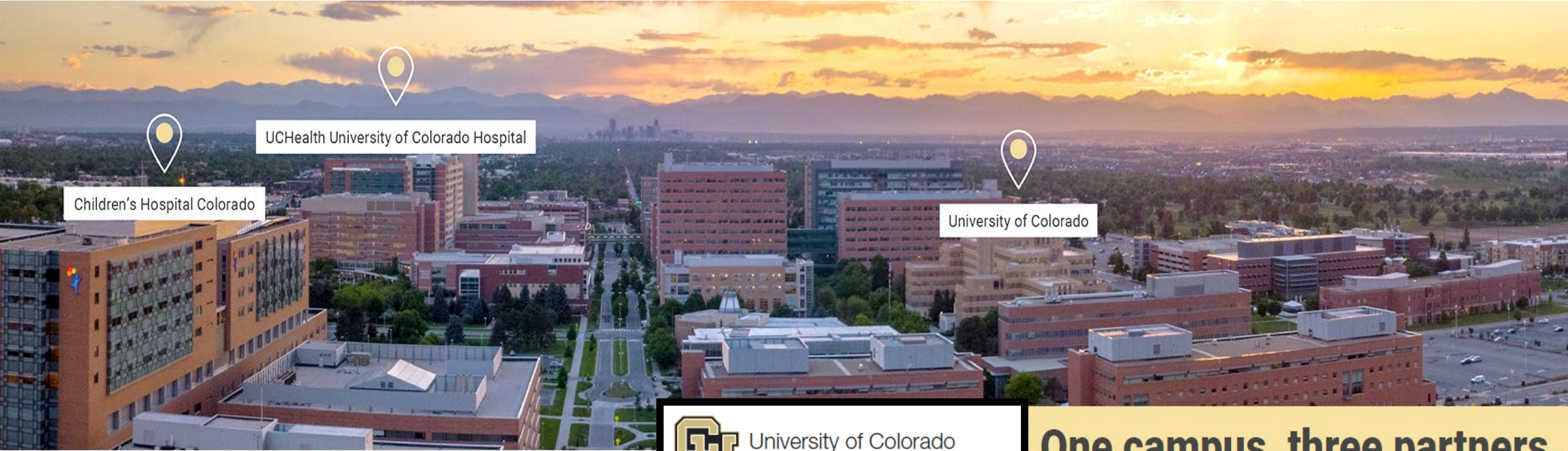


Welcome CCTSI EAC to Colorado

April 10-11, 2024



Children's Hospital Colorado

UHealth University of Colorado Hospital

University of Colorado



University of Colorado
Anschutz Medical Campus

One campus, three partners.

External Advisory Committee

Steven Dubinett, MD

Dean, David Geffen SOM;
Senior Associate Dean for
Translational Research at
UCLA, Director of Clinical
and Translational Sciences
Institute; UCLA (CTSA PI)



Alexander Krist, MD, MPH

Director of Community-
Engaged Research at the
Wright Center for Clinical
and Translational
Research, Professor of
family medicine and
population health at
Virginia Commonwealth
University



External Advisory Committee

**Cynthia Morris,
PhD, MPH**

Sr. Associate Director
and co-PI, Oregon
Clinical and
Translational Research
Institute, Professor of
Medical Informatics and
Clinical Epidemiology,
School of Medicine,
OHSU



**Tesheia Johnson,
MBA, MHS**

Deputy Director and
Chief Operating Officer
of Yale Center for Clinical
Investigation and the
Director for Clinical
Research for Yale School
of Medicine



External Advisory Committee

Dan Cooper, MD

Interim Executive
Director of Institute for
Precision Health at UC
Irvine, Associate Director
of Institute for Clinical
Translational Science,
Professor of Pediatrics



Peter Embi, MD, MS

Chair and Senior Vice
President for Research
and Innovation,
Department of
Biomedical Informatics,
Vanderbilt University
Medical Center



External Advisory Committee

**Jareen Meizen-Derr,
PhD, MPH**

Co-Director, Center For
Clinical and Translational
Science & Training,
Professor Dept. of
Pediatrics, Co-Director,
Faculty Diversity, Equity &
Inclusion, Cincinnati
Children's Hospital Medical
Center, University of
Cincinnati SOM (CTSA MPI)



NCATS Program Officer

Pablo Cure, MD

Program Director, Division
of Clinical Innovation,
NCATS, Digital & Mobile
Technologies Section of
NCATS



This Year's Format for EAC Meeting

- In person/virtual sessions Wednesday pm, evening and Thursday am.
- Overview & Plans for year 1 of the UM1 grant cycle
- Emphasis this year will be on plans for CCTSI 4.0 (2023-30)
- Reports from Leaders of Modules within new structure
- Closed EAC Session
- Feedback Session



Progress Report of UM1 Yr. 1 and Summary of Future Directions and Goals



Ronald J. Sokol, MD, FAASLD
Director and M.P.I. of CCTSI

Assistant Vice Chancellor of Clinical and Translational Science
Chief Scientific Officer, Child Health
University of Colorado – Anschutz Medical Campus



Clinical and Translational Research Leadership – CU Anschutz

Vice Chancellor of Research

Thomas Flaig, MD

Professor of Medicine

Oncology



Clinical and Translational Research Leadership – CU Anschutz

**Associate Vice Chancellor for Regulatory
Compliance**

Alison Lakin, RN, LLB, LLM, PhD
Office of the VCR



Clinical and Translational Research Leadership – CU Anschutz

**Chief Clinical Research Officer UC Health
Associate Dean Clinical Research SOM**

Thomas Campbell, MD
Professor of Medicine
Infectious Disease



Clinical and Translational Research Leadership – CU Anschutz

Chief Scientific Officer, Child Health
Associate Dean for Child Health Research,
SOM

