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July 2019



Issue  
**ONE**

The latest chatter from the CVVR CTU!

# THE CAB GAB



Boston Pride Parade >>>

## CVVR CTU Team at Boston Pride

The Boston Pride Parade kicked off at noon on June 8<sup>th</sup>, 2019. Members of the CVVR CTU marched their way through the streets of Boston in support of equality. "It was so great to see so many people of all ages and backgrounds coming together to celebrate the LGBTQ community!" said Kate Jaegle, an RN in the CTU. The group had a blast dancing in the streets and connecting with the community on the beautiful sunny day!



## HIV Vaccine Facts

### The truth about vaccine trials

#### What is an HIV Vaccine?

There are two kinds of HIV vaccines that scientists are researching. A *preventative* vaccine would help reduce the risk of HIV transmission in people who are HIV-negative. A *therapeutic* vaccine would potentially help people to control their HIV virus without antiretroviral drugs (ART), or be used as a supplement to ART.

#### How does HIV vaccine research happen?

Research first starts in a lab, where vaccines are tested on animals such as mice and monkeys. Once the vaccine is shown to be safe in animals, it can move forward to testing in humans. Initial studies, also known as "phase 1," focus on vaccine safety and tolerability. If a vaccine is deemed safe in humans, it may go on to efficacy testing. In efficacy testing, researchers look to see how effective a vaccine is with improving the body's immune response to HIV. Efficacy testing is done in larger groups of participants.

#### What are the discoveries with HIV vaccine research so far?

Perhaps the most well known of HIV vaccine trials is the RV144 study. RV144 was conducted in Thailand in 2009 and showed that participants who got the vaccine were 31% less likely to get HIV

*"A preventative vaccine would help reduce the risk of HIV transmission in people who are HIV negative."*

during the trial compared to those who received placebo. The Uhambo trial (HVTN 702) is currently ongoing and testing updated versions of the R144 vaccine. The Imbokodo study (HVTN

705) started in December 2018 and is testing a preventative vaccine regimen across sub-Saharan Africa. The study plans to enroll 2600 women. Interestingly, the vaccine regimen being tested in the Imbokodo study is one that was tested right here at the CVVR CTU. Our dedicated study participants in Boston are partially to thank for the success and progression of this study!

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# Updates from CROI 2019

The 2019 Conference on Retroviruses and Opportunistic Infections (CROI) kicked off on March 4<sup>th</sup>, 2019 in Seattle, Washington. Katy Stephenson, Director of the CTU presented preliminary results from the PGT121 Monoclonal Antibody trial (T001). The T001 study was a randomized, double blinded, placebo-controlled trial of a dose escalation of PGT121 in both HIV positive individuals on ART and HIV negative individuals. A second part of the study looked at giving PGT121 in HIV-infected individuals not on ART with high viral loads. All participants in the study were monitored for side effects. Blood work was obtained to assess the immune system's response to PGT121.



## Results

PGT121 was safe and well tolerated with no related moderate or severe side effects. The average half-life of PGT121 was 22 days in both the HIV negative and HIV positive individuals. In HIV positive participants not on ART, PGT121 was effective in lowering the HIV viral load. In the high viral load group (those with baseline viral loads between 3.3-4.8 logs) the median drop in viral load was 1.7 logs. The viral load in these participants remained low for 28 days, until viral rebound occurred. In the low viral load group (those with baseline viral loads between 2.0-2.6 logs), PGT121 was able to decrease the viral load to undetectable. Of the three participants in this group, one showed viral rebound at 6 months.



The remaining two participants had viral loads that remained undetectable at the end of the study. Additional follow up was approved by the IRB and is currently ongoing to follow the suppressed participants and determine the ultimate duration of virologic remission. For more information on Katy's talk, please click [here](#).



## On Location!

### CVVR CTU attends the 34<sup>th</sup> Annual AIDS Walk & Run Boston

On June 2<sup>nd</sup>, 2019, the CTU team participated in the 34<sup>th</sup> annual AIDS Walk & Run Boston. The BIDMC team was co-chaired by hospital president Pete Healey and CTU's fearless leader, Dr. Kathryn Stephenson. Team BIDMC raised \$7,781 in donations.

## Clinicaltrials.gov

Clinicaltrials.gov is a registry of clinical trials. It provides patients, family members, and healthcare professionals with access to information about clinical trials being conducted within the United States and other countries. Study investigators or sponsors are responsible for registering and updating study information on the website. Information about CTU studies as well as other studies nearby are posted on Clinicaltrials.gov. Check it out!

### What information can I find on Clinicaltrials.gov?

- The disease or condition being studied
- The intervention used
- A description of the study
- The requirements for study participation
- Contact information for the study
- Links to other relevant information (i.e. patient health information)
- Outcomes and results of some studies

NIH U.S. National Library of Medicine

**ClinicalTrials.gov**

Visit <https://clinicaltrials.gov/> to start exploring studies today!

# CTU Studies: What's the latest?

Since opening in 2015, the CVVR CTU has conducted 8 clinical trials. In each CAB Gab issue, we provide you with the latest updates on our progress. Read below to see what's new!



