

# **The HIV Prevention Trials Network**

#### BACKGROUND AND MISSION

The mission of the HIV Prevention Trials Network (HPTN) is to prevent HIV in priority populations, including cisgender women, adolescents and young people, cisgender men who have sex with men (MSM), transgender people, and people who use substances at sites located in Asia, Europe, sub-Saharan Africa, South America, and the United States (U.S.).



#### SINCE ITS INCEPTION IN 1999.

the HPTN has a long history of successfully designing, and implementing, complex clinical research studies with a focus on biomedical interventions and integrated strategies to prevent HIV acquisition and transmission with more than 60 sites globally. The HPTN has long-standing partnerships with pharmaceutical companies, academic researchers worldwide, the Bill and Melinda Gates Foundation and several other organizations. In addition, the HPTN has forged collaborations to develop integrated strategies with PEPFAR, the Centers for Disease Control of Prevention (CDC) and both ministries and departments of health in several countries. The U.S. National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director, National Institutes of Health (OD), National Institute on Drug Abuse (NIDA) and National Institute of Mental Health (NIMH) co-fund the HPTN.



Women

#### **GLOBAL REACH**

#### AS OF 2020, THE HPTN HAS OVER 60 STUDY SITES IN 16 COUNTRIES





# SITES IN:

Atlanta (2), Aurora, Baltimore, Birmingham, Boston, Chapel Hill, Chicago (2), Cincinnati, Columbus, Greensboro, Houston, Los Angeles (2), Memphis, New Orleans, New York (4), Newark, Oakland, Philadelphia, San Francisco, St. Louis, Washington, DC

#### **INTEGRATED PARTNERSHIPS**

Governance of the HPTN includes oversight by the Network Principal Investigators (PIs) and the Executive Management Committee (EMC) that provides oversight of all Network activities.

The Network is anchored by three key central resources that are also responsible for scientific oversight and implementation of the research – A Leadership and Operations Center (LOC), a Statistical and Data Management Center (SDMC) and a Laboratory Center (LC).

- Leadership and Operations Center (LOC)
- Statistical and Data Management Center (SDMC)
- Laboratory Center (LC)

#### HPTN LEADERSHIP AND OPERATIONS CENTER (LOC)

The HPTN LOC staff facilitates and manages the HPTN scientific agenda and research operations, including research plan development, concept and protocol review and approval, study conduct, financial management, and publication and results dissemination. The LOC has specific expertise in its management and implementation of several U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) application studies, following all FDA standards for industry-level research.



The LOC staff also coordinates and facilitates logistical and administrative services of all Network activities for the HPTN Executive Committee, Science Advisory Group, science committees, and working groups. The LOC staff also supports study research teams, study participants, funders, community partners and other key stakeholders.

The HPTN LOC has successfully engaged community members at all stages of science development, from concept generation, protocol development and study implementation to dissemination of study results, as an integral part of the team and as partners at participating sites. Communication with Network members, collaborators, study participants and stakeholders occurs through many platforms, including websites, emails, newsletters and social media channels (e.g., Facebook, Twitter, YouTube).



HPTN 091 Community Stakeholder Consultation in Brazil



Baylor-Uganda CRS Community Staff on World AIDS Day 2019

The HPTN LOC is based at FHI 360 in Durham, North Carolina. FHI 360, a nonprofit 501(c)3 global organization operating in more than 60 countries, is recognized as a worldwide leader in clinical research and service delivery. FHI 360 has diverse research expertise including prevention and treatment of HIV and other STIs; other infectious diseases, including tuberculosis, malaria, Zika, and Ebola; maternal, adolescent and child health; substance abuse; epidemiology and health-related behaviors.

## HPTN STATISTICAL AND DATA MANAGEMENT CENTER (SDMC)

The HPTN SDMC is responsible for helping to shape the Network's scientific agenda and plays a key role in all phases of science generation, protocol development, and study implementation. The SDMC is responsible for all aspects of data collection, reporting, and statistical analysis for HPTN trials following the principles of Good Clinical Data Management Practices (GCDMP) as well as Good Clinical Practices (GCP). The SDMC manages the HPTN study databases and guides protocol teams on both the statistical components of study design and the collection and analyses of study data. The SDMC for the HPTN is the Statistical Center for HIV/AIDS Research and Prevention (SCHARP) located at the Fred Hutchinson Cancer Research Center (FHCRC, Fred Hutch) in Seattle, Washington.

#### HPTN MODELLING CENTRE

The HPTN Modelling Centre, part of the SDMC, is a collaboration between the Department of Infectious Diseases Epidemiology at Imperial College London and SCHARP. The Centre supports HPTN research activities, clinical trials, product development, and future HPTN research directions by conducting mathematical modelling studies to: 1) Understand the dynamics and drivers of HIV epidemics, 2) Assess the impact of HIV interventions, 3) Inform the design, conduct, interim, final analysis of trials, 4) Explore innovative lines of investigation, and 5) Improve mathematical models and study designs.

## **HPTN LABORATORY CENTER (LC)**

The HPTN LC is responsible for helping to shape the Network's scientific agenda and plays a key role in all phases of science generation, protocol development and study implementation. The LC oversees all laboratory activities including specimen collection, testing, and reporting of results for testing performed at HPTN CRSs. The HPTN LC also performs Quality Assurance/Quality Control (QA/QC) testing and specialized testing for HPTN protocols to advance the scientific agenda of the network. The LC evaluates and validates assays for use in HPTN protocols and develops novel assays and laboratory methods to achieve study objectives. The LC assists in the development and quality assessment of CRSs, including building laboratory expertise and capacity at non-US CRSs, primarily in resourcelimited settings. The LC plays a leadership role in cross-network activities by updating, harmonizing and streamlining laboratory procedures used in other networks and groups. The LC is centralized at the Johns Hopkins University School of Medicine in Baltimore, Maryland.