Ronald Sokol, MD

Distinguished Professor of Pediatrics

Pediatric GI, Hepatology, Nutrition



Clinical and Translational Research Leadership – CU Anschutz

Director of Operations, MPI, CCTSI

**Vice Chair Research, Dept. of Medicine,
SOM**

Janine Higgins, PhD

Professor of Medicine

Endocrinology, Diabetes, & Metabolism



New Clinical and Translational Research Leadership – CU Anschutz

**Director of Adult & Child Center for
Outcomes Research and Delivery Science
(ACCORDS)**

Jerica Berge, PhD, MPH

Professor of Family Medicine, SOM



New Clinical and Translational Research Leadership – CU Anschutz

**Executive Director, Center for Health Equity
CU Anschutz (new center on campus)**

Deborah Parra-Medina, PhD, MPH
Professor of Family Medicine, SOM



Transitions Stepping Down from Dean Position

John J. Reilly, Jr., MD

Dean, School of Medicine

Vice Chancellor for Health Affairs

Search for new Dean nearing completion



Transitions Leaving CU Anschutz April 2024

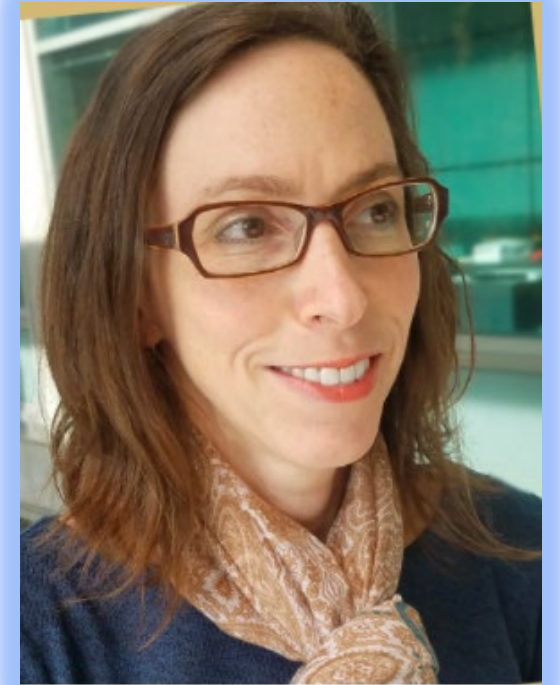
Melissa Haendel, PhD

**Former Chief Research Information
Officer**

**Co-Director of Health Informatics
Element**

**Professor of Biomedical Informatics,
Biochemistry and Molecular Genetics**

**New Director of Health Informatics -
pending**



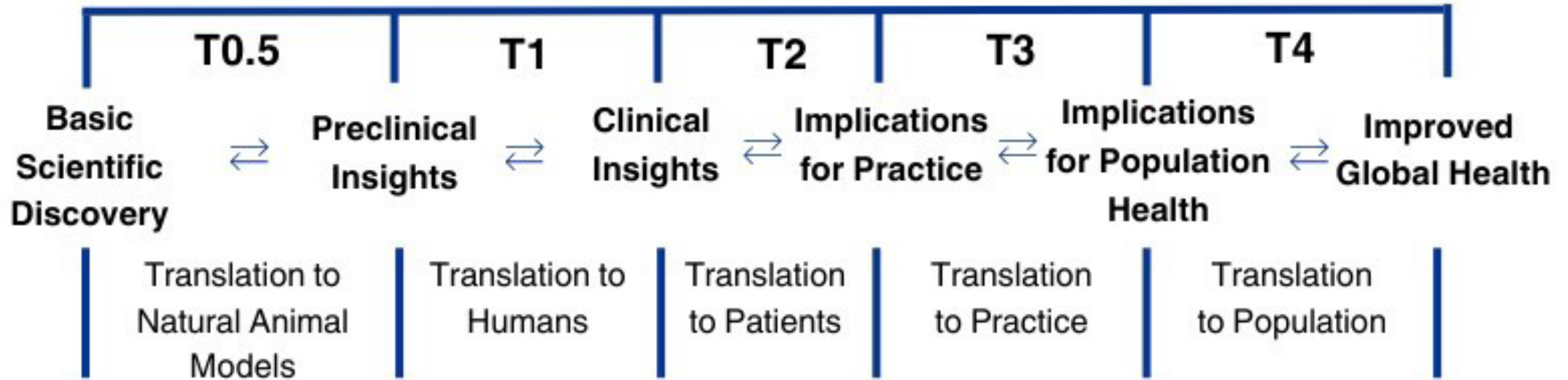
CCTSI Vision



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



Spectrum of Translational Research



Emphasis in UM1 Grant

1. Address translational science – remove Roadblocks/Obstacles to efficiency, success and job satisfaction
2. Address diversity and inclusion at all levels
Leadership, faculty, students, staff, community partnerships, enrollment in clinical research and trials, education, etc.
3. Address health disparities and health equity
4. Innovation – bring our research and data science to the community and to all patients/persons in need – disseminate and implement
5. Engage stakeholders, communities, build partnerships & trust and bidirectional communication channels
6. PEET – pragmatic, decentralized clinical trials embedded in EHR system (Element E)



