

April 2017



UPCOMING MEETINGS

Apr 9-13: HPTN Annual Meeting; Washington, DC

May 23-29: HVTN Annual Meeting; Washington, DC

May 30-Jun 4: 2017 IMPAACT Annual Meeting; Washington, DC

Jun 4-6: Adherence 2017; Miami, FL

Jun 25-29: ACTG Annual Meeting; Washington, DC

Jul 23-26: IAS 2017; Paris, France

Oct 25-26; SBSRN CFAR Meeting, San Francisco, CA

Mar 4-7; CROI 2018; Boston, MA

Jun 20-24: 2018 Annual ACTG Network Meeting; Washington, DC

For details on these and other events, go to the [HANC calendar](#).

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HANC & Network Announcements

HANC: On May 3, 2017, Community Partners will be hosting a webinar on Anticipatable Incidental Findings (IFs): Ethical & Practical Considerations in Diverse--Resource Settings Workshop, held September 21-22, 2016. Alberto (Betto) Ortiz, Linda Ehler and Allegra Cermak will be presenting.

The goal of this workshop was to discuss potential models, including the new concept of Actionability at the Participant's Research Site Level (APRSL), for moving the IFs field forward, considering the local setting when planning for and communicating IFs discovered during the conduct of research in resource-diverse settings. The objectives were that given the presentations in the workshop, participants will be able to evaluate different aspects related to the planning and communicating of anticipatable IFs from clinical research conducted in diverse--resource settings: (1) Related ethical concepts and their challenges; (2) Current practices and introduction of the new concept of APRSL; and (3) Practical approaches

[Click here to register for the webinar.](#)



ACTG recently released its latest [newsletter](#). In this edition of the newsletter, you'll find an update on [ACTG Network Clinical Trial](#)

[A5345](#) among other items.

In February, the Clinical Pharmacology Quality Assurance (CPQA) Program, led by Dr. Gene Morse, PharmD, CPQA Principal Investigator, and Distinguished Professor at the State University of New York at Buffalo School of Pharmacy and Pharmaceutical Sciences, and Sue Siminski, Director of Frontier Science's Amherst, NY office, and Principal Investigator of the Statistical and Data Management Center for the CPQA Program, launched the new and improved CPQA website, www.cpqaprogram.org. The new website includes links to CPQA publications and resources, news and information about the CPQA program. Simply stated, it is a modern, attractive and easy to use website that supports a very important mission.



The HPTN Annual Meeting will take place April 9-13, 2017 at the Washington Marriott Wardman Park in Washington, D.C. The meeting will include an engaging lineup of speakers and topics in several sessions and a main plenary featuring Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases (NIAID), and Ambassador-at-Large Deborah L. Birs, M.D., coordinator of the United States Government Activities to Combat HIV/AIDS

and U.S. special representative for Global Health Diplomacy. The Statistical and Data Management Center (SDMC), Laboratory Center (LC) and HPTN Scholars will also present their work, and study teams will highlight key study findings and lessons learned in an evening poster session and reception.



**HIV VACCINE
TRIALS NETWORK**

The HVTN is working with The Rochester Alliance and 15 other Centers for AIDS Research (CFARs) on the CFAR Faith & Spirituality Research Collaborative (CFSRC) Workshop. The goal for this group is to shape a research agenda around the topic and connect leaders in academia and public health with those in the faith/spiritual community, including meaningful involvement of people living with or affected by HIV/AIDS. Thus, members of the CFSRC will work collaboratively to generate evidence-based best practices to optimize the role of faith and spirituality in controlling the HIV pandemic and impacting clinical research.

Fifteen HVTN protocols are represented in the abstracts accepted for presentation at this year's Keystone Vaccine Symposium in Steamboat Springs, CO. Recent publications have included the topics "Current views on the potential for development of a HIV vaccine", "Predictors of durable immune responses six months after the last vaccination in preventive HIV vaccine trials", and "Higher T cell responses induced by DNA/rAd5 HIV-1 preventive vaccine are associated with lower HIV-1 infection risk in an efficacy trial". More details can be found [here](#).



