

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)	POS/PAC (Projected)	Target Accrual	Actual Accrual as of report date
IMPAACT 2050	Phase IV Study of the Pharmacokinetics and Safety of Long-acting Injectable Cabotegravir and Rilpivirine in Pregnant and Postpartum Adults with HIV-1 (CREATE)	TBD	In Development	Therapeutics	1-Sep-25	01-Dec-25	TBD	TBD	TBD	TBD	TBD	NA
IMPAACT 2049	Phase I Phase IIA Randomized, Placebo-Controlled Study of the Safety and Immunogenicity of ID93/GLA-SE in Individuals Ages 9-14 Years Living with and without HIV (LEAP)	TBD	In Development	Tuberculosis	TBD	TBD	TBD	TBD	TBD	TBD	160	NA
IMPAACT 2048	Phase I Study of the Safety and Pharmacokinetics of VRC07-523LS, ePGT121v1-LS, and PDGM1400LS Alone and in Combination in Breastfeeding Infants	TBD	In Development	Therapeutics	TBD	TBD	TBD	TBD	TBD	TBD	92 pairs	NA
IMPAACT 2047	Pharmacokinetics, Safety and Tolerability of High Dose Rifapentine Given With Moxifloxacin for Tuberculosis During Pregnancy (Radiant-Moms Plus)	TBD	In Development	Tuberculosis	TBD	TBD	TBD	TBD	TBD	TBD	302	NA
IMPAACT 2046	Understanding Practices of Lactation and Infant Feeding Together with Women with HIV in the United States (UPLIFT)	US	In Development	Brain & Mental Health	31-Jul-25	31-Sep-25	14-Oct-25	30-Sep-28	30-Sep-29	30-Sep-30	650	NA
IMPAACT 2044	Phase IV Study of the Pharmacokinetics and Safety of Ceftriaxone and Benzathine Penicillin G During Pregnancy	US	In Development	Therapeutics	31-Aug-25	30-Nov-25	15-Jan-26	31-Jul-26	30-Apr-27	30-Apr-27	58	NA
IMPAACT 2020	Phase II Study of Shortened Oral Treatment for Rifampicin-Resistant Tuberculosis in Children	TBD	In Development	Tuberculosis	TBD	TBD	TBD	TBD	TBD	TBD	112 children and their caregivers	NA
IMPAACT 2039A	Phase I Study of the Safety and Immunogenicity of HIVconvX Vaccines and the Safety and Pharmacokinetics of Broadly Neutralizing Antibodies in Children Living with HIV	US/INTL	In Development	Cure & Immunotherapy	07-Aug-25	TBD	TBD	TBD	TBD	TBD	Up to 46	NA
IMPAACT 2041	Phase I/II Study of the Pharmacokinetics and Safety of Glecaprevir/Pibrentasvir Initiated in Pregnancy in Women with Hepatitis C with and without HIV	US	Pending	Therapeutics	29-Apr-25	18-Aug-25	17-Sep-25	17-Sep-26	15-May-27	20-Nov-27	30 pairs	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	INTL	Pending	Tuberculosis	25-Mar-25	31-Aug-25	30-Dec-25	30-Dec-27	30-Jun-28	30-Aug-28	90	NA
IMPAACT 2037	Open Label, Phase I 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	Pending	Therapeutics	09-Dec-24	15-Jul-25	14-Aug-25	14-Aug-26	16-Jun-28	16-Jun-28	48	NA
IMPAACT 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 (Tatelo Plus)	INTL	Enrolling	Cure & Immunotherapy	09-May-24	23-Oct-24	11-Nov-24	01-Jul-25	05-Nov-27	21-Apr-28	approx 41	12
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 (CRAYON)	US/INTL	Enrolling	Therapeutics	04-Oct-22	12-Dec-23	24-Jan-24	30-Jun-26	30-Jun-28	30-Jun-28	90	61

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IMPAACT Protocols Snapshot: In Development through Closed to Follow Up

