

JANUARY 2021

NEWSLETTER

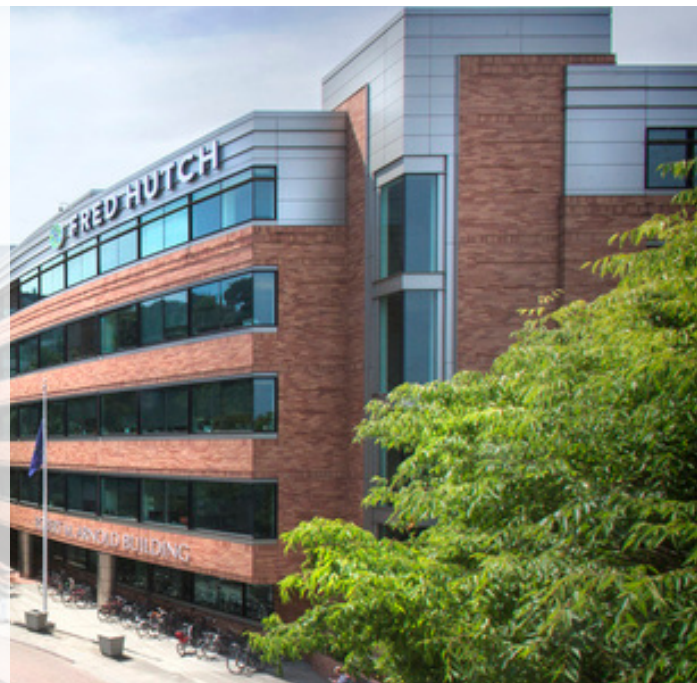
Office of HIV/AIDS Network Coordination



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

Assessing Efficacy of COVID-19 Therapeutic Products and Interventions: A Community-focused Discussion

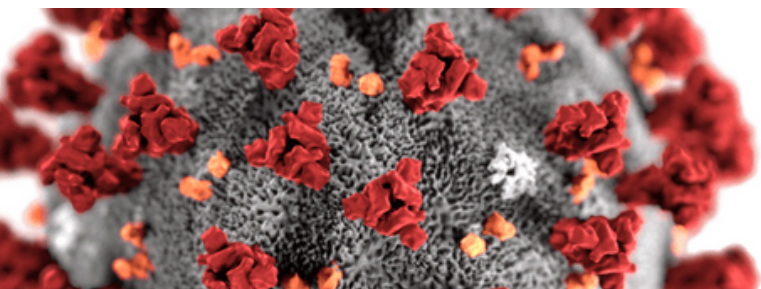
Join the HANC-facilitated COVID-19 CAB Coalition on January 14 at 10AM PT / 1PM ET in a panel discussion for the community. HANC Director, Dr. Jeff Schouten will moderate a conversation with Dr. Rachel Bender-Ignacio, Medical Director of the COVID-19 Clinical Research Center at Fred Hutch; Dr. William Fischer, ACTIV-2 Protocol Team, UNC Dept. of Medicine; and Orbit Clanton, ACTIV-2 CAB Member on the challenges to assess efficacy of COVID-19 therapeutic trials and products. Each panelist will present a few introductory slides and participate in the Q&A session.

The panel will address topics such as assessing therapeutic products effectiveness, study end points, the various products and methods being tested in trials, and other community concerns. Participants are encouraged to engage with the panelists and submit their questions during the session. Register for the event [here](#).

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



COVID-19 Updates

COVID-19 CAB Coalition Update

Assessing Efficacy of COVID-19 Therapeutic Products and Interventions: A Community-focused Discussion

January 14 at 10AM PT / 1PM ET

The HANC-facilitated COVID-19 CAB Coalition invites you to a panel discussion for the community (part 2) on assessing efficacy of COVID-19 therapeutic products and interventions. Dr. Rachel Bender-Ignacio (Medical Director of the COVID-19 Clinical Research Center at Fred Hutch), Dr. William Fischer (ACTIV-2 Protocol Team, UNC Dept. of Medicine), and Orbit Clanton (ACTIV-2 CAB Member) will discuss the challenges to assess efficacy of therapeutic trials and products. The panel discussion will address topics such as assessing therapeutic products effectiveness, study end points, the various products and methods being tested in trials, and other community concerns. [Register here.](#)

Science in the Face of Fear: A Commentary on Vaccine Hesitancy and Public Trust

COVID-19 Vaccine Matters is a blog series discussing the evolving science and policy of COVID-19 vaccines, led by internationally renowned experts in vaccine development, Dr. Larry Corey and Dr. Chris Beyrer.

