

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 2039	Phase I/II Study of the Safety, Immunogenicity, Efficacy of HIVconsvX Vaccines in Children Living with HIV	TBD	In Development	Cure	TBD	TBD	TBD	TBD	TBD	TBD	NA
IMPAACT 2040	Phase I/II 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	31-May-23	TBD	TBD	TBD	TBD	45 pairs	NA
IMPAACT 2037	Open-Label, Phase I Study of the Safety and Pharmacokinetics of PGT121.414LS alone and in combination with VRC07-523LS in Infants Exposed to HIV-1	US/INTL	In Development	Treatment	28-Feb-23	31-Aug-23	30-Sep-23	31-Mar-25	31-Mar-27	48	NA
IMPAACT 2036	Phase I/II 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	In Development	Treatment	31-Oct-22	01-Mar-23	01-May-23	TBD	TBD	90	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	In Development	Tuberculosis	29-Jul-22	27-Oct-22	25-Jan-23	25-Apr-25	09-May-25	72	NA
IMPAACT 2024	Phase I/II 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	US/INTL	In Development	Tuberculosis	TBD	TBD	TBD	TBD	TBD	80	NA
IMPAACT 2035/HVTN 604	Phase III Randomized, Placebo-Controlled Study of the Safety and Immunogenicity of VPM1002 Vaccination or BCG Re-Vaccination against Tuberculosis in South African Pre-Adolescents Living with and without HIV in South Africa	INTL	Pending	Tuberculosis	13-Jul-22	30-Nov-22	31-Mar-23	30-Sep-24	30-Sep-25	480	NA
IMPAACT 2023	A Phase I Study of the Safety, Tolerability, and Pharmacokinetics of Dolutegravir in Neonates Exposed to HIV-1	US/INTL	Pending	Treatment	25-Oct-21	15-Aug-22	15-Aug-22	30-Sep-24	28-Feb-25	108	NA
IMPAACT 2016	Evaluating a Group-Based Intervention to Improve Mental Health and ART Adherence Among Youth Living with HIV in Low Resource Settings	INTL	Open to Accrual	Complications	08-Nov-18	27-Nov-19	TBD	TBD	TBD	256	0
IMPAACT 2028	Long-Term Clinical, Immunologic, and Virologic Profiles of Children who Received Early Treatment for HIV Infection	US/INTL	Enrolling	Cure	31-Dec-20	08-Nov-21	02-Feb-22	30-Nov-26	30-Nov-27	250	4
IMPAACT 2026	Pharmacokinetic Properties of Antiretroviral and Anti-Tuberculosis Drugs during Pregnancy and Postpartum	US/INTL	Enrolling	Treatment	04-Feb-20	08-Jun-21	01-Sep-21	30-Apr-26	01-Sep-26	325	37 pairs
IMPAACT 2021	Randomized Phase I/II Study of the Safety and Immunogenicity of a Single Dose of the Recombinant Live-Attenuated Respiratory Syncytial Virus (RSV) Vaccines RSV ΔNS2/Δ1313/11314L, RSV 6120/ΔNS2/1030s, or RSV 276 or Placebo, Delivered as Nose Drops to RSV-Seronegative Children 6 to 24 Months of Age	US	Enrolling	Complications	28-Mar-19	16-May-19	20-Jun-19	14-Oct-22	30-Apr-23	130	42

TBD = information is to be added once timeline is clearer
 Grey text boxes indicates a projected (rather than actual) date

