

MARCH 2021

NEWSLETTER

Office of HIV/AIDS Network Coordination



Land, Labor, and Justice Acknowledgements

We acknowledge the land we occupy today as the traditional home of the Duwamish, Tulalip, Muckleshoot, and Suquamish tribal nations, the original caretakers of this land who are still here. Without them we would not have access to this working, teaching, and learning environment. We commit to conducting ourselves with dignity and treating this land and all the life it sustains with respect. We ask you to join us in this commitment, wherever you may reside. We also acknowledge exploited labor and ongoing struggles for justice on this land. We reflect on the ancestors of our various peoples, nations, tribes, and families; ancestors whose struggles, pain, power, privilege, and strivings we hold in our very bodies.

Pictured: Fred Hutch, home of HANC offices in Seattle, WA.



HANC ANNOUNCEMENTS

Join us in observing National Women and Girls HIV/AIDS Awareness Day on March 10 and National Native HIV/AIDS Awareness Day on March 20



The Women's HIV Research Collaborative (WHRC) has created an infographic to commemorate National Women & Girls HIV/AIDS Awareness Day. Check it out [here](#)!

March 20, the first day of Spring, marks the annual observation of National Native HIV/AIDS Awareness Day (NNHAAD). In recognition of NNHAAD, the Legacy Project will be hosting a webinar on March 19 to examine ways to center and respect the experiences of Two-Spirit and Indigenous peoples in health research, policies, and programs. See the **Webinars & Training** section for more details and registration!



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

NETWORK PRESENTATIONS AT CROI 2021



Several of the NIH HIV/AIDS networks will have a presence at the annual Conference on Retroviruses and Opportunistic Infections ([CROI](#)) held virtually from March 6 to 10, 2021. Links to listings of presentations accepted by network can be found [here](#) on the HANC website.

NETWORK ANNOUNCEMENTS



This month the ACTG announced the addition of four new therapies to ACTIV-2. The new agents, which will be evaluated in phase 2 studies among non-hospitalized adults with COVID-19 are:

- AZD7442 (AstraZeneca): a combination of two monoclonal antibodies (AZD8895 and AZD1061) being studied as both an infusion administered over 15 minutes and an intramuscular injection
- SNG001 (Synairgen): a nebulized formulation of beta interferon being studied as an inhalant
- Camostat (Sagent Pharmaceuticals): an orally administered serine protease inhibitor that inhibits viral entry by blocking a host cell protease

Read the full press release [here](#).



The Conference on Retroviruses and Opportunistic Infections (CROI) takes place virtually from March 6- 10. Live interactive and engaging sessions will be featured each day, along with on-demand content. HPTN researchers will present six abstracts (one oral;

five Scientific Spotlights™) covering HPTN 052, HPTN 071, and HPTN 083.

Presentations will be available online after their initial presentation at

hptn.org/presentedresearch.

[View schedule of HPTN presentations and sessions.](#)

We look back at 2020, a year that brought many unexpected challenges due to the ongoing COVID-19 pandemic, as well as new HIV prevention research findings.

[Watch "Our Year in Review" here.](#)



NETWORK ANNOUNCEMENTS



CROI 2021, taking place March 6-10, is geared toward researchers and clinical educators actively involved in the study and management of HIV, other retroviruses, and related medical conditions. This year, live and on-demand sessions will be available online to registered attendees during the conference. [Linked here](#) is a selection of talks and abstracts by HVTN-affiliated investigators at CROI (please note: this list may not reflect the entire HVTN program).

For more schedule details, visit the [CROI Agenda webpage](#).



IMPAACT 2032

The IMPAACT Network is pleased to share that [IMPAACT 2032](#) has opened to accrual. The study will enroll pregnant and non-pregnant women who are receiving remdesivir for treatment of COVID-19.

