

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 2029 | Phase I/II Study of Switching to Fixed Dose Combination Dolutegravir/Rilpivirine among Virologically Suppressed Children and Adolescents Living with HIV | US/INTL | In Development | Treatment | 15-Jan-21 | 31-Mar-21 | 20-Jun-21 | 30-Jun-22 | 31-Dec-23 | 40 | NA |
| IMPAACT 2028 | Long-Term Clinical, Immunologic, and Virologic Profiles of Children who Received Early Treatment for HIV Infection | US/INTL | In Development | Cure | 15-Jan-21 | 15-Feb-21 | 15-Mar-21 | 30-Nov-26 | 30-Nov-27 | 250 | NA |
| IMPAACT 2027 | Low Dose Aspirin for Prevention of Preterm Birth in Women Living With HIV | TBD | In Development | Complications | TBD | TBD | TBD | TBD | TBD | TBD | NA |
| IMPAACT 2025 | Safety, Tolerability, and Pharmacokinetics of One Month of Daily versus Three Months of Weekly Isoniazid and Rifapentine in HIV-Infected Pregnant and Postpartum Women | TBD | In Development | Tuberculosis | TBD | TBD | TBD | TBD | TBD | TBD | NA |
| IMPAACT 2024 | Phase I/II Dose Finding and Safety Study of Daily Rifapentine Combined with Isoniazid (1HP) for Tuberculosis Prevention in Infants, Children and Adolescents | TBD | In Development | Tuberculosis | TBD | TBD | TBD | TBD | TBD | TBD | NA |
| IMPAACT 2023 | A Phase I Trial to Evaluate the Safety and Pharmacokinetics of Dolutegravir in Neonates Exposed to HIV-1 Infection | TBD | In Development | Treatment | 31-Mar-21 | 14-Jul-21 | 13-Aug-21 | 13-Aug-23 | 14-Dec-23 | 72 | NA |
| IMPAACT 2022 | Phase II Study of the Virologic Efficacy and Feasibility of Long Acting Injectable Antiretroviral Medications in Non-Adherent Youth with HIV | TBD | In Development | Treatment | TBD | TBD | TBD | TBD | TBD | 70 | NA |
| IMPAACT 2020 | A Phase II Study of Shortened Oral Treatment for Multidrug-Resistant Tuberculosis in Children (SMaRT Kids) | INTL | In Development | Tuberculosis | 28-Feb-21 | 28-Aug-21 | 28-Sep-21 | 27-Mar-24 | 28-Jan-26 | 169 children and 169 caregivers | NA |
| IMPAACT 2032 | Pharmacokinetics and Safety of Remdesivir for Treatment of COVID-19 in Pregnant and Non-Pregnant Women in the United States | US | Pending | COVID-19 | 03-Aug-20 | 15-Oct-20 | 15-Oct-20 | 01-Apr-21 | 01-Apr-22 | 40 | NA |
| IMPAACT 2026 | Pharmacokinetic Properties of Antiretroviral and Anti-Tuberculosis Drugs during Pregnancy and Postpartum | US/INTL | Pending | Treatment | 04-Feb-20 | TBD | TBD | TBD | TBD | 650 | NA |
| IMPAACT 2016 | Evaluating a Group-Based Intervention to Improve Mental Health and ART Adherence Among Youth Living with HIV in Low Resource Settings | INTL | Open to Accrual | Complications | 08-Nov-18 | 27-Nov-19 | TBD | TBD | TBD | 256 | 0 |
| IMPAACT 2019 | Phase I/II Study of the Pharmacokinetics, Safety, and Tolerability of Abacavir/Dolutegravir/Lamivudine Dispersible and Immediate Release Tablets in HIV-1-Infected Children Less than 12 Years of Age | US/INTL | Enrolling | Treatment | 08-Oct-18 | 20-Jul-20 | 09-Sep-20 | 09-Sep-21 | 09-Sep-24 | 75 | 3 |
| IMPAACT 2021 | 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/Δ1313/11314L, RSV 6120/ΔNS2/1030s, or RSV 276 or Placebo, Delivered as Nose Drops to RSV-Seronegative Children 6 to 24 Months of Age | US | Enrolling | Complications | 28-Mar-19 | 16-May-19 | 20-Jun-19 | 14-Oct-21 | 30-Apr-22 | 160 | 30 |

