



# **CCTSI Town Hall**

## **Update – February 2022**

**Ronald J. Sokol, MD**

**Director and P.I. of CCTSI**

**Assistant Vice Chancellor of Clinical and Translational Science**  
**University of Colorado – Anschutz Medical Campus**



Colorado Clinical and Translational  
Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO DENVER | 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.
- CTSAs provide many local resources, facilities, research personnel, pilot funding, regulatory and informatics support, research units and education & training programs
- 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
- 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, special functions and more



# CCTSI Vision

Accelerate and catalyze the translation of innovative science into improved health and patient care



# 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

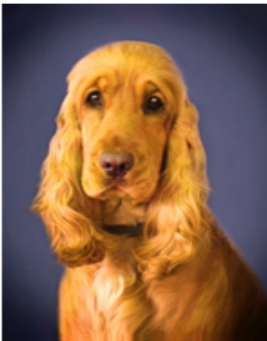
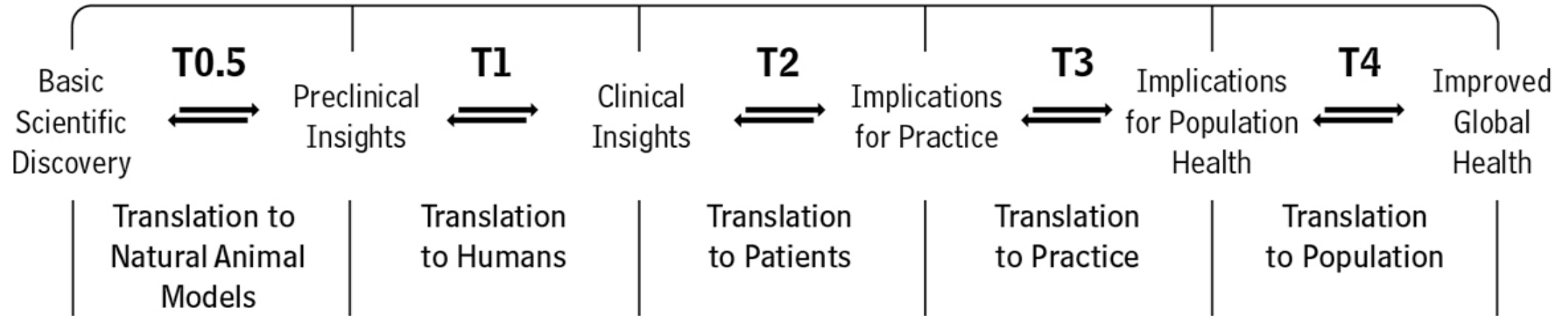
**CCTSI** → **COLLABORATION**  
**INNOVATION**  
**TRANSLATION**



# Spectrum of Translational Research

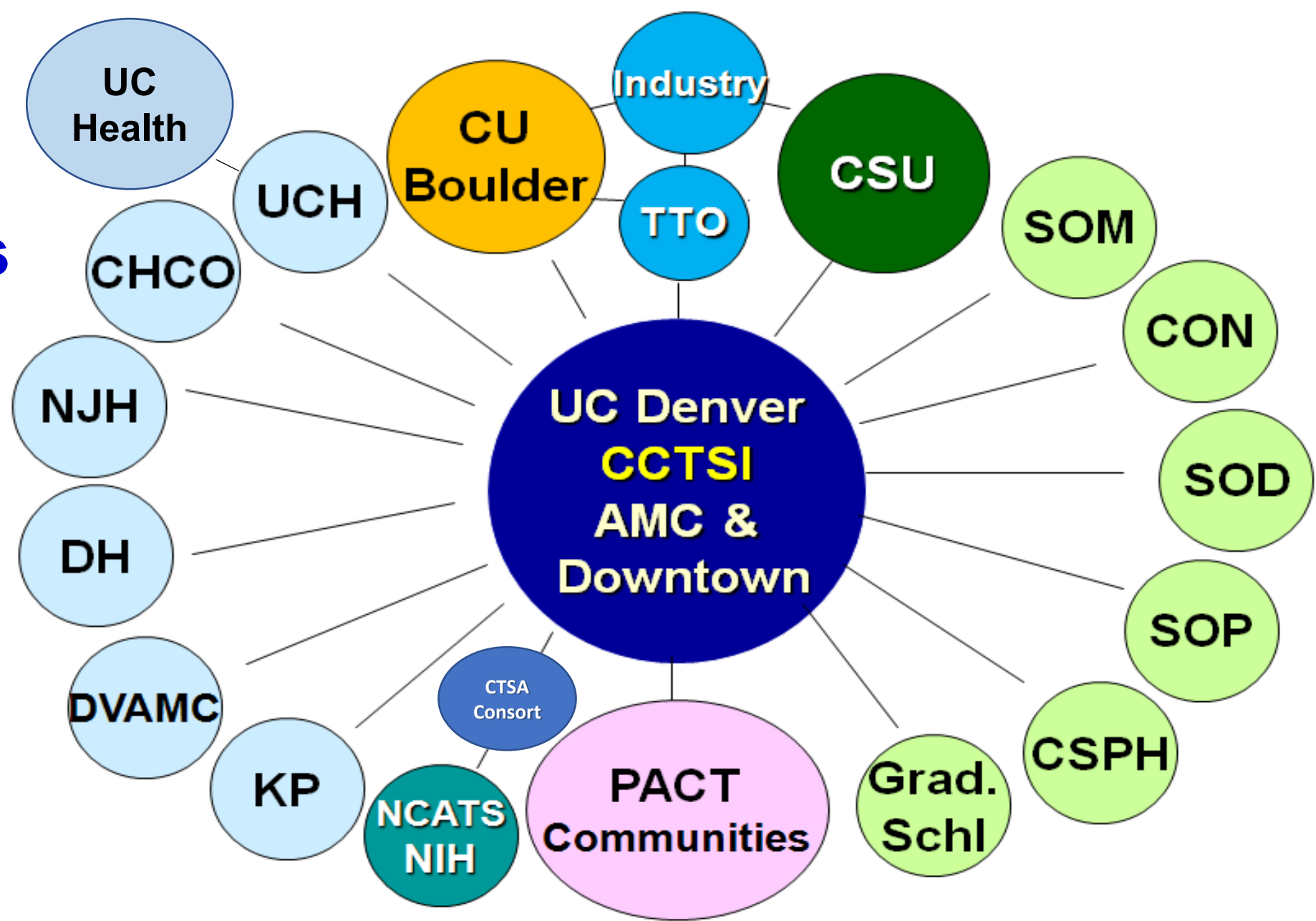
- Bi-Directional
- Collaboration
- Team Science

