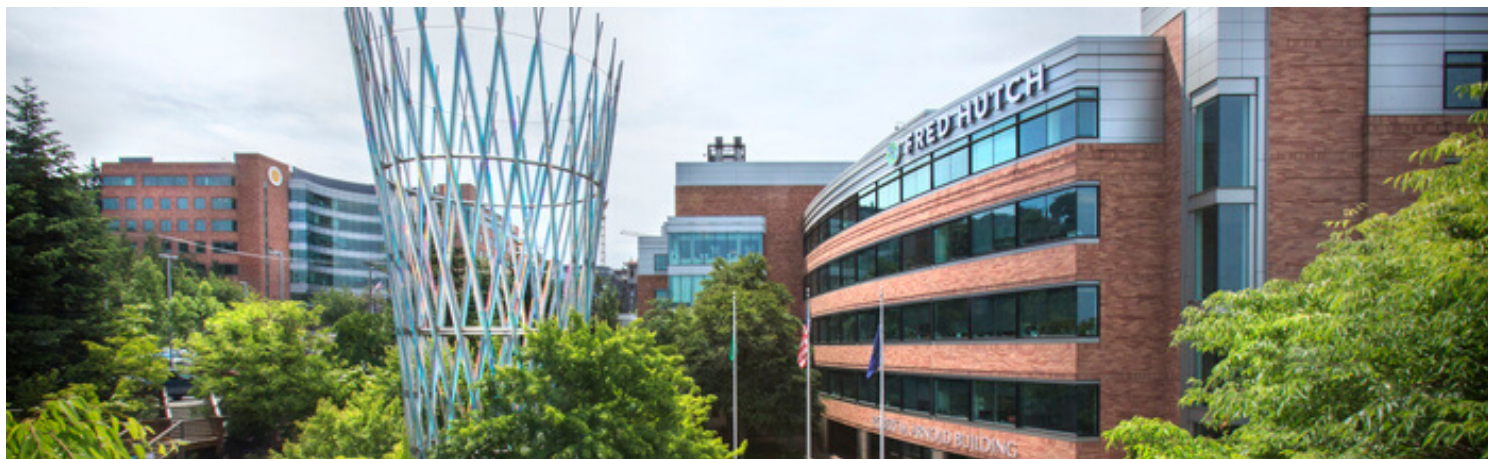


FEBRUARY 2020

# NEWSLETTER

Office of HIV/AIDS Network Coordination



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

## HANC ANNOUNCEMENTS

*Join us in recognizing National Black HIV/AIDS Awareness Day on February 7, 2020.*

Read a commemorative statement from the Legacy Project and Women's HIV Research Collaborative [here](#).

### ***A conversation about Black Gay Men, Research, and the CDC***

The importance of HIV research in the Black gay community is often stated, but rarely framed through the lens of Black gay men themselves. While Black men who have sex with men (MSM) are disproportionately impacted by HIV in the United States, narratives of Black gay men combating the epidemic in their own communities through their gifts and resiliency are often overlooked.

Join the Legacy Project and the Centers for Disease Control and Prevention (CDC) in a webinar conversation highlighting the importance of Black gay men's involvement in HIV research. This webinar, entitled, "Our Time, Our Stories: A Conversation about Black Gay Men, Research, and the CDC" will feature an open panel discussion and offer attendees an opportunity to directly engage with our speakers. Find more details in the **Webinars & Training** section and [register now](#).

