

Welcome EAC to Colorado

January 12-13 , 2023



University of Colorado
Anschutz Medical Campus



Colorado Clinical and Translational
Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

External Advisory Committee

Steven Dubinett, MD

Associate Vice Chancellor for Research, UCLA; Interim Dean, David Geffen SOM; Director of Clinical and Translational Sciences Institute; Chief, Pulmonary and Critical Care, UCLA (CTSA PI)



Alexander Krist, MD, MPH

Director of Community-Engaged Research at the Wright Center for Clinical and Translational Research, Associate 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
Associate Director for
Clinical Research for
Yale School of Medicine



External Advisory Committee

Dan Cooper, MD

Associate Vice
Chancellor for Clinical
and Translational
Research at UC Irvine,
Associate Director of UC
Irvine's 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 Meinzen-Derr,
PhD, MPH**

PI – 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

Division of Clinical
Innovation, NCATS,
formerly Program Officer /
Health Scientist
Administrator at National
Heart, Lung, and Blood
Institute



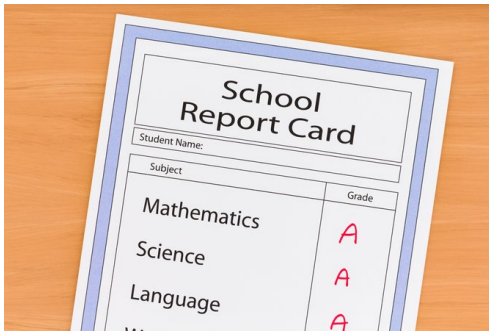
This Year's Format for EAC Meeting

- In person/virtual sessions Thursday pm, evening and Friday am.
- Tour of new CCTSI facility at AHSB – Thurs. pm
- Overview & Plans for year 5 of this grant cycle, and next 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 Yr 5

Summary of Future Directions and Goals



Ronald J. Sokol, MD, FAASLD
Director and 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



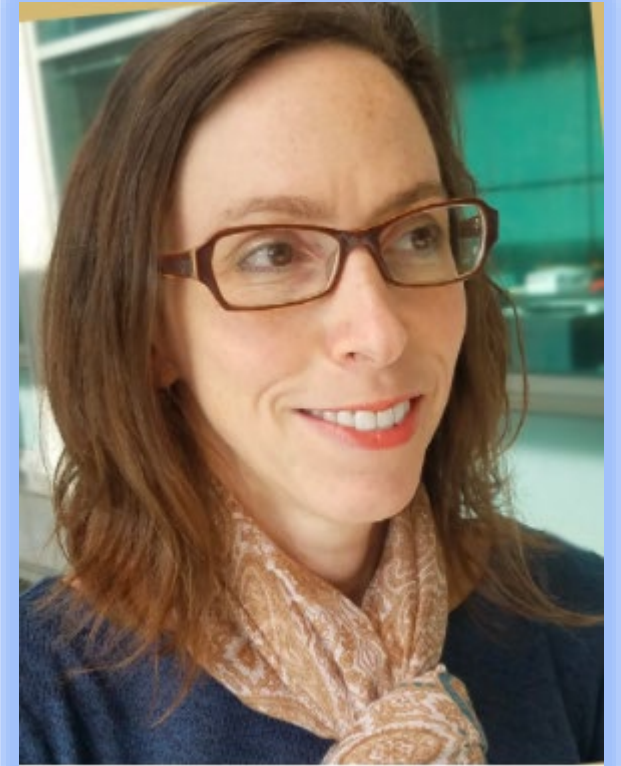
Clinical and Translational Research Leadership – CU Anschutz

Chief Research Informatics Officer

Melissa Haendel, PhD

Professor of Biomedical Informatics,
Biochemistry and Molecular Genetics

CD2H, N3C, Monarch, NCI Data
Harmonization, RECOVER RWE



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

Admin-Research



CCTSI Vision



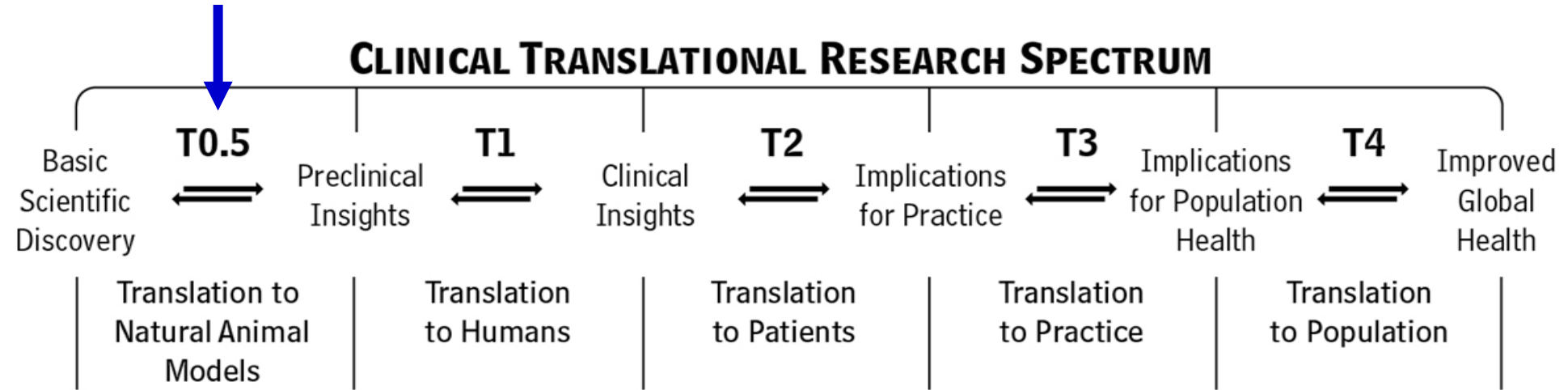
Accelerate and catalyze the translation of innovative science into improved, equitable health and patient care for all

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



CCTSI 3.0 Overall Strategic Goals

Goal 1: Develop, educate and sustain a **diverse translational science workforce** to ensure highest research innovation, quality and safety

Goal 2: Create a translational research environment in which **team science and collaboration** both locally and nationally are facilitated, supported and valued

Goal 3: Engage **local and national communities** and stakeholders in all phases of the translational research process



CCTSI 3.0 Overall Strategic Goals

Goal 4: Create **novel methodologies and resources** to support and integrate research in **special populations**, including children, the elderly, the underserved and those with rare diseases.

Goal 5: Further innovate and **streamline our processes and enhance our informatics** capacity for research start-up, implementation and oversight to promote quality, efficiency, & safety of our research and our active participation in the national CTSA Trial Innovation Network.



