



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.



Understanding the Clinical Trial Enrollment Process: A Three Part Series

Part Two: Understanding the Study Entry and Randomization Process

In last month's newsletter, Part One: Understanding the Clinical Trial Enrollment Process covered the informed consent and screening process and highlighted the importance of the relationship between researchers and study participants. In addition, it addressed the need to fully educate potential study participants to ensure they can reach a truly informed decision about whether or not to enroll in a clinical trial. Part Two of this three part series provides an overview of the study entry and randomization process and how it relates to successful and long-term participation in ACTG Network trials.

Once all inclusion criteria have been met and a study participant has elected to enroll in a trial, the first step is a fairly lengthy clinical visit for study entry and randomization. During this visit, participants are again provided an overview of the study drug and reminded that they may be taking a placebo for the length of the trial. They are advised of any potential side effects of the study drug they may experience and are provided with an overview of all future clinical visits. Cheryl Keenan is a Research Nurse at our Brigham and Women's Hospital Clinical Research Site in Boston, MA and notes the study entry process allows for yet another opportunity to connect with study participants and make them feel as comfortable as possible. [Read more>>](#)

To read Part One: Understanding the Informed Consent and Screening Process, [click here](#).

ACTG Network Clinical Trial Update: A5336

Protocol A5336: A Randomized, Pilot Study of Ruxolitinib in Antiretroviral-Treated HIV-Infected Adults

Chronic systemic inflammation and immune activation are known key contributors to end-stage organ, age-related diseases in individuals living with HIV. Not only can this lead to decreased survival rates, it can also greatly affect the quality of life for those who are virologically suppressed while on antiretroviral treatment (ART) for long periods of time. As ACTG Network researchers continue to investigate ways to reduce inflammation caused by HIV, it is becoming more and more common to test drugs used to treat other inflammatory conditions. If a currently approved FDA drug can be shown to be effective in inhibiting inflammation in HIV suppressed patients on ART, these strategies could be implemented in order to mitigate or delay the emergence of serious age-related conditions. One such drug that has this potential is ruxolitinib, a tyrosine kinase inhibitor that has been used to treat intermediate and high-risk myelofibrosis, a disorder disrupting the normal production of blood cells in bone marrow resulting in extreme inflammation. Since ruxolitinib was proven to reduce this inflammation, this led investigators to consider that it may also have a similar effect in those living with HIV.

[Read more>>](#)

REPRIEVE Releases "Follow YOUR Heart" Video



New Video Designed to Educate HIV Positive Women about Relationship Between HIV and Heart Disease and Clinical Trial Research Participation

The "Follow YOUR Heart" video was released in early April and will be issued at the national, community, and site level over the next few months. Spearheaded by Dr. Sara Looby and Dr. Markella Zanni of Massachusetts General Hospital, the video features women living with HIV and discusses the importance of inclusion of women in REPRIEVE (Randomized Trial to Prevent Vascular Events in HIV). In addition to the video, the campaign includes marketing materials geared specifically towards women living with HIV and even has its very own "Follow YOUR Heart" song!

The investigators were funded by the National Institute of Allergy and Infectious Disease to support the "Follow YOUR Heart" campaign as well as the evaluation of sex-specific mechanisms of cardiovascular disease risk and risk reduction in the context of REPRIEVE.

To review all of the "Follow YOUR Heart" campaign materials, [click here](#).

Annual HIV/AIDS Walks Dates Announced

Local Awareness Walks Provide Unique Opportunity for Clinical Research Sites to Connect with HIV Community

Each spring and summer, cities across the country host a variety of annual HIV/AIDS awareness walks to help raise funds for research and to walk in solidarity with those infected or affected by the disease. In the past, several ACTG Network Clinical Research Sites have participated in local awareness walks and have found this to be a great way for staff and clinicians to connect with the greater HIV community.

Upcoming walks in cities near ACTG Network Clinical Research Sites include:

May 1, Newark, NJ - New Jersey AIDS Walk

May 1, Baltimore, MD - AIDS Walk & Run Baltimore

May 14, Los Angeles, CA - AIDS Walk Orange County

May 15, New York, NY - AIDS Walk New York

June 5, Boston, MA - AIDS Walk Boston and 5K Run

June 25, San Francisco, CA - Annual East Bay AIDS Walk

July 17, San Francisco, CA - AIDS Walk San Francisco

If your site participates in an HIV/AIDS awareness walk be sure to take pictures to submit for the newsletter.

CAB Member Profiled in HIV Plus Magazine

Angel L. Hernandez Selected as One of the Most Amazing HIV Positive People of 2016

Angel L. Hernandez is a Community Advisory Board (CAB) Member at our Clinical Research Site in San Juan, Puerto Rico. He is the co-chair the ACTG Network Community Scientific Subcommittee and also serves on a variety of protocols as a community representative.

Angel was recently profiled in HIV Plus magazine's Most Amazing HIV Positive People of 2016. The article notes Angel's passion for "reaching out to communities of color and translating the complexities of the HIV/AIDS spectrum into lay terms with cultural proficiency" as well as the advocacy work he has conducted over the past eight years. To read this article, [click here](#).



Mr. Hernandez

This Year in HIV/AIDS History: 1990

January: U.S. Public Health Service issues a statement on managing occupational exposure to HIV, including considerations regarding post-exposure use of AZT.

May: ACT UP protests at the NIH, demanding more HIV treatments and the expansion of clinical trials to include more women and people of color.

June: 6th International AIDS Conference meets in San Francisco CA. Domestic and international non-governmental groups boycott the conference to protest U.S. immigration policy barring people with HIV from entering the country.

August: U.S. Congress enacts the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, which provides \$220.5 million in Federal funds for HIV community-based care and treatment services in its first year.

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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AIDS Clinical Trial Group (ACTG) Network,
900 Commonwealth Avenue, Boston, MA 02115