HANC ANNOUNCEMENTS

NEW Long-Acting Antiretroviral Injectables Information Sheet

A Long-Acting Antiretroviral Injectables (LAARVI) Information Sheet was developed on behalf of The Legacy Project to provide general information about LAARVI. The info sheet can be found on the Community Resources page of the HANC website, or directly linked here.

NEW Clinical Pharmacology Study Conduct Tutorial - Now Available on the DAIDS LMS

The Clinical Pharmacology Quality Assurance Program has released a new online tutorial for clinical trials unit research staff who conduct protocols with clinical pharmacology objectives. The new tutorial is expanded, with new content, interactive activities for users, and quizzes. The tutorial consists of eight modules on pharmacology-related topics including terminology, outcomes, design, sampling, data and measures, that will improve the quality of pharmacology data from DAIDS HIV Research Network protocols. The tutorial is available through the DAIDS Learning Management System. There is no cost for registration.
This month, we are highlighting the exciting presentations ACTG made at the recent International AIDS Society (IAS) meeting in Mexico City, July 21-24, 2019:

**VRC 607/ACTG 5378** was featured as an oral presentation at IAS 2019 by Dr. Grace Chen and colleagues. A two-part study conducted by the Vaccine Research Center (VRC) and ACTG, VRC 607/ACTG 5378 investigated two CD4 binding site HIV-1 broadly neutralizing antibodies (bNAbs) in treatment naïve HIV-infected adults: VRC01LS (Part A) and VRC07-523LS (Part B). This is the first in-person trial conducted of these agents among people living with HIV, with previous studies restricted to pre-clinical evaluations or those in HIV-uninfected volunteers. The study evaluated the safety, tolerability, antiviral activity, and pharmacokinetic parameters of these bNAbs in 16 HIV-infected viremic adults between the ages of 18-70 years. Overall, both were safe and well-tolerated, with minimal side effects. Importantly, antiviral activity of ≥ 0.5 log was observed in 3/7 VRC01LS recipients and >1.2 log for 8/9 VRC07-523LS recipients in this small study, providing tantalizing hope for the efficacy of these novel agents as they advance into later stage trials.

The OPTIONS Study (**A5241**), which asked whether NRTIs are essential in salvage regimens, was presented as a poster at IAS 2019 by Dr. Rajesh Gandhi and colleagues. This study, which found that salvage regimens that did not include NRTIs gave similar rates of durable virologic suppression as those that included NRTIs, was also published in the *Journal of Infectious Diseases* in May. For more information on this important study, please read the summary that appeared in the *June HANC newsletter*.

Representatives from the HPTN and HIV Vaccine Trials Network (HVTN), together with colleagues from the US National Institutes of Health and the AIDS Clinical Trials Group (ACTG) will visit Cape Town, South Africa, 6-7 August for a stakeholder symposium and protocol development meeting for **HVTN 804/HPTN 095** (AMP Analytical Antiretroviral Treatment Interruption Study). Stakeholder symposium sessions will introduce and explore HIV remission research, explore bioethics, and community and clinical perspectives on HIV remission research and ART interruptions. The protocol development team will use information gained from the symposium for the development of HVTN 804/HPTN 095 to ensure cultural and scientific appropriateness.
HVTN provided three opportunities for IAS 2019 attendees to learn about our HIV vaccine and bnAB research in depth, while demonstrating the complex global consortium of partners working to conduct these clinical trials.

**AMP Oral Presentation** – “The game-changing nature of early and ongoing community engagement in HIV prevention efficacy trials”: The AMP studies’ experience (HVTN 703/HPTN 081 & HVTN 704/HPTN 085) was presented by HVTN’s Director of Social and Behavioral Sciences and Community engagement, Dr. Michele Andrasik. She highlighted the importance of relationship building and having sufficient resources to: conduct Community Consultations; establish Community Working Groups; facilitate ongoing communication with study specific Community Working Groups; utilize Community-Based Participatory Research (CBPR) approaches for materials development; develop geographically specific materials and websites; hold Retention workshops; and provide Cultural Responsiveness training. You can see the abstract and slides, as well as Kate MacQueen’s related presentation on Good Participatory Practice [here](#).