In the latest post, Dr. Larry Corey discusses the efficacy of the Pfizer and Moderna COVID-19 vaccines and the political context in which COVID-19 vaccines were developed. Read the post [here](#).

Upcoming CoVPN Webinars

Missed a past webinar? Find previous recordings on the [CoVPN Youtube](#).

January 11
3:30PM PT / 6:30PM ET **COVID-19 Vaccine and You**
[Eventbrite registration](#)

January 13
3PM PT / 6PM ET **Islam, COVID-19, Vaccines & Mistrust**
[Eventbrite registration](#)

January 14
11:30AM PT / 2:30PM ET **PANDEMIA Episode 3: COVID-19 y el impacto de las políticas de inmigración**
[Zoom registration](#)

January 21
11:00AM PT / 2:00PM ET **Facebook Live Chat with the Center for African American Health**
[Watch on Facebook Live](#)

NETWORK ANNOUNCEMENTS



There are no updates from the ACTG this month. For the latest news, visit the [ACTG website](#).



Drs. Myron S. Cohen and Wafaa M. El-Sadr, principal investigators of the HIV Prevention Trials Network (HPTN), in collaboration with FHI 360, have received a seven-year award from the U.S. National Institutes of Health as part of the next funding cycle (2020-2027) for the Network. The core and protocol-specific funding will enable the HPTN to continue its HIV prevention research

efforts focused on developing new biomedical prevention methods and optimizing the integration of proven biomedical, behavioral and structural interventions. [Click here](#) to view the press release.



The HPTN Executive Committee has expanded to include Drs. Sinead Delany-Moretlwe, Sybil Hosek, Raphy Landovitz, and Darrell Wheeler. Also, Dr. Nyaradzo Mgodzi will assume an international HPTN leadership role. New committee leadership includes Dr. Nittaya Phanuphak Pungpaong, who will serve as the Sexual and Gender Minority Committee co-chair. Dr. Linda-Gail Bekker, will co-chair the Adolescent

Committee. Drs. Steve Shoptaw and Nyaradzo Mgodzi's terms as investigator representatives ended 30 November. The solicitation for two new investigator representatives will take place in 2021.



HIV VACCINE
TRIALS NETWORK

HIVR4P will take place virtually on January 27-28 and February 3-4. The HVTN will present the following abstracts at the conference:

Abstract Title	Type / Co-authors
Risk factors for HIV transmission in heterosexual men, men who have sex with men, and transgender women participating in the HVTN 702 "Uhambo" and HVTN 503/503-S "Phambili" HIV vaccine trials	Oral presentation Mookho Malahleha, Holly Janes, Fatima Laher et al.
Utilizing a robust HIV prevention Community Engagement framework to engage communities in COVID-19 prevention efforts	Oral presentation Michele Andrasik, Francisco Rentas, Linda Oseso et al.