## INSIDE THIS ISSUE:

<b>Network Announcements</b>	<b>2-5</b>
<b>Meeting Calendar</b>	<b>6</b>
<b>Webinars &amp; Training</b>	<b>6</b>
<b>HANC Program Highlights</b>	<b>7-8</b>
Behavioral & Social Sciences	7
Community Partners	7
Cross-Network Coordination	7
Laboratory Coordination	8
The Legacy Project	8
<b>WG Member Spotlight</b>	<b>9</b>
<b>Resources</b>	<b>10</b>

*Do you have questions, comments, or content suggestions? Email the Editor, Milan Vu, at [mhvu@fredhutch.org](mailto:mhvu@fredhutch.org)*

# NETWORK ANNOUNCEMENTS



This month, the ACTG is highlighting three important studies:

## **A5288: Diverse Drug Resistance Profiles among People Experiencing Virologic Failure on Second-line ART in Resource Limited Settings**

A5288 assessed third-line antiretroviral treatment (ART) in individuals who were failing second-line ART. This publication aimed to define resistance profiles among individuals failing second-line ART in low- and middle-income countries (LMIC), as this information is vital to optimize individual patient management and to develop treatment guidelines for this group. Of the 653 individuals screened for A5288, more than three-quarters (78%) had resistance to one or more drugs. One-fifth (20%) of participants showed resistance to at least one drug in a drug class, 32% showed resistance to at least one drug in two drug classes, and 26% showed resistance to at least one drug in all three commonly available drug classes. Susceptibility to at least one second-line regimen was preserved in 59% of individuals, as was susceptibility to etravirine (78%) and darunavir/r (97%). Susceptibility to a second-line regimen was significantly higher among women, younger individuals, those with higher nadir CD4+T-cell count, and those who had received LPV/r, and was lower among prior nevirapine recipients.

Therefore, highly divergent HIV drug resistance profiles, ranging from no resistance to resistance to three drug classes, were seen among individuals failing second-line ART in LMIC. These results underscore the need for ready access to resistance testing and newer antiretrovirals for optimal management of third-line ART in LMIC.

([Clinical Infectious Diseases](#). 2019 Nov 14;. doi: 10.1093/cid/ciz1116. [Epub ahead of print] PubMedID: 31724034; Wallis C, et al)

## **A5260s: Fungal Marker $\beta$ -D-Glucan Increased After Antiretroviral Therapy, Associated with Fat Gains**

A5260s was a sub-study of A5257 in which ART-naïve individuals with HIV were randomized to receive atazanavir (ATV)/ritonavir (r), darunavir/r, or raltegravir. The objectives of A5260s were to compare cardiovascular markers, body composition, and immune activation between those initiating the three different regimens. This analysis in the A5260s study found that, among participants of A5257, beta-D-glucan (BDG, a marker of fungal translocation) increased over two years, irrespective of whether individuals were randomized to either of the two protease inhibitors or the integrase inhibitor. This finding may be as a result of ongoing intestinal damage that occurs despite successful ART. The study also found that BDG was associated with larger fat gains on therapy, supporting prior data from ACTG 5260s showing that a marker of intestinal injury was a strong predictor of fat gains on treatment. This research highlights the potential effect of gut dysfunction on metabolic comorbidities in HIV.

*(continued on next page)*

# NETWORK ANNOUNCEMENTS



([Open Forum Infectious Diseases](#). Vol 6. Iss 11. 2019 Nov 11;. doi: 10.1093/ofid/ofz434. eCollection 2019 Nov. PubMedID: 31737737; Dirajlal-Fargo S, et al)

## **ACTG DACS 325: Screening and Enrollment by Sex in HIV Clinical Trials in the United States**

While women represent about one-quarter of adults living with HIV in the United States, many HIV clinical trials enroll fewer than 25% women. ACTG DACS 325 sought to assess how people living with HIV are recruited into the network's clinical trials and whether ACTG enrolled proportionally lower percentages of women compared to men from the United States (and if so, why).

This analysis included all ACTG trials recruiting people living with HIV in the United States from 2003 (when the screening database started) through 2013. Data from 31 trials recruiting at 99 clinical research sites across the United States resulted in information on almost 11,000 persons. About one fifth (19%) of those screened were women living with HIV. Among those assessed, 28% did not enroll, which was only slightly higher than the 27% observed among men. These results did not differ when considering race, ethnicity, or age. Researchers were not able to investigate gender identity as it was not added to the ACTG screening questions until 2017. The most common reasons for people not enrolling were not meeting trial requirements or persons opting-out, and these reasons did not differ by sex. Pregnancy, breastfeeding, and trial contraceptive requirements were rarely reported as reasons to not enroll, though researchers speculate that women for whom these requirements applied may have been excluded (or excluded themselves) from trial consideration prior to screening.

