IMPAACT Study Overviews

What is IMPAACT 2026?

IMPAACT 2026 is a Phase IV, prospective, pharmacokinetic (PK) study of selected antiretroviral (ARV), anti-tuberculosis (TB), hormonal contraceptive, and related drugs during pregnancy and postpartum. The study is designed to evaluate the following: the PK of ARV medicines used in clinical care during pregnancy and postpartum; the PK of ARVs when used in combination with first-line TB medicines in clinical care during pregnancy and postpartum; the PK of second-line TB medicines when used in clinical care during pregnancy and postpartum; the kinetics of placental and breastmilk transfer of long-acting injectable ARVs after maternal dosing during pregnancy; the PK of selected ARVs in postpartum women before and after starting hormonal contraceptives; the concentrations of ethinyl estradiol, etonogestrel and other progestins in postpartum women using hormonal contraceptives and ARVs; and the kinetics of breastmilk transfer of ARV and TB drugs from mother to child during breastfeeding.

What is IMPAACT 2023?

IMPAACT 2023 is a phase I, multi-centered study of HIV-1-exposed infants born to HIV-1-infected mothers. The study is designed to evaluate the safety, tolerability and pharmacokinetics (PK) of dolutegravir (DTG) solution given during the first six weeks of life to infants with two sequential dosing cohorts stratified by maternal use of efavirenz (EFV) and DTG. The purpose of the study is to determine the appropriate dose of DTG solution for prophylaxis and treatment of neonates and infants during the first six weeks of life.

What is IMPAACT 2022?

IMPAACT 2022 is a Phase II, multi-center, open-label, non-comparative study to evaluate the effectiveness, feasibility, and pharmacokinetics of long-acting injectable cabotegravir and rilpivirine in non-adherent HIV-1 infected youth. This study will assess the rate of virologic control of these long acting antiretroviral medications among 70 non-adherent youth age 13 to <25 years.

What is IMPAACT 2021?

IMPAACT 2021 is a double-blind, randomized, placebo-controlled trial that will evaluate the safety and immunogenicity of recombinant live-attenuated respiratory syncytial virus vaccines RSV ΔNS2/Δ1313/I1314L, RSV 6120 ΔNS2/1030s, RSV 276 or placebo in children confirmed to be RSV-seronegative within 42 days prior to study product administration. Approximately 160 healthy RSV-seronegative children ≥6 months (180 days) to <25 months (750 days) of age will be enrolled. Eligible children will receive a single dose of RSV ΔNS2/Δ1313/I1314L vaccine, RSV 6120 ΔNS2/1030s vaccine, RSV 276 vaccine or placebo intranasally at entry. Participants will be enrolled in the study outside of RSV season and will remain on study until they complete the post-RSV season visit between April 1st and April 30th in the calendar year following their enrollment.

What is IMPAACT 2020?

IMPAACT 2020 is a Phase III, two-arm, partially randomized, open-label study of HIV-infected and HIV-uninfected children less than 15 years of age with confirmed or probable multidrug-resistant (MDR) tuberculosis (TB) or rifampin mono-resistant (RMR)-TB. The study is designed to compare the efficacy, safety, and tolerability of an all-oral, six-month regimen to an injectable/oral, nine- to twelve-month World Health Organization (WHO) recommended regimen for MDR-TB or RMR-TB-infected children less than 15 years of age.

What is IMPAACT 2019?

IMPAACT 2019 is a Phase I/II open-label, multicenter, multiple dose study of dolutegravir/lamivudine/abacavir (Triumeq®) fixed dose combination tablets in treatment-experienced and treatment-naïve HIV-1-infected children less than 12 years of age. The study is designed to compare the pharmacokinetic exposure of dolutegravir, as contained in this pediatric formulation of Triumeq®, to exposures shown to be efficacious in adults. The study will also evaluate the safety and tolerability of this pediatric formulation over 48 weeks of treatment.

What is IMPAACT 2018?

IMPAACT 2018 is a double-blind, randomized, placebo-controlled trial that will evaluate the infectivity, safety, and immunogenicity of two recombinant live-attenuated respiratory syncytial virus vaccines (RSV ΔNS2/Δ1313/I1314L and RSV 276) in infants confirmed to be RSV-seronegative within 42 days prior to inoculation. Approximately 80 healthy RSV-seronegative infants ≥6 months (180 days) to <25 months (750 days) of age will be enrolled. Eligible infants will receive a single dose of RSV ΔNS2/Δ1313/I1314L or RSV 276 vaccine or placebo intranasally at entry. Participants will be enrolled in the protocol between April 1st and October 14th (outside of RSV season) and will remain on study until they complete the post-RSV season visit between April 1st and April 30th in the calendar year following enrollment.