The aim of the study is to determine how pregnant and non-pregnant women metabolize the drug, and whether there are any potential side effects. The study will be conducted at 16 sites in the United States. The study is supported by NIAID and NICHD, with Gilead Sciences, Inc., also providing funding to IMPAACT to support the study.

The NIH press release announcing this milestone can be found [here](#).

IMPAACT at CROI 2021

The IMPAACT Network will present research in two oral presentations and six Science Spotlight™ presentations across six studies at virtual CROI 2021, 6-10 March 2021.

The oral presentations will focus on [IMPAACT 2010](#) and the Science Spotlight™ presentations will focus on [IMPAACT P1026s](#), [PROMISE](#), [IMPAACT P1106/PACTG 321](#), [IMPAACT P1112](#), and [IMPAACT 2014](#).

See the full list of abstracts at <https://www.impaactnetwork.org/impaact-croi-2021>

Network MOP Update

The [IMPAACT Manual of Procedures \(MOP\)](#) has been updated and several new sections have been added. Of note, there are three new sections included in this update: **Section 3** (Good Documentation Practices), **Section 7** (General Policies and Procedures), and **Section 14** (Study Close-out).

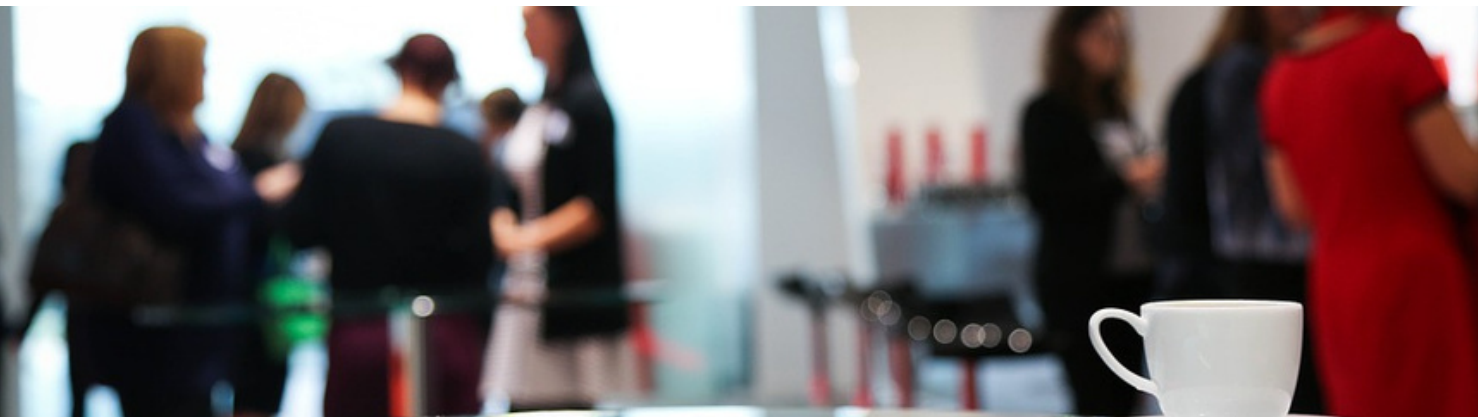
Sections were updated to reflect the Network's scientific agenda and organization per the new NIH grant award; other updates include clarifications about single IRB requirements for U.S. sites, process and sign-off requirements, and protocol deviations guidance. An overview of current sections and recent changes are shown in full by section [here](#).

NETWORK ANNOUNCEMENTS



MTN offers our congratulations to the [HOPE](#) (MTN-025) team for the long-anticipated publication of the study's [primary results in Lancet HIV](#). HOPE (HIV Open Label Prevention Extension) was an open-label follow-on trial to [ASPIRE](#) (MTN-020) in which former ASPIRE participants were offered the opportunity to use the dapivirine vaginal ring to collect additional information about its safety and how it would be used by women when it was known to reduce the risk of HIV in ASPIRE. HOPE enrolled 1,456 women at 14 sites in Malawi, South Africa, Uganda and Zimbabwe. Also included in this issue of the journal were the results of a second open-label trial of the ring, the DREAM study, conducted by the ring's developer, the International Partnership for Microbicides. The publication of these studies coincided with the World Health Organization's recommendation of the dapivirine vaginal ring as an HIV prevention method for cisgender women.





