Clinical Research in Primary Care: A Public Workshop

June 7, 2024

National Institutes of Health

Welcome

Tara A. Schwetz, Ph.D.

NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives

Director of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the NIH Office of the Director

Communities Advancing Research Equity for Health

“**Clinical trials should reflect the diversity of Americans** – because we know that delivers the best results. We are taking a big step towards ensuring communities that are historically underrepresented in clinical research are fully included and have the same access to the best available results and analysis. **There has never been more potential for progress than we have today**.”

- HHS Secretary, Xavier Becerra

NEWS RELEASES

Thursday, June 6, 2024

NIH launches $30 million pilot to test feasibility of a national primary care research network

Initiative aims to improve health outcomes by integrating research in everyday primary care settings.

The National Institutes of Health (NIH) is investing approximately $30 million in total over fiscal years 2024 and 2025 to pilot a national primary care research network that integrates clinical research with community-based primary care. The new initiative called Communities Advancing Research Equity for Health – or CARE for Health – seeks to improve access to clinical research to inform medical care, particularly for those in communities historically underrepresented in clinical research or underserved in health care. Informed by the health needs of these

EDITORIAL

Connecting lab, clinic, and community

“...the network will offer a wider menu of studies...”

Read the announcement

Agenda

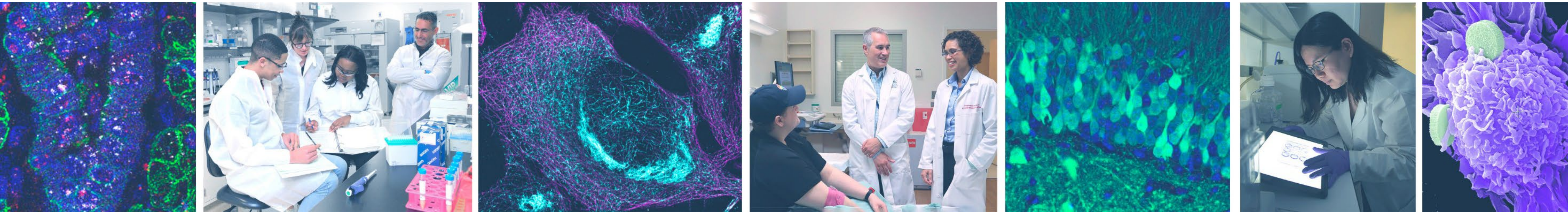
Time	Agenda Item
10:00 AM	Welcome & Our Vision for Communities Advancing Research Equity (CARE) for Health
10:20 AM	Overview of Listening Sessions: *What We Heard*
10:35 AM	Panel Discussion 1: *Visions of Success from Providers and Patients*
11:15 AM	Panel Discussion 2: *Visions of Success from Networks and Feds*
11:55 AM	The Path Forward for CARE for Health
12:10 PM	Open Q&A

Housekeeping

- All participants except the speakers and panelists will be **muted**
- Questions are welcome using the **Q&A function** and can be submitted **anonymously**. Questions will be answered during the panel discussions and the Open Q&A
- The Workshop will be **recorded**
- The Workshop recording and slides will be **posted on the** **CARE for Health website**

Our Vision for Communities Advancing Research Equity (CARE) for Health™

Clinical Research in Primary Care: A Public Workshop
June 7, 2024

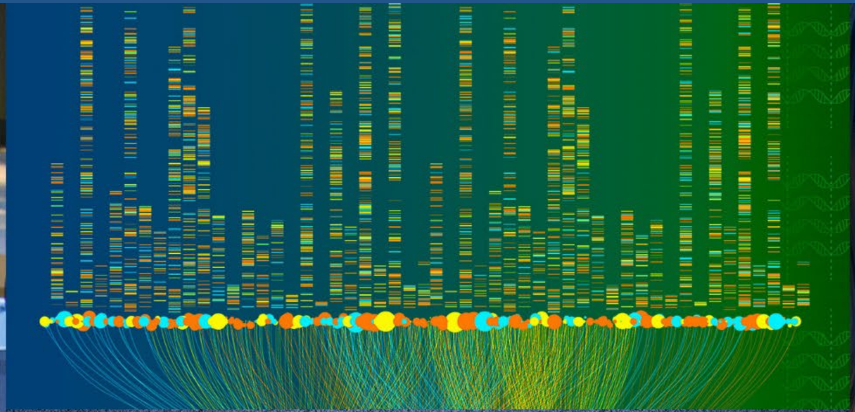


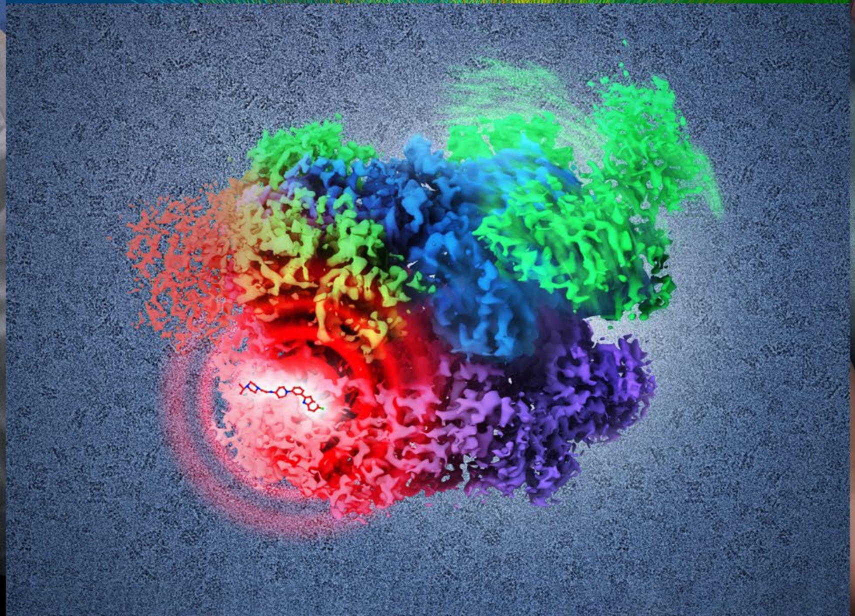
Monica M. Bertagnolli, MD
Director, National Institutes of Health

Our work is not finished when we deliver scientific discoveries, our work is finished when all people are living long and healthy lives.

NIH research encompasses the laboratory, the clinic, and the community.

