

## 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 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          | 31-Mar-26                     | TBD                         | TBD                                  | TBD                           | TBD                             | NA                                | 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          | 30-Nov-25                     | TBD                         | TBD                                  | TBD                           | TBD                             | TBD                               | NA                               |
| IMPAACT 2046 | Understanding Parental Lactation and Infant Feeding Decisions Tailored to People with HIV (UPLIFT)   | US      | In Development | Brain & Mental Health | 1-Jul-25                      | TBD                         | TBD                                  | TBD                           | TBD                             | TBD                               | 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                   | 31-Jan-26                            | 31-Jul-26                     | 30-Apr-27                       | 58                                | NA                               |
| IMPAACT 2020 | Phase II Study of Shortened Oral Treatment for Rifampicin-Resistant Tuberculosis in Children   | INTL    | In Development | Tuberculosis          | 30-Sep-25                     | 27-Feb-26                   | 30-Apr-26                            | 29-Apr-28                     | 30-Apr-29                       | 112 children and their caregivers | NA                               |
| IMPAACT 2039 | Phase I/II Randomized Study of the Safety, Immunogenicity, and Efficacy of HIVconsvX Vaccines and Broadly Neutralizing Antibodies in Children Living with HIV (EXCEED)   | US/INTL | In Development | Cure & Immunotherapy  | 30-Sep-25                     | 29-Dec-25                   | 29-Mar-26                            | TBD                           | TBD                             | 42 (Part A); 40 (Part B)          | NA                               |
| IMPAACT 2041 | Phase I/II Study of the Pharmacokinetics and Safety of Glecaprevir/Pibrentasvir Initiated in Pregnancy in People with Hepatitis C with or without HIV  | US      | In Development | Therapeutics          | 31-Mar-25                     | 29-Jun-25                   | 29-Jul-25                            | 29-Jul-26                     | 26-Mar-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    | In Development | Tuberculosis          | 07-Mar-25                     | 14-Jun-25                   | 14-Sep-25                            | 14-Sep-27                     | 14-Mar-28                       | 302                               | 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                     | 30-Apr-25                   | 30-Jul-25                            | 30-Jul-26                     | 30-Jul-28                       | 48                                | NA                               |
| IMPAACT 2040 | Phase I/II Study of the Pharmacokinetics and Safety of Long-Acting Injectable Cabotegravir and Rilpivirine in Pregnant and Postpartum Adults with HIV-1 (CREATE)   | US/INTL | Pending        | Therapeutics          | 16-Feb-24                     | 01-Apr-25                   | 01-May-25                            | 30-Jan-27                     | 30-Jan-28                       | 45 pairs                          | 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                            | 08-Apr-25                     | 27-Jul-27                       | 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                            | 27-Jul-25                     | 27-Jul-27                       | 90                                | 55                               |

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Based on data available through 25 February 2025  
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## 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 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                       | 72                             | 27   |
| IMPAACT 2023                                    | 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                            | 21-Jan-25 (pending review of PK & safety data) | 20-May-25                       | 108                            | 48   |
| IMPAACT 2028                                    | 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                            | 161  |
| IMPAACT 2026                                    | 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                            | 102 pairs                                    |
| 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                       | 905 pairs                      | 893 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                                      | 01-Feb-27                       | 3557 (household); 1830 (index) | 3905 (household); 1927 (index)               |
| 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 Accrual | Tuberculosis   | 21-Mar-17                     | 30-Jan-18                   | 18-Feb-19                            | 08-Nov-24                                      | 11-Sep-26                       | 48                             | 37   |
| 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 Accrual | Brain & Mental Health                                | 08-Nov-18                     | 27-Nov-19                   | 11-Nov-23                            | 03-Oct-24                                      | 03-Oct-25                       | 256 pairs (randomized trial)   | 254 youth, 230 caregivers (randomized trial) |
| 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    | Closed to Accrual | Tuberculosis   | 09-Mar-16                     | 18-Aug-17                   | 21-Sep-17                            | 25-Aug-23                                      | 20-May-25                       | 54                             | 54   |
| 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 | Closed to Accrual | Therapeutics   | 16-Mar-18                     | 19-Mar-19                   | 03-Apr-19                            | 03-Aug-23                                      | 31-Mar-25                       | 155                            | 155  |
| <b>Research Area: Brain &amp; Mental Health</b> |   |         |                   | 2046, 2016   |                               |                             |                                      |  |                                 |                                |  |
| <b>Cure &amp; Immunotherapy</b>                 |   |         |                   | 2042, 2039, 2028, P1115                              |                               |                             |                                      |  |                                 |                                |  |
| <b>Therapeutics</b>                             |   |         |                   | 2048, 2044, 2041, 2040, 2037, 2036, 2026, 2023, 2017 |                               |                             |                                      |  |                                 |                                |  |
| <b>Tuberculosis</b>                             |   |         |                   | 2047, 2034, 2024, 2020, 2005, 2003b/A5300b, P1108    |                               |                             |                                      |  |                                 |                                |  |

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