



CU-CSU Summit 2023

CCTSI Overview & Goals

August 16, 2023

Ronald J. Sokol, MD
Director and P.I. of CCTSI
University of Colorado – Anschutz Medical Campus



CTSA Program

- **Clinical and Translational Science Award (NIH)**
- **An NIH-funded national consortium of biomedical research institutions collaborating to transform how clinical and translational science is conducted nationwide**
- **Currently, ~60 funded Hubs, many of which include multiple universities and hospitals.**
- **Grants originate from NCATS at NIH**



Colorado Clinical & Translational Sciences Institute

- CCTSI is the Colorado CTSA Hub
- Created in 2008, refunded by NIH in 2013, 2018, **2023**
- Substantial institutional support (funding)
- Supports all faculty, post-docs, trainees involved in clinical or translational research at 3 universities and 6 hospital partners
- “Disease – agnostic”
- Infrastructure, research facilities, education and training, resources & services, pilot grant funding, biostatistics & informatics, and much more.....



CCTSI Vision

Accelerate and catalyze the translation of innovative science into improved, equitable health and patient care for all



CCTSI 3.0 Mission

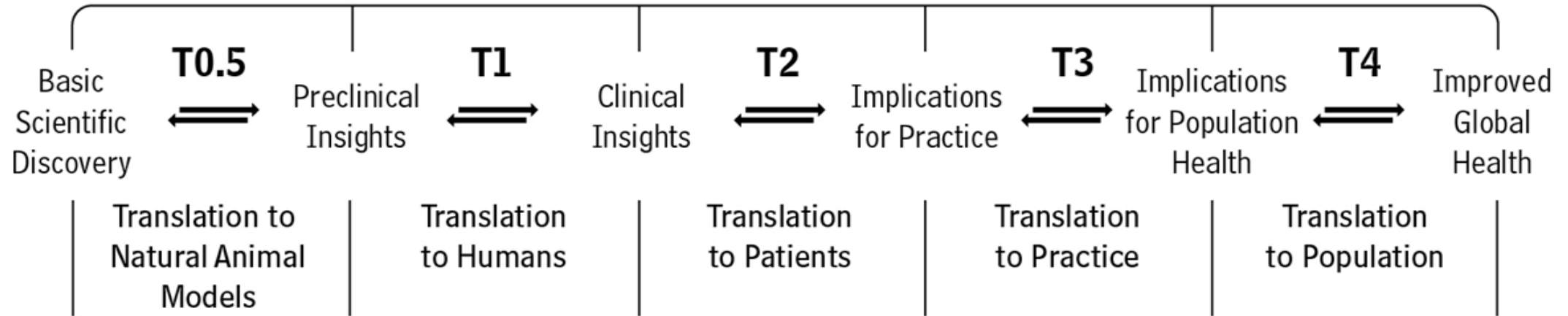


- **Catalyze** and enhance scientific discovery, innovation, dissemination and translation across the lifespan
- **Educate** and sustain a resilient, innovative and diverse translational science workforce
- Promote and ensure an efficient, safe, collaborative and integrated **research environment**
- **Engage stakeholders and communities** across the entire translational spectrum

Spectrum of Translational Research

- Bi-Directional
- Collaboration
- Team Science

CLINICAL TRANSLATIONAL RESEARCH SPECTRUM



CCTSI

Leaders from all CU Anschutz Schools, Colleges,
Hospitals, Key Research Stakeholders

CTSA UM1 PI: Sokol
MPI: Higgins

Administrative Core
Sokol, Higgins, Lockie

Executive Committee

CQI &
Evaluation

Hub Liaison
Team

D&I Core

Internal Advisory
Committee

External Advisory
Committee

All CTSA Module Leaders and Representatives from all Partner
Institutions, URM Community Members, & Workforce

CTS Workforce
Development
Element C1
(Cicutto)

Community and
Stakeholder Engagement
Element C2
(Nease/Tamez)

CTS Resources and
Services
Element D1
(Kohrt)

CTS Pilot Grant
Program
Element D2
(Serkova)

Health Informatics
Element D3
(Haendel/Bennett)

PEET: CTS
Research Program
Element E
(Ginde/Kwan)

RC2-1
(TBD)

RC2-2
(TBD)

Planning

- BERD
- Pragmatic Trials
- Clinical Trials/TIN
- Bioethics
- Research Studios

Conduct

- CTRC Network
- RKS
- Data Management
- Natural Animal Models

Analysis

- CTRC Core Labs
- Nutrition & Exercise Cores
- Cardiovascular Imaging
- BERD

Dissemination

- D&I Core
- Communication
and Marketing

K12
(Burnham)