## CLINICAL TRANSLATIONAL RESEARCH SPECTRUM



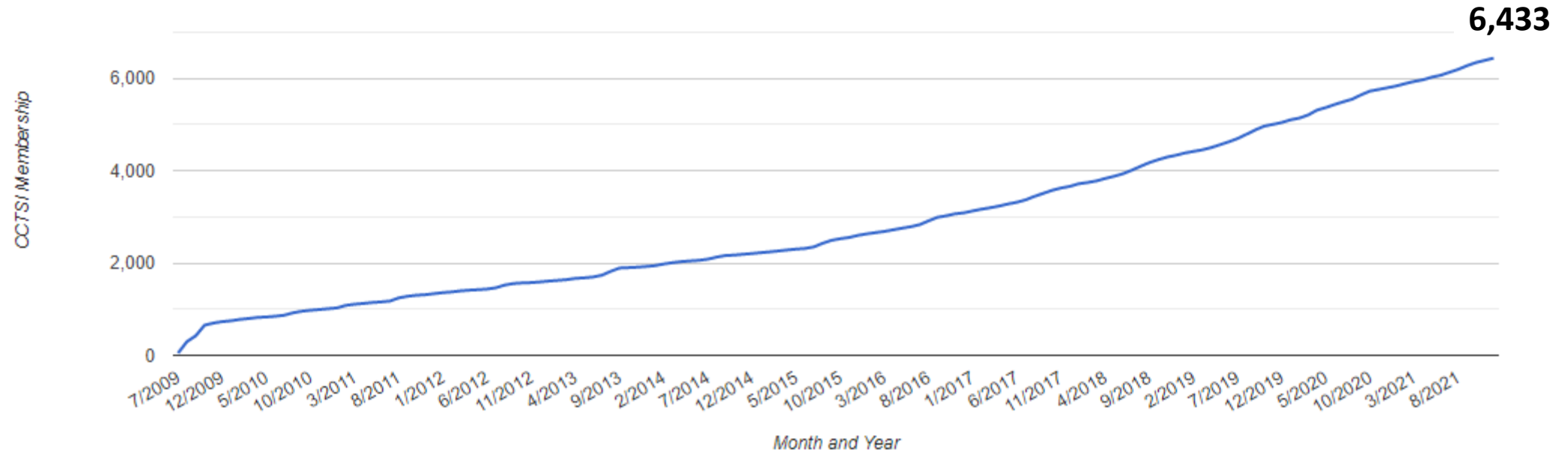


# CCTSI Hub & Partners

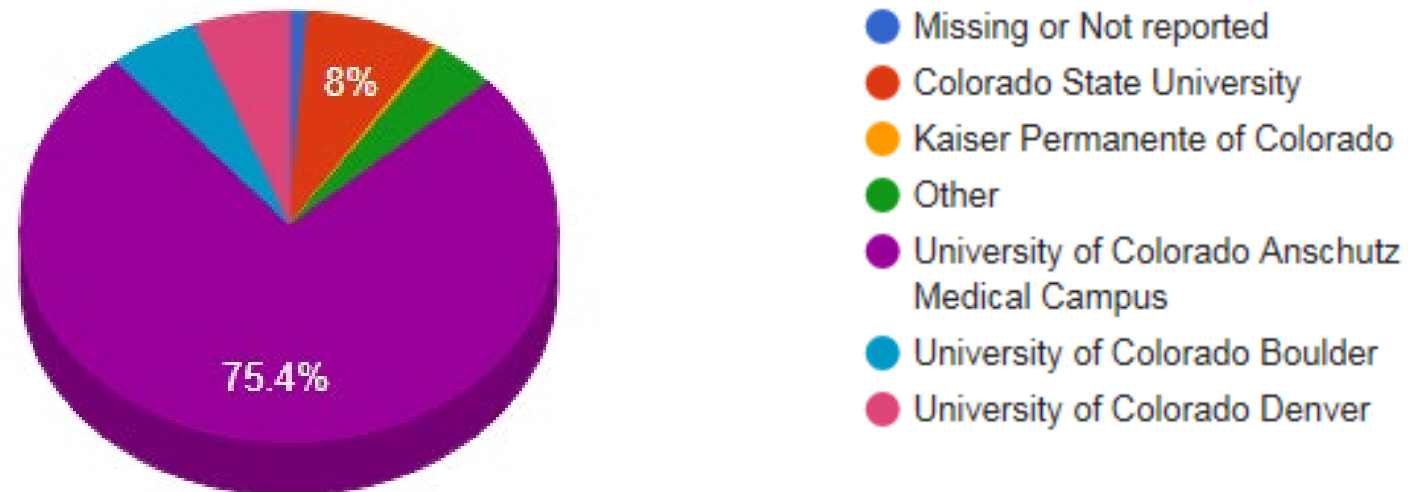




# CCTSI Monthly Membership Growth

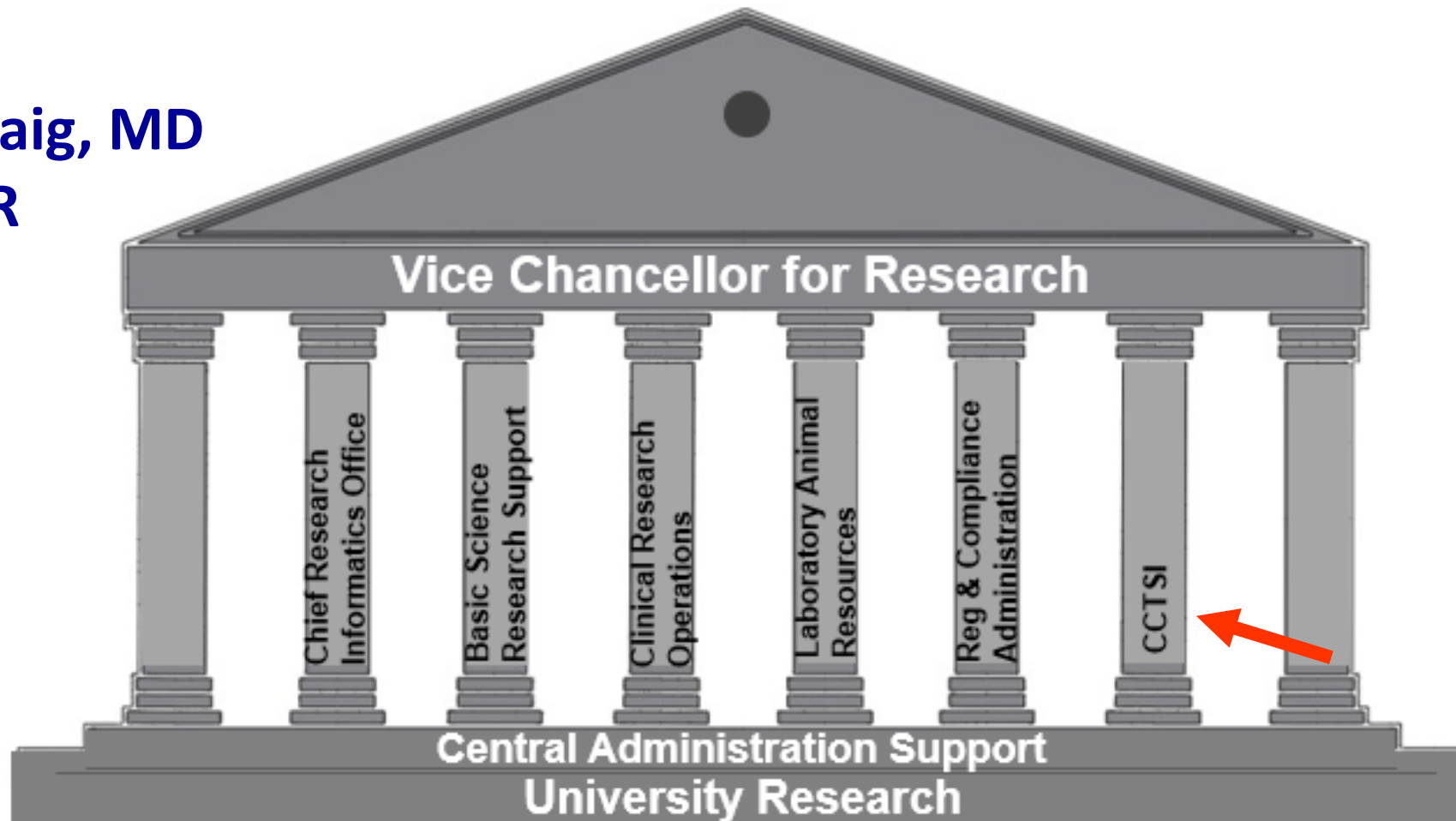


CCTSI Membership by Academic Affiliation



# OFFICE OF THE VICE CHANCELLOR FOR RESEARCH CENTRAL ADMIN ORGANIZATION

Thomas Flaig, MD  
VCR



# CCTSI Leadership

**Director:** Ronald Sokol, MD

**DFA:** Tim Lockie, MS, MBA

**Director of Operations:** Janine Higgins, PhD

## **Associate Directors:**

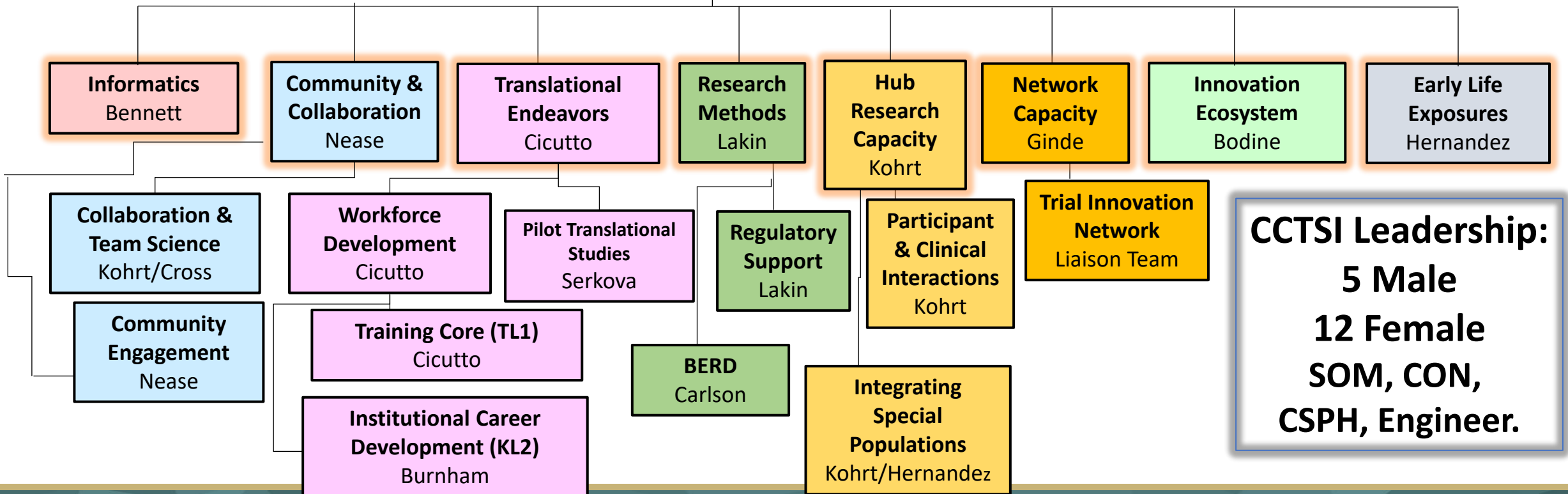
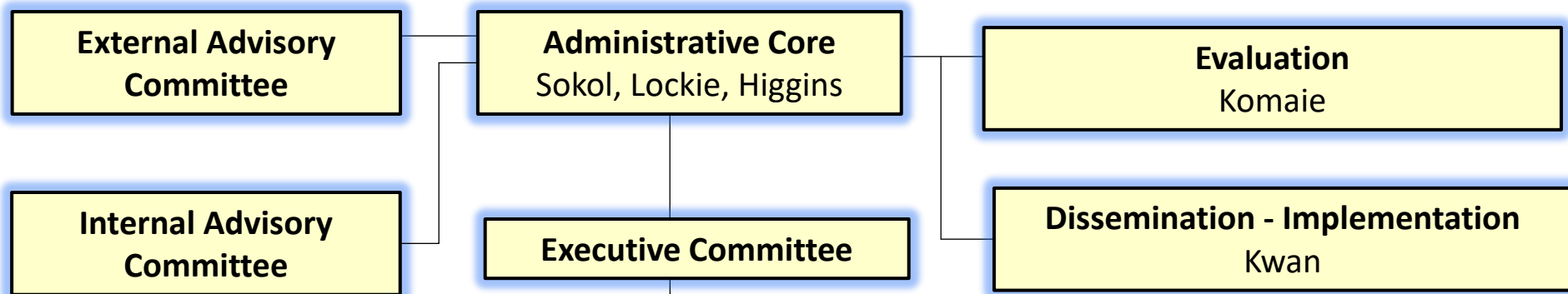
- Wendy Kohrt, PhD
