



## Reflections on the Past Year

Dear Colleagues -

On World AIDS Day 2017, 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

### **IMPAACT Studies Impacting Guidelines**

Recently, two IMPAACT studies helped inform United States (US) and European guidelines for pediatric antiretroviral dosing.

IMPAACT P1110, a Phase I, dose-finding study of raltegravir in HIV-1 exposed full-term neonates, informed the US Food and Drug Administration (FDA) approval of labeling changes for raltegravir (Isentress®) to include neonates who weigh at least two kilograms in the US. [Read More Here](#)

IMPAACT P1093, a Phase I/II study of the safety and pharmacokinetics (PK) of dolutegravir in HIV-1 infected children, informed the Committee for Medicinal Products for Human Use (CHMP) positive opinion to lower the age and weight limit for dolutegravir (Tivicay®) in children and adolescents living with HIV in Europe. [Read More Here](#)

## New Protocols Finalized

Six protocols across four key research areas were finalized and distributed to sites, including IMPAACT 2015, IMPAACT 2014, IMPAACT 2010, IMPAACT 2009, IMPAACT 2008, and IMPAACT 2005. A full summary snapshot of IMPAACT studies can be found [here](#).

## Newly Enrolling Studies

IMPAACT was pleased to begin enrolling participants into six new studies, across three key research areas.

### *Complications and Co-Morbidities*

[IMPAACT 2013](#) and [IMPAACT 2018](#) began enrolling to evaluate the infectivity, safety, and immunogenicity of vaccines for respiratory syncytial virus (RSV) among infants in the US. [IMPAACT 2002](#) began enrolling in March to examine if a cognitive behavioral therapy and medication management for depression improves outcomes for HIV-infected youth in the US.

### *Tuberculosis*

[IMPAACT P1108](#) began enrolling in September to evaluate dosing of bedaquiline among children with multidrug-resistant (MDR) TB. [IMPAACT 2001](#) began enrolling in March to evaluate safety and PK of rifapentine and isoniazid among pregnant women.

### *Treatment*

[IMPAACT 2007](#) began enrolling in June to evaluate safety and PK of maraviroc among HIV-1 exposed neonates.

## Newly Approved Proposals

The network also approved five new proposals for protocol development, across three key research areas.

### *Complications and Co-Morbidities*

Two studies were approved: [IMPAACT 2018](#), as described above, and [IMPAACT 2016](#), a study to examine if a cognitive behavioral therapy intervention demonstrates improved mental health outcomes and ART adherence for HIV-infected youth.

### *Tuberculosis*

[IMPAACT 2020](#) was approved to compare the efficacy, safety, and tolerability of a shortened, all-oral regimen to the World Health Organization (WHO) recommended regimen for MDR-TB infected

participants less than 15 years of age.

### ***Treatment***

Two studies were approved: [IMPAACT 2017](#), a study to evaluate safety, tolerability, and PK of oral cabotegravir, long-acting injectable cabotegravir, and long-acting injectable rilpivirine among HIV-1 infected children and adolescents, and [IMPAACT 2019](#), a study of a fixed-dose combination of dolutegravir, lamivudine, and abacavir (Triumeq®) among HIV-1 infected children.

### **Publications and Presentations**

The network has continued to successfully [publish](#) and [present](#) results from our studies, with 28 manuscripts published in NEJM, JAIDS, PLoS One, among others. The network presented three abstracts at [IAS 2017](#) and 16 abstracts at [CROI 2017](#).

Of note, [results from PROMISE 1077HS](#), published in PLoS One, demonstrated that continued ART was safe and was associated with a halving of the rate of WHO 2/3 conditions. Results from PROMISE presented at CROI 2017 also further described risk factors for adverse birth outcomes as well as outcomes related to subsequent pregnancies.



### **Investigator Achievements**

Lisa M. Frenkel, an IMPAACT investigator from the University of Washington/Seattle Children's Research Institute, is among the 396 new fellows of the American Association for the Advancement of Science (AAAS). Dr. Frenkel was selected for her distinguished research on HIV infections in newborns, children and adults. She practices at the Pediatric Infectious Diseases Virology Clinic at Seattle Children's and co-directs the Seattle Children's Center for Global Infectious Diseases. [Read More Here](#)