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| IMPAACT 2003b/A5300b | 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 | 28-Aug-23 | 27-Aug-25 | 3452 (household); 1726 (index) | 391 (household); 247 (index) |
| IMPAACT 2017 | Phase I/II Study of Safety and Pharmacokinetics of Oral & Long-acting Injectable Cabotegravir and Long-acting Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents | US/INTL | Enrolling | Treatment | 16-Mar-18 | 19-Mar-19 | 03-Apr-19 | 31-Mar-22 | 30-Mar-25 | 155 | 33 |
| IMPAACT 2009 | Pharmacokinetics, Feasibility, Acceptability, & Safety of Oral Pre-Exposure Prophylaxis for Primary HIV Prevention during Pregnancy & Postpartum in Adolescents & Young Women & their Infants | INTL | Enrolling | Prevention | 02-Nov-17 | 09-Jul-18 | 04-Mar-19 | 28-Feb-22 | 28-Feb-23 | 390 | 40 pairs |
| IMPAACT 2005 | A Phase I/II Open-label, Single-Arm Study to Evaluate PK, Safety, & Tolerability of Delamanid in Combination with OBR for MDR-TB in HIV-infected & HIV-uninfected Children with MDR-TB | INTL | Enrolling | Tuberculosis | 21-Mar-17 | 30-Jan-18 | 18-Feb-19 | 31-Jan-22 | 31-Jan-24 | 48 | 4 |
| P1108 | Phase I/II, Open-Label, Single Arm Study to Evaluate PK, Safety, & Tolerability of Bedaquiline in Combination with Optimized Individualized MDR-TB Therapy in HIV-infected & HIV-uninfected Infants, Children & Adolescents with MDR-TB Disease | INTL | Enrolling | Tuberculosis | 09-Mar-16 | 18-Aug-17 | 21-Sep-17 | 30-Sep-22 | 30-Sep-24 | 72 | 16 |
| P1107 | Cord Blood Transplantation with CCR5Δ32 Donor Cells in HIV-1 Infected Subjects who Require Bone Marrow Transplantation for any Indication and Its Observed Effects on HIV-1 Persistence | US | Enrolling | Cure | 08-Aug-13 | 04-Mar-14 | 05-Feb-15 | 31-Oct-20 | 31-Oct-22 | 25 | 2 |
| P1115 | Very Early Intensive Treatment of HIV-Infected Infants to Achieve HIV Remission: A Phase I/II Proof of Concept Study | US/INTL | Enrolling | Cure | 20-Mar-14 | 24-Jun-14 | 23-Jan-15 | 31-Dec-23 | 30-Dec-32 | 905 pairs | 461 pairs |
| P1112 | Open-Label, Dose-Escalating, Phase I Study to Determine Safety and Pharmacokinetic Parameters of Subcutaneous (SC) VRC01, VRC01LS, and VRC07-523LS, Potent Anti-HIV Neutralizing Monoclonal Antibodies, in HIV-1-Exposed Infants | US/INTL | Closed to Accrual | Prevention | 22-Aug-14 | 21-Apr-15 | 30-Jun-15 | 24-Feb-20 | 28-Feb-22 | 79 pairs | 83 pairs |
| IMPAACT 2008 | Phase I/II Multisite Randomized Controlled Study of Monoclonal Antibody VCR01 with Combination Antiretroviral Therapy to Promote Clearance of HIV-1-Infected Cells in Infants | US/INTL | Closed to Accrual | Cure | 09-Nov-16 | 08-May-18 | 06-Aug-18 | 11-Mar-20 | 12-Mar-21 | 68 pairs | 61 infants and 58 mothers |
| P1093 | Phase I/II, Multi-Center, Open-Label Pharmacokinetic, Safety, Tolerability and Antiviral Activity of Dolutegravir, a Novel Integrase Inhibitor, in Combination Regimens in HIV-1 Infected Infants, Children and Adolescents | US/INTL | Closed to Accrual | Treatment | 21-Dec-10 | 14-Mar-11 | 20-Apr-11 | 19-Feb-20 | 19-Feb-24 | 300 | 181 |
