Community Partners F2F Meeting
Community Partners (CP) hosted its annual face-to-face meeting in Washington, DC from October 26-27. CP members engage with each other virtually throughout the year to identify and address challenges related to participation in clinical trials. The face-to-face meeting is an opportunity for members to convene in-person to meet their fellow members, discuss key areas of interest, and strategize activities for the upcoming year. Find more details and photos from the meeting under the Community Partners section of the HANC Program Highlights!

Pictured below: CP members at the 2019 F2F meeting.

Do you have questions, comments, or content suggestions? Email the Editor, Milan Vu, at mhvu@fredhutch.org
Study A5381 Opens!
ACTG is happy to announce that study A5381, “Observational Cohort to Assess Therapeutic Efficacy and Emergence of HIV Drug Resistance Following Initiation of Tenofovir-Lamivudine-Dolutegravir (TLD) for First- or Second-Line ART” is now open and has enrolled the first participant in Malawi! This study, chaired by Drs. James Hakim and Cissy Kityo, and performed with support from PEPFAR, will enroll 1,350 participants across PEPFAR-supported low and middle-income countries. It is designed to identify the risks and benefits of the roll-out of dolutegravir containing ART (tenofovir-lamivudine-dolutegravir, or TLD) in settings that may not have access to frequent viral load and resistance testing to guide ART management. Each study participant will be assigned to one of four groups:

- Group 1: Participants switching to TLD after taking ART containing an NNRTI (such as efavirenz or nevirapine).
- Group 2: Participants switching to TLD after taking ART containing a boosted PI (such as lopinavir/ritonavir or atazanavir/ritonavir).
- Group 3: Participants taking TLD and receiving medication for TB that includes rifampicin. These participants must be starting one or both of these medications when they enter the study.
- Group 4: Participants starting TLD who have not previously taken ART.

Since dolutegravir is now recommended as first-line therapy for all populations worldwide, this important study will help define outcomes with TLD in typical-use settings for both treatment-naïve and experienced patients. For more information, please click here!

Diane Havlir, MD named to National Academy of Sciences
A hearty congratulations to Diane Havlir, MD on being named to the National Academy of Medical Sciences. This is one of the highest honors in the field of health and medicine and is awarded to celebrate exceptional professional achievement and commitment to service. Diane has been a leader in the ACTG for decades and is the former Vice Chair of the Tuberculosis Transformative Science Group. Everyone at the ACTG is very proud of her accomplishments – well done, Diane!

Following concept review, the HPTN Executive Committee approved protocol development of HPTN 097 (submitted as HPTN 074 Plus): A Phase III Randomized Clinical Trial to Optimize HIV Viral Suppression Comparing the HPTN 074 Intervention and Immediate Antiretroviral Therapy as the Standard of Care with an Integrated Intervention of Immediate Medication-Assisted treatment Plus Enhanced Social Support Among HIV-Infected People Who Inject Drugs.
The HVTN is headed to ICASA 2019! Taking place December 2-7 in Kigali, Rwanda, ICASA is the biggest AIDS conference in Africa, with over 10,000 delegates from across the world expected to attend. The HVTN will be represented in the following activities:

**Opening Plenary**
On December 3, HVTN Principal Investigator Dr. Larry Corey will share the opening plenary stage with Hon. Donatille Mukabalisa, Speaker of Chamber of Deputies, Rwanda, and global health advocate Rosemary Mburu. Dr. Corey’s plenary topic is titled “Towards developing a globally effective HIV vaccine”.

**Community Booth**
The HVTN is collaborating with colleagues at the HPTN to host a community booth recognizing the collaborative work of the two organizations on HVTN 703/HPTN 081 and HVTN 704/HPTN 085, also known as the AMP Studies.

**Media Workshop**
An HVTN workshop on December 2 will feature topics on HIV prevention research, including the need for a safe and globally effective HIV vaccine, an overview of the AMP studies, updates on HVTN’s large-scale HIV vaccine efficacy clinical trials, and how women in the region are disproportionally affected by HIV/AIDS.

