

## 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
<b>IMPAACT 2020</b>	Shortened Oral Treatment for Multidrug-Resistant Tuberculosis in Children (SMaRT Kids): A Phase III Randomized Multi-center Trial	US	In Development	TB	30-Jun-18	TBD	TBD	TBD	TBD	346	NA
<b>IMPAACT 2019</b>	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	30-Jun-18	TBD	TBD	TBD	TBD	50	NA
<b>IMPAACT 2017</b>	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	28-Feb-18	29-May-18	28-Aug-18	28-Jun-20	28-Jun-22	155	NA
<b>IMPAACT 2016</b>	Evaluating a Group-Based Intervention to Improve Mental Health & ART Adherence in HIV-Infected Adolescents in Low Resource Settings	INTL	In Development	Complications	28-Feb-18	15-Jun-18	15-Dec-18	15-Jun-20	30-Jan-22	220	NA
<b>IMPAACT 2003b/A5300b</b>	Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant TB Patients (PHOENix MDR TB)	INTL	In Development	TB	15-Feb-18	05-Jun-18	06-Jun-18	02-Jun-22	08-Aug-24	3452 (household); 1726 (index)	NA
<b>IMPAACT 2009</b>	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	05-Mar-18	02-Jun-18	03-Dec-21	03-Dec-22	385	NA
<b>IMPAACT 2014</b>	Phase I/II Trial of PK, Safety, & Tolerability of Doravirine & Doravirine/3TC/TDF in HIV-1-Infected Children & Adolescents	US/INTL	Pending	Treatment	19-Oct-17	15-Dec-17	15-Mar-18	30-Aug-19	30-Jun-21	65	NA
<b>IMPAACT 2015</b>	Evaluating the HIV Reservoir in the CNS in Perinatally-infected Individuals on ART	Pending	Pending	Cure	02-Oct-17	15-Feb-18	02-Mar-18	30-Nov-18	31-Dec-18	45	NA
<b>IMPAACT 2005</b>	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	31-Jan-18	30-Apr-18	31-Oct-19	31-Oct-21	45	NA
<b>IMPAACT 2010</b>	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-Nov-17	01-Dec-17	01-May-19	31-Oct-20	549	NA
<b>IMPAACT 2008</b>	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-Dec-17	31-Jan-18	31-Jan-19	31-Jan-20	68	NA

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<b>IMPAACT 2018</b>	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	Enrolling	Complications	03-Jul-17	04-Aug-17	22-Sep-17	15-Oct-18	30-Apr-19	80	20
<b>P1108</b>	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	31-Oct-19	31-Jan-22	72	1
<b>IMPAACT 2007</b>	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	14 pairs
<b>IMPAACT 2001</b>	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	24 pairs
<b>IMPAACT 2002</b>	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	57
<b>P1106</b>	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	88
<b>P1112</b>	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-18	31-Jul-20	59 pairs	46 pairs
<b>P1107</b>	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	2
<b>P1115</b>	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	458 pairs
<b>P1097</b>	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)	10 pairs
<b>P1026s</b>	PK Properties of ARV & Related Drugs During Pregnancy & Postpartum	US/INTL	Enrolling	Treatment	NA	17-Mar-03	09-Jun-03	31-Mar-18	30-Sep-18	250 (V10)	91

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<b>P1093</b>	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	114
<b>P1110</b>	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	51 pairs
<b>P1101</b>	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)	28-Feb-19	30-Nov-19	108	24
<b>IMPAACT 2013</b>	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
<b>P1090</b>	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-22	50 (V4)	26
<b>P1113/ Aeras 404</b>	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	15-Dec-17	230	243
<b>P1102/ START</b>	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
<b>P1092</b>	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
<b>IMPAACT 2003/A5300</b>	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)
<b>P1078</b>	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
<b>IMPAACT 2012</b>	Phase I Placebo-Controlled Study of the Infectivity, Safety & Immunogenicity of a Single Dose of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine, LID cp ΔM2-2, Lot RSV#009B, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age	US	Closed to Follow-up*	Complications	17-Aug-16	21-Sep-16	05-Oct-16	13-Feb-17	24-Apr-17	33	17

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<b>IMPAACT 2011</b>	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</i> , Lot RSV#010A , 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	07-Jul-17	34	33
<b>P1066</b>	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	18-May-17	160	153

\* last 8 months

**Research Area:**

<b>Complications</b>	2018, 2016, 2013, 2012, 2011, 2002
<b>Cure</b>	2015, 2008, P1115, P1107
<b>Prevention</b>	2009, P1112
<b>Treatment</b>	2019, 2017, 2014, 2010, 2007, P1110, P1106, P1102/START, P1101, P1097, P1093, P1092, P1090, P1066, P1026s
<b>Tuberculosis</b>	2020, 2005, 2003b/A5300b, 2003/A5300, 2001, P1113/AERAS 404, P1108, P1078