NETWORK ANNOUNCEMENTS



Abstract Title	Type / Co-authors
Alum-adjuvanted protein administered in combination with ALVAC-HIV downregulates early serum cytokine responses to the vaccine whereas MF59 enhances the early cytokine burst	Oral presentation Erica Andersen-Nissen, Valentin Voillet, Anneta F. Naidoo et al.
Variables predictive of HIV seroconversion among sub-Saharan African heterosexual women: A systematic review	Poster presentation Michele P. Andrasik, PhD, Linda Oseso, MPH, Stephaun Wallace, PhD, MS et al.
High HIV Incidence among Women in the HVTN 702 Vaccine Trial with Limited Ability to Elucidate Drivers of HIV Risk	Poster presentation Jackline Odhiambo, Fatima Laher, Linda-Gail Bekker et al.
Similar antibody responses to subtype C ALVAC-HIV/gp120 vaccine regimens using different adjuvants (MF59 vs. alum) do not explain efficacy differences between HVTN 702 in South Africa and RV144 in Thailand	Oral presentation Kathryn Mngadi, Zoe Moodie, Nicole Grunenberg et al.
Early Vaccine-Induced V1V2 Antibody Responses in Four Pox-Protein Public Private Partnership (P5) HIV Vaccine Trials	Oral presentation F. Laher, C. DiazGranados, C. Innes et al.
Association Between Basal Metabolic Index and Vaccine-induced HIV-1 Adaptive Immunity	Poster presentation Hussein Magale
PrEP stigma affects PrEP uptake: attitudes towards pre-exposure prophylaxis (PrEP) amongst HIV vaccine trial participants in Soweto, South Africa	Poster presentation Fatima Laher, Taibat Salami, Stefanie Hornschuh et al.
Exploring community's understanding of HIV vaccine-induced seropositivity in Soshanguve, South Africa	Poster presentation M Malahleha, M Keefer, J Jean
Baseline host determinants of human HIV vaccine response disparity – a meta-analysis of 26 vaccine regimens	Poster presentation Yunda Huang, Lily Zhang, Kelly Seaton et al.

NETWORK ANNOUNCEMENTS



IMPAACT at HIV R4P

The IMPAACT Network will present data from IMPAACT P1112 and IMPAACT 2009 at the 4th HIV Research for Prevention (HIVR4P) Conference, held virtually from 27-28 January and 3-4 February.

[IMPAACT P1112](#) is an open-label, dose-escalating, phase I multicenter trial to determine the safety and pharmacokinetics (PK) of VRC01, VRC01LS, and VRC07-523LS when given to HIV-1 exposed infants. This presentation describes safety and PK results from the first cohort enrolled to the VRC07-523LS dose group: infants who were not breast fed and received a single dose at birth. These results will be presented during the [Clinical March of bNAbs](#) oral abstract session on Wednesday, 27 January, 12:30-1:30 PM EST.

[IMPAACT 2009](#) is a study of the PK, feasibility, acceptability, and safety of oral PrEP for primary HIV prevention during pregnancy and postpartum in young women and their infants. This presentation compliments the primary [PK Component findings](#) in Clinical Infectious Diseases by describing site experiences with successful implementation of Directly Observed Therapy.

Network Rebrand and New Website

The new IMPAACT logo and website launch is next week! The rebrand is a culmination of a year's work to attempt to capture our identity and core values. Be sure to visit our website, impaactnetwork.org, next week to see these exciting changes and learn more about the rebrand.

Publications

Recent publications of IMPAACT studies include [IMPAACT 2009](#) in Clinical Infectious Diseases, IMPAACT P1026s in [Antimicrobial Agents and Chemotherapy](#) and in [AIDS](#), [PROMISE 1077BF/FF](#) in JAIDS, [IMPAACT 2007](#) in AIDS, and IMPAACT [P1115](#) in Lancet HIV.



MTN is pleased to announce that the final site for the [DELIVER](#) study (MTN-042) evaluating the safety and acceptability of two different HIV prevention approaches – the monthly dapivirine vaginal ring and Truvada as daily oral PrEP – when used during pregnancy has started screening. The College of Medicine-Johns Hopkins University Research Project in Blantyre, Malawi joins three other sites currently enrolling for DELIVER – the Wits Reproductive Health and HIV Institute Shandukani Research Centre in Johannesburg, South Africa; the Makerere University-Johns Hopkins Research Collaboration in Kampala, Uganda; and the University of Zimbabwe College of Health Sciences Clinical Trials Research Centre, Zengeza.

NETWORK ANNOUNCEMENTS



DELIVER is a first-of-its-kind study of the dapivirine vaginal ring in pregnant women and will also provide much needed information about the safety of Truvada as PrEP in this population. Ultimately, the goal of the DELIVER, in concert with a companion study called [B-PROTECTED](#) (MTN-043) in breastfeeding women, is to ensure cisgender women have safe and effective HIV prevention options they can use throughout their lives.



