

State of the Network

Sharon Nachman, MD
IMPAACT Network Chair
24 October 2023



IMPAACT

International Maternal Pediatric Adolescent
AIDS Clinical Trials Network

ANNUAL MEETING
2023

2

State of the Network: A Snapshot



- ▶ Research agenda
- ▶ Network activities and achievements
- ▶ Study updates and achievements
- ▶ Upcoming studies and protocols in development
- ▶ Continued and new partnerships



IMPAACT's Mission

To improve health outcomes for infants, children, adolescents, and pregnant and postpartum people who are impacted by or living with HIV by evaluating novel treatments and interventions for HIV and its complications and for tuberculosis and other HIV-related conditions

IMPAACT Research Agenda

2023 - 2027



Pregnant & PP People



Infants



Children



Adolescents

Novel and Durable Therapeutic/Preventive Interventions



Cure and Immunotherapy



Tuberculosis



Brain and Mental Health



Revised Scientific Aims

1

Advance **treatment during pregnancy and postpartum**, aiming to optimize maternal and child health outcomes and accelerate the evaluation (pharmacokinetics (PK), safety, antiviral efficacy), licensure and optimal use of **potent and durable ARVs and other therapeutics** for pregnant people and infants, children, and adolescents with HIV and related diseases and conditions

2

Evaluate the potential for **ART-free HIV remission** through therapeutic interventions aimed at prevention, clearance and post-treatment control of HIV reservoirs in infants, children and adolescents with HIV and leverage expertise for evaluation of **vaccines** for HIV and related/co-occurring conditions in these populations

3

Evaluate novel approaches for **TB prevention, diagnosis and treatment** in infants, children, adolescents and pregnant and postpartum women with and without HIV that will lead to optimal dosing and regimens, licensing and decreased morbidity and mortality

4

Determine optimal and feasible biological and behavioral methods for the prevention and management of **neuropsychological and mental health complications of HIV and its treatment** in infants, children, adolescents and pregnant and postpartum people

Current Portfolio

includes evaluation of the following interventions/agents

Therapeutics

- DTG in Neonates, Infants, Children and Adolescents
- Selected ARV and TB drugs in Pregnant/ Postpartum People
- LA CAB/RPV in Children & Adolescents and in Pregnancy
- Oral PrEP (TDF/FTC) in Pregnancy & Postpartum
- GLE/PIB for Hepatitis C in Pregnancy

Brain and Mental Health

- Group-based Counseling Intervention in Treatment Non-adherent Adolescents

HIV Cure and Immunotherapy

- LPV and NVP containing early intensive treatment, RAL and NVP containing early intensive treatment, and VRC01 in Infants
- Cord Blood Transplantation with CCR5Δ32 Donor Cells
- HIVconsvX Vaccines
- bNAbs in Infants and Children
- RSV Vaccines in Children

Tuberculosis

- VPM1002/BCG in Pre-Adolescents
- Pretomanid in Children
- RPT/INH in Children
- BDQ in Children
- DLM in Children
- Combination Regimen for RR-TB in Children



IMPAACT

International Maternal Pediatric Adolescent
AIDS Clinical Trials Network

Current Portfolio

25 active studies

	3 Proposals Recently Approved	6 Protocols in Development	3 Pending and Open	10 Enrolling	1 in Follow-Up	2 Closed to Follow-Up*
Therapeutics	2043^	2041^, 2040^, 2037	2036	2026^, 2023, 2017	2009^	P1093
Tuberculosis	2020	2024	2035	2034, 2005, 2003B, P1108		
Brain and Mental Health			2016			
Cure and Immunotherapy	2042	2039, 2038		2028, 2021, P1115		P1107

Approximately 30 additional studies and ancillary studies (NWCS, DACS, DR) in analysis and manuscript writing phase

