3 slots/yr)	Current Position
2021-22	Following TL1 completion, 1 surgical residency, 1 DVM completing PhD, 1 university instructor (Physical Therapy)
2020-21	1 Surgeon completing PhD and 2 DVM completing PhD
2019-20	1 Surgical residency and 2 DVM completing academic post-doctoral fellowships
2018-19	1 Assistant Professor (Physical Therapy), 1 DVM completing PhD (took a LOA), and 1 Instructor (CSU) and Fellowship at Center for Disease Control

and commitment to **conducting CTR through team science (100%)**. An area for targeted improvement and commitment is increasing the

involvement of underrepresented trainees. Our target for the proposed T32 is that **25% will be URM trainees**. In the TL1 program, a postdoctoral award was not accepted by a URM. One URM trainee was offered the award but declined it for a two-year program. We are hopeful this year will change; a URM trainee was selected for the award at our May 2022 meeting and will be offered the position. See section 5e and **Attachment Recruitment Plan to Enhance Diversity**.

1e. Mission/Goal, Objectives. The CCTSI Post-Doctoral Program's goal is to meet the needs of the CTSR community by preparing diverse interdisciplinary translational scientists that are team-oriented and have developed characteristics and associated competencies necessary for successful CTSR careers. To accomplish our overall goal, the following program objectives will be met:

1. Attract, recruit and retain diverse trainees by demonstrating that Diversity Accelerates Research and Translation (DART) is a core program value and commitment.
2. Promote trainee development of foundational characteristics of Translational Scientists: Domain Expert, Rigorous Researcher, Boundary Crosser, Process Innovator, Team Player, Skilled Communicator, and Systems Thinker, and in doing so, enhance the overall scientific community.
3. Apply evidence informed mentoring practices to support developing trainees from all backgrounds for career persistence and success in CTSR.
4. Develop trainees' knowledge, skills and abilities to conduct research in diagnostics, therapeutics, clinical interventions, and behavioral modifications that improve health.
5. Support study conduct concordant with ethical and regulatory principles through required training in research ethics, RCR, GCP, regulatory compliance, rigor and reproducibility, diversity, equity and inclusion and data science principles.
6. Develop trainee's ability to communicate effectively (writing, speaking and listening) with diverse stakeholder groups.

7. Engage trainees with a new translational community and network that brings new insights, perspectives, and skills through immersion experiences with translational mentors.
8. Approach CTSR as a team endeavor and foster trainees' teaming and leading skills for high performing teams.
9. Apply the One Health Framework to culminate the integration of translational scientist competencies.
10. Identify, monitor, track, review and respond to, as necessary, indicators and metrics of an effective and successful program through continuous quality improvement.

1f. Core Value- Diversity. Diversity is instrumental for the translational workforce to advance discovery, eliminate health disparities, and achieve patient-centered outcomes in the quest for better health.¹⁰ As a result, our CCTSI T32 Post-Doctoral Program and our Workforce Development's (WD) core value and philosophy are aligned in **Diversity Accelerates Research and Translation (DART)**. A sustainable way to achieve diversity in the workforce is through training, education and career development of all individuals involved in the conduct of CTSR. Amira del Pino-Jones MD is our T32 Director of Diversity, Equity and Inclusion (DEI). Staying true to our DART value we will: 1. explicitly identify our DEI statement on the CCTSI's Post-Doctoral T32 webpages and all CCTSI's WD program webpages, 2. outreach and advertise our program to a diverse mixture of communities, 3. identify that holistic review of applications is followed and that all reviewers have received training in holistic review, 4. require all CCTSI T32 faculty and trainees to participate in DEI training provided by Dr. del Pino-Jones that addresses systemic racism, implicit bias, microaggressions, allyship, upstander, power and privilege, and mentoring trainees with differing backgrounds/experiences, 5. provide a welcoming and safe space for trainees to voice concerns and experiences and to discuss and plan next steps, and 6. ensure that Dr. del Pino-Jones connects with all awardees to inform them of her open-door policy, her desire to be a part of the mentoring team, and allyship. **Our program aim is to integrate our value of DART across all programmatic activities and mentoring relationships to create a safe, inclusive, and supportive research training environment.**

1g. Model for Persistence of a Diverse Clinical and Translational Research Workforce. Individual preparedness is necessary but not sufficient for lasting change and persistence. Integration into the clinical and translational fabric strengthens a person's connection, self-efficacy, and identity formation, thus increasing the likelihood that T32 trainees remain in the translational workforce. A conceptual framework for diversifying the CTSR workforce and driving this integration- **Model for Persistence of a Diverse Clinical and Translational Research Workforce**¹¹⁻¹³- identifies the bi-directional interaction of the individual and the environment as critical to success. The model was developed by our CCTSI colleagues, Nearing and Manson.¹³ Based on our Model of Persistence for a Diverse Clinical and Translational Workforce (**Figure 1**) and consistent with our value of DART, **five overarching strategies** will be applied.

(1) Create **pathways to CTSR** by forming strategic partnerships to achieve continuity of trainee support and collective impact. We will leverage the assets and efforts of CU's 18 pathway programs (including CCTSI partnered Summer Undergraduate Multicultural Mentoring in Translational Science, SUMMiT) to CTSR and health professional careers that begin in middle and high school continues as undergraduate, graduate and professional students and extends to staff and faculty. SUMMiT is a collaborative effort of 12 summer undergraduate programs focusing on the unique needs of traditionally underrepresented students to enhance their experience in clinical and translational research. Specifically, CU's Office of Inclusion and Outreach and the School of Medicine's (SOM) Office of Diversity and Inclusion URM programs and CSU's Offices of Student Diversity Programs and Services, Office of Inclusive Excellence, and the Diversity and Inclusion Committee of the Graduate Student Council will be leveraged to attract and recruit highly prepared applicants and trainees from diverse backgrounds (See grant sections 5b, 5e-1 and **Attachment Recruitment Plan to Enhance Diversity**). To facilitate pathways to CTSR, CCTSI (Cicutto, del Pino-Jones, Thamm, Nadeau) and university educational and training program directors and leaders (including leaders of DEI university offices Martinez, del Pino-Jones and Zimmer) will meet monthly through the Leadership Advisory Council of the CCTSI WD program to intentionally work in a coordinated and integrated fashion (See Section 2b-2).

2) **Provide meaningful research opportunities** to support identity formation as a scientist and sustain motivation to pursue and persist in CTSR careers. Engaging budding CTSR investigators in meaningful research opportunities fuels motivation and will be accomplished by a) having trainees reflect on how their research interests and career support their personal values and goals; b) having mentors assist mentees to

clarify goals and motivations; c) trainee participation in meaningful research and translational immersion experiences; and d) facilitating collaborations and teaming across the translational spectrum. Every T32 trainee will have meaningful mentored research project and translational immersion experiences, providing

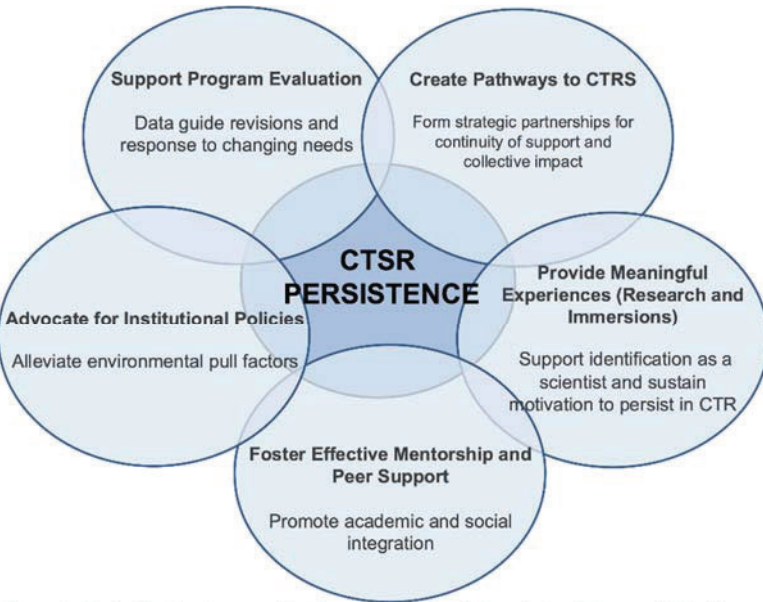


Figure 1. Model for Persistence of a Diverse Clinical and Translational Research Workforce

essential engagement for competency development, socialization, and identification and integration into the CTSR workforce. Additionally, research projects will lead to trainee presentations and publications, which build a stronger portfolio and increases their future competitiveness.

(3) Foster an environment for **effective mentorship and peer support** to promote academic and social integration. Our program will provide mentorship and peer support, two effective strategies for promoting CTSR integration.¹¹⁻¹³ T32 mentors will assist with a) setting strategic goals, b) devising pathways to success that include alternative strategies when challenges emerge, c) accessing resources and services, d) developing translational scientist competencies, and e) providing emotional support. Each trainee will have mentors for the

contexts of research, translation, and career development that will form a Mentor Advisory Team. To address the need for effective mentoring, mentees and mentors will attend the CCTSI's Mentoring³: Mentor, Mentee, Peer, a formalized program for effective mentoring relationships. URM trainees will have the support and mentorship of our DEI Director, Amira del Pino-Jones MD for contextualized support and guidance for success, including mentoring through differences in backgrounds and life experiences.

(4) Advocate for institutional policies by **alleviating environmental pull factors**. Environmental pull factors are demands that compete or conflict with trainee engagement, integration, and performance that ultimately diminish persistence. The Post-Doctoral T32 Internal Advisory Committee (**IAC**) and WD Leadership Advisory Council (**LAC**) will proactively advocate for institutional policies to support the translational workforce in their work. For example, the WD LAC advocated for required training for all workforce members regarding DEI to support a culture that values and recognizes that excellence requires diversity. As a result, policy was implemented that required DEI to be integrated into mandatory career development activities for CCTSI and university leaders, faculty, staff, and trainees. Training topics for the T32 Post-Doctoral Program (leaders, faculty, trainees) will include cultural humility, holistic review, unconscious/implicit bias, systemic racism, power and privilege allyship, and mentorship for diverse mentees and will be integrated into T32 seminars, IAC and faculty workshops, Mentoring³, and Leading and Teaming.

(5) Support program evaluation - particularly, the **examination of longitudinal outcomes** - to guide programmatic efforts and respond to changing demands. (See **Grant Section 4**)

These 5 overarching strategies identified by Nearing et al.¹³ were informed by our experience leading and evaluating programs and extensively reviewing the literature. Our T32 Post-Doctoral Program applies these lessons learned and best practices to prepare a highly qualified workforce. (See **Grant Section 3**)

2. PROGRAM PLAN

2a. Program Administration (Please see **Figure 2** for program's organizational structure.)

Director: **Lisa Cicutto RN, ACNP(cert), PhD** will serve as director (see **Biosketch**) and provide overall program leadership. (See **Table 3** for a list of responsibilities). She was selected based on her credentials in translational research that spans the T1-T4 spectrum in lung health, her extensive experience with interdisciplinary graduate students and post-doctoral trainees, experiences with interprofessional education and training programs, and importantly her leadership roles at CU Anschutz and the CCTSI. Starting in 2018, she directed the CCTSI TL1 Training Program, which included both pre- and post-doctoral awardees. In 2016, she was appointed director of CCTSI Workforce Development and has directed the Clinical Science (**CLSC**)

Graduate Program since 2008. Currently, she is a member of the national CTSA TL1 Directors' Group and the WD Enterprise Committee and was recently elected to serve on its Leadership Team. Additionally, she serves on 5 Internal Advisory Committees for R25, T32 and KL2 training/career development grants and 2 External Advisory Committees for a K and a T training program. She collaborated with PIs, Drs. Rubio (University of Pittsburgh) and Patino-Sutton (University of Southern California), in a multi-site CTSA trial to understand the effectiveness of different formats of individualized career development plans. At National Jewish Health, she is Director, Community Outreach and Research. Her research focuses on developing, evaluating, disseminating and implementing innovative best practice programs to improve health of people living with lung conditions by partnering with health providers, schools, and individuals and families. Her work has received national recognition/awards for research in underserved populations and contributions to advancing the field from Press-Ganey, Association of School Nurses, and the Canadian Network for Asthma Care. As principal or multiple principal investigators, she holds active NHLBI UG3/UH3 DECIPHeR (Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Risk) and Colorado Department of Public Health funding to improve the health of those with lung conditions living in rural and disadvantaged communities. She has held consistent external funding as a PI since 1998. Her passion is to work with, mentor, and train future clinician scientists to answer important patient/public health-oriented questions that are subsequently translated to patients/people and their communities. She has served in key roles and capacities for over 45 students related to their research with 85% remaining engaged in research. Many have gone onto receive T32, F- and K awards and independent research grants. She was awarded the teacher/mentor of the year for the CLSC Graduate Program. Dr. Cicutto will dedicate **1.8 calendar months** to provide an excellent program. She will oversee day-to-day operations; provide overall direction, management, and administration; work with CCTSI Evaluation Core; and submit all documents/reports as required. She will remain a member of the CCTSI Executive Committee, which is its governing and decision-making body that meets twice monthly.

Importantly, she will integrate and leverage training resources across the CCTSI, University, and participating programs. If Dr. Cicutto is unable to fulfill her responsibilities for the Post-Doctoral T32 program, Dr. Sokol (CCTSI PI and Director) will meet with the Program Administration and the CCTSI WD LAC to mutually decide on next steps and processes to find her replacement. In the interim, Dr. Kristen Nadeau (Associate Director; see below) will assume the Director role for the CCTSI T32 Post-Doctoral program.

Director, DEI /Mentor: **Amira del Pino-Jones MD** will serve as Director of Diversity, Equity, and Inclusion (DEI) for our CCTSI T32 Post-Doctoral Program and WD programs (See **Biosketch**). She is an Associate Professor and Assistant Dean of Student Affairs and in the DEI Office, School of Medicine. Dr. del Pino-Jones is a hospitalist improving transitions of care for under- and uninsured patients as well as improving care of patients with Sickle Cell Disease. She is an alumnus of CU high school and undergraduate URM pathway programs and is an outstanding exemplar of their success. She has rich personal experiences to share with trainees and faculty, as a woman of color growing-up in an urban disadvantaged community and part of a family that had never attended university. She will be actively involved in trainee mentoring. Importantly, she will direct our DEI strategic plan, aligned with DART (see **Section 1.e**), and be responsible for its implementation and refinement. The strategic plan will include activities for attracting, recruiting and retaining URM trainees, educational programming (implicit bias, holistic review, microaggressions, allyship, etc.) for trainees, faculty, IAC, and will oversee our holistic review process. She will work closely with the DEI offices across the University to attract, support application development, and retention of URM trainees. She supports many programs within the SOM related to DEI. Additionally, she will fulfill responsibilities outlined in **Table 3** above and dedicate **0.6 calendar months**.

Table 3. Program Administration Roles
<ul style="list-style-type: none"> Attend/receive counsel at Internal Advisory Committee & Leadership Advisory Council meetings
<ul style="list-style-type: none"> Attend program directors meeting monthly
<ul style="list-style-type: none"> Work to attract and retain diverse trainees and create environment of excellence through diversity
<ul style="list-style-type: none"> Support trainee selection process: answer questions, assist trainees/applicants in faculty matching, review applications, vet mentor selection
<ul style="list-style-type: none"> Curriculum oversight and participation in teaching
<ul style="list-style-type: none"> Organize and participate in 2x/month T32 Seminars
<ul style="list-style-type: none"> Trainee advising and mentoring: Review/update ICDP, review manuscripts & proposals, provide career advice and support management of environmental pull factors
<ul style="list-style-type: none"> Ensure trainees are current with GCP, RCR and other required regulatory training
<ul style="list-style-type: none"> Mentor Review: Attend MAT meetings with mentors and mentees to ensure research and scholarly productivity and review mentor-mentee dyad evaluation, and resolve conflict, if necessary
<ul style="list-style-type: none"> Participate in T32 faculty career development
<ul style="list-style-type: none"> Program Evaluation: Review formative and summative reports to identify areas for revision

Associate Director, CU Clinicians: **Kristen Nadeau MD, MSCS** at CU will oversee the training of clinicians. She is a CLSC alumnus and currently a Professor of Pediatric Endocrinology at Children's Hospital of

Colorado, holds several leadership positions locally and nationally (See **Biosketch**) and is a member of the Prairie Band Potawatomi tribe. She is the Research Director for Pediatric Endocrinology and its Fellowship Program, Co-Chairs the NIH Diabetes Research Center Clinical Research Core, Co-Chairs the CCTSI Scientific Advisory and Review Committee that reviews CU's CTSR protocols, directs the CLSC course in Scientific Review of Clinical Research Proposals, and is a regular member of the NIH HSDO study section. Her research focuses on reducing long-term complications of type 1 (T1D) and type 2 diabetes (T2D), inactivity and obesity in youth, including mechanisms of insulin resistance, β -cell and exercise dysfunction. She was recently awarded the American Diabetes Association Outstanding Investigator Award and the Juvenile Diabetes Research Association's Excellence in Clinical Research Award. She is Principal Investigator (PI) of a NIDDK RO1 study of bariatric surgery in youth-onset T2D, Pediatric Chair and PI of the NIDDK multi-center longitudinal RISE U01 study of β -cell preservation in obese patients with prediabetes/early T2D, PI of several NIH and foundation studies of adjunctive therapies to improve insulin resistance and cardiovascular disease in T1D, and Co-I of an NIH U01 multi-center gestational diabetes prevention study in American Indian girls. She also has an interest in sex and ethnic differences and underserved populations. She is PI of an NHLBI K24 grant focused on mentoring K23 trainees on cardiovascular research. She has mentored over 100 junior faculty, fellows, graduate and undergraduate students across multiple departments. She currently directs the CU Medical School Mentored Scholarly Activity Research Course in which she pairs medical students with research mentors and supports their research training. If the CCTSI T32 Program is funded, she will step away from this directorship to make time for the program. However, this experience will be leveraged to engage and recruit medical trainees into the program. In addition to attracting and recruiting trainees, another important role is supporting trainees is finding translational mentors and immersion experiences. Dr. Nadeau will fulfill responsibilities outlined in **Table 3** and dedicate **0.6 calendar months**.

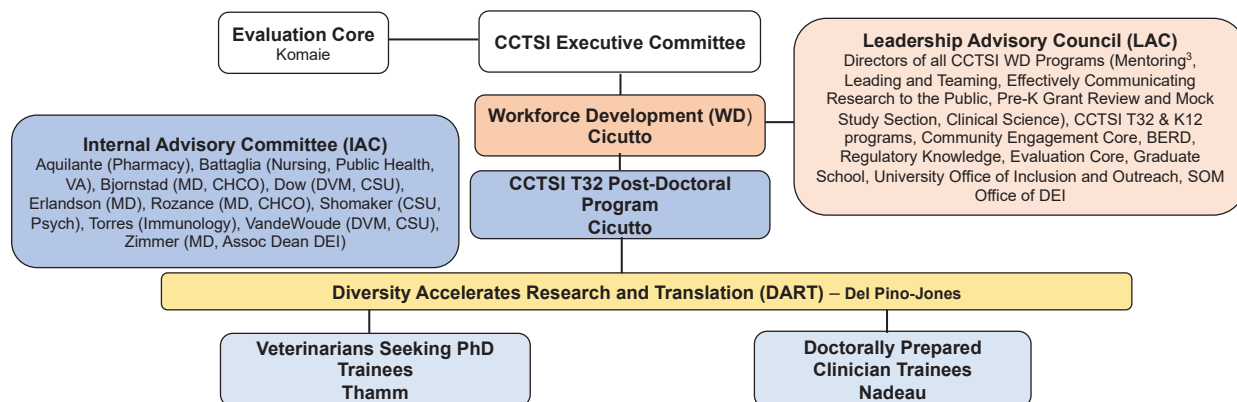
Associate Director, Veterinary Trainees: Douglas Thamm, VMD, DACVIM (Oncology) at CSU's College of Veterinary Medicine and Biomedical Science (**CVMB**) will oversee the training at CSU for veterinary medicine trainees (See **Biosketch**). He is the Barbara Cox Anthony Professor of Oncology and Director of Clinical Research at Flint Animal Cancer Center, overseeing the Clinical Trials Program in addition to running a NIH-funded translational laboratory dedicated to exploring novel therapeutics and therapeutic combinations in human and animal cancer models and providing pharmaco-dynamic support for ongoing clinical cancer trials. His laboratory focuses on therapeutic targets in human oncology that have parallels in spontaneous tumors of animal species sharing the environment with humans. His laboratory's work has involved tyrosine kinase signaling in animal cancer cells, validation of biomarkers for novel therapeutics, enhancement of cancer cell chemosensitivity, and use of modern adoptive cell transfer immunotherapies such CAR-T cell therapy in canine cancers as models for human cancers in translational studies with the CU Cancer Center. Dr. Thamm's laboratory is supported by pharma collaborations, private foundations, and the NIH. Dr. Thamm has served as primary mentor for 13 graduate and DVM/PhD students and as committee member for an additional 31 graduate students. His extensive research and mentoring experience and commitment to post-DVM graduate education and research will provide strong leadership for the program. Dr. Thamm was an Associate Director of the TL1

program last cycle and is dedicated to taking lessons learned to grow and make the program the best it can be. He will fulfill

responsibilities outlined in **Table 3** and will dedicate **0.6 calendar months**.

Galit Mankin, BA, MSW has extensive experience and skill for managing and administering training programs. For 13 years she has served as Program Administrator for the CLSC Program, and for the last 6 years, program administrator for the CCTSI WD and the TL1 program. Ms. Mankin will work closely with the Directors

Figure 2. Organizational Chart of CCTSI T32 Post-Doctoral Program



to coordinate recruitment and selection of new trainees; communicate program information, maintain and update the website and distribute program brochures/advertisements; support the IAC, program and faculty meetings, T32 seminars and other programmatic activities; track and report records for trainees to ensure compliance with NIH guidelines/ regulations (such as GCP, RCR, etc.); manage the xTrain system; and collect/compile annual progress reports and alumni curriculum vitae.

2b. Oversight Committees

2b-1 Internal Advisory and Candidate Selection Committee (IAC): The IAC is comprised of faculty that represent the SOM and their Office of Diversity and Inclusion, the College of Nursing, School of Pharmacy and CSU's CVMBS. It will meet three to four times a year to review applicants for upcoming awardee positions, assess trainee progress and program continuation, and to assess the program's progress. All committee members have mentored trainees conducting translational research and have training program experience through academic programs and past/present T-type training program experience. Members will serve a 5-year term and include Drs. Aquilante, Battaglia, Bjornstad, Dow, Erlandson, Rozance, Shomaker, VandeWoude, and Zimmer. All members have agreed to serve on the committee and have outlined their commitment in the attached letters. (See **attachment Internal Advisory Committee**)

2b-2 CCTSI Workforce Development Leadership Advisory Council (LAC): The T32 Post-Doctoral Program (if funded) will be part of the CCTSI's WD LAC (See **Figure 2**), which consists of directors and leaders of all WD programs, Director of DEI (del Pino-Jones), CCTSI K12 (pending funding), T32 Pre-doctoral Program (pending funding), CCTSI Evaluation Core, other CCTSI initiatives (Community Engagement, Innovation Ecosystem, BERD), the Graduate School, and the University's Office of Inclusion and Outreach. The LAC uses shared decision making and will meet monthly to review all programs' activities (including the T32 program), metrics and outcomes, discuss integration across programs (WD, T32 and K12 programs, CCTSI and university), progress towards milestones, need for revision and current events/issues. The LAC will ensure coordination, integration, synergy, and mutual reinforcement among all CCTSI programs and activities. The LAC has proved extremely valuable to ensure that education/training leaders are aware of one another's services, have the agility to collaborate/integrate across programs, leverage resources, avoid reinventing the wheel and competing with one another. An example of a benefit was the creation of the teaming program, which was a collaborative effort of the CCTSI, the Graduate School, SOM, and CSU. It has also been instrumental for operationalizing our value of DART through a strategic planning process. Through our strategic planning process with the last TL1 renewal, we identified that some programs and faculty were not implementing best practices. Our strategic planning process unified our approaches for attraction, recruitment, and holistic review. (See **attachment Coordination and Interaction**)

2b-3 CCTSI Executive Committee: To integrate the CCTSI Post-Doctoral Program into the larger CCTSI community and infrastructure, Dr. Cicutto is a member of the CCTSI Executive Committee that twice monthly to communicate, coordinate and integrate activities. Following the selections of T32 awardees by the IAC, the slate of recommended awardees will be presented to the Executive Committee for funding approval.

2b-4 CCTSI External Advisory Committee: The CCTSI's External Advisory Committee meets yearly. The T32 Post-Doctoral Program will be reviewed by members to advise on our objectives, milestones and metrics. Committee members will meet separately with current trainees, without program leadership, to identify issues, resource needs and areas for improvement. Additionally, our alumni provide presentations to the committee regarding their research, program experiences, accomplishments and future directions. The committee consists of senior faculty that represent CTSA hubs across the country that include Oregon Health Sciences, University of California- Irvine and Los Angeles, Vanderbilt, Virginia Commonwealth, Cincinnati, and Yale.

2c. Program Faculty

2c-1 Faculty Selection and Pool: We have a diverse group of 111 talented and experienced interdisciplinary research faculty (**Table 4**) to potentially serve as research mentors for our postdoctoral trainees. **Table 5** below provides a representative sample, not including Program Administration. All have active graduate faculty appointments, active CCTSI membership, and have a track record of success in training new investigators. All are highly accomplished clinical and translational scientists, with 63% at the rank of full professor. The largest

proportion are physician scientists (50%), 41% are females, and 11% are Black, Indigenous or people of color (BIPOC). Mentors represent the full T0.5-T4 research spectrum and all participate in more than one translational category: 32% in T0.5, 65% in T1, 60% in T2, 58% in T3 and 15% in T4. Many have had, or currently hold, leadership roles at national or international levels by serving on grant review panels, editorial boards of major journals, as officers of major scientific societies, and organizers at major scientific conferences. Collectively, our research faculty mentors currently hold research grant funding as a PI with total annual direct costs of approximately \$107.5 million in external funding, averaging \$968,000 in grant support per faculty member (See **Required Table 4**). Taken together, the faculty research mentors represent diversity in scientific specialty and discipline, gender, race/ethnicity, and background, and provide a critical mass for trainees in their development to advance CTSR.

Table 4. Features of Research Mentors (n=111)	
Doctoral Degree(s)	
- DVM/PhD	12 (11%)
- DVM or VMD	2 (2%)
- MD	36 (32%)
- MD/PhD	20 (18%)
- Clinician, non-MD/PhD	8 (8%)
- Clinician, non-MD	3 (3%)
- PhD	30 (27%)
Rank	
- Assistant Professor	6 (6%)
- Associate Professor	34 (31%)
- Professor	71 (63%)
Translational Spectrum	
- T.5 Shared animal-human disease	35 (32%)
- T1 Pre-clinical	72 (65%)
- T2 Patients	67 (60%)
- T3 Clinics	64 (58%)
- T4 Community/public health	17 (15%)
Female	46 (41%)
BIPOC	12 (11%)

Our research faculty mentor pool is fluid in that trainees can introduce new faculty to the pool given they meet the requirements to serve as a mentor, are vetted by Program Administration and found to be appropriate. Applicants identify their research mentors in T32 applications, and the strength of the trainee’s mentoring team is a criterion scored during application review. If an applicant does not have a defined mentor, Program Administration will assist the applicant in finding and selecting a mentor. All research mentors of awarded CCTSI T32 Post-Doctoral trainees will be vetted by Program Administration (Cicutto, Nadeau, Thamm, del Pino-Jones). Criteria for serving as a primary research mentor include: 1) demonstration of a deep commitment and excellence for mentoring early investigators as evidenced by their track record; 2) active peer-reviewed research funding; and 3) active involvement in CTSR as evidence by their publication history. If gaps are identified with the proposed research mentor, Program Administration will work with the mentor and mentee to identify an additional senior mentor that fits our research mentor criteria. In addition to senior faculty, we have also included “rising star” junior faculty (Calcaterra, Feldman, McGilivray, Kading, Olson, Regan) who recently received national research funding. Although early stages in their academic careers, they all hold graduate faculty appointments indicating active involvement in mentoring trainees. These rising stars will be paired with a more established research mentor creating a junior-senior mentoring relationship to support trainees. Early career faculty participation will ensure growth of the mentor pool and strengthen the program by serving as more relevant mentors because they more recently completed their postdoctoral training and successfully launched their own academic careers. A beneficial consequence of young faculty’s involvement is that they will gain valuable mentoring experience.

In addition to research mentors, postdoctoral trainees are required to have a translational mentor for the completion of an immersion experience, which will be discussed in more depth below. This is also a reviewed and scored element of the T32 application. All immersion mentors will have previous experience with mentoring trainees in their respective settings, be committed to the trainee and have clearly demonstrated a plan for the immersion experience as demonstrated in their Letter of Support. Program Administration will assist trainees with the identification of translational mentors, if needed. Translational mentors will serve on the trainee’s Mentoring Advisory Team (**MAT**) and their PhD thesis committee (CSU trainees) or MSCS Final Examination committee (CU trainees). These mentors are not included in our grant faculty tables.

2c-2 Faculty Oversight and Removal: There may be times when a mentor changes institutions or needs to be removed for various reasons, such as poor performing mentoring relationship, conflicts of interests, personality clashes, or lack of resources. Program Administration and the IAC will carefully monitor annual mentee-mentor assessments in conjunction with their semi-annual Mentoring Advisory Team (**MAT**) reports and monthly check-ins with mentees and will arbitrate the removal of a mentor if necessary. (**Attachments Mentoring Assessment and Internal Advisory Committee**). Should this occur, Program Administration will assist the trainee to find an appropriate substitute. In the case of a lapse in funding affecting a faculty mentor with a T32 trainee, the mentor will be required to submit a plan to the IAC that identifies a source for continued

trainee funding. We are committed to our trainees for the time required to complete their degree (MSCS or PhD) and prepare for a successful academic career.