CCTSI 4.0 UM1 Overall 6 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**



CCTSI 4.0 UM1 Overall 6 Strategic Goals

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



CCTSI 4.0 Grants



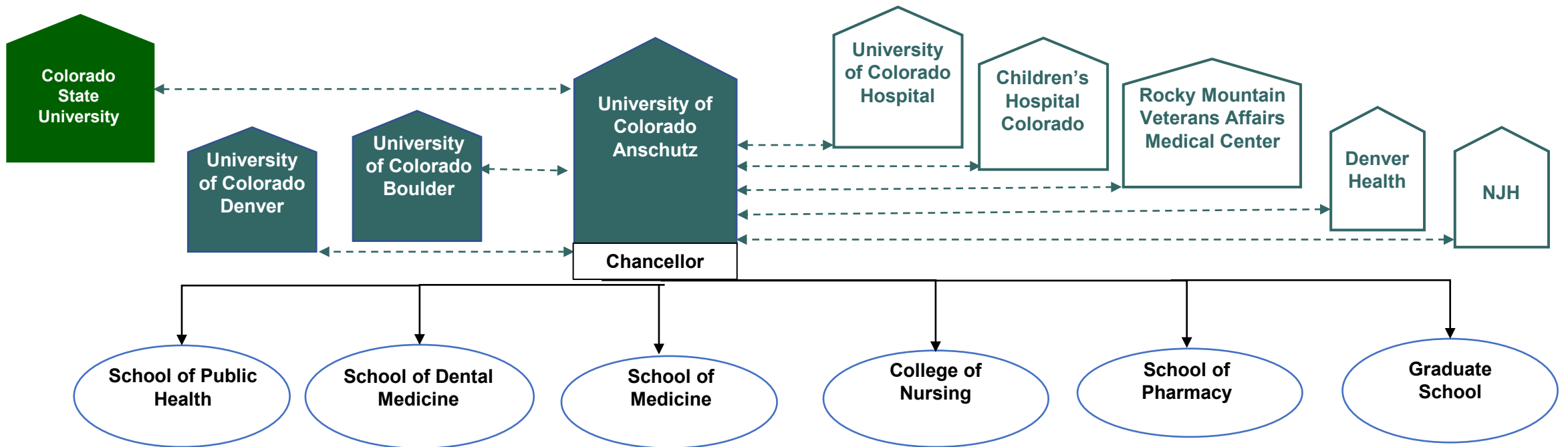
- **UM1** Funded in September 2023

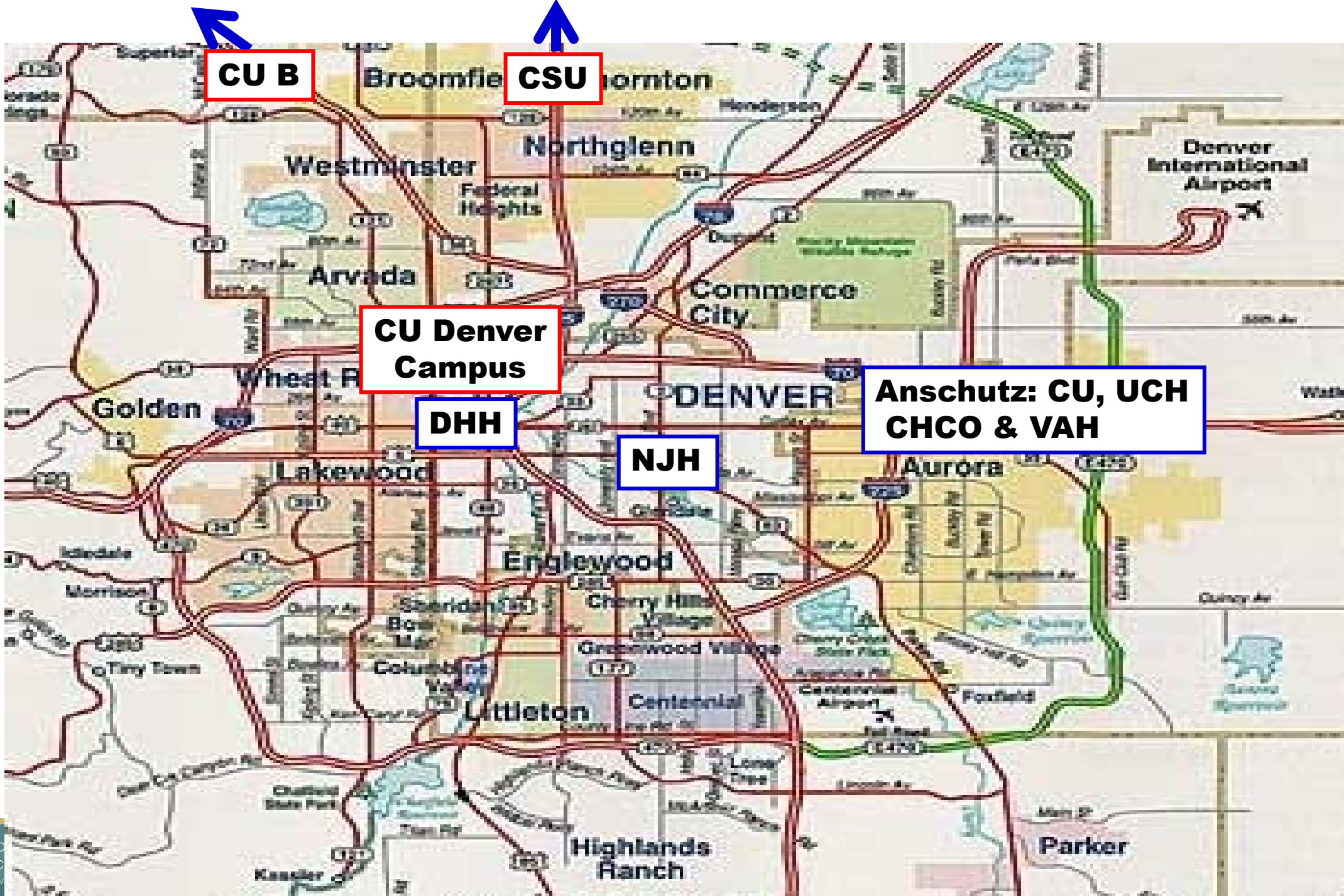
UM1 Funding Period: Sept. 14, 2023 - July 31, 2030

- **Predoctoral T32:** Sept 20, 2023 – August 31, 2028
 - Lisa Cicutto, PhD, RN
- **Postdoctoral T32:** Sept 18, 2023 – August 31, 2028
 - Lisa Cicutto, PhD, RN
- **K12:** Dec. 1, 2023 – November 30, 2028
 - Ellen Burnham, MD
- **Total funding** from grants ~ \$64 Million