**closed to follow-up in the last year
^study during pregnancy/postpartum*

IMPAACT Protocols Snapshot: In Development through Closed to Follow Up

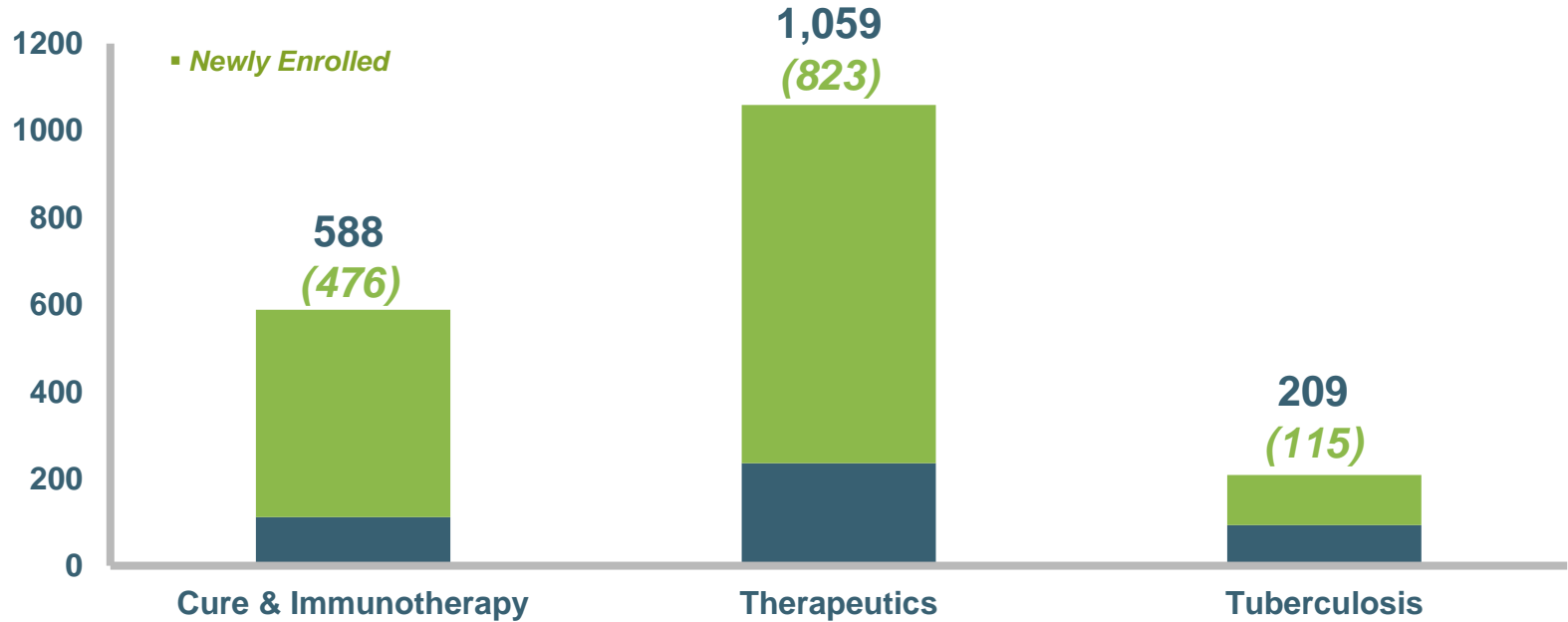
Protocol #	Title	Sites	Study Status	Research Area	Protocol to Sites (Projected)	Open to Accrual (Projected)	1st Participant Enrolled (Projected)	Closed to Accrual (Projected)	Closed to Follow Up (Projected)	Target Accrual	Actual Accrual as of report date
IMPAACT 2043/A5425	Randomized study of long-acting ART in postpartum women with a history of adherence challenges (The PRACTICAL Study)	US/INTL	In Development	Treatment	TBD	TBD	TBD	TBD	TBD	TBD	NA
IMPAACT 2042	Phase III Trial to Evaluate the Impact of Three Broadly Neutralizing Antibodies or Analytic Treatment Interruption on Viral Reservoir, Immune Function, and Maintenance of HIV Suppression in Early-Treated Children in Botswana	INTL	In Development	Cure	TBD	TBD	TBD	TBD	TBD	TBD	
IMPAACT 2020	A Phase II Study of Shortened Oral Novel Treatment for Rifampicin-Resistant Tuberculosis in Children	INTL	In Development	Tuberculosis	TBD	TBD	TBD	TBD	TBD	112 children and their caregivers	
IMPAACT 2038	Phase I Study of the Infectivity, Safety, and Immunogenicity of a Single Dose of Recombinant, Live-Attenuated, Bovine/Human, Parainfluenza Virus Type 3 (B/HPiV3) Vector Vaccines B/HPiV3/RSV/PrF, B/HPiV3/RSV/PrF/IM, or Placebo, Delivered via Nasal Spray to HPiV3-Seronegative Children 6 to 24 Months of Age	US	In Development	Complications and Comorbidities	31-Mar-24	19-May-24	23-Jun-24	23-Jun-26	22-Oct-26	70	
IMPAACT 2041	Phase III Study of the Pharmacokinetics and Safety of Glecaprevir/Pibrentasvir Initiated During Pregnancy in People with Hepatitis C with or without HIV	US	In Development	Complications and Comorbidities	31-Mar-24	29-Jun-24	29-Jul-24	29-Jul-25	26-Mar-26	30 pairs	
IMPAACT 2039	Phase III Study of the Safety, Immunogenicity, Efficacy of HIVconsX Vaccines in Children Living with HIV	US/INTL	In Development	Cure	28-Jun-24	26-Sep-24	25-Dec-24	TBD	TBD	42 (Part A); 90 (Part B)	
IMPAACT 2040	Phase III Pharmacokinetics and Safety of Long-Acting Injectable Cabotegravir and Rilpivirine in Virologically Suppressed People with HIV During Pregnancy and Postpartum	US/INTL	In Development	Treatment	15-Dec-23	12-Jun-24	10-Jul-24	03-Oct-25	28-Sep-26	45 pairs	
IMPAACT 2037	Phase I Open Label Study of the Safety and Pharmacokinetics of PGT121.414.LS Alone and in Combination with VRC07-523LS in Infants Exposed to HIV-1	US/INTL	In Development	Treatment	31-Jan-24	29-Jul-24	28-Aug-24	26-Feb-26	26-Feb-28	48	NA
IMPAACT 2024	Phase III Dose Finding, Safety and Tolerability Study of Daily Rifapentine Combined with Isoniazid (1HP) for Tuberculosis Prevention in Children Two to less than 13 Years of Age with and without HIV	INTL	In Development	Tuberculosis	30-Jan-24	30-Jun-24	31-Aug-24	31-Aug-26	28-Feb-27	80	NA
IMPAACT 2036	Phase III Study of the Safety, Tolerability, Acceptability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Rilpivirine in Virologically Suppressed Children Living with HIV Two to Less than 12 Years of Age	US/INTL	Pending	Treatment	04-Oct-22	31-Oct-23	31-Dec-23	03-Jul-25	03-Jul-26	90	NA
IMPAACT 2035/HVTN 604	Phase III Randomized, Placebo-Controlled Study of the Safety and Immunogenicity of VPM1002 Vaccination or BCG Revaccination against Tuberculosis in Pre-Adolescents Living with and without HIV in South Africa	INTL	Pending	Tuberculosis	13-Jul-22	29-Feb-24	30-Apr-24	30-Oct-25	30-Oct-26	480	NA
IMPAACT 2034	Phase I Study of the Pharmacokinetics, Safety, and Acceptability of a Single Dose of Pretomanid Added to an Optimized Background Regimen in Children with Rifampicin-Resistant Tuberculosis	INTL	Open to Accrual	Tuberculosis	04-Aug-22	17-Feb-23	14-Oct-23	12-Jan-26	26-Jan-26	72	0