Table 5. Potential T32 Post-Doctoral Program Faculty Research Mentors (CU and CSU)					
Mentor	Title/Appointment/Institution/	Department or Training Program	Area of Research Expertise	Research Funding	Post docs
Steve Abman, MD	Professor, SOM AMC, CHCO	Pediatrics Pulmonary, Director	Role of inhaled NO in diverse clinical settings	2X RO1, R38, UG3	14
Ramesh Akkina, DVM, PhD	Professor, CVMBS, CSU	Microbiology, Immunology and Pathology	HIV and Dengue virus, gene and antimicrobials in humanized models	R21	15
Peter Anderson, PharmD, PhD	Professor, SOP AMC	Pharmaceutical Sciences	Optimize drug therapy in humans	4X RO1, 2X UM1, U19	4
Randall Basaraba, DVM, PhD	Professor, CVMBS, CSU	Microbiology, Immunology and Pathology	Mycobacterial pathogenesis synergism and diabetes	1X U19, 5X other NIH	2
Catherine Battaglia, RN, PhD	Associate Professor, CON, CSPH AMC, VA	Health System Management Nursing, Clinical Science	Health services research, dissemination/implementation of interventions and mixed methods	2X I50, Other Fed grant	13
Richard Bowen, DVM, PhD	Professor, CVMBS, CSU	Biomedical Sciences	Zoonotic infectious diseases, modeling, animal models	R21, 7X other NIH, 8X other	3
Russell Bowler, MD, PhD	Professor, SOM, NJH	Pulmonary Medicine	Multi-Omics research in obstructive lung diseases	2X RO1	7
Sheana Bull, PhD	Professor, CSPH, DH	Community and Behavioral Health	Mobile and social media technologies for health promotion	UH3	6
Ellen Burnham, MS, MD	Professor, SOM AMC	Critical Care	Alcohol and lung Injury and Immunity	R21, R24, R01	7
Cory Christiansen, PhD	Professor, SOM AMC, VA	Physical Medicine & Rehabilitation	Optimizing physical health for older adult patients	RO1, 2X IO1, UO1, UG3	10
Gregg Dean, DVM, PhD	Professor, CVMBS, CSU	Microbiology, Immunology and Pathology	Viral Immunopathogenesis, Mucosal immunology, Vaccine development	2X R01, R21, Other NIH	5
Kevin Deane, MD, PhD	Associate Professor, SOM AMC	Rheumatology	Influence of genetic and environmental factors on the development of RA	P30, Other Fed grant, Univ	10
Robert Dellavalle, MD, PhD	Professor, SOM, VA	Dermatology	Skin disease prevention and dermatoeidemiology	R01	11
Ivor Douglas, MD	Professor and Chief, SOM, DH	Pulmonary and Critical Care Medicine	Immunoregulation, recovery from critical illness -ARDS and sepsis	R01, 2X UO1	3
Steven Dow, DVM, PhD	Professor, CVMBS, CSU	Clinical Sciences, Flint Animal Cancer Center, Small Animal Internal	Liposome-based vaccines/ immunotherapeutics, cancer immunology/immunotherapy	U01, Other Fed, 2X Foundation, 2X Other	15
Stephen Dreskin, MD, PhD	Professor SOM, NJH	Immunology	Functional IgE-allergen interactions and food allergies	R03, R01	12
Gregory Ebel, SM, ScD	Professor, CVMBS, CSU	Microbiology, Immunology and Pathology	Arboviral genetic diversity and adaptation to host and vectors	R01, R21, 2X F series,	11
Kristine Erlandson, MD, MSCS	Associate Professor, SOM	Infectious Diseases	Aging among persons living with HIV	3X R01, R21, UO1, Univ grant	8
Ana Fernandez-Bustamante MD, PhD	Associate Professor, SOM AMC	Anesthesiology	Pulmonary insults, lung inflammation and injury in humans	UH3, Other Fed grant	7
Joseph Frank, MD	Associate Professor and Director, VA	Internal Medicine, Chronic Pain & Wellness Center	Chronic pain management and health services research	Fdn grant, 3X Other Fed grant	4
Robert Fuhlbrigge, MD, PhD	Professor, SOM AMC, CHCO	Pediatric Rheumatology	Pediatric rheumatology	RO1, Fdn grant	17
Debashis Ghosh, PhD	Professor and Chair, CSPH	Biostatistics and Informatics	Biostatistics, bioinformatics, biomarker discovery in cancer	UO1, RO1, Fdn grant	11
Adit Ginde, MD	Professor, SOM AMC	Emergency Medicine, Anesthesiology	Multicenter translational clinical trials in acute care	2X UO1, R01, 6X Other Fed	13
Laurie Goodrich, DVM, PhD	Professor, CVMBS, CSU	Clinical Sciences, Orthopaedic Research	Cartilage healing; growth promotion mechanisms of stem cells	2X Other Fed, 3X Other	4
Melissa Haendel, PhD	Professor, SOM AMC	Research Informatics & Biochemistry and Molecular Genetics	Translational informatics, interoperability and semantic engineering	RM1, 2X U24, 2X U2C, R24, Fdn grant	5
Terri Hernandez, RN, PhD	Professor, Associate Dean Research, CON,	Nursing, Endocrinology, Metabolism & Diabetes	Nutrition, metabolic health, and early life exposures	RO1, Fdn grant	7
Michael Ho, MD, PhD	Professor, SOM, VA	Cardiology	Quality and outcomes of cardiovascular care	UH3, Other Fed grant	27
Jodi Holtrop, PhD	Professor, SOM AMC	Family Medicine	Obesity prevention and treatment in primary care, mixed-methods	R18	15
Edward Hoover, DVM, PhD	Professor, CVMBS, CSU	Microbiology, Immunology and Pathology	Pathogenesis and intervention for retrovirus and prion infections	R01	3
Antonio Jimeno, MD, PhD	Professor, SOM AMC	Medical Oncology	Developing cancer molecular therapeutics	RO1, Fdn grant	8
Melanie Joy, PharmD, PhD	Professor, SOP AMC	Pharmaceutical Sciences	Developing cancer molecular therapeutics	RO1	2
Rebekah Kading, PhD (Jr Faculty)	Assistant Professor, CVMBS, CSU	Microbiology, Immunology and Pathology	Transmission dynamics of vector-borne pathogens, arboviruses	R21, NSF Sub, 2X Other Fed	2

Allison Kempe, MD	Professor, SOM AMC, CHCO	Pediatrics	Community translational and outcomes research	R01	21
Jennifer Kiser, PharmD, PhD	Professor, SOP AMC	Pharmaceutical Sciences	Drug interaction studies with antivirals	RO1, 2X UM1	4
Kirk McGilivray, PhD (Junior Faculty)	Assistant Professor, Engineering, CSU	Mechanical Engineering	Relationship(s) between biomechanics and biology following disease, trauma, and surgical intervention	R01, Other Fed, 5X Other	1
Andrew Monte, MD, PhD	Associate Professor, SOM, DH	Emergency Medicine	Medical toxicology	R35, R21	3
Ernest Moore, MD	Professor, SOM, DH	Surgery	Gut ischemia in the pathogenesis of distant organ injury, trauma	4X Other Fed grants, RM1	24
Lee Newman, MD	Professor and Director, SOM, CSPH	Center for Health, Work & Environment	Occupational health surveillance, lung disorders, workplace health and safety	R01, U19, Other Fed grant	26
Jerry Nick, MD	Professor, SOM, NJH	Pulmonary and critical care	Lung exacerbations and interferon-stimulated genes	2X R01, 4X Fdn,	7
Rocio Pereira, MD	Associate Professor, SOM, DH	Endocrinology, Metabolism, and Diabetes	Adipose tissue dysfunction, insulin resistance in Latinx populations	Fdn grant	2
Daniel Regan, DVM, PhD (Junior Faculty)	Assistant Professor, CVMBBS, CSU	Clinical Sciences, Flint Animal Cancer Center, Pathology	Cancer pathology, role of the lung microenvironment in metastasis, exosome biology	R03, Other NIH, 13X Other	3
Scott Sagel, MD, PhD	Professor, Director, SOM, CHCO	Pediatrics, Cystic Fibrosis Center	Biomarkers of lung disease in children with CF	U54, 2X Fdn grants	11
Lauren Shomaker, PhD (Psychology)	Associate Professor, CSU	Human Development and Family Studies	Role of social stress and depression in obesity and cardiometabolic disease	2X Other Fed grant, Fdn grant	4
Ron Sokol, MD	Professor, CHCO, Vice Chancellor Clinical Translational, Director (PI) CCTSI	Pediatric Gastroenterology, Hepatology, Nutrition	Chronic cholestatic, genetic/metabolic/mitochondrial liver diseases of infancy and childhood, and mechanisms of hepatocyte injury and cell death	UL1, UO1, Fdn grant	20
Jennifer Stevens-Lapsley, DPT, PhD	Professor, SOM, VA	Physical Therapy and Rehabilitation,	Clinical trials of patients with total knee and hip replacements	4X R01, Other Fed grant	11
Glenn Telling, PhD	Professor, CVMBBS, CSU	Microbiology, Immunology and Pathology	Molecular events in prion propagation, strain generation, and species barriers	2X R01, Other NIH	5
Kenneth Tyler, MD	Professor, Chair, SOM AMC	Neurology	Viral infections of CNS, model development	RO1, Other Fed grant	4
Susan VandeWoude, DVM, PhD	Professor, CVMBBS, CSU	Microbiology, Immunology and Pathology; CSU CCTSI Director	Trans-species infectivity, and co-evolution of HIV-like retroviruses of domestic and nondomestic felids	R21, 2X Other NIH, 3X NSF, Other	7

2d. Mentoring

Program objective- Apply evidence informed mentoring practices to support the development of trainees from all backgrounds for career persistence and success in CTSR.

2d-1 Mentoring Oversight: Effective mentoring is crucial for program retention, trainee productivity and satisfaction, engagement with CTSR community and persistence in the field. Mentees with influential and sustained mentoring are more likely to remain in research, publish more papers, become PIs, and mentor others.¹⁴⁻¹⁶ Evidence informed practices applied will include: 1) signed Expectations for Mentoring Agreements, 2) development and regular review of Individualized Career Development Plans (**ICDP**), 3) completion of Mentoring³: Mentor, Mentee and Peer, an effective mentoring training program attended by both mentors and mentees, 4) annual mentor-mentee dyad reviews with feedback, and 5) trainee MAT reviews with feedback.

Each CCTSI T32 Post-doctoral trainee will have a **Mentoring Advisory Team (MAT)** that consists of a research mentor, a translational mentor, and a T32 director mentor. The MAT will meet twice yearly to review and revise the trainee's **Individual Career Development Plan (ICDP)** and review progress regarding trainee's development of knowledge, skills and abilities to advance CTSR. Mentees can also call a MAT meeting whenever they feel the need for support, clarity or to advance their ICDP. MATs are a strategy to effectively coordinate training and mentorship responsibilities among team members, prevent conflicting guidance and help trainees broaden their professional networks.

Steps will be taken to ensure mentor commitment and time devoted to the trainee. In their Letters of Support accompanying the trainee's application, research and translational mentors will be required to explicitly identify their time commitment to the trainee. Additionally, the research mentor will be required to sign both the ICDP and the Expectations for Research Mentoring Agreement. Research Mentoring Agreements will be signed and returned to program administration within the first month of the award and explicitly identify the need for weekly trainee meetings, attendance at T32 seminars when their trainee is presenting, regular review and updating of the ICDP, and attendance at MAT meetings (twice yearly). The T32 Expectations for Research Mentoring

Agreement is based on the Association of American Medical Colleges Group on Graduate Research, Education, and Training compacts for mentors and mentees.¹⁷ T32 core program administration mentors will regularly (monthly) check-in with trainees to ensure that they are experiencing mentor engagement and that there is a good match. Additionally, the T32 IAC will provide mentoring oversight in several ways: annually, IAC members will 1) meet with each trainee to learn of their progress, program experiences and needs; and 2) review each trainee's mentoring dyad assessment report provided by the CCTSI Evaluation Core to identify quality of mentoring and at-risk mentoring relationships. Assessment and evaluation of our mentoring efforts are important to understanding effectiveness and need for improvement and modification. The CCTSI Evaluation Core will complete annual 360 mentoring assessments where mentees report on their mentor's performance, their own performance, and the mentoring relationship and mentors report on their mentee, their own performance, and the mentoring relationship. (See **Attachment Mentoring Assessment Plan**). This will be completed upon program entrance, and towards the end of years one and two. Additionally, trainees will be surveyed about mentorship provided by Program Administration twice yearly.

2d-2 Creating Effective Mentoring Relationship: The CCTSI and our T32 program are committed to providing excellent mentorship through the provision of important infrastructure and processes. The CCTSI WD, CCTSI T32 Post-Doctoral Program and other T32 programs will collaborate to develop and provide a new bi-directional program that all mentors and mentees will complete, called **Mentoring³: Mentor, Mentee and Peer**. This will include 12 hours of training that involves sessions with mentors only, mentees (trainees) only, and mentor-mentee dyads to optimize the mentee's experience and the mentee/mentor relationship, improve the skills of mentors, and teach mentees how to mentor others. Our curriculum and approach are based on best evidence practices from CIMER¹⁵ (Center for the Improvement of Mentored Experiences in Research (CIMER); <https://cimerproject.org>) and our established CO-Mentor¹⁷ program. Members of our CCTSI WD team (CO-Mentor: Austin and Libbey, KL2: Burnhum, Teaming: Cross) will continue to serve as leaders in professional development programs to build skills in mentoring at a national level¹⁸⁻²¹ by participating in the development and provision of this program. Mentoring³ will be directed by Bruce Mandt PhD, Assistant Dean-Graduate School and the Postdoctoral Office and Career Development Office. He has completed CIMER (including Entering Mentor Facilitator Training) and CO-Mentor programs and has extensive experience developing and facilitating workshops on mentorship and mentoring relationships, as well as other career development topics and skills. Mentoring³ will include aligning expectations, addressing equity and inclusion, articulating your mentoring philosophy and plan, ethical behavior in research, enhancing work-life integration, fostering independence and mentee self-efficacy, well-being, and career development skills. Specific to DEI, Dr. del Pino-Jones MD, our T32 DEI Director, will provide training to all mentors and mentees on micro-aggressions, implicit bias, mentoring across differing life experiences, and other topics. Mentoring³ will begin with a 2-hour workshop attended separately by mentors and mentees and designed to be a primer for understanding benefits and traits of effective mentoring, roles and expectations, and ICDPs. Mentors and mentees will attend workshops separately to develop individual skills and as mentee-mentor dyads for two workshops. Mentor-mentee dyad workshops will be separated by 8-10 weeks to allow for application of skills following workshop attendance and feedback from workshop faculty. To develop a pool of faculty trainers for Mentoring³, a train the trainer program involving workshops and resource materials will be developed and provided to mentoring faculty. In this way, we will foster a culture for effective mentoring practices to create safe, inclusive and supportive environments for trainees to excel.

3. PROPOSED TRAINING

Best practices for adult learning will be applied in our CCTSI Post-Doctoral T32 Program. Methods and practices that actively involve learners in acquiring, using, evaluating, and reflecting on new knowledge and practice have the most positive consequences on learner outcomes.²²⁻²³ The literature also demonstrates that the most effective practices integrate multiple methods for learning, such as didactic training, small group interactive learning, experiential and applied learning with feedback provision occurring in groups of no more than 30 learners, provided over multiple occasions.²²⁻²³ Program **learning outcomes for T32 trainees are:** Following 2 years of CCTSI T32 Post-Doctoral Program participation, trainees will:

1. Exhibit foundational characteristics of Translational Scientists: Domain Expert, Rigorous Researcher, Boundary Crosser, Process Innovator, Skilled Communicator, Team Player, and Systems Thinker.

2. Possess Individualized Career Development Plans (ICDP), which incorporate the 7 domain characteristics of translational scientists.
3. Exhibit regulatory, operational, and scientific competencies that advance clinical and translational sciences across the translational spectrum and project life course through comprehensive educational programming tailored to address the trainee's learning needs.
4. Demonstrate effective scientific communication for multiple audiences.
5. Exhibit research practices concordant with research ethics, RCR, GCP, regulatory compliance, rigor and reproducibility and data science principles.
6. Report being part of a new translational community and network with new insights, perspectives, and skills because of immersion experiences with translational mentors and their communities.
7. Demonstrate effective skills in teaming and leading necessary for high performing teams that advance CTSR.
8. Demonstrate ability to integrate, synthesize and apply Translational Scientist domains during a One Health Hackathon.

Refer to **Table 6-8**, for a listing of program elements supporting the development of successful and persistent translational scientists and how trainee outcomes are achieved.

3.1 Exhibit foundational characteristics of Translational Scientists: Domain Expert, Rigorous Researcher, Boundary Crosser, Process Innovator, Skilled Communicator, Team Player, and Systems Thinker.

Translational Scientist Seminars will provide the building blocks and space to practice, integrate and refine trainee's knowledge, skills and abilities to become successful translational scientists (See **Table 6**). Seminars are required for trainees, held every two weeks for two hours, and will showcase and support development of foundational characteristics of translational scientists. These Translational Scientist seminars will be held as part of a graduate course that can be applied to the Master of Science in Clinical Science (**MSCS**; CU trainees) or the PhD (CSU trainees). To kick off the program, the first seminar will introduce awardees to the program, differences between clinical and translational research and clinical and translational science and to the foundational characteristics of translational scientists. The point will be made that CTSR is not an individual endeavor but rather a team endeavor and that success requires a good working knowledge in all translational scientist domains and the ability to work as a high performing team with shared learning and problem solving to overcome bottlenecks and challenges in clinical translational research and to contribute to the field of translational science. Seminars will lay the groundwork for this success by addressing regulatory, operational, and scientific topics and highlighting the application of translational scientist domains. Our trainees will represent a mix of clinical disciplines, bodies of knowledge, translational spectrum (T0.5-T4), and backgrounds. This rich mix of perspectives, experiences and expertise will be shared through trainee presentations and dialogue. Seminar formats will always engage trainees in dialogue, identification of issues and exploration of approaches and solutions. These seminars will create the structural model for a learning community of translational scientists by including the fundamental elements of domain of knowledge, a community of people and a shared practice of developing as translational scientists.²⁴ This will be brought together by trainees annually presenting on their ICDPs (with a review of each translational scientist domain), research in progress presentations, and translational scientist practices. Presentations will have them discuss their research across the translational spectrum, team-driven research, bottlenecks and possible solutions in research and application of the translational scientist domains. Program directors will organize, lead, teach, and facilitate Translational Scientist seminars. Many seminars will involve CCTSI Post-Doctoral faculty mentors to provide instruction and lead discussion on important topics. For example, Melissa Haendel PhD, Chief Research Informatics Officer for the University and Professor in Biochemistry and Molecular Genetics, Epidemiology and Tell Bennett MD, MS, Director of CCTSI Informatics Core, Associate Professor of Pediatrics will speak about informatics and data sharing, cloud and information architecture, clinical data interoperability, and development and deployment of novel computational models and tools for real-time clinical decision support. CCTSI postdoctoral alumni will attend to share their lessons learned, provide input into current trainees' ICDPs, and to share their own journeys of career transition. A significant proportion of trainees will interact and collaborate or develop careers with industry, government/regulatory, or non-governmental

organizations (NGO). As such, it is important to include seminars involving scientists working in these sectors. We are fortunate to have several avenues to identify industry, government/regulatory, and NGO scientists that include CCTSI T program alumni, CLSC alumni, and industry members of the Academic Industry Alliance, which strengthens connections between academia and local industries. These non-academic sector seminar speakers/facilitators will cover academia-industry collaborations, industry sponsored research, research sub-

contracting, non-academic careers and responsibilities, pros/cons and similarities/differences between academia and non-academic sectors (industry, NGO, govt), negotiation, and building networks outside academia. Additionally, we will invite teams that represent industry-academic partnerships to present their research and experiences highlighting projects in diagnostics and therapeutics. These events are intended to develop the working knowledge needed for trainees to understand and prepare for the next step in the varied research career options in the CTSR workforce.

Other activities and topics include research issues from T0.5 to T4, entrepreneurship, partnering with communities and community engaged research, effectively translating research across target audiences (patients, citizens, researchers, clinicians, funders, and policy makers), grant and manuscript writing, rigor and reproducibility, DEI in research, issues in conducting clinical trials, and networking opportunities. Examples of presenters include Montelle Tamez, CCTSI Community Engagement Core discussing community engaged research and partnering with community; Ben Echaliier MS, MBA, CCRP, Associate Director, Regulatory and Trials Operations discussing challenges in performing clinical trials and drug development, and Cathy Bodine PhD, Director of CCTSI Innovator Ecosystems discussing commercialization and the start-up ecosystem. (See **Attachment Coordination and Interaction Plan**)

Program Element	Translational Scientist Characteristics	Trainee learning outcome (see list above)
Individualized Career Development Plan (ICDP) Goal/objective identification for each translational scientist characteristic	Section for each domain: DE, RR, BC, PI, ST, SC, TP	1,2
Mentorship: Mentoring Advisory Team (MAT)	DE, BC, PI, ST, SC	1,2,3,4,5
Mentored Research Project (<i>Integrated into coursework towards MSCS or PhD degree</i>)	DE, RR, BC, PI, ST, SC, TP	1,3,5,7
Immersion Experience with Translational Mentor	DE, BC, ST, PI, SC,TP	1,3,4,5,6,7
Seminars for Translational Scientists (<i>Incorporated into coursework towards MSCS or PhD degree</i>)	BC, PI, ST, SC, TP,RR	1,2,3,4,5,6,7
Ethics, RCR, GCP, DEI in research (<i>Includes coursework towards MSCS or PhD degree</i>)	PI, RR, SC, TP	1,3,5
Rigor and Reproducibility (<i>NEW</i>)	DE, PI, RR	1,3,5
Teaming and Leadership in CTSR (<i>NEW; Incorporated into coursework towards MSCS or PhD degree</i>)	BC, SC, TP	1,4,7
Mentoring ³ : Mentor, Mentee, Peer (<i>NEW</i>)	BC, SC, TP	1,2,5,7
Effectively Communicating Research (<i>NEW</i>)	BC, SC	1,4
Pre-K Grant Review and Mock Study Section	DE, SC, RR	1,3,4,5
Writing Accountability Group (<i>NEW; incorporated into coursework towards MSCS or PhD degree</i>)	SC, RR	1,3,4,5
Science on Tap (a Café Scientifique) (<i>NEW</i>)	BC, ST, SC	1,4
ACTS/CTSA Conference	SC	1,4,5
Translational Scientists Characteristics: Domain Expert (DE), Rigorous Researcher (RR), Boundary Crosser (BC), Process Innovator (PI), Systems Thinker (ST), Team Player (TP), and Skilled Communicator (SC)		

An additional purpose of Translational Scientist seminars is to support identity as a clinician translational scientist and to create a community of practice for clinician translational scientists. Concerns about the sustainability of this workforce have been expressed for decades.²⁵ Although recommendations have been made to increase the workforce, room for improvement remains. A recent international expert meeting identified new gaps to address that include articulating the value proposition of clinician scientists, supporting professional identity, and the integration of practice (service provision) and research.²⁵ The importance of these identified gaps is supported by our Model for Persistence of a Diverse Clinical and Translational Research Workforce and begins to work towards system-level changes. During our seminars, we will work as a community of practice to address these gaps. Together we will: 1) articulate the value proposition of clinician scientists- this will help trainees articulate the added value of the clinician-scientist role within the health and clinical and translational research system; 2) support professionalization and professional identity to explore and develop a collective culture with distinct understandings of the social purpose and meaning of the clinician translational scientist, and; 3) support and role model the integration of clinical practice and research by addressing clinical and translational scientist domains in the context of clinical practice. Many aspects of the

dual clinician–translational scientist role can create confusion and threaten professional identity, including vague job descriptions that may cause a “blurring of boundaries,” which can lead to a lack of professional identity resulting in poor retention.²⁵⁻²⁷ This training program will support affirmation of professional identity through internalization of roles, responsibilities, values, and ethical standards and address the call for explicit integration of clinical and research thinking, which are the characteristics of a clinician translational scientist.

Table 7. Attaining regulatory, operational, and scientific competencies for CTSR: Alignment with Degree Programs (MScS and PhD)			
Competency Area	Courses	Timing	Translational Scientist Domain
Biostatistics	Applied Biostatistics I & II or Design and Data Analysis for Researchers I & II	Year 1	RR
Study Design	Epidemiology, Design and Conduct of Clinical Trials, Planning Research and Grant Proposals	Year 1	RR
Ethics & RCR (Regulatory)	Ethics and Responsible Conduct of Research, Responsible Conduct of Research	Year 1	RR
Critical Appraisal Rigorous Research	Critical Appraisal and Rigor of Clinical Studies or Critical Analysis of Scientific Literature	Year 1	DE, RR
Scientific Writing	Grant Writing and Disseminating Research: Manuscript Preparation and Rigorous Reporting (Using WAGs)	Summer & Year 2	SC, DE
Operational & Regulatory Foundations	Conducting Clinical Trials for Investigators: Regulatory and Operational Issues in Translational Science	Summer	RR, PI, ST, TP
Leading, Teaming	Leading and Teaming for Effective and Efficient Translational Studies (Integrated with CCTSI Leading and Teaming)	Years 1- 2	SC, TP, BS, ST, PI
Integration of Competencies	Seminar Topics for Translational Scientists	Years 1- 2	RR, BC, PI, ST, SC
Integration of Competencies	Mentored Research Project (Thesis/Publishable papers)	Years 1- 2	DE, RR, BC, PI, ST, TP, SC
Tailored to ICDP	Electives	Years 1- 2	Address ICDP gaps

RR: Rigorous Researcher, DE: Domain Expert, SI: Skilled Communicator, PI: Process Innovator, ST: Systems Thinker, TP: Team Player, BC: Boundary Crosser

3.2 Possess Individualized Career Development Plans (ICDP), which incorporate domain characteristics of translational scientists that are informed by and regularly reviewed with mentors. ICDP formation with mentor input plays a central role in the developmental process of trainees.¹¹⁻¹³ Therefore, all trainees will complete an ICDP within the first month of starting the program. Our ICDP was recently revised, along with that of the CCTSI K12 program, to include the characteristic domains of translational scientists: Domain Expert, Boundary

Crosser, Process Innovator, Systems Thinker, Rigorous and Reproducible Researcher, Effective Teaming and Leading, and Skilled Communicator (written and oral). Added to the ICDP is a specific call out to identify learning needs for skill development in each domain. ICDP sections have trainees identify learning needs/gaps, propose activities to close learning gaps (including course requirements, webinars re: RCR, GCP, R&R), milestones (grants, presentations, publications, degree exams, etc.) with a corresponding timeline. Planning out activities with timelines is an essential skill and necessary for navigating the complex landscape as an investigator. Trainees will report on their ICDP progress twice yearly at Translational Scientist seminars, and MAT and IAC meetings.

3.3. Exhibit regulatory, operational, and scientific competencies that advance CTSR across the translational spectrum and project life course through comprehensive educational programming tailored to address the trainee’s learning needs.

Each trainee will be provided funds to complete either the MScS degree for CU trainees or the PhD degree for CSU trainees. When possible, required elements of the CCTSI Post-Doctoral Training Program will be integrated into the degree curriculum as coursework to take advantage of scholarly activities trainees complete. **Table 7** details courses that will be completed by trainees in the areas of biostatistics, study design, ethics and RCR, critical appraisal and rigorous research, scientific writing, operational and regulatory foundations, leading and teaming for effective and efficient CTSR, translational scientist domains and competency integration, and tailoring of coursework to meet individual trainee’s learning needs through elective courses. Operational and regulatory foundation courses will cover advancing translational interventions across the spectrum considering safety, quality and performance and operational science, such as clinical studies operations, protocol compliance, data quality, timely publication and dissemination. The MScS degree requires 30 credit hours and is designed to be completed in 4-5 terms. A principle followed in

courses to support addressing the learner's needs is that assignments should facilitate application to the learner's research interests. The CLSC has graduated 89 MSCS students in the last 5 years of which 83% were physicians and 7% were non-physician-clinicians (e.g., pharmacists, physical therapists, speech language pathologists). **CLSC alumni are persistent (92%)** in clinical and translational research, have **published over 7,000 peer-reviewed publications** and **secured over 600 federal and 1,000 non-federal grants**. If trainees desire to become PhD prepared, all didactic MSCS credits can be transferred into the CLSC PhD program. During a T32 seminar in fall of year 2, trainees will be alerted to the option of transferring from the MSCS to the PhD program (CU trainees). Many MSCS students complete the PhD program as part of a K award. As trainees will be writing career development award grants (grant writing course and Pre-K Grant Review Program), PhD preparation will be covered as part of their career development plan.

Programming tailored to address the trainee's learning needs is an important characteristic of our T32 program and the companion degree programs. Trainees will be able to complete electives that address needs identified in their ICDPs. In addition, completion of a mentored translational research project is a main path for customization of training and skill development. In the MSCS program, the research project will culminate in a publishable paper and will account for 4 credit hours (CLSC 6699). In the PhD, the research project will be conducted over the duration of the degree program and is equivalent to 3 publishable papers.

