HANC ANNOUNCEMENTS

2019 HANC Workplan Now Available

The HANC Workplan for 2019 is now posted on the HANC website. Working group objectives for the upcoming year and more can be found within the report.

Newly Revised IT Best Practice Standards

The 2018 edition of the Information Technology Best Practice Standards at NIH HIV/AIDS Clinical Research Networks’ Study Sites and Site Affiliated Laboratories is now available here on the HANC website. This document serves as a resource for baseline technological standards at DAIDS sites.

New Legacy staff member: Kacie Sadorra

Legacy is pleased to announce that Kacie Sadorra, who has been working with HANC as an intern this summer, has joined the Legacy team as our new temporary administrative assistant and will be working closely with Brian Minalga and Russell Campbell assisting with the Legacy Project and the Women's HIV Research Collaborative (WHRC) while Louis Shackelford is away on military leave from January 7th, 2019 through September 4th, 2019. During his leave, Louis will undergo training to join the US Air Force Reserves and become an Air Force Medical Technician.
The AIDS Clinical Trials Group (ACTG) would like to highlight the upcoming opening of a landmark study on HIV treatment. ACTG’s new LATITUDE study (Long-Acting Therapy to Improve Treatment Success in Daily Life) (ACTG 5359) is an innovative study that may shift the paradigm for treating participants with the most difficulty adhering to daily medications. This population may benefit from a novel approach to treating HIV by using injectable agents administered once monthly in the clinic instead of requiring daily consumption of medications. These injectables could be life-saving for participant with adherence struggles. LATITUDE (A5359) will compare treatment outcomes among participants with a past history of non-adherence and virologic failure randomized to once monthly long-acting injectable rilpivirine plus cabotegravir versus standard-of-care daily combination ART (SOC). Participants will be randomized to one of the two strategies after achieving short-term virologic suppression with the help of milestone-driven financial incentives, and will be followed for 52 weeks with the SOC arm offered open-label injectable ART thereafter for another 52 weeks. LATITUDE will begin enrolling soon at 35 sites across the U.S. To learn more about the upcoming LATITUDE opening, visit ACTGNetwork.org, or contact Mwenda Kudumu at MKudumu@s-3.com

**HPTN 083** has enrolled more than 3100 out of a target enrollment of 4500 participants. The study is evaluating long-acting injectable cabotegravir (CAB LA) compared to daily oral pre-exposure prophylaxis (PrEP) in HIV-uninfected men and transgender women who have sex with men (MSM and TGW) in the Americas, Asia and South Africa.

**HPTN 084** has enrolled more than 550 participants. The target enrollment is 3200 participants. The study is evaluating long-acting injectable cabotegravir (CAB LA) compared to daily oral pre-exposure prophylaxis (PrEP) in HIV-uninfected women in sub-Saharan Africa.

The National AIDS Education and Services for Minorities (NAESM) conference will take place January 17-20 in Arlington, Virginia. During the four day event, representatives from the HPTN and the Black Caucus will deliver two presentations. “HPTN Responds to the BGRG Research Agenda: A Multi-Disciplinary Approach” will provide an overview of the HPTN's research, as well as of additional research strategies that can be used to inform the development of community programs. “Be The Generation: Empowering Communities to End the HIV/AIDS Epidemic” will feature representatives from the Legacy Project, HPTN, HVTN, and MTN discussing the Be the Generation (BTG) project.
NETWORK ANNOUNCEMENTS

HVTN is pleased to end the year with the following notes of progress:

- We have 4 efficacy trials underway. The AMP trials completed enrollment September 30, 2018, HVTN 702 is almost 92% enrolled, and HVTN 705 now has over 1300 persons enrolled. The HVTN has the largest Phase 2b-3 program it has ever had. All studies are excelling in enrollment, retention and data quality parameters, and the reviews by the independent Data Safety Monitoring Board have continued to confirm the safety of our participants.

- This past year has seen a rapid expansion of our broadly neutralizing antibody (bnAb) program. Since AMP opened in early 2016 to evaluate the bnAb VRC01, which targets the CD4 binding site, we have seen several other antibodies enter, or prepare to enter clinical trials, including: additional VRC01-class antibodies with modifications to extend half-life; several antibodies that bind other HIV Env epitopes including the membrane proximal external region (MPER), V2 region, and V3 glycan region; and antibodies with multiple specificities (e.g., trispecific bnAb). The HVTN has collaborated with the HPTN, VRC, Sanofi, Rockefeller, BIDMC, and IAVI to advance these products into protocols designed to explore multiple concepts (e.g., neutralization, administration route, and interval) to inform the next bnAb efficacy trial.

