

Community & Stakeholder Input to Inform the Future of HIV Research

January 8, 2025





Advancing Clinical
Therapeutics Globally
for HIV/AIDS and
Other Infections

Priority areas: Therapeutics (co-morbidities, cure, TB, hepatitis)



HIV VACCINE
TRIALS NETWORK

Priority areas: HIV vaccines

The Office of HIV/AIDS Network
Coordination (HANC) coordinates
across all networks



HPTN
HIV Prevention
Trials Network

Priority areas: Non-vaccine
prevention; PrEP, integrated
strategies



Priority areas: Maternal,
adolescent & pediatric therapeutics

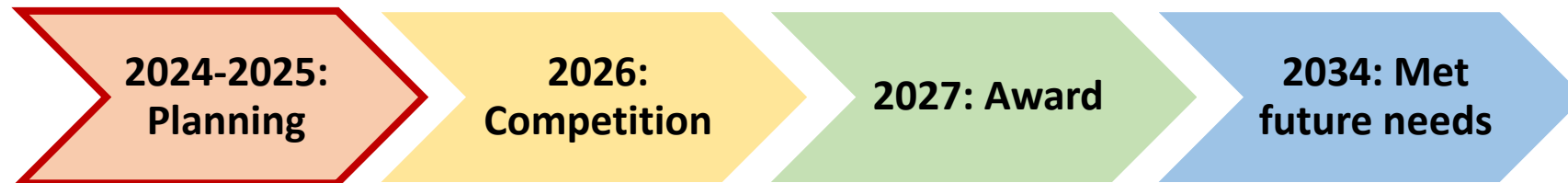
Webinar Moderator



Russell Campbell, MA
HANC Director

Setting the 2034 Research Agenda

- **Every 7 years, NIH competitively reviews its HIV network funding, addressing significant changes in research priorities**
- **By establishing a forward-looking agenda now, NIH will determine the focus and structure of its HIV clinical trials networks through 2034**



Network Competition Timeline

- Spring 2024: Launch process with network presentations to SWG
- **Summer through January 2025: Input from the stakeholders (investigators, community, etc.)**
 - Webinars, blog posts on selected topics, thematic discussions, townhalls, written feedback
- **Fall 2024: Preliminary discussion at ARAC and other advisory committees**
- **Jan 2025: Formal presentation to ARAC of the refined network and units structure for approval**
- 2025: Begin RFA authorship
- Jan 2026: Publish RFAs
- Fall 2026: Applications due
- Winter/Spring 2027: Review
- Sept 2027: Applications to Council
- Dec 2027: Earliest start date

Outreach with Stakeholders

- **The vision and plans have been presented and discussed at multiple venues and at all annual network meetings**
- **This is the third webinar with Network community members and stakeholders, facilitated by the Office of HIV/AIDS Network Coordination (HANC)**
 - The first focused on scientific priorities, May 30, 2024
 - The second on clinical trial units and clinical research sites, September 4, 2024
- **The webinar today will focus on the proposed structures and research agendas for the next grant cycle**

Outreach with Stakeholders

HIV Clinical Research Enterprise

Blog Series

Community Stakeholder Input

Webinar Recordings

Previous Consultations and Network Competitions >

Research

HIV Clinical Research Enterprise

Shaping the Future of the NIH HIV Clinical Trials Networks

NIAID supports [four research networks](#) as part of its HIV clinical research enterprise. Every seven years, the Institute engages research partners, community representatives, and other public health stakeholders in a multidisciplinary evaluation of network progress toward short- and long-term scientific goals. This process takes account of knowledge gained since the networks were last funded and identifies essential course corrections based on the latest scientific and public health evidence. Subsequent NIAID HIV research investments build on the conclusions of these discussions.

