

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 2036	Phase I/II Study of the Safety, Tolerability, Pharmacokinetics, and antiviral activity of Oral and Long-Acting Injectable Cabotegravir and Rilpivirine in Virologically Suppressed HIV-Infected Children > 2 years of age and weighing > 10 kgs and < 50 kgs	TBD	In Development	Treatment	TBD	TBD	TBD	TBD	TBD	60	NA
IMPAACT 2035/ HVTN 604	Phase I/II Study of the Safety and Immunogenicity of VPM1002 Vaccination and BCG Re-Vaccination against Tuberculosis in South African Pre-Adolescents Living with and without HIV	TBD	In Development	Tuberculosis	01-Nov-21	01-Feb-22	01-Apr-22	01-Apr-24	01-Apr-25	480	NA
IMPAACT 2034	An Open-Label, Single-Dose Study to Assess the Pharmacokinetics, Safety and Acceptability of Pretomanid in Children with Multidrug-Resistant or Extensively Drug-Resistant Tuberculosis (MDR-TB or XDR-TB)	TBD	In Development	Tuberculosis	TBD	TBD	TBD	TBD	TBD	TBD	NA
IMPAACT 2029	Phase I/II Study of Switching to Fixed Dose Combination Dolutegravir/Rilpivirine among Virologically Suppressed Children and Adolescents Living with HIV	US/INTL	In Development	Treatment	14-Apr-21	15-Jun-21	15-Jul-21	15-Jul-22	15-Jan-24	40	NA
IMPAACT 2025	Safety, Tolerability, and Pharmacokinetics of One Month of Daily versus Three Months of Weekly Isoniazid and Rifapentine in HIV-Infected Pregnant and Postpartum Women	TBD	In Development	Tuberculosis	TBD	TBD	TBD	TBD	TBD	TBD	NA
IMPAACT 2024	Phase I/II Dose Finding and Safety Study of Daily Rifapentine Combined with Isoniazid (1HP) for Tuberculosis Prevention in Infants, Children and Adolescents	TBD	In Development	Tuberculosis	TBD	TBD	TBD	TBD	TBD	TBD	NA
IMPAACT 2023	A Phase I Trial of the Safety, Tolerability, and Pharmacokinetics of Dolutegravir in Neonates Exposed to HIV-1	US/INTL	In Development	Treatment	14-May-21	14-Jul-21	13-Aug-21	13-Aug-23	14-Dec-23	108	NA
IMPAACT 2022	Phase II Study of the Virologic Efficacy and Feasibility of Long Acting Injectable Antiretroviral Medications in Non-Adherent Youth with HIV	TBD	In Development	Treatment	TBD	TBD	TBD	TBD	TBD	70	NA
IMPAACT 2020	A Phase II Study of Shortened Oral Treatment for Multidrug-Resistant Tuberculosis in Children (SMaRT Kids)	INTL	In Development	Tuberculosis	TBD	TBD	TBD	TBD	TBD	169 children and 169 caregivers	NA
IMPAACT 2028	Long-Term Clinical, Immunologic, and Virologic Profiles of Children who Received Early Treatment for HIV Infection	US/INTL	Pending	Cure	31-Dec-20	12 – 23 Apr 2021	14-Jun-21	30-Nov-26	30-Nov-27	250	NA
IMPAACT 2026	Pharmacokinetic Properties of Antiretroviral and Anti-Tuberculosis Drugs during Pregnancy and Postpartum	US/INTL	Pending	Treatment	04-Feb-20	30-Apr-21	15-May-21	30-Apr-26	30-Apr-26	325	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 2032	Pharmacokinetics and Safety of Remdesivir for Treatment of COVID-19 in Pregnant and Non-Pregnant Women in the United States	US	Enrolling	COVID-19	03-Aug-20	12-Feb-21	31-Mar-21	01-Sep-21	01-Sep-22	40	1

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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	Enrolling	Treatment	08-Oct-18	20-Jul-20	09-Sep-20	09-Sep-21	09-Sep-24	75	49
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/I1314L, 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	160	30
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	20-Oct-23	20-Oct-25	3452 (household); 1726 (index)	554 (household); 342 (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-Dec-22	31-Jul-25	155	32
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	31-Aug-22	31-Aug-23	390	40 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 HIV-infected & HIV-uninfected Children with MDR-TB	INTL	Enrolling	Tuberculosis	21-Mar-17	30-Jan-18	18-Feb-19	31-Oct-24	31-Oct-26	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-Sep-22	30-Sep-24	72	27
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	498 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	31-Oct-21	25	2
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 Accrual	Prevention	22-Aug-14	21-Apr-15	30-Jun-15	24-Feb-20	28-Feb-22	79 pairs	83 pairs

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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 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	Closed to Accrual	Treatment	19-Oct-17	21-Mar-18	02-Jul-18	26-Feb-20	29-Dec-21	65	55
P1102/START	Strategic Timing of Antiretroviral Treatment (START)	US	Closed to Accrual	Treatment	12-Dec-08	20-Jul-11	22-Sep-11	23-Dec-13	31-Dec-21	4685	4561
IMPAACT 2008	Phase I/II Multisite Randomized Controlled Study of Monoclonal Antibody VCR01 with Combination Antiretroviral Therapy to Promote Clearance of HIV-1-Infected Cells in Infants	US/INTL	Closed to Follow-up*	Cure	09-Nov-16	08-May-18	06-Aug-18	11-Mar-20	11-Feb-21	68 pairs	61 infants and 58 mothers
IMPAACT 2010	Phase III Study of the Virologic Efficacy and Safety of Dolutegravir-Containing versus Efavirenz-Containing Antiretroviral Therapy Regimens in HIV-1-Infected Pregnant Women and their Infants	US/INTL	Closed to Follow-up*	Treatment	13-Dec-16	12-Dec-17	19-Jan-18	08-Feb-19	02-Feb-21	639	643 pairs
P1026s	Pharmacokinetic Properties of Antiretroviral and Related Drugs During Pregnancy and Postpartum	US/INTL	Closed to Follow-up*	Treatment	NA	17-Mar-03	09-Jun-03	30-Dec-19	30-Sep-20	1300	1037 mothers and 541 infants
IMPAACT 2018	Randomized Phase I Study of the Infectivity, Safety and Immunogenicity of a Single Dose of the Recombinant Live-Attenuated Respiratory Syncytial Virus (RSV) Vaccines RSV delta NS2/delta 1313/I1314L or RSV 276 or Placebo, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age	US	POS/PAC*	Complications	03-Jul-17	04-Aug-17	22-Sep-17	14-Oct-19	01-Oct-20	80	65
P1090	A Phase I/II Open-Label Trial to Evaluation the Safety, Tolerability, Pharmacokinetics and Antiviral Activity of Etravirine in Antiretroviral Treatment-Experienced HIV-1 Infected Infants and Children, Aged ≥2 Months to <6 Years	US/INTL	POS/PAC*	Treatment	15-Nov-11	07-Mar-12 (V2); Re-opened, 06-Feb-15 (V4)	14-Mar-13	02-Oct-17	26-Aug-20	50 (V4)	26

* last 8 months

Research Area:	Complications 2021, 2018, 2016
	Cure 2028, 2008, P1115, P1107
	Prevention 2009, P1112
	Treatment 2036, 2029, 2026, 2023, 2022, 2019, 2017, 2014, 2010, P1102/START, P1093, P1090, P1026s
	Tuberculosis 2035/HVTN 604, 2034, 2025, 2024, 2020, 2005, 2003b/A5300b, P1108
	COVID-19 2032

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