Because the data around some of the factors relevant to participant recruitment (for example, childcare access, transportation, or participant reimbursement) were not available in the database, researchers were not able to address their role in recruitment sex differences in this study. Investigators concluded that efforts to expand screening of women for trial eligibility is needed to improve rates of enrollment.

([Clinical Infectious Diseases](#). 2019 Sep 29;. doi: 10.1093/cid/ciz959. [Epub ahead of print] PubMed PMID: 31563942; Smeaton LM, et al)



Dr. Jonatan Gioia and Mia Ryan were featured in the OutSmart Magazine article entitled, "[A New Generation of Queer Activists](#)." Dr. Gioia is an [HPTN 083](#) study team member and research associate at the Houston HIV/AIDS Research Team at the University of Texas Health Science Center (UTHealth) in Houston. Mia Ryan is an HPTN 083 Community Working Group member and HPTN 091 community protocol representative. Mia is also a lay health promoter and outreach worker for UTHealth in Houston. OutSmart is Houston's award-winning LGBTQ magazine.

# NETWORK ANNOUNCEMENTS



HVTN 706/HPX3002, also known as Mosaico, is underway, with the first study participants receiving study injections at sites in Houston, Washington D.C., and Philadelphia. Mosaico evaluates an investigational vaccine based on mosaic immunogens—vaccine components made from elements from multiple strains of HIV—that aim to induce immune responses against the wide variety of global HIV strains. We look forward to the support and participation of study participants and communities globally.

As Mosaico gears up, the HVTN's Social and Behavioral Sciences and Community Engagement Unit (SBS/CEU) is hard at work training and preparing sites. The SBS/CEU conducts training on community education, recruitment, and retention to enhance the skills and tactics study teams employ to encourage community involvement in the study. The SBS/CEU team has recently traveled to sites in the U.S., Europe, and South America to prep sites for Mosaico. In the HVTN model of community engagement, community education is a critical component that involves spreading information throughout local communities relating to HIV, HIV vaccine science, and the study. "Our community engagement model helps to ensure that interested study participants hear accurate information from their trusted voices: persons who they go to for information and advice," says Dr. Stephaun Wallace, Social and Behavioral Sciences Junior Investigator Liaison for the HVTN.



*Pictured: HVTN Staff at the Vila Mariana CRS in Sao Paulo, Brazil after a site preparation visit. (L-to-R) Patricia Segura (HVTN); Dr. Valdez Madruga (PI, Vila Mariana CRS); Dr. Stephaun Wallace (HVTN); Shelly Ramirez (HVTN); Luciana Kamel (HVTN)*

Teams at trial sites educate communities about the study, the broader HIV prevention landscape, and HIV vaccine science, paving the way for study participants and communities to be involved and meaningfully participate in Mosaico. Community engagement and outreach activities are critical, and underscore how the local study teams gain an intimate understanding of the structural and social drivers of HIV in their communities.



# NETWORK ANNOUNCEMENTS



The IMPAACT Network is proud to announce 14 abstracts have been accepted for the 2020 [Conference on Retroviruses and Opportunistic Infections \(CROI\)](#): three as oral presentations, three as posters with themed discussions, and eight as poster presentations. Studies to be presented include P1112, P1115, PROMISE, P1041, P1106, PHOENIX, P1101, IMPAACT 2007, P1078, IMPAACT 2010, IMPAACT 2001, and IMPAACT 2009. More information will be available at <https://impaactnetwork.org/publications/CROI2020.html> closer to the conference.

Recent publications on IMPAACT studies have been released and include [IMPAACT 1077BF](#) in the Journal of Acquired Immune Deficiency Syndromes (JAIDS), [IMPAACT 1077BF/1077FF](#) in PLoS One and [IMPAACT 2013](#) in The Journal of Infectious Diseases.