CCTSI 3.0 Grants

NOGA (UL1, KL2, TL1) - 2018

Admin Supplement (OnCore Acceleration) 2018

Admin Supplement INCLUDE -Trisome project 2019

Admin Supplement KL2-INCLUDE 2020

Admin Supplement Participation in N3C 2020

Admin Supplement Prior Approval Process Professional 2020

KL2 Diversity Supplement 2021

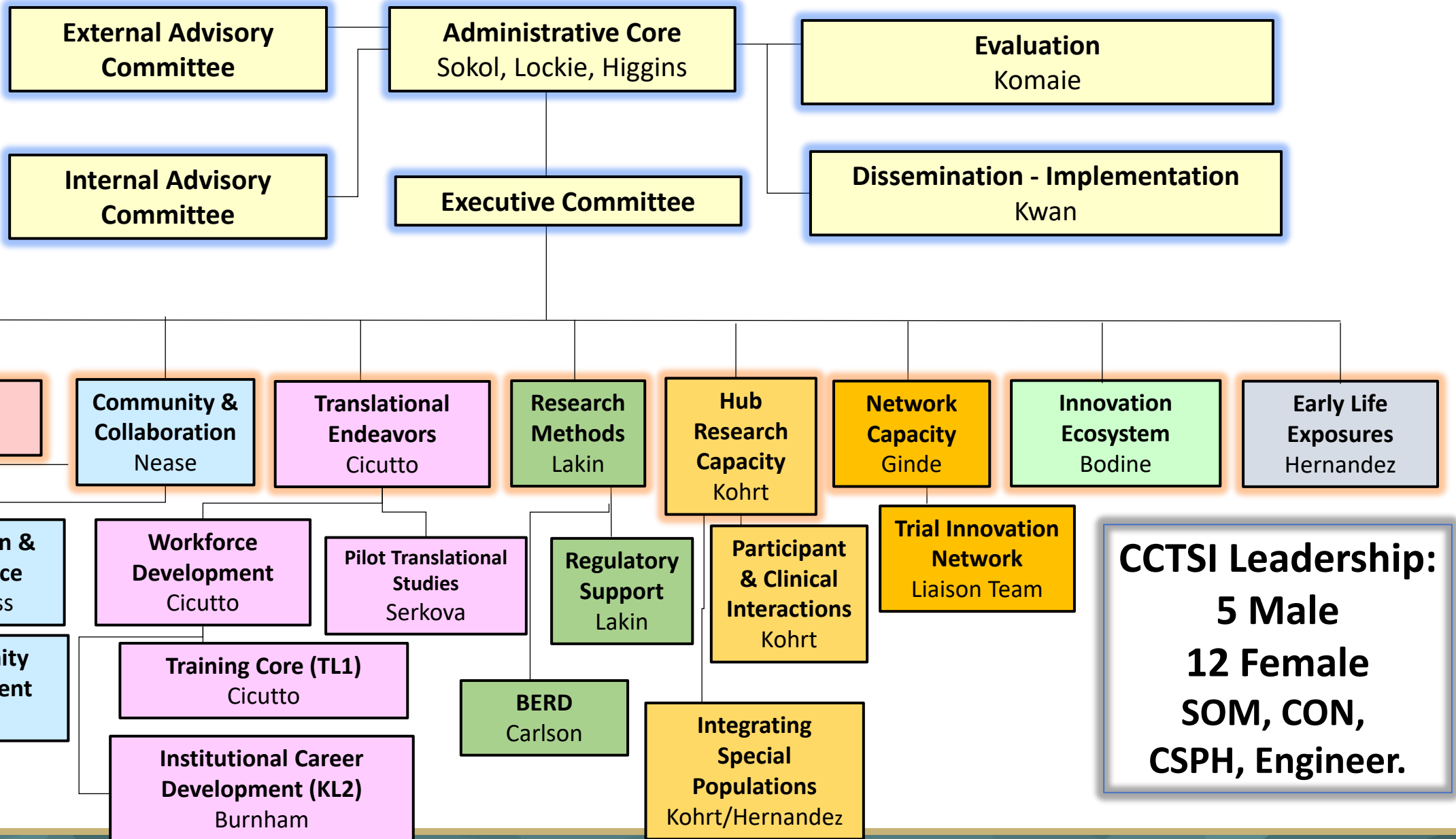
Admin Supplement COVID mAb RWE project 2021

- Funding Period May 1, 2018 to April 30, 2023

UL1 total = \$40,466,652 TL1 total = \$ 2,783,180 KL2 total = \$ 4,551,5 **TOTAL = \$47,801,382 + 1,339,032 + 775,742 + 99,812, + 140,430 + 322,233 (+ 8,699,359) = \$50,478,631 (\$59,177,990)**



CCTSI 3.0



CCTSI Leadership Team

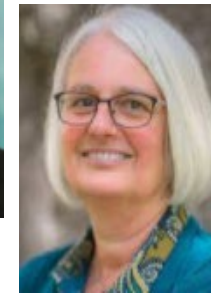
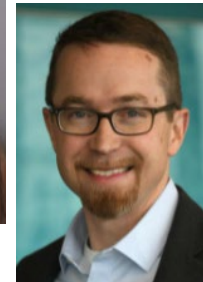
Director: Ronald Sokol, MD

Director of Operations: Janine Higgins, PhD

DFA: Tim Lockie, MS, MBA

Associate Directors:

- Wendy Kohrt, PhD
- Lisa Cicutto, PhD, RN
- Tell Bennet MD, MS
- Alison Lakin RN, JD
- Donald Nease, MD, MPH
- Thomas Campbell, MD
- Adit Ginde, MD, MPH



CCTSI Partnering Institutions

- **Three Universities**

CU Denver (CU-D)

- CU-Anschutz Medical Campus:
6 health profession schools/colleges*
- Downtown Denver



CU Boulder (CU-B)



Colorado State University (CSU)

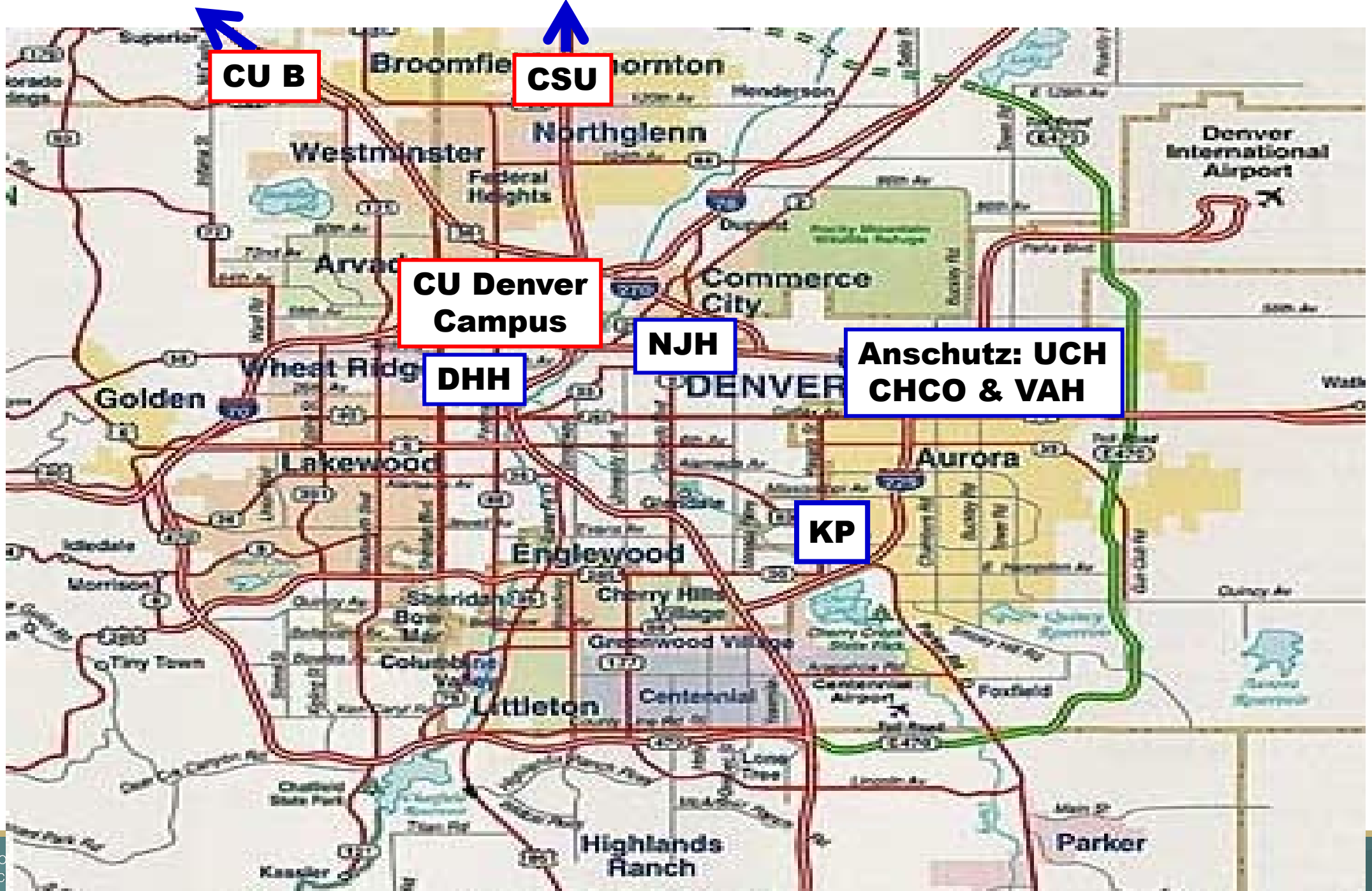
- **Six Affiliated Hospitals and Health Care Organizations****

UCH (UCHealth), CHCO, DHH, NJH, RMVAMC, KP

* *Only medical, pharmacy, dental and public health schools in Colorado*

** *Each is a separate legal entity, none owned by Univ. of Colorado*





CCTSI Community Partners



- **>20 Communities** across the state, including
- **Community Engagement**
 - **Under-Resourced**
 - Native American partnerships
 - **PACT Focus**
 - San Luis Valley
 - High Plains