Updated monthly and posted to the IMPAACT website

<https://www.impaactnetwork.org/studies/impaact-study-snapshots>

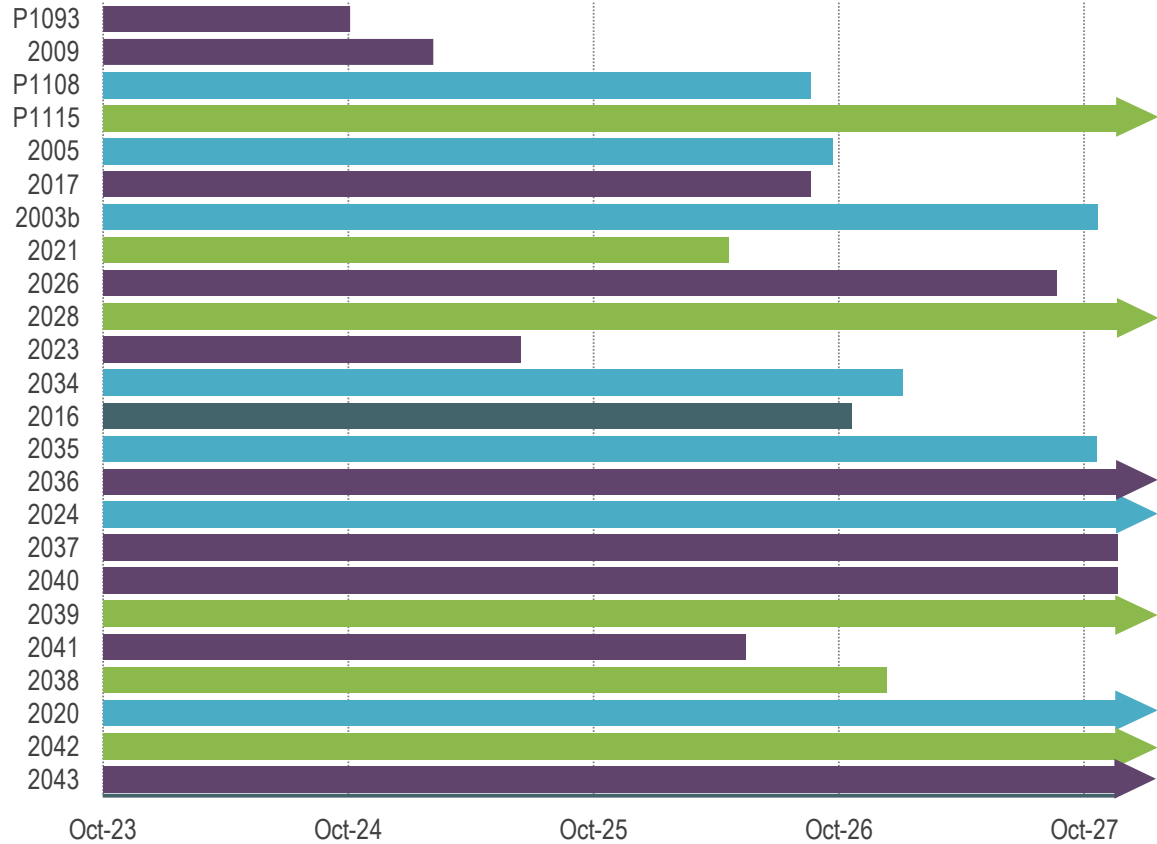
IMPAACT Participants on Study

June 2022 to September 2023



Total On Study = 1,856 participants
Newly Enrolled = 1,414 participants

The Network has a robust and growing portfolio of current studies and new proposals in the pipeline



- Brain & Mental Health
- Cure & Immunotherapy
- Therapeutics
- Tuberculosis

Network Activities and Achievements

Contributions to Expanded Treatment Options

Data from two studies informed regulatory decisions:

- ✓ **IMPAACT 2032, Remdesivir:** Label updated to add PK and safety data from **pregnant people with COVID-19** (US FDA and EMA)
- ✓ **IMPAACT 2019, ABC/3TC/DTG:** expanded approval of *Triumeq PD* to **infants and children living with HIV** as young as 3 months of age who weigh at least 6 kg (US FDA, submitted to EMA)

Contributions to Expanded Treatment Options – *Looking Forward*






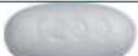





Additional data from two studies anticipated to be submitted to regulatory authorities through 2024:

- ▶ IMPAACT 2017 – CAB/RPV
- ▶ IMPAACT P1093 – DTG



Drug Licensure based on IMPAACT Data

15

		Birth	1 mth	2 mths	6 mths	2 yrs	6 yrs	12 yrs	18 yrs	Pregnancy	
Dolutegravir (DTG)		Dispersible tablet	Dispersible and film-coated tablets								
Abacavir (ABC)/DTG/lamivudine (3TC)*			Immediate-release and dispersible fixed-dose tablets								
Raltegravir (RAL)		Oral granules for suspension and chewable tablets									
Cabotegravir/rilpivirine (CAB/RPV)			Long-acting injectable				Long-acting injectable		Long-acting injectable		
Doravirine (DOR)/3TC/TDF									Fixed-dose tablet		
Etravirine (ETR)			Tablet								
Maraviroc (MVC)*		Oral liquid									
Bedaquiline (BDQ)		Tablet									
Pretomanid (Pa)*			Immediate-release and dispersible tablets								
Remdesivir										Injection	
Glecaprevir/pibrentasvir (GLE/PIB)										Fixed-dose tablet	

Approved
In progress
Developing

*Approved in children using weight-based dosing

Ongoing Collaborations to Enhance and Accelerate Research in IMPAACT's Populations



- ▶ Special issue guest edited by Martina Penazzato (World Health Organization) and Elaine Abrams (ICAP at Columbia University)
- ▶ This work builds on the strong and ongoing collaboration between WHO and IMPAACT, following the Call-to-Action to accelerate the study of new drugs for HIV in pregnancy

Ongoing Collaborations to Enhance and Accelerate Research in IMPAACT's Populations

- ▶ The NIH/DAIDS Cross-Network (ACTG/HVTN/IMPAACT) TB Working Group called for people living with HIV to be included in tuberculosis vaccine development
- ▶ Paper published in *The Lancet HIV* on 11 October 2022

Developing tuberculosis vaccines for people with HIV: consensus statements from an international expert panel

Maurine D Miner, Mark Hatherill, Vidya Mave, Glenda E Gray, Sharon Nachman, Sarah W Read, Richard G White, Anneke Hesselning, Frank Cobelens, Sheral Patel, Mike Frick, Theodore Bailey, Robert Seder, Joanne Flynn, Jyothi Rengarajan, Deepak Kaushal, Willem Hanekom, Alexander C Schmidt, Thomas J Scriba, Elisa Nemes, Erica Andersen-Nissen, Alan Landay, Susan E Dorman, Grace Aldrovandi, Lisa M Cranmer, Cheryl L Day, Alberto L Garcia-Basteiro, Andrew Fiore-Gartland, Robin Mogg, James G Kublin*, Amita Gupta*, Gavin Churchyard*

Community Engagement

- ▶ Community representation and input on all network groups and levels – clinical research sites, leadership groups, scientific and other committees, protocol teams, cross-network activities
- ▶ ICAB ensures that the principles of community participation and partnership are at the foundation of all community engagement activities and provides community input throughout the research process (concept development, study implementation, and results dissemination)



Early Career Investigators Program

Overall goal: to prepare the next generation of health care professionals with skills to maintain and strengthen HIV programs for IMPAACT's populations of interest, experience the collaborative nature of network research, hone presentation skills, and develop a scholarly work that is suitable for publication.



