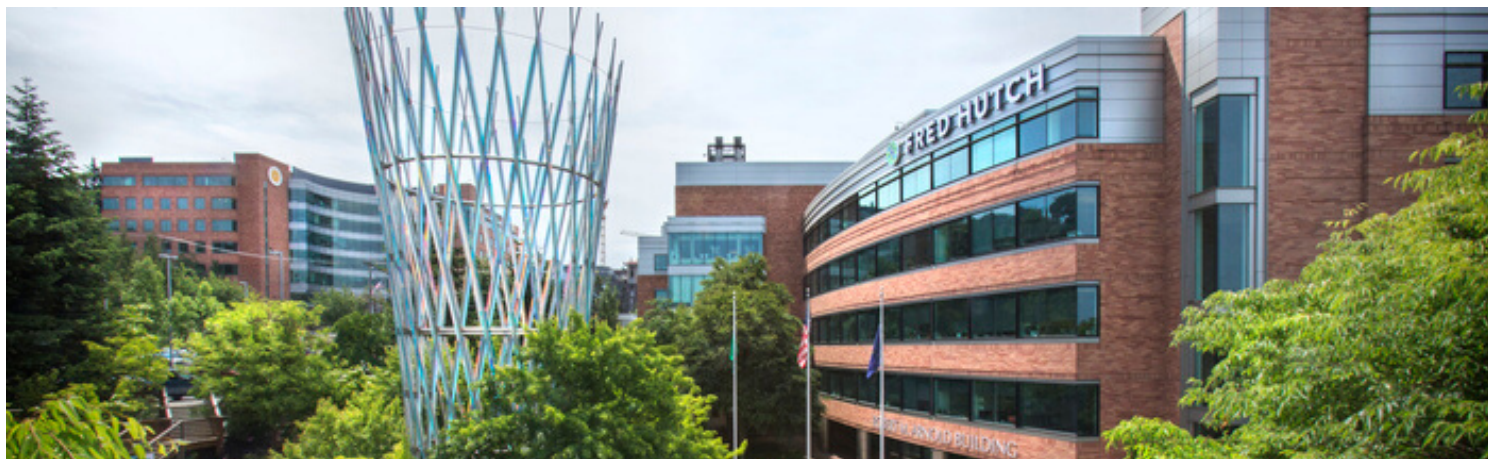


JANUARY 2020

NEWSLETTER

Office of HIV/AIDS Network Coordination



Pictured: Fred Hutch campus, home of HANC offices and staff in Seattle, WA

HANC ANNOUNCEMENTS

Guidance for Transgender Inclusive Research

The Division of AIDS Cross-Network Transgender Working Group has released a document to focus attention on inclusive practices for study protocol development and design, data collection, and data reporting. [Click here](#) to access the document.

The purpose of the guidance document is to:

- Reiterate that all studies should be gender inclusive, allowing for the enrollment of transgender and cisgender participants unless there is a scientific reason to limit enrollment, with exclusion rationale provided in study documents.
- Reinforce the importance of collecting data on gender identity and sex assigned at birth using the two-step method.
- Ensure the networks accurately, appropriately, and systematically describe the study population in terms of gender identity and sex assigned at birth in all research protocols using non-stigmatizing and gender-inclusive language.
- Encourage accurate description of the study population in terms of gender identity and sex assigned at birth when enrollment and other study data are published and/or presented.

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Do you have questions, comments, or content suggestions? Email the Editor, Milan Vu, at mhvu@fredhutch.org

NETWORK ANNOUNCEMENTS



There is no update from the ACTG this month.



Congratulations to the HPTN 083-01 and HPTN 084-01 study teams for reaching protocol V1.0. Both are sub-studies of HPTN 083 and HPTN 084, investigating safety, tolerability, and acceptability of the long-acting cabotegravir (CAB LA) injection in adolescent populations in the U.S. and sub-Saharan Africa. Screening and enrollment are set to begin in December 2019 for HPTN 083-01 and April 2020 for HPTN 084-01.