We were fortunate to join the HPTN, MTN, colleagues from Fred Hutch, BMGF and NIH-NIAID for the HIV Prevention Efficacy Trial Designs of the Future symposium organized by Dr. Holly Janes, Dr. Deborah Donnell, and Dr. Martha Nason held in Seattle in November 2018. The objectives of the symposium were to identify potential statistical trial design approaches worthy of further investigation, key barriers or gaps in understanding that need to be addressed, and necessary next steps in exploring these ideas and filling gaps. Follow up activities are being planned with community stakeholders.

In December, Dr. Sharon Nachman was re-elected as IMPAACT Network Chair, Dr. Philippa Musoke was elected as International Vice Chair and Dr. Patricia Flynn was elected as US Domestic Vice Chair.

MTN is pleased to announce the launch of MTN-038, a Phase 1 study that will evaluate the safety and pharmacokinetics of a 90-day vaginal ring containing the antiretroviral drug tenofovir. The study plans to enroll 48 cisgender women at sites in Birmingham (Alabama), Pittsburgh and San Francisco.

Save the date for the MTN 2019 Annual Meeting! The meeting will be held February 10-13 at the Crystal Gateway Marriott. A dedicated hotel booking website has been created for guests to make, modify and cancel hotel reservations online.

A meeting agenda will be forthcoming and available on MTN’s website.
WEBINARS & TRAINING

Upcoming Webinars

Historical Trauma & HIV
February 7, 2019 @ 9AM PST
As part of National Black HIV/AIDS Awareness Day on February 7, 2019, the Legacy Project invites you to register and participate in this informative webinar featuring Dr. Michele Andrasik. Register here.

Part 3: Experiences of Black Women Living and Aging with HIV
Community Partners and the Legacy Project have assembled a diverse group of experts working in community advocacy, biomedical research, and Geriatrics to guide us through a three-part webinar series focused on the connections between HIV and aging and the impact of age-related factors on older adults with HIV. Previous webinars can be found here.

Part 3 of the series (Date TBD) will focus on the following:
• Experiences of Black women living and aging with HIV
• Loneliness, isolation and/or depression related to HIV and aging
• Resources for African Americans and women living and aging with HIV

Stay tuned…

Save the date!
Registration and details for these upcoming webinars are forthcoming.
April 18, 2019 (National Transgender HIV Testing Day)
A webinar on HIV phylogenetics research featuring Dr. Carl Dieffenbach (NIH, Division of AIDS) and Venita Ray (Positive Women's Network).

April 25, 2019
A webinar on molecular HIV surveillance featuring Dr. Eugene McCray (CDC) and Naina Khanna (Positive Women's Network).

HANC Webinar Archives

HANC Working Groups host webinars throughout the year and post recordings to the HANC website. Click here to view archives of past webinars.
HANC PROGRAM HIGHLIGHTS

Need to contact a HANC staff member? Click here to go to the About the HANC Staff page.

Behavioral & Social Sciences
Greg Davis, HANC Project Manager

The Behavioral Science Consultative Group (BSCG) has decided that it will meet face-to-face at the conclusion of the 2019 Adherence Conference in Miami, FL. The BSCG’s meeting will be held on June 20. The BSCG also continues planning an upcoming webinar series.

Community Partners
Russell Campbell, HANC Deputy Director

Community Partners (CP) and the Legacy Project have assembled a diverse group of experts working in community advocacy, biomedical research, and Geriatrics to guide us through a three-part webinar series focused on the connections between HIV and aging and the impact of age-related factors on older adults with HIV. A link to previous webinar recordings and details on Part 3 of the series can be found under the Webinars & Training section.

CP and the National CFAR CAB Coalition (NCCC) are discussing ways to mutually assist each other through regular exchange of information, ideas and resources.

CP and CRAG are working on developing community engagement materials for the benefit of PHOENIx study staff and participants.

Cross-Network Coordination
Milan Vu, HANC Project Coordinator

The Cross-Network Evaluation Working Group (EWG) held a joint call with network community engagement staff representatives to discuss approaches to community engagement metrics and challenges with harmonizing community indicator surveys. The group reviewed a master library of questions asked across each network's community indicator survey, identifying areas of commonality as well as fundamental differences in network philosophies regarding community advisory board (CAB) structure, survey audience, and utilization of other methods for collecting data on community engagement.
HANC PROGRAM HIGHLIGHTS

(Cross-Network Coordination, continued)
The IT Best Practices Task Force has completed biennial updates to the Information Technology Best Practice Standards at NIH HIV/AIDS Clinical Research Networks’ Study Sites and Site Affiliated Laboratories, a resource outlining recommended baseline technological standards for DAIDS sites. The latest edition of the document can be found here on the HANC website.

Laboratory Coordination

Tyler Brown, HANC Project Manager

The CPQA Monoclonal Antibodies and Small Molecule Tissue Pharmacology Working Group (mAb WG) met and approved plans to draft a white paper for publication that will summarize the current landscape of tissue collection and processing of broadly neutralizing antibodies. The monthly mAb WG calls will discontinue starting in January as the group moves forward with manuscript development.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to review new proficiency testing reports from RNA035, DNA208BS, DNA209BS, DNA213BS, and DNA214BS.

