

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 2021	Randomized Phase IB Study of Safety & Immunogenicity of Single Dose of the Recombinant Live-Attenuated RSV Vaccines RSV ΔNS2/Δ1313/11314L or RSV 276 or Placebo, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age	US	In Development	Complications	22-Jun-18	TBD	TBD	TBD	TBD	450	NA
IMPAACT 2020	Shortened Oral Treatment for Multidrug-Resistant Tuberculosis in Children (SMaRT Kids): A Phase III Randomized Multi-center Trial	INTL	In Development	TB	31-Oct-18	TBD	TBD	TBD	TBD	438	NA
IMPAACT 2019	Phase I/II study of the pharmacokinetics, safety, and tolerability of dolutegravir/lamivudine/abacavir (Triumeq®) in HIV-1-infected children less than 12 years of age	US	In Development	Treatment	31-Jul-18	TBD	TBD	TBD	TBD	50	NA
IMPAACT 2016	Evaluating a Group-Based Intervention to Improve Mental Health & ART Adherence in HIV-Infected Adolescents in Low Resource Settings	INTL	In Development	Complications	30-Jun-18	15-Oct-18	15-Apr-19	15-Oct-20	31-May-22	220	NA
IMPAACT 2003b/A5300b	Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant TB Patients (PHOENIX MDR TB)	INTL	In Development	TB	30-Apr-18	31-Jul-18	31-Jul-18	31-Jul-22	01-Oct-24	3452 (household); 1726 (index)	NA
IMPAACT 2017	Phase I/II Study of Safety & PK of Oral & Long-acting Injectable Cabotegravir & Long-acting Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents	US	Pending	Treatment	16-Mar-18	15-Jul-18	31-Jul-18	31-Oct-20	31-Aug-23	155	NA
IMPAACT 2009	Pharmacokinetics, Feasibility, Acceptability, & Safety of Oral Pre-Exposure Prophylaxis for Primary HIV Prevention during Pregnancy & Postpartum in Adolescents & Young Women	INTL	Pending	Prevention	02-Nov-17	30-Apr-18	28-Jul-18	28-Jan-22	28-Jan-23	385	NA
IMPAACT 2015	Evaluating the HIV Reservoir in the CNS in Perinatally-infected Individuals on ART	Pending	Pending	Cure	02-Oct-17	30-Apr-18	15-May-18	14-Feb-19	17-Mar-19	45	NA
IMPAACT 2008	Phase I/II Multisite Randomized Controlled Study of Monoclonal Antibody VCR01 Combined with ART to Promote Clearance of HIV-1 Infected Cells in Infants	US/INTL	Pending	Cure	09-Nov-16	30-Apr-18	12-Jun-18	12-Jun-19	12-Jun-20	68	NA
IMPAACT 2014	Phase I/II Trial of PK, Safety, & Tolerability of Doravirine & Doravirine/3TC/TDF in HIV-1-Infected Children & Adolescents	US/INTL	Open to Accrual	Treatment	19-Oct-17	21-Mar-18	15-Apr-18	31-Dec-18	30-Oct-20	65	0
IMPAACT 2005	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	Open to Accrual	TB	21-Mar-17	30-Jan-18	30-Apr-18	30-Jun-19	30-Jun-21	45	0

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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	Enrolling	Treatment	13-Dec-16	12-Dec-17	19-Jan-18	31-Oct-18	29-Apr-20	639	143 pairs
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 deltaNS2/delta1313/11314L or RSV 276 or Placebo, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age	US	Enrolling	Complications	03-Jul-17	04-Aug-17	22-Sep-17	15-Oct-18	30-Apr-19	80	20
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	TB	09-Mar-16	18-Aug-17	21-Sep-17	30-Sep-19	31-Jan-22	72	7
IMPAACT 2007	Phase I Safety & Pharmacokinetics of Maraviroc in HIV-1-Exposed Neonates at Risk of Acquiring HIV-1 Infection	US/INTL	Enrolling	Treatment	26-Apr-16	01-May-17	05-Jun-17	31-Mar-20	31-Jul-20	72 pairs	15 pairs
IMPAACT 2001	Phase I/II Trial of PK, Tolerability, & Safety of Once-Weekly Rifapentine & INH in HIV-1-infected & HIV-1-uninfected Pregnant & Postpartum Women with Latent TB Infection	US/INTL	Enrolling	TB	25-Nov-15	15-Feb-17	13-Mar-17	13-May-18	13-May-19	82 pairs	37 pairs
IMPAACT 2002	Combined Cognitive Behavioral Therapy & Medication Management Algorithm for Treatment of Depression among Youth Living with HIV in the US	US	Enrolling	Complications	24-Aug-16	20-Dec-16	06-Mar-17	06-Mar-19	06-Mar-20	156	80
P1106	PK Characteristics of ARVs & TB Medications in Low Birth Weight Infants	INTL	Enrolling	Treatment	13-May-13	23-Jul-15	04-Aug-15	30-Sep-19	16-Mar-20	158	91
P1112	Open-Label, Dose-Escalating, Phase I Study to Determine Safety & PK Parameters of Subcutaneous VRC01 and VRC01LS, Potent Anti-HIV Neutralizing Monoclonal Antibodies, in HIV-1-Exposed Infants	US/INTL	Enrolling	Prevention	22-Aug-14	21-Apr-15	30-Jun-15	31-Jul-19	31-Jul-21	59 pairs	61 pairs
P1107	Cord Blood Transplantation Using CCR5 delta 32 Donor Cells in HIV-1 Infected Subjects who Require Bone Marrow Transplantation for any Indication & Its Observed Effects on HIV-1 Persistence	US	Enrolling	Cure	08-Aug-13	04-Mar-14	05-Feb-15	30-Mar-20	30-Mar-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	01-Apr-20	01-Apr-29	472 pairs	460 pairs
P1097	Raltegravir PK & Safety in Neonates	US	Enrolling	Treatment	24-Jan-14 (V2)	24-Jun-14 (V2)	26-Jan-15 (V2)	30-Jun-18	30-Aug-18	20 pairs (V2)	18 pairs
P1026s	PK Properties of ARV & Related Drugs During Pregnancy & Postpartum	US/INTL	Enrolling	Treatment	NA	17-Mar-03	09-Jun-03	31-Mar-20	30-Sep-20	225 (V10)	79