Michele Andrasik led the writing of an editorial for the American Journal of Public Health (AJPH) in response to the current administration's "Ending the HIV Epidemic: A Plan for America" initiative. Titled "Stigma, Implicit Bias, and Long-Lasting Prevention Interventions to End the Domestic HIV/AIDS Epidemic," it was published in the January 2020 issue, which was released online in December 2019. Contributing authors included Gail Broder, Linda Oseso, Stephaun Wallace, Francisco Rentas, and Larry Corey, with editing assistance from Mindy Miner. Read the editorial here:

<https://ajph.aphapublications.org/doi/10.2105/AJPH.2019.305454>

The HVTN will host its Sub-Saharan Africa Regional Meeting on 26-28 February 2020 in Cape Town, South Africa. This meeting provides the sites across sub-Saharan Africa a chance to gather for a focus on the ongoing efficacy trials, upcoming studies, and issues of regional interest.



The IMPAACT Network is pleased to share the announcements of primary results from four studies: IMPAACT P1104s in [Clinical Infectious Diseases](#) (see the NIAID press release [here](#)), IMPAACT 2011 in the [Journal of Infectious Diseases](#), IMPAACT P1101 in [AIDS](#), and IMPAACT P1112 in the [Journal of Infectious Diseases](#).

In addition, results related to the PROMISE studies were published in [AIDS](#) and highlighted in [Reuters Health](#).

Finally, two IMPAACT studies, [IMPAACT P1101](#) and [IMPAACT 2007](#), have successfully closed to follow-up.

NETWORK ANNOUNCEMENTS



MTN is pleased to announce the launch of [MTN-039](#), a Phase I study evaluating whether a fast-dissolving insert containing the antiretroviral drugs tenofovir alafenamide (TAF) and elvitegravir (EVG) is safe to use in the rectum. The study will include 20 HIV-negative individuals at two sites in the United States. It will help determine whether further testing on the safety and acceptability of a TAF/EVG rectal insert for preventing HIV from anal sex can be conducted in a larger population.

Registration for the [2020 MTN Annual Meeting](#) is now open. The meeting will take place February 9-12 at the Crystal Gateway Marriot in Arlington, Virginia. Topics covered at the meeting will include: HIV prevention in pregnant and breastfeeding women and adolescents, rectal microbicides, and the future of MTN's research agenda.

Want to hear more from the networks?

Subscribe to the network newsletters and stay up to speed on the latest publications, news coverage, and community activity.

ACTG Monthly Newsletter

<https://actgnetwork.org/actg-newsletters/>

HPTN Monthly Newsletter

<https://www.hptn.org/news-and-events/newsletters>

HVTN Community Compass

<http://www.hvtn.org/en/community/community-compass.html>

IMPAACT Newsletter

https://impaactnetwork.org/news_/newsletters.html

MEETING CALENDAR

Feb 9-12

MTN Annual Meeting
(Arlington, VA)

Mar 6-7

10th International
Workshop on HIV &
Women
(Boston, MA)

Mar 8-11

CROI 2020
(Boston, MA)

Apr 16-18

ACTHIV 2020
(Chicago, IL)

May 27-29

HVTN Full Group
Meeting
(Washington, DC)

May 30-June 3

HPTN Annual
Meeting
(Washington, DC)

June 7-10

Adherence 2020
(Orlando, FL)

June 8-12

IMPAACT Annual
Meeting
(Washington, DC)

June 15-21

ACTG Annual
Meeting
(Washington, DC)

July 5-7

HIV2020
(Mexico City, MX)

For details and other
events, visit the
[HANC calendar](#)



WEBINARS & TRAINING

Upcoming Webinars

There are no webinars scheduled for January.