MTN-045 has launched! [MTN-045](#) is a cross-sectional study using questionnaires and other measures to assess couples' preferences for dual purpose prevention products to prevent unintended pregnancy and HIV infection. The study will be enrolling 400 couples and is taking place in Uganda and Zimbabwe. Study findings will inform the future design and delivery of products.

On January 28-29 in Harare, Zimbabwe, the MTN held its final in-country stakeholder meeting for the [DELIVER](#) (MTN-042) and [B-PROTECTED](#) (MTN-043) studies that will be evaluating the safety of the dapivirine vaginal ring and Truvada as oral PrEP in pregnant and breastfeeding women, respectively. Approximately 60 stakeholders, advocates, former study participant and researchers attended the meeting, which was co-hosted by AVAC as well as the Pangea Zimbabwe AIDS Trust and the Organization for Public Health Interventions and Development. The meeting was coordinated with the Zengeza Clinical Research Site of the University of Zimbabwe College of Health Sciences – Clinical Trials Research Centre, which will be conducting the study.

## 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

#### **Our Time, Our Stories: A Conversation about Black Gay Men, Research, and the CDC**

*February 27 @ 10AM PST / 1PM EST*

The Legacy Project, in collaboration with the Centers for Disease Control and Prevention (CDC), invites you to join an engaging and interactive conversation highlighting the efforts and motivations of Dr. Damian Denson, behavioral scientist within the Prevention Research Branch of the Division of HIV/AIDS Prevention at the CDC; and Dr. Errol Fields, Assistant Professor at Johns Hopkins School of Medicine.

Dr. Denson and Dr. Fields will be discussing their motivations and work in HIV research. They will highlight the importance of Black gay men's involvement in HIV research, as well as the CDC's role in ending the HIV epidemic in the Black gay community. In addition, Lamont Scales from the Office of Health Equity, Office of the Director, Division of HIV/AIDS Prevention at the CDC will provide an update on HIV in the Black community. [Register here](#).

### Training

#### **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 website](#) to access the new tool kits.

Newly released tool kits:

- Activity 12: Causes, Solutions and Forces
- Activity 13: Regulatory Updates

### 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 Consultative Group (BSCG) will meet on Monday, May 4, 2020 in Seattle, WA. The BSCG will begin discussing agenda items for the meeting on the groups next call. The group is currently planning a spring webinar. More information on the webinar will be available in the near future.

The Behavioral Science Working Group (BSWG) will hold its next call on February 20, 2020.

The Youth Prevention Research Working Group (YPRWG) discussed submitting a satellite symposium proposal at AIDS 2020 on its last call. The group has previously hosted satellite symposiums at IAS 2017, AIDS 2018, and IAS 2019. In lieu of hosting a session at AIDS 2020, the YPRWG will submit a proposal to HIVR4P once submissions open. The YPRWG will host a webinar in the spring. More information will be available once presenters are confirmed.



### Community Partners

*Russell Campbell, HANC Deputy Director*

Morénike Giwa Onaiwu and Ernest Moseki are the new Community Partners Co-Chairs.



### Cross-Network Coordination

*Milan Vu, HANC Project Manager*

The Data Management Center Working Group (DMCWG) discussed the ongoing Safety Data Reconciliation Policy pilot and DMC approaches to capturing screen failure data and demographics.

The Communications Working Group (CWG) discussed upcoming network presence at the annual Conference on Retroviruses and Opportunistic Infections (CROI) happening March 8-11, 2020 in Boston, Massachusetts. Links to accepted network sessions will be posted on the HANC website closer to the conference date. Guests from DAIDS, NIAID, and Community Partners also shared several resources with the group relating to gender-inclusive research and stigmatizing language in the context of HIV and tuberculosis.