The Lab Focus Group (LFG) held a conference call with the DAIDS Clinical Laboratory Oversight Team (DCLOT) to continue developing cross-network terminology standards for laboratory site action plans.

The Cross Network Clinical Pharmacology Laboratories Forum hosted a webinar on the topic of small molecule drug quantification in tissue, presented by Dr. Mark Marzinke from Johns Hopkins University School of Medicine. In January the FSTRF Data Management Center (DMC) will be launching a working group to review and revise data transfer methods for data traveling from the DMC to pharmacologists.

The Legacy Project

Brian Minalga and Louis Shackelford
HANC Legacy Project Community Engagement Officers

“We Can Do It! Screening for Intimate Partner Violence in HIV Research.” The conference will take place in Seattle March 2-3 (before CROI).

The WHRC is creating two slide sets: HIV Prevention for Women and HIV Cure Research for Women. These resources will be made available later in 2019.

The Women’s HIV Research Collaborative has selected its co-chairs for the 2019-2021 term. Congratulations to Clare Collins (MTN staff) and Moréniike Giwa Onaiwu (community)! This will be Clare’s second term as WHRC co-chair and Moréniike’s first. The WHRC also thanks Liz Barr who served the WHRC as co-chair for the maximum of four years.

Brian Minalga and Russell Campbell will represent Legacy staff at the National African American MSM Leadership Conference on HIV/AIDS and Social Justice in Washington, DC, January 17-20.
(The Legacy Project, continued)
Brian Minalga will facilitate a workshop, “Be the Generation: Empowering Community to End the HIV/AIDS Epidemic,” featuring Clare Collins (MTN), Christopher Hucks-Ortiz (HPTN Black Caucus), and Step haun Wallace (HVTN).

Brian Minalga is collecting updates from the HPTN, HVTN, and MTN to include in the quarterly Be the Generation newsletter. Send updates to him no later than February 6.

WWW.HANC.INFO/LEGACY
BE THE GENERATION
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RESOURCES

Newsletters

Be the Generation Newsletter
The Be the Generation (BTG) project builds scientific literacy and community capacity to engage with biomedical HIV prevention research. BTG News is its quarterly newsletter publication on biomedical HIV prevention research, geared for community audiences who are interested in the HIV prevention research field. Click here to view current and past newsletters. Email btg@hanc.info to subscribe.

Behavioral Science Interest Group Newsletter
Interested in behavioral science? Join the Behavioral Science Interest Group (BSIG) and subscribe to the BSIG Newsletter. Email Greg Davis at gpdavis@fredhutch.org for more details.

Network Publications
Several of the HIV/AIDS clinical trials networks and collaborators publish their own newsletters, covering a range of topics from network-wide news to community level events. Links to various network publications are on the Newsletters page of the HANC website. Click here for more information.

OCSO MOB Newsletter
Looking for the latest on site monitoring and regulatory compliance? Check out the Monitoring Operations Branch (MOB) Newsletter, produced by the DAIDS Office of Clinical Site Oversight (OCSO). Click here to find newsletter archives.

Laboratory

CNICS Research Network
The CFAR Network of Integrated Clinical Systems (CNICS) provides peer-reviewed-open access to a rapidly evolving clinical research platform that prospectively collects patient data, including validated outcomes, longitudinal resistance data, and detailed PROs with readily available biological specimens. Click here for more information.

EQAPOL
The goal of the External Quality Assurance Program Oversight Laboratory (EQAPOL) is to establish a panel of fully characterized viruses from acute/early and chronic HIV infections. Viral Diversity samples are available to NIAID-approved laboratories, and products created for the EQAPOL Viral Diversity Program are available to order. Click here for more information.

Specimen Repository
The specimen repository is a collaboration between the ACTG and IMPAACT clinical trial networks to make the large body of specimens collected for HIV research available to investigators. Click here to visit the site and request specimens.

NIH Corner

ClinRegs
ClinRegs is an online database of country-specific clinical research regulatory information designed to assist in planning and implementing international clinical research. Click here to explore ClinRegs.

NICHD Data and Specimen Hub (DASH)
NICHD DASH is a centralized resource for researchers to store and access data from NICHD-funded research studies to use for secondary research. Click here to explore DASH.

Protocol Quick Summary
HANC developed the Protocol Quick Summary tool to allow users to search for information pertaining to DAIDS-funded protocols. Study design, status history, protocol documents, and more can be found via this tool. Data displayed on the tool is pulled from the NIAID Clinical Research Management System (CRMS), which is the database of record and should be referred to for real-time protocol information. Click here to explore the tool. Note that a HANC Portal username and password are required for access.

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