| IMPAACT 2014 | Phase I/II Study of the Pharmacokinetics, Safety, and Tolerability of Doravirine (MK-1439) and Doravirine/Lamivudine/Tenofovir Disoproxil Fumarate (MK-1439A) in HIV-1 infected Children and Adolescents | US/INTL | Closed to Accrual | Treatment | 19-Oct-17 | 21-Mar-18 | 02-Jul-18 | 26-Feb-20 | 29-Dec-21 | 65 | 55 |
| P1026s | Pharmacokinetic Properties of Antiretroviral and Related Drugs During Pregnancy and Postpartum | US/INTL | Closed to Accrual | Treatment | NA | 17-Mar-03 | 09-Jun-03 | 30-Dec-19 | 30-Sep-20 | 1300 | 1037 mothers and 541 infants |

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| IMPAACT 2018 | Randomized Phase I Study of the Infectivity, Safety and Immunogenicity of a Single Dose of the Recombinant Live-Attenuated Respiratory Syncytial Virus (RSV) Vaccines RSV delta NS2/delta 1313/11314L or RSV 276 or Placebo, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age | US | Closed to Accrual | Complications | 03-Jul-17 | 04-Aug-17 | 22-Sep-17 | 14-Oct-19 | 30-Sep-20 | 80 | 65 |
| IMPAACT 2010 | Phase III Study of the Virologic Efficacy and Safety of Dolutegravir-Containing versus Efavirenz-Containing Antiretroviral Therapy Regimens in HIV-1-Infected Pregnant Women and their Infants | US/INTL | Closed to Accrual | Treatment | 13-Dec-16 | 12-Dec-17 | 19-Jan-18 | 08-Feb-19 | 31-Oct-20 | 639 | 643 pairs |
| P1102/START | Strategic Timing of Antiretroviral Treatment (START) | US | Closed to Accrual | Treatment | 12-Dec-08 | 20-Jul-11 | 22-Sep-11 | 23-Dec-13 | 31-Dec-21 | 4685 | 4561 |
| IMPAACT 2015 | Evaluation of the HIV-1 Reservoir in the Central Nervous System of Perinatally-Infected Youth and Young Adults with Cognitive Impairment | US | Closed to Follow-up* | Cure | 02-Oct-17 | 17-May-18 | 06-Feb-19 | 28-Feb-20 | 26-Mar-20 | 45 | 24 |
| P1106 | Pharmacokinetic Characteristics of Antiretrovirals and Tuberculosis Medicines in Low Birth Weight Infants | INTL | Closed to Follow-up* | Treatment | 13-May-13 | 23-Jul-15 | 04-Aug-15 | 06-Sep-19 | 14-Feb-20 | 158 | 124 |
| IMPAACT 2002 | Combined Cognitive Behavioral Therapy and a Medication Management Algorithm for Treatment of Depression among Youth Living with HIV in the United States | US | Closed to Follow-up* | Complications | 24-Aug-16 | 20-Dec-16 | 06-Mar-17 | 05-Mar-19 | 04-Feb-20 | 156 | 156 |
| P1090 | A Phase I/II Open-Label Trial to Evaluate the Safety, Tolerability, Pharmacokinetics and Antiviral Activity of Etravirine in Antiretroviral Treatment-Experienced HIV-1 Infected Infants and Children, Aged ≥2 Months to <6 Years | US/INTL | POS/PAC* | Treatment | 15-Nov-11 | 07-Mar-12 (V2); Re-opened, 06-Feb-15 (V4) | 14-Mar-13 | 02-Oct-17 | 26-Aug-20 | 50 (V4) | 26 |
| * last 8 months | | | | | | | | | | | |
| Research Area: | | | Complications | 2027, 2021, 2018, 2016, 2002 | | | | | | | |
| | | | Cure | 2028, 2015, 2008, P1115, P1107 | | | | | | | |
| | | | Prevention | 2009, P1112 | | | | | | | |
| | | | Treatment | 2029, 2026, 2023, 2022, 2019, 2017, 2014, 2010, P1106, P1102/START, P1093, P1090, P1026s | | | | | | | |
| | | | Tuberculosis | 2025, 2024, 2020, 2005, 2003b/A5300b, P1108 | | | | | | | |
| | | | COVID-19 | 2032 | | | | | | | |

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