**October 2021:
CU Denver and CU Anschutz:
Hispanic Serving
Institution Designation
(US Dept. of Education)**

**New Center for Health Equity
CU-Anschutz**

throughout the

(PACT)

Programs, Nursing

Native Programs,
CHAR

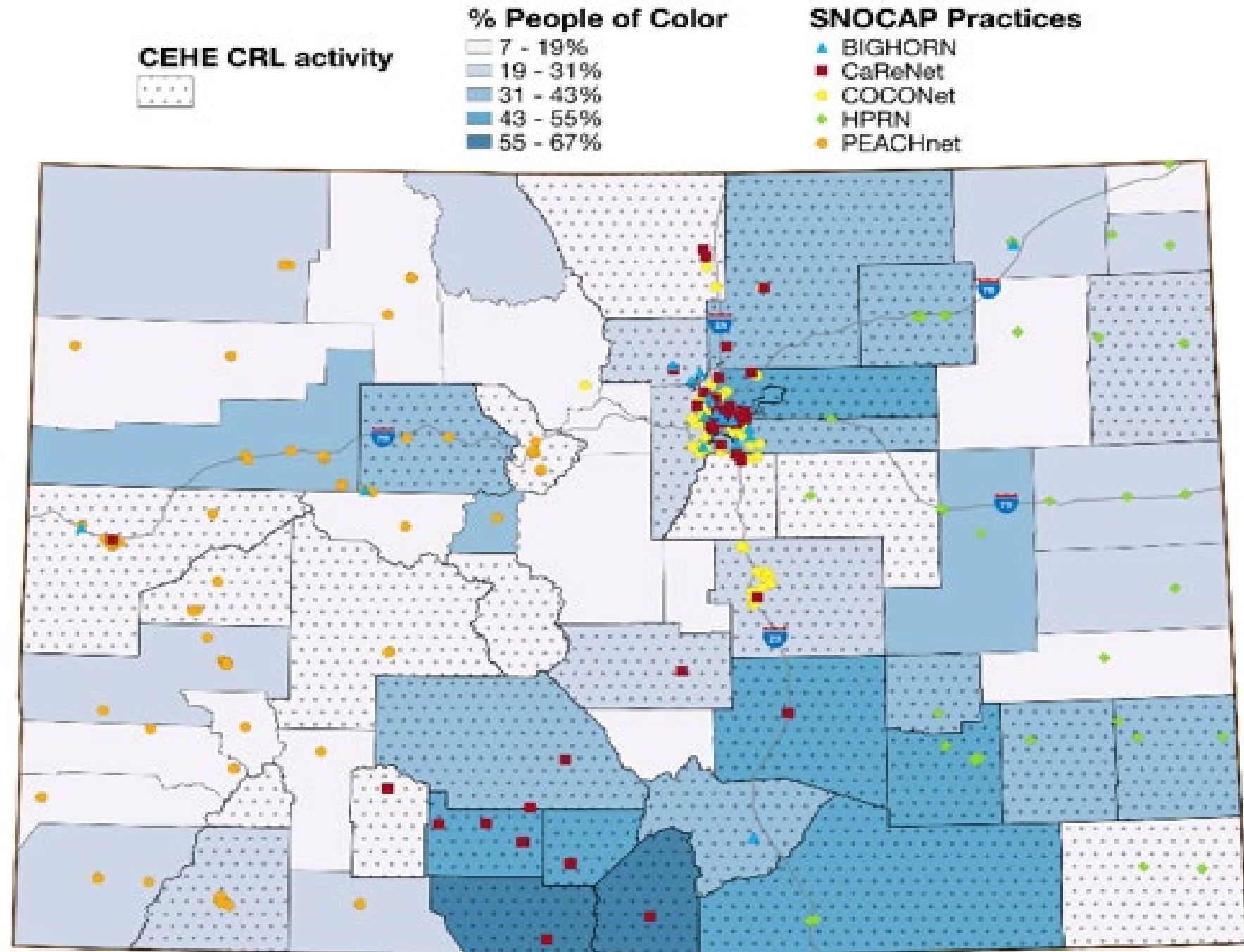


CE&R Reach in Colorado

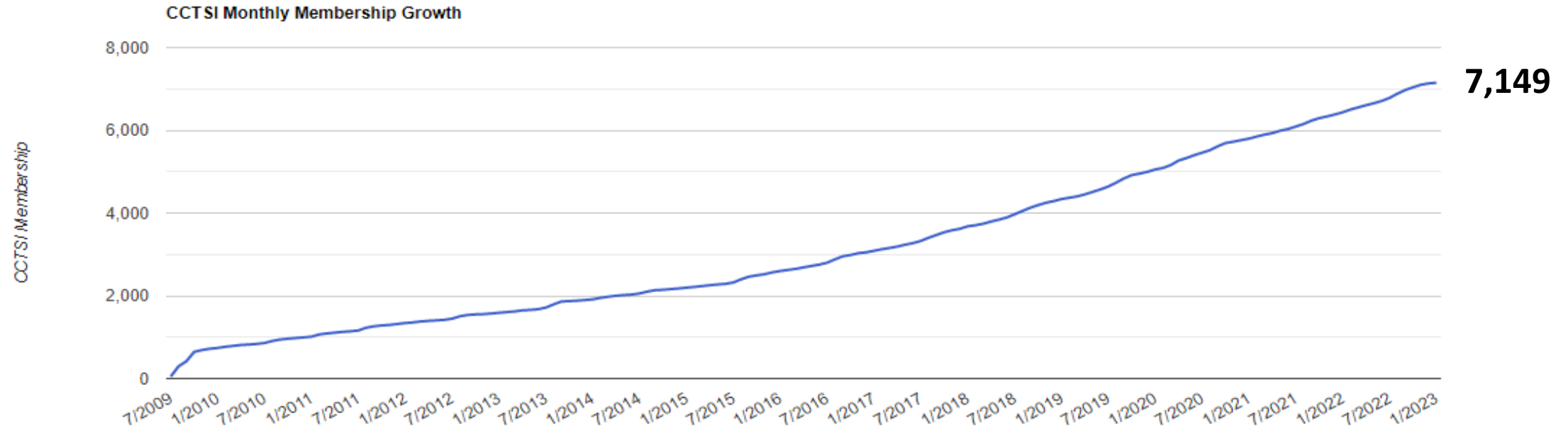
PBRNs = SNOCAP

CRL = Community
Research Liaisons

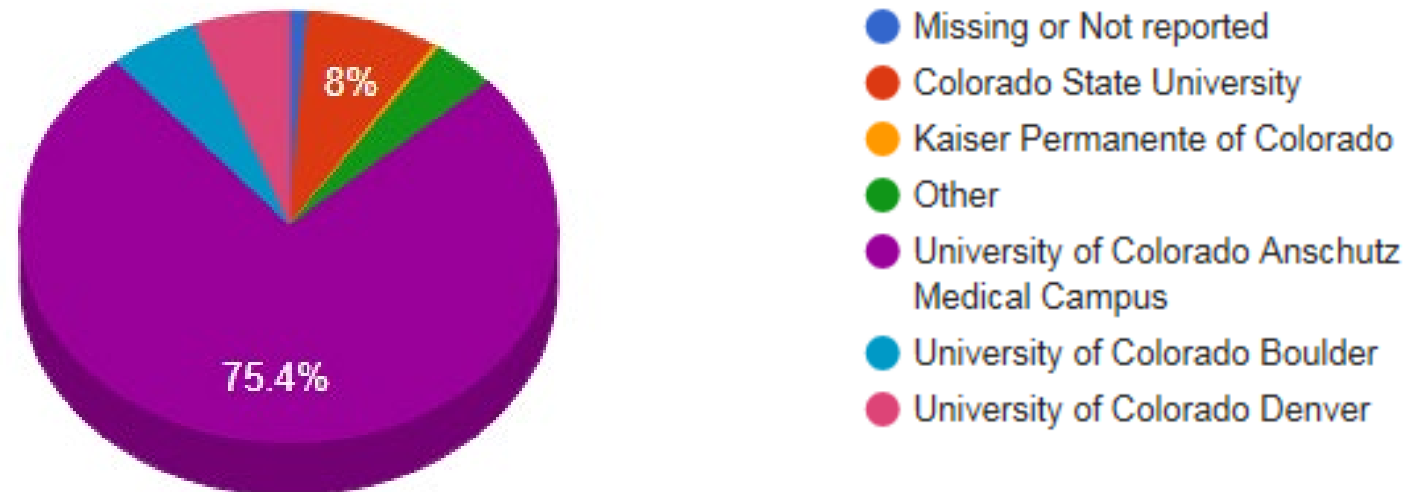