Registration for the IMPAACT Annual Meeting, to be held from 29 May to 2 June 2017 in Washington, DC is now open; the draft agenda and additional information are available on the network's website at http://impactnetwork.org/network_information/annual_meeting.html.



MTN's Annual Meeting took place in March 20-21 at the Bethesda North Marriott Hotel & Conference Center. Plenary sessions addressed dapi-virine vaginal ring developments, mediators of product efficacy, HIV prevention in young women, and the need for data in pregnant and lactating women. Slides from these presentations can be accessed on [annual meeting page of MTN's website](#).



REMINDERS

- The “[Portal Trainings & FAC](#)” pages and documents have been updated for SharePoint 2010.
- Have you ever wondered how to reach a colleague at another network or DAIDS? Check out the [cross-network contact list](#), the [DAIDS staff list](#), or the [DAIDS Topic-specific contact list](#) on the left-hand navigation bar of the [portal homepage](#).
- **Did you know?** NIAID posts funding opportunities to its public website. For more details, [click here](#).
- Check out the [NIH Clinical Regulation website](#), created with the goal of helping researchers learn about international clinical regulations. Users can compare clinical regulations between countries in navigable side-by-side format, in topics such as Ethics Committees, Sponsorship, Clinical Trial Lifecycle, and more!
- Did you know you can access real time accrual information and protocol documents on the HANC portal? [Click here to go to the Quick Protocol Summary!](#)

HELPFUL TIPS

- Forgot your portal password? Reset it by going to [Log On Help](#).
- Find many HIV/AIDS [resources and links](#) [www.hanc.info](#).

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HANC Program Highlights

Behavioral Science: On April 5, Ira Wilson and Jane Simoni (co-Chairs of the Behavioral Science Consultative Group), will hold a call with Chris Gordon of NIMH to discuss the agenda for the BSCG F2F meeting that will take place on June 7th.

Communications: The Communications Working Group discussed plans for upcoming network meetings. Representatives from HANC will be attending each of these meetings.

Community Coordination: Community Partners is in the process of planning its annual face-to-face meeting which will be held in the Washington DC area and the date is TBD.

CP will be submitting an abstract the United States Conference on AIDS which takes place September 7-10, 2017 in Washington DC.

On March 29th Dr. Carl Dieffenbach presented to CP, Legacy and WHRC members to solicit community input into the 2020 Network Recompetition. Every 7 years NIH competitively renews its funding of the HIV clinical research networks operating in the United States and internationally. Given the pace of discovery in the HIV field, 7 years can see significant changes in research priorities. The current agreements supporting the existing network structure are set to end in 2020. NIH is taking a proactive approach to refining the research enterprise and driving HIV discovery. By establishing a forward-looking agenda to guide this process, NIH will determine the focus and priorities of its HIV clinical trial networks through 2027. More Additional webinars to follow. DAIDS wants to hear your research questions and areas of emphasis, as well as what areas you think are most impactful. Share feedback and other inquiry via NIAIDnet-workrefinement@mail.nih.gov. More information will be posted on <https://www.niaid.nih.gov/research/HIV-Research-Enterprise> throughout this process.

Data Management Center (DMC): The DMC Working Group discussed updates to the DAIDS AE Grading Table (v2.1). The group also discussed the migration of ongoing studies such as [IMPAACT P1093](#) to Medidata Rave.

Financial Disclosure: HANC has asked the team at Freelock (a Seattle-based Drupal and Web Development company) to add a password reset function on the log-in page of the HANC Financial Disclosure website. Users will now be able to reset their passwords without having to contact a network or HANC representative.