MEETING CALENDAR

In light of the COVID-19 pandemic, numerous events have been postponed or made virtual. Please check each event's website for the latest details.

Mar 6-10

[CROI 2021](#)

(Virtual)

Mar 30-31

[Biomedical HIV Prevention Summit](#)

(Virtual)

May 5-8

[HVTN Full Group Meeting](#)

(Virtual)

May 20-22

[ACTHIV 2021](#)

(Virtual)

July 18-21

[IAS 2021](#)

(Virtual)

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

WEBINARS & TRAINING



Two-Spirit Health Research: Collecting Data in a Culturally Affirming Way

Friday, March 19, 2021 @ 9 - 10:30am PT

[Register Here](#)

In recognition of NNHAAD, the Legacy Project invites you to join the webinar: Two-Spirit Health Research: Collecting Data in a Culturally Affirming Way. Centering Two-Spirit and Indigenous experiences is critical for more respectful, reciprocal, relevant, and responsible health research. Two-Spirit is often equated to an LGBTQ Indigenous participant; thereby, rendering this community's unique experience and history invisible and erases important distinctions tied to living openly and proudly as Two-Spirit. The challenge is how to collect Two-Spirit data in a culturally safe and affirming way, so health research(ers) can conduct rigorous sex- and gender-based analysis that promotes science that considers biological sex and accounts for all genders in an effort to expand our collective understanding(s) within a diversity framework.

During this presentation Harlan Pruden, Tyler Adamson and Jessy Dame will examine some decolonizing practices to better formulate health research, policies and programs that are relevant, respectful and mindful to Two-Spirit people and communities or, in other words, be a site of reconcilia(c)tion in research.

Training

DAIDS Learning Portal Updates

New and updated trainings on the DAIDS Learning Portal (DLP) have been added to improve adherence to and understanding of DAIDS policies and procedures and current ICH GCP guidelines. Check out the new and updated trainings on the [DLP](#).



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) continues to meet monthly. A subgroup of the BSCG is revising a paper for resubmission. On the most recent call, the BSCG discussed HPTN's call for concepts, ACTG's request for submissions for Chair for the newly formed Behavioral Science Subcommittee, and, provided updates on ongoing Network studies.

The Youth Prevention Research Working Group is compiling edits for its new site survey. The survey should be finalized in the upcoming weeks. Sites that are new to the NIH HIV/AIDS Clinical Research Networks will receive the survey. The survey will assess site knowledge and familiarity with adolescent research.

The COVID-19 CAB Coalition (CCC) is discussing recording brief videos from the various COVID-19 Community Advisory Boards that make up the CCC. The videos would detail community involvement in the CABs, as well as COVID-19 resources that are available for the community. The CCC has also discussed additional webinar topics that will be explored further.



Community Partners

Russell Campbell, HANC Deputy Director

Community Partners is excited to welcome Milton Mathonsi as the new Community Partners Co-Chair! Milton represents ACTG at the South Africa, Johannesburg PHRU Soweto Site. Milton will be sharing Community Partners Co-Chair responsibilities with Ernest Moseki.

Community Partners will be collaborating with the [ATN National Community Advisory Board](#), called Youth Experts and Advocates for Health, or ATN-YEAH, to host a webinar/presentation as part of National Youth HIV/AIDS Awareness Day on April 10th. Stay tuned for the webinar announcement.

Community Partners and the Legacy Project co-hosted the webinar: HIV & Aging: Resilience & Research on February 22nd. The recording is available [here](#).

