

## IMPAACT Protocols Snapshot: In Development through Closed to Accrual

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<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	15-Dec-17	17-Mar-18	14-Jun-18	14-Apr-20	14-Apr-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	31-Dec-17	15-Apr-18	15-Oct-18	15-Apr-20	30-Nov-21	220	NA
<b>IMPAACT 2015</b>	Evaluating the HIV Reservoir in the CNS in Perinatally-infected Individuals on ART	Pending	In Development	Cure	15-Sep-17	15-Oct-17	30-Oct-17	30-Jul-18	30-Aug-18	45	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	In Development	Treatment	22-Sep-17	21-Dec-17	05-Jan-18	22-Jun-19	22-Apr-21	65	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	In Development	Prevention	15-Sep-17	15-Jan-18	15-Apr-18	15-Oct-21	15-Oct-22	385	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	01-Oct-17	22-Jan-18	23-Jan-18	19-Jan-22	25-Mar-24	3452	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	15-Oct-17	15-Jan-18	15-Jul-19	15-Jul-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-Oct-17	15-Nov-17	17-Apr-19	15-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	31-Oct-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	Open to Accrual	Complications	03-Jul-17	04-Aug-17	15-Sep-17	15-Oct-18	30-Apr-19	80	0
<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	Open to Accrual	TB	09-Mar-16	18-Aug-17	18-Sep-17	21-Mar-19	18-Sep-21	72	0
<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	11 pairs
<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	Enrolling	Complications	27-Feb-17	30-Mar-17	07-Apr-17	15-Oct-17	30-Apr-18	33	26
<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	47
<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	87
<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	41 pairs
<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	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)	26

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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	455 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)	10 pairs
P1026s	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)	75
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	112
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	45 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)	28-Feb-19	30-Nov-19	108	23
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	15-Dec-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

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<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, <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 Follow-up*	Complications	17-Aug-16	21-Sep-16	05-Oct-16	13-Feb-17	20-Apr-17	33	17
<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, 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	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
<b>P1076</b>	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

\* last 8 months

**Research Area:**

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