DMC

P1106: Pharmacokinetic Characteristics of Antiretrovirals and Tuberculosis Medicines in Low Birth Weight Infants

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If you have questions during the study...

• If you have questions about schedules or forms, e-mail the Protocol Data Managers:
  – Bobbie Graham: graham@fstrf.org
  – Stephanie Popson: popson@fstrf.org

• If you have questions about eData, Smart Update, or other technical issues, e-mail User Support: usersprt@fstrf.org

• If you have questions about patient management or the protocol itself, e-mail the P1106 Protocol Team: impaact.teamp1106@fstrf.org

• impaact.prot@fstrf.org is used by protocol team to convey information to registered sites
Data Collection Forms Schedule

**SCHEDULES:**
- Days of Life
- Weeks of Life
- Form Week

**SCREENING:**
Screening may start from any point after birth, up until 14 days of life.

**ENTRY:**
Entry must wait until at least 7 days of life, but must occur before 14 days of life.
SCREENING FAILURE

Notice the Screening Failure visit listed on the schedule.

- Complete for all participants who are consented, but ultimately do not enroll, regardless of the reason for non-enrollment.

- Form is located on the DMC Portal.
SCR0036: IMPAACT P1106 Screening Failure and Non-Enrollment Results

- Only completed if participant was screened, but did not enroll for any reason.
- Collects information as to which Eligibility Checklist criteria were not met.
- In future, may change to use PS2001-IMPAACT Screening System.
ELIGIBILITY CHECKLIST

Notice that “STEP” appears in both enrollment options.

EVERY participant starts by enrolling under STEP=1. This applies to ALL Arms (1-6).
What does this statement mean?

It is possible that a small subset of HIV-Exposed participants from Arms 1-3 may eventually test as HIV+. This subset of infants are encouraged to enroll into Arms 5-6.

**HOW do you do this?**
ELIGIBILITY CHECKLIST

That subset of participants are then consented and enrolled onto either Arm 5 or 6.

NOTE: Although the word STEP is not used within the protocol, the study is managed as a STEP protocol.
TRK0158: IMPAACT P1106 ENTRY STATUS and Gestational Age

• Documents whether Screening and Entry visits were separate or combined
• Affects the Delinquency expectations
### Information needed by statisticians to describe participant population.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the infant’s gestational age by infant exam available?</td>
<td>1-Yes, 2-No</td>
</tr>
<tr>
<td>If No, go to question 3.</td>
<td></td>
</tr>
<tr>
<td>If Yes, continue.</td>
<td></td>
</tr>
<tr>
<td>a. Weeks</td>
<td></td>
</tr>
<tr>
<td>b. What is the type of exam used to determine the infant’s gestational age?</td>
<td>1-Ballard, 2-Dubowitz, 3-Other, specify, 4-1-Unknown</td>
</tr>
<tr>
<td>c. If ‘9’-Other, specify [70]:</td>
<td></td>
</tr>
<tr>
<td>Is the classification of the newborn by intrauterine growth and gestational age available?</td>
<td>1-Large for Gestational Age (LGA) &gt; 90%, 2-Appropriate for Gestational Age (AGA), 3-Small for Gestational Age (SGA) &lt; 10%, 4-Intrauterine Growth Retardation (IUGR) &lt; 3%</td>
</tr>
<tr>
<td>If No, go to question 4.</td>
<td></td>
</tr>
<tr>
<td>If Yes, continue.</td>
<td></td>
</tr>
<tr>
<td>a. Indicate the classification:</td>
<td></td>
</tr>
</tbody>
</table>

*For Protocol P1106: Codes 1 and 2 do not apply.*
TXW0277: P1106 Antiretroviral Regimen Record

For Arms 1-3: Record all antiretrovirals ever taken since birth on this form, including ARVs for PMTCT.

Note different instructions for Arms 1-3 vs Arms 5-6.

For Arms 5-6: For infants originally enrolled in Arms 5 or 6, record all prior antiretrovirals taken since birth on the Antiretroviral Concomitant Medications (PE0420) form. After entry, record all antiretrovirals taken while on study on this form.

For infants who were initially enrolled in Arms 1-3 and later determined to be HIV infected and then enrolled onto Arms 5-6, continue to record all antiretrovirals on this form, however indicate the step change.
TXW0277, Continued
Indicate whether ARV is “study treatment” and indicate “manufacturer type”.

NOTE: Study treatment is defined as ARVs required by or supplied by the study. Non-study treatment is defined as ARVs that are part of the participant’s ARV regimen but are not required by or supplied by the study.
For Protocol P1106: Study defined antiretroviral medications are NVP and/or LPV/r, and must be identified as “study treatment” within question 1. Medications are not provided through the study.

1. Were any of the ARVs started, stopped or modified at this visit or since the study participant’s last visit? .......... (1-Yes, 2-No) □
   (This includes all initial doses, dose/formulation modifications, manufacturer modifications, interruptions, and permanent discontinuation.)
   If No, go to question 2.
   If Yes, continue. Use the Tab Key after the last entry.
   a. Specify Drug 1 [70]:
   b. Manufacturer Type 2
   c. If Other Formulation, specify [70]:
   d. Frequency Taken 5
   e. If Generic Code ‘2’ or ‘3’, specify Manufacturer [70]:
   f. Date Modification Started (dd/mmm/yyyy):
   g. Reason for Modification 8
   h. Specify Reason [70]:
   i. Is this study treatment? (1-Yes, 2-No) □
   j. Dose Status 3
   k. Total Daily Dose 4
   l. Formulation 5
   m. Toxicity Grade 3

2 Manufacturer Type
1-Brand name
2-FDA-approved or tentatively approved generic, specify drug manufacturer
3-Non-FDA approved generic, specify drug manufacturer
Expected vs Unexpected Events

• Expected Events: Defined as those limited events listed in Protocol Appendix IV.

• Unexpected Events: Defined as all other events outside the scope of Protocol Appendix IV. The term SUSAR (Suspected Unexpected Serious Adverse Reaction) is used throughout CRFs.

INSTRUCTIONS:

• Record the expected events routinely noted in low birth weight infants as listed in Protocol Appendix IV on this form. Abstract information collected by neonatologist from the “Expected Event Reporting Worksheet for Neonatologist” (WKW0004) onto this form. This provides a snapshot (i.e. whether the event was identified in the infant at the time of the visit) check of those expected events as listed in Protocol Appendix IV.

• Record unexpected (SUSAR) events and protocol required hematologies/chemistries on appropriate form.
  - Diagnoses III - (PE6852)
  - Signs and Symptoms - III - (PE6832)
  - IMPAACT P1106 Hematologies and Chemistries - (LBW0143)
Reporting Expected Events

Neonatologist report findings on the WKW0004-IMPAACT P1106 EXPECTED EVENT REPORTING WORKSHEET FOR NEONATOLOGIST.

Data Group transcribes that information onto the TGW0004-IMPAACT P1106 EXPECTED EVENT REPORTING.
Reporting Expected Events
TGW0004-IMPAACT P1106 EXPECTED EVENT REPORTING

TGW0004 is laid out to mirror the reporting on the WKW0004.

[NOTE: This makes the transcription process easier!]

The transcribed information is what gets keyed into the database.

[TIP: Make sure there is good communication between neonatologist and data group to ensure accurate reporting.]
Reporting Unexpected Events

Unexpected events reported on the primary safety CRFs:

- LBW0143-IMPAACT P1106 Hematologies and Chemistries
- PE6832-Signs and Symptoms-III
- PE6852-Diagnoses - III
Questions?