People of Color



CCTSI Members



CCTSI Membership by Academic Affiliation





CU Anschutz Campus

AHSB
CTRC

RKS

2022

UCH
CTRC

CHCO
CTRC

VAH

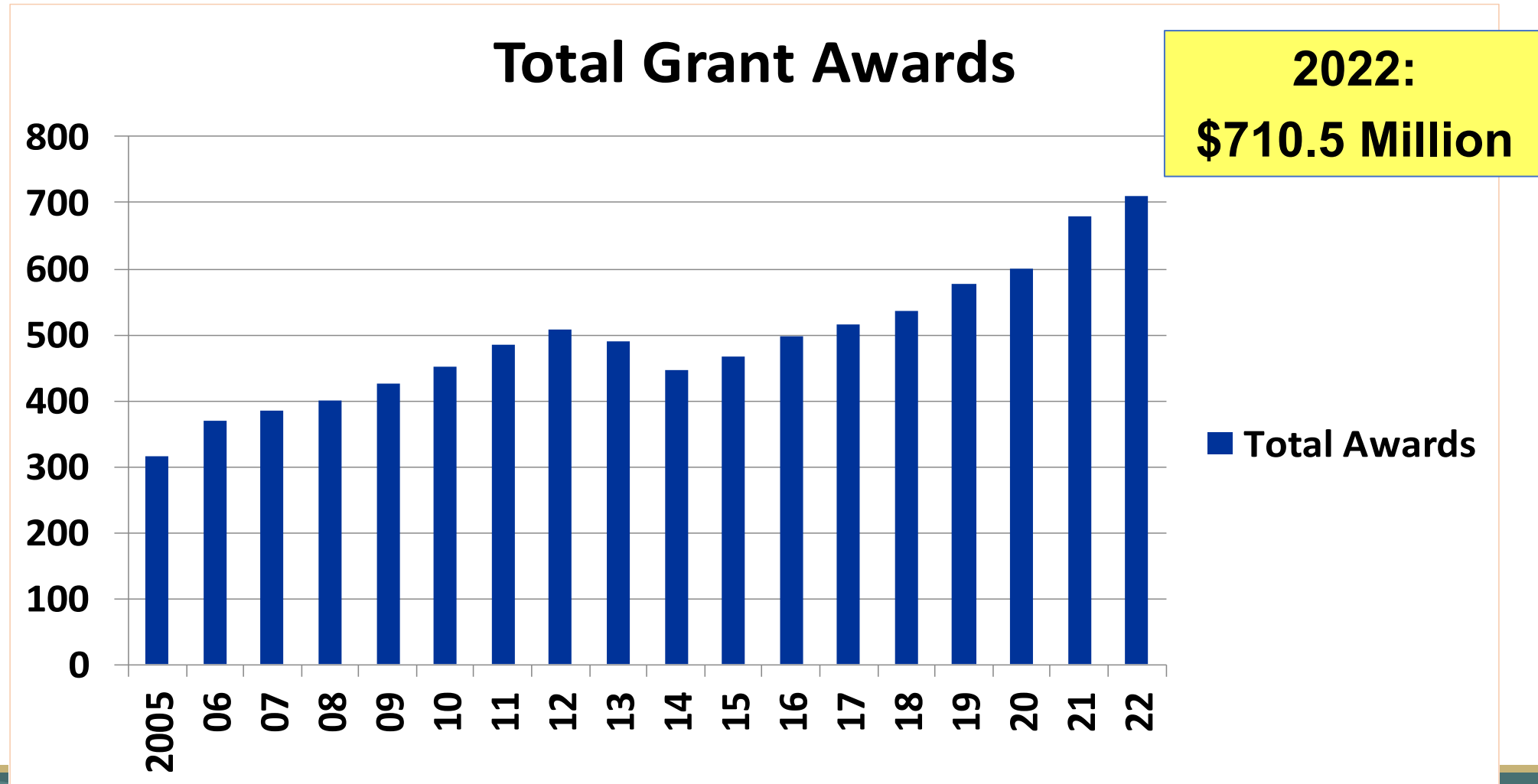
Anschutz Health Sciences Building



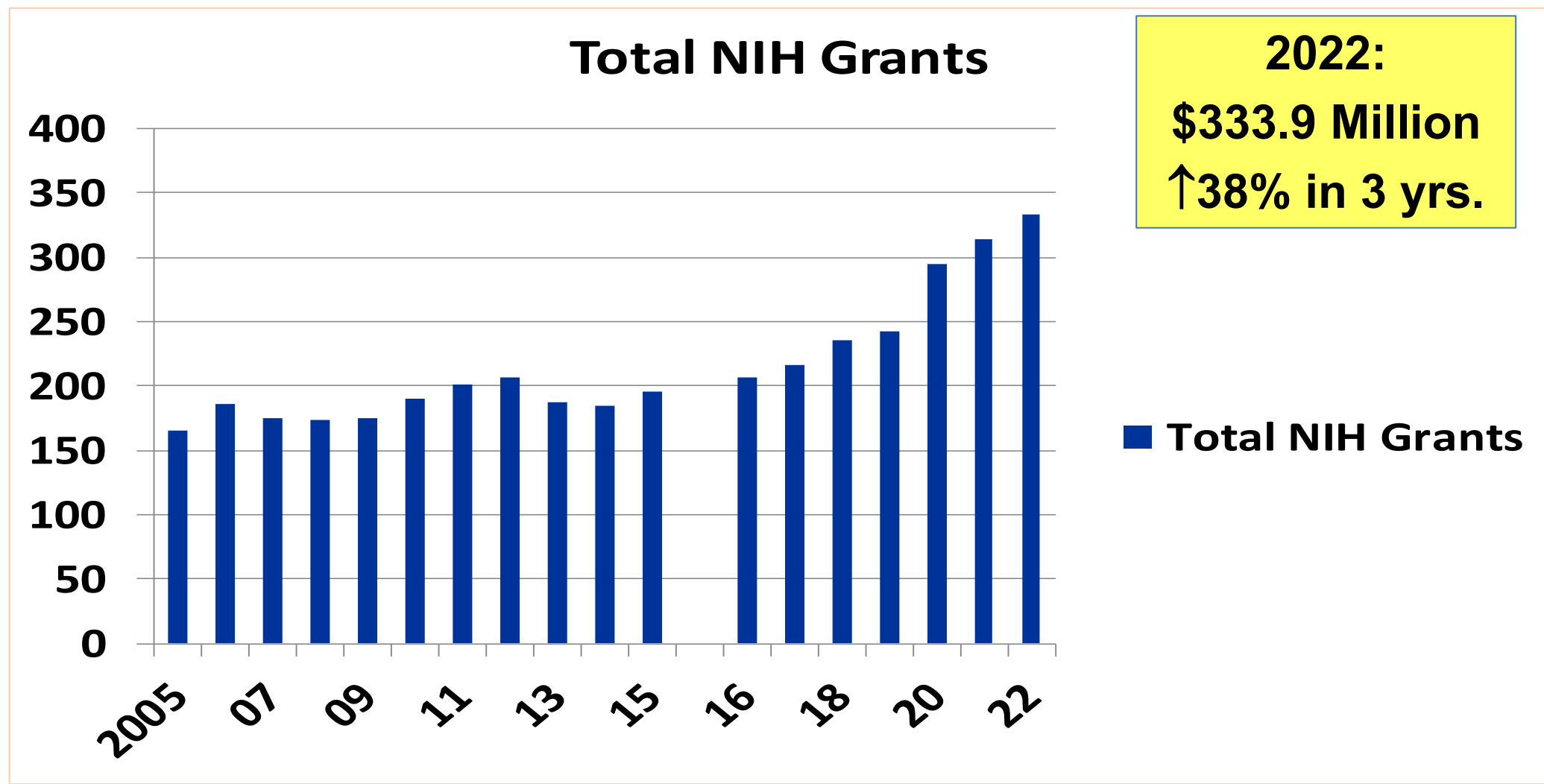
Colorado Clinical and Translational
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Total Research Grants – CU Denver Millions