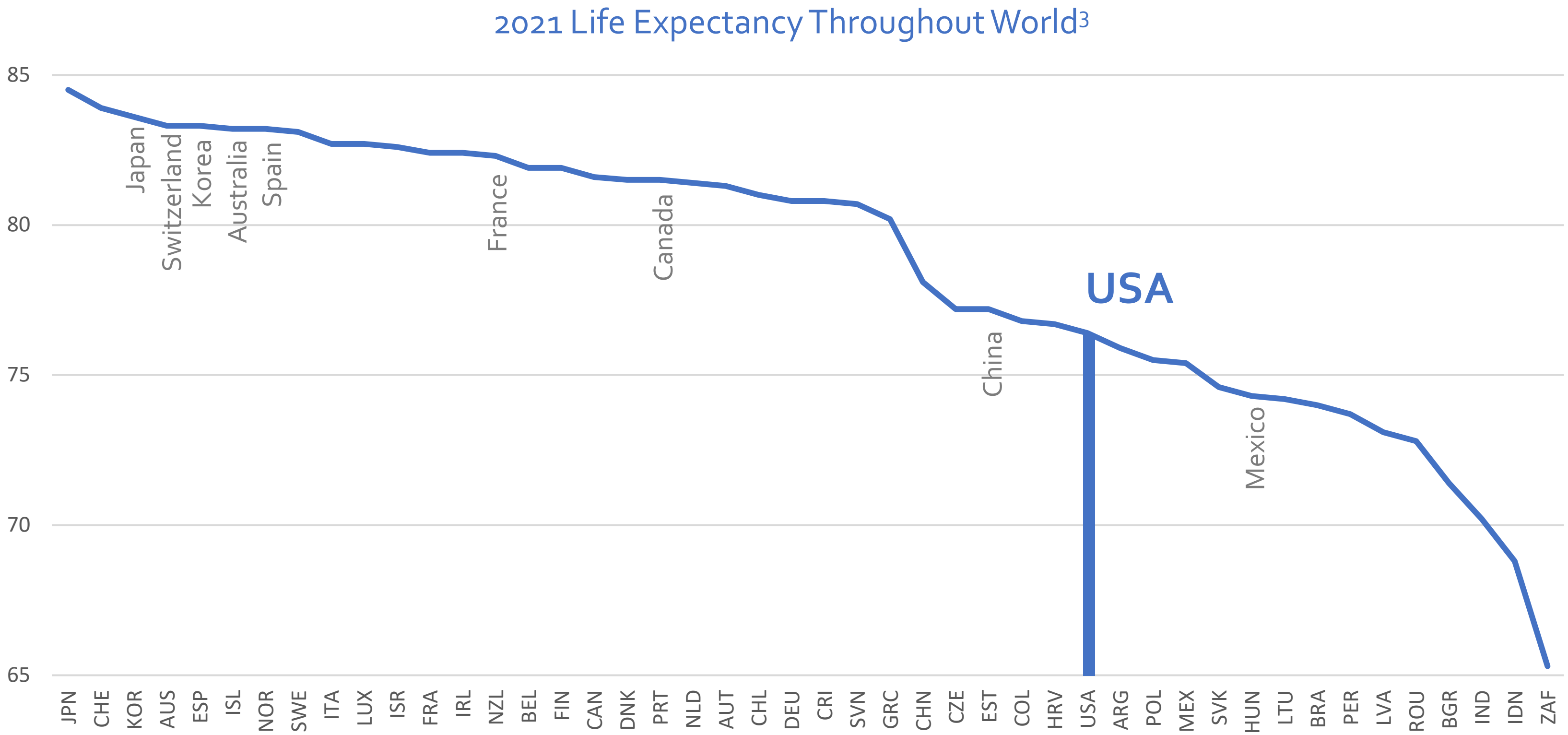
Progress is accelerated when advanced scientific methods, such as new data analytics, are applied to data that includes everyone, and when new discoveries are rapidly and equitably adopted in clinical care.





Disturbing trends in the health of the U.S. population

U.S. life expectancy ranks low among peers


2021 Life Expectancy Throughout World[3]

Concerning U.S. life expectancy trends:

- Declined 2014–2017[1]
- Dropped significantly—2.4 years—between 2019 and 2021[2]
- Increased in 2022 by 1.1 years; gain does not make up for pandemic losses.[2]

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(1) National Academies of Sciences, Engineering, and Medicine. 2021. *High and Rising Mortality Rates Among Working-Age Adults*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25976.
(2) Arias E, Kochanek KD, Xu JQ, Tejada-Vera B. Provisional life expectancy estimates for 2022. Vital Statistics Rapid Release; no 31. Hyattsville, MD: National Center for Health Statistics. November 2023. https://dx.doi.org/10.15620/cdc:133703.
(3) Chart data: OECD (2024), Life expectancy at birth (indicator). DOI: 10.1787/27e0fc9d-en (Accessed on 10 January 2024)

What Should NIH Do?

Connect research to primary care

Research

Clinical Care

Preparations for Launch

- Listening sessions
  - Patients
  - Community Groups
  - Primary Care Providers
  - Hospital Systems
  - Research Networks
  - Federal Agencies

Communities **A**dvancing **R**esearch **E**quity **for Health**

CARE for Health™

Conduct research addressing **issues important to diverse communities**, particularly those **underrepresented** in biomedical research

Reduce burden on providers using innovative data collection methods

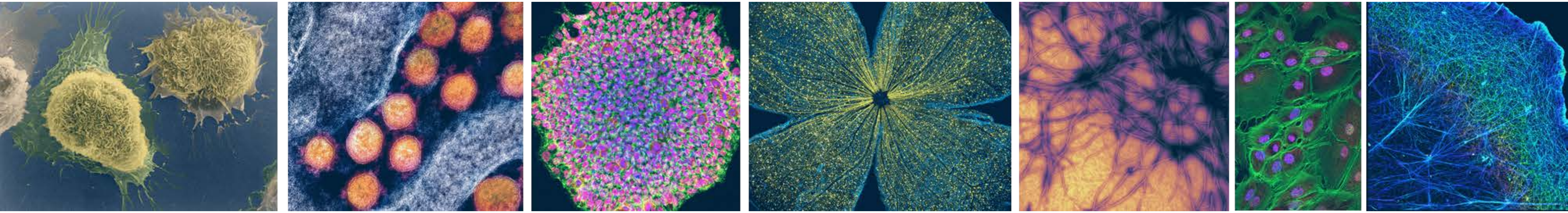
Increase adherence to **evidence-based care**

Improve **efficiency of care delivery**

Integrate research into the clinical care environment

Engender trust in science by addressing community needs

Achieve **longitudinal collection of clinical data** to address health across the lifespan



NIH

Turning Discovery Into Health

Overview of Listening Sessions: What We Heard

Joni Rutter, Ph.D.
Director, National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health (NIH)

We Hosted 4 Listening Sessions in Spring 2024

Listening Session 1: Early, Sustained Engagement of Patients and Community Organizations

Listening Session 2: Clinical Research Network Capabilities

Listening Session 3: Needs of Providers and Healthcare Systems for Research Participation

Listening Session 4: Clinical Research Innovations to Reduce Site and Provider Burden

The listening sessions engaged **78** unique participants with perspectives from:

- Research Networks
- Hospital Systems
- Primary Care Providers and Organizations
- Patient and Community Organizations
- Federal Agencies

What We Heard

Bridging Gaps and Building Connections

Accounting for Provider Needs in Research Integration

Balancing Financial Implications of Research Involvement

For more details on the Listening Sessions, please review the executive summary posted on the CARE for Health website

Bridging Gaps and Building Connection

Building Sustainable and Effective Partnerships

- Transition from episodic to continuous engagement
- Build and maintain capacity through mentorship, administrative support, and sustained staffing
- Maintain ongoing relationships (including financially) with local community partners

Demonstrating Trustworthiness Through Balanced and Bi-directional Partnerships

- Co-develop and shape the research agenda
- Trust and consistency stem from a deep-seated physical community presence
- Active observation to understand and meet community needs

Understanding the Diverse Needs of Communities

- There is no "one size fits all"; adapt research engagement approaches
- Raise provider and researcher cultural competency and enhance community literacy
- Implement decentralized research studies to increase participation