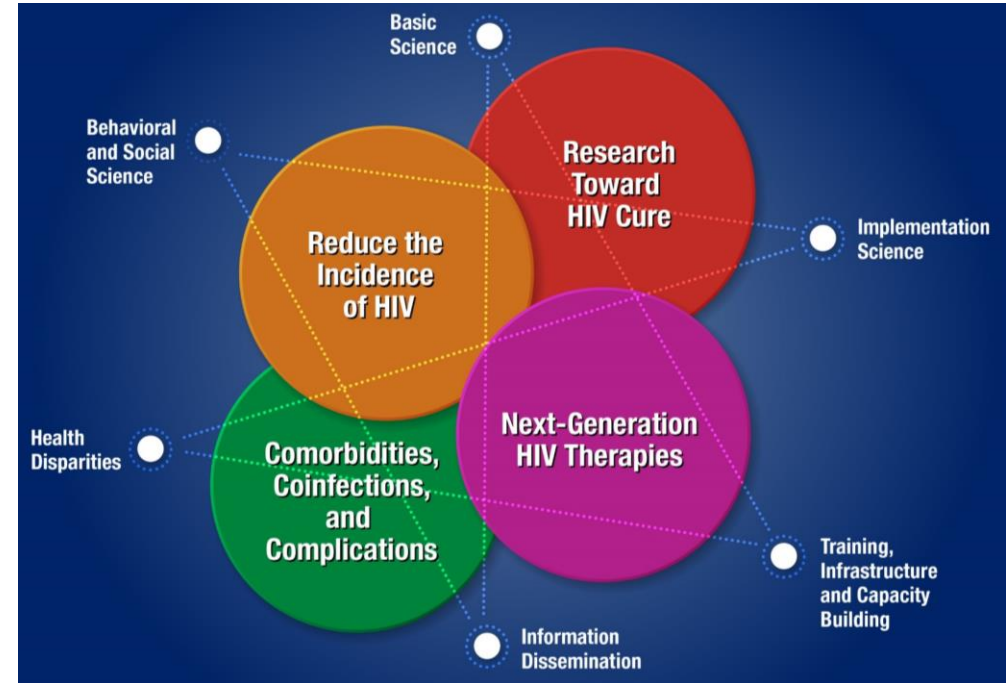
NIAID is currently seeking feedback from the research community, which plays an essential role in shaping NIAID's scientific direction and research enterprise operations. Please share your questions and comments at NextNIAIDHIVNetworks@mail.nih.gov or in the form below. Please note entries through the form below are anonymous unless contact details are provided. NIAID responses to submitter questions are [summarized in a public Q&A](#).

Feedback on the NIAID HIV Clinical Research Enterprise

<https://www.niaid.nih.gov/research/hiv-research-enterprise>

Research Priorities

- HIV Prevention
- HIV Vaccines
- HIV Treatment
- HIV Cure
- HIV Co-infections & Co-morbidities
- Ending the HIV Epidemic (EHE)
- Pandemic Response



Network Evolution

- **NIH proposes to maintain four leadership groups**
- **The overarching themes of this renewal are innovation and collaboration**
 - In this current grant period, the groundbreaking studies often sprouted from collaborations
 - Significant collaborations with NIMH, NICHD, NIDA, NHLBI, NIA, NIDCR, and NINDS
 - Enhance collaborations within NIAID
- **Moving forward, additional collaborations are essential to address the full research agenda and advance implementation research plans**
 - Expand collaborations with parts of NIH that lead the research agenda on non-infectious co-morbidities and other relevant diseases
 - Implementation research projects will originate through partnerships with implementers—CDC, HRSA, PEPFAR and others
- **Equipping the clinical trials enterprise with the tools to maintain readiness for pandemic response is essential**

Seven Notice of Funding Opportunity (NOFOs) – UM1 RFAs

4 NOFOs for Leadership and Operations Centers (LOCs)

HIV Prevention
UM1

HIV Vaccines
UM1

HIV/AIDS Adult Therapeutics
UM1

HIV/AIDS Maternal, Adolescent and Pediatric Therapeutics
UM1

1 NOFO for Statistical and Data Management Centers (SDMC)
(2-4 awards)

SDMC
UM1

1 NOFO for Laboratory Centers (LC)
(2-4 awards)

Laboratory
UM1

1 NOFO for Clinical Trials Units (CTUs)
(30-35 awards)

CTU
UM1

Seven NOFOs Yield Four Networks

Prevention Scientific Foci

**Novel biomedical methods
of HIV prevention**

**Behavioral and social
science partnerships**

**Protection in key populations,
including adolescents, women,
MSM, and U.S. populations
affected by health disparities**

**Improve implementation of
new biomedical and
behavioral prevention
strategies**

Pandemic preparedness and response

HIV Vaccines Scientific Foci

Establish vaccine efficacy

- Evaluate vaccines against sites of vulnerability
- Initiate pediatric studies once efficacy is established

Define correlates of protection

- Partner to evaluate the most efficacious vaccine based on progress in the field

