Welcome

Thomas Flaig

Vice Chancellor for Research

Agenda

10:00a-12:15p- Speaker Presentations

12:15p-12:30p- Short Break to grab lunches

12:30p-2:00p- Interactive Workshop

CU University of Colorado
Anschutz Medical Campus

Jameel Mallory

Director of Community Data & Strategic Initiatives

Office of Diversity, Inclusion and Community Engagement

University of Colorado
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OFFICE OF DIVERSITY, EQUITY, INCLUSION & COMMUNITY ENGAGEMENT

#EveryoneBelongsHere

CU Office of Diversity, Equity, Inclusion and Community Engagement

UNIVERSITY OF COLORADO **ANSCHUTZ MEDICAL CAMPUS**

Agenda

Time flies when your having fun!

- Introduce our Office: Who we are & What we do

- Briefly discuss our DEI Strategic Initiatives

- Connecting DEI & Research

- URM Research Faculty Data

- Get Connected

Office of Diversity, Equity, Inclusion and Community Engagement
UNIVERSITY OF COLORADO **ANSCHUTZ MEDICAL CAMPUS**

UNREST

In 2020 the social and political climate in the country was at an all time high. **This was the year that Office of Diversity, Equity, Inclusion and Community Engagement was established**. Addressing institutional racism became a top priority for our campus.

Office of Diversity, Equity, Inclusion and Community Engagement
UNIVERSITY OF COLORADO **ANSCHUTZ MEDICAL CAMPUS**

Who We Are

- We're a **diverse and eclectic group** of 16+ Educators, Healthcare Professionals and DEI Practitioners

- **We provide centralized support, resources and campuswide oversight** for offices, departments, centers and institutes working on DEI project, policies, programs and initiatives

- We are governed by the **Chancellor's DEICE Leadership Council** which is comprised of 6 Dean appointed DEI Leaders w/ FTE. from the schools/college, and approximately 20+ representatives from campuswide business units & hospital partners
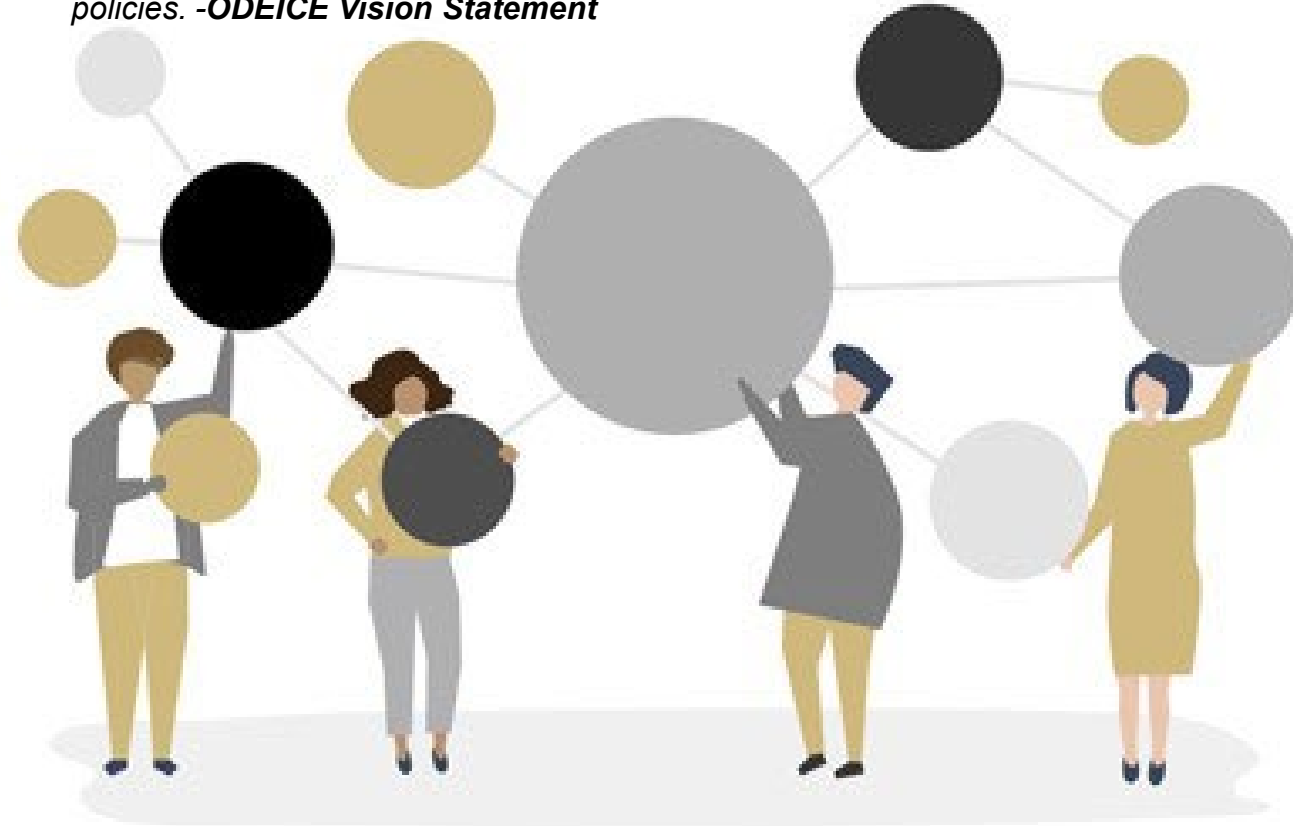
*We are committed to transforming and advancing policies, programs and practices that address social injustices and health disparities **alongside** the communities we serve – **ODEICE Mission Statement***

LEADING *TOGETHER*

Office of Diversity, Equity, Inclusion and Community Engagement
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What We Do

We aspire to build a medical campus community that thrives on diversity, equity, inclusion and community engagement; strives to eliminate social injustices and health disparities through measurable commitments, strategic, systemic and sustainable systems of accountability; and demonstrates trust and respect for ALL through inclusive practices and policies. -**ODEICE Vision Statement**

- **DEI Training & Education -** Health Equity in Action (HEAL) Lab & LGBTQ+ Hub

- **Educational Pathways & Community Engagement/Outreach Programs -** Resident Leadership Council, El Alba Co-op, Science & Career Exposure, CUPS and UPP programs

- **Provide Strategic Direction -** Vice Chancellor of DEI, Data & Evaluation Core, Partnership with the Office of Strategic Initiatives

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Leveraging Data

- ORIE URM Student/Employee Data
- Leadership Council Policy & Practice Survey
- Office of Equity (*Affirmative Action Data*)
- Human Resources (*Employee Retention Data*)
- CWC Survey & Action Plans
- OVCR Bioinformatics Research Data
- DEI Campus Directory and Resource Repository
- Campuswide CRM

Research

- Anschutz Center for Health Equity (*New Executive Director*)
- CRIO Council (*Office of Vice Chancellor of Research*)
- (OARS) Older Adult Research Specialist Program

Patient-Centered Care

UCHealth & Children's Hospital

Center for Health Equity

(AWC) Aurora Wellness Community
Aurora Health Access

ODEICE PRIORITIES

MISSION FOCUSED AREAS
&
STRATEGIC ALIGNMENT

Education

- Education Outreach & Career Pathways Programs ($1M HRSA grant)
- (HEAL) Health Equity in Action Lab
- (OARS) Older Adult Research Specialist Program
- CIMER Campus-wide Mentoring Program
- LGBTQ+ Hub
- Restorative Justice Program
- Search Advocate Training Program

Community Engagement

- Resident Leadership Council
- El Alba Co-op (Community Wealth Building)
- Supplier Diversity Initiative
- (OARS) Older Adult Research Specialist Program
- LGBTQ+ Hub

Investing in our people

- Holistic Hiring
- Staff Career Pathways
- Search Advocate Training Program (*Pilot Project*)
- Elevating the Student Experience
- Sense of Belonging

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Graphic designed in partnership with the Office of Strategic Initiatives
www.cuanschutz.edu/offices/strategic-initiatives

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ADDRESSING SOCIAL DETERMINANTS

Reaching Beyond the Walls

Employment & Economic Stability

Search Advocate Training Program - this program embodies our commitment to recruiting, hiring and retaining diverse faculty, staff and trainees.

Supplier Diversity Initiative - is designed to connect CU Anschutz to local businesses in North Aurora, NE Denver to meet some of the University's needs for good and services by including diverse, minority owned businesses in our supply chain.

El Alba Food Cooperative - offers culturally appropriate business incubation, via a co-op model, and shared access to a commercial kitchen and food truck to economically disadvantaged business owners.

OARS Training Program - is a program where older adults can embrace careers in research and provide leading an innovative solutions to address the problem of a lack of participant diversity in clinical trials.

Access to Quality Education

Educational Outreach & Pathway Initiatives - provides programs (CUPS and UPP) to increase the number of underrepresented populations in healthcare.

Social & Environmental Safety

Resident Leadership Council - a group of community leaders dedicated to improving the quality of life of residents in Aurora and the surrounding neighborhoods by promoting equitable access to education, health, and economic opportunities.

Access to Quality Health Care

Center for Health Equity - is a research center being designed to eliminate disparities in health care because of race, gender, age, socioeconomic status or geography.

Aurora Wellness Community & Aurora Health Alliance – are two strategic partners among many in Aurora

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UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

Connecting DEI to Research

The Science of Integration

We are committed to transforming and advancing policies, programs and practices that address social injustices and health disparities **alongside** the communities we serve. –ODEICE Mission Statement

Some things to think about are…

Who is missing? Is my research lacking a diverse perspective? e.g., race, gender, sex, socio-economic status etc.

What am I missing? What can be achieved by integrating DEI within my research? What are my DEI research deficits?

Where does Bias show up in research? How does incorporating an equity lens help to address bias and enhance research?

When does research objectives conflict with Equity? For example, deciding to start a recruitment cycle for a clinical trial during cultural holidays.

Why is Diversity important to research? Only you can answer that question.

How can DEI optimize my research? Each research project is different which means that this question should be asked constantly, even before applying for grants.

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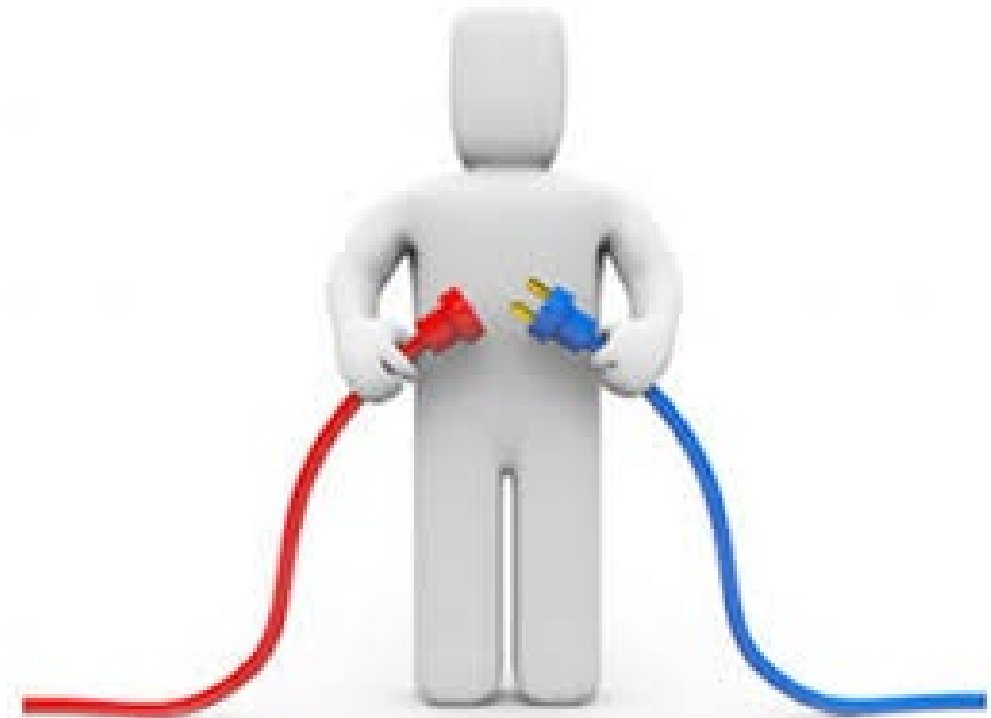
BE before you DO

WE ALL HAVE A PIECE OF THE PUZZLE and EACH PIECE IS NEEDED

Some things to remember…

Relationships are the Key to Research: No matter basic science, clinical research or bioinformatics, remember that it all goes back to people, and people are more than subjects, projects or problem to be solved.

Intentionality: Remember to set your intentions on developing meaningful, bi-directional relationships.

Connect with the community: Remember that trust is earned; where there no relationship, there is no trust.

Value unique perspectives: Remember that we all bring a unique perspective to the table based on life experience. Nonetheless, our perspectives are limited in scope. DEI us helps to expand our limitations.

We are committed to transforming and advancing policies, programs and practices that address social injustices and health disparities **alongside** the communities we serve.

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A Glance at Research Faculty

ANSCHUTZ MEDICAL CAMPUS

	Total	People of Color* #	People of Color* %	American Indian/ Alaska Native #	Asian #	Black/ African American #	Hispanic/ Latino #	Native Hawaiian /Pacific Islander #	More than one race #	White #	Unknown #	Inter-national[1] #	Disability[2] #	Disability[2] %
Faculty	**5,511**	**867**	**16%**	**13**	**465**	**63**	**271**	**5**	**50**	**3,564**	**932**	**148**	**75**	**1%**
Instructional Faculty	4,541	648	14%	13	333	51	205	4	42	3,062	800	31	64	1%
Tenured/Tenure Track	**2,379**	**398**	**17%**	**8**	**228**	**26**	**110**	**3**	**23**	**1,604**	**356**	**21**	**37**	**2%**
Full Professor	591	83	14%	2	46	1	26	-	8	461	45	2	11	2%
Associate Professor	735	132	18%	2	73	8	44	2	3	525	76	2	14	2%
Assistant Professor	1,053	183	18%	4	109	17	40	1	12	618	235	17	12	1%
Non-Tenure Track	2,162	250	12%	5	105	25	95	1	19	1,458	444	10	27	1%
Instructor/Sr. Instructor	1,647	176	11%	1	70	17	69	1	18	1,094	371	6	21	1%
Other	515	74	14%	4	35	8	26	-	1	364	73	4	6	1%
Research and Public Service Faculty**	**970**	**219**	**26%**	-	**132**	**12**	**66**	**1**	**8**	**502**	**132**	**117**	**11**	**1%**
	-													
Staff	**5,768**	**1,532**	**27%**	**35**	**441**	**285**	**683**	**11**	**77**	**3,131**	**1,058**	**47**	**155**	**3%**
Officers	23	2	9%	-	-	1	1	-	-	19	2	-	-	0%
With Faculty Status	8	2	25%	-	-	1	1	-	-	6	-	-	-	0%
Without Faculty Status	15	-	0%	-	-	-	-	-	-	13	2	-	-	0%
Management/Other Professionals/Support Staff	5,745	1,530	27%	35	441	284	682	11	77	3,112	1,056	47	155	3%
With Faculty Status	1,581	376	24%	13	133	26	177	3	24	969	215	21	46	3%
Exempt Professionals	3,866	1,027	27%	19	296	216	440	6	50	1,992	821	26	101	3%
Classified Staff	298	127	43%	3	12	42	65	2	3	151	20	-	8	3%
Faculty/Staff Total	**11,279**	**2,399**	**22%**	**48**	**906**	**348**	**954**	**16**	**127**	**6,695**	**1,990**	**195**	**230**	**2%**

Race/Ethnicity and *Disability[2]* are column group headers.

1 "Nonresident alien" is a cateogry reported within race/ethnicity in the IPEDS HR survey. The race/ethnicity categories are meant to reflect U.S./domestic categories of race and ethnicity.

2 Disability indicates only those employees who have self-identified as having a disability to the UCD|AMC HR office.

Opportunities to get Connected

Visit our Website

- **Recruit Diverse Talent**: Work our trained *Search Advocates*, learn how to *Attract, Attain and Retain* diverse researchers and ensure that the search process is equitable.

