

Community & Stakeholder Input to Inform the Future of HIV Research

September 4, 2024





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

NIAID Strives to End the Use of Stigmatizing Language

- Certain language is insensitive to people and their basic human dignity; it can be offensive and stigmatizing, and alienates study participants and the communities in which we work
- Using person-first, inclusive, and respectful language emphasizes humanity, highlights autonomy, and promotes the idea that someone's health and health determinants are only facets of their full life and identity
- NIAID strongly supports and requests the use of person-first, non-stigmatizing language at all NIAID-supported meetings
- The NIAID HIV Language Guide can be found at: <https://www.niaid.nih.gov/research/hiv-language-guide>

Emphasizing use of Non-stigmatizing, Person-first Language

- **Do not describe people by their disease, infection or condition**
 - *People with HIV rather than HIV-infected people*
 - *People who inject drugs rather than injection drug users*
- **Do not use “subjects” or “patients” to describe people enrolled in research studies or clinical trials**
 - *Participant or Volunteer*
- **Do not use “sex” and “gender” interchangeably**
 - *Sex (refers to sex assigned at birth)*
 - *Gender (refers to psychosocial or cultural identity)*
 - *Use cisgender for people whose gender matches their sex assigned at birth and transgender for people whose gender does not match their sex assigned at birth*
- **Do not use “at risk” or “high-risk” person/population**
 - *Person/population with greater likelihood of HIV exposure*
 - *Population experiencing a disproportionate impact of HIV*
 - *High incidence population*
 - *Affected community*
- **Do not use “sterilizing” when referring to HIV cure**
 - *Eradication, Clearance*



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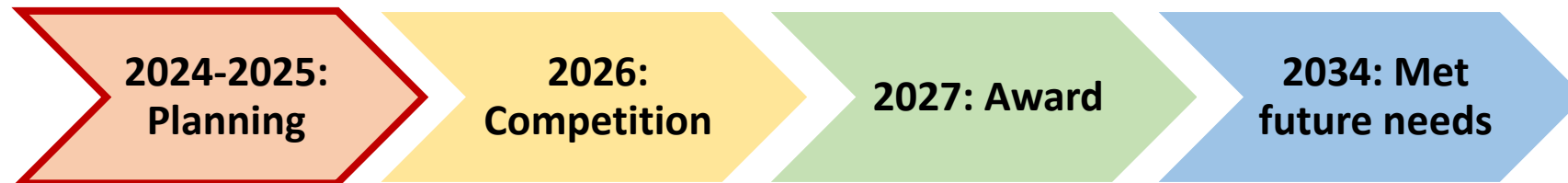
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DEPUTY DIRECTOR OF OCSO,
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Setting the 2034 Research Agenda

- 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 trial networks through 2034



Network Competition Timeline

- Spring 2024: Launch process with network presentations to SWG
- **Summer until Dec 2024: 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**