3.4 Demonstrate effective scientific communication.

Effective communication skills (writing, speaking and listening) for differing target audiences and purposes are essential for scientists. A multi-faceted approach will be used to develop competency and comfort with connecting, listening to and communicating science to differing audience members/patients/ families. In year one, T32 trainees will complete the CCTSI's **Effectively Communicating Research to the Public** program, which is a three-part workshop series that provides an overview of why and how to engage the public -- everyone from television reporters to neighbors -- and the world on social media. Each workshop is 1.5 hours and includes hands-on training and practice. To apply these skills, annually, each postdoctoral trainee will participate in a type of **Café Scientifique**, regionalized to **Science on Tap**, as a nod to our communities' pride in pubs and microbrews. A Café Scientifique (Science on Tap) is a place where anyone can come to explore the latest ideas in science and technology. Cafés are known for their informal and friendly atmosphere and are believed to improve the image of scientists/science, careers in science, and science literacy.²⁸⁻²⁹ Each year the CCTSI T32 training programs, both the pre- (if funded) and post-doctoral programs, along with the CCTSI Community Engagement Core and CSU, will organize and hold two **Science on Tap** events where T32 trainees will talk with and listen to community citizens about their research. Trainees will give an overview of their research for the first 5-7 minutes (without using presentation software) followed by 10-15 minutes of discussion and dialogue. Science on Tap will engage people in a conversation about issues in science and health and promote the cultural examination of research. The aim of our Science on Tap events is to make the research conducted by our T32 trainees relevant, powerful and important to community and to provide a relevant experience to

Table 8. Learning Outcomes and Evidence: Postdoctoral trainees will...
Exhibit foundational characteristics of Translational Scientists
Characteristics demonstrated through ICDP progress, annual Translational Scientist presentations, IAC annual presentation, One Health Hackathon
Possess Individualized Career Development Plans (ICDP), which incorporates domain characteristics of clinical and translational researchers
Entry and Annual ICDP submission to Program Admin documenting progress
Exhibit regulatory, operational, and scientific competencies that advance CTSR across translational spectrum and project life course
Demonstrated through research in progress presentation during T32 seminars, IAC and MAT meetings, manuscripts, grant proposals
Demonstrate effective scientific communication (oral and written)
Demonstrated at Science on Tap with citizen feedback, annual research in progress presentation with Program Admin + peer feedback, record of submitted and published abstracts, peer reviewed manuscripts/publication, and presentations
Exhibit research practices concordant with research ethics, RCR, GC
Submission of documents related to completion of required training, IACUC and IRB approvals, ethics/RCR/GCP course grade (B+ or better), MAT reports
Report being part of a new translational community and network with new insights, perspectives, and skills
Demonstrated through trainee report of expanded network and top 3 new insights and skills, MAT assessment reports, annual Translational Scientist presentation at T32 seminar, PhD thesis chapter or personal reflection report for non-PhD trainees
Demonstrate effective skills in teaming and leading
Demonstrated through increased membership in interdisciplinary teams, improvements in self-efficacy and increased application of effective strategies for teaming and leading
Apply evidence informed mentoring practices
Mentee-Mentor Assessments (program entry, end of year 1, end of year 2)

our trainees for honing communication skills with the public. Science on Tap events will be promoted through the CSU, CU, CCTSI's network of partners and members (>10,000) through websites, newsletters, Facebook, Twitter, and the networks of the Science on Tap hosts. It is anticipated that 30-40 people will attend these events. We are unaware of other CTSA T32 programs organizing Science on Tap events but will be excited to disseminate this program to other Hubs.

Research communication skills (writing, listening and speaking) for the scientific community will occur through 1. **formal coursework** in grant writing and/or scientific writing (CLSC 6130, CLSC 7101, CM7011), 2. **Translational Scientist Seminars** (writing abstracts, manuscripts, grants; preparing and delivering posters and presentations), 3. CCTSI **Career Development (Pre-K) Grant Review and Mock Study Section** Program (at least once during the two-year award), 4. **ACTS/ CTSA conference** and conference presentations in their specialty areas, and 5. **Writing Accountability Groups (WAG)** to help develop good writing habits. A career development milestone of the program is preparing trainees to present at the National CTSA/ ACTS Annual Translational Science Meeting. In preparation, 4 weeks prior to the conference, a practice session will be held for all to practice and receive feedback on their posters/presentations. This conference is an excellent networking opportunity outside of the university for trainees. **WAGs** are a strategy to improve writing productivity (quantity and quality), increase a sense of control over the writing process, improve goal-setting and time management, and build relationships with peers.³⁰ They were piloted in our CCTSI K program during the COVID pandemic and evaluated well by KL2 Scholars. Scholars reported learning successful strategies to help writing productivity and accountability, increased peer connectedness, and all achieved their goals set at the beginning of WAG sessions. WAG groups will meet weekly for a 1-hour block for eight weeks. WAGs will be completed as coursework applied to the MSCS or PhD degree for trainees, CLSC 6130 Disseminating your Research: Manuscript Preparation and Rigorous Reporting or MIP 666 Writing Scientific Manuscripts. Trainees will be required to produce a manuscript for submission as the course assignment.

Grant writing is an essential skill that takes practice. Trainees will complete a **Grant Writing Course** in their second year. They will be required to identify a granting agency award that they are interested in and then prepare the grant. Many will write a career development award that will subsequently be reviewed in the **Career Development Grant Review and Mock Study Section Program (Pre-K)**. Pre-K runs three times per year corresponding with NIH deadlines. It consists of six steps: 1) Attend or view "How to prepare your grant" workshop; 2) Submit specific aims page that is reviewed by program faculty with applicant feedback; 3) Submit a full K grant; 4) Grant reviewed by three reviewers with written feedback; 5) Required applicant attendance at the mock study section to hear all grant reviews with discussion and questions; 6) Applicant ability to request a meeting with faculty for follow-up feedback. Reviewers are solicited across the CU, CSU, and CCTSI affiliates based on the LOI topics for full application review. Reviewers include both senior investigators with current membership on NIH or similar grant panels, and junior reviewers who benefit from participating in the review process and communicating their reviews in a group setting. Providing these structured opportunities in a formal study section to recently funded junior faculty prepares them to function in this role at a national level. What sets the Pre K grant review processes apart from other study sections is that applicants, mentors and reviewers all attend the mock study section. Mock study sections are organized like a standing NIH panel, apart from the fact that the applicants and mentors are present for the discussion, and ALL submissions are discussed. After a proposal is reviewed, the chair requests comments/insights from participants and the applicant is permitted to respond to criticisms, or ask questions. The spectrum of approaches of applications allows the chair and core members to reflect on strengths and weaknesses across all applications and to educate all on common themes of style, language and approach. Since 2014, the Pre-K Program has reviewed 182 applications (approximately 38 grants/year). Of those reviewed, 68% were submitted to agencies for review, with **39% funded on the first submission**, and **52% on resubmission**, compared to the **36.5% national average** from FYs 2016-2020.³¹

3.5 Exhibit research practices concordant with research ethics, RCR, GCP, regulatory compliance, rigor and reproducibility and other data science principles.

Training in ethical, regulatory, and reproducibility principles, including Responsible Conduct of Research (RCR) and Good Clinical Practice (GCP) is critical to the efficient and rigorous conduct of clinical translational research and maintaining societal trust in the research enterprise. It is thus an essential part of the CCTSI Post-Doctoral T32 Training Program. CU, CSU, and the CCTSI are committed to fostering a research environment that promotes the responsible conduct of research, discourages research misconduct, and deals

promptly with allegations or evidence of possible research misconduct. (See **Attachment Institutional Letter of Support**). The CCTSI, CU and CSU will provide several RCR and rigor and reproducibility educational opportunities to T32 trainees, their mentors and collaborating faculty and staff. Educational opportunities are designed to be in full compliance with the policy requirements for RCR education promulgated by NIH in NOT-OD-10-019 and NOT-OD-22-055, and the NIH Grants Policy Statement, Section 11.3.3.5. All CCTSI T32 trainees will be required to complete a formal ethics and responsible conduct of research course (CLSC 7150 or CM 601) that entails over 14 hours of face-to-face instruction, dialogue, and application PLUS completion of Collaborative Institutional Training Initiative (CITI) modules in order to receive CCTSI T32 funding. To enhance the reproducibility of research findings, the five identified elements of the U.S. National Institutes of Health (NIH) published notice NOT-OD-15-103 will guide our instruction through coursework (CLSC 7150, CM601), workshops, web modules and Translational Scientist seminars. Translational Scientist seminars will provide instruction on bioinformatics, data sharing and access, data management, data security, and data privacy in human subject research. Every year the CCTSI T32 program, WD, and Regulatory Knowledge Core will review evaluations and discuss strengths and limitations of offerings to identify the need for and types of revisions necessary. The CCTSI, CSU and CU are strongly committed to upholding the highest ethical, regulatory and professional standards for reproducible research endeavors and ensures that anyone involved in research is trained and remains current in best practices. See grant sections 7 and 8 below and **Attachments Responsible Conduct of Research** and **Plan for Instruction in Methods for Enhancing Reproducibility**.

3.6 Become a member of new translational communities and networks with new insights, perspectives, and skills, because of immersion experiences with translational mentors.

As recognized in our Model of Persistence for a Diverse Clinical and Translational Workforce, T32 trainees are novice researchers, so it is essential that they begin to sense that they are a part of the CTSR community. It is critical to have socialization and acculturation experiences that avail broadening ways of thinking. Therefore, each trainee will have a translational mentor that will be a liaison to the community of a target audience appropriate to the individual and their area of research. To sense being a CTSR community member, trainees will conduct a meaningful research project with their research mentor and will gain insight into the translational aspects through their translational mentor and immersion experience. The combination of immersion experiences of conducting translational research and its translation permits growth and character for all translational scientist domains and builds skill development in translational research and translational science.

Translational immersion experiences can take many forms: laboratory, veterinary medicine (for CU trainees), clinical service (for CSU trainees), community service, or industry. Trainees will be required to complete an immersion experience in a new translational community for them. For instance, CU clinician trainees will not be allowed to complete human clinical service immersions, but CSU DVM trainees would be allowed. **Clinical service immersions** include regular engagement with the clinical translational mentor and that mentor's clinical team regarding patients and their experiences. Activities include discussing patients after visits or in group settings such as rounds or registry meetings, discussing clinical research related to patients, assisting with study recruitment, bio-specimen collection, observing/participating in clinical study visits and obtaining informed consent. **Veterinary medicine immersions** activities may include shadowing in clinics, attendance at rounds- clinical, pathology, imaging, oncology research, laboratory experiences (data collection and analysis), participating in research in progress meetings, and discussing research approaches in animal and human research for shared models of disease. **Laboratory immersions** include learning new lab techniques, analyzing and interpreting data, participating in lab meetings and research in progress meetings. **Community immersion** experiences with patient advocacy organizations or government agencies may include attendance at community meetings, assisting with development and review of translational/educational materials, grant reviews, community assessments and working on policy briefs. **Industry immersions** include biotech, regulatory affairs or technology transfer settings. Experiences may include working in labs, attending meetings, protocol development, involvement in process of bringing a product to market, academic-industry relationships, and report preparation. Immersion experiences will occur for the two-year award period and are expected to continue until degree completion. In general, trainees will spend about 8-10 hours/month with their translational mentor and immersion site. Requirements for the immersion experience include: 1) attending an orientation, 2) shadowing with their translational mentor and integrating, to the extent possible, into the immersion environment, understanding cultural norms, and language, and 3) maintaining a reflective diary with entries regarding issues, insights and learnings. Students will report on their immersion experience at MAT meetings.

Program directors and others will support the identification of translational mentors and immersion experiences. Dr. Nadeau will support the identification of clinical mentors. Dr. Cicutto and CCTSI's Community Engagement Core and Community Liaisons will assist trainees in finding a community translational mentor and, if necessary, provide an orientation for partnering and building relationships. (See **Attachment Coordination and Integration**). Dr. MacLean, Associate Director of the PhD biomedical track of the CCTSI T32 Pre-doctoral Program and CCTSI Pre-K (See **Attachment Coordination and Interaction Plan**) will assist with identifying biomedical laboratory translational mentors. Dr. Thamm will assist with identifying veterinary medicine immersion experiences. Dr. Cicutto will support identifying industry immersions and will leverage the infrastructure of the University's Biomedical Science and Biotechnology Master's program by collaborating with the program's director, Dr. Inge Wefes (See **Institutional Letter of Support**). An industry internship is a requirement of this master's program and thus an infrastructure already exists, such as a list of industry partners and university approved MOUs, IP and agreements for student internship/ immersions. Additionally, many CCTSI T alumni work in industry, located in the Denver/Boulder/Fort Collins area, and desire engagement with trainees. **Translational mentors and immersion experiences were consistently our most highly rated and impactful program element** over the last 10 years of the CCTSI TL1 program.

3.7 Demonstrate effective skills in teaming and leading necessary for teams that advance CTSR.

Translational teams are composed of dynamic and diverse interprofessional and cross-disciplinary members that generate new knowledge to address a shared translational objective. Highly qualified and thoroughly prepared interdisciplinary teams fuel discovery that is translated to communities for improved health and lives of its citizens. It addresses the shift in science from an individual-based approach to a teamwork model of designing and conducting CTSR. To prepare our trainees to be contributing members of high-performance teams, trainees will complete our CCTSI **Leading and Teaming in Clinical Translational Science and Research** program over the two-year T32 program. Completion of the Leading and Teaming program will be applied as course credit for the MSCS degree (CLSC 6240 Leading and Teaming for Effective and Efficient Clinical Studies) and elective credits in the CSU PhD degree. Previous studies indicate that team training results in the application of knowledge, skills and abilities and improves team performance and innovation.³¹⁻³⁴ Our curriculum is designed to build capacity to participate in and lead effective, interdisciplinary, and translational scientific teams. It is based on current evidence and best practices and is concordant with competency development outlined by the CTSA Team Science Affinity Group.³⁵ The five domains of competency, which are addressed in our program, include facilitating team bonding, team communication, managing team research, collaborative problem solving, and team leadership. Both individual and team competency development are necessary; Individual competencies: facilitating awareness and exchange, cognitive openness, self-awareness, interdisciplinary research management, perseverance, and Team competencies: team-based communication, shared visioning, understanding complexity, team learning, meeting management, collaboration, and trust. Learners start the program by completing Teaming 101, a self-paced online web-module, followed by participation in six, two-hour workshops. CCTSI partner faculty from CSU will provide the workshops. Jeni Cross PhD, a Professor in the Department of Sociology and renowned for her team science research, will direct and instruct the program. Last grant cycle, we created and added Team Science to our CCTSI TL1 program curriculum. Initially, it was one 4-hour workshop; however, trainee evaluations revealed increased time was necessary, so the program curriculum was expanded. Our most recent expanded version was very favorably evaluated, earning scores of 4.4 or higher (out of 5) for overall training, ability to apply training, and trainer-trainee engagement. Statistically significant improvements were noted for trainees' familiarity with teaming concepts, self-confidence in ability to apply teaming strategies, and report of more frequent use of strategies for effective teams. Feedback identified that it would be beneficial to add more on leading/leadership. As a result, the new program will combine and integrate competency development for leading and teaming, with greater attention to leading.

3.8 Demonstrate ability to integrate, synthesize and apply Translational Scientist domains during a One Health Hackathon. As noted above, One Health is an approach to designing and conducting research in which teams work together to achieve better public health outcomes. A One Health Hackathon will be held to realize synergies of our collaborative interprofessional trainees and faculty. This hackathon research design event will focus on antimicrobial resistance and will bring together teams of our interdisciplinary trainees and faculty to develop a research agenda and program of projects within the One Health paradigm. Antimicrobial

resistance is one of the most serious threats to health across the world. The emergence and spread of drug-resistant microbials is driven by over-use and inappropriate use of antibiotics in both humans and animals (pets and food producing). This issue affects more than just human health and healthcare. Whenever we make an environment favorable for infectious microbes, they take advantage. This affects farming, the environment and ultimately the food we eat. Teams will be asked to spend the day together tackling this issue to develop an outline for a research program project grant that encompasses the triad of One Health, human health, animal health and the environment. This will allow for integration, synthesis and application of translational scientist domains using a team-based activity. This activity will occur at the end of the second year, but orientation and preparation will start early in the second year. Trainees will form their “dream teams” prior to the event to tackle this complex issue. At the end of the event, teams will present their projects.

4. TRAINING PROGRAM EVALUATION

4a. Approach: The CCTSI Post-Doctoral T32 program is measurement and outcomes focused. Our program will continue to work with the CCTSI Evaluation Core for program evaluation and ongoing informed continuous quality improvement. The CCTSI Evaluation Core has securely collected and stored data for the CCTSI TL1 program since 2008 and will continue in this role. We will follow-up with program alumni for 20 years; in 2028 we will revisit the decision to determine if longer follow-up should occur.

Table 9. Logic Model for Post-Doctoral T32 Program Evaluation				
Inputs	Program Output (Program Objectives)	Trainee Outcomes and Impact		
		Short-term (1-2 yrs.)	Medium-term (3-4 yrs.)	Long-term (> 5yrs.)
<ul style="list-style-type: none"> • CCTSI infrastructure and integrated network for training and promoting CTSR across translational spectrum • CU/CCTSI MSCS and CSU PhD programs • Culture of team-oriented science • Protected time • Diverse network of translational and research mentors (clinical, community, and research) • Diverse array of integrated education, training and career development offerings in T32, such as <ul style="list-style-type: none"> - Mentoring³ - Leading and Teaming for CTSR - Effectively Communicating Research - T32 seminars - Pre-K grant review - OneHealth Design Hackathon - ACTS conference 	<ul style="list-style-type: none"> • Attract and retain diverse trainees to ↑ diversity in applicant pool, funded trainees and future faculty • Trainee development of Translational Scientist characteristics • Evidence informed mentoring practices: multi-disciplinary teams (MAT), ICDP, tailored career coaching • Rigorous training to build CTSR competencies • Study conduct concordant with ethical and regulatory principles • Modeling and skill development for team-based CTSR • Exposure and experiences in CTSR across the study lifespan and translational spectrum • Meaningful research and translational experiences • Provide positive validating experiences 	<ul style="list-style-type: none"> • ↑Confidence in 7 characteristic domains of Translational Scientist • Maintenance of ICDP use • CTRS competencies (regulatory, scientific, operational; CRAI) <ul style="list-style-type: none"> • Study design • Research conduct • Ethical and regulatory principles • Dissemination • Grant writing • Clinical studies operations • Advancing interventions across the spectrum considering safety, quality and performance • Identity formation and characteristics of Translational Scientist • Integration into CTSR community • Enhanced team research orientation • ↑Self-efficacy in leading and teaming • Satisfaction with mentoring team and their mentorship skills 	<ul style="list-style-type: none"> • CTSR connectedness • Accelerated achievement of academic milestones • Production and dissemination of scholarly products • Positive stress management and coping • Expanded team-orientation and network in CTSR • Broad dissemination strategies (interdisciplinary, community) • Persistence in CTSR (continued training, career development award, employment) 	<ul style="list-style-type: none"> • Alumni actively engaged in team science • More diverse clinical and translational research workforce/teams • Infusing Clinical Translational Research and Clinical Translational Science with new perspectives, approaches/ methodologies and technologies • Secure first Career Development Award • Assumes leadership positions • Mentoring of more junior investigators • Career advancement • Persistence in CTSR

Evaluation of the CCTSI T32 Post-Doctoral T32 program will focus on our ability to achieve program and trainee objectives and goals. Evaluative emphasis will be placed on achieving our program goal of attracting and supporting the training and persistence of individuals from diverse backgrounds who have the potential to infuse both clinical translational science and clinical translational research with new perspectives and approaches that are efficient and effective. Both qualitative and quantitative data will be collected with

triangulation of data for some outcomes to provide a fuller and deeper understanding. Refer to **Table 9** for an illustration of our logic model that identifies program inputs and outputs, and short, intermediate and long-term objectives of our trainees. Program outputs align with our program objectives described above in Section 3.0. Additionally, **Attachment-Outcomes, Data Collection and Storage** details variables/outcomes, their time of data collection timing, and the data collections sources.

Primary data collection will occur through interviews, focus groups, validated instruments, curriculum vitae, and surveys. Surveys will be conducted with current T32 trainees, mentors of active trainees, T32 program administration and T32 alumni. The CCTSI Evaluation Team will also use secondary data sources, such as NIH Reporter, PubMed, Web of Science and CU's and CSU's Office of Grants and Contracts, to track research productivity – specifically, grant success and funding levels and publications. In general, data collection will occur upon program entry and then annually. When trainees participate in CCTSI training programs integrated into the T32 Post-Doctoral Program, such as Mentoring³, Leading and Teaming, etc., they will complete the standard pre and post assessments that capture knowledge, confidence, and satisfaction for those programs. The Clinical Research Appraisal Inventory (CRAI-12), a validated instrument,⁹ will be administered upon program entry and annually for assessing growth in relation to essential clinical and translational science and research skills. We are piloting a questionnaire to capture trainees' abilities regarding the seven characteristic domains of a translational scientist⁷⁻⁸. Preliminary data from this year's cohort upon program entry suggest that trainees start the program reporting feeling most confident being a team player and rigorous researcher and least confident in abilities related to boundary crosser, systems thinker and process innovator.

Both formative and summative evaluations/reports will be generated by the CCTSI Evaluation Core. Results will be presented in aggregated format in reports summarizing data/themes from all data collection sources to yield a comprehensive, mixed-methods evaluation of immediate, intermediate and long-term outcomes of the program. Reports will be used to inform modifications and next steps consistent with our continuous quality improvement processes. Aggregate-level reports will be publicly available off the T32 Post-Doctoral website.

4b. Develop, Demonstrate and Disseminate: An important contribution to the translational science field is identifying best evidence practices for preparing a highly qualified workforce that persist in translational careers. Our evaluative framework will allow us to contribute to the evidence base by identifying the program's overall and individual elements successes and contributions, as well as gaps in training and areas in need of improvement. Many elements of our program are innovative and newly **developed** (Mentoring³, Teaming and Leading, Science on Tap (a type of Café Scientifique), Writing Accountability Groups) and thus require evaluation to **demonstrate** effectiveness and lessons learned before they can be **disseminated** as contributions to the knowledge base for uptake by other CTSA hubs and training programs. Additionally, the 360 Mentee-Mentor assessment was developed by a sub-group of the CCTSI WD LAC members for the purposes of identifying at-risk mentor-mentee dyads and for evaluating training programs. The 360 Mentee-Mentor assessment will be used by both CCTSI T32 (pre- and post-doctoral) programs and KL2 program, if all funded. There will be several lessons learned from the use of this approach that include the ability of the approach to discriminate between effective and non-effective relationships and identify the extent to which mentoring relationships evolve over the two years. Please see the **Dissemination Attachment**.

5. TRAINEE CANDIDATES

5a. Training Slots. Based on the size of our CCTSI CTSA Hub, we are requesting **4 postdoctoral slots** for full-time trainees for a two-year duration per trainee (maximum of 4 trainees per year) contingent on good progress as determined by a written 1-year update report and review by the IAC. We are proposing a **multiple discipline collaborative program between CU and CSU**. Program trainees will be divided between CU interdisciplinary doctorally prepared clinicians (physicians (MD), pharmacists (PharmD), nurses (DNP), physical therapists (DPT), psychologists (PsyD), and others) and CSU veterinarians (DVM/VMD) enrolled in a CVMBMS PhD program. Each competitive cycle there will be at least one CU trainee and one CSU trainee. The remaining two slots will be selected and recommended by the IAC based on our holistic review process. Candidates must be US citizens or permanent US residents. During the first TL1 grant cycle involving postdoctoral trainees, we learned that our TL1 eligibility criterion for clinician trainees of being within 2 years of completing their doctoral training was extremely strict and limiting for physician trainee participation. As a result, we are expanding the eligibility criteria to PGY6. Every RFA cycle we received numerous inquiries from

physician fellows that wanted to apply but we had to inform them of their ineligibility. Initially, we were afraid of receiving too many applicants for one funded position.

Eligibility criteria include:

- Clinicians with a PhD must apply within 2 years of completing their PhD degree.
- Non-MD clinicians who are not completing a clinical fellowship must apply within 2 years of completing their doctoral degree. To our knowledge there are clinical fellowships of 1-2 years duration for non-MD clinicians.
- MD prepared clinicians can apply during their residency or fellowship up to PGY6.
- Veterinarians enrolled in a CVMBS PhD program must be within 3 years of completion of their residency/ fellowship training, or within 2 years of completion of the DVM/VMD degree if specialty training is not pursued.

5b. Recruitment. Every two years, requests for CCTSI Post-Doctoral applications (RFA) will be made. **A multi-faceted approach for recruitment will be used.** 1) CCTSI Post-Doctoral T32 program will be highlighted on our CCTSI WD landing page, which receives over 6,000 visits/month, and will provide informational materials. 2) Email announcements, promotions, and informational materials will be distributed to doctoral health care professional students in their last year of training, all residents and fellows, all CSU CVMBS programs, and to all members of the CCTSI. This will include CCTSI partners such as CU-Boulder, CU-Denver, CSU, Denver Health, National Jewish Health, Veteran’s Administration, and Kaiser Permanente. 3) Program administrators and Program Directors for all doctoral health professional programs (physicians, dentists, nurses, pharmacists, etc.), all medical resident and fellowship programs and all CVMBS DVM programs (DVM students, residents and fellows) and CVMBS PhD programs will be sent informational materials to distribute to their students/trainees. 4) The CCTSI T32 will be discussed at mentorship and CU academic programming URM pathway programs by Drs. Zimmer (IAC member and Associate Dean, DEI - SOM), del Pino-Jones and (CCTSI T32 DEI Director), and Martinez (Director, Office of Outreach and Inclusion) to increase awareness, support recruitment and application development. All three are members of CCTSI WD LAC. Similarly, at CSU, the CCTSI T32 program (Dr. Thamm) will work with the Vice President for Diversity Office and the Graduate School Center for Inclusiveness to ensure that the program is highlighted at Annual

Diversity Symposium (Thamm will present), Bridges to the Doctorate program and other local and national events. 5) Program Administration, IAC members and faculty mentors will provide personal outreach to faculty and trainees (potential applicants) during meetings and seminars they attend. IAC members were selected based on their connection and network. Intensive marketing will start 15 weeks before the application deadline, but general marketing will occur throughout all years to increase awareness of program and deadlines. Refer to **Attachment Recruitment Plan to Enhance Diversity.**

Table 10. 2021 Feeder Program Enrolment of Doctorally Prepared URM Students/Trainees			
Program/Primary Major	Non-BIPOC	BIPOC/ URM	Total
Clinical Health Psychology	6	1 (14%)	7
Clinical Science (clinicians only)	51	15 (23%)	66
Medicine (Residents/Fellows)	1124	142 (11%)	1266
Nursing	30	3 (9%)	33
Periodontics Residency	8	0	8
Physical Therapy/ Rehabilitation Science	7	1 (13%)	8
Dental Medicine (DDS)	60	20 (25%)	80
Pharmacy (PharmD)	74	21 (22%)	95
Psychology (PsyD)	12	5 (29%)	17
Veterinary Medicine Residents (DVM)/VMD	77	3 (4%)	80
CVMBS PhD student and DVM	42	2 (5%)	44
Grand Total	1366	214 (14%)	1580

5c. Applicant Pool. In AY2020-2021, there were 1,266 CU medical residents and specialty fellows of which 11% (n=142) were BIPOC trainees. CU programs apart from the SOM were able to provide data for underrepresented students, which include BIPOC in addition to students living with disability and from disadvantaged backgrounds. There were 314 non-MD prepared clinicians of which 21% (n=66) were BIPOC/ URM trainees that would be eligible.

Trainees will be recruited from CSU’s CVMBS’s pool of DVM prepared PhD students (n=44) and DVM interns/residents/fellows (n=80). Of this pool, 5 trainees are BIPOC (4%) trainees. Given these data, we are confident that we will attract a highly qualified pool of T32 postdoctoral applicants to select 3 outstanding trainees (See **Table 10** and **Required Tables 1** and **6A**). Differences exist between the TL1 program and the proposed Post-Doctoral T32 Program that will likely increase interest and expand our applicant pool. Changes include that the T32 (compared to TL1) program will fund trainees for 2 years instead of 1 year, which will allow/require CU clinician trainees to complete the MSCS degree instead of a certificate. Additionally, slots

available will increase from 3 to 4. Initially, we allocated the three slots to two being awarded to DVM trainees completing a PhD and one to a clinician who was not required to complete a degree. In 2021, we revised this to be at a minimum of one dedicated DVM slot. For this proposal, for each cohort, there will be at least one CSU trainee and one CU trainee with the remaining 2 slots determined by the quality of the application. Additionally, for the T32 eligibility criteria for physician trainees was expanded from PGY3 to PGY6. For the previous TL1 postdoctoral award cycles we averaged 5-6 applicants for 3 slots (See **Table 11**). The program was very successful in attracting surgeons but not physician trainees, which is attributed to our limited eligibility criteria. Review of these data highlight our need to attract and recruit underrepresented trainees. This will be a major focus and emphasis for the Program Administration. Under-represented groups for this application are consistent with NIH guidelines and include underrepresented racial and ethnic populations (Black or African American, Hispanic, American Indian, Alaskan Native, Native Hawaiian, or Pacific Islander), individuals with disabilities, and individuals from disadvantaged backgrounds (NOT-OD 15-053).

5d. Trainee Selection. (See **Attachment Trainee Selection Process**) Each application will be independently reviewed by three reviewers. Prior to reviewing applications, all reviewers will have completed a workshop on holistic review of applications provided by Dr. Amira del Pino-Jones, our CCTSI T32 program DEI Director. Additionally, all reviewers will have participated in an orientation to the CCTSI's T32 Post-Doctoral Program and our holistic review and selections process, including our review and scoring criteria sheet. A form was developed during the last cycle of our TL1 program to assist with the review and selection of the most appropriate awardees. It was felt that the typical NIH criteria needed to be expanded to capture elements of a holistic review. Because diversity is stressed in our program and aligns with our DART philosophy and value, one criterion is the applicant's diversity statement. Our scoring and review sheet allows for a total of 100 points to be allocated according to six domains, which have varying weights or possible point ranges. The six domains include: the applicant, personal statement, diversity statement, research proposal and mentoring, translational immersion and mentoring, and letters of support.