HANC PROGRAM HIGHLIGHTS



Cross-Network Coordination

Milan Vu, HANC Project Manager

The Cross-Network Site Coordinators Working Group discussed updates on various DAIDS initiatives including remote monitoring, electronic information systems, and the SCORE Manual.

The Data Management Center Working Group (DMCWG) discussed updates on safety data reconciliation practices, standardized protocol deviation reporting, electronic information systems training, other data management training collaborations, and remote audit experiences.

The DAIDS [Site Clinical Operations and Research Essentials \(SCORE\) manual](#) recently launched. The SCORE Manual consolidates DAIDS operational and procedural requirements needed to support implementation of DAIDS-sponsored clinical research. The manual serves as a reference describing DAIDS requirements and may be a resource for current site staff as well as for onboarding new research staff.

In addition to the SCORE manual resources on the NIAID website, there is a [recording of the SCORE Manual launch presentation](#) and [presentation slides](#) posted on the HANC website. All resources are captured on the [DAIDS Resources page](#) of the HANC website.

HANC has also assembled a repository of SOP templates to assist sites with developing site-specific SOPs. [Find the SOP Template page here.](#)



Laboratory Coordination

Tyler Brown, HANC Project Manager

The Laboratory Technologists Committee (LTC) held two calls in February to discuss A5401 specimen shipping changes, lab supply shortages, and LTC procedures for Lab Processing Chart and protocol preparation. The LTC SOP Subcommittee met in February to finalize revisions to the ACTG/IMPAACT Laboratory Shipment Evaluation Procedure.

The CPQA Cross-Network Clinical Pharmacology Forum (CNCPL Forum) met in February to discuss future HIV and COVID-19 study compounds, upcoming proficiency testing round schedules and new DAIDS Good Clinical Lab Practice (GCLP) training requirements.

The Lab Focus Group (LFG) met in February to discuss the Patient Safety Monitoring in International Laboratories group (pSMILE) contract outage and plans to convene a working group to revise the Cross-Network PBMC Processing Standard Operating Procedure. The LFG held a second call to discuss and plan for the anticipated resumption of pSMILE services.

Announcement: Due to laboratory supply shortages, the ACTG and IMPAACT Lab Center is urging CTU staff to contact their processing laboratories regarding supply availability prior to scheduling visits with large blood collections. More information on this issue is available [here](#).

HANC PROGRAM HIGHLIGHTS



The Legacy Project

Brian Minalga and Pedro Goicochea, HANC Legacy Project Community Engagement Officers

March 1: The latest issue of the Be the Generation newsletter is now available, bringing you the latest in HIV prevention research! Check it out in [English](#) and en [español](#).

March 3: Along with the US PLHIV Caucus and Latino Commission on AIDS, the Legacy Project co-hosted a webinar on COVID-19 vaccination considerations for people living with HIV. The [recording](#) is available on our website.

March 8: The Women's HIV Research Collaborative is recording and livestreaming a radio program with WHRC Co-chair, Dazon Dixon Diallo, to commemorate National Women & Girls HIV AIDS Awareness Day. Check our [Facebook](#) for more details!

March 10: The Women's HIV Research Collaborative commemorates National Women & Girls HIV/AIDS Awareness Day with our [2021 infographic](#). Share widely!

March 19: The American Indian/Alaska Native Working Group invites you to join the webinar, "Two-Spirit Health Research: Collecting Data in a Culturally Affirming Way" from 9 to 10:30 Pacific. To register [click here](#).

March 30-31: Join the Legacy Project for our sessions at the NMAC Biomedical HIV Prevention Summit:

- March 30 at 2:30 p.m. Eastern: "PrEP's Getting a Makeover: Shots, Rings, and Other Splendid Things"
- March 30 at 4:00 p.m. Eastern: "Mentoring Researchers and Care Providers to Address Disparities"
- March 31 at 4:00 p.m. Eastern: "Participation of Racial/Ethnic Minorities in Clinical Research"

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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