- **Get Involved in Community**: Signup for our *Community and Campus Connections* weekly email, build relationships with our campus neighbors.

- **DEI Training & Education**: Get connected with our *HEAL Lab & LGBTQ+ Hub*

- **Support URM Junior Faculty**: Find ways uplift underrepresented researchers through mentorship, and grant writing opportunities.
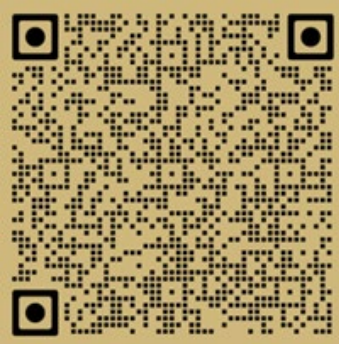
www.cuanschutz.edu/offices/diversity -equity-inclusion-community

Email Us:
odeice@cuanschutz.edu
jameel.mallory@cuanschutz.edu
regina.richards@cuanschutz.edu

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Thomas Campbell

Professor, Department of Medicine-Infectious Disease

University of Colorado Anschutz Medical Campus

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Anschutz Medical Campus

DEI Focused Recruitment for the COVID-19 Vaccination Studies

Thomas Campbell, MD
Department of Medicine/Infectious Diseases Division

University of Colorado
Anschutz Medical Campus

Moderna COVE study

Geographic distribution
Interim data snapshot - October 21, 2020 - subject to change

moderna
© 2020 Moderna

"Given the disproportionate disease burden of COVID-19 in racial and ethnic minorities, the study will also aim to enroll a representative sample of participants from these minority population and adjust site selection and enrollment accordingly"
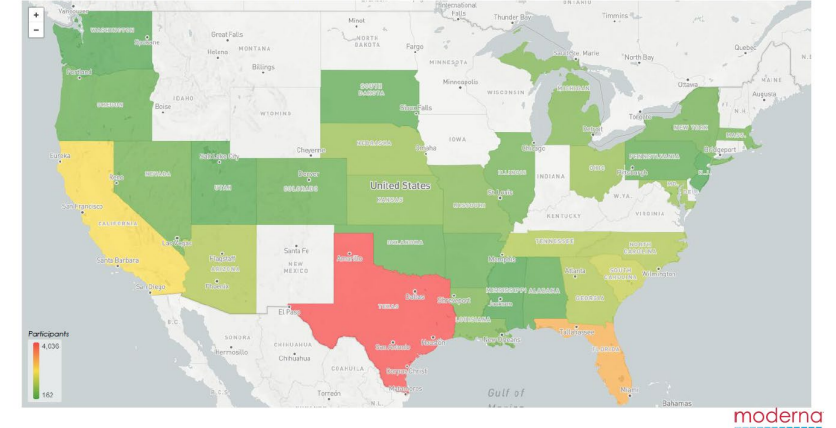
- <u>Purpose</u>: Demonstrate the safety and efficacy of mRNA-1273 COVID-19 vaccine
- <u>Design</u>: Phase 3 randomized placebo-controlled clinical trial
  - 1:1 randomization to active vaccine or placebo
  - Double blinded
  - Oversight by NIAID DSMB
- <u>Study population</u>: Individuals at high risk of COVID-19 either due to occupation, living circumstances, age, or health conditions
- <u>Planned duration</u>: 25 months
- Enrollment 27 July – 23 October 2020
  - >30,000 participants at 90 sites across the United States

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Local approaches for diverse enrollment

- Community outreach activities
  - Community Outreach Co-investigator – Dr. Jose Castillo Mancilla
  - CCTSI Community Engagement consult
  - Endorsements by local community members
  - Local community groups
  - Local media coverage
- Clinical trials registries
  - NIH national registry (COVID Prevention Network)
  - Local registry through UCHealth Epic

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Outreach

UCHealth COVID Vaccine Research Registry (N = 124,000)

Diversity Results

UCHealth/CU-AMC

217 participants
- 88 Female (41%)
- 59 ≥ 65 years (27%)
- 110 People of Color (51%)
  - 64 Hispanic (30%)
  - 19 Black (9%)
  - 6 Asian (3%)
  - 15 Native American (7%)

National

30,351 participants
- 14,366 Female (47%)
- 7,512 ≥ 65 years (25%)
- 12,280 People of Color (40%)
  - 6,235 Hispanic (21%)
  - 3,090 Black (10%)
  - 1,382 Asian (5%)
  - 233 Native American (0.8%)

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Lessons Learned

Combining community outreach and an EHR-based research registry facilitated rapid recruitment of a cohort of research participants with diverse race, ethnicity, age, and sex

Caveats

- COVE was implemented in response to a national health emergency
  - High public awareness and motivation
  - High level of media coverage
  - High level of institutional support
- Recruitment was rapid
  - 30,000 enrolled in less than 3 months
- DEI was a priority from the start
  - NIH leadership required diversity – diversity targets clearly stated
  - Enrollment was closed nationally to non-Hispanic Caucasians when protocol diversity goals were not being met
- Although racial, ethnic, sex and age diversity was achieved, socioeconomic diversity was not targeted

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THANK YOU

Erin Sandene

Director, Research Operations and Administration

Children's Hospital Child Health Research Enterprise

Darcy Thompson

Interim Clinical Research Director

Children's Hospital Child Health Research Enterprise

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Patricia Gesualdo

Senior Research Instructor

Barbara Davis Center for Diabetes

Flor Sepulveda

Research Services Principal Professional

Barbara Davis Center for Diabetes

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Shared Experience in the Inclusion of a Spanish-Speaking Cohort in T1D Research

Flor Sepulveda, Research Services Principal Professional
Tricia Gesualdo, Senior Research Instructor
Barbara Davis Center for Diabetes
Clinical Epidemiology Division

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Anschutz Medical Campus

Background

- Hispanic youth have a 4.2 percent annual increase of new diagnosed cases of type 1 diabetes.

- 60% of Colorado youth present in diabetic ketoacidosis (DKA) at onset of type 1 diabetes.

- < 6% of active study participants present in DKA.

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Mayer-Davis, et al N Engl J Med, 2017
Alonso, et al Diabetes Care, 2020
Jacobsen, et al Diabetes Care, 2022

Background

- NIH-funded studies focus on:
  - identifying high genetic risk children
  - discovering environmental triggers
  - delaying, preventing and treatment

- JDRF is committed to the promotion of general population screening to reduce life-threatening DKA in children.

What did we do?

- Targeted hospitals for recruitment

- Hired bilingual screeners to recruit

- Employed culturally-sensitive bilingual research assistants to conduct study visits

- Tailored translations of informed consent and subject materials

- Promoted the professional growth of the existing bilingual staff

Results

- Of 110,000 screened, over 12,000 are Spanish speaking preferred.

- Increased Spanish speaking screening from 5.3% to 23.4%

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Screening of Spanish Speaking Preferred Cohort by Study

Screened

76714

5.3%

34055

23.4%

4004

8022

TEDDY 2004-2010

ASK 2017-PRESENT

■ Total Screened ■ Total SSP
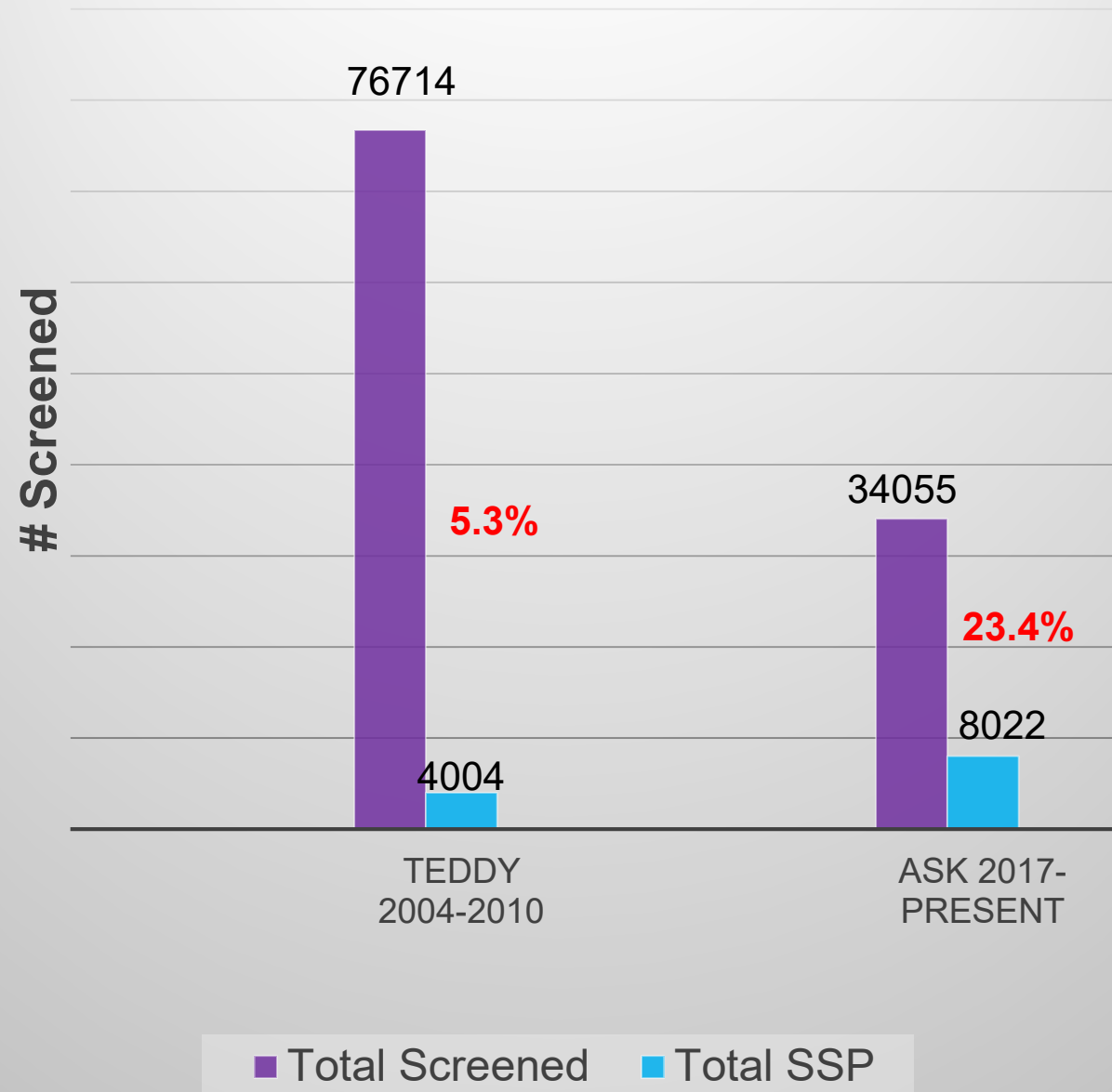
Lessons Learned: What works?

- Staffing of 2 or more bilingual research staff to ensure 100% coverage.

- Translation of all education materials, newsletters, source documents, and informed consents/assents.

- Creative approaches to address lack of trust in research

- Use of technology to conduct research visits

- Adapting flexible hours of operation

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What can be improved?

- Diversity in the research investigators

- Ensuring bilingual staff are supported in training and workload

- Improve innovative approaches for recruitment

- Solid plan for community and stakeholder partnerships

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Additional resources?
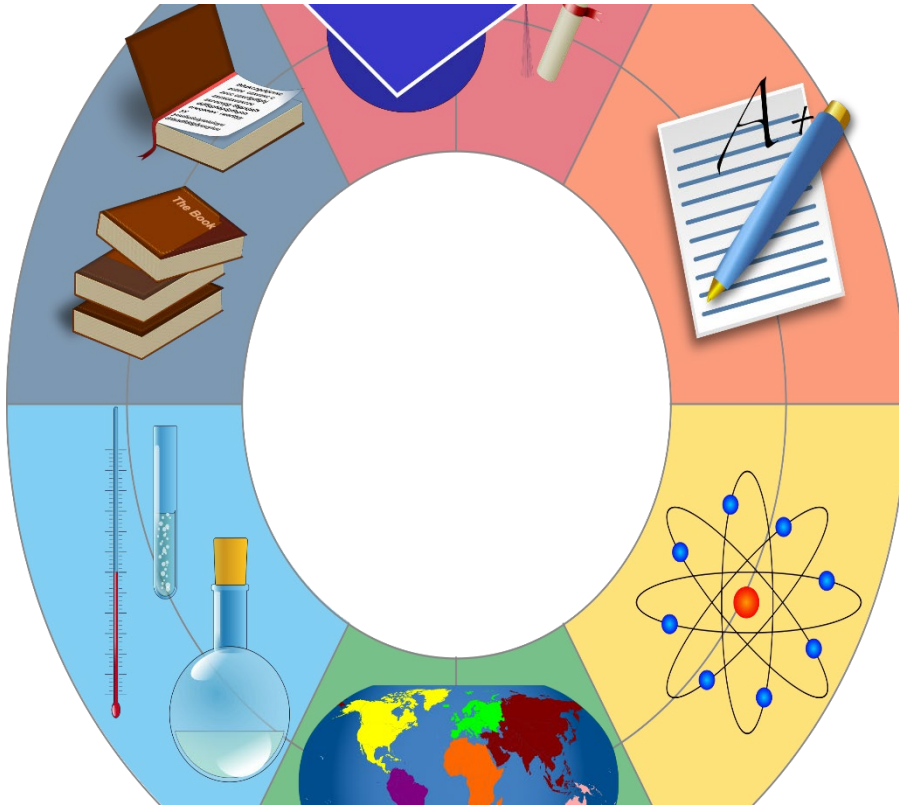
- Translation services

- Promotion and support for bilingual staff professional development opportunities

- Diverse physician/advanced practice/subject matter expert consultation

- Building a research coordinator support network

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THANK YOU

Bethany Kwan

Associate Professor and Associate Vice Chair for Research

Department of Emergency Medicine

University of Colorado
Anschutz Medical Campus

Designing for Dissemination: Promoting Equitable Access to Treatment for COVID-19

mAb Colorado Specific Aims

Dissemination, Implementation, and Real-World Effectiveness of Neutralizing Monoclonal Antibody Therapy for COVID-19

Using a type 2 hybrid implementation-effectiveness design:

- Aim 1: Assess barriers and facilitators to use of mAbs statewide, based on diffusion of innovations theory

- Aim 2: Develop, implement, and evaluate innovative strategies statewide to optimize equitable mAb access

- Aim 3: Determine the real-world effectiveness and safety of mAb treatment in high-risk COVID-19 outpatients

Goals

- Develop scalable infrastructure for real-time, implementation and real-world effectiveness data for mAb treatment

- Help policymakers, clinicians, and patients manage issues of uncertainty, risk, urgency, equity, and resource limitation