# Applied	URM	Discipline
6	2	Clinical Science, Nutrition, Microbiology, Pathology (x2), Surgery
4	1	Clinical Science, Physical Therapy, Surgery, Pathology (x2)
6	1	Physical Therapy, Microbiology, Pathology, Rehabilitation Science, Surgery, Veterinary Anatomic Pathology
4	0	Clinical Science, Surgery, Bioengineering, Microbiology, Orthopedics
8	0	Clinical Science, Physical Therapy, Cell and Molecular Biology, Nutrition, Surgery (x2), Microbiology, Zoonotic Diseases

5e. Program Objective: *Attract, recruit and retain diverse trainees by demonstrating program commitment to DART.*

The stated value and philosophy of our CCTSI Post-Doctoral Program and CCTSI WD is that **Diversity Accelerates Research and Translation (DART)**. Diversity is instrumental for the workforce to advance discovery, eliminate health disparities, and achieve patient-centered outcomes in the quest for better health.¹⁰ Strategies and concepts we will use to promote DART include: (1) weaving DART and DEI considerations across the totality of the CCTSI Post-Doctoral Program, not in just certain parts (e.g. across advertising, recruiting, programming, product generation); (2) coordination and implementation of DEI efforts across the CCTSI systematically (particularly in WD efforts), and (3) ensuring Post-Doctoral T32 leadership and faculty are well-trained and committed to supporting DEI principles.³⁶ (See above sections 1f, 1g, 2d-2) The CCTSI T32 Post-Doctoral Program and the CCTSI WD will provide training opportunities throughout the year and during Translational Scientist seminars. Support for DEI training was underscored in our 2021 CCTSI Needs Assessment where the need to enhance DEI on research teams and in research study participants was voiced by 35% of the >800 respondents (trainees, faculty, staff). This request will be met by the addition of a workshop/seminar in the required RCR series related to DEI in research, the expansion of the topic in Leading and Teaming, Mentoring³, and our program's Translational Scientist seminars.

5e-1. Attract and Recruit for Diversity: On a program level, Drs. Zimmer and Del Pino-Jones, both part of our T32 Post-Doctoral Program faculty, organize and hold SOM URM seminars every 4-8 weeks for medical students and residents/fellows and will ensure that URM trainees are aware of the T32 program. Interested potential applicants will be offered/provided mentorship and support for completing the T32 application by Drs. Zimmer, del Pino-Jones and Nadeau. Dr. Martinez, Director of Office of Inclusion and Outreach (**OIO**)

organizes student life activities for URM students. He will ensure that our program is advertised and promoted at these events and through OIO's website, publications and social media accounts. The OIO has worked diligently to develop and maintain relationships with URM students and to engage them. On average, the OIO meets monthly with 274 BIPOC students to assist with identifying and navigating education/training opportunities and supporting their applications. As CCTSI T32 and OIO goals are aligned, Dr. Martinez and his staff will ensure URM students are aware of and provided support in the application process. Additionally, CCTSI T32 program administration (Cicutto and del Pino-Jones) will present at the twice-yearly OIO student conferences and Dr. Thamm will participate in similar events at CSU. Drs. Zimmer, del Pino-Jones and Martinez all serve on the CCTSI WD LAC and a standing agenda item will be recruitment and retention of URM trainees (See **Attachment Coordination and Interaction Plan**). CSU's commitment to DEI includes the Vice President for Inclusive Excellence Office, which provides leadership, accountability and education to advance an inclusive university culture that prioritizes equity at individual, organizational and structural levels, and the Graduate Center for Inclusion, which assists with the recruitment of underrepresented graduate students. Additionally, CU and CSU DEI offices attend national, regional and local conferences focused on reaching underrepresented students/trainees in the sciences, health professions and human and veterinarian medicine. We are confident that we will reach our **goal of 25% of trainees being from URM backgrounds**. During the last grant cycle of the CCTSI TL1 program a strategic plan was implemented to attract and recruit URM doctoral students. We were rewarded for this effort by having a 127% increase in URM participation over the last 4 years and profiled nationally by CLIC coordinating center for our ability to bend the curve for increasing URM representation. However, what became clear to us in preparation for this application was that our efforts were too focused on predoctoral applicants. This will change immediately and a strategic plan for postdoctoral trainees will be implemented by Program Administration and the CCTSI WD under the direction of Dr. del Pino-Jones our DEI director. See Attachment **Recruitment Plan to Enhance Diversity**.

5e-2. Trainee Retention: (See **Attachment Retention Plan**). Each year we will provide training for trainees and faculty to grow and align our actions to support DART that include building a safe and inclusive environment to conduct CTSR.³⁷⁻³⁸ Required trainee/mentee and mentor training through the Mentoring³ program will directly address environmental issues surrounding inclusivity and safety. CU-Anschutz Office of Diversity and Inclusion offers numerous trainings that can be incorporated into the ICDP and required for mentors. Further, our Translational Scientist seminars provide a forum to talk about work environment dynamics in a safe, confidential space with Dr. del Pino-Jones, our DEI Director, and other T32 Program Directors and peers. Additionally, trainees have monthly check-ins with program directors where they are encouraged to share career obstacles or stalled progress that could be attributable to a dysfunctional work environment. Our annual 360 mentoring assessments provide a *bi-directional evaluation process* to identify at-risk mentoring relationships. Mechanisms are developed and will be implemented to address issues efficiently should they arise. See **Attachments Mentor Assessment and Internal Advisory Committee**.

6. INSTITUTIONAL ENVIRONMENT AND COMMITMENT TO TRAINING (See **Attachments Facilities and Other Resources and **Institutional Letter of Support**)**

Starting in 2022, the Office of the Vice Chancellor of Research, CU-Anschutz will recognize and acknowledge the importance of mentoring by providing awards for Excellence in Peer Mentoring, Excellence in Junior Faculty Mentoring, and Outstanding Senior Faculty Mentoring. Up to this point, awards from the Office of the Vice Chancellor of Research were provided to acknowledge excellence in research. Notably absent from the list of recognitions were awards for *mentoring excellence*. The CCTSI K and T program directors (Burnham and Cicutto) brought this to the attention of the CCTSI LAC who wanted to address and change this. As a result, Drs. Burnham and Cicutto met with the Office of the Vice Chancellor of Research who agreed that *mentoring excellence* should be recognized. The creation of these awards show responsiveness and progress in addressing environmental pull factors identified as important in our Model for Persistence of a Diverse Clinical and Translational Research Workforce.

The **CCTSI** will provide several sources of support for our CCTSI T32 Post-Doctoral Program. The CCTSI has committed salary support in the UM1 application for the effort of Drs. Cicutto, del Pino-Jones, Thamm, Nadeau and Mankin (administrator) to lead this training program. The CCTSI will also provide funds (UM1 application) for the delivery of required elements that include Mentoring³, Leading and Teaming, Pre-K Grant Review and Mock Study Section, CLSC, and Effectively Communicating Research to the Public. The WD LAC, a key venue for integration of programmatic and DART activities, is also supported by the CCTSI (UM1 application).

CSU joined the CCTSI in 2013. It is a public land-grant institution founded in 1870 and located in Fort Collins, a midsize city one hour north of Denver. CSU includes 8 colleges, including the renowned College of Veterinary Medicine and Biomedical Sciences (**CVMBBS**). CSU has leading research programs in animal science, team science (Jeni Cross, Director of CCTSI Teaming and Leading), health and exercise science, atmospheric science, clean energy technologies, health physics, and environmental science. CSU CVMBBS will continue to participate in the CCTSI Post-Doctoral program through our novel integrated translational scientist training program for post-DVM/VMDs. **CSU's CVMBBS is ranked third in the nation by U.S. News and World Report 2021** with a total extramural research budget of ~\$50M and a 60+year record of post-DVM graduate training. CVMBBS faculty participate in several established research affinity groups that have direct human application, including the Arthropod Borne Infectious Disease Laboratories, Mycobacteria Research Laboratories, Retroviral Research Laboratories, Flint Animal Cancer Center, Center for Regenerative Medicine, Prion Research Center, and the Translational Medicine Institute. CCTSI support of a Natural Animal Models Core during the current funding period resulted in increased interactions and synergies in translational studies between Anschutz and CSU in areas of stem cell research, interventional cardiology, and cancer therapies. Collaborative CSU and Anschutz research and education programs have occurred for decades, but through the CCTSI we have observed a significant increase over the last 10 years: Currently, > 100 ongoing CSU-CU Anschutz research collaborations, > 600 CSU CCTSI members (44% increase since last renewal), and significant expansion in the use of natural animal models of human diseases in translational research projects.

7. PLAN FOR INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH (See Attachment Plan for Instruction in the Responsible Conduct of Research). Training in ethical and regulatory principles, including Responsible Conduct of Research (RCR) and Good Clinical Practice (GCP), are critical to the efficient conduct of CTSR and maintaining societal trust in the research enterprise. It is thus an essential part of the education and training of the Post-Doctoral T32 Training Program, as evidenced by our learning objective that trainees' will *Exhibit research practices concordant with research ethics, RCR, GCP, regulatory compliance, rigor and reproducibility and other data science principles (See above section 3.7)*. It is integrated across programmatic elements and accomplished through required course work (CLSC 7150, CM601), CITI modules, submission of IRB and/or IACUC approval (as necessary), ICDP, mentored research project, and Translational Science seminars. Educational opportunities are designed to be in full compliance with the policy requirements for RCR education promulgated by NIH in NOT-OD-10-019 and NOT-OD-22-055, and the NIH Grants Policy Statement, Section 11.3.3.5.

8. PLAN FOR INSTRUCTION IN METHODS FOR ENHANCING REPRODUCIBILITY (See Attachment Plan for Instruction for Enhancing Reproducibility) To enhance reproducibility of research findings through increased scientific rigor and reproducibility, the U.S. NIH published notice NOT-OD-15-103. Its five identified elements will guide instruction to our postdoctoral T32 trainees. These elements include: 1) evaluation of foundational research underlying a project (i.e., rigor of prior research); 2) rigorous experimental design and data interpretation; 3) consideration of relevant biological variables such as sex; 4) authentication of key biological and/or chemical resources; and 5) transparency in reporting. T32 programming will provide a critical role in supporting competency development for applying rigorous methods for acquiring, analyzing and reporting data. Processes for effectively developing these skills, methods, and concepts to trainees is through modeling (by research mentors, program leaders and peers) and training. A multi-faceted approach will be used involving coursework, completion of NIH Rigor and Reproducibility modules, research in progress seminars, MAT meetings, ICDPs, mentored research project, and Translational Scientist seminars that will include didactic elements, application, issue identification and problem solving.

Translational science seeks to understand the scientific and operational principles underlying each step in the translational process. Translational research seeks to produce more meaningful, applicable results that directly benefit human health. Our Post-Doctoral T32 Program will prepare competent translational scientists that characterize- Domain Expert, Rigorous Researcher, Boundary Crosser, Team Player, Systems Thinker, Skilled Communicator, and Process Innovator. As translational scientists they will be able to make discoveries through rigorous and efficient research that overcomes challenges and bottlenecks along the way so that the health of individuals and community are improved.

Coordination and Interaction Plan

The CCTSI is an integrated research and training program for clinical and translational science (CTS) and research based at the University of Colorado Anschutz Medical Campus with several Partnering Institutions. The CCTSI will be funded by 7 grant applications in response to the 2021 CTSA grant FOAs, including a K12 and two T32 applications. The leaders of Programs for all of these awarded grants will be successfully integrated seamlessly into our current CCTSI Executive Committee and overall program, as they have been for the past 14 years. The CCTSI Post-Doctoral T32 Program is a critical element of the CCTSI, essential for the preparation of a highly qualified workforce. It is supported and coordinated with several UM1 Hub programs including the CCTSI Workforce Development (WD) Core (Module C1) for much of its required programming; the services and support of CTS Resources and Services (Module D1); Community and Stakeholder Engagement (Module C2); Health Informatics (D3); Strategic Management (Element B); and the Colorado Innovator Ecosystem RC2 application. We have an ongoing integrated and coordinated CCTSI governance structure for these and other UM1 and education/training components which will be adapted for the new Pre- and Post-Doctoral T32 programs. Thus, our CCTSI governance and operational capabilities will be leveraged fully to provide necessary and flexible programming to support the development of postdoctoral translational scientists and to facilitate navigation of resources and services by our trainees. Interactions and coordination with key CCTSI Cores and Programs for the Post-Doctoral T32 trainees are included in **Figure 1**, however all CCTSI Cores and resources will be available to the Post-Doctoral T32 program and trainees as needed.

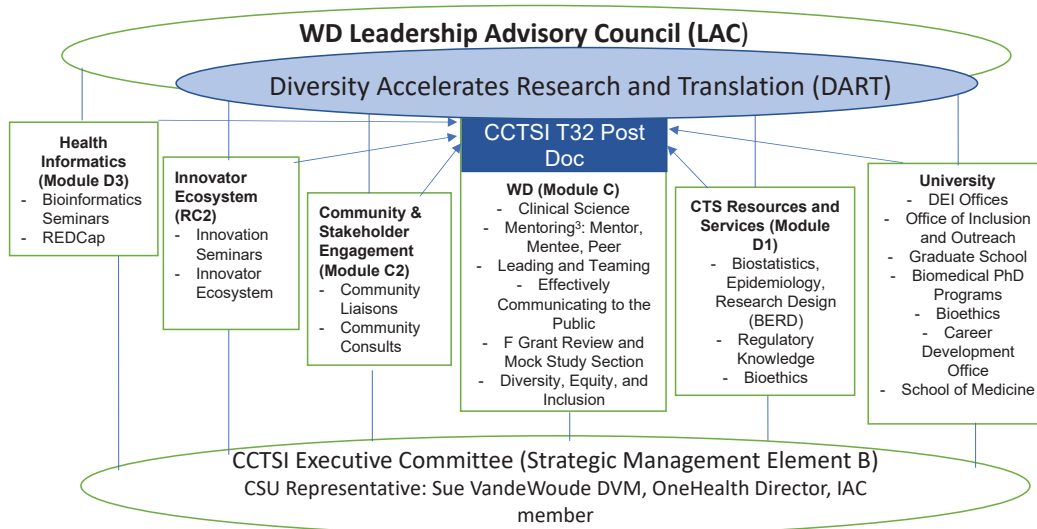
Central Governance, Coordination, Interaction, Integration

Two committees will support the coordination and integration of services to support the CCTSI T32 Post-Doctoral Program. Central governance and coordination of coursework and career development programs and services supporting T32 Post-Doctoral trainees will be administered by the CCTSI's **WD Leadership Advisory Council (LAC)**. The WD LAC is comprised of directors and leaders from **all WD core programs** (Module C1), including the K12 and T32 programs, the Director of Diversity, Equity and Inclusion (DEI), and directors/leaders from other UM1-supported programs found in Modules C2 (Community and Stakeholder Engagement), D1 (Regulatory Knowledge, & Support, Biostatistics, Epidemiology, Research Design (BERD)), and the RC2 (Innovator Ecosystem) and Module B (CCTSI Evaluation Core). The CCTSI T32 Post-Doctoral Program Director, Lisa Cicutto PhD, will lead the monthly meeting in her role as WD Director. At monthly meetings, a standing item is DEI activities, approaches and integration strategies to support our value of Diversity Accelerates Research and Translation (**DART**). Additionally, meetings focus on annual review of each WD program consistent with our continuous quality improvement process and monitoring of metrics, integration across programs (WD, CCTSI and university), progress towards mutual milestones, need for revision, and current events/issues. The LAC will ensure coordination, integration, synergy, and mutual reinforcement among all WD CCTSI programs and activities, and will work with the Evaluation Core to evaluate all WD services. The WD LAC has proved to be extremely valuable to ensure that education/training leaders are aware of one another's services, have the agility to collaborate/integrate across programs, leverage resources, avoid duplication and competing with one another. An example of a benefit was the creation of the teaming program, which was a collaborative effort of the CCTSI, the Graduate School, School of Medicine (SOM), and Colorado State University. Notably, T32 Post-Doctoral Program Administration that will attend the LAC, in addition to Lisa Cicutto, are Drs. del Pino-Jones, Thamm, and Nadeau. As such, they will be intimately familiar with the Post-Doctoral T32 program objectives, trainee outcomes and milestones for areas that include recruitment, training to prepare translational scientists, and mentorship, and ensure that these areas are discussed and integrated. Dr. Bruce Mandt is also important to integration and coordination as he directs Mentoring³ and is part of the Graduate School's leadership team and directs the Offices of Career Development and Post-Doctoral Fellows.

DART will be realized through having the University DEI offices represented (University Office of Inclusion and Outreach, Dr. Martinez and Office of DEI, School of Medicine (SOM), Dr. Zimmer), CCTSI WD and Post-Doctoral T32 DEI Director del Pino-Jones) and all WD program directors meeting monthly through the LAC. The SOM's Office of DEI includes the medical school students, medical residents and fellows and all biomedical PhD programs. The University's Office of Inclusion and Outreach focuses on attracting URM students/trainee for undergraduate programs and non-SOM health professional programs and works in an integrated fashion with the SOM.

The second committee to support integration and coordination is the **CCTSI Executive Committee (EC)**, which consists of the leaders for all the CCTSI cores including Dr. Cicutto and is chaired by the CCTSI Director and UM1 Principal Investigator, Dr. Ronald Sokol who oversees governance, operations and decision-making. This is outlined in UM1 **Module B-Strategic Management** with the EC goal to integrate, coordinate, track and improve all CCTSI programs and cores. Dr. Sokol reports to the Vice Chancellor (VC) for Research and to the VC Health Affairs (the Dean, SOM), who in turn report to the Chancellor at CU Anschutz. His positions and roles allow for coordination, integration and responsiveness across the University community. This EC meets twice monthly to discuss new initiatives, approve pilot grants, review activities and evaluation of programs, and respond to arising needs and issues. Programmatic support to administer the CCTSI T32 Post-Doctoral Program (Lisa Cicutto, Doug Thamm, Kristen Nadeau, Amira del Pino-Jones, Galit Mankin), its activities and

Figure 1. Coordination and Integration of Programs and Services Supporting CCTSI T32



financial oversight will be conducted with Module B personnel support. Using the LAC-EC interface, the EC will provide ultimate oversight for major operational issues that arise in the program. If Dr. Lisa Cicutto is unable to fulfill her responsibilities for the CCTSI T32 Post-Doctoral Program, Dr. Sokol will meet with the Post-Doctoral Program Administration and the LAC to mutually decide

on next steps and processes to find her replacement. In the interim, Dr. Nadeau will assume the Director role for the CCTSI Post-Doctoral program. Element B also includes the Evaluation Core under the direction of Dr. Komaie who is a member of the LAC and the lead evaluator for the CCTSI T32 Post-Doctoral Program.

1. Module C1- Workforce Development Core (WD)

The goal of Module C1 programs is to develop, deliver, demonstrate and disseminate clinical and translational science research training and career development programs that create and retain a highly qualified, interdisciplinary, team-oriented workforce prepared to apply scientific and operational innovative strategies to improve efficiency and effectiveness of research that embraces diversity, equity and inclusion. The T32 Post-Doctoral program, housed in this core, and all its trainees will highly utilize and benefit from WD programs.

The Clinical Science (CLSC) Graduate Program's goal is to prepare clinical/clinician scientists for career success and as such will provide foundational education to ensure T32 trainees can conduct high quality, rigorous and efficient CTS research and clinical trials. Lisa Cicutto PhD, ACNP(cert) *will ensure integration and coordination of* CLSC, TOTTS, CCTSI Pre-doctoral T32 program, and Module C: WD, as she serves as director for all of them. In this way Dr. Cicutto is 1. able to anticipate and identify issues and make changes to avoid and overcome bottlenecks, and 2. identify gaps and redundancies and take corrective actions. Dr. Kristen Nadeau (Associate Director) completed her master's degree through the CLSC and teaches its *Scientific Review of Clinical Research and Clinical Trials* course and thus is very familiar with the program, providing her with significant expertise in advising and counseling trainees.

Leading and Teaming in Clinical Translational Science and Research program, a requirement for T32 post-doctoral trainees, is directed by Jeni Cross who attends LAC meetings. She led the development of *Science of Team Science* during the last grant cycle, which will be expanded this renewal to include more on leading/ leadership. This curriculum expansion will occur collaboratively with Bruce Mandt (Mentoring³ and Graduate School's Office of Career Development and Post Doctoral Office), Lisa Cicutto, Amira del Pino Jones (DEI) and SOM T32 representatives.

Mentoring³: Mentor, Mentee, Peer completion is required for T32 trainees and their mentors. Bruce Mandt will develop and direct the program, which also includes building a pool of future program faculty/instructors. His involvement in post-doctoral training will be leveraged to attract faculty to participate in curriculum development, complete the train the trainer program, serve as future faculty and support a culture of strong mentorship that creates safe, inclusive and supportive environments (the goal of CCTSI T32 Post-Doctoral program, other T32 programs, and the university). Amira del Pino Jones will integrate DEI activities into Mentoring³ by assisting with curriculum development and seminar delivery.

Pre-K Grant Review and Mock Study Section participation by T32 post-doctoral trainees will support effective grant writing and attainment. Faculty that lead this program, attend the LAC, and serve as research mentors for postdoctoral trainees include Drs. Paul MacLean (Pre-Doctoral T32 leader), Kristine Erlandson (CLSC alumnus), Jose Castillo-Mancilla, and Lauren Shomaker. This integration allow them to understand and support the needs of trainees and advise for the next career milestone of career development awards.

Communicating Research to the Public will be completed by T32 trainees to accomplish the mutual goal of effective communication skills. Comilla Sasson MD, PhD is a CLSC alumnus that bridges academic clinical practice, patient advocacy/professional society organizations (a vice president for American Heart Association), active researcher and local and national news spokesperson. The wearing of many hats and speaking in many voices is congruent with program's goal of exposing trainees to multiple career options.

2. Module D1- Resources and Services

The goal of this module is to enable researchers to leverage key resources and services not otherwise available to successfully conduct research and obtain necessary training and support. Opportunities within the core span the spectrum from fundamental CTS research training (e.g., biostatistics, ethics, regulatory sciences) to dissemination strategies for non-academic audiences. Regulatory Knowledge & Services (LAC member) is a mandatory T32 element, a collaborative effort of the CCTSI and University. CCTSI's BERD (LAC member) supplements coursework by providing workshops on biostatistics, reproducibility, and study design, and can support and collaborate with postdoctoral trainees. Dr. DeCamp, Bioethics director, will provide a T32 seminar. CTRC Networks and Core Labs, directed by Wendy Kohrt, PhD, provide infrastructure for mentees and mentors to conduct research at lower cost. Bethany Kwan, PhD directs the CCTSI's Dissemination and Implementation service and will provide a workshop on designing for dissemination to trainees during a T32 seminar. Importantly, all leaders of these services and programs have agreed to provide priority access for trainees. Programs that are not represented on the LAC are part of the CCTSI Executive Committee that Lisa Cicutto attends twice monthly to ensure easy access to services and resources for trainees.

3. Module C2-Community and Stakeholder Engagement Research

Module C2's goal is to develop the bi-directional capacity of investigators and research staff to equitably engage diverse communities and stakeholders in CTSR, while establishing, building and maintaining trust. Trainees will benefit from this core through seminars provided by Montelle Tamez, MS (Deputy Director; LAC member) on partnering and community engaged research; support with organizing Science on Tap events in community; and assisting with the identification of translational and immersion experiences in community.

4. Module D3-Health Informatics

The goal of CCTSI Health Informatics Core is to manage data, democratize access, maintain critical software applications, and advance informatics education. Services provided to trainees include REDCap support and training and T32 seminars. Depending on the post-doctoral trainee's needs, additional support may include accessing Health Data Compass, CU's multi-institutional data warehouse, and the clinical and translational research data hub for CU-Anschutz. Tell Bennett, MD is a co-director and a T32 faculty mentor.

5. RC2-Innovator Ecosystem of Colorado

CCTSI's Innovator Ecosystem's goal is to conduct broad efforts to educate and support Innovators to expand commercialization of ideas and discoveries into products that will improve health, and to build the infrastructure to support this translational work. Ecosystem programs interact with University-sponsored SPARK | REACH initiatives that also have provided funding to TL1 trainees and their mentors. Cathy Bodine, PhD is director, serves as a CCTSI T32 Post-Doctoral Program mentor, and will provide a T32 seminar to discuss the program and to introduce concepts in biotechnology, entrepreneurship, and commercialization.

Dissemination Plan

Developing, demonstrating and disseminating effective training programs is crucial for responding to trainees' needs and to identifying best practices and advancing the field. CCTSI training programs have and will continue to actively pursue and contribute to advancing the field through innovative and effective training programs.¹⁻⁴ We will continue to contribute to the field and CTSA hub community in several ways.

During the last four years, we developed and evaluated a program called *Teaming for Early Career Clinical and Translational Researchers*, for pre- and post-doctoral trainees. Evaluation from trainees revealed that they wanted additional content on leading/leadership, which will occur with this CCTSI renewal. The program will consist of a self-paced web module and six workshops. We are now completing our second year of evaluation, which will include data from over 300 people regarding knowledge, attitudes, self-efficacy and application. We will disseminate our experiences and evaluative data through posters and presentations/ workshops at the national CTSA and International Science of Team Science conferences, and through peer-reviewed manuscripts. It is our intent to share the self-paced web module, which can be accessed through Canvas freeware, with other CTSA hubs. Dr. Jeni Cross, program director, has heard from three other CTSA hubs (Ohio, Kansas and University Southern California) that are interested in implementing our program. Our future direction is to work with other interested CTSA hubs to permit replication at their hub.

Starting three years ago, in response to our recognition and appreciation for the importance of mentoring and understanding the perspectives of both mentors and mentees, we developed a questionnaire to assess the mentoring relationship that allows analyses for data as a dyad, in addition to the mentee and mentor. We call this a **360 Mentoring Assessment**. Mentor and mentee questionnaires were based on the literature and consist of three parallel sections: self-report and reflection of one's own personal skills and relationship qualities, reported assessment of your mentee's or mentor's mentoring skills and report on the quality of important elements in the mentoring relationship. Mentors and mentees involved in the CCTSI T and K programs completed and will continue to complete these 360 type mentoring relationship experiences upon program initiation and end of years 1 and 2 (TL1 end of program was year 1). Our intent is that this type of information on individual mentoring relationships will assist with identifying dyads in need of support and extra attention (at-risk relationships), will identify areas of focused training efforts for effective mentoring, and will determine if these mentored programs improve mentoring relationships over time. Our experiences, results and questionnaires will be shared through our website, ACTS conferences, CTSA T and K program directors' meetings, and publications.

Café Scientifiques, called **Science on Tap** for our program, are a dissemination strategy that will be used to engage and inform community citizens regarding research conducted by CCTSI T32 trainees and to provide trainees with the opportunity to highlight and practice communicating and engaging with lay audiences. A Café Scientifique is a place where anyone can come to explore the latest ideas in science and technology. Meetings always occur in communities outside a traditional academic context, such as micropubs and taco bars. Each year we will hold two events where Post-Doctoral T32 trainees will start discussion about their research for 7-10 minutes followed by discussion. Cafés will engage people in a conversation about issues in science and health and promote the cultural examination of research. Cafés are known for their informal and friendly atmosphere and are believed to improve the image of scientists/science, careers in science, and science literacy,⁵ which aligns with the goals of the CCTSI. Evaluative efforts will explore attendee's pre-post perspectives regarding the image/relevance of scientists/science, science literacy, and interest in science, as well as satisfaction. We are unaware of other CTSA hubs using Café Scientifiques. CSU and the CCTSI have a track record for organizing these types of education and engagement events. We will share our experiences at the national CTSA/ACTS conference and post our "How to Kit" off our CCTSI T32 Post-Doctoral website.

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PAR 21-337, “Limited Competition: Ruth L. Kirschstein National Research Service Award (NRSA) Predoctoral Research Training Grant for the Clinical and Translational Science Awards (CTSA) Program (T32 Clinical Trial Not Allowed)

CTSA Predoctoral T32 at University of Colorado Denver

Principal Investigator:

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Grant Number: T32TR004367

Performance Period: 09/20/2023 – 08/31/2028

Training Slots Funded: 8

TRAINING PROGRAM

1. JUSTIFICATION

1a. Rationale. The Colorado Clinical and Translational Sciences Institute's (CCTSI) T32 Pre-doctoral Program aligns and supports the goals of NCATS to ensure that a diverse pool of highly trained scientists is available in adequate numbers and in appropriate research areas to

URM	127% increase in URM participation over 4 years
TOTTS Completion	100% awardee program completion
Publications	708 publications published by alumni
Persistence	89% persistent in clinical and translational research 100% URM trainees are persistent

carry out the nation's clinical and translational science research (CTSR) agenda. Successful translation of discovery for community benefit is a team effort. More than 20 distinct scientific disciplines are needed to traverse the translational journey from target to intervention to patient to practice.¹⁻² It requires multi-directional and multi-disciplinary integration of basic research, patient-oriented research, and population-based research that was rigorously designed, conducted, and reproducible.³ Translation absolutely requires a team as its unit of operation. To ensure success of our efforts, future scientists will need to be highly trained and skilled to perform translational science and research as a team. Understanding the science of translation is needed to solve well-appreciated inefficiencies and high failure rates of new health intervention/strategies. Therefore, training programs to support this understanding are essential and a major priority of translational science for the coming years.¹ Future translational research scientists must possess competencies for translational research and translational science and possess the fundamental characteristics of a translational scientist identified as: Domain Expert, Rigorous Researcher, Boundary Crosser, Process Innovator, Team Player, Skilled Communicator and Systems Thinker. Following this paradigm, our proposed **Team Oriented Training across the Translational Sciences Spectrum (TOTTS)** T32 Pre-Doctoral training program will support trainees' competency development and foster characteristic development for translational research scientists. We are requesting **8 slots** for diverse trainees that represent the translational spectrum across 3 streams, biomedical and bioengineer PhD students, population health/health outcomes PhD students, and clinician doctoral students. PhD students will complete our **2-year** pre-doctoral TOTTS program, contingent on trainee progress during year one, and doctoral clinician students (MD, Pharm D, DPT, etc.) will have the option of a one- or two-year duration to accommodate educational demands of clinicians (many clinician doctoral programs only allow one year to step out of full time program status). The proposed T32 TOTTS program represents a shift from a one- year TL1 to a two-year T32 program that will promote better integration of translational scientist characteristics and domains into their normal/usual practice as a translational scientist; year one will emphasize knowledge and skill development and year 2 will stress the application during the trainee's research conduct across the study life span.

