

## 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 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	31-Dec-20	31-Jan-21	31-Mar-21	31-Mar-22	31-Mar-23	TBD	NA
IMPAACT 2028	Long-Term Clinical, Immunologic, and Virologic Profiles of Children who Received Early Treatment for HIV Infection	US/INTL	In Development	Cure	30-Nov-20	31-Dec-20	15-Jan-21	30-Nov-26	30-Nov-27	TBD	NA
IMPAACT 2027	Low Dose Aspirin for Prevention of Preterm Birth in Women Living With HIV	TBD	In Development	Complications	TBD	TBD	TBD	TBD	TBD	TBD	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 to Evaluate the Safety and Pharmacokinetics of Dolutegravir in Neonates Exposed to HIV-1 Infection	TBD	In Development	Treatment	31-Mar-21	14-Jul-21	13-Aug-21	13-Aug-23	14-Dec-23	72	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	Shortened Oral Treatment for Multidrug-Resistant Tuberculosis in Children (SMaRT Kids)	INTL	In Development	Tuberculosis	31-Jan-21	31-Jul-21	31-Aug-21	28-Feb-24	31-Dec-25	169 children and 169 caregivers	NA
IMPAACT 2032	Pharmacokinetics and Safety of Remdesivir for Treatment of COVID-19 in Pregnant and Non-Pregnant Women in the United States	US	Pending	COVID-19	03-Aug-20	01-Oct-20	01-Oct-20	01-Apr-21	01-Apr-22	40	NA
IMPAACT 2026	Pharmacokinetic Properties of Antiretroviral and Anti-Tuberculosis Drugs during Pregnancy and Postpartum	US/INTL	Pending	Treatment	04-Feb-20	TBD	TBD	TBD	TBD	650	NA
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	Open to Accrual	Treatment	08-Oct-18	20-Jul-20	01-Sep-20	31-Aug-21	31-Aug-24	75	NA
IMPAACT 2016	Evaluating a Group-Based Intervention to Improve Mental Health & ART Adherence in HIV-Infected Adolescents in Low Resource Settings	INTL	Open to Accrual	Complications	08-Nov-18	27-Nov-19	TBD	TBD	TBD	256	0
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-21	30-Apr-22	160	30

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<b>IMPAACT 2003b/A5300b</b>	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	13-Jun-23	13-Aug-25	3452 (household); 1726 (index)	324 (household); 216 (index)
<b>IMPAACT 2017</b>	Phase I/II Study of Safety & PK of Oral & Long-acting Injectable Cabotegravir & Long-acting Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents	US/INTL	Enrolling	Treatment	16-Mar-18	19-Mar-19	03-Apr-19	31-Mar-22	30-Mar-25	155	32
<b>IMPAACT 2009</b>	Pharmacokinetics, Feasibility, Acceptability, & Safety of Oral Pre-Exposure Prophylaxis for Primary HIV Prevention during Pregnancy & Postpartum in Adolescents & Young Women	INTL	Enrolling	Prevention	02-Nov-17	09-Jul-18	04-Mar-19	28-Feb-22	28-Feb-23	390	40 pairs
<b>IMPAACT 2005</b>	Phase I/II Open-label, Single-Arm Study to Evaluate 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-Jan-22	31-Jan-24	48	4
<b>P1108</b>	Phase I/II, Open-Label, Single Arm Study to Evaluate 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	16
<b>P1112</b>	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	Enrolling	Prevention	22-Aug-14	21-Apr-15	30-Jun-15	24-Feb-20 (existing dose groups)	28-Feb-22	79 pairs	83 pairs
<b>P1107</b>	Cord Blood Transplantation Using CCR5 delta 32 Donor Cells in HIV-1 Infected Subjects who Require Bone Marrow Transplantation for any Indication & Its Observed Effects on HIV-1 Persistence	US	Enrolling	Cure	08-Aug-13	04-Mar-14	05-Feb-15	30-Sep-20	30-Sep-22	25	2
<b>P1115</b>	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-22	31-Dec-31	905 pairs	461 pairs
<b>IMPAACT 2008</b>	Phase I/II Multisite Randomized Controlled Study of Monoclonal Antibody VCR01 Combined with ART to Promote Clearance of HIV-1 Infected Cells in Infants	US/INTL	Closed to Accrual	Cure	09-Nov-16	08-May-18	06-Aug-18	11-Mar-20	12-Mar-21	68 pairs	61 infants and 58 mothers
<b>P1093</b>	Phase I/II, Multi-Center, Open-Label Pharmacokinetic, Safety, Tolerability & Antiviral Activity of Dolutegravir, a Novel Integrase Inhibitor, in Combination Regimens in HIV-1 Infected Infants, Children & Adolescents	US/INTL	Closed to Accrual	Treatment	21-Dec-10	14-Mar-11	20-Apr-11	19-Feb-20	19-Feb-24	300	181
<b>IMPAACT 2014</b>	Phase I/II Trial of PK, Safety, & Tolerability of Doravirine & Doravirine/3TC/TDF in HIV-1-Infected Children & Adolescents	US/INTL	Closed to Accrual	Treatment	19-Oct-17	21-Mar-18	02-Jul-18	26-Feb-20	29-Dec-21	65	55

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P1026s	PK Properties of ARV & Related Drugs During Pregnancy & Postpartum	US/INTL	Closed to Accrual	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 deltaNS2/delta1313/I1314L or RSV 276 or Placebo, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age	US	Closed to Accrual	Complications	03-Jul-17	04-Aug-17	22-Sep-17	14-Oct-19	30-Sep-20	80	65	
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 Accrual	Treatment	13-Dec-16	12-Dec-17	19-Jan-18	08-Feb-19	30-Sep-20	639	643 pairs	
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 2015	Evaluating the HIV Reservoir in the CNS in Perinatally-infected Individuals on ART	US	Closed to Follow-up*	Cure	02-Oct-17	17-May-18	06-Feb-19	28-Feb-20	26-Mar-20	45	24	
P1106	PK Characteristics of ARVs & TB Medications in Low Birth Weight Infants	INTL	Closed to Follow-up*	Treatment	13-May-13	23-Jul-15	04-Aug-15	06-Sep-19	14-Feb-20	158	124	
IMPAACT 2002	Combined Cognitive Behavioral Therapy & Medication Management Algorithm for Treatment of Depression among Youth Living with HIV in the US	US	Closed to Follow-up*	Complications	24-Aug-16	20-Dec-16	06-Mar-17	05-Mar-19	04-Feb-20	156	156	
P1090	Phase II/III Open-Label Trial to Evaluate the Safety, Tolerability, PK & Antiviral Activity of ETR in ARV Treatment-Experienced HIV-1 Infected Infants & 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									
<b>Research Area:</b>			<b>Complications</b>	2027, 2021, 2018, 2016, 2002								
			<b>Cure</b>	2028, 2015, 2008, P1115, P1107								
			<b>Prevention</b>	2009, P1112								
			<b>Treatment</b>	2029, 2026, 2023, 2022, 2019, 2017, 2014, 2010, P1106, P1102/START, P1093, P1090, P1026s								
			<b>Tuberculosis</b>	2025, 2024, 2020, 2005, 2003b/A5300b, P1108								
			<b>COVID-19</b>	2032								

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