Pre-Doc
T32
(Cicutto)

Post-
Doc T32
(Cicutto)

R25
(TBD)



CCTSI Leadership and Diversity

MPI, Director: Ronald Sokol, MD

MPI, Director of Operations: Janine Higgins, PhD

DFA: Tim Lockie, MS, MBA

Associate Directors:

- Wendy Kohrt, PhD
- Tell Bennet, MD, MS & Melissa Haendel, PhD
- Alison Lakin, RN, JD
- Donald Nease, MD, MPH & Montelle Tamez
- Natalie Serkova, PhD
- Lisa Cicutto, PhD
- Bethany Kwan PhD & Adit Ginde MD, MPH

CSU: Susan VandeWoude, DVM

CU-Boulder: Chris Desouza, PhD

VAMC: Jane Reusch, MD

CCTSI Leadership:

50% Female

50% PhD or equivalent

**Representation across Schools &
Depts**

SOM, CON, CSPH, Engineering

CCTSI Exec Committee:

52% Female

55% PhD or other

2 URM Community

Representatives

**Representation across AMC
Schools and Depts, and all
Partner Institutions**



Colorado Clinical and Translational Sciences Institute

<https://cctsi.cuanschutz.edu/>

Resources ▼

Training ▼

Funding ▼

Community Engagement ▼

News and Events ▼

About Us ▼

Volunteer for a Study 

WEBSITE:

6,000 - 7,000 visits per month

PROFILES:

15,000 – 20,000 visits per month

ACCELERATING RESEARCH TO IMPROVE HEALTH

The CCTSI helps build research teams of the future, speed the development of new treatments and improve human health

Clinical Translational Research Centers (CTRCs) – Wendy Kohrt, PhD



- **Adult-AHSB, CHCO, NJH, CU-B**
 - Inpatient and outpatient facilities – **no charge for space (except industry studies)**
 - **Research Nursing** – inpatient, outpatient, mobile teams (NICU, PICU, ED, etc.)
 - **Nutrition** - metabolic kitchen, whole room calorimeter and body composition
 - Adult Vascular Ultrasonography, ECHO, and liver elastography
 - **Core laboratories** & specimen processing
 - **Microgrants** to Jr. Investigators (\$10,000/yr. x 3)
 - **200** unique PI's conduct research on **>500 CTRC** Protocols each year
- **Subsidized pricing for investigator-initiated studies**



Pilot Grant Awards

Natalie Serkova, PhD

- **5 Pilot Grant programs** – CO-Pilot, CMH, Community Engagement, New Methods, CU-CSU Collaboration Award
- **~\$900,000 available**
- **\$25,000 for Community Engagement**
- **\$30,000 for Translational Methods**
- **\$40,000 for CO-Pilot and CMH mentored, junior, and early career diversity pilots**
- **\$60,000 for CU-SCU collaborative pilots**



Translational Informatics

Tell Bennett, MD, MS & Melissa Haendel, PhD



- **REDCap** – operated for entire campus by CCTSI
 - >9,000 users, >6,000 active projects
- **Health Data Compass** – enterprise-wide research data warehouse
- **Colorado PROFILES**, CTRC Scheduler, Harvest, LIS
- **Data Delivery & Cohort Discovery** – TrinetX, Compass, ACT, N3C
- **Multiple applications** to support Grant Review and Education programs



Education, Training and Career Development

Translational Workforce Development

Lisa Cicutto, PhD, APN, RN



- 1. Summer Undergraduate Minority Mentoring in Translational Science (SUMMiT) (n=14)**
- 2. Pre and Post Doc T32: Pre- and Post-doctoral PhD/MD training programs**
- 3. Clinical Sciences Graduate Program (Masters, PhD)**
- 4. K12 Research Scholar program - up to 3 yrs. of support – Ellen Burnham, MD**
- 5. Support for Clinical Faculty Scholars Program – Anne Libby, PhD**
- 6. Clinical Research Training and Education Program (CRSC)**



Education, Training and Career Development

Lisa Cicutto, PhD, APN, RN



- 8. Colorado Mentor (CO-Mentor) Training Program – Greg Austin MD**
- 9. K-to-R Transition Grant Review – Maggie Wierman MD**
- 10. Pre-K Award Assistance and Grant Review – Paul MacLean, PhD**
- 11. Research Studios – Jane Reusch MD, Alan Prochazka MD**
- 12. Innovation Corps @ CCTSI – Cathy Bodine, PhD**
- 13. Leading and Teaming – Jeni Cross, PhD**
- 14. Communicating Your Science to the Public – C. Sasson, MD**



Colorado Clinical and Translational
Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

