

# 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 |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-----------------|-----------------------|-------------------------------|-----------------------------|--------------------------------------|-------------------------------|---------------------------------|---------------------|-----------------------------------|----------------------------------|
| <b>IMPAACT 2050</b>  | 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      | In Development  | Therapeutics          | 17-Nov-25                     | 15-Feb-26                   | 1-Mar-26                             | 1-Dec-26                      | 1-Oct-27                        | 01-Apr-28           | 40 pairs                          | NA                               |
| <b>IMPAACT 2049</b>  | 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                               |
| <b>IMPAACT 2048</b>  | 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                               |
| <b>IMPAACT 2047</b>  | 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                               |
| <b>IMPAACT 2046</b>  | Understanding Practices of Lactation and Infant Feeding Together with Women with HIV in the United States (UPLIFT)                                                                                                                               | US      | In Development  | Brain & Mental Health | 30-Oct-25                     | 29-Dec-25                   | 12-Jan-26                            | 11-Jan-29                     | 11-Jan-30                       | 11-Jan-31           | 650                               | NA                               |
| <b>IMPAACT 2020</b>  | 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                               |
| <b>IMPAACT 2044</b>  | Phase IV Study of the Pharmacokinetics and Safety of Ceftriaxone and Benzathine Penicillin G During Pregnancy                                                                                                                                    | US      | Pending         | Therapeutics          | 20-Aug-25                     | 30-Nov-25                   | 15-Jan-26                            | 30-Jul-26                     | 02-Apr-27                       | 02-Apr-27           | Up to 78 and ~22 infants          | NA                               |
| <b>IMPAACT 2039A</b> | Phase I Study of the Safety and Immunogenicity of HIVconsVX Vaccines and the Safety and Pharmacokinetics of Broadly Neutralizing Antibodies in Children Living with HIV                                                                          | US/INTL | Pending         | Cure & Immunotherapy  | 15-Aug-25                     | TBD                         | TBD                                  | TBD                           | TBD                             | TBD                 | Up to 46                          | NA                               |
| <b>IMPAACT 2024</b>  | 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                     | 28-Nov-25                   | 15-Mar-26                            | 15-Mar-28                     | 15-Sep-28                       | 15-Nov-28           | 90                                | NA                               |
| <b>IMPAACT 2041</b>  | 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      | Open to Accrual | Therapeutics          | 29-Apr-25                     | 13-Aug-25                   | 17-Oct-25                            | 02-Oct-26                     | 30-May-27                       | 05-Dec-27           | 30 pairs                          | NA                               |
| <b>IMPAACT 2037</b>  | 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 | Open to Accrual | Therapeutics          | 09-Dec-24                     | 12-Aug-25                   | 30-Oct-25                            | 30-Oct-26                     | 01-Sep-28                       | 01-Sep-28           | 48                                | NA                               |
| <b>IMPAACT 2042</b>  | 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                            | 30-Nov-25                     | 04-Feb-28                       | 21-Jul-28           | 30                                | 27                               |
| <b>IMPAACT 2036</b>  | 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                                | 62                               |

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 30 September 2025

# 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             |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|----------------------|-----------------------|-------------------------------|-----------------------------|--------------------------------------|-------------------------------|---------------------------------|---------------------|--------------------------------|----------------------------------------------|
| <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                       | 09-Jul-26           | 72                             | 28                                           |
| <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                            | 31-Dec-26                     | 31-Dec-35                       | 07-Jul-36           | 905 pairs                      | 930 pairs                                    |
| <b>IMPAACT 2003b/A5300b</b> | 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)               |
| <b>IMPAACT 2026</b>         | Pharmacokinetic Properties of Antiretroviral and Anti-Tuberculosis Drugs during Pregnancy and Postpartum                                                                                                                                                                                                | US/INTL | Closed to Follow-up* | Therapeutics          | 04-Feb-20                     | 08-Jun-21                   | 01-Sep-21                            | 28-Nov-24                     | 10-Jul-25                       | 31-Mar-26           | 325                            | 102 pairs                                    |
| <b>IMPAACT 2005</b>         | 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                                           |
| <b>IMPAACT 2023</b>         | 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                                           |
| <b>IMPAACT 2028</b>         | Long-Term Clinical, Immunologic, and Virologic Profiles of Children who Received Early Treatment for HIV Infection                                                                                                                                                                                      | US/INTL | Closed to Follow-up* | Cure & Immunotherapy  | 31-Dec-20                     | 08-Nov-21                   | 02-Feb-22                            | 08-Apr-25                     | 30-Jul-25                       | 26-Jan-26           | 250                            | 163                                          |
| <b>IMPAACT 2016</b>         | Evaluating a Group-Based Intervention to Improve Mental Health and ART Adherence Among Youth Living with HIV in Low Resource Settings                                                                                                                                                                   | INTL    | POS/PAC*             | Brain & Mental Health | 08-Nov-18                     | 27-Nov-19                   | 11-Nov-23                            | 03-Oct-24                     | 02-Jun-25                       | 31-Jul-25           | 256 pairs (randomized trial)   | 254 youth, 230 caregivers (randomized trial) |
| <b>IMPAACT 2017</b>         | 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                                          |
| <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    | 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** 2046, 2016  
**Cure & Immunotherapy** 2042, 2039A, 2028, P1115  
**Therapeutics** 2050, 2048, 2044, 2041, 2037, 2036, 2026, 2023, 2017  
**Tuberculosis** 2049, 2047, 2034, 2024, 2020, 2005, 2003b/A5300b, P1108

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