Brenda Catherine Kakayi, BPharm

MU-JHU Research Collaboration CRS
Project: *Insulin-like growth factor/growth hormone axis alterations and stunting in HIV-exposed uninfected children from the 1077BF/P1084s study*



Allen Matubu, PhD

University of Zimbabwe Clinical Trials
Research Centre
Project: *Fetal cfRNA as a predictive biomarker for adverse pregnancy outcomes in women on antiretroviral therapy*



Clement Gascua Adu-Gyamfi, PhD

University of the Witwatersrand
Project: *Indoleamine 2, 3-dioxygenase as a Tuberculosis biomarker in pregnant women living with HIV*

Early Career Investigators Program

20

Overall goal: to prepare the next generation of health care professionals with skills to maintain and strengthen HIV programs for IMPAACT's populations of interest, experience the collaborative nature of network research, hone presentation skills, and develop a scholarly work that is suitable for publication.

Key Dates:

- ▶ Completed! August 2023: Application announcement
- ▶ Completed! 2 October 2023: submission deadline
- ▶ **End November 2023: anticipate notifications to applicants**
- ▶ **1 December 2023: funding initiated**

In Person Study Trainings Resumed!



IMPAACT 2036

Regional and site-specific trainings in South Africa, Thailand, Uganda, and the US

6

7

IMPAACT 2016

Expert trainer trainings and regional study trainings in Botswana, Malawi, South Africa, and Zimbabwe

IMPAACT 2034

Regional training in South Africa

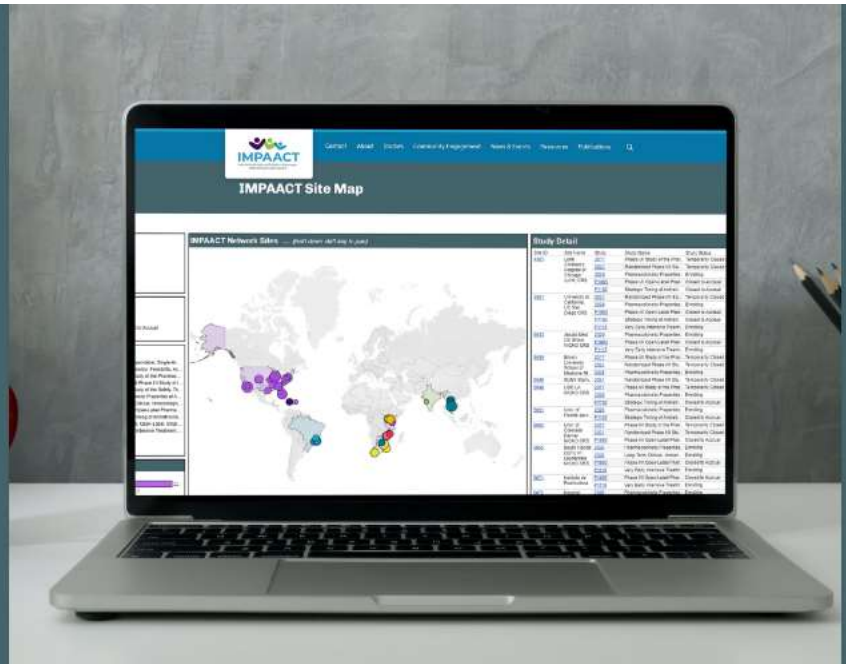
1

IMPAACT Network Data Visualization Map

IMPAACT Network Data Visualization Map

The IMPAACT Data Management Center, in collaboration with the Operations Center, has developed a new data visualization to highlight IMPAACT sites and their work. The visualization includes options to sort and view participating IMPAACT studies by country, study, or research area, with additional details on study status and accrual by site. The visualization is best viewed in Microsoft Edge, but is also compatible with Google Chrome and other internet browsers.

[View the Map](#)



IMPAACT Lab Center Website

New Laboratory Center Website

Providing information and training videos for laboratories.



IMPAACT Social Behavioral Scientific Core SpotLight Series

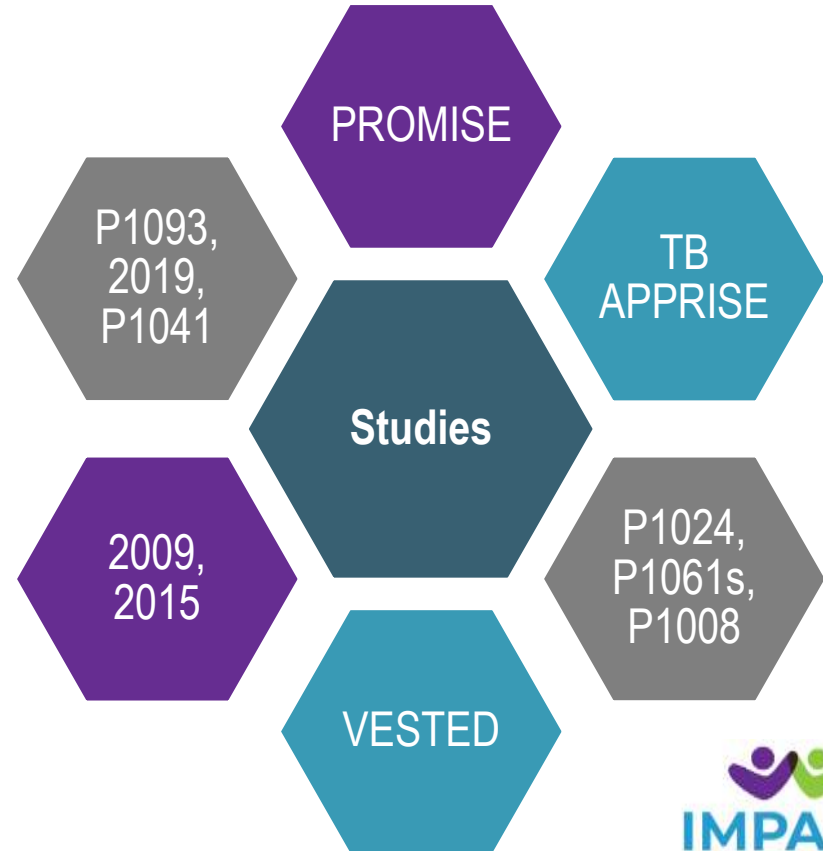
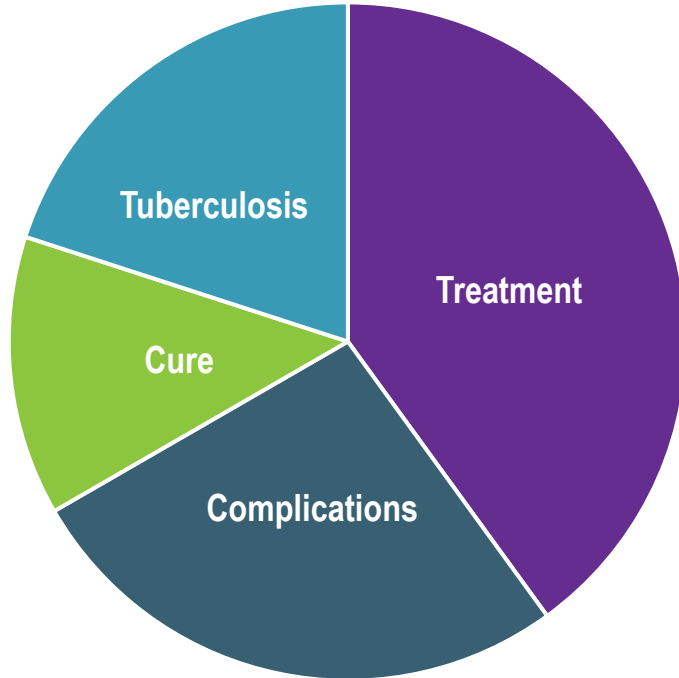
Nine SpotLight webinars