**Poster Presentation**
Linda Oseso, HVTN Project Manager, will present a poster summarizing the use of a Community-Based Participatory Research (CBPR) approach to develop culturally relevant and community-informed educational videos on preventive HIV vaccine trials in South African communities.

The pharmacokinetic (PK) and safety data for Cohort 1 and Cohort 2 of IMPAACT P1101 has been published ahead of print in AIDS. The study found that giving 12 mg/kg twice daily of the chewable Raltegravir (RAL) formulation achieved PK targets safely in HIV-infected children receiving rifampicin (RIF) for TB treatment. Participants were enrolled across four sites in South Africa. Read the article [here](#).

Other recent publications on IMPAACT studies include IMPAACT P1025 in JAIDS, IMPAACT P1055 in the Journal of Pediatric Psychology, and IMPAACT P1076 in Clinical Infectious Diseases.
MTN is excited to share the news that the Lima, Peru and Blantyre, Malawi sites for MTN-035, fondly called the DESIRE study, have activated and are beginning to enroll study participants. DESIRE is exploring three placebo methods for the delivery of a rectal microbicide – a douche, suppository and fast-dissolving rectal insert – in 210 transgender men and women and cisgender men who have sex with men.

The DESIRE study will be discussed at a workshop taking place from 2:45-4:15 p.m., Dec. 3, at the upcoming Biomedical HIV Prevention Summit in Houston, Texas. The presentation, Flirt, Insert, and Squirt: Community Desire in HIV Prevention, will focus on the unique design of DESIRE that provides participants with the opportunity to “try on” potential HIV prevention methods and share their experiences before specific products have been developed.

A fun and informative music video to promote the REACH study (MTN-034) was developed by the Makerere University-Johns Hopkins University Research Collaboration in Kampala, Uganda. The video features Ugandan performer Joanita Kawalya, and is being used as a tool to educate and inform potential study participants. REACH (Reversing the Epidemic in Africa with Choices in HIV prevention) is a Phase IIA study evaluating how adolescent girls and young women use the monthly dapivirine vaginal ring and Truvada as daily PrEP and their preferences for either or both approaches. The study is collecting much needed information on the safety of these approaches in young cisgender women.
MEETING CALENDAR

Oct 30-Nov 2
Union World Conference on Lung Health (Hyderabad, India)

Nov 6-8
17th European AIDS Conference (Basel, Switzerland)

Dec 2-7
ICASA (Kigali, Rwanda)

Dec 3-4
Biomedical HIV Prevention Summit (Houston, TX)

Jan 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)

WEBINARS & TRAINING

Upcoming Webinars
No HANC webinars are scheduled for the month of November.

Training
Creating a Gender-Affirming HIV Research Environment
Available on the DAIDS Learning Portal
This module is designed to facilitate transgender inclusion in HIV research by creating more gender-affirming spaces through staff understanding and responsiveness, the physical environment, and research study design. This is the third of the five-module Transgender Training Curriculum for HIV Research created by the Division of AIDS (DAIDS) Cross-Network Transgender Working Group. Access the course here.

To supplement the eLearning course, an in-person training tool is also available so you can provide in-person training at your site or in the community. It includes a PowerPoint presentation, facilitator’s guide, scenarios for an exercise, and selected resources all in English, Spanish, and Portuguese.

HANC Webinar Archives
Missed out on a webinar you wanted to attend? Visit the HANC website to view archived recordings of past webinars!