- Tell Bennet, MD, MS
- Alison Lakin, RN, JD
- Donald Nease, MD, MPH
- Thomas Campbell, MD
- Lisa Cicutto, PhD

**CSU:** Susan VandeWoude, DVM

**CU- Boulder:** Chris Desouza, PhD

**VAH:** Jane Reusch, MD





**CCTSI Leadership:**  
**5 Male**  
**12 Female**  
**SOM, CON,**  
**CSPH, Engineer.**



# CCTSI Programs & Resources

1. **Education, Training and Career Development** – KL2, TL1, CLSC, LITeS, etc.
2. **Clinical Research Resources & Facilities** (CTRCs – inpt., outpt., mobile; CReST)
3. **Community Engagement & Research** – Don Nease, MD
4. **Dissemination – Implementation Research** – Bethany Kwan, PhD
5. **Team Science** – Jeni Cross, PhD
6. **Biostatistics, Epidemiology and Research Design** – CIDA - Nichole Carlson, PhD
7. **Translational Informatics** – Tell Bennett, MD, MS & Melissa Haendel PhD
8. **Research Bioethics** – Matt DeCamp, PhD
9. **Regulatory Knowledge and Support** – Alison Lakin JD, RN
10. **Pilot Grant Programs** – Natalie Serkova, PhD
11. **Trial Innovation Network** – Adit Ginde, MD & Hub Liaison Team
12. **Innovation and Entrepreneurship** – Cathy Bodine, PhD
13. **Early Life Exposures Program (ELEP) Research** – Teri Hernandez, PhD



# CCTSI Website

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

or Google “CCTSI”

WEBSITE:

6,000 - 7,000 visits per month

PROFILES:

15,000 – 20,000 visits per month

- **Portal of entry**
- **Information, applications, links to services, RFAs, training, announcements, stories, etc.**
- ***Membership* online**
- ***Quarterly Newsletter* (Found in Translation – Wendy Meyer)**
- **Colorado Profiles – “Find a Researcher”**





## Colorado Clinical and Translational Sciences Institute

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

Resources ▼


Training ▼

Funding ▼

Community Engagement ▼

News and Events ▼

About Us ▼

Volunteer for a Study 



### ACCELERATING RESEARCH TO IMPROVE HEALTH

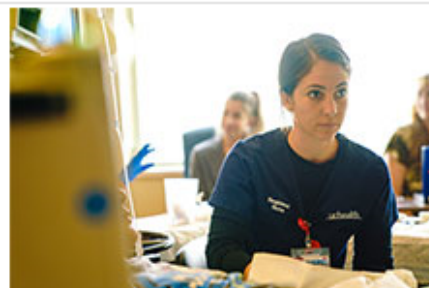
The CCTSI helps build research teams of the future, speed the development of new treatments and improve human health





## Resources and Services

CCTSI supports translational research by providing resources, integrating facilities and services, developing innovative research tools and catalyzing interdisciplinary research programs.



## Funding

Each year, the CCTSI awards more than \$2 million in pilot grants, microgrants, and pre-doctoral and post-doctoral research scholar awards. You can find more information on each grant and how to apply



## Education, Training and Career Development

The Education, Training and Career Development (ETCD) program provides clinical-translational scientists and trainees with knowledge, training and career skills



## Clinical Translational Research Centers

The CTRC provides infrastructure, resources and dedicated space to conduct clinical research.

**Cite our grant**

**Become a member**

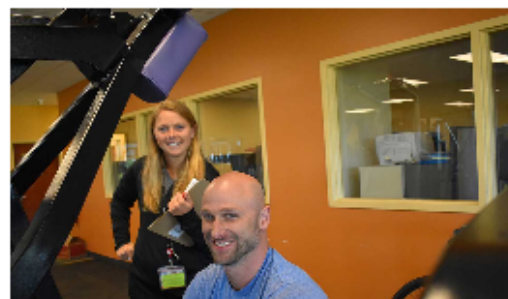
Join the CCTSI for free

**Find a researcher**

Colorado PROFILES



**Found In Translation**  
*News from around the CCTSI*



## Mapping Our Molecules »

Jun 25, 2019, 12:00 AM by Wendy Meyer

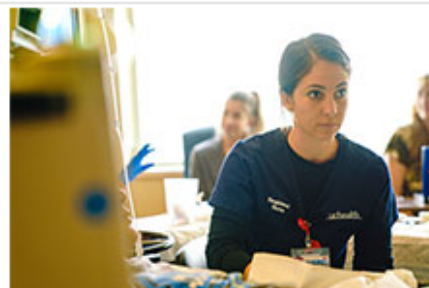
Why know that exercise is good for us. Professor Wendy Kohrt aims to find out why. She is leading an exercise study called MoTrPAC to develop a so-called molecular map of tissue-specific and circulating signals produced by physical activity.

**Full story »**



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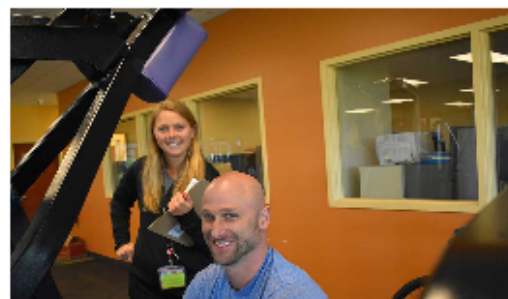
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**Full story »**



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8309 Total Profiles



[Jonathan Harris](#)

September 30, 2019

added a publication from: Applied and environmental

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**Search for Investigators  
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[Carmen Ledesma-Feliciano](#)

October 2, 2019

added a publication  
from: JFMS open  
reports

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### Most viewed (month)

[oncology](#)[cigarette](#)[smoke](#)[genomics](#)[Endocrinology](#)[Artificial Pancreas](#)[Regeneration](#)[Driving Automobile](#)[Suicide](#)[anatomy](#)

**Search for Investigators  
by Key Words**



## Keywords

## Last Name

## Institution

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## Search Results (38)

Click the **Why** column to see why a person matched the search.

Sort

Show

[More Search Options](#)

## Search Criteria

biliary atresia

| Name                                     | Institution   | Why                  |
|--|---|----------------------|
| <a href="#">Cara Lynn Mack</a>           | University of Colorado Denver - Anschutz Medical Campus | <a href="#">Why?</a> |
| <a href="#">Ronald J Sokol</a>           | University of Colorado Denver - Anschutz Medical Campus | <a href="#">Why?</a> |
| <a href="#">Frederick M Karrer</a>       | University of Colorado Denver - Anschutz Medical Campus | <a href="#">Why?</a> |
| <a href="#">Amy G. Feldman</a>           | University of Colorado Denver - Anschutz Medical Campus | <a href="#">Why?</a> |
| <a href="#">Shikha Seksaria Sundaram</a> | University of Colorado Denver - Anschutz Medical Campus | <a href="#">Why?</a> |
| <a href="#">Rebecca Michelle Tucker</a>  | University of Colorado Denver - Anschutz Medical Campus | <a href="#">Why?</a> |
| <a href="#">Frederick J Suchy</a>        | University of Colorado Denver - Anschutz Medical Campus | <a href="#">Why?</a> |
| <a href="#">Michael R Narkewicz</a>      | University of Colorado Denver - Anschutz Medical Campus | <a href="#">Why?</a> |
| <a href="#">Alexandra Leigh Kilgore</a>  | University of Colorado Denver - Anschutz Medical Campus | <a href="#">Why?</a> |