CCTSI Partnering Institutions





CU B

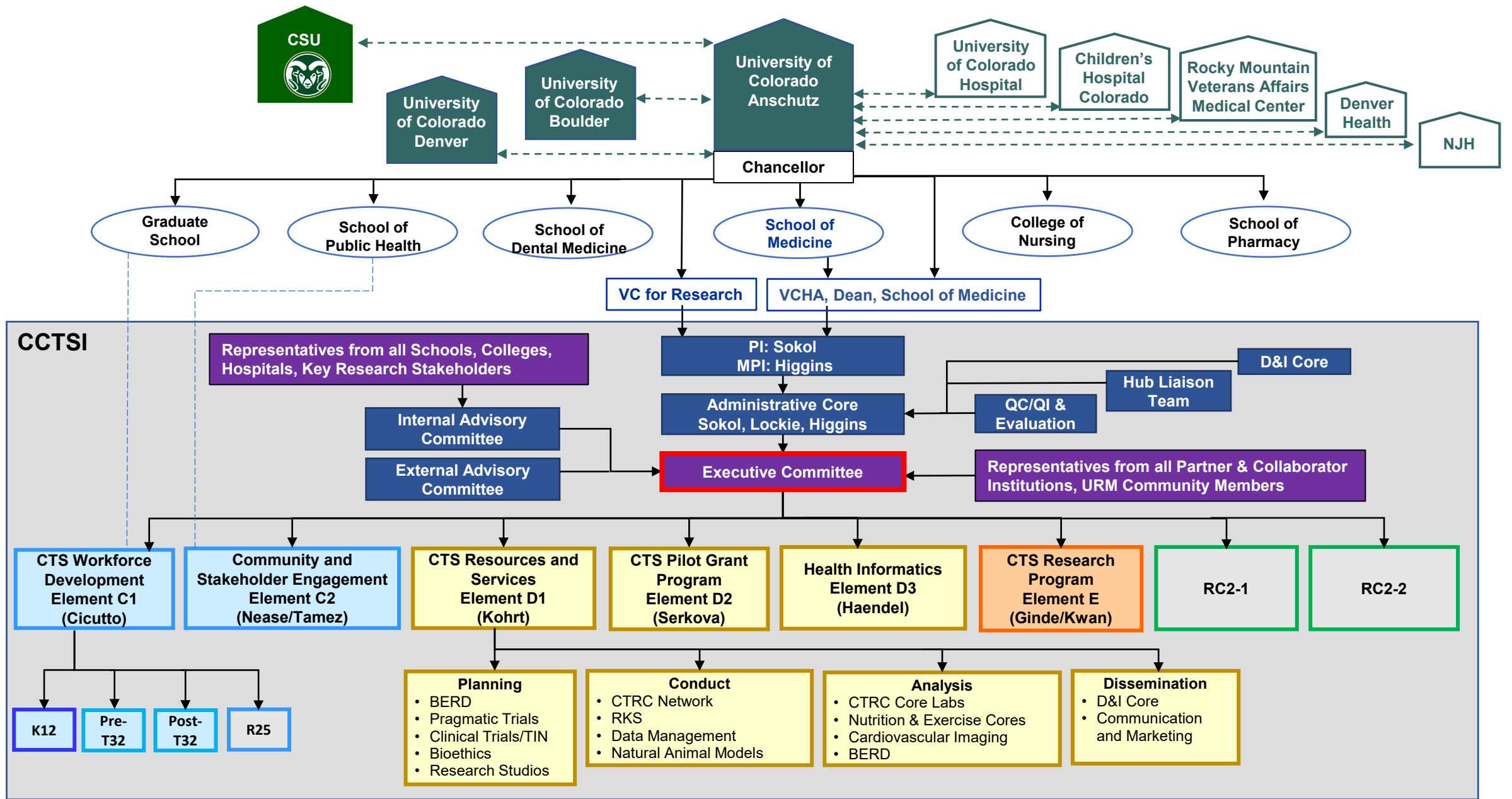
CSU

**CU Denver
Campus**

DHH

NJH

**Anschutz: CU, UCH
CHCO & VAH**



CCTSI Leadership Team

Director: Ronald Sokol, MD, MPI

Director of Operations: Janine Higgins, PhD, MPI

DFA: Tim Lockie, MS, MBA

Associate Directors:

- Wendy Kohrt, PhD
- Lisa Cicutto, PhD, RN
- Alison Lakin RN, JD
- Donald Nease, MD, MPH
- Natalie Serkova, PhD
- Thomas Campbell, MD
- Adit Ginde, MD, MPH
- Bethany Kwan, PhD



Diverse Representation Among Leadership

CCTSI Leadership:

50% Female

50% PhD or equivalent

**Representation across Schools & Depts in 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 Partnering Institutions (Universities and Hospitals)**



CCTSI Community Partners



- **>20 Community-Academic partnerships** throughout the state, including multiple **PBRNs (SNOCAP)**
- **Community Engagement & Health Equity (PACT Council)**
 - **Under-Resourced Populations:**
 - Native Americans, LatinX, African-Americans, Rural populations, Nursing partnerships, Catholic churches, Ranching, LGBT, etc.
 - **PACT Focus Groups:**
 - San Luis Valley, Stapleton 2040, American Indian/ Alaskan Native Programs, High Plains Research Network, Kaiser Patient/provider, LUCCHAR