# HANC PROGRAM HIGHLIGHTS

*(Cross-Network Coordination, continued)*

The Site Coordinators Working Group (SCWG) discussed site experiences with software tools for fiscal management along with questions related to site monitoring. The group also hosted members from the DAIDS Learning Portal team to discuss tracking of staff training certifications.



## Laboratory Coordination

*Tyler Brown, HANC Project Manager*

The CPQA Advisory Board (CPQAAB) held a conference call to discuss CPQA program updates on proficiency testing, CPQAAB sub-working groups, and the AVR/SOP Peer Review Program.

The Lab Technologists Committee (LTC) held two conference calls to discuss LDMS-generated reports, new backup aliquot requirements, changes to the Lab Processing Chart review process and QA/QC for barcode scanning. The LTC SOP Working Group held four conference calls to continue developing new Lab Processing Chart Standard Wording Documents, and to begin developing a new LTC SOP Template and Shipment Evaluation Procedure.

The Laboratory Focus Group (LFG) and DAIDS Clinical Laboratory Oversight Team (DCLOT) held a joint conference call with members of the Virology Quality Assurance Program (VQA) to discuss ongoing quality assurance measures for virology laboratories within the National Institutes of Health (NIH)-Division of AIDS Clinical Trials Networks.

### Opportunity Available: International Lab QA/QC Coordinator

Patient Safety Monitoring in International Laboratories (pSMILE) is hiring a new International Lab QA/QC Coordinator to support the National Institutes of Health (NIH)-Division of AIDS research contract. More information about this position can be found on the Johns Hopkins University Careers webpage, or by clicking [here](#).



## The Legacy Project

*Brian Minalga and Louis Shackelford  
HANC Legacy Project Team*

February 7: The Legacy Project and Women's HIV Research Collaborative have released [this statement](#) in commemoration of National Black HIV/AIDS Awareness Day

February 9-11: Brian Minalga will represent HANC at the Microbicide Trials Network annual meeting

February 27: Legacy is hosted a webinar entitled "[Our Time, Our Stories: A Conversation about Black Gay Men, Research, and the CDC](#)". A description of the webinar and registration details can be found in the provided link.

February 28: The latest issue of BTG News, the Legacy Project's quarterly publication on HIV prevention research, will be available at the bottom of the [Be the Generation website](#)



## 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:



### Maria del Rosario Leon

Maria del Rosario (MaR) is a member of Community Partners based in Lima, Peru. She is the head of the Community Engagement Resource Unit for the Peru CTU at Impacta Salud y Educación.

MaR currently leads community engagement, recruitment and retention strategies for vaccine and no-vaccine prevention trials (MTN, HVTN, HPTN) and treatment trials (ACTG).

**What do you like most about community engagement?** The passion from the communities, stakeholders and participants about new answers from science for HIV Prevention. Revolution is here!!!! and we are going to transform this epidemic with the participation, commitment and efforts from all of us. I can see and feel this same passion and commitment from the community educators from sites all around the world. To have the opportunity to share our experiences and to learn from others is priceless.

**What might surprise you about me:** I wrote a Poem book “Madrugada con los pies desnudos” many years ago. I am a city gardener and I loveeeee to dance :)



### Abraham Johnson

Abraham Johnson is a member of the Legacy Project. He is a community program associate at FHI 360 for the HPTN, IMPAACT, and MTN. His work specifically focuses on clinical research management, community engagement, community capacity building and advocacy of HIV/AIDS public health programs and research both domestically and internationally.

Prior to joining with FHI 360, Mr. Johnson was employed at Georgia Southern University as a Project Coordinator for “Project Prep” His responsibilities initially focused on conducting educational seminars on Prep for MSM in South Georgia. He later transitioned to a research assistant where he worked with an assigned faculty member on various research projects. Mr. Johnson holds a Master’s degree in Public Health from Georgia Southern University and a Bachelor’s degree in Biology from Savannah State University.

# 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](mailto: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](mailto: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](mailto: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.

FOLLOW HANC ON



FIND MORE RESOURCES AT  
[WWW.HANC.INFO](http://WWW.HANC.INFO)