What is IMPAACT 2017 (MOCHA)?

IMPAACT 2017 is a Phase I/II, multi-center, open-label, non-comparative study to confirm the dose and evaluate the safety, tolerability, acceptability, and PK of oral CAB, long-acting injectable CAB (CAB LA), and long-acting injectable RPV (RPV LA) among up to 155 virologically suppressed HIV-1 infected children and adolescents aged 12 to <18 years. Up to 60 parents/caregivers of adolescent participants will also be enrolled to take part in in-depth qualitative interviews. The MOCHA study (More Options for Children and Adolescents) will enroll two sequential cohorts (Cohort 1 and Cohort 2), each with an oral lead-in phase followed by an injection phase. Cohort 1 will be followed for 16 weeks, whereas Cohort 2 will be followed for 96 weeks. Participants discontinuing study product injections will be followed for an additional 48 weeks to evaluate tolerability and acceptability, and characterize long-term safety and washout PK.

What is IMPAACT 2016?

IMPAACT 2016 is a multi-site, two-arm, randomized, controlled study preceded by a feasibility and acceptability pilot to examine if an Indigenous Leader Outreach Model (ILOM) of trauma-induced cognitive behavioral therapy (TI-CBT) intervention demonstrates improved mental health outcomes and ART adherence for youth living with HIV. The study will proceed in two stages over approximately three and one-half years. In Stage, 1 the feasibility and acceptability of the ILOM of TI-CBT program, consisting of 6 two-hour sessions, will be evaluated for 15-19 year-olds living with HIV and their caregivers using the ADAPT-ITT Model. In Stage 2, the efficacy of an ILOM of TI-CBT intervention using a 2-arm randomized controlled trial design will be evaluated for 15-19 year-olds living with HIV and their caregivers. This study will prioritize implementation in countries with high volumes of 15 - 19 year-olds living with HIV, and sites with minimal mental health care infrastructure in order to achieve the biggest impact and deliver the program in areas of greatest need.

What is IMPAACT 2015?

IMPAACT 2015 is a cross-sectional study that will investigate the central nervous system reservoir in perinatally HIV-infected adolescents and young adults on effective antiretroviral therapy with neurocognitive impairment. The study will assess the frequency with which HIV is detected in the cerebral spinal fluid (CSF) in this population and assess whether detectable HIV in the CSF correlates with markers of inflammation and neuronal injury.

What is IMPAACT 2014?

IMPAACT 2014 is a Phase I/II, multi-center, open-label, non-comparative pharmacokinetic (PK) and safety study of doravirine (DOR, MK-1439) and a fixed dose combination of doravirine, lamivudine and tenofovir disoproxil fumarate (DOR/3TC/TDF, MK-1439a) in HIV-infected adolescents (less than 18 years of age and weighing at least 35 kgs). Two sequential dosing cohorts will be enrolled:

Up to 20 virologically suppressed adolescents will be enrolled in Cohort 1. Participants receiving an ARV regimen of dolutegravir (DTG) or raltegravir (RAL) plus 2 NRTIs will be given a single dose of DOR, added to the ARV regimen, and intensive PK sampling will be conducted around DOR. These participants will be followed for two weeks for safety.
Up to 45 ARV treatment naïve or virologically suppressed adolescents will be enrolled in Cohort 2. DOR/3TC/TDF will be initiated at entry and these participants will be followed for 96 weeks for safety, virologic and immunologic outcomes.

What is IMPAACT 2010?

IMPAACT 2010 is a Phase III, two-arm, randomized, open-label study of HIV-1-infected pregnant women initiating either dolutegravir/tenofovir alafenamide/emtricitabine (DTG/TAF/FTC) or efavirenz/tenofovir disoproxil fumarate/emtribitabine or lamivudine (EFV/TDF/FTC or 3TC) at 14-28 weeks gestation. The

study will compare the two regimens with regard to safety and virologic efficacy during pregnancy and through 48 weeks of maternal and infant follow-up postpartum.

What is IMPAACT 2009?