- Create a model for rapidly generating high quality real-world evidence in infectious disease pandemics and other future public health emergencies

mAb Colorado Partners

SAP Kick Off Meeting_2021_0421

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https://dicemethods.org/stakeholder-panel
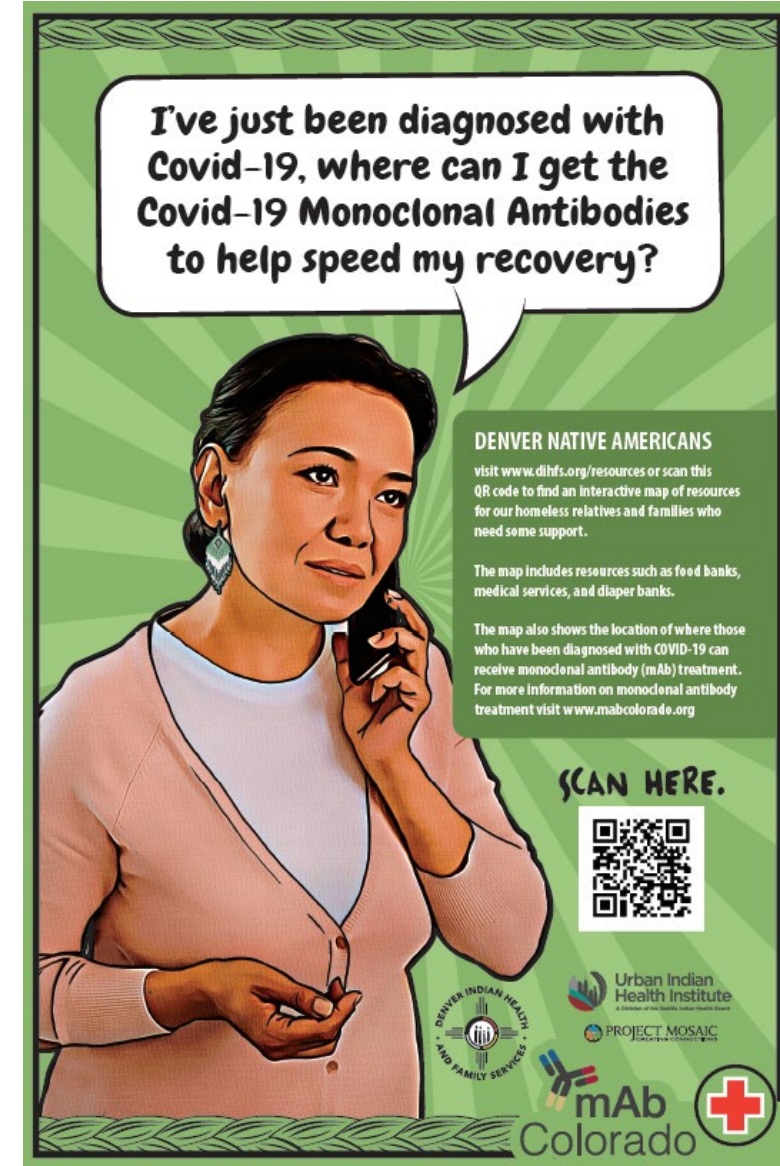
Health Equity Focus

- Equitable access to care
  - Rural areas
  - Racial and ethnic minorities
    - Hispanic/Latino
      - Spanish-speaking communities
    - Native American communities
  - People who were:
    - Uninsured/underinsured
    - Undocumented
    - Unhoused

- 68 total items (awareness & attitudes towards COVID-19 treatment)
- Administered via REDCap (https://cctsi.cuanschutz.edu/resources/informatics/redcap-resources)
- Initially developed in English; Professionally translated into Spanish, French, Amharic, Russian, Korean, and Vietnamese
  - Landmark Associates (https://www.thelai.com/)
  - Languages recommended by Stakeholder Advisory Panel (SAP) members
- Eligibility: adults at least 18 years of age living in Colorado who self-identified as high risk for poor outcomes from COVID-19 or as a proxy decision maker for someone at high risk
- Compensation: $25 e-gift card (Tango card: https://www.tangocard.com/)

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05/06/2021 9:04am

projectredcap.org REDCap

Confidential

Page 3

Tests and Medications for COVID-19
The following questions are about your thoughts, opinions, and personal experiences with tests and medications for COVID-19. Please answer the following questions as accurately as possible. There are no right or wrong answers.

1. How much have you heard about each of the following?

	Nothing at all	Unsure	A little	A moderate amount	A lot
Medical tests (e.g., nasal swab) to determine if a person currently has COVID- 19?	○	○	○	○	○
Vaccines to prevent a person from getting COVID-19?	○	○	○	○	○
Monoclonal antibody medications to treat COVID-19?	○	○	○	○	○
Other medications to treat COVID-19?	○	○	○	○	○

- **Recruitment goal: 450**
  - Overrepresent respondents who identified as Hispanic/Latino relative to state demographics and those from rural areas
- **Recruitment strategies**
  - Flyers co-designed by SAP members, available in Spanish, English, and French, with QR code
  - Distributed by team and partners via email or in-person to over 100 community organizations and public entities (libraries and health departments, and primary care practices or providers)
  - Survey link shared on the project website and social media platforms (Facebook and Twitter)
  - posts were also shared by various health departments and community members on their social media.

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- **Recruitment Goal**
  - 8 Focus Groups (6 in English, 2 in Spanish; 2 in rural areas)
  - 8-10 people each (60-80 total)
- **Modality**
  - 90 minutes, all over Zoom
- **Compensation**
  - $100 e-gift card
- **Recruitment Strategies**
  - Surveys asked if respondents would be willing to be contacted to participate in a focus group
  - Emailed (batches of 20) and texted (batches of 10)
  - Yielded too few for a 2nd Spanish-language focus group
  - Partnered with Aurora's 2040 Partners for Health to do focused recruitment from the Hispanic/Latino community
    - 11 mAb Survey Ambassadors (all Hispanic/Latino)
    - Recruited from the organization's client community

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Banner CERTIFICATE OF COMPLETION

Has completed 90 minutes of Human Subjects training

Completed as of: October 25, 2021

Christy Williamson
Assistant Director | Clinical Research Support Center | University of Colorado Denver
13001 East 17th Place | MS F497 | Aurora, CO 80045 | 303-724-1111

Survey Ambassadors completed a special COMIRB Human Subjects training

Community Participant Characteristics	Overall (n=515)	Non-Focus Group Participant (n=445)	Focus Group Participant (n=69)
Age in Years: Mean (SD)	44.4 (13.9)	43.9 (13.9)	47.6 (13.7)
Gender: N (%)			
Man	120 (23.4)	105 (23.6)	15 (22.1)
Woman	383 (74.7)	331 (74.4)	52 (76.5)
Non-binary	9 (1.8)	8 (18)	1 (1.5)
Prefer not to say	1 (0.2)	1 (0.2)	0 (0.0)
Race/Ethnicity: N (%)			
Black/African American	36 (7.0)	32 (7.2)	4 (5.8)
White/Caucasian	282 (55.0)	248 (55.9)	34 (49.3)
Hispanic or Latino/a (any race)	141 (27.5)	115 (25.9)	26 (37.7)
Asian	12 (2.3)	12 (2.7)	0 (0.0)
Native Hawaiian/Pacific Islander	1 (0.2)	1 (0.2)	0 (0.0)
Native American/Alaska Native	9 (1.8)	7 (1.6)	2 (2.9)
Other	4 (0.8)	4 (0.9)	0 (0.0)
More Than One Race	28 (5.5)	25 (5.6)	3 (4.3)
Employment Status: N (%)			
Employed	391 (75.9)	343 (76.9)	48 (69.6)
Not Employed	99 (19.2)	84 (18.8)	15 (21.7)
Other/Prefer not to answer/No response	25 (4.9)	19 (4.3)	6 (8.7)
Education: N (%)			
High School/Some College	170 (33.0)	151 (33.9)	19 (27.5)
College Degree	203 (39.4)	183 (41.0)	20 (29.0)
Post Graduate Degree	131 (25.4)	104 (23.3)	27 (39.1)
Prefer not to say/No Response	11 (2.1)	8 (1.8)	3 (4.3)

Community Member Survey and Focus Group Insights

- Little baseline knowledge about monoclonal antibody treatment
  - Especially among Spanish-language participants
- Overall positive impression of monoclonal antibody treatment
- Key questions to be answered in information about mAb
  - Who can get it?
  - How can you get it?
  - How much does it cost?
  - What are the side effects?
- Priorities
  - Spread the Word-information about mAb should be shared across all available media
  - Make it easy-reduce barriers to obtaining mAb treatment when needed
  - Don't make it political-right now mAb treatment is not politicized, keep it that way
  - Equitable access

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Kwan BM, Sobczak C, Gorman C, Roberts S, Owen V, Wynia MK, Ginde AA, Pena-Jackson G, Ziegler O, Ross DeCamp L. "All of the things to everyone everywhere": A mixed methods analysis of community perspectives on equitable access to monoclonal antibody treatment for COVID-19. Plos one. 2022 Nov 23;17(11):e0274043.
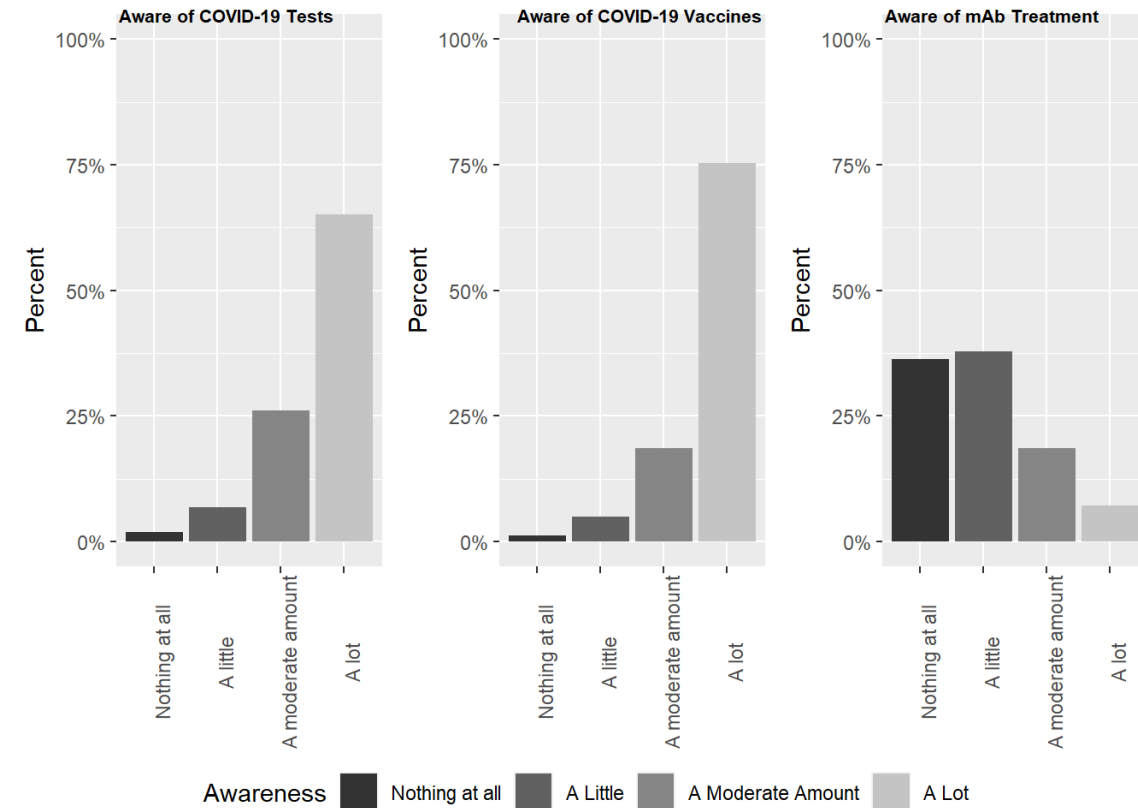
Community Member Survey and Focus Group Insights: Racial/Ethnic and Geographic Differences

- Urban/suburban focus group insights
  - More often referenced the use of national sources like the Centers for Disease Control or reading scientific manuscripts directly than other groups

- Rural focus group insights
  - Requested more specific information on the expected location of mobile treatment options.
  - Expressed concern about accessing mobile treatment sites given long distances between incorporated areas

- Spanish-language focus group insights
  - Overcoming potential barriers to treatment access within the Latino immigrant community specifically
  - Compared to English language focus groups' broader discussions of potential access disparities for multiple populations.

Attitudes towards mAbs by race/ethnicity	Overall	Hispanic/ Latino/a	White Non-Hispanic	Non-Hispanic POC	P*
N (%)	391	101 (25.8%)	228 (58.3%)	61 (15.6%)	
Willingness - mAbs (self): N (%)					.13*
No	9 (2.3)	2 (2.0)	3 (1.3)	4 (6.6)	
Yes	251 (64.2)	61 (60.4)	154 (67.5)	36 (59.0)	
Maybe	131 (33.5)	38 (37.6)	71 (31.1)	21 (34.4)	
Worry about hospitalization (self): N (%)					<.001*
Not at all worried	31 (8.0)	4 (4.0)	18 (7.9)	9 (15.0)	
A little/Somewhat worried	208 (53.5)	39 (39.0)	139 (61.0)	30 (50.0)	
Very worried	150 (38.6)	57 (57.0)	71 (31.1)	21 (35.0)	
IV Infusion Influence Decision to receive mAbs: N (%)					.004*
Less willing	60 (15.9)	22 (22.7)	26 (11.7)	12 (21.1)	
No difference	292 (77.5)	63 (64.9)	185 (83.3)	43 (75.4)	
More willing	25 (6.6)	12 (12.4)	11 (5.0)	2 (3.5)	
Willingness - Infusion sites - Hospital: N (%)					.031*
No	18 (4.7)	8 (8.3)	5 (2.2)	5 (68.5)	
Yes	323 (85.2)	75 (78.1)	197 (88.3)	50 (84.7)	
Maybe	38 (10.0)	13 (13.5)	21 (9.4)	4 (6.8)	
Willingness - Infusion sites - Specialty Care Center: N (%)					.051*
No	23 (6.2)	5 (5.6)	11 (4.9)	7 (11.9)	
Yes	284 (76.1)	61 (68.5)	177 (79.0)	45 (76.3)	
Maybe	66 (17.7)	23 (25.8)	36 (16.1)	7 (11.9)	
Willingness - Infusion sites - Mobile Care Unit: N (%)					<.001*
No	105 (28.8)	34 (39.5)	47 (21.4)	24 (41.4)	
Yes	130 (35.6)	21 (24.4)	86 (39.1)	22 (39.7)	
Maybe	130 (35.6)	31 (36.0)	87 (39.5)	11 (19.0)	

www.mAbColorado.org

Community Messaging Materials

See below for materials you can share with members of your organization or community about monoclonal antibody (mAb) treatments for COVID-19.

We are able to provide a limited number of printed materials mailed to you free-of-charge. If you would like to distribute printed materials to members of your organization or community, complete this order form.

Download flyer versions in English and Spanish with basic information about mAb treatments. Can be printed front-to-back.

Download document versions in English and Spanish with answers to common questions about mAb treatments.
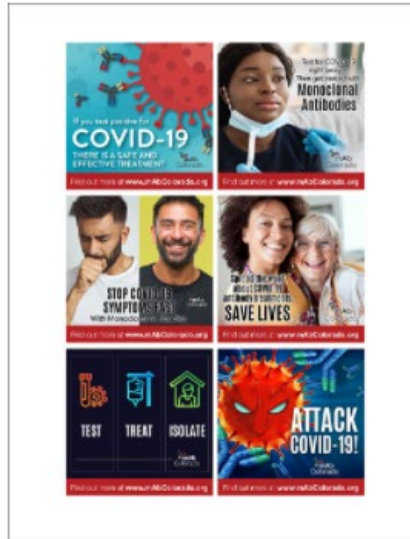
Download images to be shared as social media posts.
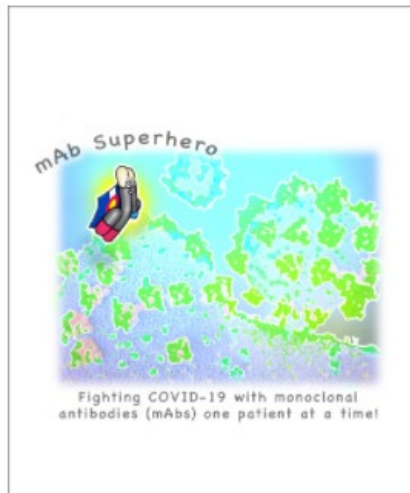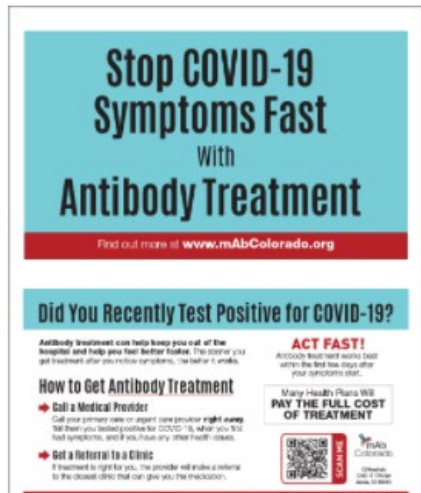
¿Dio positivo para COVID-19? Actua Rapido

Puede sentirse mejor mas rápido si recibe un tratamiento con anticuerpos. Puede ayudar a mantenerlo fuera del hospital. El tratamiento con anticuerpos funciona mejor si usted es tratado dentro de los primeros días después de haber dado positivo para COVID-19.