## IPCAVD010: A Phase 1 study of a two HIV vaccine candidates in HIV-uninfected Adults

IPCAVD010 opened in March 2016. The study looked at different vaccine schedules using two vaccines, Ad26.Mos.HIV and Clade C gp140. The study has since completed. Final data analysis is underway.

## Z001: A Phase 1 study of a Zika Virus Vaccine Candidate

Z001 opened in October 2016. The study looked at different vaccine schedules using Zika Purified Inactivated Vaccine (ZPIV) in healthy adults. The study has since completed and is officially closed out. Preliminary results were published in *Lancet* in December 2017. A link to the article can be found [here](#).

## IPCAVD012: A Phase 1/2a study of three HIV vaccine candidates in HIV-uninfected adults

IPCAVD012 opened in March 2017. The study looked at two different vaccine regimens using Ad26.Mos4.HIV, Clade C gp140, and Mosaic gp140. The study is currently in the long term extension phase.

## T001: A Phase 1 study of PGT121 Monoclonal Antibody (mAb)

T001 opened in December 2016. The study looked at different dosages of PGT121 mAb given

both intravenously and subcutaneously to HIV-uninfected and HIV-infected adults. Study enrollment is complete at BIDMC and data analysis is underway.

## T002: A Phase 1 study of PGDM1400 and PGT121 Monoclonal Antibodies (mAbs)

T002 opened in October 2017. The study looked at different dosages of PGDM1400 mAb alone and in combination with PGT121 to both HIV-uninfected and HIV-infected adults. In Spring 2019, the study added an additional mAb, called VRC07-523LS to be studied in HIV-infected adults. The study is complete at BIDMC but ongoing at outside sites.

## HTX1002: A Phase 1 study of two different vaccine regimens in HIV-infected adults

HTX1002 opened in March 2018. The study looks at different vaccine schedules of Ad26.Mos4.HIV, MVA-Mosaic, Clade C gp140 and Mosaic gp140. **The study is actively enrolling at BIDMC.**

## Z002: A Phase 1 study of a Zika Vaccine Candidate

Z002 opened in February 2018. A single dose of Ad26.ZIKV.001 was given to healthy adults. The study is fully enrolled at BIDMC. Follow up visits are still ongoing.

## T003: A Phase 1/2a study of PGT121, VRC07-523LS, and PGDM1400 Monoclonal Antibodies (mAbs)

T003 opened in December 2018. The study looks at different dosages and combinations of the mAbs given intravenously in HIV-uninfected and HIV-infected adults. **The study is actively enrolling at BIDMC.**



## DID YOU KNOW....

The CDC estimated that as of 2015, **1.1 million** adults were living with HIV. Of those, 15% had not received a diagnosis.

Among young adults ages 13-24 living with HIV, **51%** did not know they were infected at the time of diagnosis.

Nearly **40%** of new HIV infections are transmitted by people who do not know they have the virus.

The CDC recommends that everyone between the ages of 13-64 get tested for HIV at least once as part of routine health care. For those with specific risk factors (i.e. MSM, multiple sex partners, IV drug users), the CDC recommends getting tested at least once a year.

For more information visit <https://www.cdc.gov/hiv/testing/index.html>

## A Star is Born! >>>

### CTU's Katy Stephenson is honored by the Boston Red Sox!

On June 7<sup>th</sup>, Katy Stephenson was honored by the Boston Red Sox as a Medical All Star. Katy, along with her two boys Theo and Henry, joined Wally and the Red Sox on the field before the start of the game. The CTU team couldn't be more proud!



## Flyer Survey!!

The CVVR CTU has been drafting new flyers. Our goal is to target HIV-uninfected and HIV-infected individuals who are motivated to be in a clinical trial. **The CAB's input is essential** in helping our team decide on the most effective recruitment materials.

Keep an eye out in your email inbox for an upcoming flyer survey from us!

# HIV Vaccine Facts Continued

## Can HIV vaccines give people HIV?

Absolutely not! A person cannot get HIV from a study vaccine because a study vaccine does not contain real HIV. Scientists make HIV vaccines so that they look like the real virus to your body, but they do not contain any HIV.

## Do you need to be HIV positive to take part in an HIV vaccine trial?

HIV vaccine trials need both HIV-negative and HIV-positive individuals. Many studies look at the safety and side effects associated with getting the vaccine. HIV negative individuals are an integral part of studying the safety profile of potential preventative HIV vaccines.

## Do we really need an HIV vaccine now that HIV is easily treated and controlled?

While treatment for HIV has dramatically improved over the last 30 years, there is no substitute for prevention. ART medications can be expensive and also cause uncomfortable side effects. In

many countries, ART is not easily accessible. Additionally, many people who have HIV are not aware of their diagnosis. These individuals can continue to spread HIV, increasing the rate of new infections. An HIV vaccine could potentially prevent any new diagnoses and help those who are HIV positive to stay undetectable.



***Thank you for your commitment to our research!***

**We look forward to seeing you at our next meeting! Have a wonderful summer!**

**-The CTU Team**



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## Coming Soon!

**Our social media accounts have been approved by BIDMC and will be activated soon. Keep a look out and follow us!**



**BIDMC CVVR  
Clinical Trials**



**@BIDMC\_CVVRTrials**



**Next CAB Meeting >>>**

**Wednesday September 18<sup>th</sup>, 2019  
6pm-8pm**