Training

Preparation for Regulatory Inspections at Laboratories

Available on the DAIDS Learning Portal

A new training module, "Preparation for Regulatory Inspections at Laboratories," is now available on the DAIDS Learning portal. This module is intended for staff at laboratories that are participating in DAIDS-supported and/or sponsored clinical trials so that they may prepare themselves and their laboratories for potential regulatory inspections. [Click here](#) to visit the course page and get started.

DAIDS Applied Research Training Toolkits

Available on the DART website

The Division of AIDS (DAIDS) is pleased to announce the availability of three new Tool kits in support of the DAIDS Applied Research Training (DART) event held in Johannesburg, South Africa. Please visit the "Resources" tab on the [DART event site](#) to access the new tool kits.

Newly released tool kits:

- Activity 9: Safety Oversight
- Activity 10: Quality Management
- Activity 11: Good Documentation Practices

HANC Webinar Archives

Missed out on a webinar you wanted to attend? Visit the [HANC website](#) to view archived recordings 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 Consulting Group (BSCG) will continue discussing when and where to host its 2020 face-to-face meeting. The BSCG will also resume its discussion about an upcoming webinar on adherence support interventions. The BSCG hopes to host the webinar in the spring.

The Behavioral Science Working Group's (BSWG) next call is scheduled to take place in February.

Youth Prevention Research Working Group: The Youth Prevention Research Working Group (YPRWG) closed out 2019 by discussing potential webinar topics. The YPRWG is planning to host two webinars in 2020. The YPRWG also discussed its options for hosting a session at [AIDS 2020](#). The group is currently deciding if it would like to submit a proposal for a satellite symposium or for a discussion/panel in the Global Village.



Community Partners

Russell Campbell, HANC Deputy Director

Community Partners is in the process of soliciting new Co-Chairs and new members.



Cross-Network Coordination

Milan Vu, HANC Project Manager

The Cross-Network Site Coordinators Working Group (SCWG) met to discuss site use of Clinical Trial Management Systems (CTMS), site staff training needs, and the ongoing pilot for protocol deviation collection.

The Data Management Center Working Group (DMCWG) provided updates on ongoing initiatives with the Medidata platform, automation of the safety data reconciliation process, and draft policy addressing electronic information systems. The Pregnancy Outcomes Data Working Group (PODWG) held its first meeting to finalize the group charter and elect working group co-chairs.

HANC PROGRAM HIGHLIGHTS



Laboratory Coordination

Tyler Brown, HANC Project Manager

The Lab Technologists Committee (LTC) held two conference calls to discuss changes to LDMS compliance standards, new standards for leukopak shipping, and the upcoming launch of the electronic lab processing chart (MiLPC). The LTC SOP Working Group held two conference calls to continue developing new Lab Processing Chart Standard Wording Documents, and begin beta testing on the MiLPC.

The Laboratory Focus Group (LFG) held a conference call to continue discussions related to DAIDS GCLP Manual v4.0.

The CPQA Cross-Network Clinical Pharmacology Forum (CNCPL Forum) held a webinar presentation by Jennifer Norman, from the University of Cape Town Division of Clinical Pharmacology, on standard wording for collection, processing, storage, and shipment of PK samples.



The Legacy Project

*Brian Minalga and Louis Shackelford
HANC Legacy Project Team*

Happy New Year from Legacy and the Women's HIV Research Collaborative! Last year we conducted over 400 activities toward our work plan objectives, including 14 abstracts accepted to national conferences, 18 webinars, **two new trainings** on HIV research with women, and supporting the development of the **DAIDS Transgender Training Curriculum for HIV Research** and the **Guidance for Transgender-Inclusive Research** document. We also had over 12,600 hits on our **Facebook posts**, nearly 4,000 visitors to the **Be the Generation website**, and over 1,550 participants on our conference presentations and webinars.

We look forward to another productive and fulfilling year in 2020; see below for some activities we're already working on. Thanks for all you do to support the participation of underrepresented communities in HIV research!