Accounting for Provider Needs in Research Integration

Aligning Practice Needs and Research Structures

Establish relationships with entire clinical team and stakeholders

Enhance information access to relevant clinical trials for patients

Communication and flexible research designs address misalignment between pace of research and pace of care

Considering the Workload of Health Care Providers

Account for the clinical team's routine operations

Provide research support and resources for administrative tasks

Reducing Burden with Innovative Study Design and Technology

Novel research allow exploration of questions and interventions relevant to patient care

Artificial Intelligence, common data models, and data tokenization can simplify research process

Consultation with providers should inform how technology is integrated into research

Balancing Financial Implications of Research Involvement

Addressing Financial Sustainability

Ensure funding is adaptable to meet care and local needs

Consider revenue impact on providers and explore ways to provide financial remuneration for time spent on research

Valuing Patient and Community Contributions

Patient and communities should be included in the decision-making process, to effectively co-create

Existing funding structures pose challenges to compensate community organizations

Individuals and community organizations deserve equitable compensation

Panel Discussion: Visions of Success from Providers and Patients

Moderated By: Felicia Qashu, Ph.D.
Program Leader, Office of Strategic Coordination
National Institutes of Health (NIH) Common Fund

Visions of Success from Providers and Patient Organizations

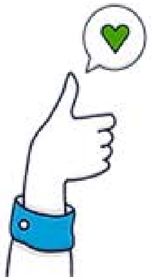
Dr. Sally Hodder
Mountaineer Health Initiative

Dr. Fornessa Randal
Asian Health Coalition; Pennsylvania State College of Medicine's Center for Advancing Health Equity in Rural and Underserved Communities

Dr. Meagan Stabler
Northern New England CO-OP Practice & Community Based Research Network

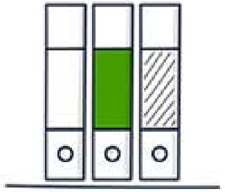
Mr. Silas Buchanan
Our Healthy Community

Community-first looks like this.



Community-vetted materials and campaigns

Equitable partnerships with the healthcare industry



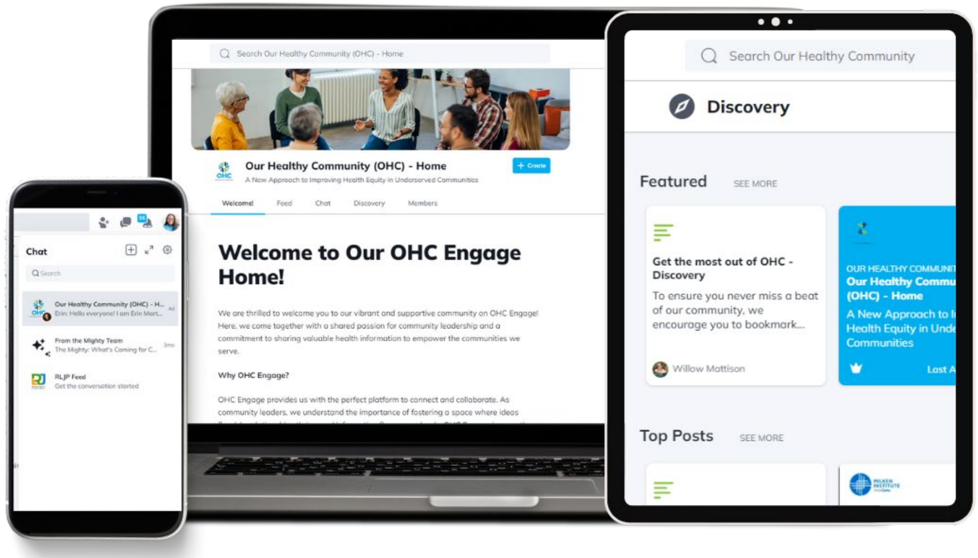
Educational content

Co-developed resources

OHC
OUR HEALTHY COMMUNITY

ENGAGE

Powered by OHC



Our Healthy Community (OHC) - Home

A New Approach to Improving Health Equity in Underserved Communities

Welcome to Our OHC Engage Home!

We are thrilled to welcome you to our vibrant and supportive community on OHC Engage! Here, we come together with a shared passion for community leadership and a commitment to sharing valuable health information to empower the communities we serve.

Why OHC Engage?

OHC Engage provides us with the perfect platform to connect and collaborate. As community leaders, we understand the importance of fostering a space where ideas

Our Healthy Community (OHC) - H...
Erin: Hello everyone! I am Erin Mort...

From the Mighty Team
The Mighty: What's Coming for C...

RLJP Feed
Get the conversation started

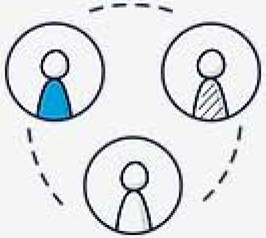
Get the most out of OHC - Discovery

To ensure you never miss a beat of our community, we encourage you to bookmark...

OUR HEALTHY COMMUNIT
Our Healthy Commu
(OHC) - Home
A New Approach to I
Health Equity in Unde
Communities

In OHCEngage, we bring community organizations together to share resources, address health disparities, converse with healthcare stakeholders, and foster dialogue and collaboration.