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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	Enrolling	Tuberculosis	04-Aug-22	17-Feb-23	03-Oct-23	01-Jan-26	15-Jan-26	09-Jul-26	72	28
P1115	Very Early Intensive Treatment of Infants Living with HIV to Achieve HIV Remission: A Phase I/II Proof of Concept Study	US/INTL	Enrolling	Cure & Immunotherapy	20-Mar-14	24-Jun-14	23-Jan-15	31-Dec-26	31-Dec-35	07-Jul-36	905 pairs	908 pairs
IMPAACT 2028	Long-Term Clinical, Immunologic, and Virologic Profiles of Children who Received Early Treatment for HIV Infection	US/INTL	Closed to Accrual	Cure & Immunotherapy	31-Dec-20	08-Nov-21	02-Feb-22	08-Apr-25	30-Jun-25	30-Jun-25	250	163
IMPAACT 2026	Pharmacokinetic Properties of Antiretroviral and Anti-Tuberculosis Drugs during Pregnancy and Postpartum	US/INTL	Closed to Accrual	Therapeutics	04-Feb-20	08-Jun-21	01-Sep-21	28-Nov-24	31-Jul-25	05-Feb-26	325	102 pairs
IMPAACT 2003b/A5300b	Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Patients ("PHOENIX MDR-TB")	INTL	Closed to Accrual	Tuberculosis	2-Oct-18 (V2)	03-Jun-19	13-Jun-19	06-Feb-25	11-Jan-27	19-Jul-27	3557 (household); 1830 (index)	3905 (household); 1927 (index)
IMPAACT 2016	Evaluating a Group-Based Intervention to Improve Mental Health and ART Adherence Among Youth Living with HIV in Low Resource Settings	INTL	Closed to Follow-up*	Brain & Mental Health	08-Nov-18	27-Nov-19	11-Nov-23	03-Oct-24	02-Jun-25	30-Jul-25	256 pairs (randomized trial)	254 youth, 230 caregivers (randomized trial)
IMPAACT 2005	A Phase I/II Open-Label, Single-Arm Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Delamanid in Combination with Optimized Multidrug Background Regimen (OBR) for Multidrug-Resistant Tuberculosis (MDR-TB) in Children with MDR-TB with and without HIV	INTL	Closed to Follow-up*	Tuberculosis	21-Mar-17	30-Jan-18	18-Feb-19	08-Nov-24	29-May-25	31-Oct-25	48	37
IMPAACT 2023	A Phase I Study of the Safety, Tolerability, and Pharmacokinetics of Dolutegravir in Neonates Exposed to HIV-1	US/INTL	Closed to Follow-up*	Therapeutics	25-Oct-21	26-Sep-22	05-Oct-22	21-Jan-25	22-May-25	31-Jan-26	108	48
IMPAACT 2017	Phase I/II Study of the 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)	US/INTL	POS/PAC*	Therapeutics	16-Mar-18	19-Mar-19	03-Apr-19	03-Aug-23	22-Apr-25	22-Apr-25	155	155
P1108	A Phase I/II, Open-Label, Single Arm Study to Evaluate the Pharmacokinetics, Safety and Tolerability of Bedaquiline (BDQ) Given in Combination with Individualized Rifampin-Resistant Tuberculosis (RR-TB) Therapy in Infants, Children, and Adolescents with RR-TB Disease, Living with or without HIV	INTL	POS/PAC*	Tuberculosis	09-Mar-16	18-Aug-17	21-Sep-17	25-Aug-23	02-Apr-25	02-Apr-25	54	54

* last 8 months

Research Area: Brain & Mental Health Cure & Immunotherapy Therapeutics Tuberculosis	2046, 2016 2042, 2039A, 2028, P1115 2050, 2048, 2044, 2041, 2037, 2036, 2026, 2023, 2017 2049, 2047, 2034, 2024, 2020, 2005, 2003b/A5300b, P1108
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