- Stigma
- Quality of life
- Trans inclusion
- Adherence
- Mental health
- Anniversary panel discussion



14 Ancillary Proposals Received

25



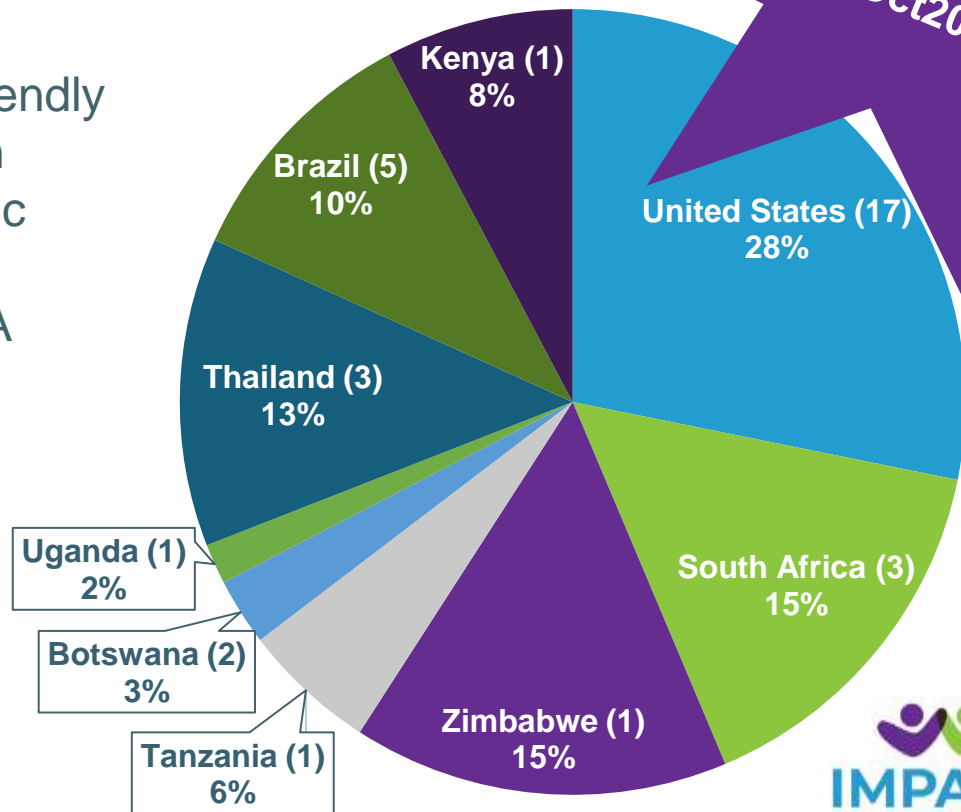
Study Updates and Achievements

Study Highlight: IMPAACT P1093

PK, Safety, & Antiviral Activity of Dolutegravir

Follow-up
completed!
18 Oct 2023

- ▶ Landmark study of child-friendly dolutegravir formulations in children across the pediatric range that continues to contribute to FDA and EMA approvals
- ▶ 1st participant enrolled in April 2011
- ▶ 181 participants enrolled
- ▶ 34 sites in 9 countries



Therapeutics

Study Highlight: IMPAACT P1115

Very Early Intensive Treatment of Infants with HIV to Achieve HIV Remission

- ▶ Network's flagship proof-of-concept study for HIV remission in infants
- ▶ 881 pairs enrolled in Version 1.0 and Version 2.0

NINE pairs remaining to be enrolled in Version 2.0

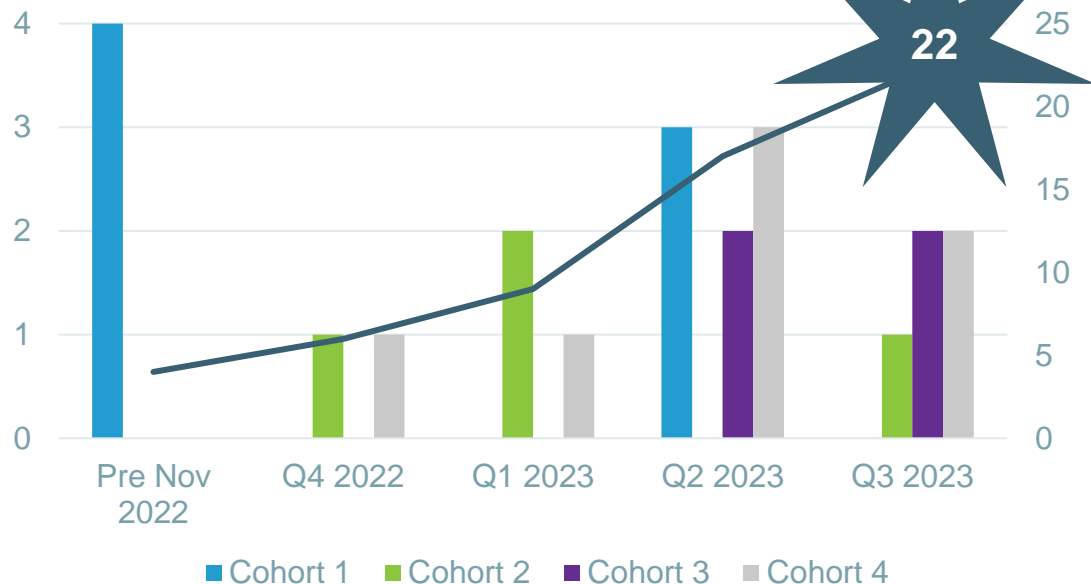


Study Highlight: IMPAACT 2005

PK and Safety of Delamanid in Infants, Children, and Adolescents with MDR-TB Disease and with or without HIV