1b. Need for CCTSI T32 Pre-doctoral. The 16 existing pre-doctoral T32 training grants at the University of Colorado Anschutz Medical Campus (CU Anschutz) (one a collaboration between CU Anschutz and CU Boulder) provide vibrant training opportunities for 90 pre-doctoral trainees. (**Required Table 3**). However, when we look at the number of slots that provide multi-disciplinary training across the translational spectrum of T1-T4 research, there are zero slots available. Not one of the existing programs provide the type of integrated interdisciplinary team-oriented training to prepare future translational science researchers. Fifteen of the 16 programs emphasize the development of domain expert and rigorous researcher with limited interdisciplinary interaction. The exception is the Medical Scientist Training Program, which prepares physician scientists in a dual degree MD and PhD program. The proposed TOTTS program will be the only program that emphasizes the development of knowledge and skills to be a boundary crosser, process innovator and systems thinker. Our CCTSI programs serve as a catalyst and role model for other pre-doctoral training programs on campus. For instance, with our last CTSA renewal, we developed and provided a program in team science designed for pre- and post-doctoral trainees that was opened to campus T32 trainees (so trainees outside our program) and it had more than 200 trainees participate. Other T32 programs are now partnering with and building off our workshops. We anticipate this also occurring with the Mentoring³ program we propose.

1c. Accomplishments.

We will build on and extend our previous program successes. Previous common metrics for the TL1 program included persistence in CTR and URM representation. (**See Tables 1-3**). For the last five years, 100% of our trainees are persistent in CTR and 89% since program existence (**Table 1**). All (100%) trainees completed the CCTSI TL1 program and 3% decelerated from a PhD to the master's degree (none of the latter were from

URM backgrounds). Most trainees were female (66%). Our program was recognized and profiled nationally by national CTSA coordinating center, CLIC, this past renewal for our ability to bend the curve by increasing URM representation. Over the last 4 years, we **more than doubled the number of trainees from**

underrepresented populations with respect to race and ethnicity from 11% to 25%, thus achieving our goal for the last CCTSI funding cycle. For the last 4 years, 19% of trainees were living with disabilities and 34% were from disadvantaged backgrounds (first generation to university, low-income families, low resourced communities; **Table 2**). Other indicators of program success include publications, grants and leadership positions. As a collective, our alumni (n=85) have published over 700 publications with many currently holding academic faculty positions as instructors, assistant and associate professors (18%), and post-doctoral fellows (35%) while 34% are working in the biomedical industry, 7% are medical students/trainees and 3% in non-government agencies (**Tables 2-3; Required Table 8A**). Shorter-term outcomes reveal that statistically **significant improvements (P <**

Table 2. Indicators of Success: Persistence, URM Involvement, Publications						
Cohort	Persists in CTR (#, %)	BIPOC (#,%)	Women (#, %)	Disability (#, %)	Disadvantaged Background/ First generation (#, %)	Publications (#)
2021-22	8, 100%	2, 25%	7, 87%	1, 13%	5, 63%	10
2020-21	8, 100%	2, 25%	7, 87%	2, 25%	1, 13%	14
2019-20	8, 100%	1, 13%	5, 63%	2, 25%	2, 25%	32
2018-19	8, 100%	3, 38%	5, 63%	1, 13%	3, 38%	26
2017-18	8, 100%	2, 25%	5, 63%	1, 13%	2, 25%	31
2016-17	7, 88%	1, 13%	4, 50%	0	No data	40
2015-16	8, 100%	1, 13%	6, 75%	1, 13%	No data	66
2014-15	7, 88%	1, 13%	4, 50%	No data	No data	55
2013-14	6, 75%	0	6, 75%	No data	No data	44
2012-13	7, 88%	0	5, 63%	No data	No data	100
2011-12	6, 86%	0	4, 57%	No data	No data	92
2010-11	8, 100%	1, 13%	6, 75%	No data	No data	108
2009-10	4, 100%	0	1, 25%	No data	No data	100

0.01) were noted in clinical research skills as measured by the validated CRAI (Clinical Research Appraisal Inventory, Robinson et al. 2013⁴). Greatest improvements occurred for data analysis, identifying collaborators outside of discipline, setting expectations and communicating them to staff/team, and ability to prepare a grant. Overwhelmingly, alumni reported that the program strengthened their commitment to conducting clinical translational research (87%) and to doing so through team science (100%).

Table 3. Pre-doc Alumni: Careers	
Academia-Faculty 18%	Instructor - CO, Asst. Prof- Tulane, U Nevada, Oregon, Stanford, Assoc Prof - CO, UT Director Cancer Research Center
Academia-Post-Doc Fellowship 35%	CU, Yale, Duke, UCSF, Tulane, UC-Davis, Case Western, Universities of Nebraska, Kansas, Minnesota
Industry 34%	Sr Research Assoc, Research Scientists I, II, Research Analyst II, Principal Scientist, Surveillance Scientist, Clinical Trials Project Manager, Associate Director, Founder and Director of a start-up
Med school 7%	CU, Mayo, U Iowa, Stanford
NGO 3%	Senior Translational Scientist, Investigator
Other 3%	Sr. Bioengineer, Physician, DNA analyst in law enforcement

1d. Mission/Goal, Objectives

The overall goal of our TOTTS program is to meet the needs of the translational science and research community by preparing diverse inter-disciplinary doctoral trainees that are team-oriented and have developed characteristics and associated skills necessary for successful Clinical and Translational Science and Research (CTSR) careers. To accomplish this, the following program objectives will be met:

1. Attract, recruit and retain diverse trainees by demonstrating that Diversity Accelerates Research and Translation (DART) is a core value and program commitment.
2. Promote trainee development of foundational characteristics of Translational Scientists: Rigorous Researcher, Boundary Crosser, Process Innovator, Team Player, Skilled Communicator, and Systems Thinker.
3. Apply evidence informed mentoring practices to support developing trainees from all backgrounds for career persistence and success in CTSR.

4. Develop trainees' knowledge, skills and abilities to advance CTSR in diagnostics, therapeutics, clinical interventions, and behavioral modifications.
5. Support study conduct concordant with ethical and regulatory principles through required training in ethics, RCR, GCP, regulatory compliance, rigor and reproducibility and data science principles.
6. Develop trainee's ability to communicate effectively (oral and written) to diverse stakeholder groups.
7. Engage trainees with a new translational community and network that brings new insights, perspectives, and skills through immersion experiences with translational mentors.
8. Approach clinical and translational science and research as a team endeavor and foster trainees' teaming and leading skills for high performing teams.
9. Identify, monitor, track, review and respond to, as necessary, indicators and metrics of an effective and successful program through continuous quality improvement.

1e. Core Value- Diversity

Diversity is instrumental for the workforce to advance discovery, eliminate health disparities, and achieve patient-centered outcomes in the quest for better health.⁵ As a result, our CCTSI Workforce Development (WD) and T32 TOTTS' value and philosophy is that **Diversity Accelerates Research and Translation (DART)**. A sustainable way to achieve diversity in the workforce is through training, education and career development of all individuals involved in the conduct of CTSR. Amira del Pino-Jones MD is our T32 Director for Diversity, Equity and Inclusion (DEI). Staying true to our DART value we will: 1. explicitly identify our DEI statement on TOTTS webpages and all CCTSI's WD program webpages, 2. identify that holistic review of applications is followed and that all reviewers have received training in holistic review, 3. require all TOTTS faculty and trainees to participate in DEI training provided by Dr. del Pino-Jones that addresses implicit bias, microaggressions, race in research, systemic racism, allyship, upstander, power and privilege, diversity statements, mentoring relationships with differing backgrounds/experiences, 4. provide an open door and safe space for trainees to voice concerns, experiences and discuss and plan next steps, 5. Dr. del Pino-Jones will connect with all awardees upon program entry to inform them of her open-door policy, her desire to be a part of the mentoring team and allyship. **Our program aim is to integrate DART across all programmatic activities and mentoring relationships to create a safe, inclusive, and supportive training environment.**

1f. Model for Persistence of a Diverse Clinical and Translational Research Workforce

Individual preparedness is necessary but not sufficient for lasting change and persistence. Integration into the clinical and translational fabric strengthens a person's connection, self-efficacy, and identity formation, thus increasing the likelihood that T32 trainees remain in the translational workforce. A conceptual framework for diversifying the CTSR workforce and driving this integration, **Model for Persistence of a Diverse Clinical and Translational Research Workforce**⁶⁻⁸ identifies the interaction of the individual and the environment as critical to success. The model was developed by our CCTSI colleagues, Nearing and Manson,⁸ leveraging Tinto's conceptual work in URM pre-doctoral education. Based on our Model of Persistence for a Diverse Clinical and Translational Workforce (**Figure 1**) and consistent with DART, **5 overarching strategies** will be applied.

- (1) **Create pathways to CTSR** by forming strategic partnerships to achieve continuity of trainee support and collective impact. We will leverage the assets and efforts of the university's 18 programs (including CCTSI partnered Summer Undergraduate Multicultural Mentoring in Translational Science, SUMMiT) that create pathways to CTSR careers that begin in middle and high school continue as undergraduate and graduate students and extend to staff and faculty. SUMMiT is a collaborative effort of 12 summer undergraduate research programs focusing on the unique needs of underrepresented students to enhance their experience in clinical and translational research. TOTTS faculty are involved in SUMMiT's lunch seminar series and individual programs. TOTTS will leverage CU's Office of Inclusion and Outreach and the SOM's Office of Diversity and Inclusion URM programs to attract and recruit highly prepared applicants/trainees from diverse backgrounds (See grant section 5d and **Attachment Recruitment Plan to Enhance Diversity**). TOTTS leaders (Cicutto, del Pino-Jones, MacLean, Nadeau) and university training program directors and leaders (including university leaders of DEI offices -Martinez, and Zimmer) will meet monthly at the Leadership Advisory Council to intentionally work in a coordinated and integrated fashion (See 2b-2).

(2) **Provide meaningful research opportunities** to support identity formation as a scientist and sustain motivation to pursue and persist in CTSR careers. Engaging budding investigators in meaningful research fuels motivation and will be accomplished by a) having trainees reflect on how their research interests and career support their personal values; b) having mentors assist mentees to clarify goals and motivations; c) involving trainees in meaningful research and translational immersion experiences; and d) facilitating collaborations and teaming across the translational spectrum. Every TOTTS trainee will have a mentored research project and a translational immersion that is meaningful to him/her, providing essential engagement for competency development, socialization, and identification and integration into the CTSR workforce. Additionally, research projects will lead to trainee presentations and publications, which builds a stronger portfolio and increases future competitiveness.

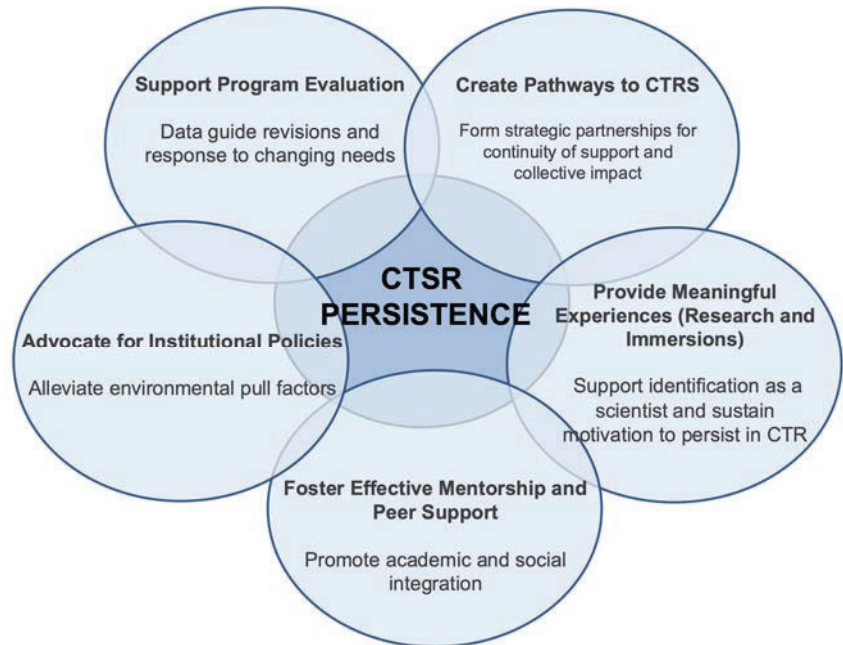


Figure 1. Model for Persistence of a Diverse Clinical and Translational Research Workforce

- (3) Foster an environment for **effective mentorship and peer support** to promote academic and social integration. Our program will provide mentorship and peer support, two of the most effective strategies for promoting CTSR integration.⁶⁻⁸ TOTTS mentors will assist trainees with a) setting strategic goals, b) devising pathways to success that include alternative strategies when challenges emerge, c) accessing resources, d) developing CTSR competencies of translational scientists, and e) providing emotional support. Each trainee will have mentors for the contexts of research, translation, and career development that will form a mentoring team. To address the need for effective mentoring, mentees and mentors will attend the CCTSI’s Mentoring³: Mentor, Mentee, Peer, a formalized program for effective mentoring relationships. Additionally, URM TOTTS trainees will have the support and mentorship of our DEI Director, Amira del Pino-Jones MD for contextualized support and guidance for succeeding in CTSR, including mentoring through differences in our backgrounds and life experiences.
- (4) Advocate for institutional policies **alleviating environmental pull factors**. Environmental pull factors are demands that compete or conflict with trainee engagement, integration, and performance that ultimately diminish persistence. The TOTTS Internal Advisory Committee (**IAC**) and CCTSI WD Leadership Advisory Council (**LAC**) will proactively advocate for institutional policies to support the translational workforce in their work. For example, the WD LAC advocated for required training for all workforce members regarding DEI. This is important to support a culture that values and recognizes that excellence requires diversity. As a result, a policy was implemented that required DEI to be integrated into mandatory career development activities for CCTSI leaders, faculty, staff, and trainees, as well as career development activities at the University level for leaders, faculty and staff. Topics included in training for the broader CCTSI community and the TOTTS program (leaders, faculty, trainees) will include cultural humility, holistic review unconscious/implicit bias, allyship, and mentorship for diverse mentees. These topics will be integrated into the following career development activities that serve TOTTS trainees and faculty: TOTTS seminars, workshop for IAC, TOTTS faculty, and LAC, Mentoring³, Leading and Teaming, etc.
- (5) Support program evaluation - particularly, the **examination of longitudinal outcomes** - to guide programmatic efforts and respond to changing demands. (See **Section 4**)

These 5 overarching strategies identified by Nearing et al.⁸ were informed by our experience leading and evaluating programs across educational and career development pathways and programs and extensively reviewing the literature. TOTTS applies lessons learned and best practices to prepare a highly qualified workforce. (Described in **Section 3**)

2. PROGRAM PLAN

2a. Program Administration (See Figure 2 for TOTTS organizational structure.)

Lisa Cicutto RN, ACNP(cert), PhD will serve as TOTTS director (see **Biosketch**) and provide overall program leadership. (**Table 4** for a list of responsibilities). She was chosen based on her credentials in translational research that spans the T1-T4 spectrum in lung health, her extensive experience with interdisciplinary graduate and postdoctoral training, and importantly her leadership roles in education and training at CU Anschutz and the CCTSI. For the last 6 years she has served on the University's Graduate School Council and Program Directors Committee for all doctoral programs (clinical and biomedical). Starting in 2018, she directed the CCTSI TL1 Training Program, which included both pre- and post-doctoral awardees. In 2016, she was appointed director of the CCTSI's Workforce Development (**WD**) and has directed the Clinical Science (**CLSC**) Graduate Program since 2008. She is a member on the national CTSA TL1 Directors Group and the Workforce Development Enterprise Committee and was recently elected to serve on its Leadership Team. Additionally, she serves on 5 Internal Advisory Committees for R25, T32 and KL2 training/career development grants and 2 External Advisory Committees for a K and T training programs. She recently collaborated with Drs. Rubio (University of Pittsburgh) and Patino-Sutton (University of Southern California), in a multi-site CTSA trial to understand the effectiveness of different formats of individualized career development plans. At National Jewish Health, she is Director, Community Outreach and Research. Her research focuses on developing, evaluating, disseminating and implementing innovative best practice programs to improve

Table 4: Program Director and Associate Director Roles
<ul style="list-style-type: none"> Attend and receive counsel at quarterly Internal Advisory Committee meetings
<ul style="list-style-type: none"> Attend and receive counsel at monthly Leadership Advisory Committee meetings
<ul style="list-style-type: none"> Attend TOTTS program directors meeting monthly
<ul style="list-style-type: none"> Work to attract and retain diverse trainees and create environment of excellence through diversity
<ul style="list-style-type: none"> Support trainee application and selection processes: answer questions, assist trainees/applicants in matching mentors, review applications, vet mentors
<ul style="list-style-type: none"> Curriculum oversight and participation in teaching
<ul style="list-style-type: none"> Support integration of TOTTS with trainees' "home" doctoral degree program
<ul style="list-style-type: none"> Organize and participate/teach in TOTTS Seminars
<ul style="list-style-type: none"> Trainee advising and mentoring: Review and update ICDP, review abstracts/manuscripts, provide career development advice
<ul style="list-style-type: none"> Ensure trainee is current with GCP, RCR and other required regulatory training
<ul style="list-style-type: none"> Mentor Review: Attend trainee MATT-C meetings to ensure research and scholarly productivity, identify & resolve issues, review mentor-mentee dyad evaluation, and resolve conflict, if necessary
<ul style="list-style-type: none"> Program Evaluation: Review formative and summative reports to identify areas for revision

health of people living with lung conditions by partnering with health providers, schools, and individuals and families. Her work has received national recognition/awards for research in underserved populations and contributions to advancing the field from Press-Ganey, Association of School Nurses, and the Canadian Network for Asthma Care. As principal or multiple principal investigators, she holds active NIH NHLBI UG3/UH3 DECIPHeR (Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Risk) and Colorado Department of Public Health funding to improve the health of those with lung conditions living in rural and disadvantaged communities. She has held consistent external funding as a Principal Investigator since 1998. Her passion is to work with, mentor and train future scientists to answer important patient/public health-oriented questions that are subsequently translated to patients/people living in their communities. She has served in key roles for more than 45 trainees (clinician and non-clinician masters and PhD students and post-doctoral fellows) of which more than 85% remain engaged in research. Many have gone on to receive T32, F- and K awards and independent research grants. In recognition of her outstanding training record, she was awarded the teacher/mentor of the year for the Clinical Science Graduate Program. Dr. Cicutto will dedicate **2.4 calendar months** with

the teamwork of Drs. del Pino-Jones, MacLean, Nadeau and Ms. Mankin, described below, to provide an excellent trainee program. She will oversee the day-to-day program operations; provide overall direction, management, and administration; work with CCTSI Evaluation Core; and submit all documents and reports as required. She is and will remain a member of the Executive Committee of the CCTSI, which is its governing and decision-making body and meets every other week. Importantly, she will integrate and leverage training resources across the CCTSI, University, and participating programs. If Dr. Cicutto is unable to fulfill her responsibilities for the TOTTS program, Dr. Sokol (CCTSI PI and Director) will meet with the TOTTS Program Administration and the CCTSI WD Leadership Advisory Council (**LAC**) to mutually decide on next steps and processes to find her replacement. In the interim, Dr. Paul MacLean (Associate Director; see below) will assume the Director role for the CCTSI TOTTS program.

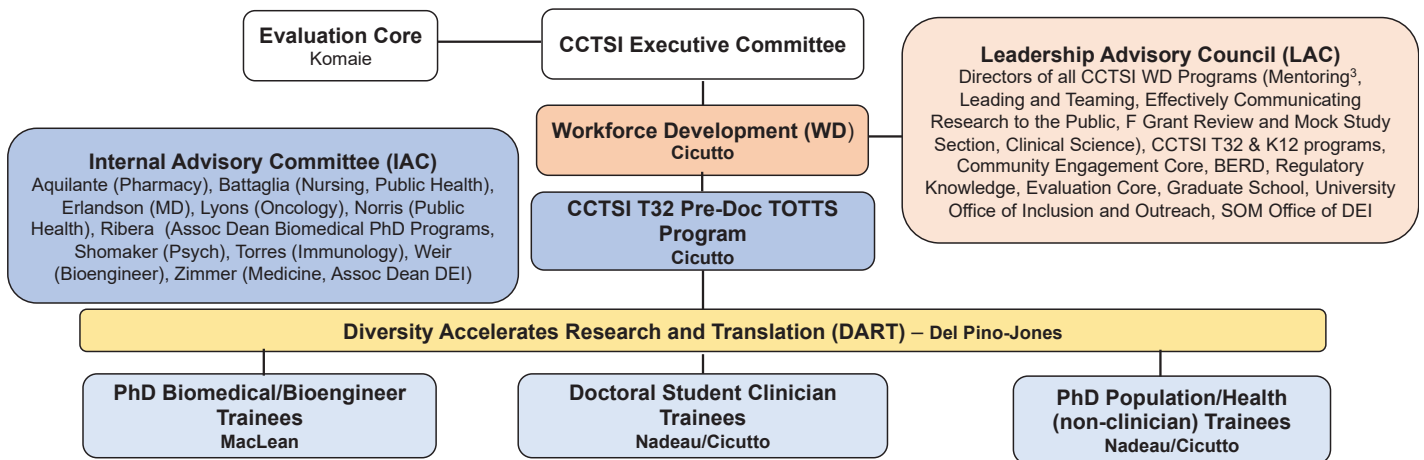
Director, DEI/Mentor: **Amira del Pino-Jones MD** will serve as Director of Diversity, Equity, and Inclusion (**DEI**) for our CCTSI TOTTS Program and WD programs (See **Biosketch**). She is an Associate Professor and Assistant Dean of Student Affairs, School of Medicine. Dr. Pino-Jones is a hospitalist improving transitions of care for under- and un-insured patients as well as improving the care of patients with Sickle Cell Disease. She is an alumnus of the CU Anschutz high school and undergraduate pathway programs, an outstanding exemplar of the success of our pathway programs. She has rich personal experiences to share with trainees and faculty, as a woman of color growing-up in an urban disadvantaged community and part of a family that had never attended university. She will be actively involved in trainee mentoring. Because her primary interest is not research, she will not serve as a sole research mentor but could be involved in a co-mentoring research faculty relationship with a more senior researcher. Importantly, she will direct our TOTTS DEI strategic plan, aligned with DART (see above 1.e), and be responsible for its implementation and refinement. The strategic plan will include activities for attracting, recruiting and retaining underrepresented trainees, educational DEI programming (implicit bias, holistic review, microaggressions, allyship, mentoring those with differing life experiences and backgrounds, etc.) and will oversee our holistic review process. She will work closely with the DEI offices across the university to attract, support application, and retention of URM trainees. She supports many programs within the School of Medicine (**SOM**) related to DEI. Additionally, she will fulfill responsibilities outlined in **Table 4** above and dedicate **0.6 calendar months**.

Associate Director: **Kristen Nadeau MD, MSCS** is a Clinical Science alumnus and currently a Professor of Pediatric Endocrinology at Children's Hospital of Colorado, holds several leadership positions locally and nationally (See **Biosketch**) and is a member of the Prairie Band Potawatomi tribe. She is the Research Director for Pediatric Endocrinology Research and the Fellowship Program and Co-Chairs the NIH Diabetes Research Center Clinical Research Core. Her research focuses on reducing long-term complications of diabetes, inactivity and obesity in youth, including mechanisms of insulin resistance, β -cell and exercise dysfunction, and cardiovascular, hepatic and renal disease. Her lab assesses pediatric cardiac, vascular, exercise, and autonomic function, as well as sleep, circadian rhythm, body composition and insulin sensitivity and secretion. She is Principal Investigator (PI) of a NIH RO1 study of bariatric surgery in youth-onset type 2 diabetes (T2D), the Pediatric Chair and PI of the NIDDK multi-center longitudinal RISE U01 study of β -cell preservation in obese youth and adults with prediabetes or early T2D, Co-I on the NIDDK multi-center longitudinal U01 TODAY trial of youth with T2D since its inception in 2002, PI of several studies of adjunctive therapies to improve insulin resistance and cardiovascular disease in type 1 diabetes (T1D), Co-I on a NIH RO1 trial of the impact of treating depression on IR in adolescent girls, and Co-I of an NIH U01 multi-center gestational diabetes prevention study in obese American Indian girls. Additionally, she has an interest in sex and ethnic differences and underserved populations. She is a very experienced mentor and teacher for both clinicians and non-clinicians across training levels. She is PI of an NHLBI K24 grant focused on mentoring K23 trainees on cardiovascular research. She has mentored over 100 junior faculty, fellows, graduate and undergraduate students across multiple departments, with work focused on preventing complications of youth-onset T1D, T2D, CFRD and GDM. She currently directs the Medical School Mentored Scholarly Activity Longitudinal Research Course, in which she pairs medical students with research mentors and support their research projects. If the CCTSI T32 TOTTS Program is funded, she will step away from this directorship to make time for the program. However, this experience will be leveraged to engage and recruit medical students into the TOTTS program. In addition to attracting and recruiting trainees, another important role is supporting trainees in finding translational mentors and immersion experiences with clinicians and clinical settings. Dr. Nadeau will fulfill responsibilities outlined in **Table 4** and dedicate **0.6 calendar months**.

Associate Director: **Paul MacLean, PhD** is a Professor of Medicine and Pathology at the University of Colorado School of Medicine with 25 years of experience studying obesity and its metabolic complications (See **Biosketch**). He is the Director and PI of the Colorado Nutrition Obesity Research Center (NIH P30 DK48520), which supports early career investigators through three biomedical research cores, an enrichment program, and a pilot and feasibility program. He has served as primary mentor or on mentoring committees for over 40 undergraduate students, graduate students, post-doctoral fellows, resident fellows, and junior faculty members. Trainees for which he has served as the primary mentor have acquired career development awards and fellowships through the federal government (K99/R00, K01, VA CDA2, KL2, BIRCRWH K12, F32, F31, T32, TL1) and foundations (Komen Foundation, the Thorkilldensen Foundation, the American Institute for Cancer Research, the Bec.ar-Fullbright Argentine Presidential Fellowship program, and the Endocrine Society. Many of his trainees have used these grants and fellowships to launch their independent research careers. For the

CCTSI, Dr. MacLean serves as one of four Associate Directors of the KL2 Research Scholars Program (transitioning to the K12 mechanism) and Co-Director of the PreK Program that provides a pre-review for proposals of K-level applicants. He is a regular reviewer for the CCTSI's F31/F32, PreK, and K to R mock

Figure 2. Organizational Chart of CCTSI Pre-Doctoral Program



study sections. Dr. MacLean's research interests include the biological drivers of weight regain after weight loss, exercise as a strategy for weight loss maintenance, and understanding how obesity affects key aspects of women's health across the lifespan. He has a particular interest in how obesity and its treatments affect the risk and incidence of breast cancer and leads a team to study the effects of intermittent fasting and time restricted eating in preclinical models and breast cancer survivors (R01 CA258766). He also serves as a projects PI for a translational team science team (U54 AG062319 SCORE) that is leveraging basic, preclinical and clinical research paradigms to study the metabolic consequences that accompany menopause. Over the past several years, Dr. MacLean has worked with program staff at the National Institutes of Health to lead the ADOPT Core Measures Project, an interdisciplinary effort to develop personalized approaches for the treatment of obesity. Dr. MacLean's overarching research objective is to translate the wealth of knowledge generated from mechanistic basic science studies of energy balance to clinically relevant concepts and applications in obesity therapeutics. Dr. MacLean will dedicate **0.6 calendar months**.

In addition to responsibilities listed in **Table 4**, a major role of directors is to address environmental factors/challenges trainees experience by providing individualized coaching, mentoring and advice regarding competing/conflicting demands, integration into projects and teams, navigating institutional obstacles and advocating for institutional policies to alleviate environmental pull factors. Pull factors could originate from the trainee's home doctoral degree program. TOTTS Directors will work with degree granting program directors to assist with the integration and alignment of the two programs' expectations. All PhD program directors are familiar with the previous CCTSI TL1 program but given that the program is now a 2-year award, the integration of the new program will be discussed at the Biomedical Program Directors meeting (Cicutto), the Graduate School Council (Cicutto), Schools of Medicine (del Pino Jones, MacCclean and Nadeau), Pharmacy (MacLean), Bioengineering (MacLean), Physical Therapy (Cicutto) and College of Nursing (Cicutto).

Galit Mankin, BA, MSW will be the TOTTS Program Administrator. She has extensive experience and skill for managing and administering training programs. For 13 years she has served as Program Administrator for the CLSC Graduate Program and for the last 6 years, administrator for the CCTSI WD and TL1 program. She has extensive experience and talent in developing relationships with trainees to provide guidance for success. Ms. Mankin will work closely with the Directors to coordinate recruitment and selection of new trainees; support the IAC, program and faculty meetings, TOTTS seminars and other programmatic activities; communicate program information and maintain and the website and distribute/mail program materials; track and report records for trainees to ensure compliance with NIH guidelines/regulations (such as GCP, RCR, etc.); manage the xTrain system; and collect/compile annual progress reports and alumni curriculum vitae.

2b. Oversight Committees

2b-1 Internal Advisory and Candidate Selection Committee (IAC): The IAC is comprised of faculty that represent all biomedical and bioengineering PhD programs, the College of Nursing (**CON**), Colorado School of Public Health (**CSPH**), School of Pharmacy (**SOP**), School of Medicine (**SOM**), and SOM Office of DEI. It will meet three to four times a year to review applicants for upcoming positions, assess trainee progress and assess the program's progress. We anticipate that some years may not require 4 meetings because the selections process will not occur due to the unavailability of slots. All members have doctoral training program experience through academic programs and T-type training programs. IAC members represent both professional doctorates and PhDs. Members will serve a 5-year term. Members will include Drs. Aquilante (pharmacist), Battaglia (nurse), Erlandson (physician), Lyons (biomedical), Norris (epidemiologist), Ribera (physiologist), Shomaker (psychologist), Torres (immunologist), Weir (bioengineer), Zimmer (physician). All members have agreed to serve on the committee and have outlined their commitment in attached **Letters of Support**. For additional information, see **Attachment Internal Advisory Committee**.