**MOSAICO Satellite Session** – Attendees participated in a pre-meeting satellite introducing Mosaico, which will evaluate an investigational vaccine based on mosaic immunogens – vaccine components comprised of elements from multiple HIV variants – that aim to induce immune responses against a wide variety of global HIV strains. Trial specific information was presented in the context that finding a safe and effective HIV vaccine is challenging. HIV is genetically diverse, more so than any other pathogen, has a complex outer structure or envelope, and the HIV subtypes in different regions vary. Anchoring the session was Dr. Jorge Sanchez (Peru) who underscored the importance of an HIV vaccine in Latin America. The outline and slides are available [here](#).

**HIV Vaccine R&D Stakeholder Meeting** – co-hosted by the IAS HIV Vaccine Enterprise, HVTN, and AVAC, an invited group participated in answering questions on the theme “HIV Vaccines: a vision for 2020 and beyond.” The objectives considered were: (1) To identify stakeholder perspectives on the current state of HIV vaccine R&D and the ongoing need for vaccine research in the larger context of HIV prevention; and (2) To identify next steps and priorities for incorporating the field’s perspectives into the research and prevention agenda by decision-makers. Sixty persons representing community stakeholders, advocates, researchers, funders and policy makers participated.
In July, MTN's Jared Baeten presented the results of the HOPE study (HIV Open-label Prevention Extension) at the 10th IAS Conference on HIV Science in Mexico City. HOPE was designed to provide former participants of the ASPIRE Phase III study of the monthly dapivirine vaginal ring the opportunity to use the ring for one year while researchers collected additional information about its safety and how women would use it knowing it reduced the risk of HIV in ASPIRE. HOPE results indicated the ring was very well-tolerated and used persistently by women for the entire year of the study. More than 90 percent of women chose the ring at the start of the study, and the majority stuck with it for the duration of HOPE. The ring, which women can insert and replace themselves, slowly releases the antiretroviral drug dapivirine into the vagina during the month it is used. The nonprofit International Partnership for Microbicides developed the dapivirine ring and is seeking its regulatory approval.

The IMPAACT Network presented findings from 6 abstracts from 7 studies, including PROMISE 1077BF, IMPAACT 2014, IMPAACT P1106, IMPAACT P1115, IMPAACT P1078, IMPAACT P1092 and IMPAACT P1093 as oral and poster presentations, as well as a satellite session on IMPAACT 2009, at the International Workshop on HIV Pediatrics and the 10th IAS Conference on HIV Science (IAS 2019) in Mexico City, Mexico.

View presentations at https://impaactnetwork.org/publications/ias2019.html
MEETING CALENDAR

Sept 5-8
2019 United States Conference on AIDS
(Washington, DC)

Sept 8-12
MTN Regional Meeting
(Cape Town, South Africa)

Oct 2-6
IDWeek
(Washington, DC)

Oct 21-22
Inter-CFAR Women and HIV Symposium
(Chicago, IL)

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

Dec 2-7
ICASA
(Kigali, Rwanda)

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

Jan 9-12
MTN Annual Meeting
(Arlington, VA)

Mar 8-11
CROI 2020
(Boston, MA)

May 27-29
HVTN Full Group Meeting
(Washington, DC)

For details and other events, visit the HANC calendar

WEBINARS & TRAINING

Upcoming Webinars

Community Perspectives on HIV Cure Research (Part 2)
August 6, 2019 @ 10 AM PST
In Part Two of the HIV Cure Research webinar series, we will discuss community perspectives of HIV cure-related research. Please join Bré Anne Rivera, Laurie Sylla, and the Legacy Project as we grapple with these questions and more. Register here.