Connect and collaborate with others, sharing successes along the way



Join regional groups, with events and programming in your own backyard

Connect with organizations for research, collaboration, and innovation

OHC
OUR HEALTHY COMMUNITY

ENGAGE

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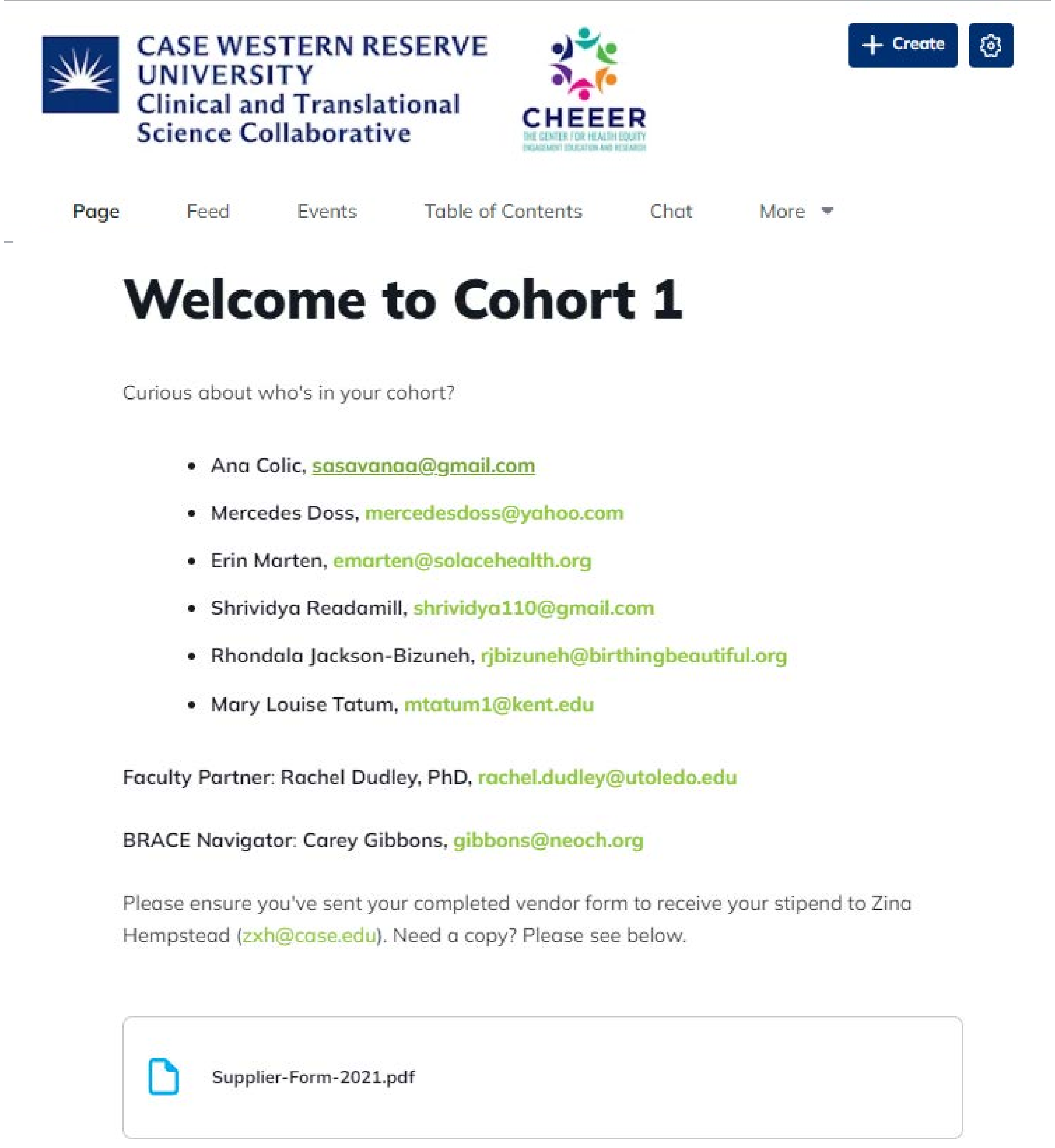

Welcome to Cohort 1

Curious about who's in your cohort?

- Ana Colic, sasavanaa@gmail.com
- Mercedes Doss, mercedesdoss@yahoo.com
- Erin Marten, emarten@solacehealth.org
- Shrividya Readamill, shrividya110@gmail.com
- Rhondala Jackson-Bizuneh, rjbizuneh@birthingbeautiful.org
- Mary Louise Tatum, mtatum1@kent.edu

Faculty Partner: Rachel Dudley, PhD, rachel.dudley@utoledo.edu

BRACE Navigator: Carey Gibbons, gibbons@neoch.org

Please ensure you've sent your completed vendor form to receive your stipend to Zina Hempstead (zxh@case.edu). Need a copy? Please see below.

Supplier-Form-2021.pdf

OHC
OUR HEALTHY COMMUNITY

Scan to join us on ENGAGE

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OHC
OUR HEALTHY COMMUNITY

Silas Buchanan, Founder & CEO
Our Healthy Community
sbuchanan@ourhealthycommunity.com

CENTER FOR ADVANCING HEALTH EQUITY
IN RURAL AND UNDERSERVED COMMUNITIES

Integrating Clinical Research in Primary Care Settings

Dr. Fornessa T Randal, EdD, MCRP
Director, CAHE-RUC
Executive Director, Asian Health Coalition
PI, All of Us Research Program, NCEP

Primary Care and The Community

Deliver the Right Care and the Right Time

(New Mexico)

Address issues of a “Whole Person” not a “study participant”

(Illinois)

Provider Cultural Competency to drive Better Health

(Pennsylvania)

Pathways to Research through Multisector Collaboration

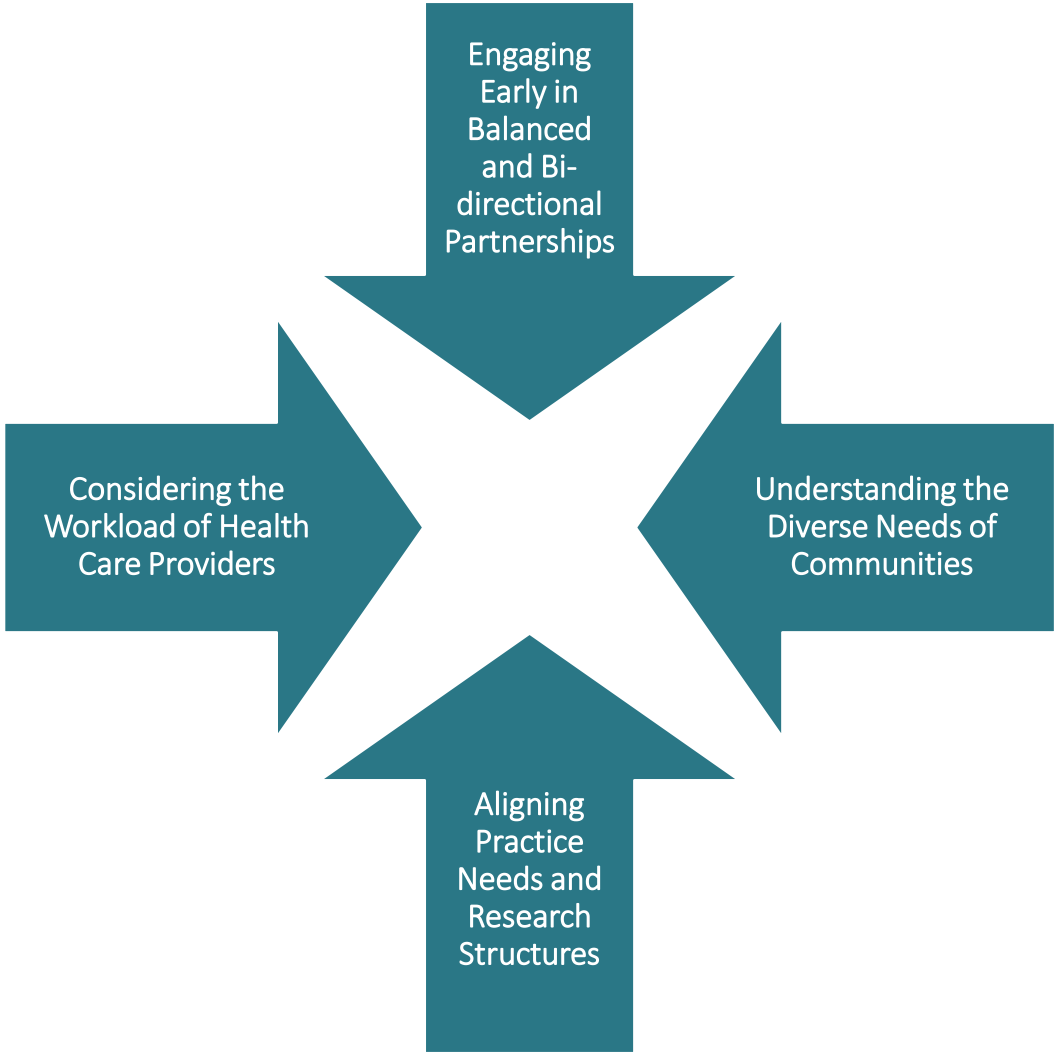
(California)

Seifert, B., Volckaert, A. E., Flaherty, E., & Pepin, R. L. Bridging the gap between primary care and community-based organizations to address complex care needs of older adults. Journal of the American Geriatrics Society, 72, S21-S25. https://doi.org/10.1111/jgs.18670

Murnik, M., Randal, F., Guevara, M., Skipper, B., & Kaufman, A. (2006). Web-based primary care referral program associated with reduced emergency department utilization. FAMILY MEDICINE-KANSAS CITY-, 38(3), 185

Randal, F. T., Lozano, P., Qi, S., Maene, C., Shah, S., Mo, Y., Ratsimbazafy, F., Boerwinkle, E., Cicek, M., & Clark, C. R. (2023). Achieving a Representative Sample of Asian Americans in Biomedical Research Through Community-Based Approaches: Comparing Demographic Data in the All of Us Research Program With the American Community Survey. Journal of Transcultural Nursing, 34(1), 59-67.

