IMPAACT 2007 ELIGIBILITY CRITERIA

VERSION 1.0, 13 APRIL 2016
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MATERNAL INCLUSION CRITERIA

4.1.1 Mother is of legal age to provide independent informed consent for research participation and is willing and able to provide written informed consent for her and her infant's participation in this study.

4.1.2 Mother has confirmed HIV-1 infection based on testing of two samples collected at different time points.

All samples tested must be whole blood, serum, or plasma. If both samples are tested using antibody tests, at least one of the samples must be tested in a laboratory that operates according to Good Clinical Laboratory Practice (GCLP) guidelines and participates in an appropriate external quality assurance program. If nucleic acid testing is used, at least one test must be performed in a CLIA-certified (US sites) or VQA-certified (non-US certified) laboratory. For tests performed in other (non-GCLP-compliant or non-VQA-certified) settings, adequate source documentation including the date of specimen collection, date of testing, test performed, and test result must be available.

INCLUSION CRITERIA

4.1.3 At entry, infant meets EFV exposure requirements, based on mother's report and confirmed by medical records if available, as follows:

Cohort 1

Stratum 1A	Stratum 1B
Infant born to a mother who did **not** receive EFV during the 8 weeks immediately prior to delivery. *Breastfeeding and formula feeding infants are eligible*	Infant born to a mother who received EFV for a minimum of 2 weeks immediately prior to delivery. *Breastfeeding and formula feeding infants are eligible*

INCLUSION CRITERIA

Cohort 2

Stratum 2A	Stratum 2B
Infant born to a mother who did **not** receive EFV during the 8 weeks immediately prior to delivery, and if breastfeeding, mother is not receiving maternal EFV *Breastfeeding and formula feeding infants are eligible*	Infant born to a mother who received EFV for a minimum of 2 weeks immediately prior to delivery, intends to breastfeed for a minimum of 6 weeks and will continue to receive maternal EFV while breastfeeding *Breastfeeding infants only are eligible*

INCLUSION CRITERIA

4.1.4 At birth, infant's estimated gestational age was at least 37 weeks.

Note: If gestational age at birth is not documented in the infant's available birth records, study staff may assess gestational age at the earliest possible opportunity during the screening period and use this assessment for purposes of eligibility determination.

4.1.5 At birth, infant's weight was at least 2 kg.

Note: If weight at birth is not documented in the infant's available birth records, study staff may assess infant weight at the earliest possible opportunity during the screening period and use this assessment for purposes of eligibility determination.

4.1.6 At entry, infant is less than or equal to 3 days old.

INCLUSION CRITERIA

4.1.7 At entry, infant has the following lab values:

- Grade 0 ALT (normal)
- ≤ Grade 1 AST and total bilirubin
- ≤ Grade 2 hemoglobin, white blood cell counts, and platelet counts.

4.1.8 At entry, infant has initiated antiretroviral prophylaxis that does not include a potent CYP3A4 inhibitor or inducer. (See protocol Section 5.11)

4.1.9 At entry, infant is assessed by the site investigator or designee as generally healthy based on review of available medical records, other available medical history information, and physical examination findings.

4.1.10 Born after singleton delivery (not after multiple birth).

EXCLUSION CRITERIA

4.2.1 Infant has any other condition that, in the opinion of the site investigator or designee, would make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives; for example, severe congenital malformation, other medical condition, or clinically significant finding from physical examination.

4.2.2 At entry, any positive infant HIV nucleic acid test result (results are not required to be available prior to entry but any positive results obtained prior to entry are exclusionary).

4.2.3 At entry, infant or breastfeeding mother is receiving any disallowed medication listed in Section 5.11.

4.2.4 Mother received maraviroc during pregnancy

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What are your questions about study eligibility?