Para obtener mas información acerca del tratamiento de anticuerpos siga estos pasos:

➡ Llame a un proveedor médico de inmediato
- Llame a su proveedor de atención primaria o de atención urgente.
- Dígales cuándo tuvo los primeros síntomas de COVID-19.
- Dígales si tiene algún otro problema de salud.
- Pregúnteles si pueden ayudarle a obtener tratamiento con anticuerpos monoclonales.

➡ Obtenga una referencia a una clínica
Si el tratamiento con anticuerpos es adecuado para usted, el proveedor hará una referencia a una clínica cercana a usted donde usted puede obtener el tratamiento. Le darán la dirección y el número de teléfono de la clínica.

Muchos planes de salud pueden pagar el costo total del tratamiento

El tratamiento con anticuerpos funciona contra la variante delta COVID-19

mAb Colorado
www.mAbColorado.org

Number of MAb Referrals per 1,000 COVID-19 Cases, Nov 2020 - Jan 2021

Data Not Reported | 0.0 - 4.1 | 4.2 - 13.2 | 13.3 - 46.5 | >46.5

Number of MAb Referrals per 1,000 COVID-19 Cases, Feb - Apr 2021

Data Not Reported | 0.0 - 4.1 | 4.2 - 13.2 | 13.3 - 46.5 | >46.5

Number of MAb Referrals per 1,000 COVID-19 Cases, May - July 2021

Data Not Reported | 0.0 - 4.1 | 4.2 - 13.2 | 13.3 - 46.5 | >46.5
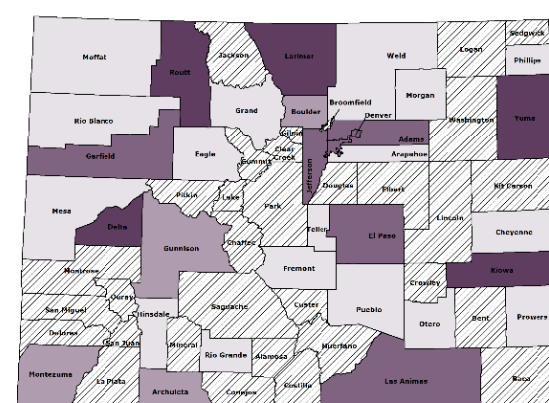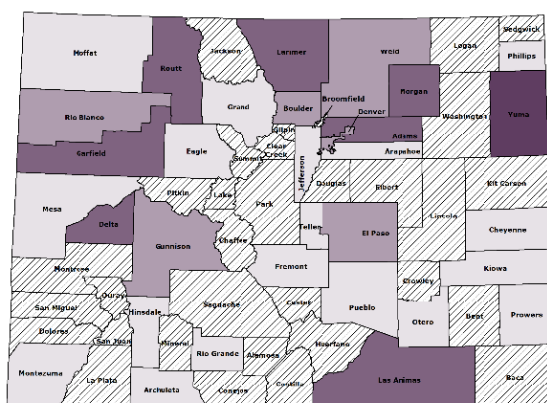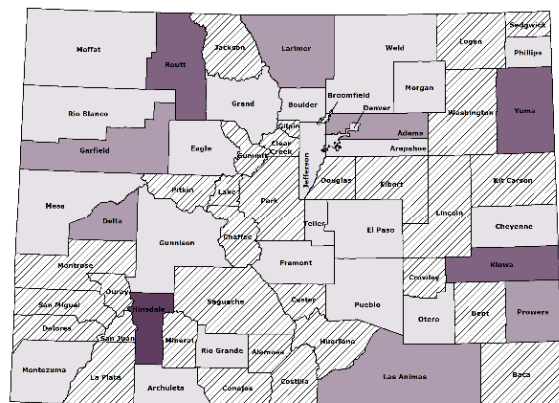
Pre (Top) vs Post (Bottom) mAb Colorado Dissemination

Number of MAb Referrals per 1,000 COVID-19 Cases, Aug - Oct 2021

Data Not Reported | 0.0 - 4.1 | 4.2 - 13.2 | 13.3 - 46.5 | >46.5

Number of MAb Referrals per 1,000 COVID-19 Cases, Nov - Dec 2021

Data Not Reported | 0.0 - 4.1 | 4.2 - 13.2 | 13.3 - 46.5 | >46.5
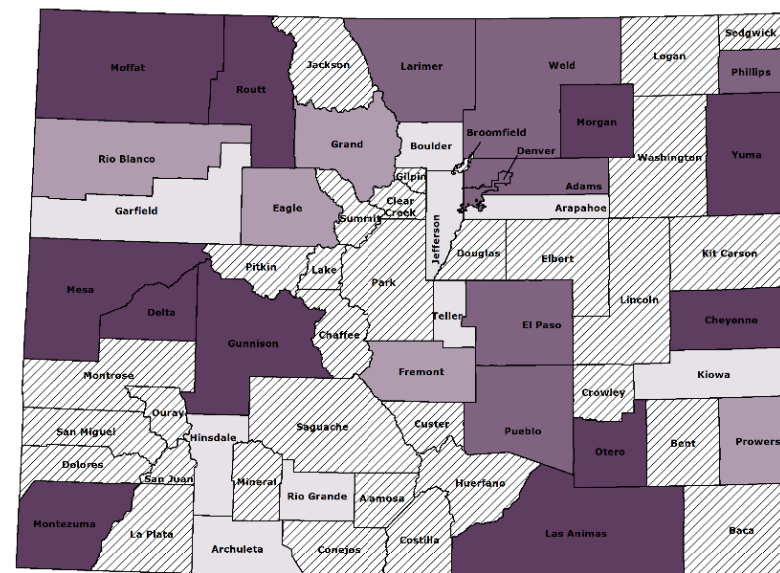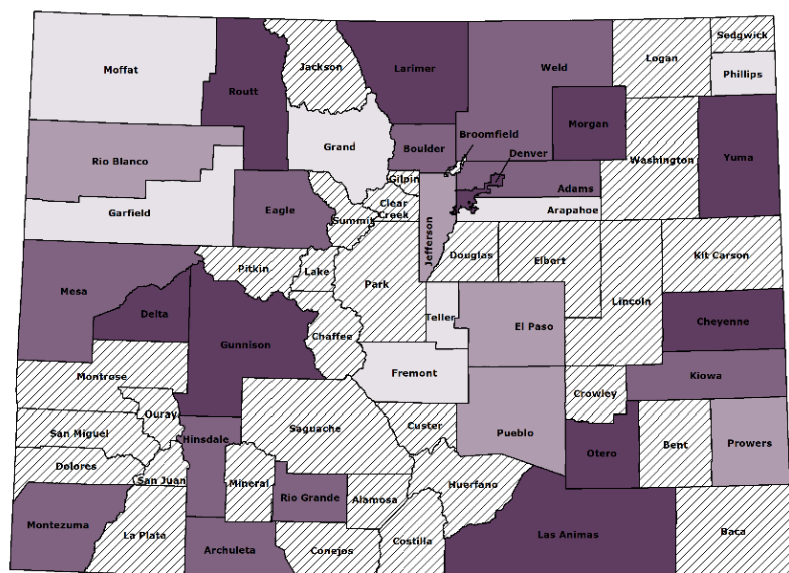
Average weekly mAb referral rates by Colorado county over time (November 2020-December 2021)

Dissemination & Implementation Science Resources

University of Colorado Anschutz Medical Campus

cctsi.cuanschutz.edu/resources/dissemination#ft-mentoring-and-consults-2

University of Colorado **Anschutz Medical Campus**

Webmail | UCD Access | Canvas | Quick Links ▾ |
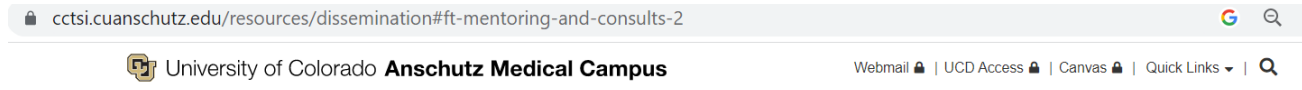
Clinical and Translational Research Centers (CTRC)

Campus Research Resources

Language For Your Grant Applications

Protocol Submission

Regulatory Knowledge and Support

DSMB Assistance

Translational Informatics

Biostatistics, Epidemiology, and Research Design (BERD)

Trial Innovation Network (TIN)

Recruit Participants

Research Ethics

Dissemination and Implementation Research

The CCTSI Dissemination & Implementation (D&I) Research Core supports innovation, education, and application of D&I science and evidence for the CCTSI community and the broader CTSA consortium. We offer support in three areas: D&I Science Resources; Educational Opportunities; Mentorship, Consultation and Collaboration.

We partner with the D&I Science Program led by Dr. Russell Glasgow in the Adult & Child Center for Outcomes Research & Delivery Science (ACCORDS) at the University of Colorado Anschutz Medical Campus.

D&I Science Resources | Educational Opportunities | Mentoring and Consults | CTSA Compendium of D&I Catalogs

If you want to share your study findings in:
- Press Releases
- Newsletters
- Policy Briefs
- Media Interviews
- Social Media
- YouTube
- Podcasts

Then ask for a CCTSI consultation!

CCTSI DISSEMINATION Service
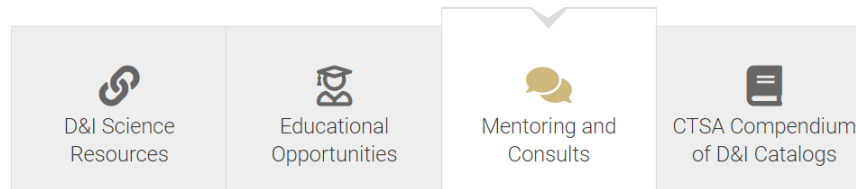
Share your impactful work beyond posters, presentations and papers

Using Design Thinking Methods to Create a Stakeholder Engagement Method Navigator Webtool for Clinical and Translational Science

Data Science to Patient Value (D2V) — UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

Purpose: The Stakeholder Engagement Navigator is an interactive webtool designed for use by researchers. It was created to help researchers choose engagement strategies while considering budget, timeline, stakeholder availability, and team expertise.

EMPATHIZE
- Review literature
- Conduct environmental scan
- Coordinate consults
- Host workshops
- Conduct ethnography

Stage 1

DEFINE
- Clarify core needs and problems
- Conduct method review and classification
- Determine user perspectives on classification

Stage 2

IDEATE
- Develop educational content
- Prioritize webtool features
- Storyboard website

Stage 3

PROTOTYPE & TEST
- Develop prototype
- Start user testing
- Begin web development
- Conduct Think Aloud testing
- Incorporate feedback

Stage 4

DICEmethods.org

Scan me!

Kwan, B. M., Ytell, K., Coors, M., DeCamp, M., Morse, B., Ressalam, J., Reno, J. E., Himber, M., Maertens, J., Wearner, R., Gordon, K., & Wynia, M. K. A stakeholder engagement method navigator webtool for clinical and translational science. J Clin Transl Sci. 2021;5(1):e180. Published 2021 Sep 13. doi:10.1017/cts.2021.850

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8596067/

@BethanyKwan
@MatthewWynia

Dissemination How To Guides:

Check out and download these helpful resources.
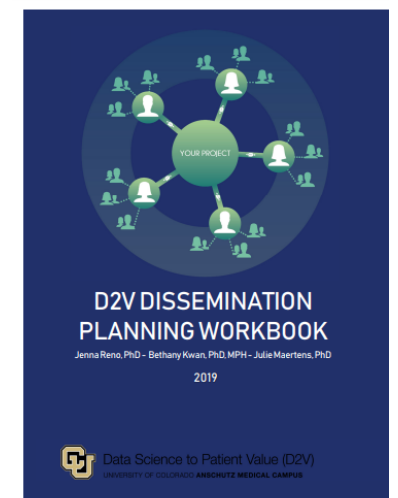
How to Create a Visual Abstract

D2V DISSEMINATION PLANNING WORKBOOK

Jenna Reno, PhD – Bethany Kwan, PhD, MPH – Julie Maertens, PhD

2019

Data Science to Patient Value (D2V) — UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

View and Download

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Don Nease

Director of Community Engagement & Research

University of Colorado Clinical and Translational Sciences Institute

Montelle Tamez

Deputy Director, Community Engagement and Health Equity

University of Colorado Clinical and Translational Sciences Institute

University of Colorado
Anschutz Medical Campus

Authentic Community Engagement to Reduce COVID-19 Vaccine Hesitancy
The Value of Investments in Community Relationships

Donald Nease, MD

Green-Edelman Chair for Practice-Based Research

Professor and Vice Chair for Community | Dept. of Family Medicine

Director of Community Engagement & Health Equity | Colorado Clinical & Translational Sciences Institute, University of Colorado Anschutz Medical Campus

University of Colorado
Anschutz Medical Campus

Colorado Community Engagement Alliance Against COVID-19 Disparities (CO-CEAL)

MISSION: *To provide trustworthy information through active community engagement and outreach to the people hardest-hit by the COVID-19 pandemic, including African Americans, Hispanics/Latinos, American Indians/Alaska Natives, and Asian Americans, Native Hawaiians and Pacific Islanders, with the goal of building long-lasting partnerships as well as improving diversity and inclusion in our research response to COVID-19*

Objective 1	Objective 2
Conduct urgent community-engaged **research and outreach** focused on COVID-19 awareness and education to address widespread misinformation and distrust in regard to COVID-19 and promote an evidence-based response to the disease	Promote and facilitate **inclusion of diverse racial and ethnic populations** in clinical trials (prevention, vaccine, therapeutics), reflective of the populations disproportionately affected by the pandemic

CO-CEAL

CO-CEAL engaged urban Hispanic and Latinx, rural Hispanic and Latinx, urban African/American, rural Somali Immigrant and urban American Indian/Alaska Native communities through Community Connectors in each community.

Community Connectors and Data Collectors led recruitment of community members for our community survey data collection (goal of 200 surveys x 3 time points from each community) and participation in our 5 Community (Boot Camp) Translations.

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Community Connector

Community Connector was hired in each community to act as a consultant to the project, recruit data collectors and Community Translation participants, and to manage research activities on the ground

Trusted and connected community member

Bilingual

Some knowledge of public health

Gatekeeper of Gatekeepers

Leadership and project management

Ensuring capacity building for community

Uphold cultural integrity

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SLV 2022

Data Collector

Community data collectors were hired in each community to recruit longitudinal survey cohorts of 100-200 people per community and to administer surveys

Must know community

Bilingual – ensuring language justice

Recruit study participants

Trusted

Uphold cultural integrity

Guiding Principle: Maintaining Cultural Integrity

- Respectful of relationships

- Community-led processes

- Reimbursement for all work
    - "Fair not Free"

- Value of knowledge

- Transparency

- Unique traditions

- Honoring history

- Observing cultural norms

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High Context Cultures

High vs. Low Context cultures provide a way of understanding why relationships and trust are so important.

- We (researchers) mostly operate in a Low Context Culture – information (science) is a commodity that has value outside of context

- In a High Context Culture context is critical. Is the information source known, trustworthy, and using cultural cues.

- Communities of color and indigenous communities are typically High Context Cultures

  Hall ET, Beyond Culture, 1976

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Estimadas Familias del Valle de San Luis,

El libro de actividades que tiene en sus manos fue diseñado por miembros de la comunidad del Valle de San Luis. Fue creado por personas como ustedes, quienes se unieron por preocupación por nuestros vecinos en la lucha contra el COVID-19 y otras enfermedades. Esperamos que proporcione una forma divertida para que su familia explore formas de mantenerse a salvo de infecciones mientras aprende lo que encontramos que son los datos más importantes sobre COVID-19.