2b-2 CCTSI Workforce Development Leadership Advisory Council (LAC): The T32 TOTTS Program (if funded) will be part of the CCTSI's WD LAC (See **Figure 2**), which consists of directors and leaders of all CCTSI WD programs, the Director for DEI (del Pino-Jones), CCTSI K12 (Burnham, pending funding), T32 Post-doctoral (pending funding), CCTSI Evaluation Core (Komaie), other CCTSI initiatives (Community Engagement, Innovation Ecosystem, BERD), Graduate School, University's Office of Inclusion and Outreach. The LAC uses shared decision making and will meet monthly to review all WD programs' (including TOTTS) activities, metrics and outcomes, and discuss integration across programs (WD, CCTSI and university), progress towards milestones, need for changes and current events/issues. The LAC will ensure coordination, integration, synergy, and mutual reinforcement among all CCTSI programs and activities. The LAC has proved extremely valuable to ensure that education/training leaders are aware of one another's services, have the agility to collaborate/integrate across programs, leverage resources, avoid reinventing the wheel and competing with one another. An example of a benefit was the creation of the teaming program, which was a collaborative effort of the CCTSI, the Graduate School, SOM, and Colorado State University, and used by other T32 programs. We will repeat this with Mentoring³: Mentor, Mentee, Peer program described below (2d. Mentoring). It has also been instrumental for operationalizing our value of DART through a strategic planning process that unified our approaches for the attraction, recruitment, and holistic review and onboarding of members (and their programs) that were not implementing the best practices. Through our strategic planning process with the last TL1 renewal, we identified that some programs and faculty were not implementing best practices. Our strategic planning process unified our approaches for attraction, recruitment, and holistic review. (See **attachment Coordination and Interaction**)

2b-3 CCTSI Executive Committee: To integrate the TOTTS into the larger CCTSI community and infrastructure, Dr. Cicutto is a member of the CCTSI Executive Committee that meets twice monthly to communicate, coordinate and integrate activities. Following the selections of T32 awardees by the IAC, the slate of recommended awardees will be presented to the Executive Committee for funding approval.

2b-4 CCTSI External Advisory Committee: The CCTSI has an External Advisory Committee (EAC) that meets yearly. As part of this meeting, the T32 TOTTS program will be reviewed by committee members to advise on our objectives, milestones and metrics/outcomes. Committee members will meet with current trainees, without program leadership, to identify potential issues, resource needs and areas for improvement. Additionally, our alumni will provide presentations to the EAC regarding their research, program experiences, accomplishments and future directions. The EAC consists of senior faculty representing CTSA hubs across the country that include Oregon Health Sciences, University of California- Irvine, Los Angeles, Vanderbilt, Virginia Commonwealth, Cincinnati, and Yale.

2c. Program Faculty and Mentoring Oversight

2c-1 Faculty Selection: We have a diverse group of 96 talented and experienced interdisciplinary research faculty to potentially serve as research mentors for TOTTS T32 Predoctoral trainees (See **Tables 5-6**, Attached **Biosketches**, **Grant Tables 2, 4**). Most faculty hold PhDs (68%) with the remaining holding professional doctoral degrees (DPT, MD, PharmD). Research conducted by faculty span the translational

spectrum with 70% conducting T1, 68% T2, 38% T3 and 16% T4 (total exceeds 100% because many conduct studies along the spectrum). Women make up 46% of our pool and 14% are Black, Indigenous or people of color (**BIPOC**; See **Table 5**). All faculty hold graduate school faculty appointments, CCTSI membership, and have a track record of success in training new investigators, including previously mentoring CCTSI TL1 pre-doctoral trainees. All are highly accomplished translational scientists, and many have had, or currently hold, leadership roles at the national or international level by serving on NIH, NSF, AHRQ, PCORI and DOD grant review panels, editorial boards, or officers/organizers of major scientific societies increasing networking and scholarly opportunities for trainees. There are 56 (58%) established mentors at full professor level and the remaining are assistant or associate professors with rising careers, research programs, and bright mentorship potential. There are “rising star” junior faculty (Gorska, Perng, Sherbeneau, Smith) identified in our pool that will serve as research mentors but in a co-mentor role paired with a more established research mentor creating a junior-senior mentoring relationship. These junior faculty have previous experience mentoring in a co-mentoring role and all hold graduate faculty appointments. Because they have more recently completed their own postdoctoral training and are successfully launching their own academic careers, they will serve as role models for trainees. In order to serve as a primary research mentor, faculty are required to have sufficient funding to cover costs of trainee’s research. Collectively, our faculty research mentors are funded by extramural grants with total annual direct costs of approximately \$95 million in external funding, averaging \$986,000 grant support per faculty member. (**Grant Table 4**). See **Table 6** for a representative sample of mentors that details discipline, title, research area, grant types held and pre-doctoral mentoring experience.

Table 5: Faculty Characteristics (n=96)	
Doctoral Degrees	
- PhD	54 (56%)
- MD	23 (24%)
- MD/PhD	14 (10%)
- PharmD	3 (3%)
- PharmD/PhD	1 (1%)
- DPT/PhD	1 (1%)
Rank	
- Professor	56 (58%)
- Associate Professor	32 (33%)
- Assistant Professor	8 (8%)
Translational Spectrum (category overlap)	
- T1 Pre-clinical	69 (70%)
- T2 Patients/Clinical	65 (68%)
- T3 Clinics/Implementation	36 (38%)
- T4 Public Health	15 (16%)
Female	44 (46%)
BIPOC	13 (14%)
Both Anschutz + affiliate/ partner appointments	31 (32%)

Our faculty mentor pool is fluid. Applicants/trainees can introduce new mentors after being vetted by Program Administration and meeting the requirements for mentoring. Trainees will identify research mentors in their T32 application, and the strength of the mentoring team is a criterion scored during review. PhD students typically have a research mentor identified through their PhD program. Program Administration will assist applicants in finding/choosing a mentor that aligns with their interests and meets program requirements for research mentor if an applicant does not have a mentor. It is anticipated that this may occur with the professional doctorate students. Program Administration will vet all research mentors before awarding a position. Criteria for serving as a primary research mentor includes: 1) demonstration of a deep commitment and excellence for mentoring early investigators as evidenced by their track record; 2) active peer-reviewed research funding to support trainee research; and 3) active involvement in translational research evidenced by their publication history. If gaps are identified with the proposed mentor, Program Administration will work with the mentor and mentee to identify an additional senior mentor to supplement the team.

2c-2 Faculty Oversight and Removal: There may be times when a mentor changes institutions or needs to be removed for various reasons, such as poor performing mentoring relationship, conflicts of interests, personality clashes, or lack of resources. Program Administration and the IAC will carefully monitor annual mentee-mentor assessments in conjunction with their semi-annual Mentoring Advisory Team/Thesis Committee (**MATT-C**) meetings and monthly Program Administration check-ins with mentees to identify at-risk mentoring relationships and will arbitrate the removal of a mentor, if necessary. (See **Attachments Mentoring Assessment and Internal Advisory Committee**). Should this occur, Program Administration will assist the trainee to find an appropriate substitute. In the case of a lapse in mentor funding, the mentor will be required to submit a plan to the IAC that identifies a source for continued trainee funding for T32 and degree completion. We are committed to our trainees for the time period required to prepare for a successful academic career. The IAC and program will assist with identifying bridge funding when necessary. **See LOS Institutional Commitment.**

In addition to research mentors, TOTTS trainees are required to have a translational mentor for the completion of an immersion experience, which will be discussed in more depth below. This is also a reviewed and scored element of the T32 application. All immersion mentors will have previous experience with mentoring trainees in

their respective settings, be committed to the trainee and have clearly demonstrated a plan for the immersion experience as demonstrated in their Letter of Support. TOTTS T32 administration will assist trainees with the identification of translational mentors, if needed. Translational mentors will participate on the trainee's Mentoring Advisory Team/Thesis Committee (MATT-C). These mentors are not included in Table 6.

Table 6: Potential TOTTS Faculty Research Mentors					
Mentor	Title/Appointment/Institution/	Department or Training Program	Area of Research Expertise	Research Funding	Pre docs
Rafael Alam, MD, PhD	Professor, SOM, NJH	Allergy and Immunology	Mechanism of persistent inflammation in asthma	3X RO1	2
Peter Anderson, Pharm D, PhD	Professor, SOP, AMC	Pharmacology	Optimize drug therapy in humans	4X RO1, 2X UM1, U19	5
Bruce Appel, PhD	CU-D SOM	Pediatrics, Stem Cell Biology	Degenerative, and cancerous diseases of nervous system	R35, RO1	11
Christina Acquilante, Pharm D, PhD	Assoc. Prof., SOP, AMC	Pharmaceutical Sciences	Cardiology and transplant	1 RO1, Univ grant	3
Emily Bates PhD	Assoc Prof, SOM, AMC, CHCO	Pediatrics, Devt Biology	Ion channels, microtubules and brain development	RO1, NSF, Univ grant	7
Cathy Battaglia RN, PhD	Assoc Prof, SON, CSPH, VA	Nursing, Health Systems	Access to care and improving the healthcare delivery system for veterans	3X VA, Other Fed grant	10
David Beckham MD	Assoc. Prof. SOM, AMC	Infectious Disease	Emerging RNA virus infections	RO1, 2X Other	5
Richard Benninger PhD	Assoc. Prof, SOE, AMC/DC	Bioengineering, Peds	Diabetes, endocrine, pancreas	2X RO1, P30	6
Audrey Bergouignan, PhD	Asst. Prof., SOM, AMC	Integrative Physiology, Endocrinology	Energetic and lipid metabolism regulation, core components of body weight, and their regulation by environmental factor	RO1, 4X Other	7
Kristen Boyle, PhD	Assoc. Prof., SOM, CHCO	Pediatrics	Pregnancy and early life exposures in the development of obesity and metabolic disease	R01	3
Jose Castillo-Mancilla MD	Assoc. Prof. SOM, AMC	Infectious Disease	HIV, AIDs, clinical studies	RO1	5
Uwe Christians MD, PhD	Professor, SOM, AMC	Anesthesiology	Toxicology	R01, Other Federal grant	8
Sean Colgan, PhD	Professor, SOM, AMC	Integrated Immunology	Inflammatory Bowel Disease	3X RO1, Federal grant, Fdn grant	5
Dana Dabelea, PhD	Professor, CSPH, AMC	Epidemiology & Biostatistics	Maternal diabetes and obesity during intrauterine life	2X U18, UH3, 5X RO1, U01	6
Tasha Fingerlin, PhD	Professor, CSPH, NJH	Epidemiology & Biostatistics	Diabetes, Chronic Beryllium disease and Schizophrenia	R01, PO1	2
Heide Ford, PhD	Professor, SOP, AMC	Pharmacology, Cancer biology	Developmental regulators and cell plasticity in tumor progression/metastasis	3X RO1, Univ grant	16
Emily Gibson, PhD	Assoc Prof, SOE, AMC/DC	Bioengineering	Optical technologies for imaging activity and stimulation in living brain	2X RO1, UF1, UO1, 2X NSF	2
Melissa Haendel, PhD	Professor, Chief Research Informatics Officer,	Biochemistry and Molecular Genetics, Epidemiology	Making phenotypic data computable for genomic health applications; national data sharing, cloud and information architecture; data interoperability	RM1, 2X U24, 2X U2C, R24, Fdn grant	3
Lynn Heasley, PhD	Professor, SOM, AMC, NJH	Craniofacial biology	Signal pathways mediating autocrine growth of cancer cells, resistance to therapeutics	P50, 2X Other Fed grants	6
Larry Hunter PhD	Professor, SOM, AMC,	Computational Biology	Development and application of advanced computational techniques for biomedicine	2X RO1	12
Melanie Joy PhD	Professor, SOP	Pharmaceutical Sciences	Discovery and translation of novel treatments in kidney diseases, clinical pharmacology	R01	9
Traci Lyons PhD	Assoc Professor, SOM, AMC	Medical Oncology	Mechanisms of lymphatic mediated metastasis of breast cancer	R01, 2X Fdn grant, Univ grant	7
Wendy Macklin, PhD	Professor, SOM, AMC	Cell and Developmental Biology	Oligodendrocyte differentiation and myelination in central nervous system	2X RO1, R37	9
Ed Melanson, PhD	Professor, SOM, AMC	Metabolism and Diabetes	Effects of lifestyle interventions on bioenergetics	P30, R56	2
Aaron Michels, MD	Assoc Professor, SOM, AMC, CHCO	Pediatrics & Immunology	Underlying immunology of autoimmune disorders with a focus on type 1 diabetes	4X RO1, 2X Fdn	4
Andrew Monte MD, PhD	Assoc Professor, SOM, DH	Emergency Medicine, Toxicology	Personalized medicine, genetics, drug effectiveness and drug safety, substance abuse	R35, R21	12
Thomas Morrison, PhD	Professor, SOM, NJH	Immunology and Microbiology	Regulation of innate immunity and response to bacterial infection	2X RO1	8
Jill Norris PhD	Professor, CSPH	Epidemiology	Influence of the environment in the development of autoimmune diseases	R21, 2X Fdn grants	9
Karin Payne, PhD	Assoc Professor, CU-D SOM, AMC	Orthopedics	Optimizing differentiation of human stem cells for bone and cartilage regeneration	R33, NSF	2
Diego Restrepo PhD	Professor, SOM, AMC	Cell and Developmental Biology	How brain circuits mediate responses to sensory input	R13, R56, 4X RO1, UF1, R25, U01, 2X NSF	10

Mary Reyland PhD	Professor, SOM, AMC	Craniofacial Biology	Salivary gland tumors	P50, R01, R25	3
Carol Sartorius, PhD	Professor, SOM, AMC	Pathology	Role of estradiol & progesterone and their cognate receptors in breast cancer therapy	R01, 2X Fdn grants	4
Jennifer Stevens-Lapsley, DPT, PhD	Professor, Physical Therapy, VA	Physical Medicine, Physical Therapy, Rehabilitation	Clinical trials involving patients with total knee replacement, geriatric rehabilitation, clinical trials, implementation science	4X R01, Other Fed grant	12
Raul Torres, PhD	Professor, CU-D SOM, NJH	Immunology	Mechanisms by which B lymphocytes develop and mount antibody responses to pathogens	2X R01	8
Jason Tregellas, PhD	Professor, SOM, AMC	Psychiatry	Neurobiology of food intake behaviors and obesity	2X R01, Other Fed grant	7
Richard Weir, PhD	CU-D SOE	Bioengineering	Advanced prosthetic systems for individuals with limb loss	R42, R21, R01, 2X R44, R43, Other Fed grant	8

2d. Mentoring

Program objective- Apply evidence informed mentoring practices to support developing trainees from all backgrounds for career persistence and success in CTSR.

2d-1 Mentoring Oversight: Effective mentoring is crucial for program retention, trainee productivity and satisfaction, engagement with the CTSR community and persistence in the field. Mentees with influential and sustained mentoring are more likely to remain in research, publish more papers, become principal investigators, and mentor others.⁹⁻¹¹ Evidence informed practices to be applied include 1) signed mentoring agreements, 2) development and regular review of Individualized Career Development Plans (**ICDP**), 3) completion of Mentoring³: Mentor, Mentee and Peer, a mentoring training program attended by both mentors and mentees, 4) annual mentor-mentee dyad reviews with feedback, and 5) trainee Mentoring Advisory Team/Thesis Committee (**MATT-C**) reviews.

Each TOTTS trainee will have a **Mentoring Advisory Team/Thesis Committee (MATT-C)** that consists of a research mentor, a translational mentor, and a T32 core program administration mentor. For trainees in a PhD program, the committee will be an expanded PhD thesis committee that includes the translational mentor. The MATT-C will **meet twice yearly, at a minimum**, as a group to review and revise the trainee's **Individual Career Development Plan (ICDP)** and review progress of the trainee's development of knowledge, skills and abilities to advance CTSR. Mentees can call a MATT-C meeting whenever they feel the need for support, clarity or to advance their ICDP. MATT-Cs are a strategy to effectively coordinate training and mentorship responsibilities among team members, prevent conflicting guidance and help trainees broaden their professional networks.

Steps will be taken to ensure mentor commitment and time devoted to the trainee. In their letters of support with the trainee's application, research and translational mentors will be required to explicitly identify their time commitment to the trainee and how they will enhance the training experience. Additionally, the research mentor will be required to sign both the ICDP and the TOTTS Expectations for Mentoring Agreement. Research Mentoring Agreements will be signed and returned to program administration within the first month of the award and explicitly identify the need for weekly meetings with the trainee, attendance at TOTTS seminars when their student is presenting, regular review and updating of the ICDP, and attendance at MATT-C meetings with one of the program directors in attendance (minimum twice yearly). The TOTTS Expectations for Research Mentoring Agreement follows the guidelines of the Association of American Medical Colleges Group on Graduate Research, Education, and Training compacts for mentors and mentees. T32 program administration mentors will regularly (monthly) check-in with trainees to ensure that they are experiencing mentor engagement and that there is a good match. Additionally, the TOTTS T32 IAC will provide mentoring oversight in several ways: annually, IAC members will 1) meet with each trainee to learn of their progress, program experiences and needs; and 2) review each trainee's mentoring dyad assessment report provided by the CCTSI Evaluation Core to identify effectiveness of mentoring and at-risk mentoring relationships.

Assessment and evaluation of mentoring efforts are important to understanding effectiveness and need for improvement and modification. The CCTSI Evaluation Core will complete annual assessments where mentees report on their mentor's performance, their own performance, and the mentoring relationship and mentors report on their mentee, their own performance, and the mentoring relationship. (See **Mentoring Assessment Plan**). Mentorship provided by T32 Program Administration will be assessed twice yearly.

2d-2 Creating Effective Mentoring Relationship: The CCTSI and our TOTTS program are committed to providing excellent mentorship through the provision of important infrastructure and processes. The CCTSI WD and TOTTS will develop a new program that all mentors and mentees will complete, called **Mentoring³: Mentor, Mentee and Peer**. This will include 12 hours of training that involve sessions with mentors only, mentees (trainees) only, and mentor-mentee dyads. Our curriculum and approach are based on best evidence practices from CIMER¹⁰ (Center for Improvement of Mentored Experiences in Research; <https://cimerproject.org>) and our CO-Mentor¹² program. Members of our CCTSI WD team serve as leaders in developing career development programs to build skills in mentoring at a national level.¹²⁻¹⁵ Mentoring³ will be directed by Bruce Mandt PhD, Assistant Dean-Graduate School and Career Development Office. He has completed CIMER (including Entering Mentor Facilitator Training) and CO-Mentor programs and has extensive experience developing and facilitating workshops on mentorship and mentoring relationships, as well as many other career development topics and skills. Mentoring³ will include aligning expectations, addressing equity and inclusion, articulating your mentoring philosophy and plan, ethical behavior in research, enhancing work-life integration, fostering independence and mentee self-efficacy, and well-being. Specific to DEI, Dr. del Pino-Jones MD, DEI Director, will provide training to all mentors that includes topics on mentoring trainees from URM backgrounds and differing backgrounds and experiences, and to mentees and mentors on micro-aggressions, implicit bias, power and privilege and other topics. Mentoring³ will begin with a 2-hour workshop attended separately by mentors and mentees, within two months of starting TOTTS, designed to be a primer for understanding benefits and traits of effective mentoring, roles and expectations, and ICDPs. Mentors and mentees will attend workshops separately to develop individual skills and as mentee-mentor dyads for two workshops. Mentor-mentee dyad workshops will be separated by 8-10 weeks to allow for application of skills following workshop attendance and feedback from workshop faculty. To develop a pool of faculty trainers for Mentoring³, a train the trainer program involving workshops and resource materials will be developed and provided to mentoring faculty. In this way, we will foster a culture for effective mentoring practices to create safe, inclusive and supportive environments for trainees to excel and build capacity for effective mentoring within PhD programs.

3. PROPOSED TRAINING

Best practices for adult learning will be applied in our TOTTS T32 program. Methods and practices that actively involve learners in acquiring, using, evaluating, and reflecting on new knowledge and practice have the most positive consequences on learner outcomes.¹⁶⁻¹⁷ The literature also demonstrates that the most effective practices integrate multiple methods, such as didactic training, small group interactive learning, experiential and applied learning with feedback provision occurring in groups no more than 30 learners, provided over multiple occasions.¹⁶⁻¹⁷ **Program learning outcomes for T32 trainees are:**

Following TOTTS T32 program participation, predoctoral trainees will:

1. Exhibit foundational characteristics of Translational Scientists: Domain Expert, Rigorous Researcher, Skilled Communicator, Team Player, Boundary Crosser, Process Innovator, and Systems Thinker.
2. Possess Individualized Career Development Plans (ICDP), which incorporates the domain characteristics of clinical and translational researchers, that are informed by and regularly reviewed with mentors.
3. Exhibit regulatory, operational, and scientific competencies that advance clinical and translational sciences across the translational spectrum and project life course through comprehensive educational programming tailored to address the trainee's learning needs.
4. Demonstrate effective scientific communication (oral and written).
5. Exhibit research practices concordant with research ethics, RCR, GCP, regulatory compliance, rigor and reproducibility and data science principles.
6. Report being part of a new translational community and network with new insights, perspectives, and skills because of immersion experiences with translational mentors and their communities.
7. Demonstrate effective skills in teaming and leading necessary for high performing teams that advance clinical and translational science and research.

Refer to **Tables 7-9** for a listing of program elements to support the development of successful and persistent translational scientists and how trainee outcomes are achieved.

3.1. Exhibit foundational characteristics of Translational Scientists: Domain Expert, Rigorous Researcher, Boundary Crosser, Process Innovator, Skilled Communicator, Team Player, and Systems Thinker. **TOTTS seminars** will provide the building blocks and space to practice, integrate and refine the knowledge, skills and abilities for trainees to become successful translational scientists. TOTTS seminars will be held every two weeks for two hours and will showcase and support foundational characteristics of translational scientists. TOTTS seminars are mandatory for trainees and optional for their mentors with the exception of when the trainee is presenting. To kick off the program, the first seminar will introduce awardees to the program, differences between clinical and translational research and clinical and translational science and to the foundational characteristics of translational scientists. The point will be made that clinical and translational research is not an individual endeavor but rather a team endeavor and that success requires a good working knowledge in all translational scientist domains and the ability to work as a high performing team with shared learning and problem solving to overcome bottlenecks and challenges and to contribute to the field of translational science. Seminars will lay the groundwork for this success by addressing regulatory, operational, and scientific topics and highlight the application of the translational scientist domains. Our trainees will represent a mix of disciplines, bodies of knowledge, translational spectrums (T1-T4), and backgrounds.

This rich mix of perspectives, experiences and expertise will be shared through trainee presentations and dialogue. Seminar formats will always engage trainees in dialogue, identification of issues and exploration of approaches and solutions. These seminars will create the structural model for a learning community of translational scientists by including the fundamental elements of domain of knowledge, a community of people and a shared practice of developing as translational

Program Element	Translational Scientist Characteristics	Trainee learning outcome (see list above)
Individualized Career Development Plan (ICDP) Requires goal/objective identification for each translational scientist characteristic	Section for each domain: DE, RR, BC, PI, ST, SC, TP	1,2
Mentorship: Mentoring Advisory Team (MATT-C)	DE, BC, PI, ST, SC	1,2,3,4,5
Individualized CTSR Training	DE, RR, PI, ST	1,3
Research Project Conduct and Supervision	DE, RR, BC, PI, ST, SC, TP	1,3,5,7
Immersion Experience with Translational Mentor	DE, BC, ST, PI, SC,TP	1,3,4,5,6,7
TOTTS Seminars	BC, PI, ST, SC, TP,RR	1,3,4,5,6,7
Ethics, RCR, GCP, DEI in research	PI, RR, SC, TP	1,3,5
Rigor and Reproducibility (NEW)	DE, PI, RR	1,3,5
Teaming and Leadership in CTSR (NEW)	BC, SC, TP	1,4,7
Mentoring ³ : Mentor, Mentee, Peer (NEW)	BC, SC, TP	1,2,4,5,7
Effectively Communicating Research (NEW)	BC, SC	1,4
F Grant Review and Mock Study Section (NEW)	DE, SC, RR	1,3,4,5
Writing Accountability Group (WAG) (NEW)	SC, RR	1,4
Café Scientifique (NEW)	BC, ST, SC	1,4
ACTS/CTSA Conference	SC	1,4,5
Translational Scientists Characteristics: Domain Expert (DE), Rigorous Researcher (RR), Boundary Crosser (BC), Process Innovator (PI), Systems Thinker (ST), Team Player (TP), and Skilled Communicator (SC)		

scientists.¹⁸ This will be brought together by trainees annually presenting on their ICDPs (with a review of each translational scientist domain), research in progress, and translational scientist practices. Presentations will have them discuss their research across the translational spectrum, team-driven research, bottlenecks and possible solutions in research and application of the translational scientist domains.

Program administration faculty will organize, lead, teach, and facilitate TOTTS seminars. Many seminars will involve TOTTS faculty mentors to provide instruction and lead discussion on important topics. For example, Melissa Haendel PhD, Chief Research Informatics Officer for the University and Professor in Biochemistry and Molecular Genetics, Epidemiology will speak about informatics and data sharing, cloud and information architecture, and clinical data interoperability. TOTTS alumni will attend to share their lessons learned, provide input into current trainees' ICDPs, and to share their own journeys of transitioning from doctoral programs. A

significant proportion of trainees will develop their careers and conduct translational research in industry. As such, it is important to include seminars involving scientists working in industry and other sectors outside of academia. We are fortunate to have several avenues to identify industry scientists that include CCTSI TL1 and Clinical Science (CLSC) alumni, and industry members of the Academic Industry Alliance, which strengthens connections between academia and local industries. Industry seminar speakers/ facilitators will cover desired/required professional skills, various industry positions and accompanying responsibilities, pros/cons and similarities/differences between academia and industry, negotiation, and networks necessary to transition into careers in the non-academic research workforce. Additionally, teams that represent industry-academic partnerships will be invited to present their research and experiences highlighting projects in diagnostics and therapeutics. These events are intended to develop working knowledge needed for trainees to understand and prepare for next steps in the varied research career options available in CTSR.

Other activities and topics include research issues from a T1 to T4 perspective, leading and working in teams, entrepreneurship, partnering with communities and community engaged research, effectively translating research across target audiences (patients, citizens, researchers, clinicians, funders, and policy makers), grant and manuscript writing, rigor and reproducibility, DEI in research, issues in conducting clinical trials, and providing opportunities for networking. Examples of presenters include Montelle Tamez, Deputy Director Community Engagement Core discussing community engaged research and partnering with community; Ben Echaliier MS, MBA, CCRP, Associate Director, Regulatory and Trials Operations discussing challenges in performing clinical trials and drug development phases, Doug Thamm DVM, PhD, Associate Director CCTSI T32 Post-Doctoral T32 Program outlining the process and criteria for selecting appropriate animal models, Cathy Bodine SLP, PhD, Director of CCTSI Innovator Ecosystems discussing entrepreneurship, commercialization, and the start-up ecosystem. (See **Attachment Coordination and Interaction Plan**)

3.2 Possess Individualized Career Development Plans (ICDP), which incorporate the domain characteristics of translational scientists, that are informed by and regularly reviewed with mentors.

Table 8: Courses to be completed for TOTTS			
	Clinician Doctoral Students	Population & Health Research PhD Students	Biomedical and Bioengineer PhD Students
Ethics, Responsible Conduct of Research	Ethics and Responsible Conduct of Research (CLSC; Yr. 1)	*Home program equivalent or Ethics and Responsible Conduct of Research (CLSC) or (Yr. 1)	*Home program equivalent or Ethics and Responsible Conduct of Research (CLSC; Yr. 1)
Statistics	Applied Biostatistics I and II (CSPH; Yr. 1)	*Applied Biostatistics I and II (CSPH; Yr. 1)	*Home program equivalent or Applied Biostatistics I and II (CSPH; Yr. 1)
Study Design	Epidemiology (CSPH; Yr. 1) AND Design and Conduct of Clinical Trials (CLSC, CSPH; Yr. 1)	*Epidemiology (CSPH; Year 1) AND Design and Conduct of Clinical Trials (CLSC, CSPH; Yr. 2)	*Translational Study Design equivalent home program or Epidemiology (CSPH; Year 1) or Design and Conduct of Clinical Trials (CLSC; Yr. 2)
Critical Appraisal/ Rigor & Reproducibility	Critical Appraisal and Rigor of CTR Studies (CLSC; Yr. 1)	Home program equivalent or Critical Appraisal and Rigor of CTR Studies (CLSC; Yr. 1)	*Home program equivalent or Critical Appraisal and Rigor of CTR Studies (CLSC; Yr. 1)
Clinical and Health Outcomes	Clinical and Health Outcomes (CLSC; Yr. 1)	Clinical and Health Outcomes (CLSC; Yr. 2)	Clinical and Health Outcomes (CLSC; Yr. 2)
Scientific communication	Disseminating Research: Manuscript Preparation and Rigorous Reporting (CLSC; Yr. 1)	*Home program equivalent for manuscript and grant writing or Grant Writing, Disseminating Research: Manuscript Preparation (CLSC; Yr. 2)	*Home program equivalent for manuscript and grant writing or Grant Writing, Disseminating Research: Manuscript Preparation (CLSC; Yr. 2)
Project Management and Operations	Conducting Trials for Investigators (CLSC) OR Project Management (BST;Yr. 1)	Conducting Trials for Investigators (CLSC) OR Project Management (BST; Yr. 1 or 2)	Conducting Trials for Investigators (CLSC) OR Project Management (BST Yr. 1-2)
Translational Research Spectrum: Discovery to Market	Drug Discovery OR Medical Devices OR Biomedical Entrepreneurship (BST; Yr. 1)	Drug Discovery OR Medical Devices OR Biomedical Entrepreneurship (BST;Yr.1 or 2)	Drug Discovery OR Medical Devices OR Biomedical Entrepreneurship (BST; Yr. 1 or 2)
BST: BioScience and Technology, CLSC: Clinical Science, CSPH: Colorado School of Public Health			
* Indicates course(s) typically completed for home PhD program			

ICDP formation with mentor input play a central role in the developmental process of trainees.⁶⁻⁸ Therefore, all trainees will complete an ICDP within the first month of starting the program. Our ICDP was recently revised, along with that of the CCTSI K12 program, to include the characteristic domains of translational scientists: Domain Expert, Boundary Crosser, Process Innovator, Systems Thinker, Rigorous Researcher, Effective Teaming and Leading, and Skilled Communicator (written and oral). Added to the ICDP is a specific call out to identify learning needs for skill development for each characteristic. ICDP sections have trainees identify learning needs/gaps, propose activities to close learning gaps (including course requirements for PhD and TOTTS, ethical and regulatory principles courses/webinars, immersion experiences, mentored research project), and milestones (presentations, publications, grants, PhD comp exams, etc.) with a corresponding timeline. Planning out activities with timelines is an essential skill for navigating the complex landscape as an investigator. Trainees will report on their ICDP at TOTTS seminars (early year 1, mid-point, program end) and at their MATT-C meetings. Previous TL1 trainees reported that presenting their ICDP during TOTTS seminars for group feedback, insight, and encouragement/reward was extremely valuable.