29

- ▶ Addressing critical need for better medications to treat children with MDR-TB
- ▶ 7 sites in Botswana, India, South Africa, and Tanzania



Tuberculosis

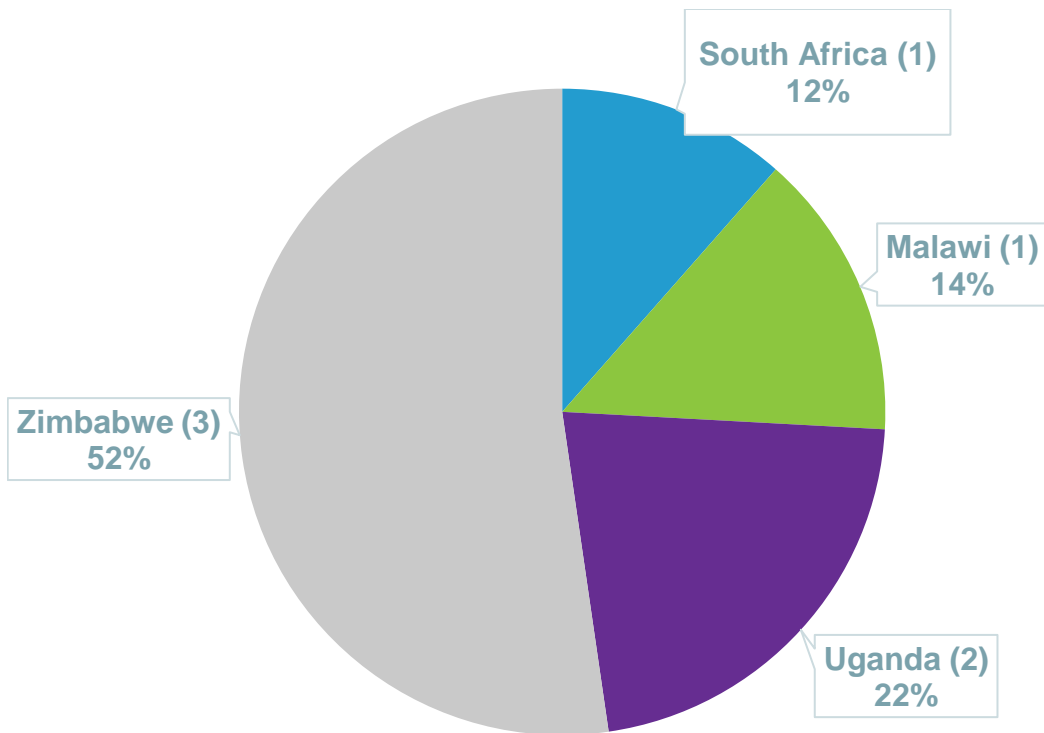
Study Highlight: IMPAACT 2009

PrEP in Pregnant Women

30

Completed accrual of 350 mother-infant pairs in the PrEP Comparison Component at 7 sites in Malawi, South Africa, Uganda, and Zimbabwe

Anticipate completion of follow-up by February 2024



Study Highlight: IMPAACT 2016

Group-Based Intervention to Improve Mental Health and ART Adherence among Youth

31

- ▶ Two-arm, randomized study to examine if an Indigenous Leader Outreach Model of trauma-informed cognitive behavioral therapy intervention improves mental health outcomes and ART adherence for youth living with HIV
- ▶ 8 sites planned for participation in Botswana, Malawi, South Africa, and Zimbabwe

First enrollment anticipated
by end of October 2023

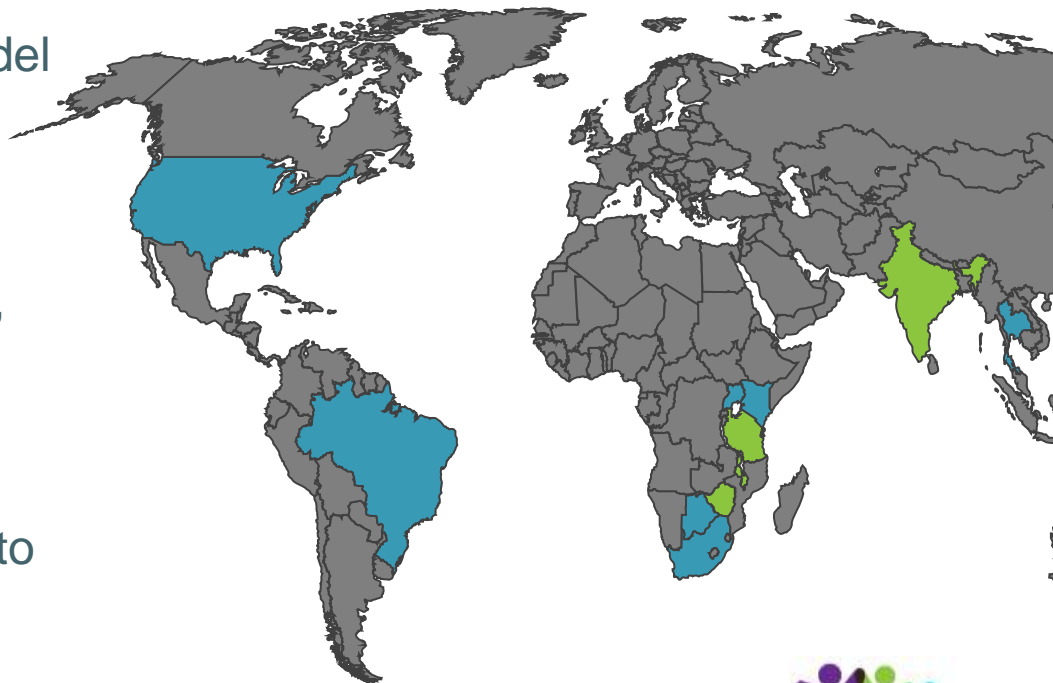
FIVE sites in
Botswana and
Zimbabwe activated
and screenings
began!