Total NIH Grant Awards – CU Denver Millions

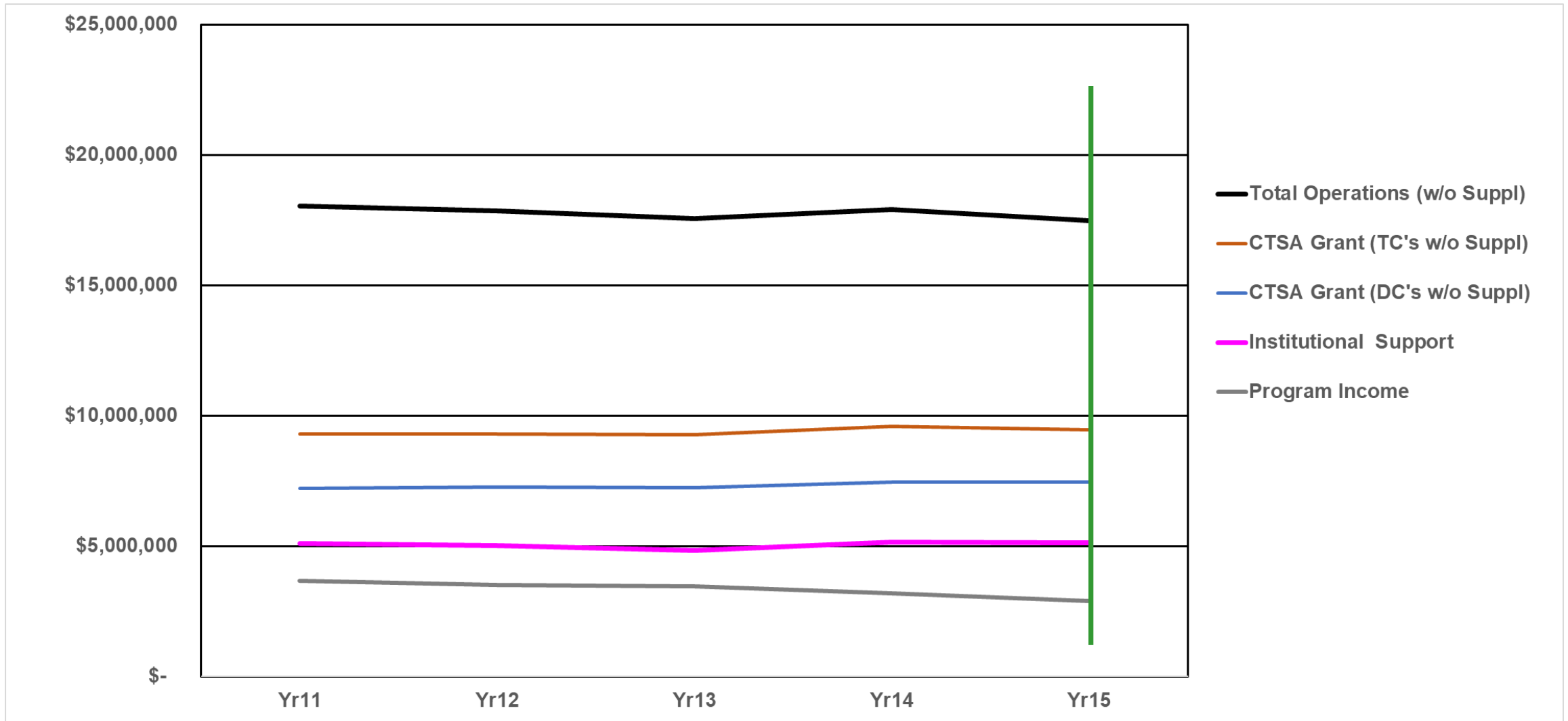


Grant Funding of CCTSI University Partners

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

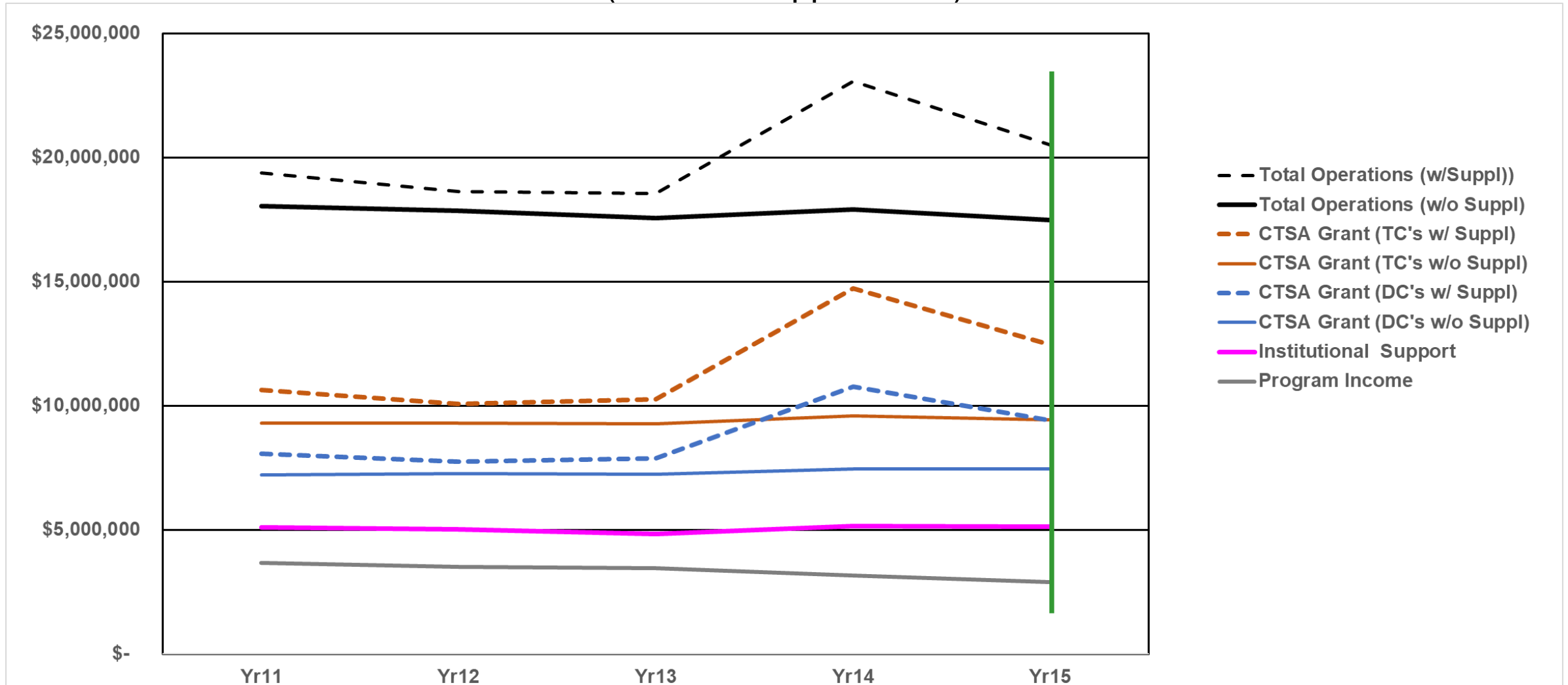


CCTSI Annual Funding: 2018 - 2023



CCTSI Annual Funding: 2018 – 2023

(includes supplements)

