

## 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 2044	Phase IV Study of the Pharmacokinetics and Safety of Ceftriaxone and Benzathine Penicillin G During Pregnancy	TBD	In Development	Therapeutics	31-May-25	TBD	TBD	TBD	TBD	TBD	NA
IMPAACT 2043/A5425	Postpartum Long-Acting Cabotegravir/rilpivirine (PRACTICAL) A Randomized Study of Long-Acting ART in Postpartum Women at Risk for Adherence Challenges	US/INTL	In Development	Therapeutics	TBD (see ACTG)	TBD	TBD	TBD	TBD	544 pairs	NA
IMPAACT 2020	Phase II Study of Shortened Oral Treatment for Rifampicin-Resistant Tuberculosis in Children	INTL	In Development	Tuberculosis	31-Jan-25	30-Jun-25	31-Aug-25	31-Aug-27	31-Aug-28	112 children and their caregivers	NA
IMPAACT 2041	Phase I/II Study of the Pharmacokinetics and Safety of Glecaprevir/Pibrentasvir Initiated During Pregnancy in People with Hepatitis C with or without HIV	US	In Development	Therapeutics	31-Aug-24	29-Nov-24	29-Dec-24	29-Dec-25	26-Aug-26	30 pairs	NA
IMPAACT 2039	Phase I/II Study of the Safety, Immunogenicity, Efficacy of HIVconsvX Vaccines in Children Living with HIV	US/INTL	In Development	Cure & Immunotherapy	31-May-25	29-Aug-25	27-Nov-25	TBD	TBD	42 (Part A); 40 (Part B)	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	In Development	Tuberculosis	TBD	TBD	TBD	TBD	TBD	TBD	NA
IMPAACT 2037	Phase I Open Label 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	13-Jun-24	01-Nov-24	30-Nov-24	01-Nov-25	01-Nov-27	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	INTL	Pending	Cure & Immunotherapy	09-May-24	30-Sep-24	31-Oct-24	31-Mar-25	19-Jul-27	approx 41	NA
IMPAACT 2040	Phase I/II Study of the Pharmacokinetics and Safety of Long-Acting Injectable Cabotegravir and Rilpivirine in Virologically Suppressed People with HIV During Pregnancy and Postpartum	US/INTL	Pending	Therapeutics	16-Feb-24	27-Feb-25	27-Mar-25	20-Jun-26	15-Jun-27	45 pairs	NA
IMPAACT 2035/HVTN 604	Phase I/II Randomized, Placebo-Controlled Study of the Safety and Immunogenicity of VPM1002 Vaccination or BCG Revaccination against Tuberculosis in Pre-Adolescents Living with and without HIV in South Africa	INTL	Pending	Tuberculosis	13-Jul-22	TBD	TBD	TBD	TBD	480	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	Enrolling	Therapeutics	04-Oct-22	12-Dec-23	24-Jan-24	27-Jul-25	27-Jul-27	90	32
IMPAACT 2016	Evaluating a Group-Based Intervention to Improve Mental Health and ART Adherence Among Youth Living with HIV in Low Resource Settings	INTL	Enrolling	Brain & Mental Health	08-Nov-18	27-Nov-19	11-Nov-23	30-Nov-24	30-Nov-25	256 pairs (randomized trial)	151 youth, 84 caregivers (randomized trial)

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Based on data available through 25 June 2024  
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<b>IMPAACT 2034</b>	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	72	18
<b>IMPAACT 2023</b>	A Phase I Study of the Safety, Tolerability, and Pharmacokinetics of Dolutegravir in Neonates Exposed to HIV-1	US/INTL	Enrolling	Therapeutics	25-Oct-21	26-Sep-22	05-Oct-22	01-Jul-25	01-Nov-25	108	28
<b>IMPAACT 2028</b>	Long-Term Clinical, Immunologic, and Virologic Profiles of Children who Received Early Treatment for HIV Infection	US/INTL	Enrolling	Cure & Immunotherapy	31-Dec-20	08-Nov-21	02-Feb-22	30-Nov-26	30-Nov-27	250	157
<b>IMPAACT 2026</b>	Pharmacokinetic Properties of Antiretroviral and Anti-Tuberculosis Drugs during Pregnancy and Postpartum	US/INTL	Enrolling	Therapeutics	04-Feb-20	08-Jun-21	01-Sep-21	30-Apr-26	01-Sep-26	325	92 pairs
<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	31-Jul-25	30-Jul-27	3452 (household); 1726 (index)	3,238 (household); 1,679 (index)
<b>IMPAACT 2005</b>	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	30-Nov-24	02-Oct-26	48	32
<b>P1115</b>	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	30-Nov-25	30-Nov-34	905 pairs	890 pairs
<b>P1108</b>	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	Closed to Accrual	Tuberculosis	09-Mar-16	18-Aug-17	21-Sep-17	25-Aug-23	15-Aug-25	54	54
<b>IMPAACT 2017</b>	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	Closed to Accrual	Therapeutics	16-Mar-18	19-Mar-19	03-Apr-19	03-Aug-23	31-Aug-25	155	155
<b>IMPAACT 2021</b>	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/Δ1313/1314L, RSV 6120/ΔNS2/1030s, or RSV 276 or Placebo, Delivered as Nose Drops to RSV-Seronegative Children 6 to 24 Months of Age	US	Closed to Follow-up*	Cure & Immunotherapy	28-Mar-19	16-May-19	20-Jun-19	20-Nov-23	25-Apr-24	130	67
<b>IMPAACT 2009</b>	Pharmacokinetics, Feasibility, Acceptability, and Safety of Oral Pre-Exposure Prophylaxis for Primary HIV Prevention during Pregnancy and Postpartum in Adolescents and Young Women and their Infants	INTL	Closed to Follow-up*	Therapeutics	02-Nov-17	09-Jul-18	04-Mar-19	15-Dec-22	24-Feb-24	390	390 pairs

\* last 8 months

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		<b>Research Area: Brain &amp; Mental Health</b> <b>Cure &amp; Immunotherapy Therapeutics</b> <b>Tuberculosis</b>		2016 2042, 2039, 2028, 2021, P1115 2044, 2043/A5425, 2041, 2040, 2037, 2036, 2026, 2023, 2017, 2009 2035/HVTN 604, 2034, 2024, 2020, 2005, 2003b/A5300b, P1108							

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