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

Jan 15-16	<u>NAESM Conference</u> (Virtual)
Jan 27-28 & Feb 3-4	<u>HIV Research For Prevention (HIVR4P)</u> (Virtual)
Feb 2	<u>IAS COVID-19 Conference: Prevention</u> (Virtual)
Mar 6-10	<u>CROI 2021</u> (Virtual)
Mar 30-31	<u>Biomedical HIV Prevention Summit</u> (Virtual)



HANC PROGRAM HIGHLIGHTS

Need to contact a HANC staff member? [Click here](#) to go to the About the HANC Staff page.

HANC Staff Situation Update

In accordance with Fred Hutch policies in response to the coronavirus situation in Washington state, HANC staff are working remotely until further notice. Work with HANC collaborators will continue with as few disruptions as possible.



Behavioral & Social Sciences

Greg Davis, HANC Project Manager

The Behavioral Science Consultative Group will meet mid-January. The BSCG will continue to provide consultation on protocols in development to the networks throughout 2021. The BSCG will discuss the possibility of holding a face-to-face meeting in 2021.

The BSCG was unable to hold its annual meeting in 2020 due to COVID-19.

In January, the Youth Prevention Research Working Group will start to review the list of CTUs/CRS' that have been funded for the next 7 years. The YPRWG is considering surveying the new sites to assess the experience that the sites have in adolescent research and any necessary training that would be needed for the sites to perform adolescent research.

Over the next several months, the Financial Disclosure Working Group will start reviewing and revising the financial disclosure SOP for the 2021 annual solicitation.



Community Partners

Russell Campbell, HANC Deputy Director

Community Partners is in the process of soliciting representatives to serve on the Strategic Working Group (SWG). Two Community Partners Executive Committee members are selected to serve as members of the National Institutes of Health (NIH)

HIV/AIDS Clinical Trials Networks SWG. Participation in these groups involves communicating Cross-Network community perspectives to the Network leadership and advancing appropriate issues related to community involvement within the NIH HIV/AIDS Clinical Trials Networks. Community Partners is also in the process of soliciting a new CP Co-Chair.

HANC PROGRAM HIGHLIGHTS



Cross-Network Coordination

Milan Vu, HANC Project Manager

The Cross-Network Evaluation Working Group met in December to discuss annual site evaluation reports, site-level evaluation metrics, network procedures for corrective actions, and utility of various metrics and milestones as markers of site performance.



Laboratory Coordination

Tyler Brown, HANC Project Manager

The Laboratory Technologists Committee (LTC) held two conference calls to discuss upcoming LTC trainings, laboratory updates regrading A5401, and solicit new Protocol Lab Technologists for new and ongoing research studies.

The CPQA Cross-Network Clinical Pharmacology Forum (CNCPL Forum) held a conference call to discuss current and upcoming proficiency testing rounds, future network study compounds, and the revised DAIDS Good Clinical Lab Practice (GCLP) manual and online trainings.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to discuss the VQAAB Annual Review executive summary, the new VQA Participation Survey, and review new proficiency testing (PT) panel data for recent PT rounds.

The Lab Focus Group (LFG) held a joint conference call with members of the DAIDS Clinical Laboratory Oversight Team (DCLOT) to discuss the new DCLOT guidelines for establishing backup support during laboratory QA contractor shutdowns. The group also discussed the recent lab site re-competition, new GCLP updates regarding training and auditing, and updates on remote laboratory audits.

Announcement: The LTC is now seeking new applicants for the upcoming membership term, which begins in March. Applications are due Friday, January 15, 2021. For further application and membership details, contact Tyler Brown (tdbrown3@fredhutch.org).



The Legacy Project

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

Jan 15: Brian Minalga's official role with the COVID-19 Prevention Network's External Relations Division comes to a close.

Jan 15 - Jan 16: [NAESM Leadership Conference](#) - Pedro Goicochea will be attending on behalf of the Legacy Project.

Jan 17 - Jan 21: [HIV Research for Prevention Conference](#).

Jan 22: Abstracts due to the NMAC [Biomedical HIV Prevention Summit](#) committee. Legacy, WHRC, and the New Investigators Working Group will be submitting abstracts.

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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