IMPAACT 2009 is a parallel, observational cohort study of HIV-uninfected pregnant adolescents and young women (aged 16-24). The study is designed to characterize adherence over time among women who initiate once daily oral PrEP during pregnancy and continue in the first 6 months following delivery, and to compare pregnancy outcomes among women who take PrEP and women who decline PrEP during the antenatal period.

What is IMPAACT 2008?

IMPAACT 2008 is a Phase I/II, multisite, randomized controlled study of monoclonal antibody VCR01 combined with antiretroviral therapy in infants. The study is designed to assess the safety of VRC01 administered with ART (through Week 14) and the effect of VRC01 on HIV-1 DNA concentrations in peripheral blood (at Week 14) among HIV-1-infected infants.

What is IMPAACT 2007?

IMPAACT 2007 is a Phase I, multi-center, study of HIV-1-exposed infants born to HIV-1-infected mothers. The study is designed to compare the overall safety and pharmacokinetics of Maraviroc solution given during the first six weeks of life to infants born to HIV-1-infected mothers with ARV prophylaxis with two sequential dosing cohorts stratified by maternal use of efavirenz.

What is IMPAACT 2005?

IMPAACT 2005 is a Phase I/II open-label, single-arm, multisite study of Delamanid (DLM) in HIV-infected and HIV-uninfected pediatric populations with multidrug-resistant tuberculosis (MDR-TB). The study is designed to characterize the pharmacokinetics of DLM using a model-based approach, and to evaluate safety and tolerability of DLM over 24 weeks of study treatment.

What is IMPAACT 2003B (PHOENIx)?

A5300B/IMPAACT 2003B --Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Patients (PHOENIx MDR TB) -- is a Phase III, open label, multi-center trial with a cluster- randomized superiority design (eligible contacts in the same household are a cluster), to compare the efficacy and safety of 26 weeks of delamanid versus 26 weeks of isoniazid for preventing confirmed or probable active TB during 96 weeks of follow-up among high-risk household contacts of multidrug-resistant tuberculosis (MDR) TB patients. It is expected that more than 3,400 high-risk contacts from about 1,700 households (assuming two eligible contacts per household) will be enrolled. This study is a collaborative effort between the IMPAACT and ACTG networks.

IMPAACT
International Maternal Pediatric
Adolescent AIDS Clinical Trials Network

What is IMPAACT 2002?

IMPAACT 2002 is multi-site, two-arm, cluster-randomized study to examine if a Health and Wellness Cognitive Behavioral Therapy and Medication Management for depression improves outcomes for HIV-infected youth in the United States. Approximately 130 HIV-infected youth, ages 14-24 with depression, will be assigned to either Health and Wellness Cognitive Behavioral Therapy and Medication Management group or the Enhanced Standard of Care group and followed for 48 weeks. The study will examine whether participants receiving Health and Wellness Cognitive Behavioral Therapy and Medication Management Algorithm treatment for depression demonstrate improved depression outcomes and improved biological measures of health compared to participants receiving the Enhanced Standard of Care therapy.

What is IMPAACT 2001?

IMPAACT 2001 is a Phase I/II, prospective, open-label, multi-center study of HIV-1-infected and HIV-1-uninfected pregnant and postpartum women with latent tuberculosis (TB) infection. The study is designed to describe the pharmacokinetics and safety of 12 once-weekly doses of rifapentine (RPT) and isoniazid (INH) in pregnant and postpartum women with latent TB and inform the practice on usage of this regimen in the second and third trimesters of pregnancy.

What is P1115?

P1115 is a Phase I/II, multi-center, proof-of-concept study that will explore the effects of early intensive antiretroviral therapy on achieving HIV remission in neonates. The study will also assess the safety and pharmacokinetics of early intensive antiretroviral therapy in neonates.

What is P1112?

IMPAACT P1112 is an open-label, dose-escalating, phase I multicenter trial to determine the safety and pharmacokinetics of VRC01 when given to HIV-1 exposed infants. VRC01 is a potent anti-HIV neutralizing monoclonal antibody. The primary objectives of the P1112 are to assess the safety of single subcutaneous dose (20 mg/kg or 40 mg/kg) of VRC01 and to determine pharmacokinetic profile of single dose, subcutaneous VRC01. The first cohort of 13 infants will receive a single dose of 20 mg/kg of VCR01 SC. If the mini-cohort of 6 infants in this group pass the Day 28 safety criteria and Cohort 1 has been fully accrued, enrollment into Cohort 2 will begin. Cohort 2 will receive a single dose of 40 mg/kg of VRC01.