Study Highlight: IMPAACT 2026

PK Properties of ARVs and Anti-TB Drugs during Pregnancy and Postpartum

- ▶ Continuation of successful model from P1026s
- ▶ 29 sites activated in Botswana, Brazil, Kenya, South Africa, Thailand, Uganda, and the US, with additional sites planned in India, Malawi, Tanzania, and Zimbabwe
- ▶ Two arms successfully closed to accrual (BIC and TAF 25mg without boosting)



Study Highlight: IMPAACT 2034

PK and Safety of Pretomanid in Infants, Children, and Adolescents with RR-TB with or without HIV

FOUR enrollments
at sites in South
Africa and
Thailand!

- ▶ Addressing critical need for better medications to treat children with drug resistant tuberculosis
- ▶ Collaborative study with TB Alliance
- ▶ Other sites planned in Brazil, India, and Tanzania

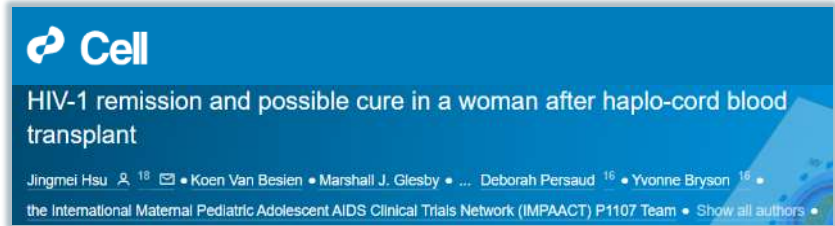


Enrolling as of
October 2023

Tuberculosis

Publications

35 manuscripts published in Lancet HIV, CID, Cell, JID, AIDS, PLoS One, JAIDS, Journal of Clinical Pharmacology, among others



Cell

HIV-1 remission and possible cure in a woman after haplo-cord blood transplant

Jingmei Hsu ¹⁸ ✉ • Koen Van Besien • Marshall J. Glesby • ... Deborah Persaud ¹⁶ • Yvonne Bryson ¹⁶ • the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) P1107 Team • Show all authors



JOURNAL OF THE
Pediatric Infectious Diseases Society

Efficacy, safety, and tolerability of doravirine/lamivudine/tenofovir disoproxil fumarate fixed dose combination tablets in adolescents living with HIV: results through week 96 from IMPAACT 2014 [Get access](#)

Supattra Rungmaitree, M.D., Linda Aungpibul, M.D., M.P.H. ✉, Brookie M Best, Pharm.D., M.A.S., Xiang Li, M.S., Meredith G Warshaw, M.S.S., M.A., Hong Wan, Ph.D., Nicole H Tobin, M.D., Patricia James, M.S., M.B.A., Randi Leavitt, M.D., Katie McCarthy, M.P.H. ... Show more



JAIDS
JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROME

CLINICAL SCIENCE

Pharmacokinetics of Tenofovir Alafenamide With Boosted Protease Inhibitors in Pregnant and Postpartum Women Living With HIV: Results From IMPAACT P1026s

Brooks, Kristina M. PharmD^a; Pinilla, Mauricio MS^b; Stek, Alice M. MD^c; Shapiro, David E. PhD^d; Barr, Emily PhD, CPNP, CNM^e; Febo, Irma L. MD^f; Paul, Mary E. MD^g; Deville, Jaime G. MD^h; George, Kathleen MPHⁱ; Knowles, Kevin PhD, MA^j; Rungruengthanakul, Kittipong MS^k; Browning, Renee RN, MSN^l; Chakhtoura, Nahida MD^m; Capparelli, Edmund V. PharmD^{n,o}; Mirochnick, Mark MD^p; Best, Brookie M. PharmD, MAS^q; on behalf of the IMPAACT P1026s Protocol Team



The Journal of
Infectious Diseases

Evaluation of Recombinant Live-Attenuated Respiratory Syncytial Virus (RSV) Vaccines RSV/ΔNS2/Δ1313/1314L and RSV/276 in RSV-Seronegative Children [Get access](#)

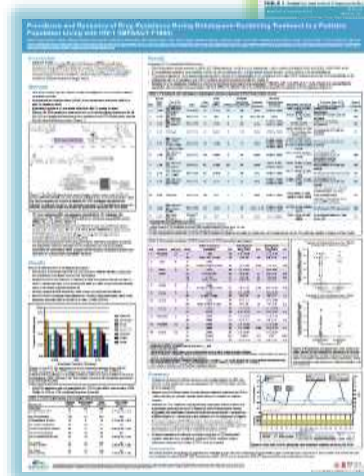
Coleen K Cunningham ✉, Ruth A Karron, Petronella Muresan, Matthew S Kelly, Elizabeth J McFarland, Charlotte Perlowski, Jennifer Libous, Jennifer Oliva, Patrick Jean-Philippe, Jack Moye, Jr ... Show more

Abstracts

7 at CROI 2023, 8 at AIDS or Peds 2022, 2 at IAS or Peds 2023

- ▶ 4 abstracts from PROMISE 1077/P1084s
- ▶ 3 abstracts from IMPAACT 2010/VESTED
- ▶ 2 abstracts each from P1093, IMPAACT 2002, and IMPAACT 2017/MOCHA and additional results from P1078/TB APPRISE, IMPAACT 2008, IMPAACT 2015, IMPAACT 2026 among others!

Additional abstracts submitted to upcoming meetings at CROI 2024



Looking Forward

Protocols Currently in Development

Two within the Tuberculosis Research Area

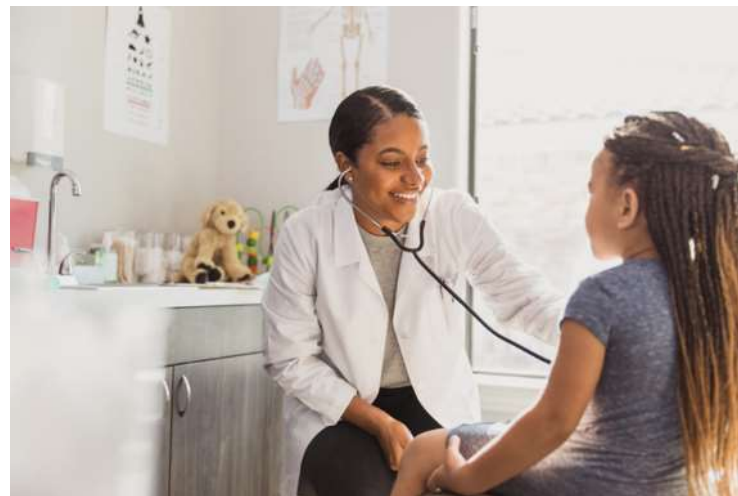
2020	A Phase II Study of Shortened Oral Novel Treatment for Rifampicin-Resistant Tuberculosis in Children
2024	Phase I/II Dose Finding, Safety, and Tolerability Study of Daily Rifapentine Combined with Isoniazid (1HP) for Tuberculosis Prevention in Children 2 to <13 years of age with and without HIV