3.3. Exhibit regulatory, operational, and scientific competencies that advance clinical and translational science across the translational spectrum and project life course through comprehensive educational programming tailored to address the trainee’s learning needs.

Trainees will be provided funds to complete coursework specific to his/her needs. All trainees will take courses in translational science methods (biostatistics, study design), ethics and responsible conduct of research including Good Clinical Practice (See **Attachment Responsible Conduct of Research**), clinical and health outcomes, critical appraisal/rigor and reproducibility, scientific communication, advancing translational interventions across the spectrum, and project management/operations. As described above (B.3), each

trainee will have a MATT-C that will work with the trainee to develop an ICDP that identifies the trainee’s specific learning needs and corresponding courses/ educational initiatives to close the gaps, as well as coursework necessary to fulfill their PhD degree and TOTTS program requirements. **Table 8** lists courses to be completed by TOTTS trainees according to their stream of PhD biomedical and bioengineering students, PhD Population and Health Research Students and Clinician Doctoral students. As displayed all groups have core threads for training that are customized to the trainee’s home program. PhD students will complete the TOTTS program over two years whereas clinician professional doctorate students will have the option for a one-year appointment.

Table 9. Program Learning Outcomes and Evidence: Predoctoral trainees will...
Exhibit foundational characteristics of Translational Scientists
Characteristics demonstrated through ICDP progress, annual Translational Scientist presentation at TOTTS seminar, IAC annual presentation
Possess Individualized Career Development Plans (ICDP), which incorporates the domain characteristics of clinical and translational researchers
Annual ICDP submission to Program Administration (PA) documenting progress
Exhibit regulatory, operational, and scientific competencies that advance CTSR across translational spectrum and project life course
Demonstrated through annual research in progress TOTTS seminars, IAC meetings, MATT-C meetings, manuscripts, grant proposals
Demonstrate effective scientific communication (oral and written)
Demonstrated at Café Scientifique with citizen feedback, annual research in progress TOTTS seminar presentation Program Admin + peer feedback, record of submitted and published abstracts, peer reviewed manuscripts/publication, and presentations
Exhibit research practices concordant with research ethics, RCR, GC
Submission of documents related to completion of required training, IACUC and IRB approvals, ethics/RCR/GCP course grade (B+ or better), MATT-C assessment reports
Report being part of a new translational community and network with new insights, perspectives, and skills
Demonstrated through trainee report of expanded network and top 3 new insights and skills, MATT-C assessment reports, annual Translational Scientist presentation at TOTTS seminar, PhD thesis chapter or personal reflection report for non-PhD trainees
Demonstrate effective skills in teaming and leading
Demonstrated through increased membership in interdisciplinary teams, improvements in self-efficacy and increased application of effective teaming and leading strategies
Apply evidence informed mentoring practices
Mentee-Mentor Assessments (program entry, end of year 1, end of year 2)

Based on our CCTSI TL1 experiences and preparatory work for this application, it would be difficult for most clinician trainees to take two-years off from their doctoral training. Because of the need to create pathways for clinician scientists, the FOA makes this 1-year option explicit in the eligibility criteria. Completion of courses in **Table 8** fulfills requirements for obtaining a Certificate in Clinical Science (**CLSC**). Additionally, all courses

listed (21 credits) can be applied to the 30 credits required for the Master of Clinical Science (**MSCS**) degree, of which the additional 4-6 publishable paper credits hours could be completed as the TOTTs research project. During the last CCTSI cycle, when the TL1 award was only one year, 3 doctoral students completed the MSCS degree. The MSCS is designed to be completed in 4-5 terms but can be completed in 3 terms, making it feasible for clinician doctoral students to acquire the MSCS degree.

3.4 Demonstrate effective scientific communication (oral and written).

Effective communication skills (written and oral) for differing target audiences and purposes are essential for scientists. A multi-faceted approach will be used to develop competency and comfort with communicating science to differing audiences and purposes in both written and oral formats. In year one, T32 trainees will complete the CCTSI's **Effectively Communicating Your Research to the Public** program, which is a three-part workshop series that provides an overview of why and how to engage the public -- everyone from television reporters to neighbors -- and the world on social media. Each workshop is 1.5 hours and includes hands-on training and practice. To apply these skills, annually, each trainee will participate in a **Café Scientifique**. A Café Scientifique is a place where anyone can come to explore the latest ideas in science and technology. Each year the TOTTs program, along with the CCTSI Community Engagement Core, will organize and hold two Café Scientifique events where TOTTs trainees will talk with community citizens about their research for 7-10 minutes (without using presentation software) followed by an additional 10-15 minutes of dialogue. These Cafés will engage people in a conversation about issues in science and health and promote the cultural examination of research. Cafés are known for their informal and friendly atmosphere and are believed to improve the image of scientists/science, careers in science, and science literacy.¹⁹⁻²⁰ The aim of our Café Scientifiques is to make research conducted by our trainees relevant, powerful and important to community and to provide a relevant experience to trainees for honing of communication skills with the public. Café Scientifiques will be promoted through CCTSI networks (websites, newsletters) and the networks of the Café Scientifique host. It is anticipated that 30-40 people will attend these events. We are unaware of other CTSA T32 programs organizing Café Scientifiques but will be excited to disseminate this program to other Hubs.

Research communication skills (written and oral) for the scientific community will be developed through 1. **formal coursework** in grant writing and/or scientific writing through their home PhD or CLSC program, 2. **TOTTs seminars/workshops** (writing abstracts, manuscripts; preparing and delivering posters and presentations), 3. participation in CCTSI **F Grant Review and Mock Study Section** (at least once during the two-year award), 4. presenting at **ACTS/ CTSA conferences** and conference presentations in their specialty areas, and 5. participating in a TOTTs **Writing Accountability Group (WAG)** to help develop good writing habits (highly encouraged). A major career development focus of the program is preparing trainees for the National CTSA/ACTS Annual Translational Science Meeting, which provides excellent networking and dissemination activities outside of the university. All trainees will be supported to attend the conference. In preparation for their presentations, 4 weeks prior to the conference, a practice session will be held for all to practice and receive feedback. **WAGs** are a strategy to improve writing productivity (quantity and quality), increase a sense of control over the writing process, improve goal-setting and time management, and build relationships with peers.²¹ WAGs were piloted in our CCTSI KL2 program during the COVID pandemic and evaluated extremely well by KL2 Scholars. Scholars reported learning successful strategies for writing productivity and accountability, increased peer connectedness, and all achieved their goals set at the beginning of WAG sessions. WAG groups will meet for 1-hour blocks weekly for eight weeks. The CCTSI **F Grant Review and Mock Study Section** runs three times per year corresponding with NIH deadlines. It consists of seven steps: 1) Attend/view "How to prepare your grant" workshop; 2) Submit specific aims page that is reviewed by program faculty with applicant feedback; 3) work with an assigned grant mentor for feedback throughout the process; 4) Submit a full F grant; 5) Grant reviewed by three reviewers with written feedback; 6) Required applicant attendance at the mock study section to hear all grant reviews with discussion and questions; 7) Applicant ability to request a meeting with faculty for follow-up feedback. Deliverables for these learning strategies include trainee production of manuscripts and complete grants and the provision and receipt of feedback from peers.

3.5 Become a member of a new translational community and network with new insights, perspectives, and skills, because of immersion experiences with translational mentors and their communities.

As recognized in our Model of Persistence for a Diverse Clinical and Translational Workforce, T32 trainees are novice researchers and early in their careers, so it is essential that they begin to sense that they are a part of the fabric of the CTSR community. It is critical to have socialization and acculturation experiences that avail broadening ways of thinking. Therefore, each trainee will have a translational mentor that will be a liaison to the community of a target audience appropriate to the individual and his/her/their area of research. To feel a sense of being a member of the translational community, trainees will conduct a meaningful research project with their research mentor and will gain insight into the translational aspects of their research through their translational mentor and immersion experience. The combination of immersion experiences of conducting translational research (mentored research experience) and its translation permits growth and character for all translational scientist domains and builds skill development in translational research and translational science.

Translational immersion experiences can take many forms- laboratory, veterinary medicine, clinical service (for non-clinician trainees), community service, or industry. Trainees will be required to complete an immersion experience in a new translational community for them. This is a required and scored element of the application and selection process. Applicants are supported by Program Administration to develop this component.

Clinical service immersions include regular engagement with the clinician translational mentor and the mentor's clinical team regarding patients and their experiences. This may include discussing patients after visits or in group settings such as rounds or registry meetings, discussing clinical research related, assisting with study recruitment, biospecimen collection, observing/participating in clinical study visits and attaining informed consent. In veterinary medicine immersions, activities may include shadowing in clinics, attendance at rounds-clinical, pathology, imaging, oncology research, laboratory experiences (data collection and analysis), participating in research in progress meetings, and discussing research approaches in animal and human research for shared models of disease. Laboratory immersions include learning new lab techniques, analyzing and interpreting data, participating in lab meetings and research in progress meetings. Community immersion experiences with patient advocacy organizations or government agencies may include attendance at community meetings, assisting with development and review of translational/educational materials, grant reviews, community assessments and working on policy briefs. Industry immersions include biotech, regulatory affairs, or technology transfer settings. Experiences may include working in labs, attending meetings, protocol development, involvement in process of bringing a product to market, academic-industry relationships, and report preparation. Immersion experiences will occur for the TOTTTS award period and are expected to continue until PhD degree completion. Clinician doctoral trainees will complete immersion experiences for the duration of their award. Trainees will spend 8-10 hours/month with their translational mentor and immersion site. Requirements for immersion experiences include: 1) orientation attendance, 2) shadowing translational mentor and integrating, to the extent possible, into the immersion environment, understanding cultural norms, language and priorities and, if applicable, understanding patients' experience with their diseases, and discussing health problems/ diseases relevant to the trainee's research, and 3) maintaining a reflective diary with entries regarding issues, insights and learnings. Trainees will report on their immersion experience at MATT-C meetings and PhD students will include an immersion experience chapter in their theses.

Program directors and others will support applicants/trainees with the identification of translational mentors and immersion experiences. Drs. Nadeau and Cicutto will support identification of clinical translational mentors. Dr. Cicutto and CCTSI's Community Engagement Core and Community Research Liaisons will assist trainees in finding a community translational mentor and, if necessary, provide an orientation for partnering and building relationships. (See **Attachment Coordination and Interaction**). Dr. MacLean will assist with identifying biomedical laboratory translational mentors. Dr. Thamm will assist with identifying veterinary medicine immersion experiences. He is a Professor at Colorado State University, School of Veterinary Medicine and served as an Associate Director of the CCTSI TL1 program and will be part of the CCTSI T32 post-doctoral program (if funded; See **Attachment Coordination and Interaction**). Dr. Cicutto will support identifying industry immersions and will leverage the infrastructure of the University's Biomedical Science and Biotechnology Master's program by collaborating with the program's director, Dr. Inge Wefes (See **Institutional Letter of Support**). An industry internship is a requirement of this master's program and thus an infrastructure already exists, such as a list of industry partners and university approved MOUs, IP, and

agreements for student internship/ immersions. Additionally, many CCTSI T and CLSC alumni work in industry, located in Denver/Boulder/Fort Collins area, and desire engagement with trainees. **Translational mentors and immersion experiences** were **consistently our most highly rated and impactful program element** over the last 10 years of the CCTSI TL1 program.

3.6 Demonstrate effective skills in teaming and leading necessary for high performing teams that advance clinical and translational science and research.

Translational teams are composed of dynamic and diverse interprofessional and cross-disciplinary members that generate new knowledge to address a shared translational objective. Highly qualified and thoroughly prepared interdisciplinary teams fuel discovery that is translated to communities for improved health and lives of its citizens. It addresses the shift in science from an individual-based approach to a teamwork model of designing and conducting CTSR. To prepare our trainees to be contributing members of high-performance teams, trainees will complete our CCTSI **Leading and Teaming in Clinical Translational Science and Research** program over or TOTTS two-year program. Clinician doctoral students will complete it during their one- or two- year program. Previous studies indicate that team training results in the application of knowledge, skills and abilities and improves team performance and innovation.²²⁻²⁵ Our curriculum is designed to build capacity to participate in and lead effective, interdisciplinary and translational scientific teams. It is based on current evidence and best practices and is concordant with competency development outlined by the CTSA Team Science Affinity Group.²⁶ The five domains of competency addressed in our program, include facilitating team bonding, team communication, managing team research, collaborative problem solving, and team leadership. Both individual and team competency development are necessary; Individual competencies: facilitating awareness and exchange, cognitive openness, self-awareness, interdisciplinary research management, perseverance, and Team competencies: team-based communication, shared visioning, understanding complexity, team learning, meeting management, collaboration, and trust. Learners start the program by completing Teaming 101, a self-paced online web-module, followed by participation in six workshops, which are each 2 hours long. CCTSI partner with faculty from Colorado State University to provide the workshops. Dr. Jeni Cross, a Professor in the Department of Sociology, and renowned for her team science research, will direct and instruct the program. The six-workshop series includes: 1. Building Relationships and a Team, 2. Setting Expectations on a Team, 3. Building a Shared Vision and Language, 4. Collaborative Knowledge Creation, 5. Change Management, Negotiation, and Conflict Resolution, 6. Leadership for All Team Members. Last grant cycle, we created and added Team Science to our CCTSI TL1 program curriculum. Initially, it started as a one, 4-hour workshop. However, trainee evaluations revealed that additional time was needed, so we expanded the program curriculum. Our most recent expanded version was very favorably evaluated, earning scores of 4.4 or higher (out of 5) for overall training, ability to apply training, and trainer-trainee engagement. Statistically significant improvements were noted for trainees' familiarity with teaming concepts, their self-confidence in ability to apply teaming strategies, and report of more frequent use of strategies for effective teams. Feedback identified that it would be beneficial to add more on leading/leadership. As a result, the new revised program will combine and integrate competency development for leading and teaming, with greater attention to leading.

3.7 Exhibit research practices concordant with research ethics, RCR, GCP, regulatory compliance, rigor and reproducibility and data science principles.

Training in ethical, regulatory, and reproducibility principles, including Responsible Conduct of Research (RCR) and Good Clinical Practice (GCP) is critical to the efficient and rigorous conduct of clinical translational research and maintaining societal trust in the research enterprise. It is thus an essential part of education and training of the TOTTS Program. The University and the CCTSI are committed to fostering a research environment that promotes the responsible conduct of research, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct. (See attachment **Institutional Letter of Support**). The CCTSI, the TOTTS program and the University will provide several RCR and rigor and reproducibility educational opportunities to predoctoral trainees, mentors and collaborating faculty and staff. Educational opportunities are designed to be in full compliance with the policy requirements for RCR education promulgated by NIH in NOT-OD-10-019 and NOT-OD-22-055, and the NIH Grants Policy Statement, Section 11.3.3.5. All TOTTS trainees will be required to complete a formal ethics and responsible conduct of research course that entails over 14 hours of face-to-face instruction, dialogue, and application PLUS completion of

Collaborative Institutional Training Initiative (CITI) modules to receive CCTSI T32 funding. To enhance the reproducibility of research findings, the five identified elements of the U.S. National Institutes of Health (NIH) published notice NOT-OD-15-103 will guide our instruction through coursework, workshops, web modules and TOTTS seminars. TOTTS seminars will supplement formal coursework and web modules by providing instruction on bioinformatics, data sharing, management, security, and privacy in human subject research. Every year the CCTSI's TOTTS program, WD, and Regulatory Knowledge Cores will review evaluations and discuss strengths and limitations of current offerings to identify the need for and types of revisions necessary. We are strongly committed to upholding the highest ethical, regulatory and professional standards for reproducible research endeavors and ensuring that trainees and mentors are trained and remain current in best practices. Please see **Attachments on Responsible Conduct of Research and Plan for Instruction in Methods for Enhancing Reproducibility**.

4. TRAINING PROGRAM EVALUATION

4a. Approach: The CCTSI TOTTS program is measurement and outcomes focused. Our program will continue to work with the CCTSI Evaluation Core for program evaluation and ongoing continuous quality improvement. The CCTSI Evaluation Core, under the leadership of Goldie Komaie PhD, has securely collected

Table 10. Program Outcomes Monitored	Program Objective	Timing	Source
T32 Pre-Doctoral Awardee			
Diversity characteristics (URM ethnicity, race, disability, disadvantaged background, discipline, program affiliations, mentors, translational spectrum)	Diversity	Entry	CCTSI WD Program registration form
Milestone achievements: Publications, presentations, grants, career progression (degree milestones and completion; TOTTS completion)	CTSR persistence and productivity	Entry and annually for 20 yrs.	Annual CV submission, progress report, PubMed, Grants.gov, Office of Grants and Contracts
Utility, strengths/weaknesses of required TOTTS elements (Leading and Teaming, F Grant Review and Mock Study Section, Effectively Communicating Research, Mentoring ³ , TOTTS seminars, Immersion Experience, etc.)	Effective program elements for fostering Translational Scientist Characteristics	Annually	Program survey evaluation with pre-post comparisons
CTSR competencies: Clinical Research Appraisal Inventory (CRAI-12) and Characteristic Domains of Translational Scientists (program developed and piloted in 2021)	Translational scientist characteristics; Regulatory, operational and scientific competencies	Entry and annually	CRAI, Translational Scientist Domains questionnaire
Overall program satisfaction: leadership/mentoring access, curriculum strengths and gaps, areas for improvement, meeting of expectations, CCTSI resources used, etc.	Effective and responsive program	Annually	Program developed questionnaire
Identity formation as CTSR investigator, integration into CTSR community, team science orientation	Team oriented, Identify as Translational Scientist	Annually	Program developed questionnaire
Diversity Accelerating Research and Translation: perception of program encouraging diversity at all levels, inclusiveness and trainees support	Diversity	Annually	Program developed questionnaire
360 Mentee-Mentor assessment (See attachment Mentoring Assessment; CCTSI developed & piloted)	Effective mentoring	Entry and annually	360 Mentee-Mentor assessment
Post Program completion review-Focus group	Effective and responsive program	Program completion	Focus group guide
T32 Awardee Mentors			
360 Mentee-Mentor assessment	Effective mentoring	Entry and annually	360 Mentee-Mentor assessment

Attendance and utility of required TOTTS elements: Mentoring ³ , MAC, T32 seminars, IAC review meeting	Engaged mentors, Effective mentoring	Ongoing with annual review	Attendance / minutes, MAC Meeting Report
T32 TOTTS Leaders			
MATT-C reports of trainee progress, barriers, identification of at-risk mentoring teams	Early identification of trainee issues	Semi-annually	MATT-C Meeting Report
Dissemination activities and national CTSA involvement- committees, presentations, publications, collaborations	CCTSI Engagement and contributions to CTSA	Annually	Survey: CTSA Engagement & Dissemination
T32 Alumni			
Milestone achievements: Publications (#, authorship location, h index) grants (#, type, source), career progression (sector, leadership, promotion, mentorship)	CTSR Persistence and productivity	Annually	Annual CV submission, Grants.gov, Office of Grants and Contracts, PubMed
Identity as CTSR investigator, integration into CTSR community, translational and team science orientation, translational spectrum of research	Team oriented, Embedded in CTSR community, Persistence	Post-program years 3, 5, 10	Program developed questionnaire
Program review: Interview/Focus group	Effective and responsive program	2-3-yr post program	Focus group guide

and stored data for the CCTSI TL1 program since 2008 and will continue in this role. Program alumni will be followed for 20 years; in 2028 we will revisit the decision to determine if longer follow-up should occur.

Evaluation of the CCTSI TOTTS program will focus on our ability to achieve program objectives, trainee learning outcomes (See **Table 9**), and goals. Evaluative emphasis will be placed on achieving our program goal of attracting and supporting the training and persistence of individuals from diverse backgrounds who have the potential to infuse CTSR with new perspectives and approaches that are efficient and effective. Both qualitative and quantitative data will be collected with triangulation of data for some outcomes to provide a fuller and deeper understanding. See **Table 10** for a listing of variables, data collection timing and sources.

Primary data collection will occur through interviews, focus groups, validated instruments, curriculum vitae, and surveys. Surveys will be conducted with current TOTTS trainees, mentors of active trainees, TOTTS Program Administration and TOTTS alumni. The CCTSI Evaluation Core will also use existing data sources, such as NIH Reporter, PubMed, Web of Science and CU's Office of Grants and Contracts, to track research productivity – specifically, grant success and funding levels and publications. In general, data collection will occur upon program entry and then annually. When trainees participate in CCTSI training programs integrated into TOTTS, such as Mentoring³, Leading and Teaming, etc., they will complete the standard pre and post assessments that capture knowledge, confidence, and satisfaction for those programs. The Clinical Research Appraisal Inventory (CRAI-12), a validated instrument⁴, will be administered upon program entry and annually for assessing growth in relation to essential clinical and translational research skills. We are piloting a questionnaire to capture trainee's abilities for the seven characteristic domains of a clinical translational scientist.¹⁻² Preliminary data from this year's cohort upon program entry suggest that trainees start the program feeling most confident in being a team player and rigorous researcher and least confident in abilities related to boundary crosser, systems thinker and process innovator. Both formative and summative evaluations with accompanying reports will be generated. Results from all participant groups will be presented in aggregated format in a report summarizing data/themes from all data collection sources to yield a comprehensive, mixed-methods evaluation of immediate, intermediate, and long-term outcomes compiled by the CCTSI Evaluation Core. Evaluative data will be analyzed as aggregate, as well as, according to each trainee stream: PhD biomedical/bioengineer, PhD health outcomes/public health, and health professional doctoral students. Reports will be used to inform modifications and next steps consistent with our continuous quality improvement processes. Aggregate-level reports will be made publicly available off the TOTTS website.

4b. Develop, Demonstrate and Disseminate: An important contribution to the translational science field is identifying best evidence informed practices for preparing a highly qualified workforce that persist in translational careers. Our evaluative framework will allow us to contribute to the evidence base by identifying the programs' overall and individual elements successes and contributions, as well as gaps in training and

areas in need of improvement. Many elements of our program are innovative and newly **developed** (Mentoring³, Teaming and Leading, Café Scientifiques, Writing Accountability Groups) and thus require evaluation to **demonstrate** effectiveness and lessons learned before they can be **disseminated** as contributions to the knowledge base and for uptake by other CTSA hubs and training programs.

The 360 Mentee-Mentor assessment was developed by a sub-group of the CCTSI LAC for the purposes of identifying at-risk mentor-mentee dyads and for evaluating training programs. The 360 Mentee-Mentor assessment will be used by both CCTSI T32 (pre- and post-doctoral) programs and KL2 program, if all funded.

Table 11. Doctoral Program Enrollment of Black, Indigenous and People of Color (BIPOC) Students

Program/Primary Major	Non-BIPOC	BIPOC (#,%)	Total
Clinical Health Psychology	26	3 (10%)	29
Epidemiology	19	1 (5%)	20
Health & Behavioral Sciences	15	3 (2%)	18
Health Economics	6	0	6
Health Services	10	1 (9%)	11
Bioengineering	27	2 (7%)	29
Biostatistics	28	1 (3%)	29
Cancer Biology	31	7 (18%)	38
Clinical Science	18	5 (22%)	23
Computational Bioscience	14	6 (30%)	20
Cell Biology, Stem Cells	29	9 (24%)	37
Structural Bio & Biochemistry	12	2 (14%)	14
Human Genetics & Genomics	18	3 (14%)	21
Immunology	34	6 (15%)	39
Integrated Physiology	11	2 (17%)	12
Integrative & Systems Biology	19	3 (13%)	22
Medicine	640	77 (11%)	717
Microbiology	16	2 (11%)	18
Molecular Biology	52	10 (16%)	62
Neuroscience	42	7 (14%)	49
Nursing (PhD)	34	5 (13%)	39
Pharmacology	27	4 (13%)	31
Pharmaceutical Sciences	19	2 (10%)	21
Rehabilitation Science	7	1 (13%)	8
Toxicology	16	5 (24%)	21
Dental Medicine (DDS)	239	84 (26%)	323
Nursing (DNP)	100	10 (9%)	110
Physical Therapy (DPT)	186	19 (9%)	205
Pharmacy (PharmD)	373	102(21%)	475
Psychology (PsyD)	46	21 (31%)	67
Public Health (DrPH)	23	8 (26%)	31
Grand Total	2137	411 (16%)	2548

There will be several lessons learned from the use of this approach that include the ability of the approach to discriminate between effective and non-effective relationships and identify the extent to which mentoring relationships evolve over the two years. Please see the **Dissemination Attachment**.

5. TRAINEE CANDIDATES

5a. Training Slots: We are requesting **8 pre-doctoral slots for full time trainees for 2 years** (maximum of 8 trainees per year), contingent on good progress as determined by a written 1-year update report and review by the IAC. We are proposing a **multiple department/ discipline program with three streams**: PhD Biomedical and Bioengineering students, PhD Population & Health Outcomes Research students, and Professional Doctorate Clinician Trainees (MD, PharmD, DPT, DPN, DDS, etc.). For full-time PhD students that have completed the first or second year of their doctoral program will be eligible. Doctoral clinician students will be offered the option of a one- or two-year duration. The one-year program duration exception is explicit in the FOA and provided to encourage clinician participation. As noted above, based on our current TL1 experiences and discussions with health professional programs, it would be difficult for these students to take a two-year break from their clinical doctoral programs. During the current TL1 program, three medical students completed the TL1 program. The 8 slots will be divided 50%-50% between biomedical/bioengineering PhD students and combined PhD Population & Health Outcomes Research students and Doctoral Clinician Trainees. Candidates must be US citizens or permanent US residents.

5b. Recruitment: A multi-faceted approach for recruitment will be used. 1) TOTTS will be highlighted on our CCTSI WD landing page, which receives over 6,000 visits per month, and will provide informational materials. 2) TOTTS email announcements, promotions, and informational materials will be distributed to students of all 32 eligible feeder programs and to all members of the CCTSI by email. 3) Program administrators of all eligible feeder programs will be sent TOTTS informational material to

distribute to their students. 4) TOTTS will be discussed at mentorship and academic programming URM pathway programs by Drs. Zimmer (TOTTS IAC member and Associate Dean, DEI - SOM), del Pino-Jones and (TOTTS DEI Director), and Martinez (Director, Office of Outreach and Inclusion) to increase TOTTS awareness, support recruitment and application development. All three are members of CCTSI WD LAC to

support integration. 5) Program Administration, IAC members and faculty mentors will ALL provide personal outreach to faculty and students during program meetings and seminars attended. IAC members were selected based on their connection and networking within the participating eligible doctoral programs. (See **Attachment Recruitment Plan to Enhance Diversity**)

5.c. Applicant Pool: Doctoral students interested in CTSR from the 32 existing CU-Denver, Boulder and Anschutz programs outlined in **Table 11** will be recruited and eligible. In 2021, there were a total of 2,548 students in these programs of which 599 were in PhD programs and 1,949 were in clinical doctoral programs. Refer to **Required Grant Tables 1 and 6A** for additional data regarding participating graduate programs. Enrollment in our doctoral programs (PhD and professional) has not decreased over the last two years during the pandemic as has occurred with many universities. However, we did notice that with the pandemic, we are receiving fewer Black, Indigenous and people of color (**BIPOC**) applicants. Despite this troubling trend, data from eligible feeder programs support the existence of a qualified applicant pool to select 8 highly qualified, diverse, and motivated trainees for TOTTS. Based on previous experience with the CCTSI TL1 program, which was only open to PhD biomedical students until 2018 and then expanded to include public health sciences

Table 12. Previous Pre-Doctoral Applicant Numbers and Characteristics			
Year	#	URM	PhD Program
2021-22	22	8	Bioengineer, Cancer biology, Cells, Stem Cell Biology, and Development Sciences, Clinical Science, Epidemiology, Immunology, Integrative Physiology, Medicine, Rehabilitation Sciences, Reproductive Science, Structural Biology, Toxicology
2020-21	29	7	Bioengineer, Cancer biology, Clinical Science, Epidemiology, Immunology, Mechanical Engineering, Medicine, Medical Science, Neuroscience, Pharmaceutical Science, Pharmacology, Rehabilitation Sciences, Structural Biology and Biochemistry
2019-20	24	7	Bioengineer, Cancer biology, Cell Biology, Stem Cells and Development, Clinical Science, Clinical health psychology, Epidemiology, Medical Genetics & Genomics, Medicine, Medical Science, Immunology, Integrative Physiology, Microbiology, Pharmaceutical Science, Pharmacology, Toxicology
2018-19	24	5	Bioengineer, Cancer Biology, Cell and Molecular Biology, Clinical Health Psychology, Clinical Science, Epidemiology, Human Bioenergetics, Immunology, Integrative Physiology, Medical Genetics Genomics, Medicine, Neuroscience, Pharmaceutical Science, Pharmacology, Physical Therapy, Stem Cell Biology
2017-18	19	1	Cancer biology, Human genetics, Immunology, Integrative Physiology, Microbiology, Neuroscience, Reproductive Science, Stem Cell Biology, and Development, Toxicology
2016-17	20	2	Bioengineer, Cancer Biology, Computational Biology, Human Genetics, Immunology, Microbiology, Neuroscience, Pharmacology, Toxicology
2015-16	20	1	Bioengineer, Cancer Biology, Human genetics, Immunology, Microbiology, Integrative Physiology, Molecular Biology, Pharmacology, Toxicology
2014-15	27	3	Biochemistry, Cancer biology, Developmental Biology, Immunology, Human Genetics, Molecular Biology, Neuroscience, Pharmacology, Microbiology, Reproductive Science
2013-14	27	2	Bioengineer, Cancer Biology, Immunology, Microbiology, Neuroscience, Human Genetics, Molecular Biology, Pharmacology, Reproductive science

PhD students and medical students, the program received 20-29 applications for 8 slots per year or program cycle. See **Table 12** below. We anticipate the number of applications to increase due to expanded eligibility, which now includes professional health doctoral students, and increased program duration from one to two years for PhD students. Many CCTSI TL1 alumni indicated that they would have preferred a two-year program as a program improvement.