Beyond preventive HIV vaccines*

- Integration of Px Vx products with HIV Tx and Cure
- Evaluation of TB vaccine candidates
- * With collaborating network partners

Pandemic preparedness and response

Therapeutic Scientific Foci

Novel and durable therapy

- Pharmacology, drug formulations
- Long-acting formulations of ART, bNABs and other novel therapeutic modalities

Cure or ART-free remission

- Clear, control or silence reservoir
- Immune-based interventions
- Gene/cell therapies

Tuberculosis

- Shorter and safer therapies for all forms of TB
- Diagnostics, drug susceptibility testing
- Biomarkers

Co-morbidities and co-infections

- HBV cure strategies
- Long-acting formulations of HCV
- Cellular and immune dysregulation
- Prevent and treat end organ disease

Pandemic preparedness and response

Maternal and Child Scientific Foci

Optimized therapeutics for HIV and infectious co-morbidities

- Pharmacology, drug formulations
- Long-acting formulations of ART and bNAbs
- Postnatal prophylaxis
- Therapeutics for key co-infections (HCV, CS)

Cure and immunotherapy

- Very early newborn treatment incl. bNAbs
- Combination Immune-based therapies to clear, control or silence reservoir
- CNS and tissue reservoir targeting
- Gene/cell therapies
- Vaccine response against priority pathogens

Tuberculosis

- Shorter therapies for DS and DR
- Improve TB preventive therapy
- Pharmacology, drug formulations
- Optimized diagnostics, biomarkers