Study in Development: IMPAACT 2024

Dose Finding, Safety, and Tolerability of Daily Rifapentine with Isoniazid (1HP) for TB Prevention in Children 2-<13 Years

- ▶ Providing data for shorter TB preventive treatment in children
- ▶ Planned at 14 sites in Botswana, Haiti, Kenya, South Africa, Thailand, Uganda, and Zimbabwe

Anticipate protocol to sites
by Q1 2024



Protocols Currently in Development

Three within the Cure & Immunotherapy Research Area

2042	Phase I/II Trial to Evaluate the Impact of Three Broadly Neutralizing Antibodies or Analytic Treatment Interruption on Viral Reservoir, Immune Function, and Maintenance of HIV Suppression in Early-Treated Children in Botswana
2039	Phase I/II Study of the Safety, Immunogenicity, and Efficacy of HIVconsvX Vaccines and Broadly Neutralizing Antibodies in Children Living with HIV
2038	Phase I Study of the Infectivity, Safety, and Immunogenicity of a Single Dose of Recombinant, Live-Attenuated, Bovine/Human, Parainfluenza Virus Type 3 (B/HPIV3) Vector Vaccines B/HPIV3/RSV/PreF, B/HPIV3/RSV/PreF/TM, or Placebo, Delivered via Nasal Sprayer to HPIV3-Seronegative Children 6 to 24 Months of Age

Protocols Currently in Development

Four within the Therapeutics Research Area

2043 (A5425)	Randomized study of long-acting ART in postpartum women with a history of adherence challenges (The PRACTICAL Study)
2041	Phase I/II Study of the Pharmacokinetics and Safety of Glecaprevir/Pibrentasvir Initiated During Pregnancy in People with Hepatitis C with or without HIV
2040	Phase I/II Pharmacokinetics and Safety of Long-Acting Injectable Cabotegravir and Rilpivirine in Virologically Suppressed People with HIV During Pregnancy and Postpartum
2037	Phase I Open Label Study of the Safety and Pharmacokinetics of PGT121.414.LS Alone and in Combination with VRC07-523LS in Infants Exposed to HIV-1

Planning for Initiation: IMPAACT 2036

Safety & PK of Oral and Long-Acting Injectable Cabotegravir and Rilpivirine in Virologically Suppressed Children with HIV

- ▶ Continued successful collaboration from IMPAACT 2017 with ViiV/Janssen to study long-acting, injectable regimens in children
- ▶ Children will be two to less than 12 years old
- ▶ Planned at 12 sites in Brazil, Botswana, South Africa, Thailand, Uganda, and the US



Anticipate open to accrual
by Q4 2023

Study in Development: IMPAACT 2037

Safety and PK Parameters of Potent Anti-HIV Neutralizing Monoclonal Antibodies

- ▶ Building on work from IMPAACT P1112, evaluating two potent anti-HIV neutralizing monoclonal antibodies
- ▶ Will be administered soon after birth to infants at high risk for peripartum or breastfeeding HIV transmission

Anticipate protocol to sites by Q1 2024



Study in Development: IMPAACT 2040

“CREATE”

PK & Safety of Long-Acting Injectable Cabotegravir and Rilpivirine in People with Virally Suppressed HIV-1 during Pregnancy and Postpartum

- ▶ Continued successful collaboration from IMPAACT 2017 and 2036 with ViiV/Janssen to study long-acting, injectable regimens
- ▶ Enrolling participants who are pregnant and living with HIV (and their infants)



Anticipate protocol to sites by December 2023

Study in Development: IMPAACT 2041

PK & Safety of Glecaprevir/Pibrentasvir during Pregnancy in People with Hepatitis C

44

- ▶ Collaboration with AbbVie and CDC
- ▶ Enrolling participants who are pregnant with Hepatitis C (and their infants)
- ▶ Planned at 10 sites in the US

Anticipate protocol to sites by March 2024



Proposals under review

Two within the Therapeutics Research Area

CS 5035	Pharmacokinetics of Benzathine Penicillin and Ceftriaxone in Pregnancy
CS 5038	A Phase I/II Trial to Evaluate the Safety and Pharmacokinetics of Bictegravir/ Emtricitabine/Tenofovir Alafenamide (B/F/TAF) in HIV-1 Exposed Neonates

And Many Other Studies Key Milestones!

46

IMPAACT 2008
POS/PAC
15 Apr 2022

A5418/STOMP
Enrolling
08 Sep 2022

IMPAACT 2035/
HVTN 604
V1.0 to Sites
13 Jul 2022

IMPAACT 2036
V1.0 to Sites
04 Oct 2022

IMPAACT 2023
1st Enrollment
05 Oct 2022

IMPAACT 2009
Closed to
Accrual
12 Dec 2022

IMPAACT 2032
POS/PAC
28 Nov 2022

P1093
Closed to
Follow-Up and
POS/PAC
18 Oct 2023

IMPAACT 2034
V1.0 to Sites
(04 Aug 2022) and
1st Enrollment
03 Oct 2023

Cross Network Study Initiatives



- ▶ MDR-TB Prevention and long-acting injectables (PHOENIX and IMPAACT 2043/A5425)



- ▶ TB Vaccine Studies (IMPAACT 2035/HVTN 604)



- ▶ Dolutegravir (P1093/ODYSSEY)



- ▶ RSV and VRC Studies (IMPAACT 2021 and 2038; P1112, IMPAACT 2008, IMPAACT 2037)

Pharma and Other Collaborations



We have had a great year with excellent work and significant accomplishments!

Let's prepare for the coming year of IMPAACT work!



Upcoming IMPAACT Annual Meetings



**Crystal Gateway Marriot
in Arlington, Virginia**

22-27 September 2024

7-12 September 2025

THANKS!



Thank you to site staff, to the communities, and to all of the individuals and families engaged in clinical research!

Let's continue to move the science forward!

**Now a message
from our new
NIAID Director,
Jeanne Marrazzo!**