**Ranked List of  
Researchers  
At CU**



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**Results: Contact info, Grants, Publications from PubMed, Networking**

[cigarette](#)[smoke](#)[oncology](#)[Genomics](#)[Endocrinology](#)[Driving Automobile](#)[Regeneration](#)[Suicide](#)[Artificial Pancreas](#)[anatomy](#)



## Keywords

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## History

[Mack, Cara](#)[Sokol, Ronald](#)[See All \(2\) pages](#)

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## Ronald J Sokol

Title Professor

Institution University of Colorado Denver - Anschutz Medical Campus

Department SOM-PEDS

Phone 720/777-3929

Email RONALD.SOKOL@CUANSCHUTZ.EDU

ORCID 0000-0001-7433-4095



## Sokol's Networks

Click the "See All" links for more information and interactive visualizations!

## Concepts

[Biliary Atresia](#)[Liver Diseases](#)[Cholestasis](#)[Parenteral Nutrition](#)[Liver](#) [See all \(1010\) concept\(s\)](#)

## Co-Authors

[Feldman, Amy](#)[Sundaram, Shikha](#)[Mack, Cara](#)[Narkewicz, Michael](#)[Suchy, Frederick](#) [See all \(83\) people](#)

## Similar People

[Mack, Cara](#)[Narkewicz, Michael](#)[Suchy, Frederick](#)[Pomfret, Elizabeth](#)[Abman, Steven](#) [See all \(60\) people](#)

## Biography

## awards and honors

|             |   |
|-------------|---|
| 1971        | Phi Beta Kappa, University of Illinois, Urbana  |
| 1972        | Bronze Tablet, University of Illinois, Urbana   |
| 1976        | Alpha Omega Alpha, University of Chicago Pritzker School of Medicine                  |
| 1986        | Basil O'Connor Award, March of Dimes  |
| 1990        | Mead Johnson Award for Nutritional Research, American Institute of Nutrition          |
| 1994 - 2016 | Best Doctors in America   |
| 2002        | America's Top Pediatricians, Consumers' Research Council of America                   |
| 2003        | 2003 Nutrition Award, American Academy of Pediatrics, Committee on Nutrition          |
| 2004        | Hall of Honor, Cincinnati Pediatric Historical Society                                |
| 2006 - 2008 | Top Doctors in Denver, 5280 Magazine  |
| 2009        | James E. Strain M.D. Award in Pediatrics, Children's Hospital Colorado Medical Staff, |
| 2009        | Pediatric Liver Research Award, Alpha-1 Kids and the Alpha-One Association            |
| 2009        | Harry Shwachman Award, North American Society for Pediatric                           |

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



- **UCH, CHCO, NJH, CU-B and Perinatal**
  - Inpatient and outpatient facilities – **no charge for space (except industry studies)**
  - Research **Nursing** – inpatient, outpatient, mobile teams (NICU, PICU, ED, etc.) – subsidized fee for service
  - Bio-nutrition, metabolic kitchen, whole room calorimeter and body composition
  - Vascular Ultrasonography and ECHO
  - Core laboratories & specimen processing – pricing on website
  - **Microgrants** to Jr. Investigators (\$10,000/yr. x 3)
  - SARC review of all protocols
  - **200** unique PI's conduct research on **>500 CTRC** Protocols each year (10,000- 15,000 visits/yr)

# CTRC Medical Directors

- **UCH/Adult** – Thomas Campbell, MD
- **CHCO/Pediatrics** – Phillip Zeitler, MD, PhD
- **Perinatal** – Christopher Baker, MD
- **NJH** – Donald Leung, MD, PhD



<https://www.nationaljewish.org/research-science/clinical-and-translational-research/ctrc>

- **CU-Boulder** – Chris DeSouza, PhD  
and Brian Stauffer, MD



<https://www.colorado.edu/ctrc/>



# Anschutz Health Sciences Building



Colorado Clinical and Translational  
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# Anschutz Health Sciences Building

- CCTSI move in date: **April 1, 2022**
- All CCTSI Leprino 3<sup>rd</sup> Floor operations moving to **6<sup>th</sup> floor – most modern facilities**
- Adult Outpt. CTRC, Infusions, Core Lab, Bionutrition, Exercise Research Lab, Offices
- Overall program space 30,746 sf
- Two large procedure rooms (~300 sf) to accommodate some activity that must currently be performed IP
- Two negative pressure rooms
- Five chair infusion suite
- Building will have a dedicated research pharmacy, Ctr. For Health AI, others





# Anschutz Health Sciences Building



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# Pilot Grant Awards

## Natalie Serkova, PhD

- **5 Pilot Grant programs** – CO-Pilot, CMH, Community Engagement, New Methods, CU-CSU Collaboration Award
- **~\$900,000 available**
- **\$20,000, \$30,000, \$60,000 levels**
  - Letter of Intent in August
  - Deadline September (end)
  - Peer Review in November- December
  - Start-up in January-April