Network Competition Timeline

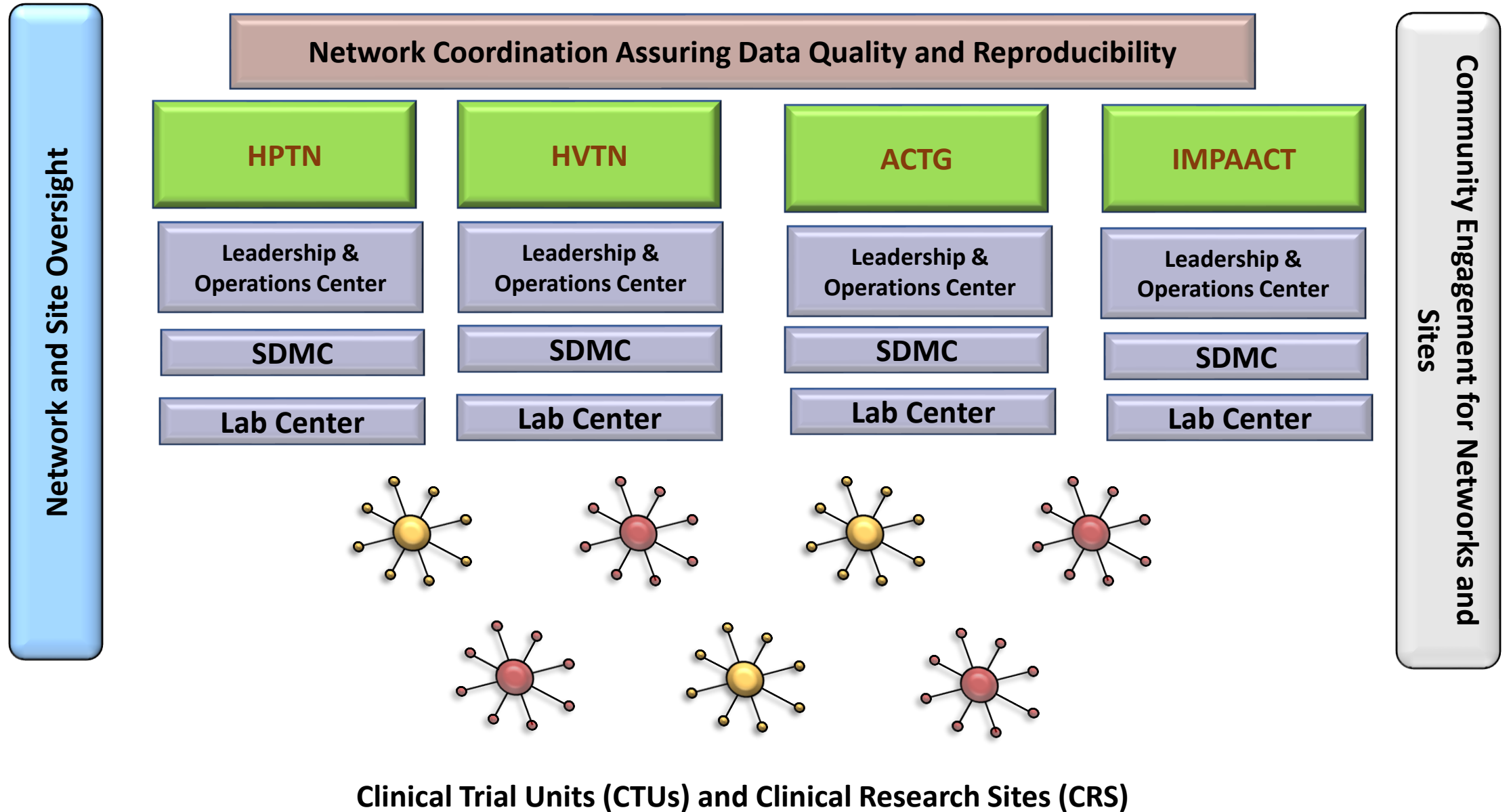
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Finishing the Current Cycle