U=U and HIV Clinical Trials Research Webinar
August 22, 2019 @ 10 AM PST
Undetectable = Untransmittable (U=U) means that people living with HIV who are on treatment with an undetectable viral load cannot transmit HIV to their sexual partners. Join us for this engaging and informative webinar featuring Dr. Carl Dieffenbach and Bruce Richman as they discuss messaging around U=U and HIV Clinical Research. Register here.

National Faith HIV/AIDS Awareness Day Webinar
August 27, 2019 @ 10 AM PST
In recognition of National Faith HIV/AIDS Awareness Day, August 27th, the Legacy Project invites you to join this open and interactive discussion focusing on the role of religious community/faith leaders in addressing HIV, including the Prevention from the Pulpit initiative, funded by Gilead, designed to create a large-scale awareness and mobilization approach aimed at increasing engagement with both national and local faith leaders to address the HIV-related needs of African Americans. Register here.

New Investigators Scholar Lessons Learned and Mentorship Opportunities
August 29, 2019 @ 11 AM PST
The Legacy Project invites you to participate in an informative webinar focusing on promoting early career investigators’ programs in HIV research. This webinar will focus on experiences, "lessons learned" and "how to make the most of mentorship opportunities". Register here.

HANC Webinar Archives
HANC Working Groups host webinars throughout the year and post recordings to the HANC website. Click here to view archives 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) met face-to-face in June 2019. The BSCG did not hold a call in July due to multiple schedule conflicts. The BSCG will resume its normal call schedule in August. The group will continue its discussions from the face-to-face meeting.

The Youth Prevention Research Working Group (YPRWG) hosted a satellite symposium at IAS 2019. The symposium, “Prevention Solutions for the Next Generation: Highlighting Adolescent Research in the NIH HIV/AIDS Clinical Trials Networks and the Adolescent Trials Network” was well attended. The slides from the symposium will be added to the YPRWG Resource Library in the near future.

Community Partners
Russell Campbell, HANC Deputy Director

The Bill of Rights and Responsibilities Working Group has developed a cross-network document that is currently undergoing review before seeking approval for distribution.

Community Partners (CP) and the Martin Delaney Collaboratory CAB are discussing ideas for collaboration.

CP is finalizing its agenda for its face-to-face meeting scheduled for October 26-27, 2019.

Cross-Network Coordination
Milan Vu, HANC Project Manager


The Data Management Center Working Group (DMCWG) met to share updates on the safety data reconciliation pilots, DAIDS Electronic Information Systems policy, and protocol deviation reporting pilot. In addition, the group discussed issues with Medidata related to reports and study migration.
HANC PROGRAM HIGHLIGHTS

Cross-Network Coordination
(continued) The Site Coordinators Working Group (SCWG) debriefed on several topics discussed at the network annual meetings, including the DAIDS Age and Identity Policy and source document harmonization. In addition, the group revisited monitoring-related concerns relating to recent changes to the Record Review Tool (RRT) Part B and announced work orders.

Laboratory Coordination

Tyler Brown, HANC Project Manager

The Lab Technologists Committee (LTC) held two conference calls to assign new protocols to committee members, discuss LDMS end-user validation, and plan a new sub-working group focused on revising the Lab Processing Chart Standard Wording Documents. The LTC SOP Sub-Working Group held three conference calls to finalize revisions to the Leukopak Collection and PBMC Isolation SOP and begin revising the Lab Processing Chart Standard Wording Documents.

The NIAID announced that the Virology Quality Assurance (VQA) contract has been awarded to Duke University, with Tom Denny as the principal investigator (PI). The VQA contract will transition from Rush University, the current VQA contract holder, to Duke on September 20, 2019. Leading up to the transition laboratories participating in the VQA program will be notified of any new procedures for proficiency testing and data reporting and timelines for transitioning to the new procedures.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to discuss the VQA contract transition and review new panel analysis reports from RNA036, DNA221-RT, DNA 221-BS, and GEN037 Integrase.