# 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**, Scheduler, Harvest, LIS, Freezerworks
- **Data Delivery & Cohort Discovery** – TrinetX, Compass, ACT, N3C
- **Multiple applications** to support Grant Review and Education programs

# National COVID Cohort Collaborative (N3C)

- A **centralized**, secure portal for hosting **national** patient-level COVID clinical EHR data and deploying statistical methods and tools for clinicians, researchers, and healthcare – to answer pressing clinical and research questions
- **EHR data (UCH, CHCO)** entered by CTSA program institutions, distributed clinical data networks (e.g., PCORnet, OHDSI, ACT/i2b2, and TriNetX), and many other clinical partners and collaborators
- <https://ncats.nih.gov/n3c>
- **Melissa Haendel, PhD** – one of the leaders of N3C



National  
COVID  
Cohort  
Collaborative



## N3C Data Enclave Statistics

Release Set: February 11, 2022

**Production version:** Release-v64-2022-02-11

 **Sites:** 70

 **Persons:** 11.9 million

 **COVID+ Cases:** 4,303,428

 **Total Number of Rows:** 13.4 billion

 **Clinical Observations:** 1.2 billion

 **Lab Results:** 6.4 billion

 **Medication Records:** 2.0 billion

 **Procedures:** 634.0 million

 **Visits:** 659.2 million

# N3C Data Enclave Access

- Researchers can access the **N3C Data Enclave**, a centralized national COVID-19 data analytics platform to enable the rapid

**Contact Tell Bennett, MD, MS - Informatics Core for more details and access**

- Secure data platform with powerful analytics capabilities
- Data – robust in scale and scope
- Harmonized data set
- Video: [https://www.youtube.com/watch?v=0JPjw1\\_iRKY](https://www.youtube.com/watch?v=0JPjw1_iRKY)

# Education, Training and Career Development

**Lisa Cicutto, PhD, APN, RN**



1. Summer Undergraduate Minority Mentoring in Translational Science (SUMMiT) (n=14)
2. TL1 (T32) Pre- and Post-doctoral PhD training program
3. Clinical Sciences Graduate Program (Masters, PhD)
4. KL2 (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)
7. Leadership in Innovative Team Science (LITeS) – Susan Johnson PhD



# 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. Teaming for Early Career Researchers – Jeni Cross, PhD
14. **NEW** Communicating Your Science to the Public – C. Sasson, MD



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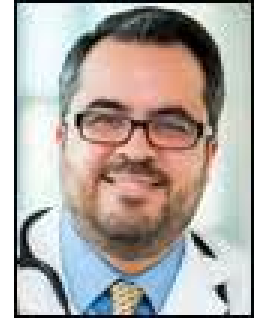
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# Pre-K Grant Review Program

## Paul MacLean PhD & Jose Castillo-Mancilla MD

- Assist junior faculty and their mentors write successful career development awards
  - 5 criteria (candidate, career development, mentors, environment, and research plan)
- 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
- Next cycle: Letter of Intent - April 18, 2022



# K to R Transition Program



- 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 4-6 weeks before submission to funding agency
  - Deadline for Letter of Intent
- Mock study section and written reviews
- PI and mentor - attend mock study section
- 3 cycles – NIH grant application deadlines
- **Maggie Wierman, MD 303-724-3952**



# Research Studio Program

## Jane Reusch, MD and Alan Prochazka, MD

- **Expert Panel** (4-6 person) formed to provide targeted advice about research project, grant application, idea generation, etc.
- T1-T2 or T3-T4 research topics
- **Studio sessions** are Face to Face (over Lunch)
  - ❖ 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)



# Research Studio Process

- Web-based Consult Request – on the CCTSI website
- Studio Consult Categories:
  - ❖ hypothesis generation
  - ❖ study design – specific aims
  - ❖ grant review
  - ❖ implementation
  - ❖ analysis and interpretation
  - ❖ manuscript review
  - ❖ translation



# Research Studio Dates

- Next Dates: Feb. 15, March 29, June 21, 2022
  - (4-5 Studios per session)
- Contact:

**Dan Holtrop, MA**

Studio Program Manager

[Daniel.Holtrop@cuanschutz.edu](mailto:Daniel.Holtrop@cuanschutz.edu)



Excellent feedback and usefulness

"Very beneficial service and significantly improved the quality of my research project"