Building Sustainable & Effective Clinical Research Partnerships



Engaging Early in Balanced and Bi-directional Partnerships

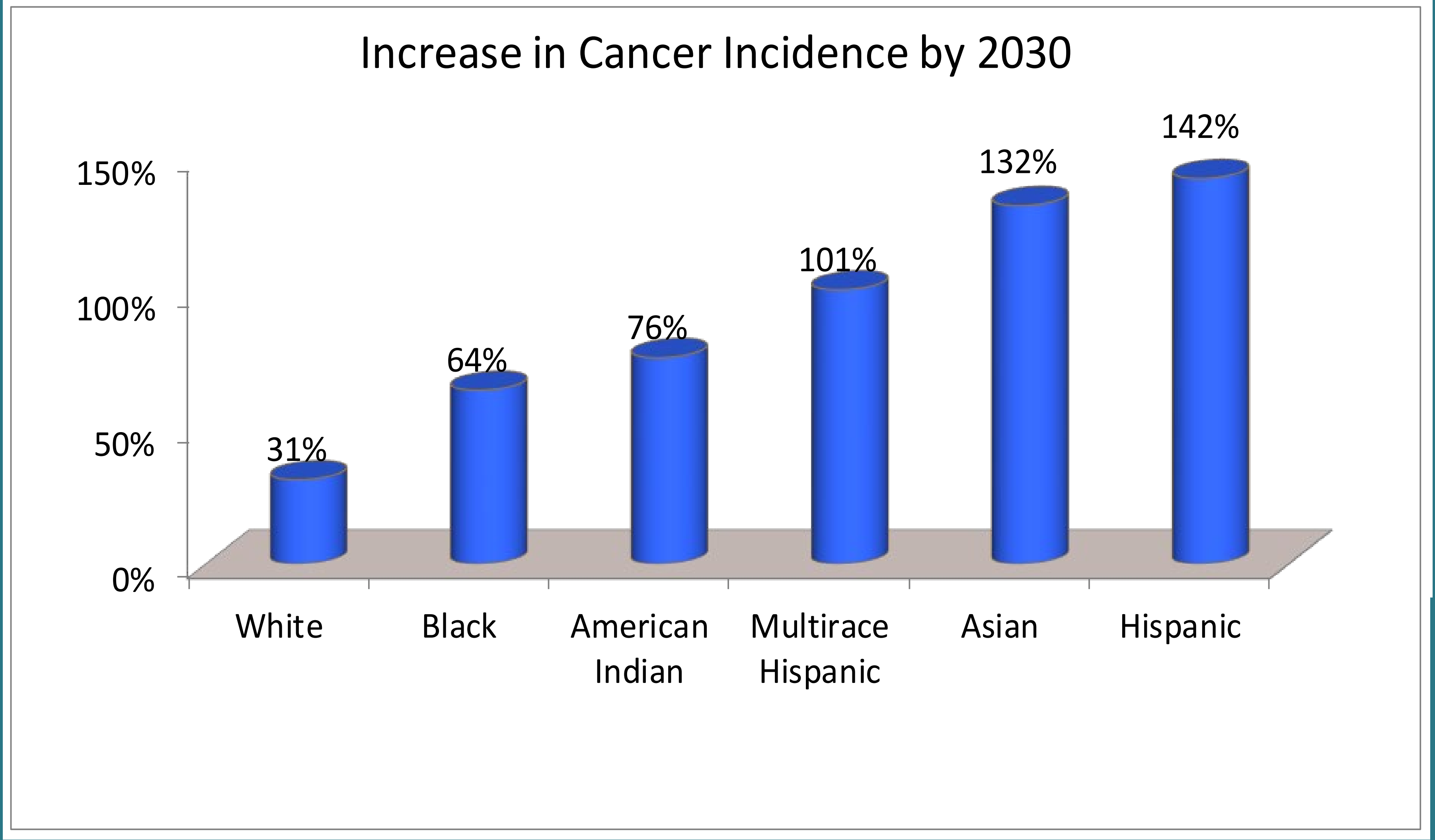
Considering the Workload of Health Care Providers

Understanding the Diverse Needs of Communities

Aligning Practice Needs and Research Structures

EXECUTIVE SUMMARY OF THE FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH (FNIH)-NATIONAL INSTITUTES OF HEALTH (NIH) LISTENING SESSIONS ON RESEARCH IN PRIMARY CARE SETTINGS (2024)

Clinical Integration reduces disease burden: Who is most at risk?



Benjamin D. Smith et al., Future of Cancer Incidence in the United States: Burdens Upon an Aging, Changing Nation. JCO 27, 2758-2765(2009). DOI:10.1200/JCO.2008.20.8983

Panel Discussion: Visions of Success from Networks and Federal Agencies

Moderated By: Tara Schwetz, Ph.D.

NIH National Institutes of Health

Visions of Success from Networks and Federal Agencies

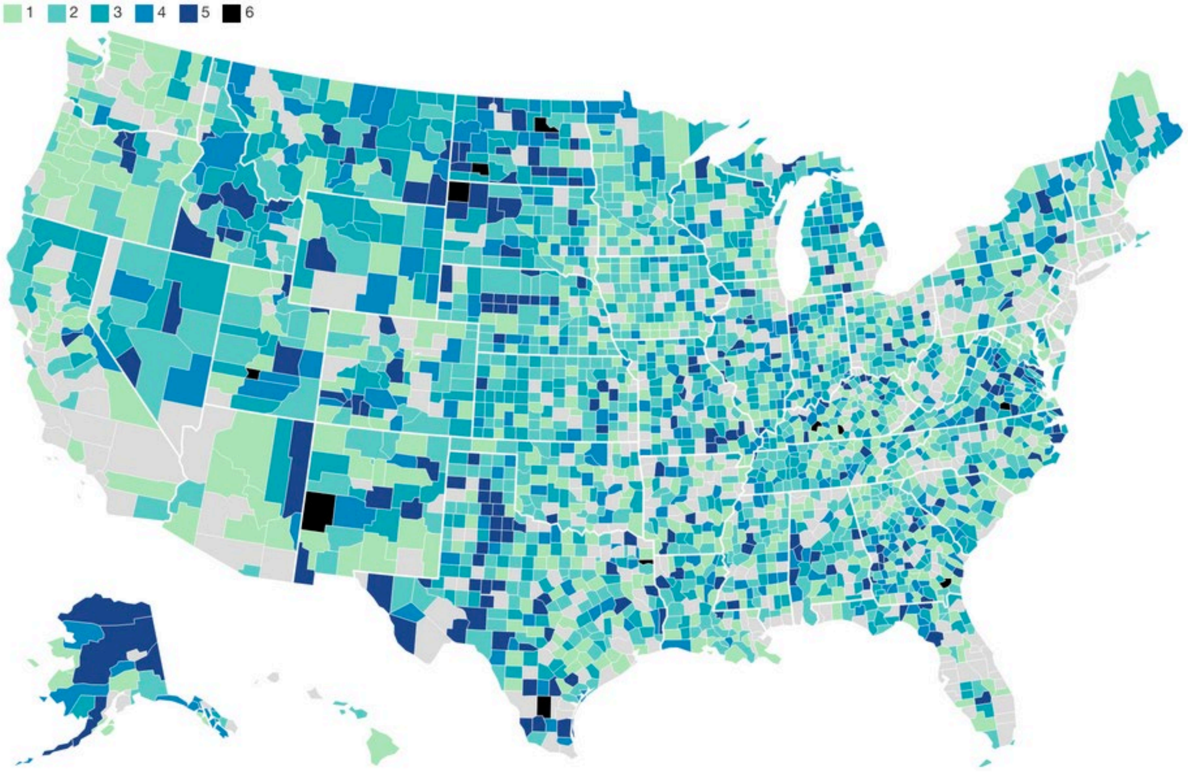
Dr. Adrian Hernandez
Duke Clinical Research Institute