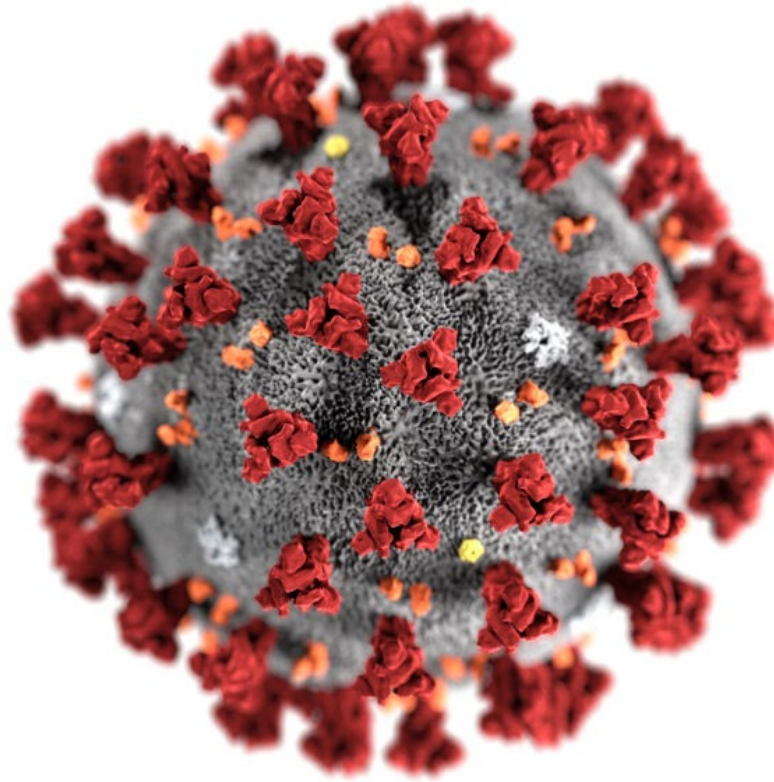


CCTSI Operating Budget: FY 2023

CCTSI Programs	NIH CTSA Grants (Total Costs)	Chancellor & VCR Funds	UCH Support	SOM Support	SOM Addn'l Support for CCTSI Ops	CHCO Support	TOTAL	Percent Total
A. Administration Core:	\$ 921,201	\$ 425,045	\$ -		\$ 83,597		\$ 1,429,843	11%
B. Informatics	\$ 771,662	\$ 503,929	\$ -		\$ -		\$ 1,275,591	10%
C. Community Engagement & Team Science	\$ 790,680	\$ 183,474	\$ -		\$ -		\$ 974,154	8%
D. Translational Endeavors (ETCD-Pilots)	\$ 1,843,215	\$ 20,208	\$ -	\$500,000	\$ -	\$ 200,000	\$ 2,563,423	20%
E. Research Methods (RKS-BERD-Ethics)	\$ 874,823	\$ 116,209	\$ 58,564		\$ 111,480		\$ 1,161,077	9%
F. Hub Research Capacity (CTRC + ISP)	\$ 2,343,696	\$ 180,649	\$1,127,047		\$ -	\$ 850,000	\$ 4,501,392	35%
G. Network Capacity (TIN)	\$ 267,111		\$ -		\$ -		\$ 267,111	2%
H1. Innovation Ecosystem	\$ 226,325	\$ 9,470	\$ -		\$ -		\$ 235,795	2%
H2. Early Life Exposures Program (ELEP)	\$ 358,409		\$ -		\$ -		\$ 358,409	3%
Total UL1 Program	\$ 8,397,123	\$ 1,438,984	\$1,185,611	\$500,000	\$ 195,077	\$1,050,000	\$12,766,795	100%
Total KL2 Program(7 Scholars)	\$ 775,990						\$ 775,990	
Total TL1 Program (11 Trainees)	\$ 638,951						\$ 638,951	
Supplements: mAB RWE & KL2 Diversity	\$ 2,881,669						\$ 2,881,669	
Total CCTSI Program Budget	\$ 12,693,733	\$ 1,438,984	\$1,185,611	\$500,000	\$ 195,077	\$1,050,000	\$17,063,405	



CCTSI Response to Public Health Emergency



Colorado Clinical and Translational
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CCTSI Response to COVID-19

- CTRCs – outpatient visits for Therapeutic and Vaccine trials
- CTRCs – inpatient visits and mobile nursing – mAb infusions & other trials
- CReST – study coordinators & regulatory teams reassigned
- Perinatal CTRC – research nurses reassigned
- Core Lab – SARS-CoV-2 testing for trials
- Logistical and scheduling support – auxiliary facilities (trailers)
- Regulatory Support – designated clinical study groups, reviewed all studies, suspended and restarted studies
- Accelerated IRB turn-around, contracting, clinical trial start-up (10 days)
- CE&R - Enhance URM and other high risk group enrollment in trials
- CCTSI COVID-19 Related Research (C2R2) Pilot Grant Program - < 2 weeks
- CU-CSU Summits x2 focusing on COVID research
- COVIDome and Biobank
- Remote learning for Educational programs
- National COVID-19 Cohort Collaborative (N3C) involvement



CCTSI Response to COVID-19

- **CHCO CTRC** – facilitated largest enrollment center (10% of all enrollees – 80 sites, 2,268) for Pfizer/BNT COVID vaccine trial in 5-11 yr-old children (NEJM Nov 9, 2021)
- **Adult CTRC and CReST** - facilitated numerous adult therapeutic trials
- **CEAL** site for Colorado (Nease)
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) NHLBI



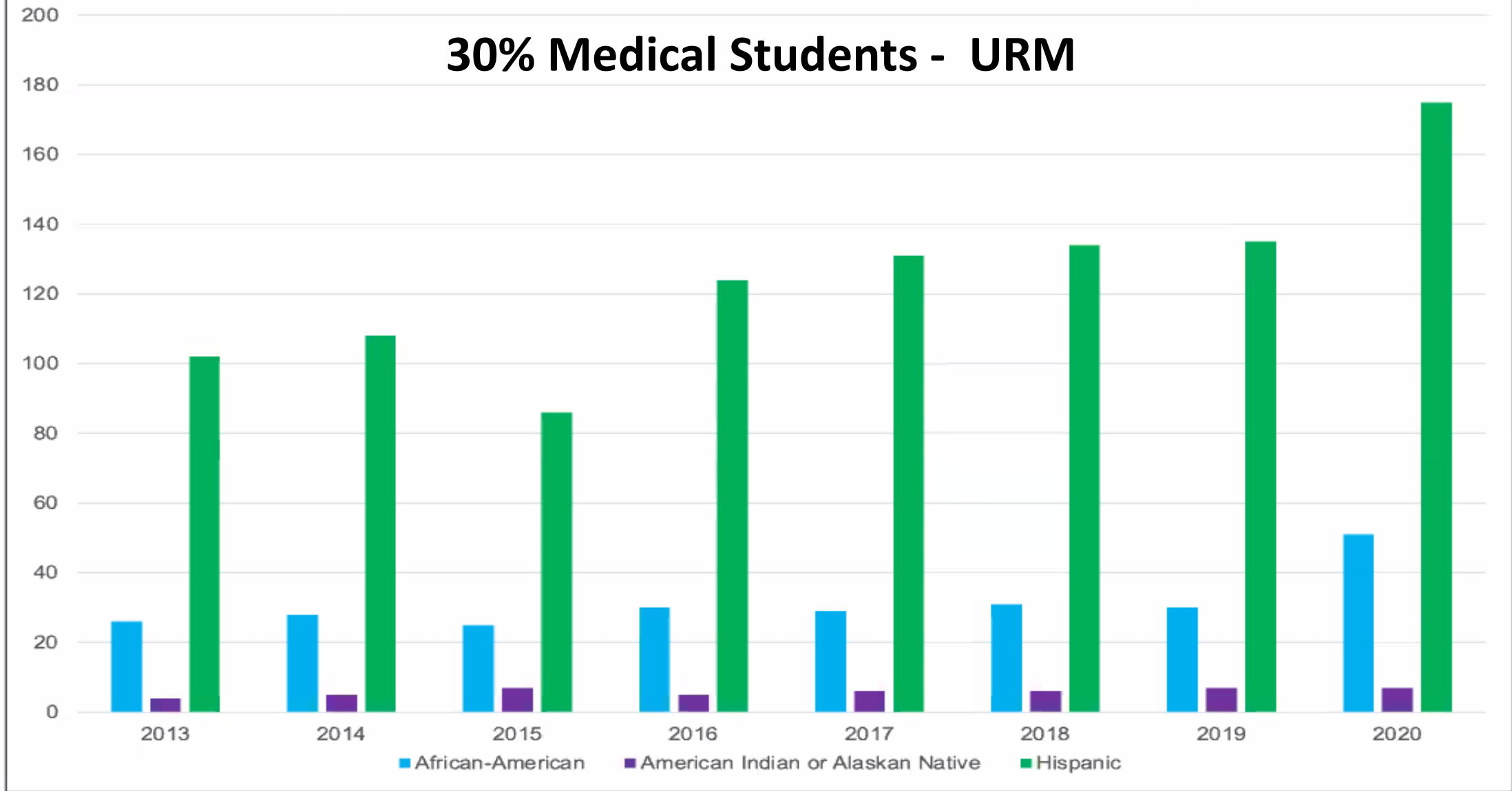
Diversity, Equity, Inclusion, Social Justice

- Formed CCTSI DEI/SJ Committee
 - 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
 - Posted “COVID-19 Impact on Latinos” Fact Sheet on website



