



The AIDS Clinical Trials Group (ACTG) Network is the largest HIV/AIDS clinical trials organization in the world. We currently have 34 domestic & 25 international sites.



## Revamped Clinical Pharmacology Quality Assurance Website Goes Live

A screenshot of the Clinical Pharmacology Quality Assurance (CPQA) website homepage. The page features a dark green sidebar on the left with a menu of navigation items. The main content area has a white background with a large image of a laboratory setting. Overlaid on the image is a white box containing the title "Clinical Pharmacology and Quality Assurance" and a sub-headline. Below the sub-headline is a "Learn More" button. At the bottom of the page, there are two columns of text: one for "Clinical Pharmacology Quality Assurance" and another for "News & Events".

**CPQA**

- About CPQA
- Program Organization
- News & Events
- Resources
- Proficiency Testing
- Assessments
- Method Review
- For Laboratories
- Learning
- Contact
- Portal Login

### Clinical Pharmacology and Quality Assurance

Developing and conducting quality assurance activities that support global HIV/AIDS translational research and clinical trials within DAIDS networks

[Learn More](#)

CPQA is a project of the University at Buffalo.

#### Clinical Pharmacology Quality Assurance

The Clinical Pharmacology Quality Assurance (CPQA) program is a global cross-network program that develops and conducts quality assurance activities in support of HIV translational research and clinical trial networks. CPQA works with laboratories participating in HIV clinical trials to improve the quality of pharmacology data, increase awareness of the importance of pharmacology at clinical sites, and provide a mechanism for ensuring the quality of pharmacology data in HIV clinical trials.

#### News & Events

Round 38 Proficiency Testing Report Now Available  
Dec 13, 2016: The Proficiency Testing (PT) Report for Round 38 is now posted on the CPQA website on the Frontier Science Portal... [read more](#)

### Introducing the New and Improved CPQA Website!

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](http://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.

We recently interviewed Sue Siminski to learn more about the CPQA website as well as the CPQA program. [Read more>>](#)

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## ACTG Network Clinical Trial Update: A5345

### **Protocol A5345: Biomarkers to Predict Time to Plasma HIV RNA Rebound**

The identification and validation of biomarkers is integral to any large-scale drug-development effort. In fact, biomarkers were crucial for the accelerated development of anti-HIV therapies. Prior to 1997, clinical trials studying antiretroviral drugs had to show significant power to detect differences in clinical endpoints, such as the development of AIDS or death. The adoption by the FDA of plasma HIV RNA suppression as a biomarker endpoint allowed for smaller and shorter clinical trials, improved participant acceptance, and accelerated HIV drug development. As the HIV field increasingly turns towards developing therapies to achieve sustained ART-free HIV remission, biomarkers that can reliably predict meaningful outcomes are once again urgently needed. There is widespread agreement that the lack of a validated biomarker for cure research is impeding progress and preventing industry from becoming engaged. With this information in mind, Protocol A5345: Biomarkers to Predict Time to Plasma HIV RNA Rebound was developed and is led by Protocol Co-Chairs Jonathan Li, MD, MMS, of our Brigham and Women's Hospital Clinical Research Site, and David Smith, MD, MAS, of our University of California, San Diego Clinical Research Site. [Read more>>](#)

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## Guest Blog: National Women and Girls HIV/AIDS Awareness Day



### **Thoughts on Women, Girls, HIV...and Funding for National Women and Girls HIV/AIDS Awareness Day**

*By Morénike Giwa Onaiwu, ACTG Network Global Community Advisory Board Co-Chair*

March 10, 2017 was the 12th annual commemoration of National Women and Girls HIV/AIDS Awareness Day (NWGHAAD). Launched in 2006, NWGHAAD exists to raise awareness of how women and girls are impacted by HIV. Initially overshadowed by the large numbers of men diagnosed with HIV, the unique needs and circumstances facing US women and girls were often overlooked and unmet. That was until it became apparent a few decades into the epidemic that they were quickly becoming one of the fastest growing groups with and/or at risk for contracting HIV.