Dr. Melinda Davis
Oregon Rural Practice-based Research Network

Dr. Jannette Dupuy
Health Resources and Services Administration (HRSA)

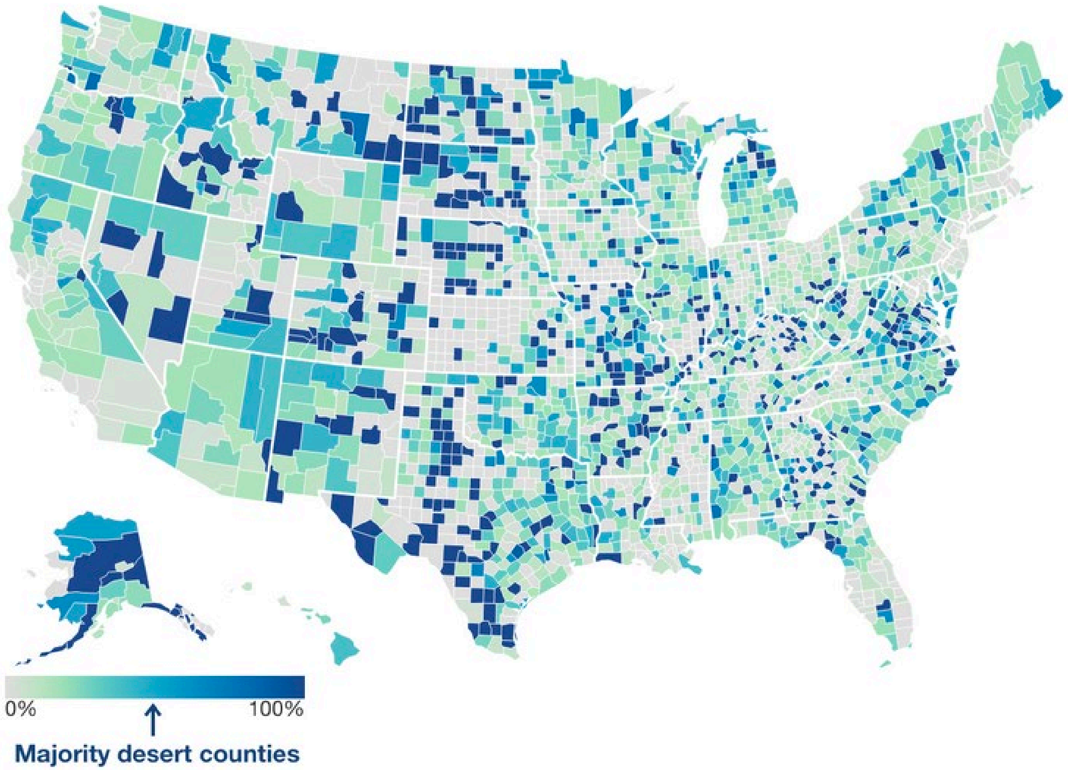
Dr. Aimee Eden
Agency for Healthcare Research & Quality (AHRQ)

The Problem: Covering Clinical Trial Deserts



Healthcare Deserts, County by County

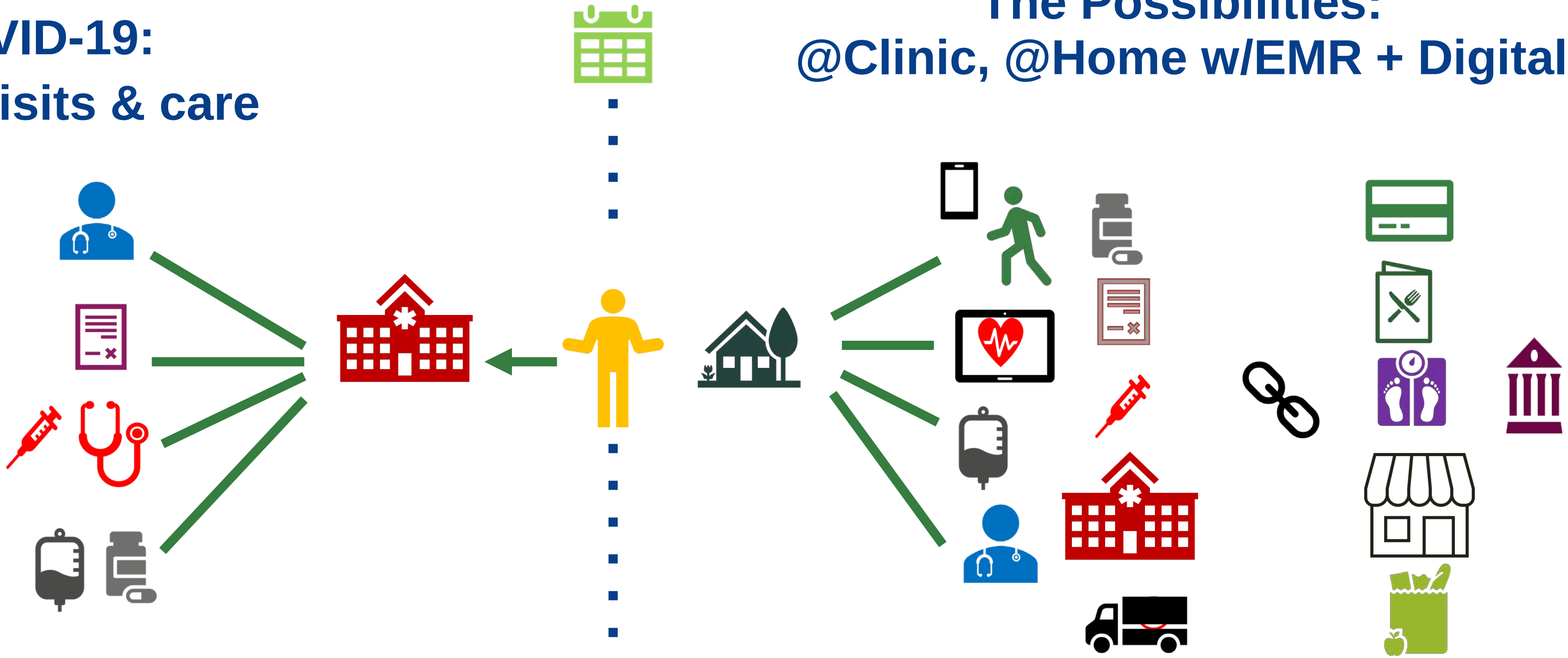
Counties where most people lack adequate access to pharmacies, primary care providers, hospitals, hospital beds, trauma centers, and/or low-cost health centers.