Recent sessions that are now posted include:
- National Latinx AIDS Awareness Day Webinar (aired October 15, 2019)
- Exploring and Disrupting Pathways to Risky Behaviors (aired October 16, 2019)
- HIV Cure Research: An Overview of ACTG’s Cure-related Research and the Socio-behavioral Aspects of Cure-related Research (aired October 31, 2019)

For details and other events, visit the HANC calendar.
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

HANC’s Behavioral Science Working Group (BSWG) closed out October with the third and final part of HANC’s Cure Research webinar series. Part One provided an overview of the state of HIV cure-related science. Part Two discussed community perspectives of HIV cure-related research. In Part Three, we discussed the cure-related research being conducted by the AIDS Clinical Trials Group (ACTG) and the socio-behavioral aspects of cure-related research. Dr. Rajesh Gandhi provided an overview of ACTG’s ongoing and upcoming cure-related research while Dr. Karine Dubé addressed the social and behavioral issues in cure-related research. A link will be available under the Behavioral Science section of the HANC Webinars webpage.

On Wednesday, October 16, the Youth Prevention Research Working Group hosted a webinar with Dr. Kevin Haggerty and Dr. Diana Fishbein. The webinar, “Exploring and Disrupting Pathways to Risky Behaviors”, reviewed what we don't know about child development and implications for their pathways to risky behavior, but it also focused on what we DO know. The webinar can be viewed here.

Community Partners

Russell Campbell, HANC Deputy Director

Community Partners held a very successful and engaging 2019 Face-to-face Meeting October 26-27 in Washington, DC. During that meeting the group finalized its 2020 Work Plan and heard presentations on a variety of research topics and collaborations, including the following:

- ATN YEAH Collaboration
- Age & Identity Verification/Co-enrollment Tracking
- DAIDS Cross-Network Transgender Working Group Updates
- Current State of Research & Challenges & Impact on Community
- Martin Delaney Collaboratory Update
- Finalize Community Partners 2020 Work Plan

(continued on next page)
(Community Partners, continued) CP representatives also attended the Tuberculosis Trials Consortium (TBTC) Community Research Advisors Group (CRAG) Meeting on October 15-17 in Atlanta Georgia.

As part of Community Partners’ efforts to establish formal collaborations with the Martin Delaney Collaboratory (MDC), CP is pleased to announce that Chris Roebuck (BEAT-HIV Community Advisory Board) and Michael Louella (defeatHIV CEC) will be serving as the representatives from the MDC to provide updates. CP will be selecting representatives in the near future. Stay tuned for more information on this collaboration, including MDC updates in future HANC Newsletters.

Cross-Network Coordination
Milan Vu, HANC Project Manager

Representatives from DAIDS Office of Clinical Site Oversight (OCSO) presented on the Clinical Quality Management Plan (CQMP) policy requirements for the Quality Assurance (QA) Summary Report on October 17, 2019. The recording of the webinar and slides are available on the HANC website, DAIDS Resources and Announcements page.

Additional resources related to the CQMP policy are linked below:
- Requirements for Clinical Quality Management Plans
- Appendix 1 - CQMP Participant CHART Review Tool
- Appendix 2 - CQMP Protocol Regulatory File Review Tool
- Appendix 3 - CRS QA Summary Report
  - Appendix 3 Section 4 Additional Lines
- CQMP Policy: Frequently Asked Questions
- QA Summary Report Preparation Guidelines

The Data Management Center Working Group (DMCWG) identified members for a new ad hoc working group focused on standardizing pregnancy outcome data collection. The group will convene to refine its scope of work and identify priorities in the coming months. In addition, the DMCWG discussed recent developments in electronic trial master file implementation and initiatives with Medidata.

Laboratory Coordination
Tyler Brown, HANC Project Manager

The Lab Technologists Committee (LTC) held a conference call to discuss policy changes for plasma aliquot storage, changes to leukopak shipping requirements, and changes included in the new Good Clinical Laboratory Practice (GCLP) Manual (v4.0). The LTC Voting Members held a conference call to review ballots for the upcoming LTC Membership Elections. The LTC SOP Working Group held three conference calls to continue revising the Lab Processing Chart Standard Wording Documents.