- The **Be the Generation website** is available once again **en español**. Please share this valuable bilingual resource on biomedical HIV prevention research that brings together the work of the HPTN, HVTN, and MTN.
- The **HIV Prevention Research Training Module** (HPR Module) is now fully updated and available to download. The 4-hour version of this module covers the latest in HIV prevention research (focused on the work of the HPTN, HVTN, and MTN), and the 8-hour version adds information on the history of HIV/AIDS and the basics of clinical research and community engagement.
- Jan 15-19: Brian Minalga and Louis Shackelford will participate in the **2020 Creating Change** conference in Dallas, TX. Brian will be presenting, "Fostering Transgender Inclusion in HIV Research" on behalf of the DAIDS Cross-Network Transgender Working Group from 9 to 10:30 a.m. on Friday, January 17th in the City View 2 Room of the conference hotel's fourth floor.

ABOUT COMMUNITY PARTNERS

Community Partners (CP) is a cross-network body charged by the Network Leadership and the Division of AIDS (DAIDS) with promoting representation of the communities within which the National Institutes of Health (NIH) HIV/AIDS clinical trials networks conduct research.

ABOUT THE LEGACY PROJECT

The Legacy Project works nationally to increase awareness and support for HIV prevention and treatment clinical and behavioral research by addressing factors that influence participation of historically underrepresented communities.

The Legacy Project Work Group (LPWG) is comprised of members from HANC, CP, network operations centers, clinical research sites, community members, and DAIDS. The LPWG works to increase representation and engagement of African-Americans, Latinos and Native Americans in HIV prevention and therapeutic research in the U.S.

WORKING GROUP MEMBER SPOTLIGHT

In an effort to highlight the work of HANC and members involved in HANC working groups, we would like to introduce you to a few of our members from Community Partners and the Legacy Project Working Group:



Morénike Giwa Onaiwu

Morénike is a current member of Community Partners. She is based in Texas, USA and serves as a Community Scientific Subcommittee member.

What do you like most about community engagement? Community engagement is the heart of HIV clinical research - it's a vital

component that is essential to our work at all stages of the process. It is also something that is constantly evolving, and with it we have to evolve as well. Meaningful community engagement brings life to the principle of "Nothing About Us Without Us."

Any other interesting facts about yourself you care to share? I'm an American citizen, but as my parents are from West Africa, I am proudly bicultural. I have five kids at home ranging from elementary to high school aged (both biological and adopted). I strive to highlight the concerns of marginalized/underrepresented voices in our community from a lens of intersectionality and inclusion. I have been involved in HIV clinical trials advocacy for a decade and intend to remain involved for another decade - unless we find a cure first!



Steve Wakefield

Steve Wakefield is the External Relations Director for the HIV Vaccine Trials Network and leads global efforts for stakeholder engagement. Wakefield (preferred name) is also founder of The Legacy Project, a program to increase racial and ethnic population involvement in trials.

Wakefield is an HIV-negative health care advocate who until recently served on the AVAC: Global HIV Prevention Board and has over thirty-five years of involvement in projects that increase community participation in HIV prevention research and ethics. A longtime human rights and HIV activist with nonprofit management, public service on Chicago's Board of Health, as well as global and U.S. advisory groups such as the World Health Organization's UNAIDS and the NIH-funded HPTN Ethics Working Group, Wakefield is passionate about implementation of evidence-based strategies to end the epidemic.

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.

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, IMPAACT, and HVTN clinical trial networks to make available to investigators the large body of specimens collected for HIV research. [Click here](#) to visit the site and request specimens.

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.

NIH Corner

C3PNO Virtual Data Repository

The C3PNO Virtual Data Repository facilitates the sharing of HIV, substance use, clinical data, behavioral, and biospecimens collected by the NIDA longitudinal HIV cohorts with outside researchers. [Click here](#) to learn more or email c3pno.info@fstrf.org to request data or specimens.

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 access data and biospecimens from NICHD-funded research studies for secondary analyses. [Click here](#) to explore DASH.

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WWW.HANC.INFO