Population Living in a Hospital Desert

Percent of county's population living over 30 minutes from the closest hospital.

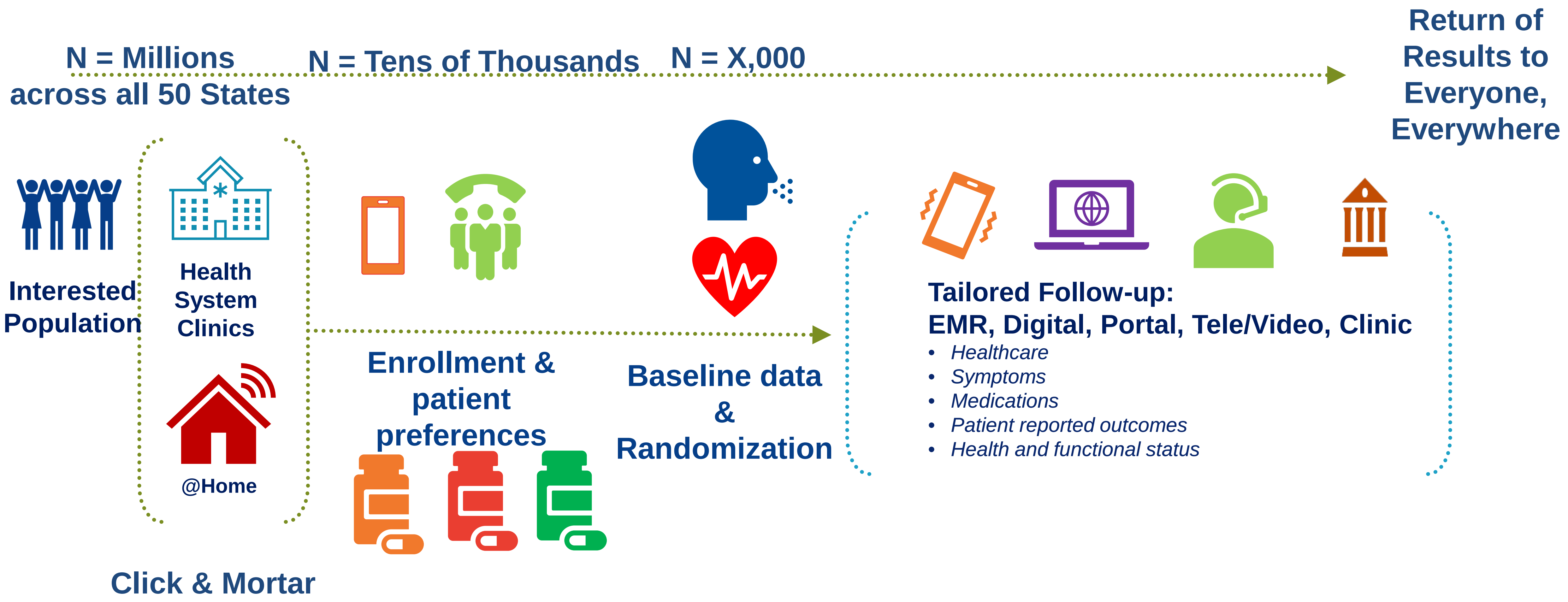
A Changed World of Possibilities



Pre-COVID-19:
Site based visits & care

The Possibilities:
@Clinic, @Home w/EMR + Digital

Art of Possible into Reality
Click and Mortar Model for Pragmatic Clinical Trial Platform



N = Millions across all 50 States

N = Tens of Thousands

N = X,000

Return of Results to Everyone, Everywhere

Interested Population

Health System Clinics

@Home

Click & Mortar

Enrollment & patient preferences

Baseline data & Randomization

Tailored Follow-up:
EMR, Digital, Portal, Tele/Video, Clinic

- *Healthcare*
- *Symptoms*
- *Medications*
- *Patient reported outcomes*
- *Health and functional status*

Definition of “primary care research”

Research conducted for the purpose of better understanding or improving primary care (as defined by NASEM 2021). It is research that is

a) conducted in a primary care setting;
b) about primary care patients, clinicians, or teams;
c) on a topic that is integral to, or has direct implications for, the delivery of primary care.

NATIONAL CENTER
FOR EXCELLENCE IN
PRIMARY CARE RESEARCH

Primary Care
Practice-based Research Networks (PBRNs)

AHRQ defines PBRNs as "groups of primary care clinicians and practices working together to answer community-based health care questions and translate research findings into practice."

Coverage of Networks

CARE for Health: the Path Forward

Amy Patterson, M.D.
Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

Establishing an NIH Network for Research in Primary Care Settings

Coordinated infrastructure that embeds innovative research into routine clinical care in primary care settings, that will…

- Support primary care-based clinical research in mission areas **spanning prevention and treatment** and with a **focus on health equity and whole person health**
- Establish a foundation for **sustained engagement with communities underrepresented** in clinical research
- Implement **innovative study designs suitable for primary care settings** that address common health issues and inform clinical practice and enhance dissemination and implementation

…thereby facilitating and accelerating research advances for adoption and implementation into everyday clinical care, improving health outcomes, and advancing health equity for all Americans.

