



Dear Colleagues -

On World AIDS Day 2018, we wish to recognize the many contributions that IMPAACT has made in the last year toward the goal of ending the AIDS epidemic (see highlights below). We are enormously grateful for the tireless efforts of all IMPAACT members and collaborators – site staff, investigators, community partners, and others – as well as for the strong support of NIAID, NICHD and NIMH, without which the Network’s activities and achievements would not be possible. While much has been accomplished, much remains to be done. As we look to the coming year, we are encouraged by the accomplishments made to date and excited about our continued collective efforts to answer the highest priority scientific questions relevant to pregnant women, infants, children, and adolescents affected by HIV/AIDS worldwide.

Sincerely,

Sharon Nachman, IMPAACT Chair

James McIntyre, IMPAACT Vice-Chair

## Community Advisory Board World AIDS Day Activities

The Community Advisory Board has joined the staff of the Siriraj site (CRS 5115) in Bangkok, Thailand, by organizing activities at Ban Somdet Chaopraya Rajabhat University. Activities will include stations to discuss any student questions, screening for HIV and other health concerns, providing knowledge about condom use and lubricant, and promoting HIV prevention strategies among young men who have sex with men.

At the Kenya Medical Research Institute - Walter Reed Project Clinical Research Center site (CRS 5121) in Kericho, Kenya, the national focus this WAD is in male engagement. The CAB and site staff are working with motorcyclists who are engaged in transport sector. Activities will include sensitization on knowing their HIV status and work towards advocacy and health promotion. There will also be a procession through town to reach out to the community.

## 2018 News

IMPAACT P1026s, a Phase IV, prospective pharmacokinetic study of selected ARV, TB, and contraceptive medications currently used in clinical care of HIV-infected pregnant and postpartum women, informed the US Food and Drug Administration (FDA) approval of labeling changes for Stribild® and Genvoya®. [Read more here.](#)

IMPAACT has partnered with the World Health Organization (WHO) and other organizations to develop a toolkit for the research and development of pediatric antiretroviral drugs and formulations. WHO's launch of the toolkit coincided with the AIDS 2018 Conference in Amsterdam. It can be accessed [here](#).

## New Protocols Finalized

Three protocols in two key research areas were finalized and distributed to sites, including IMPAACT 2019, IMPAACT 2017, and IMPAACT 2016. A full summary snapshot of IMPAACT studies can be found [here](#).

## Newly Enrolling Studies

IMPAACT was pleased to begin enrolling participants into three new studies in two key research areas.

### *Cure*

[IMPAACT 2008](#) began enrolling to assess the safety of monoclonal antibody VRC01 combined with antiretroviral therapy in HIV-1-infected infants.

### *Treatment*

[IMPAACT 2010/VESTED](#) began enrolling in January to compare the safety and virologic efficacy of the dolutegravir- and efavirenz-containing regimens during pregnancy and postpartum in mothers and infants. [IMPAACT 2014](#) began enrolling in July to evaluate the safety and pharmacokinetics of doravirine in children and adolescents.

## Newly Approved Proposals

The Network also approved four new proposals for protocol development across two key research areas.

### *Complications and Co-Morbidities*

[IMPAACT 2021](#) was approved to evaluate the safety and immunogenicity of recombinant live-attenuated respiratory syncytial virus vaccines compared to placebo.

### ***Treatment***

Three studies were approved: [IMPAACT 2022](#), a study to evaluate the effectiveness, feasibility, and pharmacokinetics of long-acting injectable cabotegravir and rilpivirine in non-adherent HIV-1 infected youth; [IMPAACT 2023](#), a study to evaluate the safety, tolerability, and pharmacokinetics of dolutegravir to infants to determine the appropriate dose for prophylaxis and treatment of neonates and infants; and [IMPAACT 2026](#), study of selected antiretroviral (ARV), anti-tuberculosis (TB), hormonal contraceptive, and related drugs during pregnancy and postpartum.

### **Publications and Presentations**

The Network has continued to successfully [publish](#) and [present](#) results from our studies. The Network presented eight abstracts at [AIDS 2018](#) and 14 abstracts at [CROI 2018](#).