Este trabajo se realizó como parte de Colorado Community Engagement Alliance Against contra COVID-19 diferencias o CO-CEAL. CO-CEAL está financiado por los Institutos Nacionales de Salud y está trabajando con seis condados de Colorado para enfrentar los graves efectos de la pandemia en los hispanos, negros e indios americanos/nativos de Alaska.

En el Valle de San Luis, la distribución de este libro de actividades se realiza en asociación con la Asociación de Salud Pública del Valle de San Luis, Valley Wide Health Systems, Rio Grande Hospital and Clinics y San Luis Valley Health. Estamos profundamente agradecidos por su asociación.

Sus amigos y vecinos,

Brenda Almeida
Gus Basterrechea
Paula Louise Espinosa
Juana Francisco
Matias Francisco
Carol Gurule
Lisa Lucero
Juanita Maestas

Oneyda Maestas – facilitator
Edgar Martinez
Lucia Miranda
Don Nease – facilitator
Eva Ramirez
Esteban Salazar
Antonio Sandoval
Jolene Webb

Community Translation

- Community members learn about COVID-19 vaccines
- Group decides which messages are most important to their community
- Group creates messages, materials and community dissemination plans

Results

Characteristic		CO-CEAL Sample Overall (N=709)	CO-CEAL Community Cohort			
			Urban Latinx Metro Denver & Pueblo (N=144)	Rural Latinx San Luis Valley (N=197)	Urban Black Metro Denver (N=180)	Rural Black Fort Morgan & Greeley (N=188)
Survey Language	English	575 **(81%)**	88 (61%)	166 (84%)	180 (100%)	141 (75%)
	Spanish	87 (12%)	56 **(39%)**	31 **(16%)**		
	Somali	47 (7%)				47 **(25%)**
Age	Mean (SD)	**41.8** (17.1)	**46.4** (17.8)	42.1 (17.3)	44.0 (17.7)	**35.8** (13.7)
	Median [Min, Max]	38.5 **[18, 101]**	45 [18, 101]	42 [18, 87]	42 [18, 92]	33 [18, 81]
Gender	Male	288 (41%)	38 (26%)	62 (31%)	83 (46%)	105 **(56%)**
	Female	413 **(58%)**	105 (73%)	132 (67%)	93 (52%)	83 (44%)
	Responded in another category	3 (0.4%)		2 (1%)	1 (0.6%)	
Education	Less than/some high school	133 (19%)	20 (14%)	31 (16%)	28 (16%)	54 **(29%)**
	High school graduate or GED	293 **(41%)**	58 (40%)	94 (48%)	88 (49%)	53 (28%)
	Any degree (Associate's/technical, Bachelor's, graduate)	208 (29%)	66 **(46%)**	67 (34%)	59 (33%)	16 (9%)
	Prefer not to answer	73 (10%)		5 (3%)	3 (2%)	65 **(35%)**
Employment status	Employed/working	442 **(62%)**	90 (63%)	142 **(72%)**	93 (52%)	117 (62%)
	Student	39 (6%)	6 (4%)	15 (8%)	4 (2%)	14 (7%)
	Retired	56 (8%)	20 (14%)	8 (4%)	26 (14%)	2 (1%)
	Other (unemployed, stay-at-home, on disability or leave)	172 (24%)	28 (19%)	32 (16%)	57 (32%)	55 (29%)
Any children in household		305 **(43%)**	59 (41%)	109 **(55%)**	70 (39%)	67 (36%)

Notes: **Preliminary** data entered as of January 3 (minimally cleaned). **Urban AI/AN** community excluded because **only 30 surveys** entered so far.

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Results

Rural Hispanic and Latino/a/x community

Urban African American/Black community

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Results

Urban American Indian/Alaska Native community

Urban Latino/a/x community

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Results
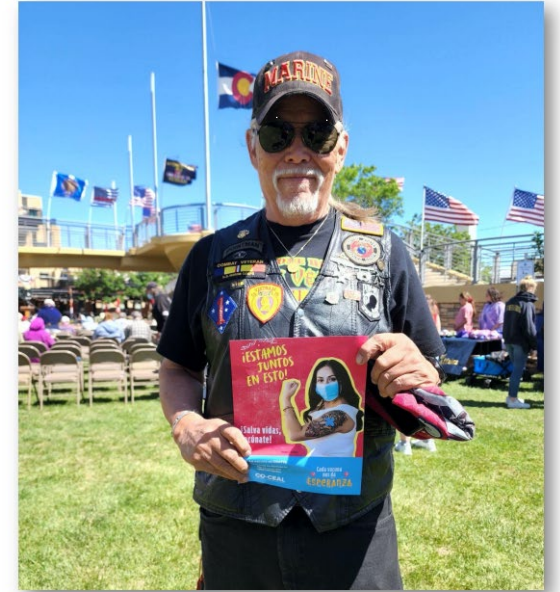
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Lessons Learned: What Worked?

- Community Connectors engaged community members rapidly and authentically in a matter of months, where it would have taken years to accomplish this goal using traditional approaches

- Hiring and training community members to serve as data collectors places data collection in the hands of trusted community members, allowing for a diverse sample within each community, including those most impacted by misinformation and vaccine hesitancy

- Prioritizing inclusiveness and flexibility at all stages of the project

- Prioritizing community safety

- Flexible human subjects research training model for data collectors

- Community training and capacity building

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Katherine (Kady) Nearing

Assistant Professor- Division of Geriatric Medicine

University of Colorado Anschutz Medical Campus

Jodi Waterhouse

Director, Outreach Programs

The Multidisciplinary Center on Aging

Innovative Approaches to Including Older Adults in Clinical Trials

Kathryn·Nearing,·PhD,·MA¶

Kathryn·(Kady)·is·an·Assistant·Professor·in·the·Division·of·Geriatric·Medicine·at·the·University·of·Colorado·Anschutz·Medical·Campus.· She·is·the·PI·of·a·National·Institute·on·Aging·R24·(research· infrastructure)·award·focused·on·increasing·the·inclusion·of·older· adults·in·clinical·trials·to·improve·health·care·and·health·outcomes· for·older·adult·populations.·The·two·aims·focus·on·1)·training·and· promoting·the·hiring·of·older·adults·to·serve·as·Older·Adult· Research·Specialists·supporting·the·recruitment·and·retention·of· peers·in·clinical·research,·and·2)·conducting·Research·Roadshows· across·Colorado·to·provide·older·adults·fun·experiential· opportunities·to·engage·with·research·and·research·teams.·Kady· also·serves·as·the·Associate·Director·for·Education·and·Evaluation· for·the·VA·Eastern·Colorado·Geriatric·Research·Education·and· Clinical·Center—a·VA·center·of·excellence·focused·on·aging.·For· the·GRECC,·Kady·directs·a·health·professions·training·program,·mentors·Advanced·Research·Fellows·and· coordinates·and·facilitates·the·Older·Veteran·Engagement·Team—a·group·of·8·Veterans·and·one·care· partner.·Members,·age·64-94,·provide·essential·feedback·and·input·on·aging-related·research·and· clinical·innovation·projects·to·enhance·services·and·supports·for·older·Veterans·and·caregivers.·¶

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Project Overview

- **Aim 1 (Yrs 1-3):** Train and promote the hiring of older adults to serve as **Older Adult Research Specialists** supporting the recruitment and retention of peers in clinical trials
  - Community outreach, engagement (recruitment)
  - Facilitating informed consent (supports recruitment and better retention by reducing decisional conflict)
  - Identifying barriers and connecting participants to needed resources (retention)
- Foundation: **Health Navigation** training
- **Computer literacy training** integrated throughout (Office Hours 2x/week)
- **Team-based projects** address barrier to inclusion of older adults in research (catalyzing innovation and development of resources)
- **Preparation for job application** process

CU Anschutz Today featured Older Adult Research Specialists Older Adults Embrace New Careers in Research (cuanschutz.edu)

Diverse Teaching Team

Matt Isola

Shannon Randall, BSN

David Kaye, JD

Katie Langland, MA

JR Kuo

Ron Blidar, M.Ed., CHES
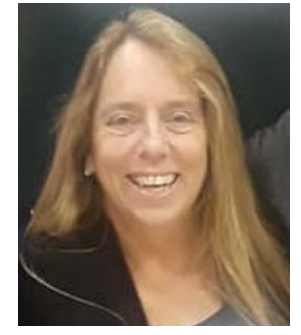
Kathy Crusan-Ford, BA

Kathryn Nearing, PhD

Leslie Wright, MA

Lorenzo Ramírez

Gordon Duvall, DNP

May Tran

Cory Sedey-Seitz, MPH

Christy Williamson, CCRP, CHRC

Applying Health Navigation Training to OARS Roles

Respect, Meeting People Where They Are, Building Rapport

- Respecting person's dignity, priorities, preferences, perspectives, situation, choice (No Judgement Zone)

- Demonstrating knowledge of person's culture

- Focusing on person's health goals

- Communicating in responsive ways e.g., based on awareness of culture, health literacy

    Draws on MI, True Colors, DEI, Cultural Competency

Partnering to Identify Barriers <u>and</u> Solutions

- Facilitating and partnering; not directing or telling

- Listening non-judgmentally seeking understanding

- Asking open ended questions

- Maintaining good working knowledge of resources and/or where to go to find information

- Identifying and drawing on strengths and assets

Trust

Facilitating the Informed Consent Process

Techniques health navigators use to support and check for understanding:

- Chunking

- Summaries

- Teach back (How might you explain [X] to someone else?)

- Promote transparency, trustworthiness, choice

Building Relationships while Maintaining Integrity to Professional Role

- Referring clinical issues/questions to principal investigator and/or clinical experts on team

- Maintaining working knowledge of organizational/institutional guidelines, policies and requirements

- Committing to professional excellence and ongoing learning and professional development

Multidisciplinary Center on Aging
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

Having trouble recruiting and retaining study participants?

Having trouble finding and retaining staff with the right skills, community connections?

WE HAVE RECRUITMENT AND RETENTION RESOURCES!

Older Adult Research Specialists (OARS)

- Trained in recruiting, consenting and retaining older adults and other underrepresented populations
- Bilingual, bicultural older adults who are connected to diverse communities
- Ready for research teams to hire; seeking full-time and part-time positions
- Interested in hiring an OARS? Scan the QR code

Traveling Research Roadshows

- Join us as we bring research to geographically/culturally diverse communities across Colorado to offer accessible ways to participate in research
- Invite people to a group interview, information and pre-consenting session (as a breakout session). They will enjoy the socialization, and you can enroll, consent, and do baseline data collection while getting to know them and getting them excited about the study.
- Interested in participating in Research Roadshows? Scan the QR code or email us at olderadultresearch@cuanschutz.edu

New Consult Service

- Free consultation service, available monthly
- Staffed by Older Adult Research Specialists
- Gives researchers new ideas and resources to support recruitment and retention
- Meet with us to brainstorm solutions and get feedback to increase participation of older adults and other underrepresented populations
- Request a consult by scanning the QR code

SCAN AND LEARN MORE AT

AIM 1

✓ Created comprehensive 14-week, 135-hour competency-based training curriculum delivered virtually; established diverse teaching team

✓ Site recognition for Health Navigation training program (eligible to be listed on Workforce Center Provider Training List)

✓ Held monthly Information Sessions (n=126), community meetings and leveraged networks to recruit increasingly diverse cohorts

✓ Trained 2 cohorts (high satisfaction; low attrition)

✓ 7 team-based projects

✓ 18 OARS graduates

✓ 12 OARS hired to date; 2 volunteer; 1 hired as a HN

✓ OARS written into 5 grant applications (Geriatrics, Family Medicine, COSPH, School of Dental Medicine)

1. In thinking about [specific session], please indicate how true each of the following statements was of your experience.

| | Not true at all | | | Very true | | | | Std | Range |
	1	2	3	4	5	n	Mean	Dev	Low-high
The presentation of information was current and evidence based.	0	0	0	3	31	34	4.91	0.29	4-5
There were sufficient opportunities for questions and discussion.	0	0	0	4	30	34	4.88	0.33	4-5
The information I gained from this session will improve my skills and performance.	0	0	0	6	28	34	4.82	0.39	4-5
I feel more knowledgeable about this content after participating.	0	0	1	5	28	34	4.80	0.48	3-5
I have a better understanding of how to access resources related to this topic as a result of participating.	0	0	2	3	29	34	4.80	0.54	3-5
The quality of the program/ content met my expectations.	0	0	1	5	28	34	4.79	0.48	3-5
This session was well organized.	0	0	2	5	27	34	4.74	0.57	3-5

2. How comfortable did you feel expressing your opinions or asking questions during this session?

| Not well at all | | | | Ext Well | | | | Range |
1	2	3	4	5	n	Mean	Std Dev	Low-High
0	0	1	8	25	34	4.71	0.52	3-5

3. How well was the information explained by the presenter(s)?

| Not well at all | | | | Ext Well | | | | Range |
1	2	3	4	5	n	Mean	Std Dev	Low-High
0	0	0	9	25	34	4.74	0.45	4-5

1. In thinking about [specific session], please indicate how true each of the following statements was of your experience.

| | Not true at all | | | Very true | | | | Std | Range |
	1	2	3	4	5	n	Mean	Dev	Low-high
The presentation of information was current and evidence based.	0	0	1	4	22	27	4.78	0.51	3-5
I feel more knowledgeable about this content after participating.	0	0	1	3	23	27	4.81	0.48	3-5
I have a better understanding of how to access resources related to this topic as a result of participating.	0	0	1	6	20	27	4.70	0.54	3-5
The information I gained from this session will improve my skills and performance.	0	0	1	5	20	26	4.73	0.53	3-5
This session was well organized.	0	0	1	8	18	27	4.63	0.57	3-5
There were sufficient opportunities for questions and discussion.	0	0	0	0	27	27	5.00	0.00	5
The quality of the program/ content met my expectations.	0	0	2	5	20	34	4.67	0.62	4-5

2. How comfortable did you feel expressing your opinions or asking questions during this session?

| Not well at all | | | | Extremely well | | | | Range |
1	2	3	4	5	n	Mean	Std Dev	Low-High
0	0	0	5	22	27	4.81	0.40	4-5

3. How well was the information explained by the presenter(s)?

| Not well at all | | | | Extremely well | | | | Range |
1	2	3	4	5	n	Mean	Std Dev	Low-High
0	0	2	7	18	27	4.60	0.64	3-5

Fall 2022 Cohort Demographics

Graduation: November 14, 2022

- N= 10
- Average age = 69 (range: 60- 79)
- Males n= 3; females n= 7
- African American/Black n= 2
- Bilingual (Spanish), bicultural participants n= 2
- Bilingual (French) n= 1
- Veterans n= 1
- Autism spectrum n= 1
- GED to PhD

Spring 2023 Cohort Demographics

Graduation: May 24, 2023

- N= 15
- Average age = 66 (range: 54 - 72)
- Males n= 2; females n= 13
- African American/Black n= 1
- Bilingual (Spanish), bicultural participants n= 1
- Asian n= 1
- Associates degree to PhD

Should I Participate in a Clinical Trial?

A decision aid for older adults

This pamphlet contains factors to consider when deciding to participate in a clinical trial.

Key Questions

You can ask your provider for a copy of the informed consent form. The informed consent form is required to include potential risks and benefits of participating in the research clinical trial. You may want to discuss these additional questions:

☐ Have I discussed the risks and benefits with my primary care provider?

☐ Will participation affect the use of any of my medications?

☐ Do I need a consult with a pharmacist?

☐ Do I fully understand the research process?

☐ Do I understand my potential benefit or gain to participating?

☐ Are blood or tissue samples required?

☐ Do I fully understand the risks of participation?

☐ If the clinical trial is randomized, am I prepared to accept that I may be in the placebo group?

☐ Does participation exclude me from choosing other treatment options?

☐ Do I have physical limitations that cannot be accommodated?

☐ Do I know who to contact on the study team?

☐ Will I know the results of the study?

Other Factors To Consider

○ Does this project align with my personal values?

○ Who is funding the project? Do I have conflicts with the funder?

○ Were patients like me involved in the design of the research project?

○ Can I record the sessions, or bring someone with me to the visits?

○ What personal data will I need to provide?

○ Who else will potentially see my data?