The CPQA Cross-Network Clinical Pharmacology Forum (CNCPL Forum) held a conference call to discuss updates on proficiency testing, new technical guidance documents and computer software validation processes. (continued on next page)
HANC PROGRAM HIGHLIGHTS

(Laboratory, continued) The December CNCPL Forum call will feature a presentation from 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 Laboratory Focus Group (LFG) held a conference call to discuss implementing changes included in the GCLP Manual v4.0, harmonizing lab site naming standards and developing new standard operating procedures for Primary Network Laboratories (PNL).

The Legacy Project
Brian Minalga and Louis Shackelford
HANC Legacy Project Team

The Women’s HIV Research Collaborative has released a new training, “Biomedical HIV Prevention for Women.” In 50 slides, this training provides a comprehensive overview of the need for HIV prevention for cisgender and transgender women, what biomedical HIV prevention options are currently available for cis and trans women, what’s happening in biomedical HIV prevention research for women, and how to get involved. This training is intended to benefit anyone interested in biomedical HIV prevention for women—especially community members. Slides, speaker notes, and a facilitator’s guide are available to download on the HANC public website. PowerPoint slides are available on request; email bminalga@fredhutch.org.

November 5-8: On behalf of HANC and the Legacy Project, Russell Campbell will co-present “Engaging HBCUs in HIV Prevention Research”, along with Drs. Lance Okeke and Kenric Ware, during the Community Symposium at the National CFAR CAB Coalition (NCCC) Meeting in Chapel Hill, NC.

November 9: On behalf of the Women’s HIV Research Collaborative, Brian Minalga presents “HIV Cure-Related Research for Women” at the Association of Nurses in AIDS Care annual conference in Portland, OR.

November 26: The latest edition of the Be the Generation newsletter will be available on the BTG website in English and Español. This newsletter features updates in biomedical HIV prevention research from the HPTN, HVTN, and MTN.

WWW.HANC.INFO/LEGACY
BE THE GENERATION
FOLLOW THE LEGACY PROJECT ON

Financial Disclosure
Greg Davis, HANC Project Manager

HANC would like to thank the Financial Disclosure Working Group for their work preparing for the HANC-facilitated annual solicitation. The annual solicitation was emailed to Network investigators that met reporting requirements on September 20.
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:

Tejaswi Sevekari
Tejaswi Sevekari has been a member of Community Partners since December 2015.

She is a post graduate student in medical and psychiatric social work and has worked in the field for the past 23 yrs. Tejaswi is a certified trainer conducting empowerment workshops of the Empowerment Institute - USA. Tejaswi is currently perusing her PhD from Tata Institute Social Sciences (Mumbai). Her focus is on HIV related issues in general and women in sex work in particular. She has initiated and coordinated the process of the formation of a sex workers collective, a community based organization - Saheli Sangh, of which she is presently the director.

Reverend Edwin Sanders
The Reverend Edwin C. Sanders, II, is a current member of the Legacy Project Working Group. He is the Senior Servant and Founder of the Metropolitan Interdenominational Church in Nashville, Tennessee. This congregation has attracted a broad cross-section of people with the mission of being “inclusive of all and alienating to none.” Metropolitan has outreach ministries in the areas of substance abuse, advocacy for children, sexual violence, and harm reduction, in addition to providing services to persons infected with, and affected by, HIV/AIDS through the First Response Center, which Rev. Sanders founded in 1992.

In addition to a rich history of serving on numerous HIV/AIDS advisory councils and presenting at World AIDS Conferences and other forums around the world, Rev. Sanders serves on the Boards of Directors of the Black AIDS Institute, The AIDS Institute, The National Minority AIDS Council, The Religious Coalition for Reproductive Choice and The Drug Policy Alliance. He is the National Coordinator for Religious Leaders for a More Just and Compassionate Drug Policy, and a former member of the National Advisory Council on Sexual Health at the National Center for Primary Care. Additionally, Rev. Sanders is one of the founding chairs of the HVTN Legacy Project Advisory Group, which evolved into the HANC Legacy Project Working Group we know today.
RESOURCES

Newletters

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 gp.davis@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, 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.

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.