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P1093	Phase I/II, Multi-Center, Open-Label Pharmacokinetic, Safety, Tolerability & Antiviral Activity of Dolutegravir, a Novel Integrase Inhibitor, in Combination Regimens in HIV-1 Infected Infants, Children & Adolescents	US/INTL	Enrolling	Treatment	21-Dec-10	14-Mar-11	20-Apr-11	30-Jun-19	30-Jun-23	160	121
P1110	Phase I Trial to Evaluate Safety & PK of Raltegravir in HIV Exposed Infants at Risk	US/INTL	Enrolling	Treatment	20-Dec-12	26-Jul-13	28-Jan-14	30-Apr-18	31-Oct-18	50 pairs	52 pairs
P1101	Phase I/II Dose-Finding, Safety, Tolerance, & PK Study of Raltegravir-Containing ART Regimen in HIV-Infected & TB Co-Infected Children	INTL	Enrolling	Treatment	13-Nov-12	21-May-14	11/12/2014; Re-opened, 14-Oct-15 (V2)	31-Dec-18	30-Sep-19	108	29
IMPAACT 2013	Phase I Placebo-Controlled Study of the Infectivity, Safety & Immunogenicity of a Single Dose of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine, RSV/NS2/N/ΔM2-2-HindIII, Lot RSV#011A, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age	US	Closed to Accrual	Complications	27-Feb-17	30-Mar-17	07-Apr-17	15-Oct-17	30-Apr-18	33	32
P1090	Phase II/III Open-Label Trial to Evaluation the Safety, Tolerability, PK & Antiviral Activity of ETR in ARV Treatment-Experienced HIV-1 Infected Infants & Children, Aged ≥2 Months to <6 Years	US/INTL	Closed to Accrual	Treatment	15-Nov-11	07-Mar-12 (V2); Re-opened, 06-Feb-15 (V4)	14-Mar-13	02-Oct-17	31-Jul-23	50 (V4)	26
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-18	4000	4561
P1113/ Aeras 404	Safety & Immunogenicity of a Recombinant Protein TB Vaccine in BCG-Primed Infants	INTL	Closed to Follow-up*	TB	02-Nov-12	25-Jun-13	16-Jul-13	21-Jul-16	10-Nov-17	230	243
P1092	Phase IV Evaluation of Steady State PK of ZDV, 3TC, & LPV/r in Severely Malnourished HIV-1-Infected Children	INTL	Closed to Follow-up*	Treatment	19-Feb-15 (V2)	11-Aug-15	26-Oct-15	29-Sep-16	29-Sep-17	50	52
IMPAACT 2003/A5300	Study of MDR TB Cases and Their Household Contacts: Operational Feasibility to Inform PHOENIX Trial Design	INTL	Closed to Follow-up*	TB	02-Jul-15	27-Oct-15	29-Oct-15	14-Apr-16	17-Aug-17	300 (index); 1016 (household)	308 (index); 1016 (household)
P1078	Phase IV Randomized Double-blind Placebo-controlled Trial to Evaluate Safety of Immediate Vs Deferred INH Preventive Therapy Among HIV-infected Women in High TB Incidence Settings	INTL	Closed to Follow-up*	TB	09-Nov-11	25-Apr-14	21-Aug-14	04-Apr-16	06-Sep-17	950 pairs	956 pairs

* last 8 months

Research Area	2021, 2018, 2016, 2013, 2002
Complications	2015, 2008, P1115, P1107
Cure	2009, P1112
Prevention	2019, 2017, 2014, 2010, 2007, P1110, P1106, P1102/START, P1101, P1097, P1093, P1092, P1090, P1026s
Treatment	2020, 2005, 2003b/A5300b, 2003/A5300, 2001, P1113/AERAS 404, P1108, P1078
Tuberculosis	

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