○ Am I comfortable with the confidentiality agreement in the consent form?

○ What is my motivation for participating?

○ Will I be compensated? What personal data is required to be compensated? Will I have to pay taxes on it? Is a W-9 required?

Travel and Timing

• How many trips will I need to make to the location?

• How long (months) is the study duration?

• What time of day are the visits?

• How long will each visit take?

• Is there adequate parking? Fees?

• Can I obtain a ride for each visit?

• Is there flexibility if my ride is delayed?

Accessibility

Are the accommodations adequate for easy access?

Will I have assistance for mobility?

Are there assistive hearing devices?

Are there visual assists?

Hidden Costs

• Will I need to purchase food during the visit?

• Is a special diet required?

Insurance and Medical Costs

• Will participation affect my insurance?

• Are there costs not covered by insurance (e.g., in case of injury or extra visits to my clinic)?

• If the research reveals I have a medical condition, do I have resources to obtain care?

Comprehension

• Do I want to ask someone to help me make the decision to participate?

Use this space for any thoughts or questions about participating.

Resources

National Institute on Aging: Benefits, Risks for Older Adults https://www.nia.nih.gov/health/clinical-trials-benefits-risks-and-safety

Multidisciplinary center on Aging https://medschool.cuanschutz.edu/center-on-aging

https://researchstudies.cuanschutz.edu/

https://www.researchmatch.org/about/

https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies

https://www.hhs.gov/ohrp/sites/default/files/questions_full_list_v5-remediated_12222016.pdf

This document was prepared by Older Adult Research Specialists (OARS). 2022.

👥 Aim 1 Resource Needs

- Cluster hiring of OARS and sustainment as a centralized resource
    - Streamlines hiring
    - Enhances visibility of OARS as a recruitment and retention resource
    - May increase/ensure access to ongoing training and mentorship support
    - Facilitates evaluation and tracking

- Advertising Consult Service
    - Drive more investigators with recruitment and retention needs to free, monthly consult service
    - Institutionalize based on positive ROI

Project Overview

Aim 2: Deliver 8 **Research Roadshows** to engage older adults in geographically and culturally diverse communities in clinical trials; each features a core set of carefully choreographed engagement activities followed by opportunities to connect with studies:

- Engagement with Older Adult Research Specialists as role models and advocates for including older adult peers in clinical trials (what is research, why research matters to me)
  - Supported by OARS' Outreach Toolkit (photo voice project and video)
- User testing of assistive devices (Center for Inclusive Design and Engineering)
  - Key take-away: participation of older adults enhances the products of research for older adults
- Connectivity to research
  - Tech resources (information about accessibility, connection to ADA compliant research studies website), skill building related to technical aspects of participation (downloading, uploading documents)
- Opportunities to connect with research teams around specific studies

Research Roadshow Theory of Change
(bi-directional outcomes)

Increase knowledge, awareness, access to resources

Access to role models

Peer-to-peer education

Connections

Positive outcome expectations

Intentions

Skill building

"I value research. I would hope that researchers are or become knowledgeable about people of color and direct research at them."
- RR participant

"My decision to enroll in a clinical trial was influenced by the potential benefit it would have for my community, and to advance the research efforts of antiretroviral therapies for people living with HIV/AIDS."
- Older Adult Research Specialist
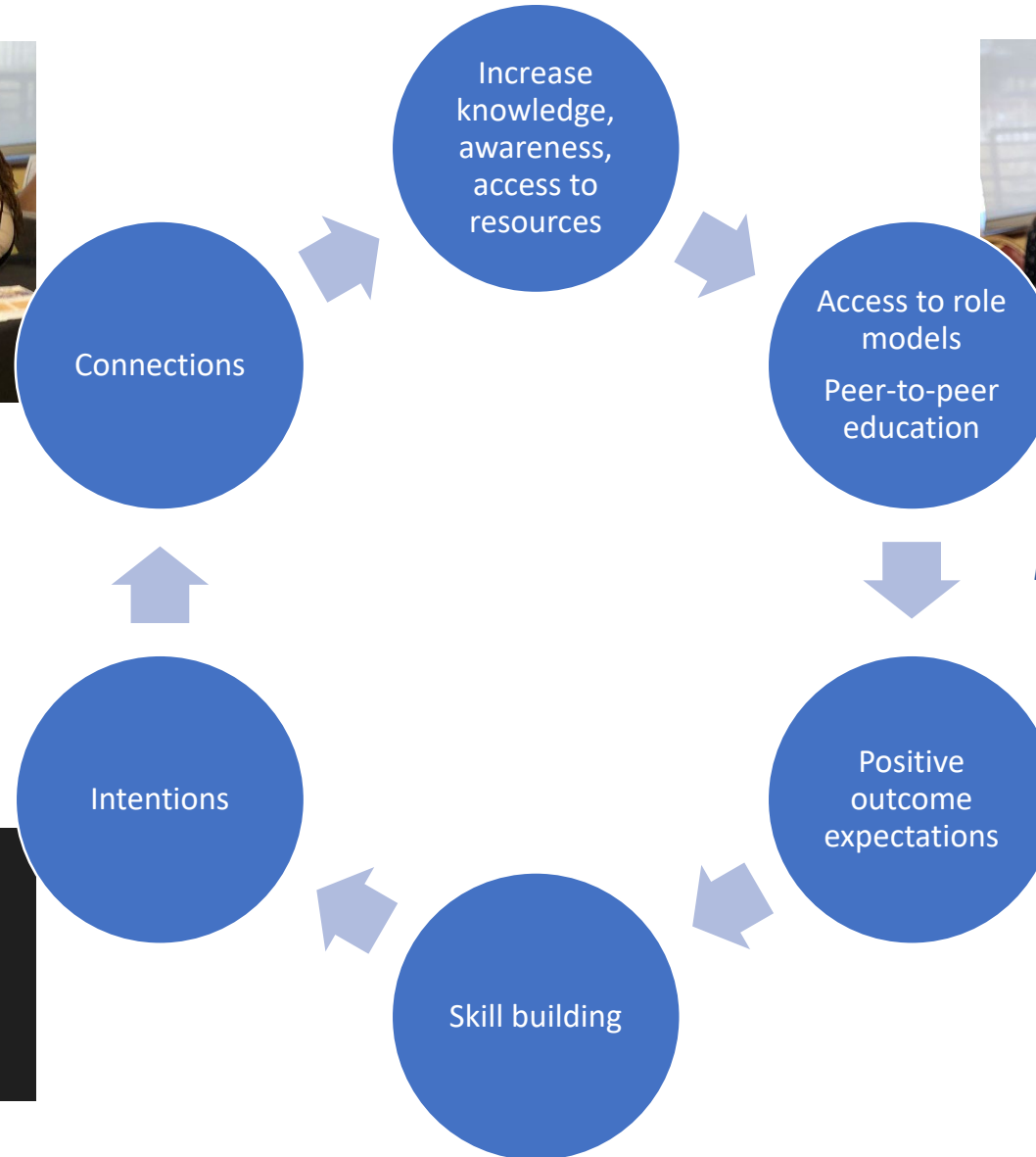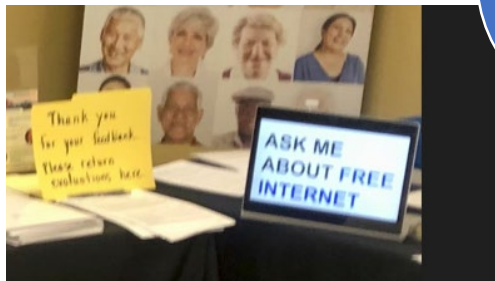
Year One Accomplishments

AIM 2

✓ Established team (includes 4 OARS, CIDE, MCoA)

✓ New partnerships: AHEC, Colorado Hospital Association, Denver Museum of Nature & Science

✓ Printed first *Older Adults in Research* newsletter (English and Spanish); established distribution list

✓ Produced video (English and Spanish)

✓ ADA-compliant research studies website (demo navigation based on participant interest)

✓ "Mapping Project" connects participants with studies actively recruiting older adults in their region

✓ Pilots

  ✓ 11.5.22: 365 Health and Research Resources Fair

  ✓ 11.19.22: Denver Indian Health Services Fair

  ✓ 2.24.23: Center for African American Health Fair

Different settings, different audiences, different versions of Research Roadshows

Aim 2 Resource Needs

- Funding from alternative sources to provide food and entertainment
- Funding to build out engagement activities/components
- Approved spaces on campus to display aspects of RR when not traveling
- Support for evaluation

Do Research Roadshows move the needle?

- Community knowledge, awareness
- Access to opportunities to participate in research
- Increased number of inquiries for studies featured
- Increased enrollment and retention of older adults and other underrepresented populations

Having Trouble Recruiting and Retaining Older Adults and other Underrepresented Populations in Your Research?

We have new Resources for You!

- ## Hire an Older Adult Research Specialist (OARS)
  - Older adult peers from diverse backgrounds specifically trained to support recruitment, retention
  - Seeking contract, part-time, full-time work, as well as volunteer opportunities to support research
  - Willing to work flexible hours; desire to work on campus, as part of teams

- ## Free Consult Service staffed by OARS (available monthly)
  - Brainstorm new solutions to recruitment, retention challenges with those who share similar backgrounds as potential study participants

- ## Traveling Research Roadshows - Join us!
  - Opportunities to recruit engaged community members at locations across the state

Acknowledgement of Partners

- Vice Chancellor of Research, **Dr. Tom Flaig**
- Vice Chancellor for Diversity, Equity, Inclusion and Community Engagement, **Dr. Regina Richards**
- Associate Vice Chancellor for Regulatory Compliance, **Dr. Alison Lakin**
- Colorado Clinical and Translational Sciences Institute, **Dr. Ronald Sokol**, PI
- The Cancer Center, **Dr. Christopher Lieu**, Chair, Clinical Cancer Research
- Division of Geriatric Medicine, **Dr. Cari Levy**, interim head
- Center for Inclusive Design and Engineering, **Dr. Cathy Bodine**, Executive Director
- Community Engagement Pillar, CCTSI: **Dr. Don Nease**, Director; **Montelle Taméz**, Deputy Director; **Community Research Liaisons**

Training Sequence for Older Adult Research Specialists (offered Fall, Spring; cohorts= 10-12)

Orientation to Online Learning Tools

2 hours

Optional "Tech Office Hours" – 2hrs/wk throughout

Health Navigator Training

(virtual, ~60 hrs, 7 wks)

Older Adult Research Specialist Training

(virtual, ~60 hrs; 7 wks)

Enhanced computer skills Introduction to tools used to support virtual learning, job readiness

Health navigator credential Qualify to be listed on state health department registry

Older Adult Research Specialists uniquely prepared to support recruitment, retention of underrepresented populations in research

Computer Literacy Training (woven throughout)

- Supports:
  - Access to virtual training programs,
  - Job readiness (PC-based) and
  - Ability to support study subjects with technical aspects of participation
- Established curriculum delivered by computer literacy instructor with 6 years of experience training older adults
- Office Hours (1 hr, 2x/wk):
  - 1st half: didactic/demonstration
  - 2nd half: participants' questions, emerging interests

Level 1, 2 Health Navigator Training Curriculum

Level 1 – Community Impact Boot Camp → (30 self-led and instructional hours)	Level 2 – Clinical or Research Focused (30 self-led and instructional hours)
Building Blocks for Level 2 and Older Adult Research Specialist Roles: • **Motivational Interviewing** • **True Colors** • **Mental Health First Aid** • **Diversity Equity Inclusion**	• **Module 1 Introduction to Health Navigation** (includes Social Determinants of Health, Need for Navigators, Role and Scope of Health Navigation, and Patient/Client Engagement) • **Module 2** (includes Healthcare Team Communications) • **Module 3** (includes Health Literacy and Cultural Competence) • **Module 4** (includes Oral Health, Trauma Informed Care and Healthcare Law and Ethics) • **Module 5** (Clients Needs and Barriers, Healthcare Coverage, Resources and Benefits, live practical practice) • **Module 6:** Introduction to Chronic Disease (self-led)

Section	Older Adult Research Specialist Training Topics (virtual Monday, Thurs 9am- 12pm)
Exploring the Roles of Older Adult Research Specialists and Foundations	Session 1: Role of Older Adult Research Specialists (compare and contrast with health navigators and community research liaisons)
	Session 2: Community Outreach, Engagement and Recruitment (CBPR Principles, cultural adaptations)
	Session 3: Overview of Clinical Trials (Types, Phases, Life Cycle, Clinical Trial Team)
	Session 4: Inclusion, Exclusion Criteria and the 5Ts and 5Ms -- Frameworks to Promote Inclusion of Older Adults in Research
Evolution of human subjects research protections, current regulations, application through informed consent	Session 5: Evolution of Human Subjects Research Protections and Current Regulations
	Session 6: Essential Elements of Informed Consent
	Session 7: Application - facilitating informed consent (Practicum I)
	Session 8: Panel discussion with clinical research study coordinators and facilitating informed consent (Practicum II)
Team-based projects and preparing for job application process	Session 9: Panel discussion with OARS + time for team-based projects
	Session 10: "Resume Refresh" Workshop + time for team-based projects
	Session 11: Mock Interviews + time for team-based projects
	Session 12: OPTIONAL – additional time for teams to work on projects
	Session 13: Virtual Job Fair
Celebration!	Graduation: presentation of projects, conferring of certificates of completion

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THANK YOU

Judy Regensteiner

Director, Ludeman Family Center for Women's Health Research

University of Colorado School of Medicine

Jane Reusch

Associate Director, Ludeman Family Center for Women's Health Research

University of Colorado School of Medicine

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Judith G. Regensteiner, PhD,
Distinguished Professor of Medicine
Judith and Joseph Wagner Chair of Women's Health Research
Director, Ludeman Family Center for Women's Health Research
Director, Women in Medicine and Science
Anschutz Medical Campus School of Medicine

Jane EB Reusch MD
Professor of Medicine, Bioengineering and Physiology
Division of Endocrinology, Metabolism and Diabetes
Associate Director, Center for Women's Health Research University of Colorado
VA Staff Physician and Merit Investigator
Anschutz Medical Campus School of Medicine

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What is our purpose in doing the important work to increase diversity in participants in our research studies?

- Increasing diversity of participants is a key goal of the Regensteiner/Reusch Lab, as well as of the Ludeman Family Center for Women's Health Research.
-

    - Only through having participants representative of the community will we gain the results that enable the best medical therapies for all. Diverse people may have different reactions to the same treatment, based on their age, gender, weight, race, ethnicity, and other factors
    - This includes women of all ethnicities and races as well as men. Currently there are not sex specific clinical treatments.
    - Gender minorities and other minoritized populations also must be included.
    - Diabetes has an increased prevalence in minoritized populations both based on ancestry and Social Determinants of Health as such diversity is of great clinical importance for our research

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Background: What have we done to date

In the community
- Long standing relationship with Center for African American Health
- Emerging relationship with Vuela for Health
- Partnership with Morehouse School of Medicine
- Work with Ludeman Center Community Advisory Board

- We have not deliberately leveraged our community partnerships to increase enrollment in studies.
- However, we have always recruited carefully to ensure that women are recruited as well as racially and ethnically diverse people. We have a recruitment matrix and we check it in lab meetings.

On campus
- Prioritize the diverse VA population
- Work with CCTSI Partnership of Academicians and Communities for Translation (PACT)
  - Community Clinical Trials Advisory Board
  - Community Consult

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What was the result of your efforts (did you improve recruitment around populations?)