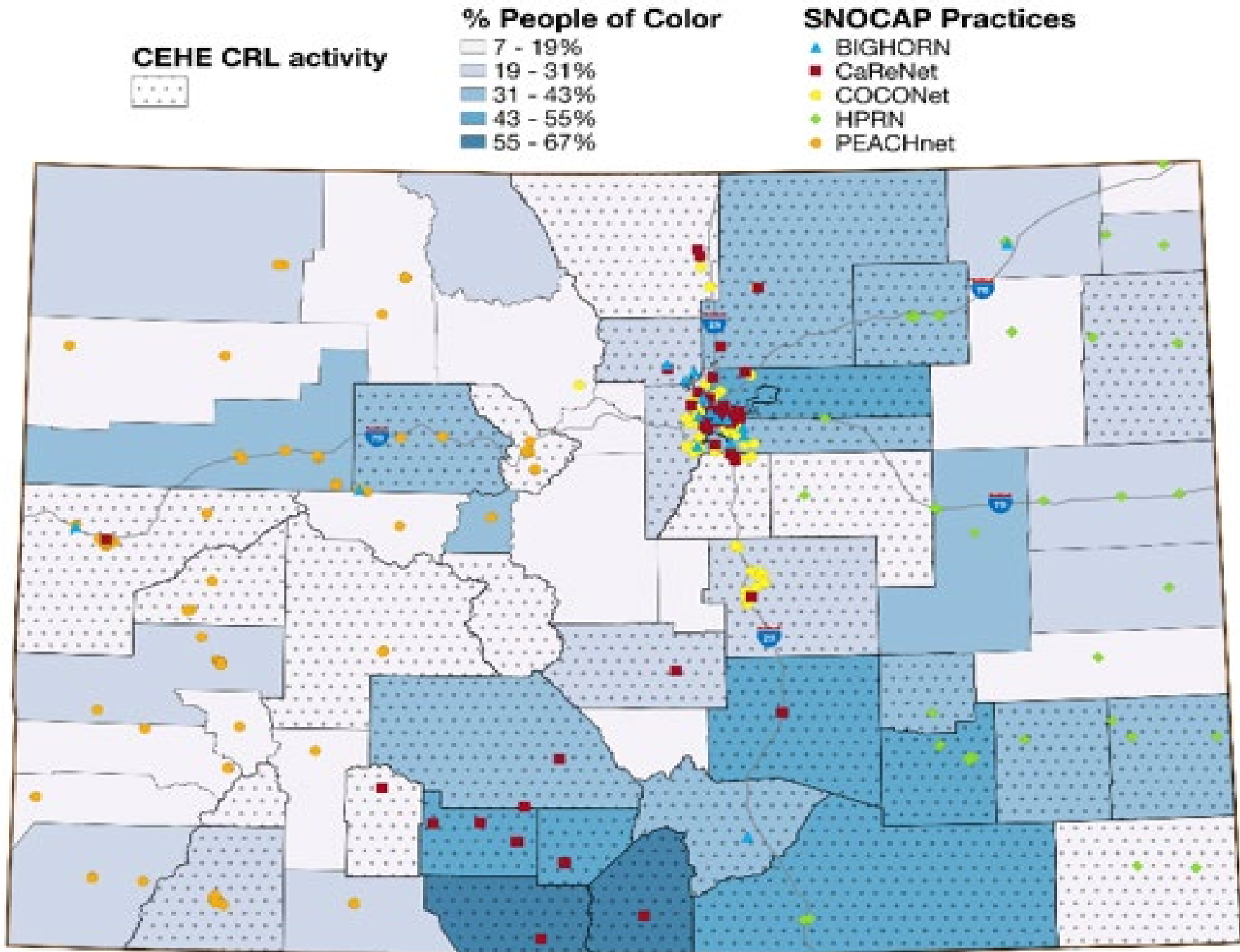


CEHE Reach in Colorado

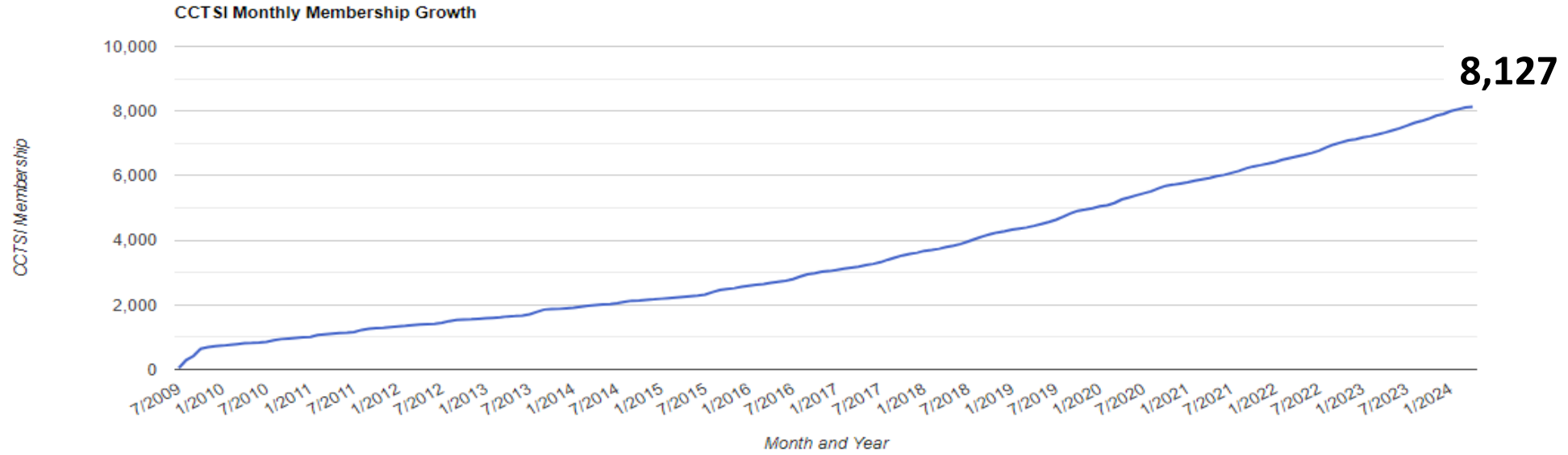
CRL = Community Research Liaisons

% People of Color

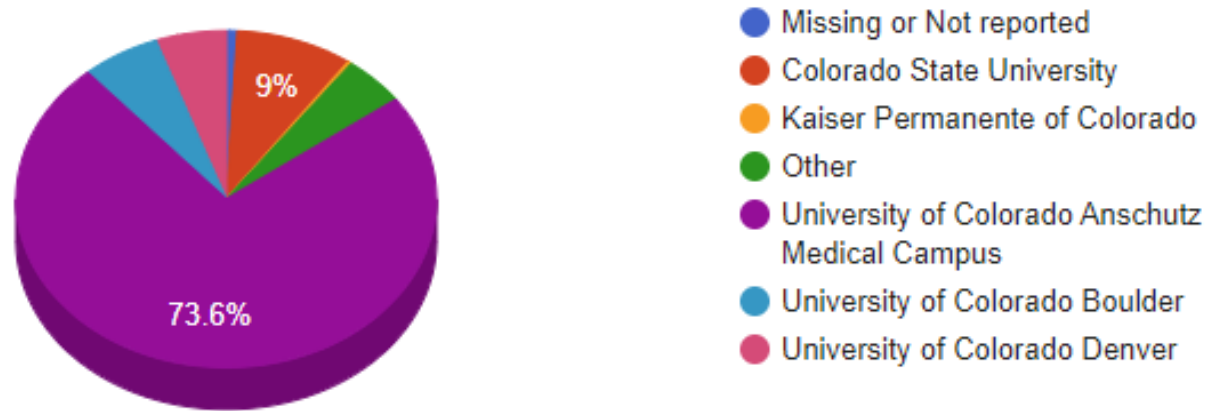
PBRNs = SNOCAP



CCTSI Members

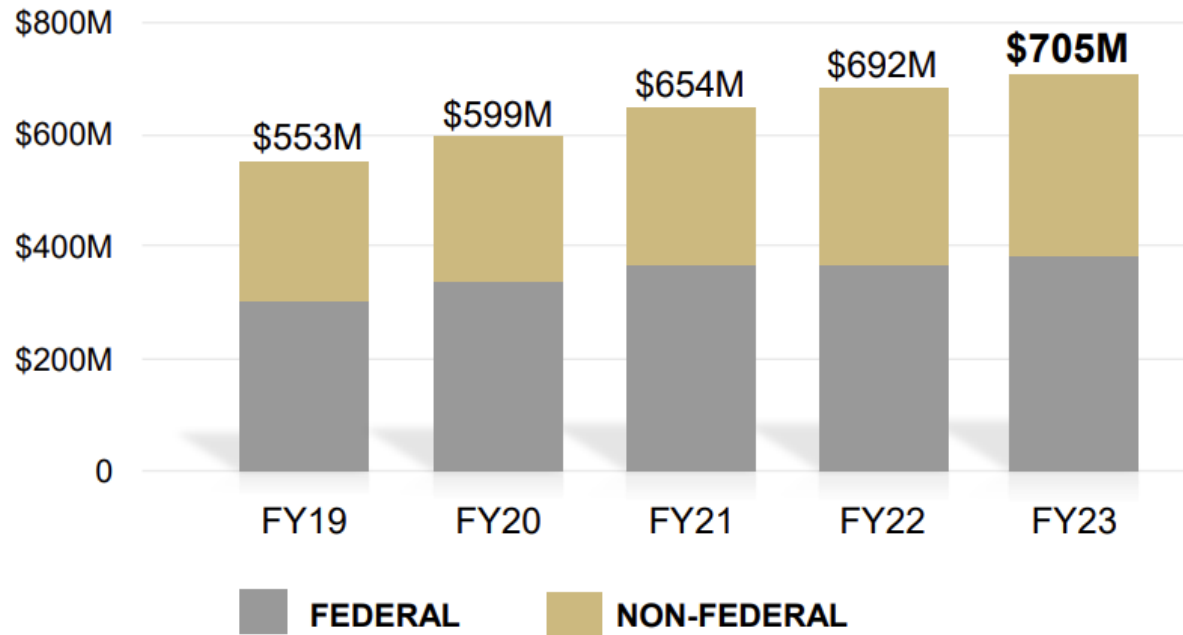


CCTSI Membership by Academic Affiliation



Total Research Grants – CU Anschutz

CU ANSCHUTZ SPONSORED RESEARCH FUNDING



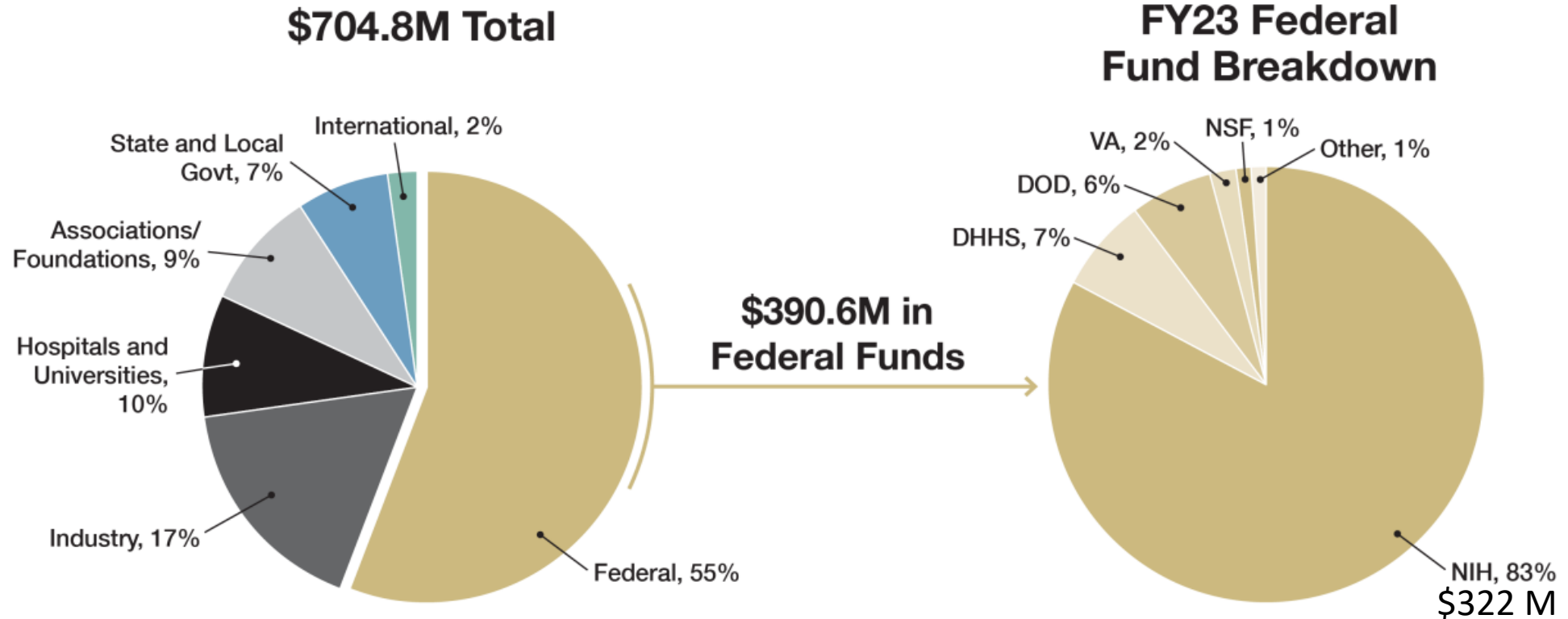
27%
increase
since
FY19

VCR – 2023 State of Research

Federal Grants Breakdown



FY23 SPONSORED AWARDS BY TYPE

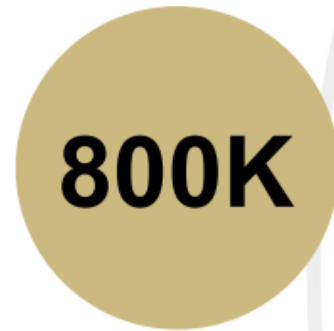


VCR – 2023 State of Research

FY23 Research Metrics CU Anschutz



**Principal
Investigators
on Campus**



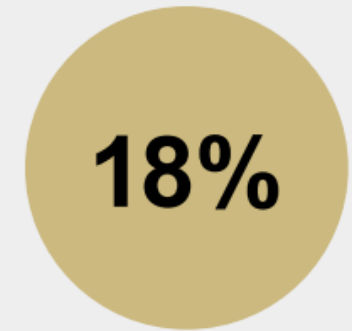
**Square Feet of
Laboratory
Space**



**People Enrolled
in Research
Studies in FY23**



**Active Clinical
Trials**



**Growth in
Clinical Research
Studies since FY20**

VCR – 2023 State of Research





CHILDREN'S HOSPITAL COLORADO

Child Health Research Enterprise is the centralized administrative, operational and scientific home for child health research at Children's Hospital Colorado and CU Anschutz.