Underrepresented in Medicine Faculty

30% Medical Students - URM



Professional Workforce Development

1. Summer Undergraduate Minority Mentoring in Translational Science (SUMMiT) (n=14) – Pathway Program
2. TL1 (T32) Pre-doctoral PhD training program
3. Clinical Sciences Graduate Program (PhD, Masters)
4. KL2 (K12) Research Scholar program - up to 3 yrs. of support
5. Clinical Research Training and Education (CRSC)
6. Support for Clinical Faculty Scholars Program



Professional Workforce Development

7. Leadership in Innovative Team Science (LITeS)
8. Colorado Mentor Training Program
9. K-to-R Transition Grant Review
10. Pre-K Award Assistance and Grant Review
11. Research Studios
12. Innovation Corps (I-Corps)
13. **NEW** Teaming for Early Career Researchers
14. **NEW** Communicating Your Science to the Public



Communicating Your Science to the Public

New workshop series - Communicating Your Science to the Public. We believe that one of the best ways to increase trust in science is to empower researchers with the skills to communicate their work. 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
- Taught by Comilla Sasson, MD, PhD



Clinical Translational Research Centers (CTRCs)

- UCH, CHCO, NJH & CU B

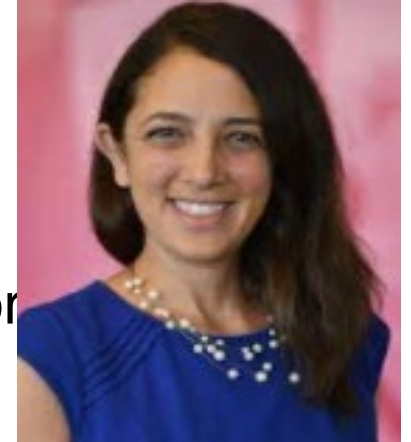


- Inpatient and outpatient facilities and mobile teams
- Nursing, Nutrition, metabolic kitchen, whole room calorimeter, body composition, exercise physiology, vascular ultrasonography and ECHO, Core laboratories & specimen processing
- **Microgrants** to Jr. Investigators (\$10,000/yr. x 3)
- **200 PI's > 500 CTRC Protocols** each year (10,000 - 15,000 visits/yr)
- **CReST**: Clinical Research Support Team – coordinators and regulatory (FFS)
 - *CReST moved into VCR Office*

Administrative Supplements

- **KL2 – INCLUDE Supplemental Award**

- **IN**vestigation of **Co**-Occurring Conditions across the **L**ifespan to **U**nderstand **D**own Syndrom**E**
- **Marisa Stahl, MD, MSCS** – pediatric gastroenterology Asst Professor
- Aim 1: Identify multi-omics signatures of celiac disease in DS.
- Aim 2: Define if signatures of celiac disease in DS are conserved in celiac disease in typical children.
- Aim 3: Define the impact of risk alleles on celiac disease in DS
- 2020-2023



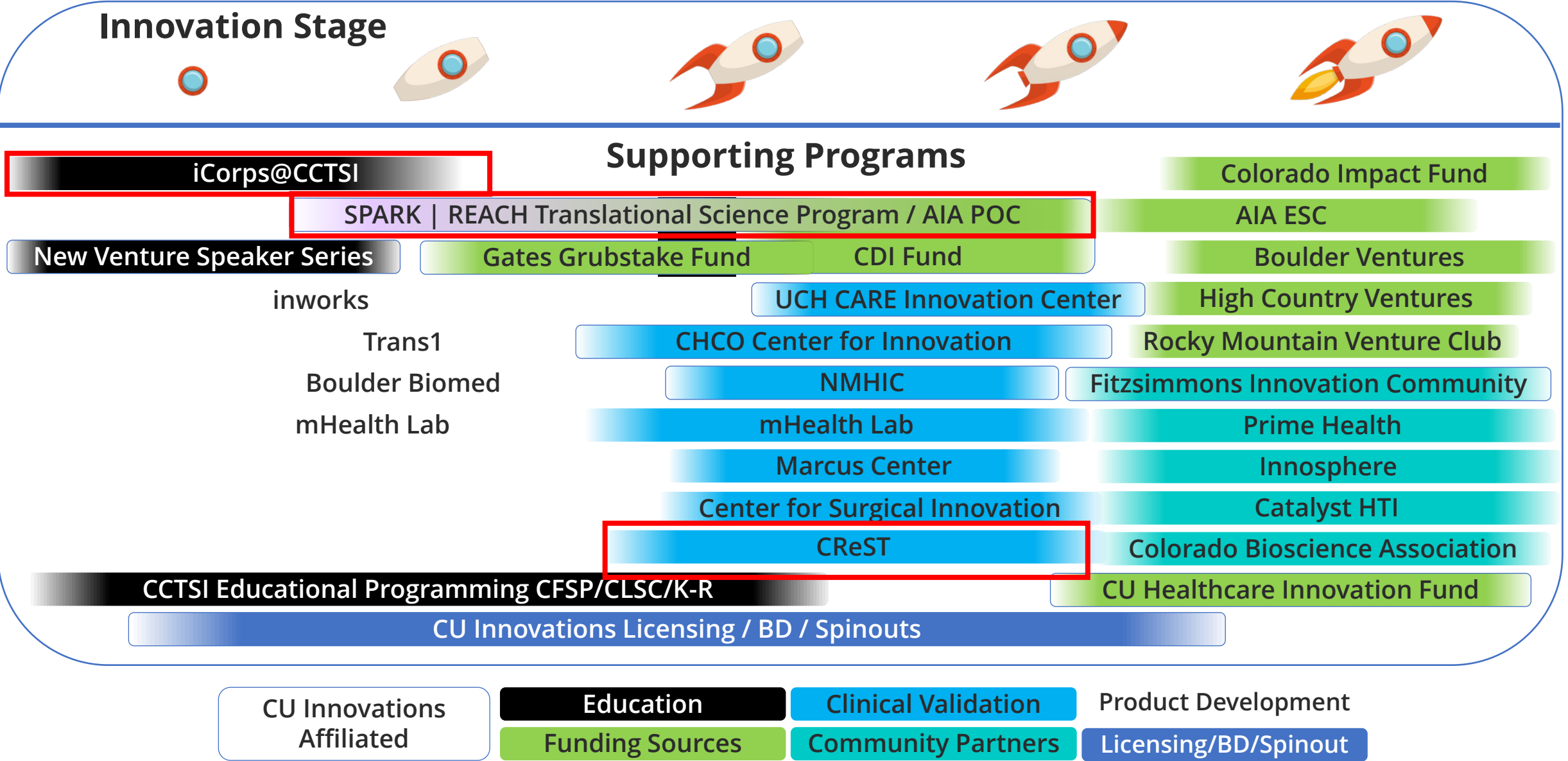
Diversity KL2 Supplement (UL1)

- **KL2 – Diversity Supplemental Award**

- **Health disparities and inequities in care delivery for peripheral arterial disease (PAD) among Black and Hispanic Americans**
- **Demetria M. McNeal PhD, MBA**– Asst Professor, Internal Medicine
- Aim 1: Determine knowledge, role in management, perceptions, etc. among clinicians related to treatment of PAD in Blacks and Latinx
- Aim 2: Determine knowledge, access to care and self-management behaviors among patients with PAD
- Aim 3: Determine how these aspects have been affected by COVID-19.
- 2021-2023



AMC INNOVATION ECOSYSTEM



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 schalier
- **Contracting Lead:** Amanda Peng
- **Central IRB Lead:** Christy Williamson
- **Recruitment (Participants) Lead:** Barbara Hammack
- **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 Vet School CSU
- Several CCIA U01 grants undergoing review
- mAb, CO-CEAL, RECOVER



CCTSI 4.0 – New Grant Submissions

- FOA PAR 21-293 released July 30, 2021: 7 grant options to replace U54
- UM1 for 7 years
K12, Pre-Doc and Post-Doc T32, RC2 (up to two) and R25 – all for 5 years
- UM1 Budget determined by NIH funding – tier C, \$5 million direct costs (\$800K below our UL1)
- New FOA emphasis on translational science and not research, new Clinical & Translational Science Research Program (Element E), 7 attachments
- **Submitted 6 grants** on May 13, 2022 (budget period May 1, 2023-2030)
- Huge effort – did not reduce our “administrative burden”
 - We submitted a UM1, K12, pre-Doc TL32, post-Doc TL32, and two RC2 applications
 - *Would not advise any CTSA to attempt to submit more than 4 of these concurrently*



