

Concept Clearance

Common Fund – Network for Research in Primary Care Settings

Background

A major barrier to participating in clinical research is lack of access to or availability of clinical studies. There is a critical need to extend research participation opportunities to broader communities, in part, because those that are traditionally underrepresented in research are also often medically underserved and disproportionately impacted by disease and illness (e.g., racial and ethnic groups, gender minority groups, people who live in rural environments, older adults, persons experiencing challenging social determinants of health and related experiences). When research study demographics don't match the demographics of the illness or condition being studied, generalizability of the evidence is compromised, further compounding these health disparities¹. While most have not talked with their doctor about participating in health research, Americans increasingly agree that opportunities for participation in clinical trials should be a part of regular healthcare². Therefore, NIH is proposing to establish a network to conduct research in primary care settings. This network will address barriers to access to clinical research participation by implementing a sustained infrastructure that integrates innovative research with routine clinical care in real world settings, with a focus on sustained engagement with communities that are traditionally underrepresented in clinical research. Improving access to clinical studies will facilitate and accelerate research advances for adoption and implementation into everyday clinical care, improving health outcomes and advancing health equity for all Americans.

Goals

- Pilot and implement the infrastructure for a network on primary care-focused clinical research to serve all ICs, particularly those without their own large-scale networks
- Establish a foundation for sustained engagement with communities underrepresented in clinical research (e.g., racial and ethnic minority groups, gender minority groups, people who live in rural environments, older adults, persons experiencing challenging social determinants of health and related experiences)
- Implement innovative study designs that address common health issues, including disease prevention
- Engage with community and health care systems to integrate innovative science with routine clinical care and change clinical practice as a result of the research outcomes

Initiatives: The network will involve the following initiatives.

1. Scientific Oversight and Innovation
 - Study oversight (protocol oversight, site and study selection, managing a Central IRB, and statistics and data management)

¹ National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research; Bibbins-Domingo K, Helman A, editors. Washington (DC): National Academies Press (US); 2022 May 17

² A Research!America survey of U.S. adults conducted in partnership with the ACRO and Zogby Analytics in October 2023.

- Clinical trial innovation to minimize burden on participants and providers
- 2. Operations – conduct site feasibility assessments, site management/contracting, regulatory/protocol support, training, and data monitoring/auditing
- 3. Network Partners – leverage existing research networks and primary care and community health partners; expand with growth of the program
- 4. Resources and Community Engagement – leverage existing resources and support new efforts to facilitate community engagement; integrate studies in primary and community care settings
- 5. Industry Partners – engage with for-profit partners for collaborative knowledge sharing, potential participation in the network

Alignment with Common Fund Criteria

- **Transformative** – Through this network on primary care research, establish the infrastructure to enable clinical research participation to become an equitable opportunity in routine clinical care
- **Catalytic** – Expand participation by individuals under-represented in clinical research through sustained and focused engagement
- **Synergistic/Enabling** – The research network will be value-added to the mission of all ICs, in particular those without large research networks
- **Cross-cutting** – The network will address diseases and conditions that cut across the missions of the ICs, and potentially multi-disease endpoints, requiring trans-NIH expertise and coordination
- **Novel** – The research network will serve as a focal point for implementing innovative clinical study designs to improve engagement with and reduce the burden of research on providers and patients

Deliverable: An infrastructure to enable clinical research participation to become an equitable opportunity in routine clinical care

Planned Budget: \$5M in FY24, \$25M in FY25; anticipate ramp up of ~\$50-100M/year after assessing feasibility and budget requirements