

IMPAACT Protocols Snapshot: In Development through Closed to Accrual

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 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/I1314L or RSV 276 or Placebo, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age	US	In Development	Complications	21-Jun-17	24-Jul-17	30-Aug-17	15-Oct-18	30-Apr-19	80	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	In Development	Treatment	13-Nov-17	13-Feb-18	13-May-18	13-Mar-20	13-Mar-22	155	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	01-Dec-17	15-Mar-18	15-Sep-18	15-Mar-20	31-Oct-21	220	NA
IMPAACT 2015	Evaluating the HIV Reservoir in the CNS in Perinatally-infected Individuals on ART	Pending	In Development	Cure	31-Aug-17	30-Sep-17	15-Oct-17	15-Jul-18	15-Aug-18	30	NA
IMPAACT 2014	Phase I/II Trial of PK, Safety, & Tolerability of Doravirine & Doravirine/3TC/TDF in HIV-1-Infected Children & Adolescents	US/INTL	In Development	Treatment	30-Jun-17	01-Dec-17	15-Jan-18	30-Jun-19	30-Apr-21	65	NA
IMPAACT 2009	Pharmacokinetics, Feasibility, Acceptability, & Safety of Oral Pre-Exposure Prophylaxis for Primary HIV Prevention during Pregnancy & Postpartum in Adolescents & Young Women	INTL	In Development	Prevention	31-Jul-17	30-Nov-17	28-Feb-18	31-Aug-21	31-Aug-22	385	NA
IMPAACT 2003b/A5300b	Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant TB Patients (PHOENIX MDR TB)	INTL	In Development	TB	01-Aug-17	22-Jan-18	23-Jan-18	19-Jan-22	25-Mar-24	3452	NA
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	Pending	TB	21-Mar-17	14-Aug-17	15-Nov-17	15-May-19	15-May-21	45	NA
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	Pending	Treatment	13-Dec-16	15-Aug-17	15-Sep-17	15-Feb-19	15-Aug-20	549	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	15-Aug-17	01-Jan-18	01-Jan-19	01-Jan-20	68	NA

TBD = information is to be added once timeline is clearer
 Grey text boxes indicates a projected (rather than actual) date

Report Date, 6 June 2017
 Page 1 of 4

IMPAACT Protocols Snapshot: In Development through Closed to Accrual

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
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	Pending	TB	09-Mar-16	30-Jun-17	30-Jul-17	30-Jan-19	30-Jul-21	72	NA
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	05-Jun-19	05-Oct-19	72 pairs	1
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	Enrolling	Complications	27-Feb-17	30-Mar-17	07-Apr-17	15-Oct-17	30-Apr-18	33	12
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-Mar-18	13-Mar-19	82 pairs	11
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	05-Mar-20	156	22
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-Jun-19	15-Dec-19	158	76
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	30-Jun-18	30-Apr-20	59 pairs	40 pairs
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	Enrolling	Treatment	15-Nov-11	07-Mar-12 (V2); Re-opened, 06-Feb-15 (V4)	14-Mar-13	31-Oct-17	31-Oct-19	50 (V4)	24
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	04-Mar-18	04-Mar-22	25	1
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	30-Mar-18	30-Apr-23	472 pairs	346 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)	9 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	275 (V10)	54

TBD = information is to be added once timeline is clearer
 Grey text boxes indicates a projected (rather than actual) date