150+

Team members at
Children's Colorado

1,100

Active clinical research
studies supported

\$69M

Philanthropy raised in support of
child health research since 2018

#8

Ranking for NIH funding*

**Dept of Pediatrics and Children's Colorado combined*



Ronald Sokol, MD
Chief Scientific Officer,
Child Health



Jenae Neiman, RN, BSN
Vice President,
CHCO Research Operations

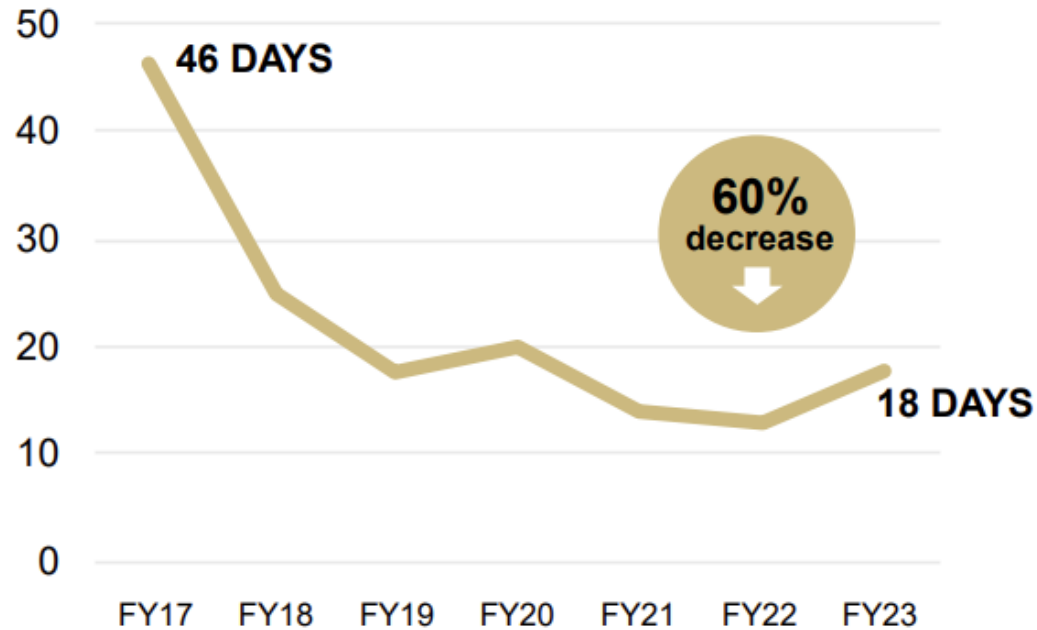


VCR – 2023 State of Research

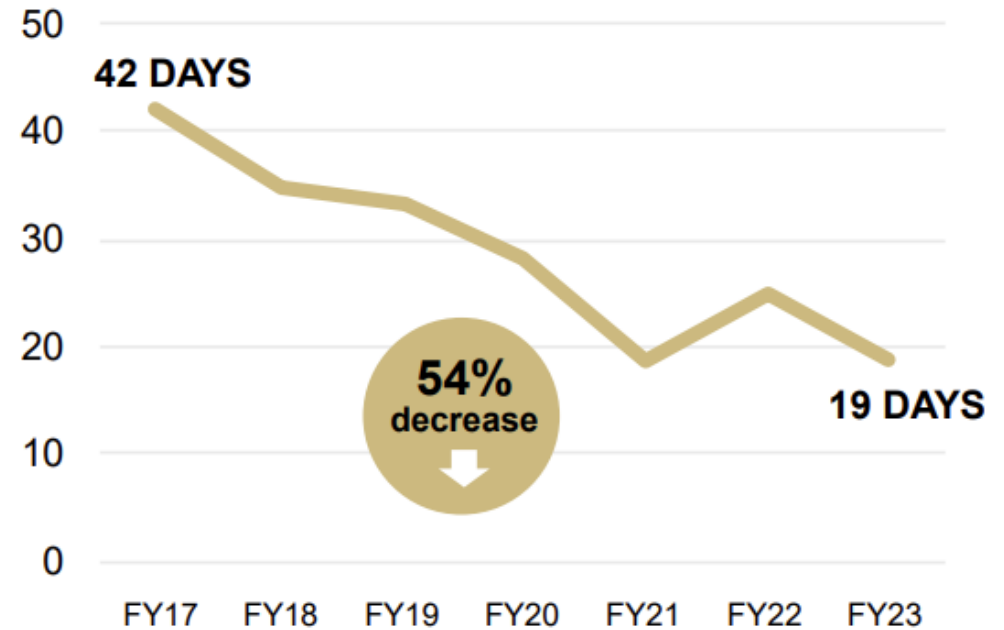


IRB Timeline Improvements

Expedited Median Days to Approval



Full Board Median Days to Approval



COMIRB application to be shortened from 76 to 20 pages

VCR – 2023 State of Research



REGULATORY COMPLIANCE

Helping investigators to conduct, safe, successful, compliant research

5577 Active human subject research protocols

795 Confidentiality Disclosure Agreements (CDAs) completed

487 Clinical Trial Agreements (CTAs) completed in FY23

37.7 Tons of chemical waste safely disposed of in 2023 (to date)

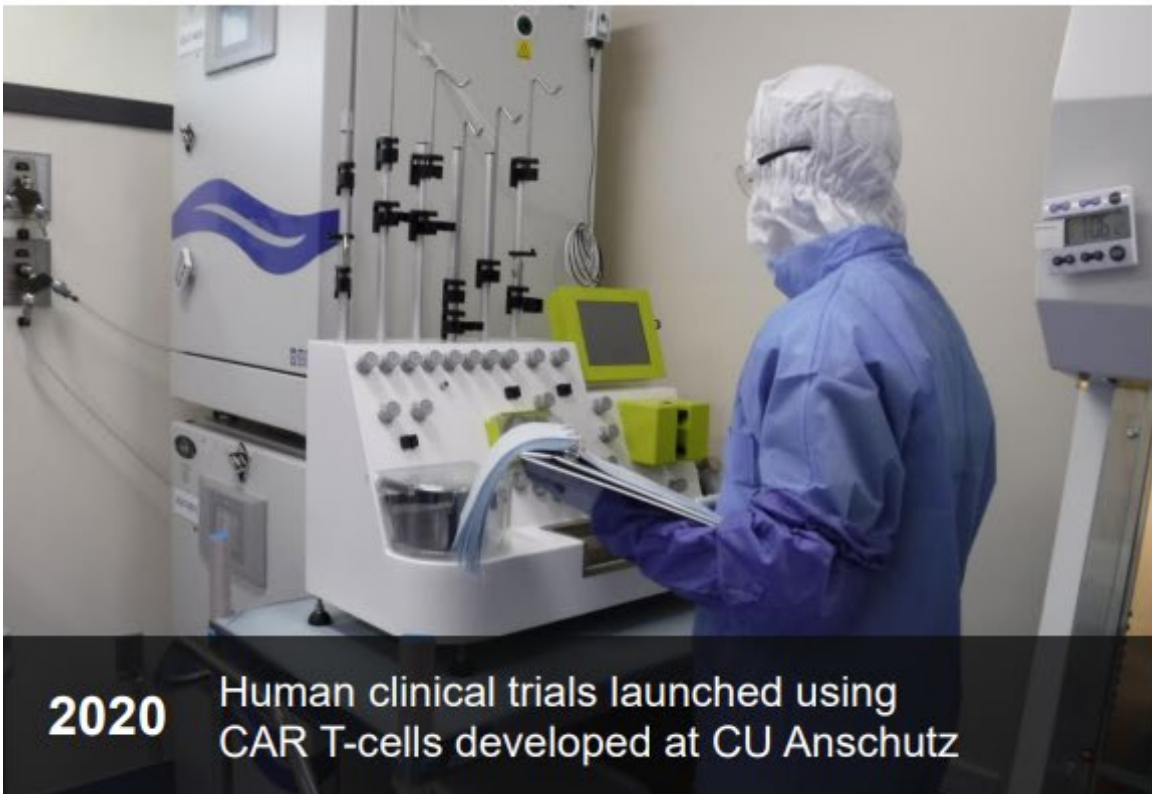


Alison Lakin, RN, LLB, LLM, PhD
Associate Vice Chancellor
Office of Regulatory Compliance

VCR – 2023 State of Research



Taking cellular therapy and precision medicine to new heights



2020

Human clinical trials launched using CAR T-cells developed at CU Anschutz



2022

Historic \$200M philanthropic commitment established the Gates Institute with Terry Fry, MD at helm



2023

Gates Institute celebrates official launch at Transforming Healthcare event





ANNUAL HIGHLIGHTS

189

Patents filed last year

145

New inventions by faculty

41

New licensing deals

\$35M

Gross revenue to campus



*Ranked a **Top 5 Innovation Hub** by the NIH and **No. 4 Leading Academic Institution** by Nature's Innovation Index.*



Publications “Ranking” University of Colorado – Anschutz

NATURE HEALTH SCIENCES INDEX RANKINGS

MY NCBI FILTERS  **1,033 results** Page 1 of 104

RESULTS BY YEAR



2013 2024

1 Deep postnatal phenotyping of a new mouse model of nonketotic hyperglycinemia.

Cite Swanson MA, Jiang H, Busquet N, Carlsen J, Brindley C, Benke TA, Van Hove RA, Friederich MW, MacLean KN, Mesches MH, Van Hove JLK.