Based on data available through 26 July 2022
 Page 1 of 3

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 2003b/A5300b	Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant TB Patients (PHOENIX MDR-TB)	INTL	Enrolling	Tuberculosis	2-Oct-18 (V2)	03-Jun-19	13-Jun-19	31-Mar-24	30-Jun-26	3452 (household); 1726 (index)	1,413 (household); 771 (index)
IMPAACT 2017	Phase I/II Study of Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents: MOCHA (More Options for Children and Adolescents)	US/INTL	Enrolling	Treatment	16-Mar-18	19-Mar-19	03-Apr-19	31-Aug-22	31-Aug-25	155	65
IMPAACT 2009	Pharmacokinetics, Feasibility, Acceptability, & Safety of Oral Pre-Exposure Prophylaxis for Primary HIV Prevention during Pregnancy & Postpartum in Adolescents & Young Women & their Infants	INTL	Enrolling	Prevention	02-Nov-17	09-Jul-18	04-Mar-19	30-Nov-22	30-Nov-23	390	269 pairs
IMPAACT 2005	A Phase I/II Open-label, Single-Arm Study to Evaluate the PK, Safety, & Tolerability of Delamanid in Combination with OBR for MDR-TB in Children with MDR-TB with and without HIV	INTL	Enrolling	Tuberculosis	21-Mar-17	30-Jan-18	18-Feb-19	15-Aug-25	18-Jun-27	48	4
P1108	Phase I/II, Open-Label, Single Arm Study to Evaluate the PK, Safety & Tolerability of Bedaquiline in Combination with Optimized Individualized MDR-TB Therapy in HIV-Infected & HIV-Uninfected Infants, Children & Adolescents with MDR-TB Disease	INTL	Enrolling	Tuberculosis	09-Mar-16	18-Aug-17	21-Sep-17	30-Apr-23	30-Apr-25	72	43
P1115	Very Early Intensive Treatment of HIV-Infected Infants to Achieve HIV Remission: A Phase I/II Proof of Concept Study	US/INTL	Enrolling	Cure	20-Mar-14	24-Jun-14	23-Jan-15	31-Dec-23	30-Dec-32	905 pairs	709 pairs
P1107	Cord Blood Transplantation with CCR5Δ32 Donor Cells in HIV-1 Infected Subjects who Require Bone Marrow Transplantation for any Indication and Its Observed Effects on HIV-1 Persistence	US	Closed to Accrual	Cure	08-Aug-13	04-Mar-14	05-Feb-15	12-Oct-20	30-Nov-22	25	2
P1093	Phase I/II, Multi-Center, Open-Label Pharmacokinetic, Safety, Tolerability and Antiviral Activity of Dolutegravir, a Novel Integrase Inhibitor, in Combination Regimens in HIV-1 Infected Infants, Children and Adolescents	US/INTL	Closed to Accrual	Treatment	21-Dec-10	14-Mar-11	20-Apr-11	19-Feb-20	19-Feb-24	300	181
IMPAACT 2032	Pharmacokinetics and Safety of Remdesivir for Treatment of COVID-19 in Pregnant and Non-Pregnant Women in the United States	US	Closed to Follow-up*	COVID-19	03-Aug-20	12-Feb-21	31-Mar-21	29-Dec-21	13-Apr-22	56	54
P1112	Open-Label, Dose-Escalating, Phase I Study to Determine Safety and Pharmacokinetic Parameters of Subcutaneous (SC) VRC01, VRC01LS, and VRC07-523LS, Potent Anti-HIV Neutralizing Monoclonal Antibodies, in HIV-1-Exposed Infants	US/INTL	Closed to Follow-up*	Prevention	22-Aug-14	21-Apr-15	30-Jun-15	24-Feb-20	16-Dec-21	79 pairs	83 pairs

TBD = information is to be added once timeline is clearer
 Grey text boxes indicates a projected (rather than actual) date

Based on data available through 26 July 2022
 Page 2 of 3

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 2019	Phase I/II Study of the Pharmacokinetics, Safety, and Tolerability of Abacavir/Dolutegravir/Lamivudine Dispersible and Immediate Release Tablets in HIV-1-Infected Children Less than 12 Years of Age	US/INTL	POS/PAC*	Treatment	08-Oct-18	20-Jul-20	09-Sep-20	28-Jun-21	14-Jun-22	75	57
IMPAACT 2014	Phase I/II Study of the Pharmacokinetics, Safety, and Tolerability of Doravirine (MK-1439) and Doravirine/Lamivudine/Tenofovir Disoproxil Fumarate (MK-1439A) in HIV-1 infected Children and Adolescents	US/INTL	POS/PAC*	Treatment	19-Oct-17	21-Mar-18	02-Jul-18	26-Feb-20	25-May-22	65	55
			* last 8 months								
Research Area:			Complications	2021, 2016							
			Cure	2039, 2028, P1115, P1107							
			Prevention	2009, P1112							
			Treatment	2040, 2037, 2036, 2026, 2023, 2019, 2017, 2014, P1093							
			Tuberculosis	2035/HVTN 604, 2034, 2024, 2005, 2003b/A5300b, P1108							
			COVID-19	2032							

TBD = information is to be added once timeline is clearer
 Grey text boxes indicates a projected (rather than actual) date

Based on data available through 26 July 2022
 Page 3 of 3