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 2053	Long-Acting Injectable Cabotegravir as Postnatal Prophylaxis During Breastfeeding: Safety, Tolerability, and Model Development for Implementation	TBD	In Development	Therapeutics	*TBD*	*TBD*	*TBD*	*TBD*	*TBD*	*TBD*	TBD	NA
IMPAACT 2052	Phase I Study of the Safety and Pharmacokinetics of an AAV-Vectored Broadly Neutralizing Antibody in Infants Living with HIV	TBD	In Development	Cure & Immunotherapy	*TBD*	*TBD*	*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 (Paused)	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 (Paused)	Therapeutics	*TBD*	*TBD*	*TBD*	*TBD*	*TBD*	*TBD*	92 pairs	NA
IMPAACT 2047	Phase II, Randomized Study of the Pharmacokinetics, Safety, and Tolerability of High Dose Rifapentine given with Moxifloxacin for Tuberculosis during Pregnancy	TBD	In Development	Tuberculosis	*01-Dec-27*	*TBD*	*TBD*	*TBD*	*TBD*	*TBD*	302	NA
IMPAACT 2051	Phase II Study of the Pharmacokinetics, Safety, Tolerability, and Anti-Mycobacterial Activity of Pretomanid with Bedaquiline and Linezolid, with or without Moxifloxacin, in Children with Rifampicin-Resistant Tuberculosis	INTL	Pending	Tuberculosis	16-Oct-26	*30-Jun-27*	*1-Oct-27*	*24-Mar-29*	*15-Sep-30*	*15-Sep-30*	50	NA
IMPAACT 2050	Phase IV Study of the Pharmacokinetics of Long-Acting Injectable Cabotegravir and Rilpivirine in Pregnant and Postpartum Women with HIV in the United States (CREATE)	US	Enrolling	Therapeutics	01-May-26	10-Sep-26	1-Oct-26	*28-Jun-27*	*23-Apr-28*	*20-Oct-28*	40 pairs	1
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	Enrolling	Tuberculosis	25-Mar-25	27-Jan-26	28-Sep-26	*30-Nov-27*	*30-May-28*	*30-May-29*	90	26
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	Enrolling	Therapeutics	29-Apr-25	13-Aug-25	25-Jun-26	*30-Nov-27*	*08-Aug-28*	*04-Feb-29*	30 pairs	1
IMPAACT 2046	Understanding Practices of Lactation and Infant Feeding Together with Women with HIV in the United States (UPLIFT)	US	Enrolling	Brain & Mental Health	06-Nov-25	16-Feb-26	24-Feb-26	*24-Apr-29*	*24-Apr-30*	*24-Apr-31*	650	108 (Core Activity 1) 19 pairs (Core Activity 2) 2 (Core Activity 3)
IMPAACT 2044	Phase IV Study of the Pharmacokinetics and Safety of Ceftriaxone and Benzathine Penicillin G During Pregnancy	US	Enrolling	Therapeutics	20-Aug-25	15-Dec-25	16-Feb-26	*31-Dec-26*	*30-Sep-27*	*30-Sep-27*	Up to 78 mothers and ~22 infants	18
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	Enrolling	Therapeutics	09-Dec-24	12-Aug-25	05-Jan-26	*05-Jul-27*	*05-Jul-28*	*05-Jul-28*	48	9

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

Based on data available through 27 October 2026

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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	*31-Jul-27*	*29-Feb-28*	*29-Feb-28*	90	70 (Cohort 1) 20 (Cohort 2)
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-Mar-27*	*30-Mar-36*	*05-Oct-36*	1120 pairs	1084 pairs
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	Closed to Accrual	Cure & Immunotherapy	09-May-24	23-Oct-24	11-Nov-24	17-Aug-26	*17-Dec-27*	*17-May-28*	41	31
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 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	POS/PAC*	Tuberculosis	04-Aug-22	17-Feb-23	03-Oct-23	14-Apr-26	28-Apr-26	14-Aug-26	72	32

* last 8 months

Research Area:		
	Brain & Mental Health	2046
	Cure & Immunotherapy	2052, 2042, P1115
	Therapeutics	2053, 2050, 2048, 2044, 2041, 2037, 2036
	Tuberculosis	2051, 2049, 2047, 2034, 2024, 2003b/A5300b

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