Share bioRxiv [Preprint]. 2024 Mar 29:2024.03.26.586818. doi: 10.1101/2024.03.26.586818. PMID: 38586005 **Free PMC article.** Preprint.

The study was supported by a grant (CNS-X-19-103) from the University of Colorado School of Medicine and the Colorado Clinical Translational Science Institute, which is supported by NIH/NCATS Colorado CTSI Grant Number UL1 **TR002535**. Contents are the authors' sole responsib ...

TEXT AVAILABILITY



Ongoing CCTSI Response to COVID-19

- **CHCO CTRC** – facilitated largest enrollment center (10% of all enrollees – 80 sites, 2,268) for Pfizer/BioNTech COVID vaccine trial in 5-11 yr-old children (NEJM Nov 9, 2021)
- **Adult and Pediatric CTRCs** - facilitated numerous adult and child vaccine and therapeutic trials
- **CEAL** site for Colorado (Nease) **ONGOING**
NHLBI
- **mAb** - Monoclonal Ab Real World Evidence study (Admin Supplement – Ginde-led Team)
NCATS
- **RECOVER** (Long COVID) – Clinical Cohort Site (Mtn. States Consortium - Erlandson), and Real-World Evidence Data Center- N3C (Haendel, Bennett) **ONGOING**
NHLBI



Diversity, Equity, Inclusion, Social Justice

CCTSI DEI/SJ Committee and CEHE PACT Council

- DEI and Land Acknowledgement Statements posted on our home page
- Examining our programs and hiring practices for systematic racism
- Surveyed our staff for DEI training readiness
- Mandatory DEI training for all CCTSI staff
- Considering mechanism to train all Clinical Research Coordinators on campus (n=600) in DEI/SJ
- Revising Selection Processes for WFD programs
- Coordinate with Regina Richards PhD, VC DEI &CE, and Dominic Martinez, Asst VC Diversity, Equity, Inclusion & Community Engagement – Pathway (Pipeline) Programs and many others
- Coordinating with new Center For Health Equity
- Posted “COVID-19 Impact on Latinos” Fact Sheet on website



Professional Workforce Development

1. Summer Undergraduate Minority Mentoring in Translational Science (SUMMiT) (n=25) – Pathway Program
2. T32 Pre-doctoral and Post-doctoral training programs
3. Clinical Sciences Graduate Program (PhD, Masters)
4. K12 Research Scholar program - up to 3 yrs. of support
5. Clinical Research Training and Education (CRSC)
6. Support for Clinical Faculty Scholars Program



Lisa Cicutto, PhD, RN



Professional Workforce Development

7. Colorado Mentor Training Program (CO-Mentor)
8. K-to-R Transition Grant Review
9. Pre-F Award grant Review
10. Pre-K Award Assistance and Grant Review
11. Research Studios
12. Innovation Corps (I-Corps)
13. Teaming and Leading for Early Career Researchers
14. Communicating Your Science to the Public



Lisa Cicutto, PhD, RN

Clinical Translational Research Centers (CTRCs)

- **UCH, CHCO, NJH & CU B**

- Inpatient and outpatient facilities and mobile teams
- Nursing, Nutrition, metabolic kitchen, whole room calorimeter, body composition, exercise physiology, vascular ultrasonography and ECHO, Core laboratories & specimen processing
- ***Microgrants*** to Jr. Investigators (\$10,000/yr. x 3)
- **200 PI's > 500 CTRC Protocols** each year (10,000 - 15,000 visits/yr)



Trial Innovation Network Hub Liaison Team

- **Director:** Adit Ginde, MD, MPH
- **Medical Directors:** Tom Campbell, MD (UCH) and Jesse Davidson, MD (CHCO)
- **Project Manager:** Ben Echaliier
- **Contracting Lead:** Amanda Peng
- **Central IRB Lead:** Christy Williamson
- **Recruitment (Participants) Lead:** TBD
- **Navigator:** Cynthia Sneddon

Local Website, workflow, educational materials, etc.



National CTSA Consortium Involvement

- Ronald Sokol, MD – National CTSA Steering Committee 2020-2023
- CD2H - Melissa Haendel, PhD
- N3C – Melissa Haendel, PhD and Tell Bennett, MD, MS
- Members of all Enterprise Committees
- U01 CCIA grant – Telehealth Research in Pediatrics (SPROUT)
- Northern LITeS (University of Minnesota CTSA)
- I-Corps@CTSA national expansion – Cathy Bodine, PhD (UAB U01)
- COHA – Sue VanDewoude, DVM, Dean Veteriniary School CSU
- Several CCIA U01 grants undergoing review
- mAb, CO-CEAL, RECOVER



CCTSI Operating Budget: FY 2024

(Yr. 1 of new grant cycles)

CCTSI Programs	NIH CTSA Grants (Total)	Chancellor & VCR Funds	UCH Support	SOM Support	SOM Addn'l Support	CHCO Support	TOTAL	Percent Total
B. Strategic Management	\$ 1,044,677	\$ 491,573	\$ 133,263		\$ 169,621		\$ 1,839,134	14%
C1. Workforce Development	\$ 714,361	\$ 152,133	\$ -		\$ -		\$ 866,493	7%
C2. Community Engagement	\$ 877,455	\$ 134,263	\$ -		\$ -		\$ 1,011,718	8%
D1. Resources & Services (CTRC-RKS-BERD-Ethics-	\$ 2,821,333	\$ 392,029	\$1,154,502		\$ 30,380	\$ 200,000	\$ 4,598,243	36%
D2. CTS Pilot Grants	\$ 669,754	\$ 10,594	\$ 10,594	\$500,000	\$ -		\$ 1,190,942	9%
D3. Health Informatics	\$ 1,157,591	\$ 327,506	\$ 40,726		\$ -	\$1,100,000	\$ 2,625,823	20%
E. CTS Research Program	\$ 415,753	\$ 2,731	\$ -		\$ -		\$ 418,484	3%
Other: Innovation Ecosystem & Early Life Exposures		\$ 259,238	\$ -		\$ -		\$ 259,238	2%
Total UL1 Program	\$ 7,700,924	\$ 1,770,067	\$1,339,086	\$500,000	\$ 200,000	\$1,300,000	\$12,810,077	100%
Total K12 Program (6 Scholars)	\$ 1,081,441						\$ 1,081,441	
Total T32-Postdoc Program (4 Trainees)	\$ 376,003						\$ 376,003	
Total T32-Predoc Program (8 Trainees)	\$ 356,292						\$ 356,292	
Total CCTSI Program Budget	\$ 9,514,660	\$ 1,770,067	\$1,339,086	\$500,000	\$ 200,000	\$1,300,000	\$14,623,813	