Sitagliptin Study

Table 3	Native American	Asian	Black	White	Hispanic	Other	Total
Female	0	3	9	12	6	0	30
Male	0	0	4	28	5	0	37
Unknown							
Total	0	3	13	40	11	0	67

Leg Blood flow study

Table 3	Native American	Asian	Black	White	Hispanic	Other	Total
Female	0	1	7	16	6	2	32
Male	2	0	4	31	3	2	42
Unknown	0	0	0	0	0	0	0
Total	2	1	11	47	9	4	74

VA Mixed study

Check here if demographics will be provided on a separate page; note COMIRB will accept NIH-formatted ethnicity/race demographics

Table 3	Native American	Asian	Black	White	Hispanic	Other	Total
Female	0	4	13	35	10	0	62
Male	1	2	11	40	4	4	62
Unknown	0	0	0	0	0	0	0
Total	1	6	24	75	14	4	124

Results from three most recent studies from our lab

Results:
- 47 % Women recruited across our most recent 3 studies
- 36% Asian, Black, Hispanic, Native American recruited across our most recent 3 studies

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Community Clinical Trials Advisory Board
Agenda Items (recent formal outreach)

- Discussed the primary aims and study design of VAMIXED
  - Aspirations to diversify participant population
  - Getting word out in a trustworthy and non-intimidating way
- Conferred about patients who are undocumented/uninsured and those who do not speak English as their primary language
  - Educating the community and building trusting partnerships is important for participant outreach
  - Critical to not "overstep" or "use" the population for research and then walk away
- Importance of culturally appropriate advertisement materials
- Need to bring the research results back to the community

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Barriers to the Follow Up

- Deliberate care must be taken to **truly partner with community**
  - Poor communication can lead to mistrust with partners and patients
  - Group events may be a strategy to present information to communities and build trust

- **High participant burden clinical trials** such as VAMIXED and REACH require interpretation on many levels for **people unfamiliar or comfortable with clinical research** and non English speakers
  - Language of research is far removed from everyday language
  - Translation into layperson accessible language and non-English languages is needed for study materials including consent forms, questionnaires, and recruitment materials
  - Interpreter will be needed for study visits as well as exercise sessions
  - Challenges in finding necessary resources for support of interpreters
  - Challenges in effectively reaching communities disproportionately affect by diabetes

Results continued

What have we learned?

- Intentionality is critical.
    - For instance, recruiting women is a key issue- we are successful in this because we are very intentional.
    - Although we have been successful at recruiting diverse participants, we need to understand how to be even more intentional in this regard.

Additional concerns

- What about gender minorities?
- How to engender trust in minoritized communities

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What additional resources would have helped
(university, third party, external/internal)

Programs which bring together community members and researchers together to hear about studies and discuss.

Further dynamic evolution of community engagement consults (in process) to see what is working and not working

For the future:

If trust is the major issue which adversely affects recruitment, work needs to be done to create a safe and trusting environment.
- Start with community and researcher survey
- Require training for all researchers
- Workshops with the community and researchers

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Summary

Summary

- Intentional recruiting likely leads to improved ability to include women, people from diverse racial and ethnic groups as well as gender minorities.
- Working to increase acceptance and trust in the community is a work in progress

Conclusion:

- It is critical to include women and men of all races and ethnicities and sociodemographic backgrounds
- Inclusive recruiting will reduce biases and promote health equity,

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THANK YOU

Alison Lakin

Associate Vice Chancellor for Regulatory Compliance

Office of The Vice Chancellor for Research

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SPECIFIC AIMS

Increase the participation of underserved populations at UCCC through expanded clinical research programs 2022

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CLINICAL PROTOCOL & DATA MANAGEMENT
LEADERSHIP

CHRISTOPHER LIEU, MD

Assoc Director, Clinical Research

Associate Professor, Medicine / Medical Oncology

- Ensures that clinical research relevant to the catchment area is conducted
- Provide oversight and build relationships between the UCCC and other offices within the university to further clinical research

BREELYN WILKY, MD

Deputy Assoc Director, Clinical Research

Associate Professor, Medicine / Medical Oncology

- Chair Investigator-Initiated Trials Committee
- Directs clinical investigator onboarding and continuing education

JESSICA MCDERMOTT, MD

Deputy Assoc Director, Diversity, Equity, and Inclusion in Clinical Trials

Associate Professor,

Medicine / Medical Oncology

- Chair – URM UCCC/UCHealth URM Task Force
- Directs diversity efforts across UCCC clinical sites for cancer clinical trial accrual

SYNERGIES & SHARED RESPONSIBILITIES

Provide central administration and oversight functions for coordinating, facilitating, and reporting on clinical and population sciences trials across the UCCC clinical sites serving the catchment

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RATING: *EXCELLENT*

ACHIEVEMENTS

- Accrual to institutional investigator-initiated trials has increased significantly

- Expansion of the Front Range Clinical Trials Network (FRCTN) provides clinical trial access to the population of Colorado

CRITIQUES

- **Hispanic patients remain underrepresented in trials relative to the state population**

- **Overall accrual to both interventional treatment and non-treatment trials has been on a downward trend**

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RESPONSE TO 2021 REVIEW

CRITIQUE

Hispanic patients remain underrepresented in trials relative to the population in state

RESPONSE

- Dedicated clinic for Hispanic patients

- PRMS tracking of minority accruals with feedback to disease group and UCCC leaders

- Clinical trial partnership and engagement with Denver Health

- COE/CPDM/UCHealth URM Task Force

- Increase access to UCCC clinics for undocumented patients

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Improve Accrual of Minorities and Underserved Populations

Dedicated Clinic to Improve Access of Hispanic Patients with Cancer to Research

Improve Accrual of Minorities and Underserved Populations

- CPDM/PRMS collaboration to evaluate planned enrollment demographics and provide current accrual metrics for minorities and rural populations

List of resources to investigators from COE	Question about URM enrollment for PRMS submission	Audit by disease group utilizing OnCore to assess URM enrollment	Trigger meeting with COE project team to reassess strategies
CPDM + COE	**PRMS**	**PRMS**	**CPDM + COE**

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IMPROVE ACCRUAL OF MINORITIES AND UNDERSERVED POPULATIONS

- CPDM/PRMS collaboration to evaluate planned enrollment demographics and provide current accrual metrics for minorities and rural populations

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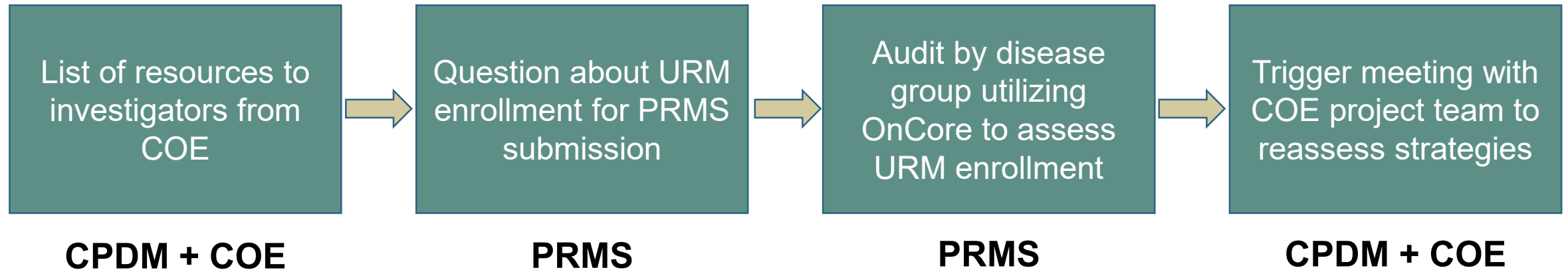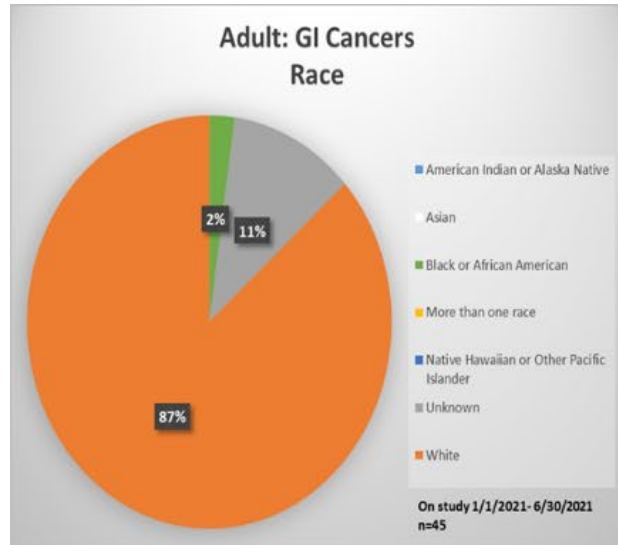
IMPROVE ACCRUAL OF MINORITIES AND UNDERSERVED POPULATIONS

- New process to evaluate planned enrollment demographics and current accrual for minorities and rural populations
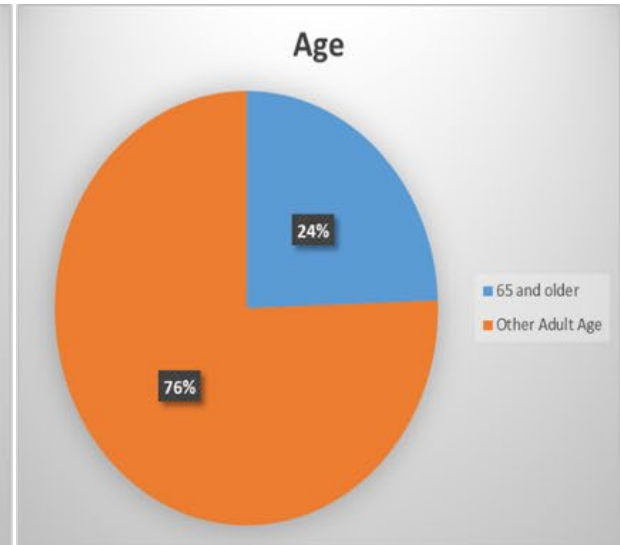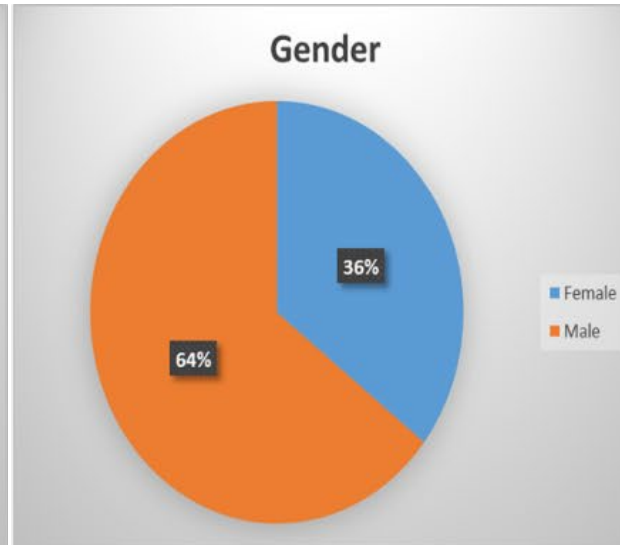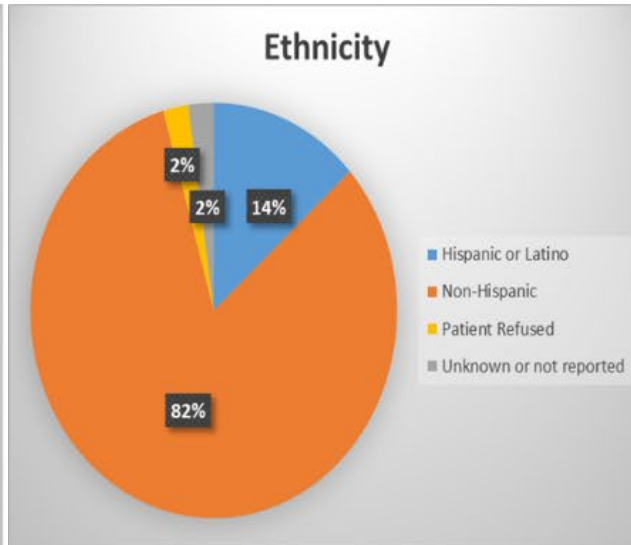
List of resources to investigators from COE	→	Question about URM enrollment for PRMS submission	→	Audit by disease group utilizing OnCore to assess URM enrollment	→	Trigger meeting with COE project team to reassess strategies
CPDM + COE		**PRMS**		**PRMS**		**CPDM + COE**
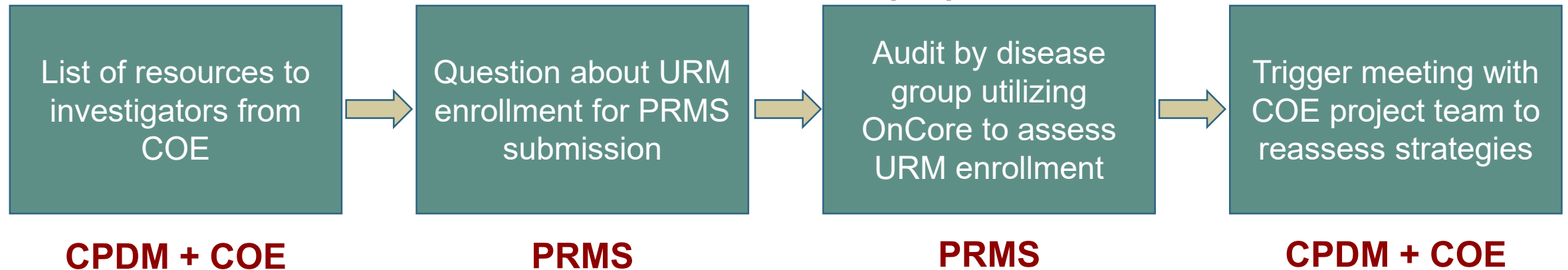
- Clinical trial partnership and agreement signed with Denver Health including support for faculty and clinical research manager

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DENVER HEALTH™
— est. 1860 —
FOR LIFE'S JOURNEY

COE / CPDM / UCHEALTH URM TASK FORCE

Goals: The UCCC seeks to accomplish the following goals via the URM Clinical Trials Task Force:

1. Identify and obtain resources to improve URM patient enrollment

2. Increase the number of URM patients seeking care at UCHealth

3. Improve financial assistance for patients to participate in clinical care and research

4. Increase collaboration with community-based hospitals, community-oncology practices, and other organizations for referrals

IMPROVEMENT: 4-fold increase in financial assistance for under- and uninsured patients engineered by Wells Messersmith, AD for Clinical Services

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Deliverables Over the Next Reporting Period

Deliverable: Increase Hispanic clinical trial accruals to 10% by the end of FY23 and exceed state cancer demographics by FY25

Deliverable: Increase overall accruals to intervention-treatment trials by 5% per year

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CLINICAL TRIAL METRICS
ACCRUAL OF MINORITIES

| | Catchment | | | Trial Accruals | | | | | |
| | | | | Intervention-Tx | | | Intervention Non-Tx | | |
	State Pop (1)	State Cancer Cases (2)	New Onc Patients (3&4)	FY20	FY21	FY22	FY20	FY21	FY22
Total Population	5,773,714	119,488	20,506	610	634	596	393	535	1478
Race/Ethnicity	%	%	%	%	%	%	%	%	%
Non-Hisp White	65.1%	81.9%	80.6%	85.4%	82.0%	80.6%	83.5%	72.9%	53.9%
Non-Hisp Black	3.8%	3.3%	4.3%	3.3%	4.4%	2.0%	6.1%	4.3%	6.1%
Hispanic (All Races)	21.9%	10.9%	8.5%	6.8%	8.3%	11.0%	7.1%	17.6%	20.2%
Asian	3.5%	1.8%	2.2%	1.7%	1.7%	3.0%	1.0%	0.7%	1.8%
Nat Haw	Pac Isldr	0.2%	0.2%	0.1%	0.3%	0.0%	0.5%	0.0%	0.6%	0.2%
Amer Ind	AK Nat	1.3%	0.7%	0.3%	0.2%	0.3%	0.3%	0.8%	1.1%	0.5%
Other	>1	NR	5.0%	2.1%	3.9%	2.3%	3.4%	2.6%	1.5%	2.8%	17.2%

(1) US Census Bureau, 2020 Decennial Census Redistricting Data, Tables P1 and P2
(2) Colorado Central Cancer Registry, 2014-2018 Incidence Data
(3) University of Colorado Health Data COMPASS New Cancer Center Patients FY20-FY21_2021.11.30; S. Das
(4) Children's Hospital Colorado Cancer Registry Data, 2019-2020