- **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?**

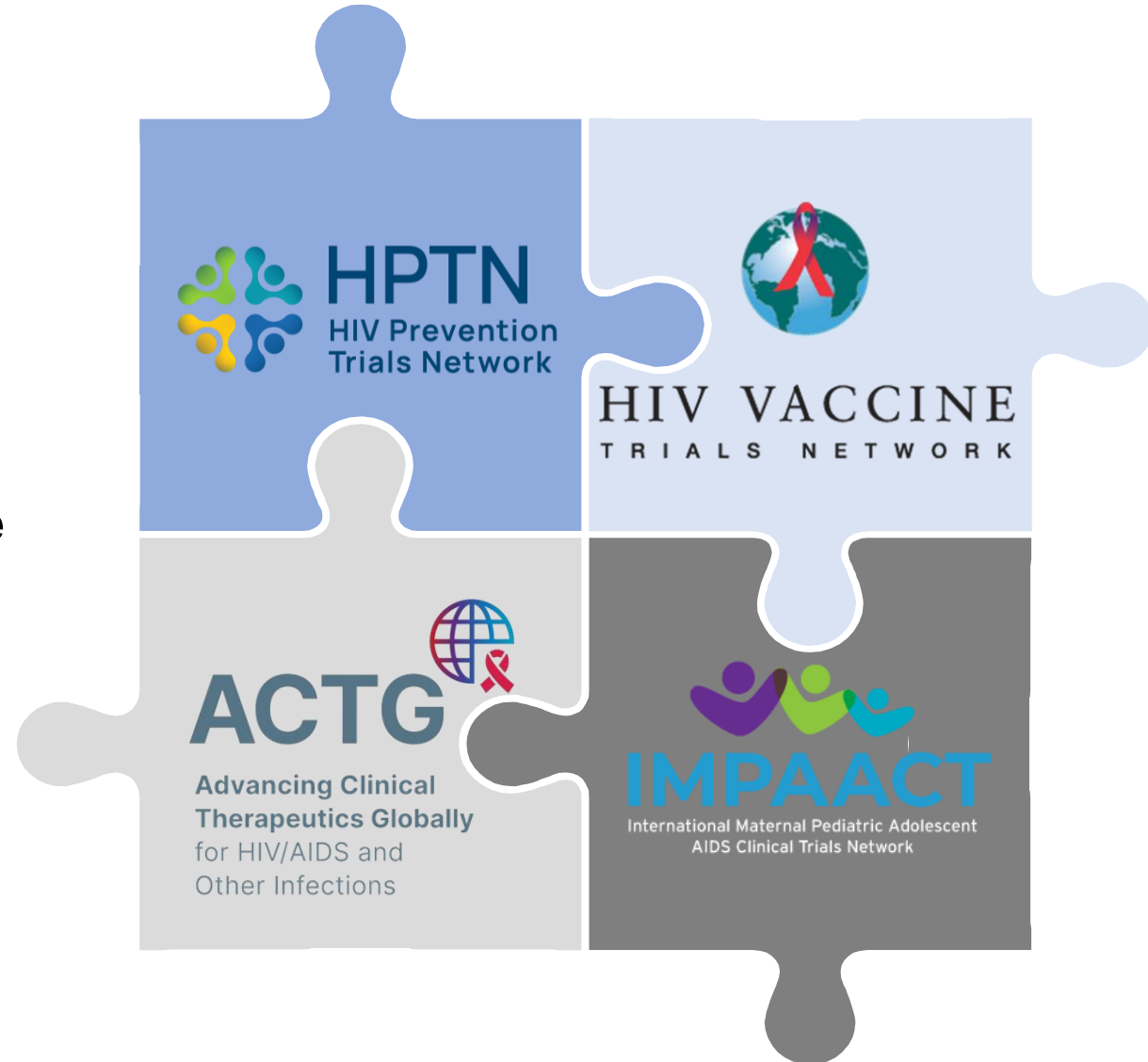
Clinical Trial Units & Clinical Research Sites

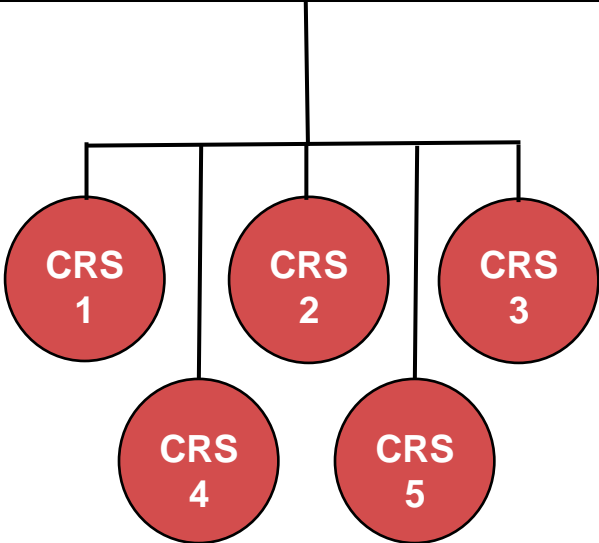
HIV/AIDS Network Structure



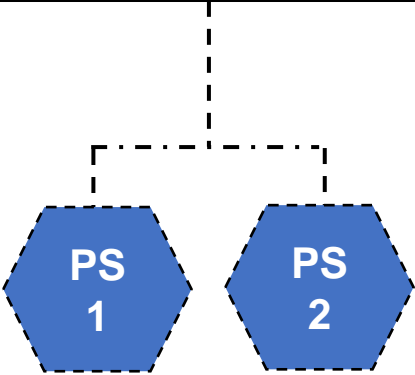
Critical Infrastructure: CTUs

- 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 participates 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