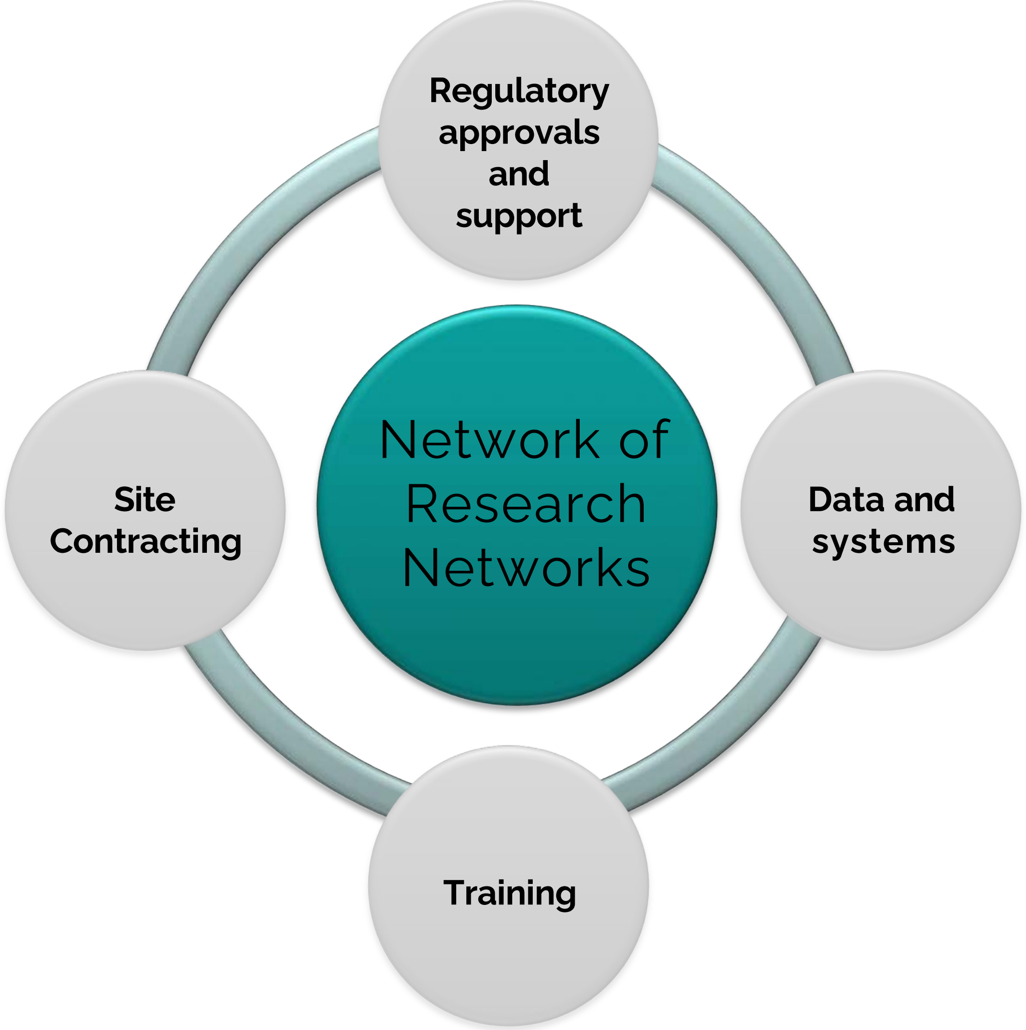
Approach

Expand enrollment efforts of existing NIH studies and pilot new studies as the infrastructure is established

Partner with existing clinical research networks and resources, expanding with new collaborations as the network grows

Engage primary care sites and community network partners on prioritizing and planning research

Implement study designs across the landscape of clinical trial innovations to minimize burden on patients and providers



Regulatory approvals and support

Site Contracting

Network of Research Networks

Data and systems

Training

Practice-based and Patient-centered

Research prioritization and planning

Clinical study innovations

Sustained community engagement

Potential Synergistic Partnerships

IDeA | Clinical and Translational Research

NIH CEAL
Community Engagement Alliance

CTSA Clinical & Translational Science Awards Program

NIH Collaboratory
Health Care Systems Research Collaboratory

pcornet®
The National Patient-Centered Clinical Research Network

Patients, Communities

Community Health Centers

Federally Qualified Health Centers

CARE for Health Partners

Professional Societies

Federal Agencies

Practice Based Research Networks

COMMUNITY HEALTH CENTER®
FQHC
QUALITY

HRSA
Health Resources & Services Administration

OASH Office of the Assistant Secretary for Health

FDA U.S. FOOD & DRUG ADMINISTRATION

INDIAN HEALTH SERVICE · PHS · 1955 ·

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

AHRQ Agency for Healthcare Research and Quality

NIH National Institutes of Health

CARE for Health Leadership

CARE for Health Oversight Committee Co-Chair

Helene Langevin, M.D.

Director, National Center for Complementary and Integrative Health (NCCIH)

CARE for Health Oversight Committee Co-Chair

Joni Rutter, Ph.D.

Director, National Center for Advancing Translational Sciences (NCATS)

CARE for Health Oversight Committee Co-Chair

Debara Tucci, M.D., M.S., M.B.A.

Director, National Institute on Deafness and Other Communication Disorders (NIDCD)

CARE for Health Oversight Committee Ex-Officio

Tara Schwetz, Ph.D.

NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives

Timeline & Budget

Spring 2024: Obtain perspectives from external partners to inform planning for the network

- Listening sessions and public workshop

Quick Launch in 2024: Expand existing NIH-funded studies to increase engagement with underrepresented rural populations and to enhance accrual and collaboration

- Research Opportunity Announcement published May 6, 2024
- Common Fund Program with an anticipated budget of $5M in FY24

Expand in 2025 and Beyond: Launch new studies across the network and further establish and solidify the network infrastructure and expand to additional populations

- Anticipated budget: $25M in FY25; anticipate ramp up of $50-100M/year after assessing feasibility and budget requirements

Network Research Hubs: Objectives

- Research in Primary Care Settings in Collaboration with Clinical Sites on Select Existing NIH-Funded Studies and New Studies
- Participant and Community Engagement
- Innovations in Clinical Study Design
- Participation in Coordinated Infrastructure Supporting Research in Primary Care Settings

Infrastructure to Embed Research into Primary Care

Infrastructure components anticipated to be piloted and implemented

Network Research Hubs

Clinical Science Center

Operations Center

Independent Review and Monitoring Boards

Community Engagement

Industry Partnerships

Phased Approach to Launching Studies and Building Infrastructure

This effort is expected to be a **two-year pilot**

1 **Year 1**

Fund Network Research Hubs

That will participate in selected existing studies. These studies may be interventional or observational and are expected to be suitable for primary care settings

2 **Year 2**

Conduct New Research

In coordination with the other components of the infrastructure

Perform a Program Evaluation

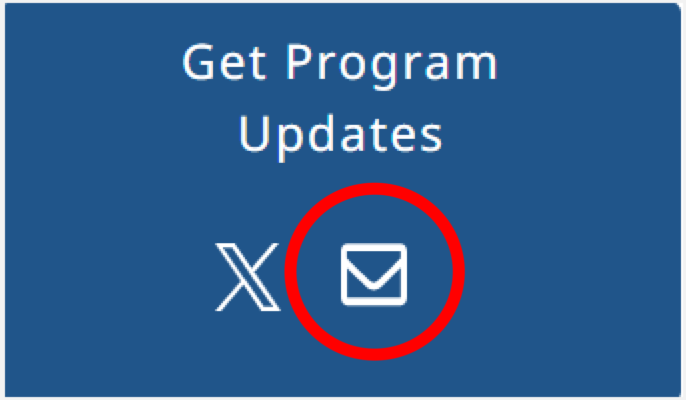
Before the end of year two, NIH will evaluate which approaches and efforts are working for broader implementation

CARE for Health: Information Resources

Additional resources can be accessed via the CARE for Health website:

- ✓ Research Opportunity Announcement (ROA)
- ✓ Technical Assistance Webinar Recording and Slides
- ✓ Listening Session Executive Summary

To stay up-to-date on program activities, please sign up for the listserv:



Get Program Updates

The listserv registration button can be found on the left side of the CARE for Health website

Open Question and Answer

Moderated By: Tara A. Schwetz, Ph.D. and Amy Patterson, M.D.

Stay in Touch!

For program updates, please visit **go.nih.gov/CARE-for-Health**. You can also sign up to join our listserv.

Reach us at: CAREforHealth@od.nih.gov

Have additional feedback? Share your thoughts via Slido.

Scan the QR code below or visit Slido.com and use code #1222418.

Thank you!

go.nih.gov/CARE-for-Health

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