CCTSI Grant Submission Outcomes

- **Scores:** UM1 - 29, K12 - 20, PreDoc T32 - 19, PostDoc T32 - 30, RC2 – both not discussed
- UM1 on the borderline for funding (must have both UM1 and K12 funded in order to receive funding for any of the grants)
- Received Summary Statement ~ Dec. 1, 2022 (you received it)
- Advised by NIH to resubmit UM1 A1 grant for January 13, 2023 deadline (yes, tomorrow) and address the Weaknesses cited (one page Introduction allowed)
- Over December – we assembled an A1 application & it is submitted. To be reviewed in May, earliest start date, Dec. 1, 2023
- Awaiting decision about funding for May 2022 submission



Contingency Plans

- Using CCSTI Reserves and Commitments – can keep all programs functioning for 9-12 months
- Will not accept new K12 or T32 scholars but complete those in program. Scale down Pilot Grant program as needed.
- Share costs (50:50) with Partnering Institutions
- Possibility to get “Cost Extension” funding from NCATS (50% direct costs for up to one year) but no guarantee
- Rewrite RC2 (? Post-Doc T32) grants for upcoming submission dates



UM1 Weakness Cited by Reviewers

- Assimilation of components into a unified form, components should complement each other, collaborations among partners
- Enhance Communication Plan
- Denver-Boulder centric – coordination of other institutions with CCTSI; statewide reach not clear
- Novel ways to enhance diversity of workforce
- Specific initiatives for URM faculty, trainees and staff
- Plans to promote health equity
- More details on Metrics and CQI plans
- Feedback from Community Stakeholders and Workforce
- Describe future plans in more details
- Concern about EHR consenting (Element E) for those without EHR access or expertise



Our A1 Application Response

- Thorough A1 grant revision performed (including new diagrams/charts)
- Improved and more detailed description of interactions and coordination of CCTSI and with/among Partnering Institutions
- Effort to add and emphasize pipeline programs for URMs, recruitment and mentoring of URMs, approach to supporting research for Health Disparities and Inequities
- Expanded Metrics for each section
- More detailed Communication Plans
- Feedback from Community and Workforce Stakeholders addressed
- Addressed EHR recruitment plans for rural, minority groups, non-EHR user patients and risk for introducing bias



CCTSI 4.0 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 will address health inequities and disparities.



CCTSI 4.0 Overall Strategic Goals

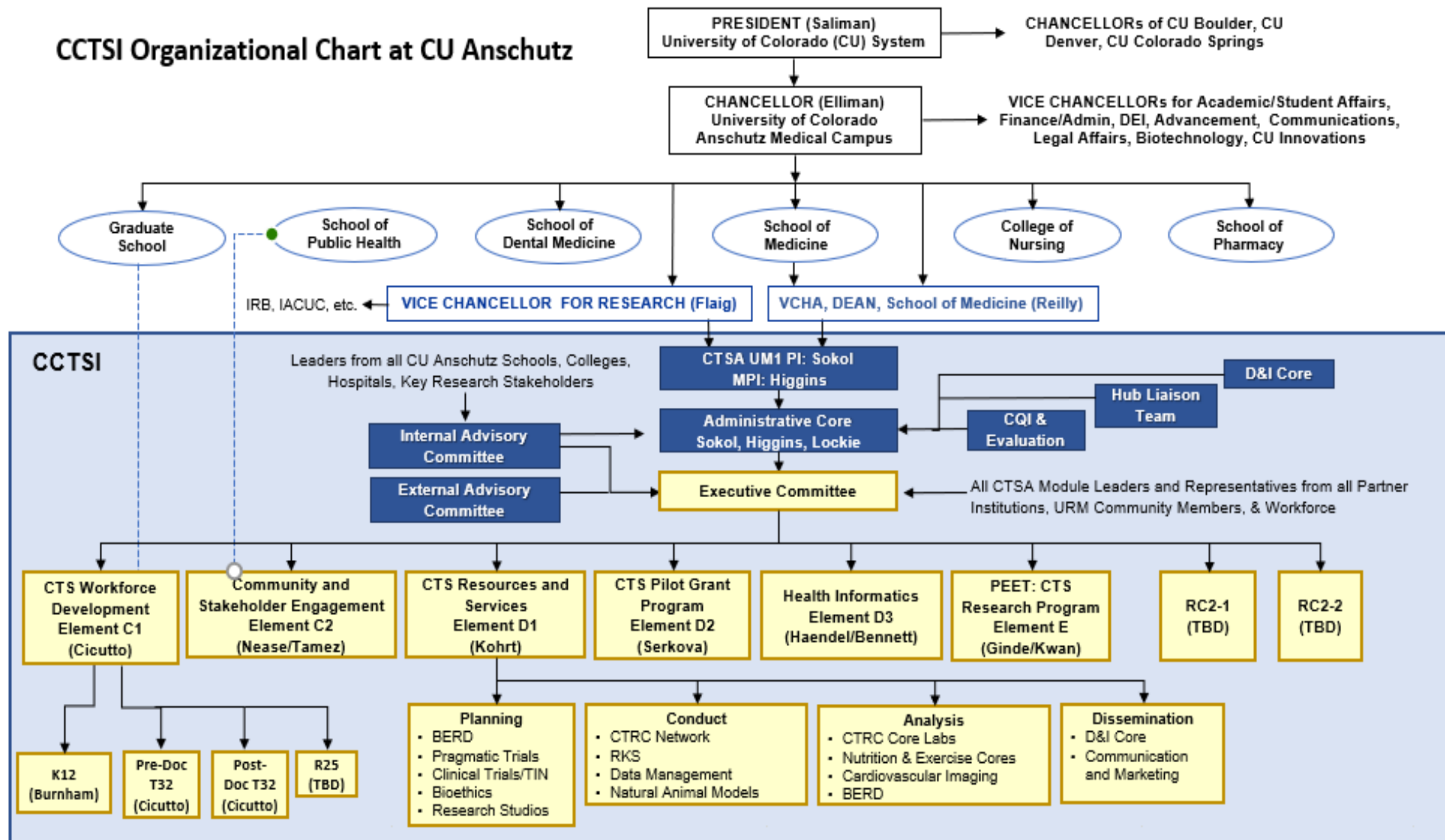
Goal 4: Further develop operational efficiencies to increase the quality, safety, efficiency, effectiveness and informativeness of clinical research.

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.



CCTSI Organizational Chart at CU Anschutz



Working Relationships Between CCTSI Hub and Partnering Institutions

Schools & Colleges Involved with CCTSI:

Medicine
Nursing
Pharmacy
Dental
Public Health
Graduate

University of
Colorado
Anschutz Medical
Campus

LAS
Evaluation Ctr.
Engineering
Education
Public Affairs
Business
Graduate

University of
Colorado Denver

Arts &
Sciences
Engineering
Business

University of
Colorado Boulder

CTRC

Veterinary Med
Engineering
Public Health
Human Sciences
Natural Sciences
Agriculture
Liberal Arts
Graduate

Colorado State
University

University Academic Partners

Deans, VCRs

Admin Directors,
Grants &
Contracts

CTR MD/PhD
Leaders

Module
Content
Experts

Research
Teams,
Faculty, Staff,
Post-Docs,
Trainees

CCTSI Hub

UM1 MPIs: Sokol & Higgins

Internal Advisory Committee

Administrative Core

CCTSI Executive Committee

CCTSI Module Leaders &
Steering Committees

CCTSI Programs,
Trainings, WFD,
Pilot Grants,
Informatics Support,
Resources and
Services, etc.

CCTSI PACT Council, Pilot
Grants, CEHE, Trainings

Hospital & Health Systems Partners

Hospital
CEOs

CTR Admin
Directors

CTR MD
Leaders

Module
Content
Experts

Research
Teams,
Faculty, Staff,
Post-Docs,
Trainees

University of
Colorado Health

CTRC

Children's
Hospital Colorado

CTRC

National Jewish
Health

CTRC

Denver Health &
Hospitals

Rocky Mountain
Veterans Affairs
Medical Center

CCTSI

Community Partners & Collaborators

Community Stakeholders &
20 Community Organizations

Interact with all above Hub
Functions

CTRC = CTR Center

CTR = Clinical &
Translational Research



Elements and Modules

A. Overall

B. Strategic Management

C. Training and Outreach

C1. Workforce Development

C2. Community and Stakeholder Engagement Research

D. Clinical and Translational Science Resources and Pilots

D1. Resources and Services

D2. CTS Pilot Program

D3. Health Informatics

E. Clinical and Translational Science Research Program

Seven Attachments/tables/charts



DISCUSSION