- *Investigator*

# I-Corps@CCTSI

## Cathy Bodine, PhD

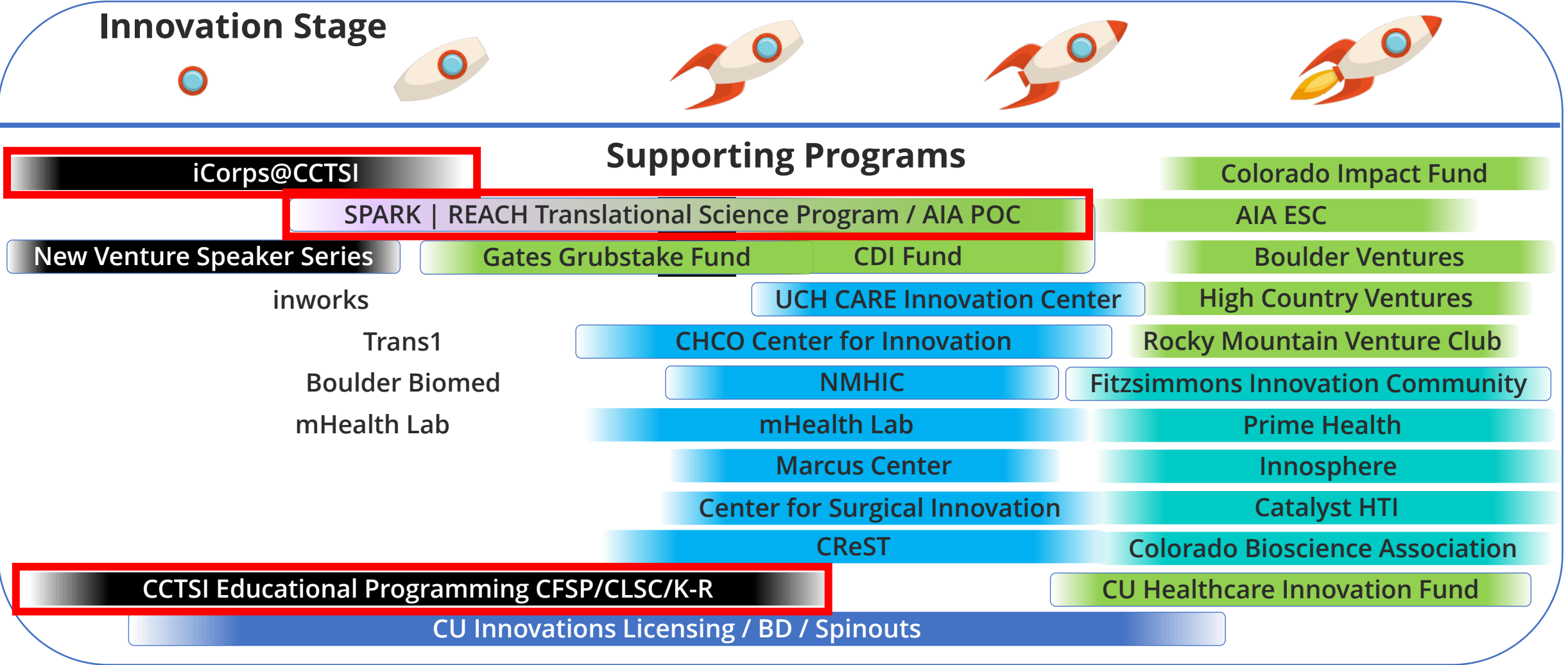


- **I-Corps @ CCTSI**
- Teams of faculty, staff or students with a biomedical discovery or health innovation idea.
- Uses customer discovery methods used for startups for academic researchers
- A team-based short course designed for faculty, staff and students
- Guides teams through early stages of customer discovery
- Test the business model hypotheses for a technology or idea
- **Spring 2022 I-Corps@CCTSI training will be held April 7, 8 and 29**  
**Location: virtual vs in-person at AMC is yet to be determined**





# AMC INNOVATION ECOSYSTEM



CU Innovations  
Affiliated

Education

Funding Sources

Clinical Validation

Community Partners

Product Development

Licensing/BD/Spinout

# Communicating Your Science to the Public

Comilla Sasson, MD, PhD

***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



# Community Engagement & Research Programs

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)

*trialinnovationnetwork.org*

- 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
- First contact the Hub Liaison Team for assistance and guidance



# Trial Innovation Network Hub Liaison Team

- **Director:** Adit Ginde, MD, MPH
  - **Medical Directors:** Tom Campbell, MD (UCH)  
Jesse Davidson, MD (CHCO)
  - **Project Manager – Aaron Mobley PhD** Phone: 720-848-5523  
aaron.mobley@cuanschutz.edu
  - **Contracting Lead** – Amanda Peng
  - **Central IRB Lead** – Christy Williamson
  - **Recruitment (Participants) Lead** – Barbara Hammack
- Local TIN Website, workflow, educational materials, etc.





# RKS - Clinical Research Support Center (CRSC) — Alison Lakin, RN, JD

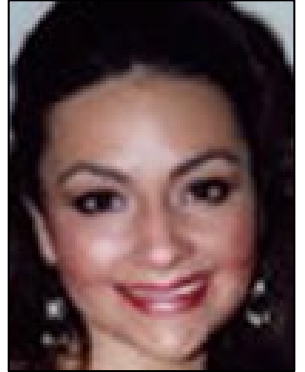
- FDA submissions
- Education and training on all aspects of study start up and management
- Assistance with IRB submissions
- Access to and maintenance of ClinicalTrials.gov records
- Research agreements (confidential disclosure agreements, clinical trial agreements and materials transfer agreements)
- Study drug/device management advice
- OnCore, the clinical trials management system



<https://research.cuanschutz.edu/crs>

# Diversity, Equity, Inclusion, Systematic Racism

- Posted “COVID-19 Impact on Latinos” Fact Sheet on website
- 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



# CCTSI NIH Grant Renewal in 2022

- Current 5-year grant cycle ends in 2023
- New: 7 simultaneous grant applications are required for renewal, deadline for submission for all is May 13, 2022
- Good news – the main grant, UM1, may be funded for 7 years
- Much planning and writing is ongoing
- Thank you to the many teams working on this application



# CCTSI is here to support you!

- <https://cctsi.cuanschutz.edu> or google “CCTSI”
- Become a Member (quick, free, powerful)
- Become familiar with the website
- Use PROFILES often
- Cite our Grants



# QUESTIONS