The Laboratory Focus Group (LFG) held a joint conference call with the DAIDS Clinical Laboratory Oversight Team (DCLOT) to discuss improving EQA-network communications, harmonizing lab site naming standards, and changes to DAIDS guidelines and SOPs, including Good Clinical Laboratory Practice (GCLP) Standards.

The Legacy Project

Brian Minalga and Kacie Sadorra
HANC Legacy Project Team

8/6: The Legacy Project and Behavioral Sciences Working Group host Laurie Sylla (DefeatHIV and MDC CABs) and Bré Anne Rivera (Trans Sistas of Color Project) for Part 2 of this webinar series on HIV cure-related research. This part of the series will focus on community perspectives of HIV cure-related research. Register here.

8/16: Updates from the HPTN, HVTN, and MTN are due to Brian Minalga for inclusion in BTG News, the Legacy Project’s quarterly newsletter on biomedical HIV prevention research, which will be released at the end of August. Check the Be the Generation website for the latest issue as well as past issues.
HANC PROGRAM HIGHLIGHTS

The Legacy Project
(continued)

8/22: The Legacy Project hosts Carl Dieffenbach and Bruce Richman for a webinar on the science and advocacy of Undetectable equals Untransmittable (U=U). Register here.

8/22: The Legacy Project in partnership with Dr. Lance Okeke and Dr. Kenric Ware will be presenting, “Engaging HBCUs in HIV Prevention Research” at the 2019 MSM HIV Prevention Institute on Columbia, South Carolina.


8/29: The Legacy Project will host a webinar on “New Investigators Scholar Lessons Learned and Mentorship Opportunities” featuring Allysha Maragh-Bass, Hyman Scott and Steve Shoptaw. Register here.

9/5: The Women’s HIV Research Collaborative presents, “The Future is Female: Women of Color Leadership in the HIV Movement” at the US Conference on AIDS in Washington, DC from 2 to 4 p.m.

9/6: The Legacy Project presents, “Indigenous Peoples, Historical Trauma, and Sexually Transmitted Bloodborne Infections/HIV” at the US Conference on AIDS in Washington, DC from 9 to 11 a.m.

9/8: The Women’s HIV Research Collaborative presents, “All About Us: Women and Biomedical HIV Prevention” at the US Conference on AIDS in Washington, DC from 9 to 11 a.m.

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

Financial Disclosure
Greg Davis, HANC Project Manager

The Annual Solicitation will take place on September 20, 2019 this year.
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:

**Emanuelli Msuya**

My name is Emanuelli Msuya. I am from Moshi Kilimanjaro Tanzania. I am an IMPAACT Community Advisory Board (ICAB) Representative, ICAB Leadership Group (ILG) Vice Chair and I just joined Community Partners.

The thing I like most about community engagement is when we are sharing information and learning from each other, by this means there is no one above another, but we are all here to learn. And last I get a chance to hear from different communities how they do things especially from their sites and local CABs.

I also enjoy doing art and music with youth as a means of breaking down barriers, breaking the silence and expressing their feelings through art and music.

**Jorge Benitez**

Meet Jorge Benitez, the Community Engagement Coordinator for the Columbia Research Unit (CRU) at Columbia University Medical Center and member of the Legacy Project.

Jorge has been employed in HIV-prevention research since 2002, working very closely with HIV-negative non-injecting drug users and their sex and drug use partners in Harlem and the South Bronx.

Jorge currently leads community education and recruitment efforts to enroll HIV-negative people at low and at substantial risk of getting HIV, particularly Latinx and Black populations that are most affected by HIV. He develops and administers structured interviews to collect data on of participants in Spanish and English as well as developing questionnaires to assess depression, social networks, and alcohol/drug use. Jorge strongly feels that Latinx people need more education around biomedical research to gain a better understanding of research so more Latinx people feel empowered to join HIV biomedical studies.
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.

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

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.

FOLLOW HANC ON

FIND MORE RESOURCES AT WWW.HANC.INFO