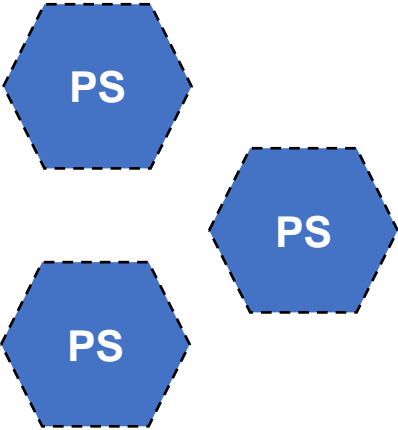




Clinical Research Sites
Scientific Contributors & Trial Implementers

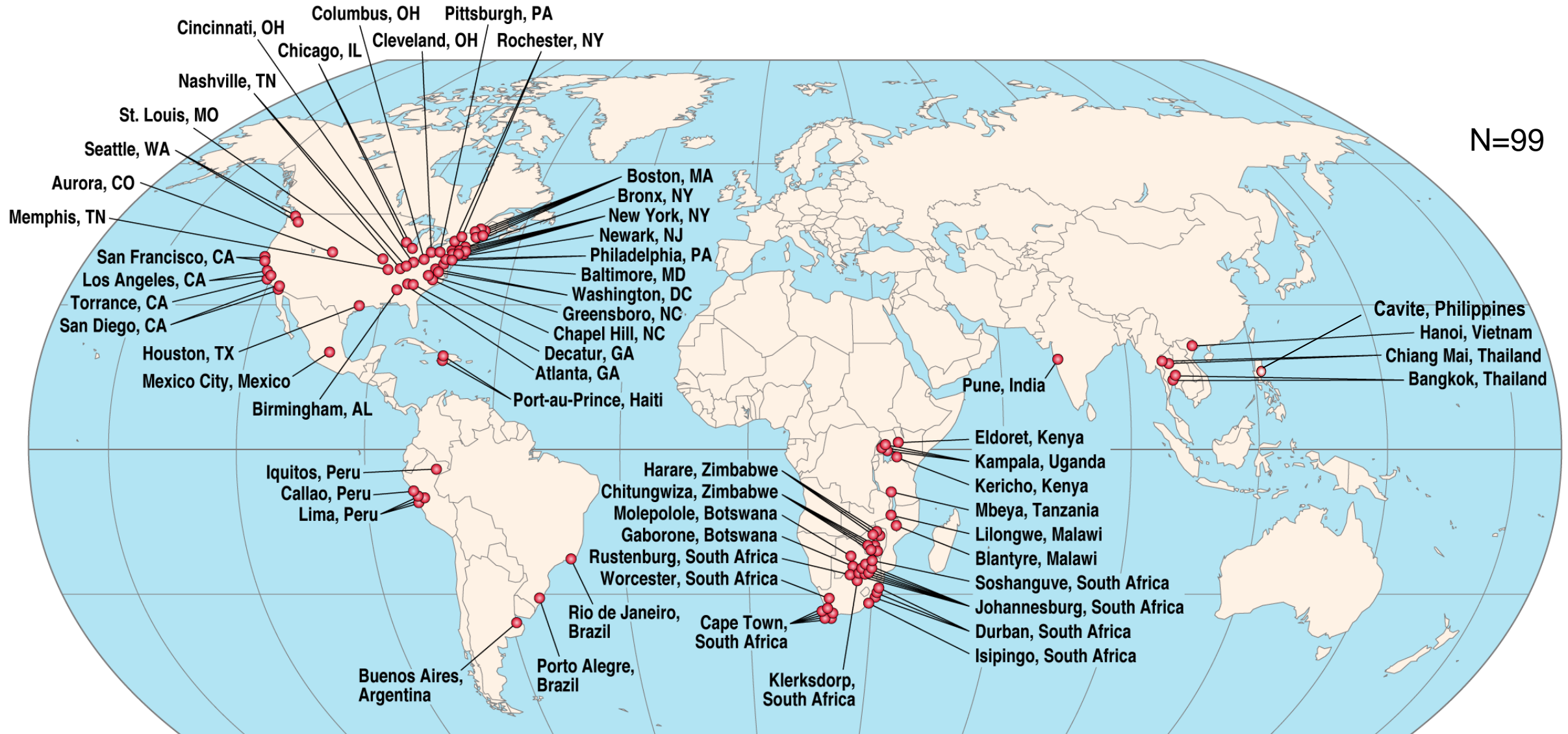


**Protocol Specific
Clinical Research Sites**
Short Term Trial Implementers

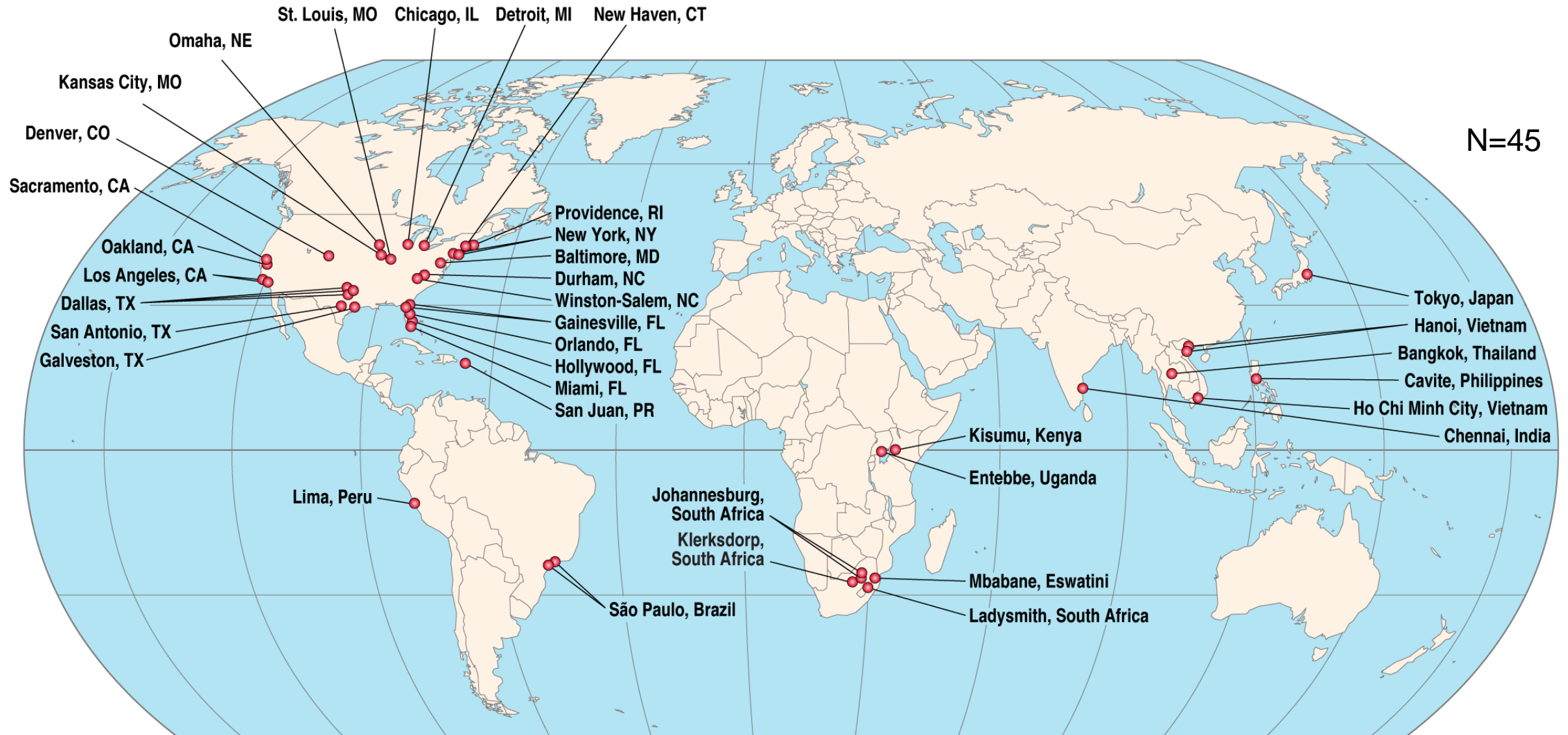


**Protocol Specific
Clinical Research Sites**
Short Term Trial Implementers

Fully Funded Sites: HIV/AIDS Networks



Protocol-Specific Sites: HIV/AIDS Networks



Looking Forward: Adjustments

- 1. Clinical research sites with strong community ties to populations that have been historically difficult to attract into research**
- 2. Advancing implementation science research**
- 3. Streamlining laboratory capacity**

Questions?