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CLINICAL TRIAL METRICS
ACCRUAL ACROSS THE AGE-SPAN

Catchment				Trial Accruals					
	State Pop (1)	State Cancer Cases (2)	New Onc Patients (3&4)	Intervention-Tx			Intervention Non-Tx		
				FY20	FY21	FY22	FY20	FY21	FY22
Total Population	5,773,714	119,488	20,506	610	634	596	393	535	1478
Lifespan	%	%	%	%	%	%	%	%	%
< 18 Years	21.8%	0.9%	5.8%	10.4%	14.7%	18.1%	4.6%	8.2%	7.9%

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ACCRUAL ACROSS THE AGE-SPAN

	Catchment			Trial Accruals					
	State Pop (1)	State Cancer Cases (2)	New Onc Patients (3&4)	Intervention-Tx			Intervention Non-Tx		
				FY20	FY21	FY22	FY20	FY21	FY22
Total Population	5,773,714	119,488	20,506	610	634	596	393	535	1478
Lifespan	%	%	%	%	%	%	%	%	%
< 18 Years	21.8%	0.9%	5.8%	10.4%	14.7%	18.1%	4.6%	8.2%	7.9%
> 64 Years	14.7%	54.6%	42.6%	35.6%	35.3%	32.6%	28.9%	25.8%	20.3%

(1) US Census Bureau, 2020 Decennial Census Redistricting Data, Tables P1 and P2
(2) Colorado Central Cancer Registry, 2014-2018 Incidence Data
(3) University of Colorado Health Data COMPASS New Cancer Center Patients FY20-FY21_2021.11.30; S. Das
(4) Children's Hospital Colorado Cancer Registry Data, 2019-2020

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ACCRUAL ACROSS THE AGE-SPAN

Future Directions

- P30 supplement: "Infrastructure Development and Team Building for a Statewide Approach to Address Cancer and Aging in Colorado" (Kessler [CPC] and Sherbenou [DT])
  - Develop interdisciplinary, multi-campus research in cancer and aging
  - Cultivate partnerships with community and rural practices throughout the state

- **R24 Grant: "Workforce Development Engages Diverse Older Adults to Catalyze Innovative Approaches for Enhanced Recruitment and Retention in Clinical Trials"**
  - **Train diverse older adults as research specialists**

- Clinical and Research agreement with Denver Health to provide pediatric leukemia access to CHCO for clinical trial enrollment

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THANK YOU

Ben Echalier

Assistant Vice Chancellor for Clinical Research Operations

Office of The Vice Chancellor for Research

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Clinical Research Operations Support

UNIVERSITY OF COLORADO **ANSCHUTZ MEDICAL CAMPUS**

Central clinical research operations support provided by the OVCR, including:

- CReST (Clinical Research Support Team)

- IND/IDE Office (coming soon)

- Recruitment Center
    - Social Media
    - Research Studies Website
    - Research Match

- CU Anschutz Research & Health Fair

- Clinical Research Staff Workforce Development

- Study Monitoring Committee (SMC)

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CReST

- The Clinical Research Support Team (CReST) offers a-la carte fee-for-service support for research conducted by CU faculty on campus.

- Supports investigator-initiated and industry-sponsored interventional, observational, and secondary research with human participants.

- Fills vital gaps to help operationalize research by providing the necessary personnel and resources.

- Experienced research staff to assist with participant recruitment

OUR MISSION

We are clinical research lifecycle experts who support a diverse community of sponsors, patients, and investigators. We connect inspiration with execution to advance science and medicine and improve human life.
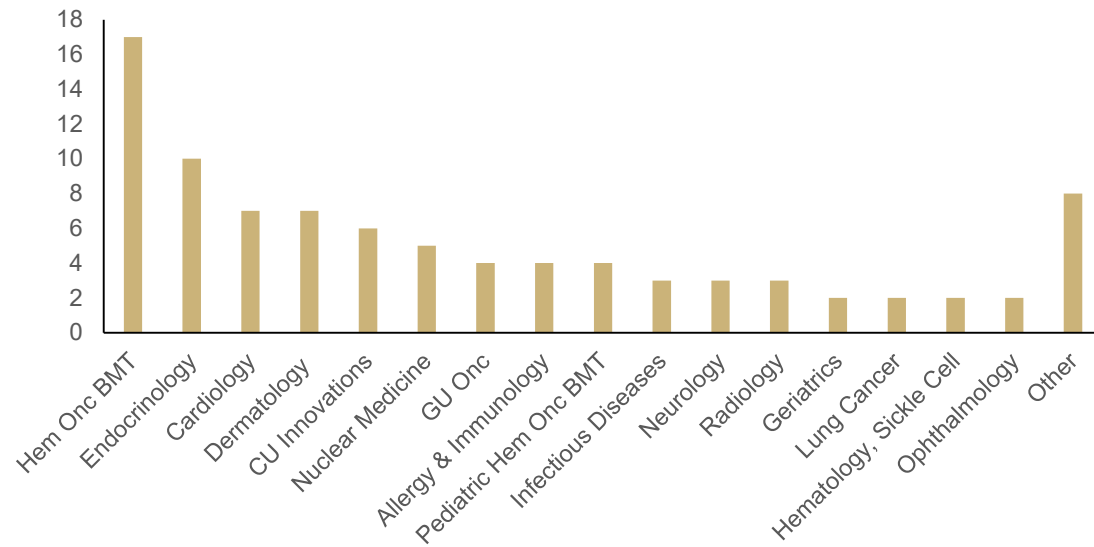
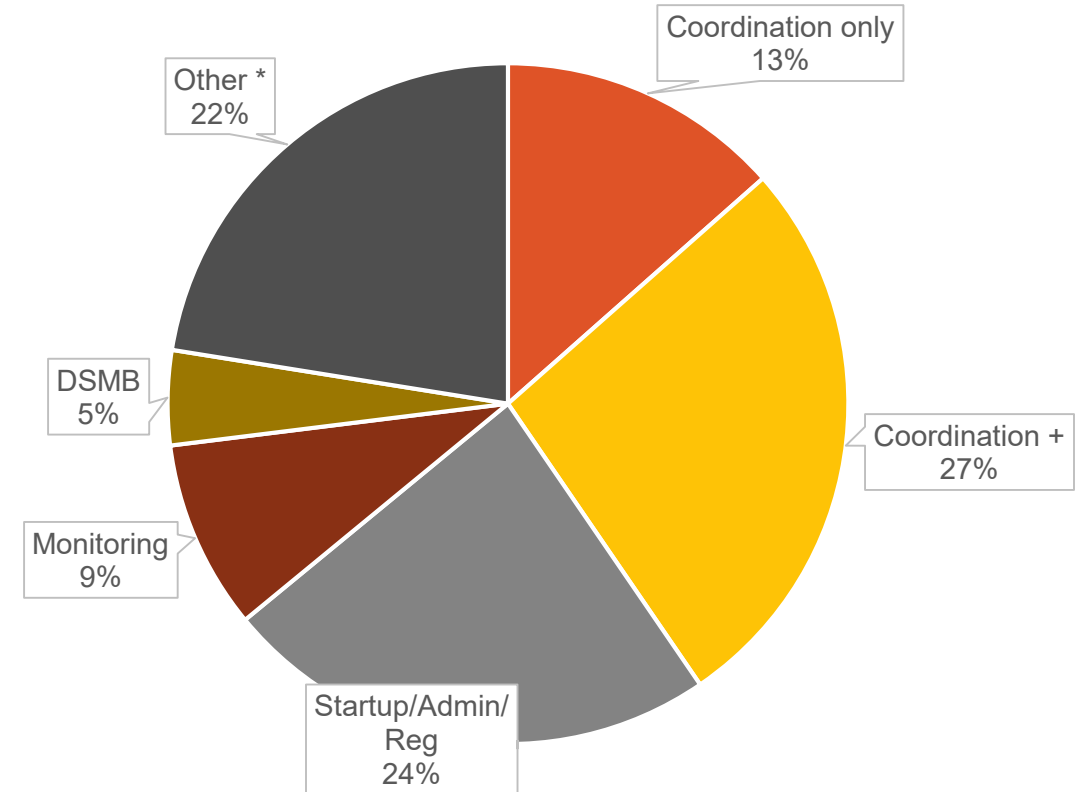CReST@ucdenver.edu

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CReST at a Glance

CReST IN 2022

- 89 Studies supported
- 24 Departments
- 58 Principal Investigators

CReST Support by Type

- Coordination only 13%
- Coordination + 27%
- Startup/Admin/Reg 24%
- Monitoring 9%
- DSMB 5%
- Other * 22%

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IND/IDE Office Current Status

- Over 100 locally held active INDs on the Anschutz Medical Campus

- Approximately 40-50 new IND/IDEs per year (including compassionate use)

- Each research team is currently responsible for their department's submissions to FDA

- No central oversight or tracking of submissions to FDA

- Compliance issues due to research staff turn over and sponsor-investigator leaving the institution

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Purpose of central IND/IDE Office

1. Alleviate administrative burdens on investigators
2. Standardize processes for research with FDA-regulated products conducted at the University of Colorado Anschutz Medical Campus
3. Ensure that FDA-regulated projects are initiated with feasible goals and appropriate resources and funding
4. Facilitate efficient startup processes
5. Minimize risk to participants and mitigate compliance risks

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IND/IDE Office Future State

Single point of entry for all projects, with triage to appropriate support team based on whether:

- Compassionate use request
- Product Manufactured on campus (Cell/Gene/Protein therapy)
- Treatment for oncology or non-oncology indication

Centrally managed responsibilities and requirements

- All communication and submissions to FDA, including expedited safety reporting
- Standardized electronic TMF and ISF structure
- 21 CFR part 11 eReg system (unless exempted by Reg Compliance)
- TMF maintenance for (FDA) regulatory submissions
- 21 CFR part 11 compliant EDC
- Training verification
- Pharmacovigilance
- Study monitoring

Recruitment Center

Current and Developing Central Resources

➢ [CU Research Studies website](#)

➢ [ResearchMatch](#)

➢ Social media campaign support – Facebook advertising

  ➢ Piloting a few studies and plan to offer to larger campus community (starting with 2-3 campaigns/month)

➢ Consult services (coming soon)

  ➢ Help with recruitment plan development

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Social Media Campaigns

Social media advertisements are an increasingly useful tool for recruiting human participants. We plan to offer centralized resources and support for research teams to utilize social media for recruitment.

Current Central Resources:

- Request to place ads via the CU Anschutz Research Studies Facebook account

- Promote your study via CU affiliated social media accounts

- Promote your study via other social media accounts

- Place ads via a third-party agency

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Social Media Campaigns

We are working with the Office of Communications to develop a central resource to provide local assistance with selected clinical trials recruiting via social media.

- Currently piloting 4th study

- Positive response from PIs/study teams and click through rate higher than expected

- Will be limited with a set number of campaigns available per month

- Must have IRB approved language and follow CU Social Media Guidelines
  - Not all studies are a good candidate for this due to FB and other restrictions

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Social Media Campaigns

Pilot 1
- Contacts received through researchstudies.cuanschutz.edu during the month of campaign: 29
- People who filled out the REDCap prescreen during the month of campaign: 26
- Number of eligible participants identified via the REDCap prescreen: 16
- Number of consented study enrollees (thus far) who learned of the study through social media: 5
- Total cost: $80 per enrolled participant

Other feedback from Dept. of Psychiatry:

Study 1 Social Media Ad Campaign Results
- 498 pre-screeners
- 55 eligible
- 6 enrolled (2 Lost to f/u); 4 completed study
- Total cost: $125 per completer

Study 2 Social Media Ad Campaign Results
- 94 pre-screeners; 24 eligible
- 8 enrolled plus 1 waiting for screening
- 5 completed, 3 still active
- Total cost thus far: $100 per completer (but this will go down as the additional people complete the study – could be as low as $56 per completer)

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Research & Health Fair

- Held Last November
  - Help educate the community about research projects available at CU Anschutz
  - Help CU Anschutz researchers interact with the community
  - Offer reduced cost blood screenings through 365 Health

- Plan to expand and include more groups this year with some OVCR support

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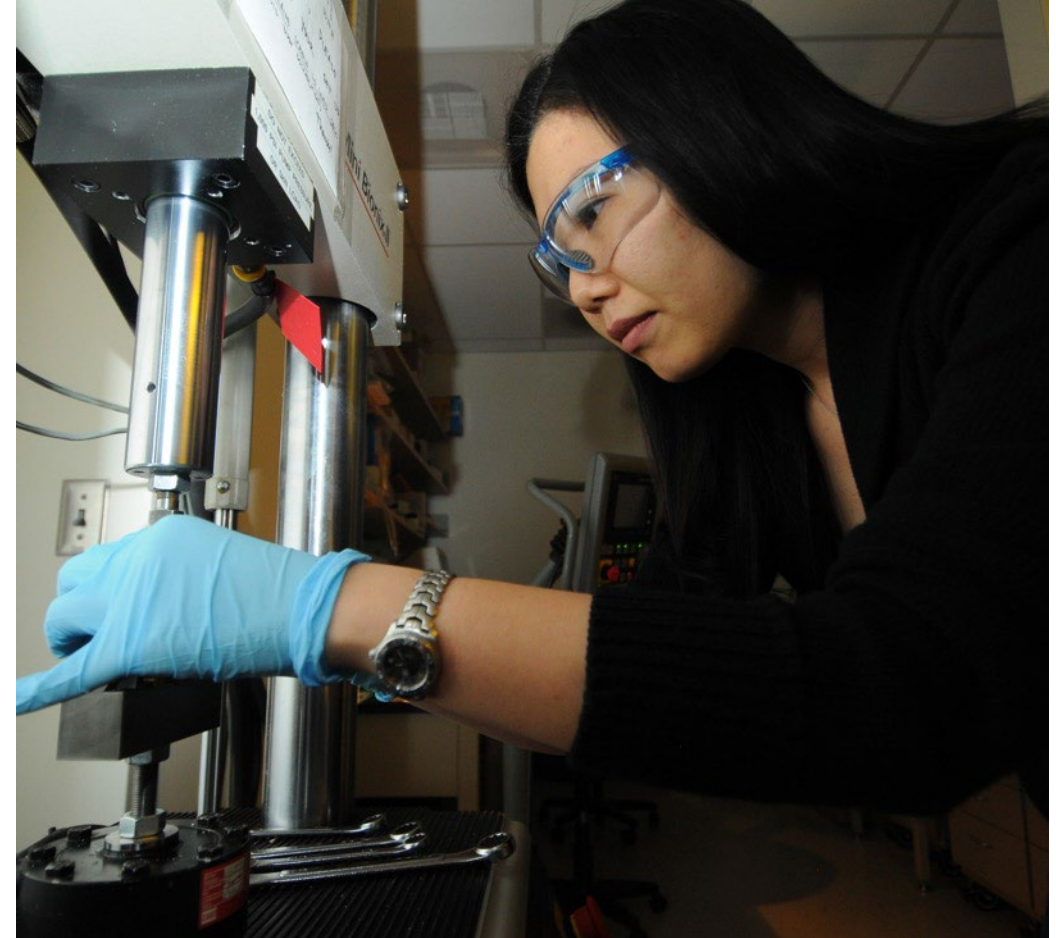
Workforce Development Initiative

Goals of Research Workforce Development Initiative:

• Identify collaborators and build partnerships

• Connect with clinical research staff to learn their needs

• Advocate for specific initiatives and recommendations

• Develop a five-year plan to improve the support, training and career development of clinical research staff

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Study Monitoring Committee (SMC)

The University of Colorado Denver | Anschutz Medical Campus Study Monitoring Committee (SMC) is a campus wide, institutional committee whose members are experts in the field of clinical research with diverse experience.

Using data entered into OnCore, the committee is charged to:

- Review recruitment metrics for ongoing studies

- Identify low-accruing studies that are at risk for not meeting their stated recruitment goals

- Evaluate and promote the appropriate inclusion of older adults in clinical research

- Monitor recruitment success and strategies to enhance the inclusion of underrepresented populations

    cu-amcstudymonitoringcommittee@ucdenver.edu

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Break for Lunch