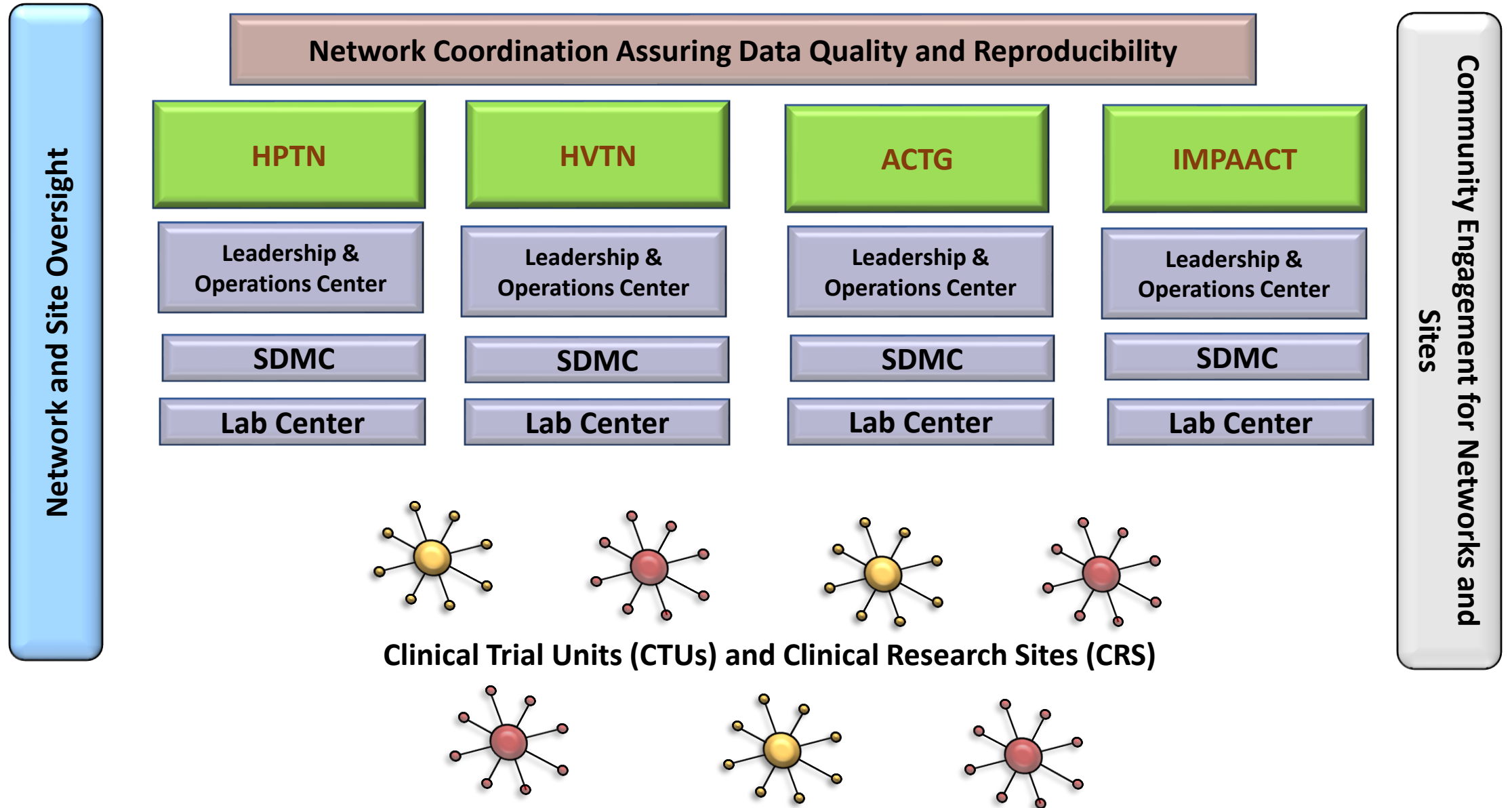
Brain and mental health

- Optimal TB neurocognitive development and mental health
- Neuroprotective therapeutic approaches or those targeting neurocognitive and mental health disorders

Pandemic preparedness and response

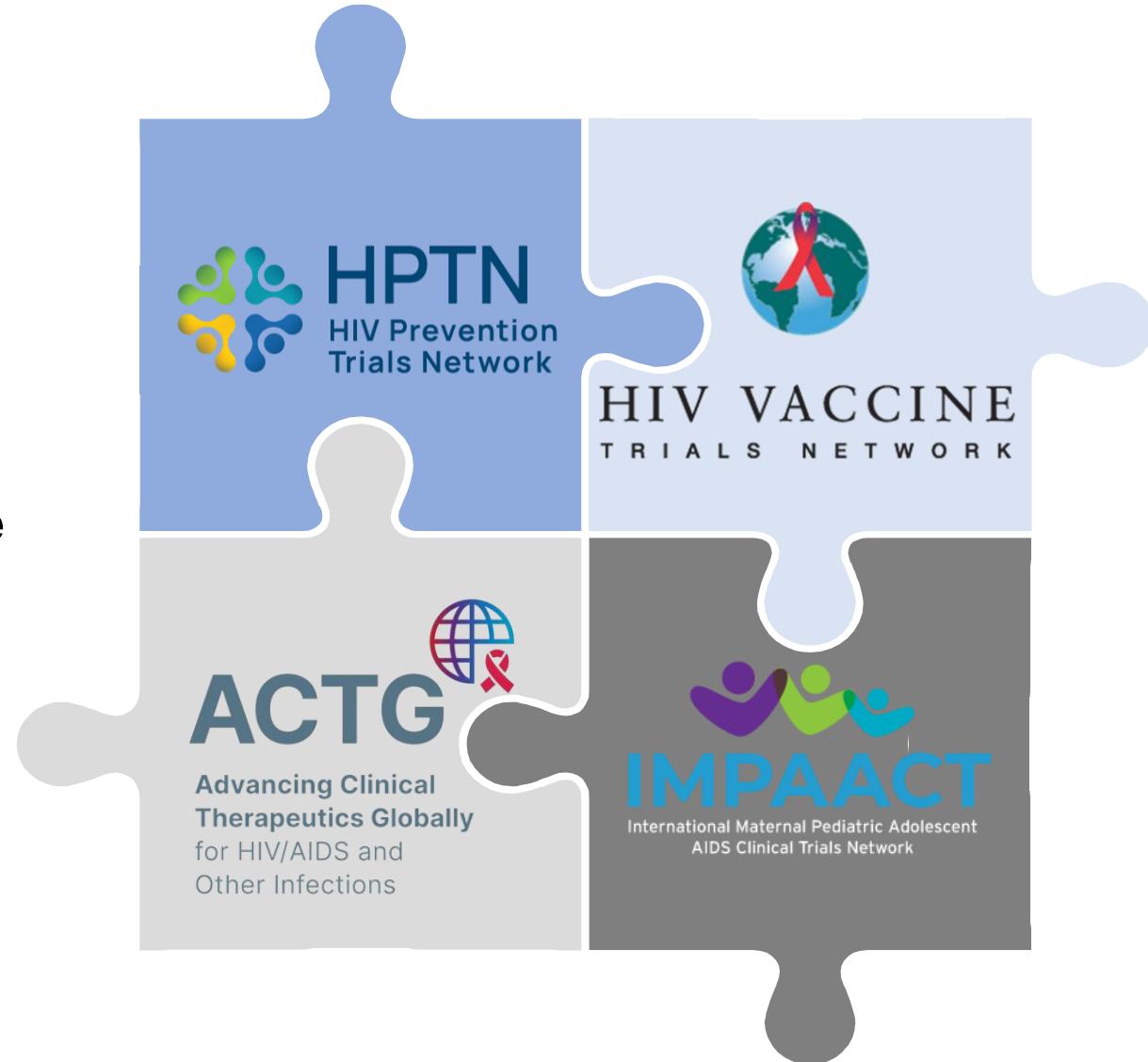
Clinical Trial Units & Clinical Research Sites