The likelihood of acquiring HIV in certain groups of women, including women of color (African American in particular), transgender women, and younger women was, and remains disproportionately higher than others. Additionally, women and girls often have less optimal outcomes than their male counterparts: women are less likely to be virally suppressed, more likely to progress quickly toward an AIDS diagnosis, more likely to have co-occurring conditions which affect virologic health, and are more likely to be at risk for mortality. With regard to HIV risk, women and girls are also less likely to have economic security, less likely to be able to negotiate safer sex practices, and more likely to have endured trauma and/or intimate partner violence. [Read more>>](#)

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## Seeking Nominations for 2017 ACTG Network Research Awards

Each year at the Annual Network Meeting select researchers are given awards for their contribution to a specific field of ACTG Network research. These include:

### **The John Carey Young Investigator Award**

This award was established to honor the memory of John Carey by recognizing junior investigators who best exemplify the ideals of the ACTG Network and the qualities exemplified by Dr. Carey. Awardees will have:

- made significant contributions to the advancement of knowledge about HIV and its complications in the clinic or the laboratory in ACTG-sponsored research;
- through participation on ACTG committees or protocol teams, demonstrated a cooperative spirit with colleagues and commitment to service; and
- shown intellectual promise and commitment to advance to a leadership position within the ACTG.

### **The Donna Davis Award**

This award was created in January of 2004 in memoriam to Donna Davis. Donna was active in establishing her local Adult ACTU Community Advisory Board (CAB) at the Nebraska Health System and active in the community as a public speaker on HIV/AIDS since 1999. Donna Davis was elected the CAB co-chair of the Adult ACTG CAB Subcommittee in July of 2002. Donna died from an AIDS-related illness on June 14, 2003 in Omaha, Nebraska.

The CAB co-chair is an individual who has demonstrated leadership qualities. This person also recognizes the importance of community participation and education in the process of HIV/AIDS research. The CAB Co-chair is committed to the ACTG scientific research agenda. Donna exemplified all of these attributes.

The person nominated should be a current ACTG staff member (Site staff, Network Coordinating Center, SDAC) who has made a significant contribution to one or more of the following:

- in local or national community participation within the ACTG
- in community education within the ACTG

- in mentorship to the community

### **The Constance B. Wofsy Women's Health Investigator Award**

This award was established to honor the memory of Connie Wofsy by recognizing investigators who have made significant contributions to research in HIV-infected women and who embody qualities exemplified by Dr. Wofsy. Awardees will have demonstrated ability to mentor junior investigators, on-going clinical involvement caring for HIV-positive women in addition to addressing priority areas of the HIV-infected Girls and Women Research Agenda.

If you have a colleague in mind that you would like to nominate for an award, watch for an email coming soon with links to nomination forms.

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## This Year in HIV/AIDS History: 1993

**January:** The year begins with the National Association of People With AIDS convening for the first annual "AIDS Watch." Hundreds of community members from across the U.S. come to Washington to lobby Congress for increased funding.

**May:** The U.S. Food and Drug Administration approves the female condom.

**June:** U.S. Congress enacts the NIH Revitalization Act, giving the Office of AIDS Research primary oversight of all NIH AIDS research. The Act requires NIH and other research agencies to expand involvement of women and minorities in all research.

**August:** The Women's Inter-agency HIV Study and HIV Epidemiology Study begin. Both are major U.S. federally funded research studies on women and HIV/AIDS.

**December:** The U.S. Centers for Disease Control and Prevention expand the case definition of AIDS, declaring those with CD4 counts below 200 to have AIDS.

Source: AIDS.gov



Thank you for taking the time to read the ACTG Network's Monthly Newsletter. If you would like to be a guest blogger, have your clinical research site highlighted or would like to nominate a colleague for the Spotlight, please [click here](#). We welcome your feedback.

Sincerely,

***Patrick Bayhille***

***Senior Research Communications Specialist***

***AIDS Clinical Trials Group Network***

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