IMPAACT Protocols Snapshot: In Development through Closed to Accrual

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
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-18	30-Jun-22	124	104
P1110	Phase I Trial to Evaluate Safety & PK of Raltegravir in HIV Exposed Infants at High Risk	US/INTL	Enrolling	Treatment	20-Dec-12	26-Jul-13	28-Jan-14	30-Apr-18	31-Oct-18	50 pairs	43 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-Mar-18	31-Dec-18	108	22
IMPAACT 2012	Phase I Placebo-Controlled Study of the Infectivity, Safety & Immunogenicity of a Single Dose of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine, <i>LID cp ΔM2-2, Lot RSV#009B</i> , Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age	US	Closed to Accrual	Complications	17-Aug-16	21-Sep-16	05-Oct-16	13-Feb-17	30-Jun-17	33	17
P1092	Phase IV Evaluation of Steady State PK of ZDV, 3TC, & LPV/r in Severely Malnourished HIV-1-Infected Children	INTL	Closed to Accrual	Treatment	19-Feb-15 (V2)	11-Aug-15	26-Oct-15	17-Nov-16	17-Nov-17	50	52
P1113/ Aeras 404	Safety & Immunogenicity of a Recombinant Protein TB Vaccine in BCG-Primed Infants	INTL	Closed to Accrual	TB	02-Nov-12	25-Jun-13	16-Jul-13	21-Jul-16	21-Jul-17	230	243
IMPAACT 2003/A5300	Study of MDR TB Cases and Their Household Contacts: Operational Feasibility to Inform PHOENIX Trial Design	INTL	Closed to Accrual	TB	02-Jul-15	27-Oct-15	29-Oct-15	14-Apr-16	TBD	300 (index)	308
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 Accrual	TB	09-Nov-11	25-Apr-14	21-Aug-14	04-Apr-16	15-Sep-17	950 pairs	956 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-18	4000	4561
IMPAACT 2011	Phase I Placebo-Controlled Study of the Infectivity, Safety & Immunogenicity of a Single Dose of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine, <i>LID ΔM2-2 1030s, Lot RSV#010A</i> , Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age	US	Closed to Follow-up*	Complications	05-May-16	14-Jun-16	15-Jul-16	18-Oct-16	20-Apr-17	34	33
P1066	Phase I/II, Multicenter, Open-Label, Noncomparative Study of IMPAACT to Evaluate Safety, Tolerability, PK, & Antiretroviral Activity of Raltegravir in HIV-1 Infected Children & Adolescents	US/INTL	Closed to Follow-up*	Treatment	23-May-07	11-Sep-07	14-Sep-07	07-Feb-13	17-May-17	160	153
P1076	Impact of Oral Alendronate on Bone Mineral Density in HIV+ Children & Adolescents with Low Bone Mineral Density at Baseline	US/INTL	Closed to Follow-up*	Complications	26-May-09	19-Aug-09	05-Nov-09	28-Mar-14	18-Jan-17	51	52

TBD = information is to be added once timeline is clearer
 Grey text boxes indicates a projected (rather than actual) date

IMPAACT Protocols Snapshot: In Development through Closed to Accrual

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
P1104s	Longitudinal Developmental & Neuropsychological Assessment of HIV-infected Participants of P1060 & HIV-uninfected Controls	INTL	Closed to Follow-up*	Complications	04-Dec-12	31-May-13	29-Oct-13	17-Dec-14	14-Dec-16	620	615
P1060	Phase II, Parallel, Randomized, Clinical Trials Comparing Responses to Initiation of NNTRI-based Vs PI-based ARV Therapy in HIV-infected Infants who Have & Have Not Previously Received Single Dose NVP for PMTCT	INTL	Closed to Follow-up*	Treatment	NA	29-Sep-06	09-Nov-06	19-Mar-10	16-Dec-16	315 (V5)	349
1077BF	Breastfeeding Version of the PROMISE Study: Promoting Maternal & Infant Survival Everywhere	INTL	Closed to Follow-up*	Prevention	06-Mar-10	08-Mar-11	05-Apr-11	01-Oct-14	30-Sep-16	4950 pairs	3463 pairs
1077FF	Formula Feeding Version of the PROMISE Study: Promoting Maternal & Infant Survival Everywhere	INTL	Closed to Follow-up*	Prevention	17-Sep-10	20-Apr-11	04-May-11	18-Jul-14	30-Sep-16	1000 pairs	284 pairs
1077HS	HAART Standard Version of the PROMISE Study: Promoting Maternal & Infant Survival Everywhere	US/INTL	Closed to Follow-up*	Prevention	20-Jul-09	13-Oct-09	15-Jan-10	30-Nov-14	31-Aug-16	2000	1653

* last 8 months

Research Area:

Complications 2018, 2016, 2013, 2012, 2011, 2002, P1104s, P1076
Cure 2015, 2008, P1115, P1107
Prevention 2009, P1112, 1077BF, 1077FF, 1077HS
Treatment 2017, 2014, 2010, 2007, P1110, P1106, P1102/START, P1101, P1097, P1093, P1092, P1090, P1066, P1060, P1026s
Tuberculosis 2005, 2003b/A5300b, 2003/A5300, 2001, P1113/AERAS 404, P1108, P1078