HIV/AIDS Network Structure



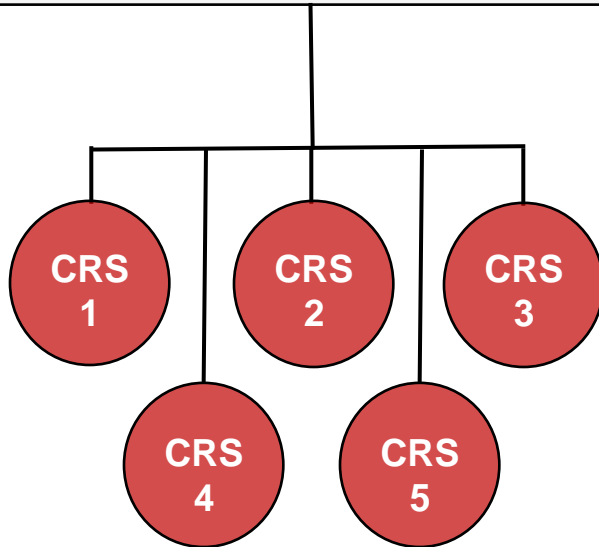
Critical Infrastructure: CTUs

- A Clinical Trials Unit (CTU) is a cohesive, integrated unit consisting of clinical research sites, community engagement structures, pharmacies, laboratories and other clinical research resources which participate in the breadth of studies developed by the NIAID HIV/AIDS networks. A CTU coordinates and executes clinical trials in accordance with the networks, NIAID and other applicable policies.
- Last recompleted in December 2020
- To be awarded in December 2027
- Funded 35 CTUs



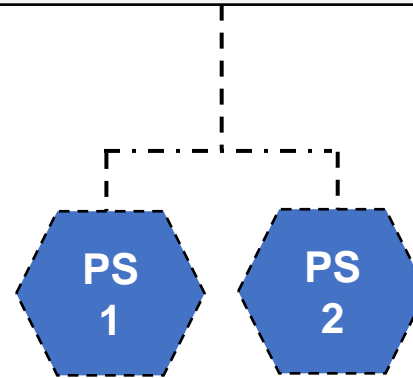
Clinical Trials Unit

- Administrative capacity
- Shared resources
- Mentoring and oversight



Clinical Research Sites

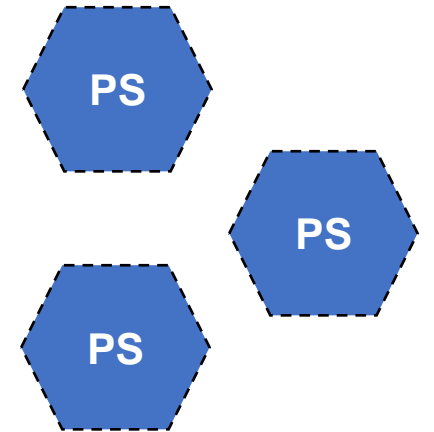
Scientific Contributors & Trial Implementers



Protocol Specific

Clinical Research Sites

Short Term Trial Implementers



Protocol Specific

Clinical Research Sites

Short Term Trial Implementers

Looking Forward: Adjustments

- 1. Clinical research sites with strong community ties to populations affected by health disparities**
- 2. Advancing implementation science research**
- 3. Streamlining laboratory capacity**

Finishing the Current Cycle

- **What can be accomplished prior to the end of the current grant cycle?**
- **What adjustments in structure and scientific direction should be made to accelerate the pace of discovery?**
- **How should we build implementation research needs into our plans?**

Questions?