Our target is **30% of TOTTS trainees will be from underrepresented backgrounds** and thus will help to address the disparity of representation in CTSR careers. Over the last 4 cycles, 27.5% of applicants were from underrepresented groups using the definition consistent with NIH guidelines, which includes underrepresented racial and ethnic populations (Black or African American, Hispanic, American Indian, Alaskan Native, Native Hawaiian, or Pacific Islander), individuals with disabilities, and individuals from disadvantaged backgrounds (NOT-OD 15-053). Refer to **Table 11** for the number of BIPOC students based on race and ethnicity alone within our T32 feeder programs. Data regarding disability, first to college, and disadvantaged background are not collected or not collected in a uniform manner across feeder programs and thus are unable to be reported. In 2021, there were 411 BIPOC students of which 88 were in PhD programs and 323 in professional clinical doctorate programs eligible for TOTTS. Please see **Attachment-Recruitment Plan to Enhance Diversity**.

In preparation for our application, discussions with leaders from participating eligible programs were held to gain their thoughts and feedback regarding program feasibility for their students. For PhD leaders, the

expansion of the program to two years was viewed favorably, although they did voice some hesitancy with the increased additional career development programs (Mentoring³, Communicating your Research to the Public, WAGs, Café Scientifique) and courses (Critical Appraisal/ Rigor & Reproducibility, Translational Research Spectrum, and Project Management/Operational Issues) compared to the one-year program. However, it was recognized that most programs now require a rigor and reproducibility course, and that the other two courses could be used as electives. Program directors pointed out that Mentoring³ would be a strength shared by all programs and create a richer mentorship culture. Based on CCTSI TL1 PhD biomedical and bioengineering trainee data, participants did not have a longer duration for degree completion. Professional doctorate program leaders indicated that it would be difficult for students to participate for two years and were pleased regarding the one-year option. All acknowledge that TOTTS provided an important new pathway for attracting, enticing, and preparing clinician scientists. We will continue to stay engaged with these leaders to ensure that TOTTS is viewed as an asset and resource or to identify changes necessary to do so.

5d. Trainee Selection: (See attachment Trainee Selection Process) Each application will be independently reviewed by three reviewers. Prior to reviewing applications, all reviewers will have completed a workshop on holistic review of applications provided by Dr. del Pino-Jones, our TOTTS program's DEI Director. Additionally, all reviewers will have participated in an orientation to the TOTTS program and our review and selections process, including our review and scoring criteria form. This form was developed during the last TL1 cycle to assist with the review and selection of the most appropriate awardees. It was felt that the typical NIH criteria needed to be expanded to capture elements of a holistic review. Because diversity is stressed in our program and aligns with our philosophy and value of DART, one criterion is the applicant's diversity statement. Our scoring and review sheet allows for a total of 100 points to be allocated according to six domains, which have varying weights or possible point ranges. The six domains include: the applicant, personal statement, diversity statement, research proposal and mentoring, translational immersion and mentoring, and letters of support.

5e. Program Objective: *Attract, recruit and retain diverse trainees by demonstrating that Diversity Accelerates Research and Translation (DART), a core value and program commitment.*

Diversity is instrumental for the workforce to advance discovery, eliminate health disparities, and achieve patient-centered outcomes in the quest for better health.⁵ Strategies and concepts we will incorporate to promote DEI include: 1) weaving DART and DEI considerations across the totality of the TOTTS program, not in just certain parts (e.g. across advertising, recruiting, programming, product generation); 2) coordination and implementation of DEI efforts across the CCTSI systematically, and 3) ensuring TOTTS leadership and faculty are well-trained and committed to supporting DEI principles.²⁷ (See above sections 1e, 1f, 2d-2). Support for DEI training was underscored in the 2021 CCTSI Needs Assessment, where the need to enhance DEI on research teams and in research study participants was voiced by 35% of the >800 respondents (trainees, faculty, staff). This request will be met by the addition of a workshop in the required RCR series on DEI in conducting research, the expansion of the topic in Leading and Teaming, Mentoring³, and our TOTTS seminars. To achieve and sustain diversity across TOTTS' trainees and faculty, the TOTTS program and the CCTSI WD will provide training opportunities throughout the year and during TOTTS seminars, provided by Dr. del Pino-Jones.

5e-1. Successes in Program Diversity and Inclusion: During the previous funding cycle, TOTTS applicants and awardees were predominantly women, who have historically been under-represented in academia, a situation made starker now due to the COVID-19 pandemic.²⁸ Our TOTTS program **demonstrated a 127% increase in URM participation over the last four years** with the initiation of our strategic approach for attracting, recruiting, and retaining URM participation. Importantly, our **TOTTS program has a 100% completion rate, 100% doctoral degree attainment rate and 100% persistence in CTSR for awardees with URM backgrounds.** Recently, the University's and its programs' diversity efforts were rewarded, CU Denver | Anschutz is now recognized as a Hispanic Serving Institution and an Asian, American Native, American Pacific Islander-Serving Institution.

5e-2. Attract and Recruit for Diversity: On a program level, Drs. Zimmer and del Pino-Jones, both part of TOTTS program faculty, organize and hold CU SOM URM seminars every 4-8 weeks for medical students and residents and will ensure that URM trainees are aware of the TOTTS program. Interested potential applicants will be offered/provided mentorship and support for completing the T32 application by Drs. Zimmer and del

Pino-Jones. Dr. Martinez, Director of Office of Inclusion and Outreach (OIO) and a member of the CCTSI WD LAC (See Attachment **Coordination and Interaction**), organizes regularly held student life activities for URM students on both CU-downtown and Anschutz campuses. He will ensure that TOTTS is advertised and promoted through the OIO's website, publications and social media accounts. The OIO has worked diligently to develop and maintain relationships with URM students and to engage them with university life. On average, the OIO meets monthly with 274 BIPOC students to assist with identifying and navigating education/ training opportunities and supporting their applications. As CCTSI T32 and OIO goals are aligned, Dr. Martinez and his staff will ensure URM students are aware of and provided support in the application process. Additionally, TOTTS T32 program administration (Cicutto and del Pino-Jones) will present at the twice-yearly OIO student conferences. Drs. Zimmer, del Pino-Jones and Martinez will all serve on the CCTSI WD LAC, and a standing agenda item will be recruitment and retention of URM trainees. We are confident that we will reach our goal of at least 30% of TOTTS trainees being from URM backgrounds. Our program was recognized and profiled nationally by CLIC coordinating center this TL1 renewal for our ability to bend the curve for increasing representation of URM trainees. See **Attachment Recruitment Plan to Enhance Diversity**.

5e-3. Trainee Retention: (See **Attachment Retention Plan**). Multiple efforts will be made to enhance trainee retention. 1) Each year we will provide training for trainees and faculty to grow and align our actions to support DART that include building a safe and inclusive environment.²⁹ 2) Required trainee/mentee and mentor training through the Mentoring³ program will directly address environmental issues surrounding inclusivity and safety. CU-AMC's Office of Diversity and Inclusion offers required trainings for mentors and numerous trainings that can be incorporated into trainees' ICDPs. 3) Further, our TOTTS seminars provide a forum to dialogue about work environment dynamics in a safe space or one-on-one confidential meetings with program directors. 4) Additionally, trainees have monthly check-ins with program directors where they are encouraged to share career obstacles or stalled progress that could be attributable to a dysfunctional work environment. 5) Our annual 360 mentoring assessments provide a *bi-directional evaluation process* to identify at-risk mentoring relationships. Effective mechanisms will be implemented to address issues efficiently should they arise (See **Attachments Mentor Assessment and Internal Advisory Committee**).

6. INSTITUTIONAL ENVIRONMENT AND COMMITMENT TO TRAINING (See Facilities and Other Resources and Institutional Letter of Support)

Starting in 2022, the Office of the Vice Chancellor of Research, CU Anschutz will recognize and acknowledge the importance of mentoring by providing awards for Excellence in Peer Mentoring, Excellence in Junior Faculty Mentoring, and Outstanding Senior Faculty Mentoring. Up to this point, awards from the Office of the Vice Chancellor of Research were provided to acknowledge excellence in research. Notably absent from the list of recognitions were awards for *mentoring excellence*. The CCTSI K and T program directors (Burnham and Cicutto) brought this to the attention of the CCTSI LAC who wanted to address and change this. As a result, Drs. Burnham and Cicutto met with the Office of the Vice Chancellor of Research who agreed that *mentoring excellence* should be recognized. The creation of these awards show progress in addressing environmental pull factors identified as important in our Model for Persistence of a Diverse Clinical and Translational Research Workforce.

The **CCTSI** is committed to the success of our TOTTS program and has committed to the following supports. The provision of salary support in the UM1 application for Drs. Cicutto, del Pino-Jones, MacLean, Nadeau and Mankin (administrator) to lead this training program. The CCTSI will also provide funds (in the UM1 application) for the delivery of required program elements that are part of the CCTSI WD and include Mentoring³, Leading and Teaming, F Grant Review and Mock Study Section, CLSC graduate program, and Effectively Communicating your Research to the Public. The WD LAC, a key venue for integration of programmatic and DART activities, is also supported by the CCTSI UM1 application. The Center for Innovative Design and Analytics/ Biostatistics, Epidemiology, and Research Design (BERD; UM1 supported) is a campus wide resource for trainees (with priority to CCTSI T32 trainees) and faculty to collaborate and consult with biostatisticians who can assist with study design, grant writing and planning of biostatistical analysis. BERD provides innovative training programs in biostatistics for non-statisticians and is a member of the CCTSI LAC. (See **Attachment Coordination and Interaction**)

CU Anschutz has a long-standing Graduate Student Council that supports speakers and workshops on career development, and sponsors social activities. The Graduate School's Office of Career Development provides

workshops on a variety of topics such as lab management, interviewing, negotiation, networking. The NIH funded **BEST program** offers a wide variety of training and career development program and emphasizes exploration of job options in addition to the traditional academic track. These include certificate programs in teaching, project management, industry internships, commercialization, etc. which are open to all trainees.

7. PLAN FOR INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH (See Attachment Plan for Instruction in the Responsible Conduct of Research).

Training in ethical and regulatory principles, including Responsible Conduct of Research (RCR) and Good Clinical Practice (GCP), are critical to the efficient conduct of CTSR and maintaining societal trust in the research enterprise. It is thus an essential part of TOTTS, as evidenced by our learning objective that trainees' will *Exhibit research practices concordant with research ethics, RCR, GCP, regulatory compliance, rigor and reproducibility and data science principles (See above section 3.7)*. It is integrated across programmatic elements and accomplished through required course work, CITI modules, submission of IRB and/or IACUC approval (as necessary), learning needs in the ICDP, mentored research project, and TOTTS seminars. Educational opportunities are designed to be in full compliance with the policy requirements for RCR education promulgated by NIH in NOT-OD-10-019 and NOT-OD-22-055, and the NIH Grants Policy Statement, Section 11.3.3.5.

8. PLAN FOR INSTRUCTION IN METHODS FOR ENHANCING REPRODUCIBILITY (See Attachment Plan for Instruction for Enhancing Reproducibility)

To enhance the reproducibility of research findings through increased scientific rigor and reproducibility, NIH published notice NOT-OD-15-103. Its five identified elements will guide instruction to our TOTTS trainees. These elements include: 1) evaluation of foundational research underlying a project (i.e., rigor of prior research); 2) rigorous experimental design and data interpretation; 3) consideration of relevant biological variables such as sex; 4) authentication of key biological and/or chemical resources; and 5) transparency in reporting. TOTTS programming will provide a critical role in supporting competency development for applying rigorous methods for acquiring, analyzing and reporting data. Processes for effectively developing these skills, methods, and concepts to trainees is through modeling (by research mentors, program leaders and peers) and training. A multi-faceted approach will be used that involves coursework, completion of NIH Rigor and Reproducibility modules, thesis committee meetings (for PhD trainees), MATT-C meetings, ICDPs, mentored research project, and the TOTTS seminars that will include a didactic element, application, and issue identification and problem solving.

Translational science seeks to understand the scientific and operational principles underlying each step in the translational process. Translational research seeks to produce more meaningful, applicable results that directly benefit human health. Our TOTTS program prepares translational scientists that characterize Domain Expert, Rigorous Researcher, Boundary Crosser, Team Player, Systems Thinker, Skilled Communicator, and Process Innovator. As translational scientists they will be able to make discoveries through rigorous and efficient research that overcomes challenges and bottlenecks along the way so that the health of individuals and community are improved. Our TOTTS program will contribute to NCATS objective of expanding the national pool of diverse, highly qualified, and competent clinical and translational science-trained investigators that are broadly representative across racial, ethnic, sex, gender, socioeconomic, geographic and disability status working to achieve health for all.

Coordination and Interaction Plan

The CCTSI is an integrated research and training program for clinical and translational science (CTS) and research based at the University of Colorado Anschutz Medical Campus with several Partnering Institutions. The CCTSI will be funded by 7 grant applications in response to the 2021 CTSA grant FOAs, including a K12 and two T32 applications. The leaders of Programs for all of these awarded grants will be successfully integrated seamlessly into our current CCTSI Executive Committee and overall program, as they have been for the past 14 years. The CCTSI Pre-Doctoral T32 Program (called TOTTS) is a critical element of the CCTSI, essential for the preparation of a highly qualified workforce. It is supported and coordinated with several UM1 Hub programs including the CCTSI Workforce Development (WD) Core (Module C1) for much of its required programming; the services and support of CTS Resources and Services (Module D1); Community and Stakeholder Engagement (Module C2); Health Informatics (D3); Strategic Management (Element B); and the Colorado Innovator Ecosystem RC2 application. We have an ongoing integrated and coordinated CCTSI governance structure for these and other UM1 and education/training components which will be adapted for the new Pre- and Post-Doctoral T32 programs. Thus, our CCTSI governance and operational capabilities will be leveraged fully to provide necessary and flexible programming to support the development of predoctoral translational scientists and to facilitate navigation of resources and services by our trainees. Interactions and coordination with key CCTSI Cores and Programs for the TOTTS T32 are included in **Figure 1**, however all CCTSI Cores and resources will be available to the TOTTS T32 program and trainees as needed.

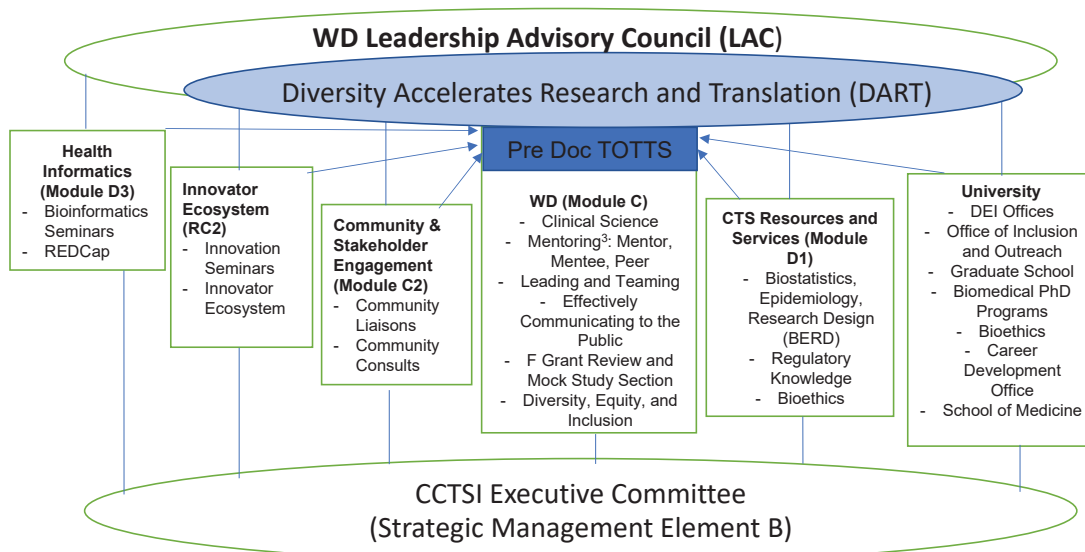
Central Governance, Coordination, Interaction, Integration

Two committees will support the coordination, interaction and integration of services to support the TOTTS T32 Program. Central governance and coordination of coursework and career development programs and services supporting TOTTS trainees will administered through the CCTSI's **WD Leadership Advisory Council (LAC)**. The WD LAC is comprised of directors and leaders from **all WD core programs** (Module C1), including the K12 and T32 programs, the Director of Diversity, Equity and Inclusion (DEI), and directors/leaders from other UM1-supported programs found in Modules C2 (Community and Stakeholder Engagement), D1 (Regulatory Knowledge and Support, Biostatistics, Epidemiology, Research Design (BERD)), and RC2 (Innovator Ecosystem) and the CCTSI Evaluation Core. The TOTTS Program Director, Lisa Cicutto PhD, will lead the monthly meeting in her role as WD

Director. A standing agenda item is DEI activities, approaches and integration strategies to support our value of Diversity Accelerates Research and Translation (**DART**). Additionally, meetings focus on annual review of each WD program consistent with our continuous quality improvement

process and monitoring of metrics, integration across programs (WD, CCTSI and university), progress towards mutual milestones, need for revision and current events/issues. The LAC will ensure coordination, integration, synergy, and mutual reinforcement among all CCTSI WD programs and activities, and will work with the Evaluation Core to evaluate all WD programs. The LAC has proved to be extremely valuable to ensure that education/training leaders are aware of each program, have the agility to collaborate/ integrate across programs, leverage resources, avoid duplication and competing with one another. An example of a benefit was the creation of the Teaming program, which was a collaborative effort of the CCTSI, the Graduate School, School of Medicine, and Colorado State University. Notably, TOTTS Directors (Drs. del Pino-Jones, MacLean,

Figure 1. Coordination and Integration of Programs and Services Supporting T32



and Nadeau) attend the LAC. As such, they will be intimately familiar with TOTTS objectives, outcomes, milestones, and recruitment goals and ensure that these areas are discussed and integrated. Dr. Bruce Mandt is also important to integration and coordination as he directs Mentoring³ and is part of the Graduate School's leadership team and directs the Office of Career Development.

DART will be realized through having the CU-Anschutz DEI offices represented (University Office of Inclusion and Outreach, Dr. Martinez and Office of DEI, School of Medicine (SOM), Dr. Zimmer), CCTSI WD and TOTTS DEI Director and all WD program directors meeting monthly through the LAC. The School of Medicine's Office of DEI includes training of medical residents and fellows and all biomedical PhD programs. The University's Office of Inclusion and Outreach focuses on attracting URM students/trainee for undergraduate programs and the non-SOM health professional programs and works in an integrated fashion with the SOM.

The second committee to support interaction, integration and coordination is the **CCTSI Executive Committee (EC)**, which consists of the leaders for all CCTSI cores, including Dr. Cicutto, and is chaired by the CCTSI Director and Principal Investigator, Dr. Ronald Sokol who oversees governance, operations and decision making. This is outlined in UM **Module B-Strategic Management** with the EC goal to integrate, coordinate, track and improve all CCTSI programs and cores. Dr. Sokol reports to the Vice Chancellor (VC) for Research and to the VC for Health Affairs (the Dean, SOM), who in turn report to the Chancellor at CU Anschutz. His positions and roles allow for coordination, integration and responsiveness across the University community. This committee meets twice monthly to discuss new initiatives, approve pilot grants, review activities, evaluation of programs, and respond to arising needs and issues and ultimately keeps us on the same page. Programmatic support to administer the TOTTS program (Lisa Cicutto, Paul MacLean, Kristen Nadeau, Amira del Pino-Jones, Galit Mankin), its activities and financial oversight will be conducted with Module B personnel support. Using the LAC-EC interface, the EC will provide ultimate oversight for major operational issues that arise within the program. In the event that Dr. Lisa Cicutto is unable to fulfill her responsibilities for the TOTTS program, Dr. Sokol will meet with the TOTTS Program Administration and the LAC to mutually decide on next steps and processes to find her replacement. In the interim, Dr. Paul MacLean will assume the Director role for the CCTSI TOTTS program. Element B also includes the Evaluation Core under the direction of Dr. Komaie who is a member of the LAC and the lead evaluator for the CCTSI T32 TOTTS Program.

Coordination with specific CCTSI UM1 components is outlined in the following:

1. Module C1- Workforce Development Core (WD)

The goal of Module C1 programs is to develop, deliver, demonstrate and disseminate clinical and translational science (CTS) research training and career development programs that create and retain a highly qualified, interdisciplinary, team-oriented workforce prepared to apply scientific and operational innovative strategies to improve efficiency and effectiveness of research that embraces diversity, equity and inclusion. The TOTTS program is housed in this core, and all TOTTS trainees will highly utilize and benefit from WD offerings.

The Clinical Science (CLSC) Graduate Program's goal is to prepare clinical/clinician scientists for career success and as such will provide foundational education to ensure TOTTS trainees can conduct high quality, rigorous and efficient CTS research and clinical trials. Lisa Cicutto PhD, ACNP(cert) *will ensure integration and coordination of* CLSC, TOTTS, CCTSI Post-Doctoral T32 program, and Module C: WD, as she serves as director for all of them. In this way, she is 1. able to anticipate and identify issues and make changes to avoid and overcome bottlenecks, and 2. identify gaps and redundancies and take corrective actions. Dr. Kristen Nadeau (Associate Director) completed her master's degree through the CLSC and teaches its *Scientific Review of Clinical Research and Clinical Trials* course and thus is very familiar with the program, providing her with significant expertise in advising trainees.

Leading and Teaming in Clinical Translational Science and Research program, a requirement for TOTTS trainees, is directed by Jeni Cross who attends LAC meetings. She led the development of Science of Team Science during the last grant cycle, which will be expanded this renewal to include more on leading/leadership. This curriculum expansion will occur collaboratively with Bruce Mandt (Mentoring³ and Graduate School's Office of Career Development), Lisa Cicutto, Amira del Pino Jones (DEI) and SOM T32 representatives.

Mentoring³: Mentor, Mentee, Peer completion is a requirement for TOTTS trainees and their mentors. Bruce Mandt will develop and direct the program, which also includes building a pool of future program faculty /instructors. His involvement in the biomedical PhD programs will be leveraged to attract faculty to participate in curriculum development, complete the train the trainer program, serve as future faculty and support a culture of strong mentorship that creates safe, inclusive and supportive environments (which is the goal of TOTTS, T32 programs, PhD programs and the university). Amira del Pino Jones will integrate DEI activities into Mentoring³.

F Grant Review and Mock Study Section participation by TOTTS trainees will support effective grant writing. Bruce Mandt PhD and Joan Hooper PhD lead this program and will attend LAC. Both are very well connected with the biomedical PhD programs.

Communicating Research to the Public will be completed by TOTTS trainees to accomplish the mutual goal of effective communication skills. Comilla Sasson MD, PhD is a CLSC alumnus that bridges academic clinical practice, patient advocacy/professional society organizations (a vice president for American Heart Association), active researcher and local and national news spokesperson. The wearing of many hats and speaking in many voices is congruent with program's goal of exposing trainees to multiple career options.

2. Module D1- Resources and Services

The goal of this module is to enable researchers to leverage key resources and services not otherwise available to successfully conduct research and obtain necessary training and support. Opportunities within the core span the spectrum from fundamental CTS research training (e.g., biostatistics, ethics, regulatory sciences) to dissemination strategies for non-academic audiences. Regulatory Knowledge and Services (on LAC) is a mandatory TOTTS element, a collaborative effort of the CCTSI and University. CCTSI's BERD (represented on LAC) supplements coursework by providing workshops on biostatistics, reproducibility, and study design, and can support and collaborate with TOTTS trainees. Dr. DeCamp, Bioethics director, will provide a TOTTS seminar. CTCRC Networks and Core Labs, directed by Wendy Kohrt, PhD, provide infrastructure for mentees and mentors to conduct research at lower cost. Bethany Kwan, PhD directs the CCTSI's Dissemination and Implementation service and will provide a workshop on designing for dissemination during a TOTTS seminar. Importantly, all leaders of these programs have agreed to provide priority access for TOTTS trainees to ensure easy access to services and resources.

3. Module C2-Community and Stakeholder Engagement Research

The goal of Module C2 is to develop the bi-directional capacity of investigators and research staff to equitably engage diverse communities and stakeholders in CTSR, while establishing, building and maintaining trust. Trainees will benefit from this core through seminar provision on developing partnerships and community engaged research by Montelle Tamez, MS (Deputy Director; LAC member); support with organizing and promoting Café Scientifiques in community; and assisting with the identification of translational and immersion experiences in community.

4. Module D3-Health Informatics

The goal of CCTSI Health Informatics Core is to manage data, democratize access, interoperability, maintain critical software applications, and advance informatics education. Services provided to TOTTS trainees include REDCap support and training and TOTTS seminars. Depending on the trainee's needs, additional support may include accessing Health Data Compass, CU's multi-institutional data warehouse, and the clinical and translational research data hub for CU-Anschutz. Tell Bennett, MD is the co-director and a T32 faculty mentor.

5. RC2-Innovator Ecosystem of Colorado

CCTSI's Innovator Ecosystem's goal is to conduct broad efforts to educate and support Innovators to expand commercialization of ideas and discoveries into products, that will improve health and to build the infrastructure to support this translational work. Ecosystem programs interact with University-sponsored SPARK | REACH initiatives that also have provided funding to TL1 trainees and their mentors. Cathy Bodine, PhD directs this module, serves as a TOTTS mentor, and will provide a TOTTS seminar to discuss the program and to also introduce concepts in biotechnology, entrepreneurship, and commercialization. The I-Corps training program will be open to TOTTS trainees.

Dissemination Plan

Developing, demonstrating and disseminating effective training programs is crucial for meeting trainees' needs and identifying best practices and moving the field forward. CCTSI training programs have and will continue to actively pursue and contribute to advancing the field through innovative and effective elements of training programs.¹⁻⁶ For this next grant cycle, we will contribute to the field and CTSA community in several ways.

During the last four years, we developed and evaluated, *Teaming for Early Career Clinical and Translational Researchers*, which targeted pre- and post-doctoral trainees. Program development was based on evidence and contextualized for the pre- and post-doctoral development stage. It consists of a self-paced web module and 6 workshops. We are now completing our second year of evaluation, which will include data from > 300 people regarding knowledge, attitudes, self-efficacy and application. We will disseminate our experiences and evaluation at the national CTSA and International Science of Team Science conferences, and through peer-reviewed manuscripts. It is our intent to share the self-paced web module, which can be accessed through Canvas freeware, with other CTSA hubs. Dr. Jeni Cross, program director, has heard from three other CTSA hubs (Ohio, Kansas and University Southern California) that are interested in implementing our program. Our future direction is to work with other interested CTSA hubs to permit replication at their hub.

Starting three years ago, in response to our recognition and appreciation for the importance of mentoring and understanding the perspectives of both mentors and mentees, we developed a questionnaire to assess the mentoring relationship that allows analyses for data as a dyad, in addition to the mentee and mentor. We call this a **360 Mentoring Assessment**. Mentor and mentee questionnaires were based on the literature and consist of three parallel sections: self-report and reflection of one's own personal skills and relationship qualities, reported assessment of your mentee's or mentor's mentoring skills and report on the quality of important elements in the mentoring relationship. Mentors and mentees involved in the CCTSI T and K programs completed these 360 type mentoring relationship experiences program initiation and end of years 1 and 2 (TL1 end of program was year 1). Our intent is that this type of information on individual mentoring relationships will assist with identifying dyads in need of support and extra attention (at-risk relationships), will identify areas of focused training efforts related to effective mentoring, and will determine if these mentored programs improve mentoring relationships over time. Our experiences, results and questionnaires will be shared through our website, ACTS conferences, CTSA T and K program directors' meetings, and publications.

Café Scientifiques are a dissemination strategy that will be used to engage and inform community citizens regarding research conducted at the CCTSI TOTTS trainees and to provide trainees with the opportunity to highlight their research and practice communicating their research with lay audiences. A Café Scientifique is a place where anyone can come to explore the latest ideas in science and technology. Meetings always occur in communities outside a traditional academic context, such as cafes. Each year we will hold two Café Scientifique events where the TOTTS T32 trainees will talk about their research for 5-10 minutes followed by discussion with community citizens. Cafés will engage people in a conversation about issues in science and health and promote the cultural examination of research. Cafés are known for their informal and friendly atmosphere and are believed to improve the image of scientists/science, careers in science, and science literacy,⁷ which aligns with the goals of the CCTSI. These events will be organized with the CCTSI Community Engagement Core, which has a track record of partnering with community to organize educational and engagement events. We are unaware of other CTSA programs having their T32 trainees participate in Café Scientifiques. Evaluative efforts will explore attendee's pre-post perspectives regarding the image/relevance of scientists/science, science literacy, and interest in science, as well as satisfaction. We are unaware of other CTSA hubs using Café Scientifiques. We will share our experiences at the national CTSA/ACTS conference and post our "How to Kit" off our CCTSI T32 TOTTS website.

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