Pre-K Grant Review Program

Paul MacLean PhD & Josie Broussard PhD



- Assist junior faculty and their mentors write successful career development awards
- Mock grant reviews: 3 times a year
 - Applicants and mentors attend
 - K24 awardees, K12 directors, biostats, other K awardees are reviewers
 - Format: reviewers and then panel discusses, followed by Q&A
- Helpful materials on website relevant to K applicants



K to R Transition Program

Maggie Wierman, MD



- Pre-submission mock grant review process
- Faculty with K-level awards who are submitting first R-level grant award or any R-level grant submission
- Submit grant proposal for internal review about 6 weeks before submission to funding agency
- Mock study section and written reviews
- PI and mentor - attend mock study section
- 3 cycles – NIH grant application deadlines



Research Studio Program

Jane Reusch, MD and Alan Prochazka, MD



- **Expert Panel** to provide targeted advice about research project, grant application, idea generation, etc.
- **Studio sessions** are Face to Face - 90 Minutes
 - Investigator presents brief summary (10-15 minutes)
 - Focused discussion with experts for 3 or 4 predetermined questions from the investigator - focus on problem-solving and the development of helpful solutions (60-70 minutes)
 - Moderator and panelists provide summarized comments (10-15 minutes)
- 2019-2020 participants believed the experience contributed **>\$2M in subsequent grant funding**



I-Corps@CCTSI

Cathy Bodine, PhD



- **I-Corps @ CCTSI**
- Teams of faculty, staff or students with a biomedical discovery or health innovation idea.
- Uses customer discovery methods used for startups for academic researchers
- A team-based short course designed for faculty, staff and students
- Test the business model hypotheses for a technology or idea

Communicating Your Science to the Public

Comilla Sasson, MD, PhD

- Offered Quarterly for up to 30 per session. Started in Spring 2021.
- Workshop #1: Effectively communicating your message to the public
- Workshop #2: Sharing your message effectively and giving/receiving feedback
- Workshop #3: Expanding your media horizons



Community Engagement & Health Equity

Don Nease, MD

- Community Research Liaison (CRL) program
- Colorado Immersion Training in Community Engagement (CIT)
- Research Readiness Certification for Community Based Organizations
- Community Engagement Consults
- CE Pilot Grant Program
- Boot Camp Translation for Patient-Centered Outcomes: Facilitator Training
- Introduction to CBPR for Community-Academic Partnerships



Trial Innovation Network (TIN)



- National CTSA Consortium effort to facilitate design and conduct of Multi-Site (NIH) Clinical Trials
- Provides local and national support for the entire study lifespan
 - Study design, central IRBs, study operations, data collection and analysis, recruitment and retention strategies, etc.
 - TIN Hub Liaison Team – Local linkage to national TIN
- Investigators can request a single service (e.g., single IRB) or complete study life cycle assistance

RKS - Clinical Research Support Center (CRSC) – Alison Lakin, RN, PhD, JD

- FDA submissions
- Education and training for study start up and management
- Access to and maintenance of ClinicalTrials.gov records
- Research agreements (confidential disclosure agreements, clinical trial agreements and materials transfer agreements)
- Study drug/device management advice – IND/IDE
- OnCore, the clinical trials management system



Pragmatic EHR Embedded Trials (PEET)

Adit Ginde, MD, Bethany Kwan, PhD, Janine Higgins, PhD

- ***New Program!***
- Build the Program infrastructure at UCH/UCHealth (initially)
- Engage stakeholders in co-design of materials and for dissemination across the CTSA consortium.
- Conduct PEET trials – for up to three years each, 2 ongoing per year
 - Initial demonstration trial – metformin in men with prostate cancer
- Watch for RFAs for submission of new trial proposals in 2024





11th Annual CU-CSU CCTSI Summit – at the Spur!

- **Goals:**

1. ***“Enhancing Impact of Clinical and Translational Research Through Dissemination and Implementation Science”***
2. Highlight ongoing research, resources and progress in Colorado
3. Promote new collaborations, scientific exchange, mentor-mentee relationships

- **In Person Format :** 5 sessions, Lightning Talks and a Poster Session, Breakfast and Lunch, Networking Time, Finish by 3:30 pm



Thank You

CU-CSU Summit Planning Committee

- *Program Chair Bethany Kwan, PhD, MSPH, CU Anschutz*
- *Matthew Hickey, PhD, Colorado State University*
- *Wendy S. Meyer, MA, CU Anschutz*
- Lisa Cicutto, PhD, CU Anschutz
- Heather Gilmartin, PhD, CU Anschutz
- Janine Higgins, PhD, CU Anschutz
- Ronald J. Sokol, MD, CU Anschutz