Laboratory: VQAAB reviewed 2 reports during their March Call and 4 reports during via e-mail: RNA032 (3 reports) Aptima RNA032, Integrase 032, and GEN032. Members were also, requested to review the HIV DNA/TNA Control SOP for HIV NAT. Labs were newly approved for RNA, DNA, and DNA-DBS Testing. IQA provided results for the 1st Quarter 2017 of the PBMC Cryopreservation Proficiency Testing. Eighty-eight labs received Approved Status. Labs, INBRIS and CIDRZ, were approved for their last pre-qualification samples and will be participating in the next round. New Sigma FBS Lot #16J365 was approved by the IQA. Price quote and availability to post on HANC, as soon as information is available. Information regarding Irradiated Gemini FBS available for purchase via BARC in South Africa will also be posted, as it becomes available. New DAIDS TB-QA Contractor, MRIGlobal, introduced themselves to the TB Lab Diagnostics WG. They have been meeting with the networks, cross-network lab working groups, and EQA providers, SMILE and NHL, regarding current programs. All CAP evaluations have

been submitted and most are 100% successful (SMILE EQA). GeneXpert MTB/RIF panels for 2017 have been shipped and 1st round submissions are due at the end of April.

Leadership: The NIAID Strategic Working Group (SWG) will meet on June 6, 2017 for a one day meeting.

At the request of the Network Leadership Group, HANC has asked DAIDS if the NIH is considering the establishment of a central IRB for multi-center trials at domestic sites for new awards effective September 25, 2017 per the [NIH announcement](#) of June 21, 2016. (Note this requirement will not apply to the Networks until the new awards after the next recompetition.) At this time it does not appear that this is under consideration, although the [National Cancer Institute](#) did so after adopting a similar requirement a few years ago.

Legacy Project: April 5, 7 to 9 pm: The Legacy Project along with three local partners in Seattle will host an event in commemoration of Women and Girls HIV/AIDS Awareness Day, which was observed nationally on March 10th. The event will be facilitated by Dr. Michele Andrasik of the HVTN and will include seven local speakers from the community. Dr. Andrasik will provide scientific updates for a community audience on the latest research on HIV treatment and prevention that is particularly relevant to cisgender and transgender women in the US. The event will take place at the Central Library in Seattle.

April 7: Abstracts due to the United States Conference on AIDS. Members of the Legacy Project and Women’s HIV Research Collaborative are submitting several abstracts representing a wide variety of tracks in the National Minority AIDS Council’s call for submissions. Presenters will be notified of acceptance status in June.

April 9-12: Both Legacy Community Engagement Officers--Louis Shackelford and Brian Minalga—will be in attendance at the HPTN annual meeting.

April 10: [Applications](#) due for the part-time Framework for Dialogue National Coordinator position. The Legacy Project is assisting with the implementation of the Framework for Dialogue, a tool to bring together religious leaders and people living with HIV to combat HIV-related stigma. Candidates need not be affiliated with any religious organization to apply. The application closes April 10th. Contact Brian Minalga with any questions.

Members of the Women’s HIV Research Collaborative (WHRC) have conducted interviews with representatives from DAIDS, ACTG, HPTN, HVTN, and two CRSs to begin assessing the acceptability and feasibility of screening for interpersonal violence in the HIV clinical research setting. The WHRC will begin interpreting data from these interviews with the ultimate goal of writing a position statement on this issue.

Research Site Management & Clinical Trials Logistics: The Site Coordinators Working Group discussed implications of the Protocol Funding Pilot webinar recently presented by DAIDS leadership on CRS and CTU budgeting procedures. A recording of that webinar is available [here](#).

Youth Prevention Research Working Group: The Youth Prevention Research Working Group will be presenting a satellite symposium at IAS in July titled “Prevention Solutions for the Next Generation: Highlighting Adolescent Research in the NIH HIV/AIDS Clinical Trials Networks and the Adolescent Trials Network.” This symposium will highlight NIH-sponsored multi-center international adolescent prevention research including [HPTN 082](#), [MTN-034](#), [IMPAACT 2009](#), and the [ATN iTech](#) studies.