HPTN 084: Pregnancy Data Requirements and Version 5.0 Updates

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All Sites Call
Data Management Topics

- Pregnancy Data Requirements
- Walk thru data collection
- Details of missing data
- Retrospective collection
- Protocol V5.0 Updates to Rave
- Open floor comments/questions
Pregnancy data requirements and reporting

• Ultrasound at 12 weeks
• Pregnancy Outcomes- *PTIDs for all live births*
• AE/SAE Infant data-
  • *Non 4d- SAE collection 48 weeks post-partum*
  • *4d AE collection- Grade ≥ 2 AEs will be reported from delivery to Week 24. SAEs, including deaths and congenital anomalies will be reported throughout the post-partum period.*
• Infant Assessments 48 weeks post-partum
Scenario prospective data collection

- Participant in Step 4c becomes pregnant and does not qualify for the sub-study. She is followed and transitioned to Step 5. She delivers baby, then learns of infant having SAE of Neonatal Respiratory Distress Syndrome.
- These are the CRF requirements
Ultrasound data are required for all pregnancies

- Monitor fetus ~12 weeks
- Add form using:
  - Interim Visit
  - Additional Procedures CRF add to current visit
Infant PTID required for ALL live births in OLE

- Pregnancy Outcome:
  - Full term live birth ≥ 37 weeks
  - Premature term live birth < 37 weeks

- At what visit is pregnancy reported and Infant PTID required data
Infant PTID

CRF name updated, was ‘Sub-study Infant PTID’

Removing subject ID cap in Rave

Steps:
1. Create infant PTID using ‘Add Subject’
2. Select ‘Infant PTID’ CRF and save it to infant casebook
3. Enter **Mother’s PTID on form**, to link mom and baby
Infant SAE collection - 48 wk follow up (Not in Step 4d)

- Record under mother and enter infant PTID
- Report SAEs as they become known
Infant Assessment - 48 weeks

- Use Additional Procedures CRF add to visit or Interim Visit to add form
- Required for all live births
- In the event information re status of infant is known prior to 48 weeks, like in this example, this form should be completed early
Completion of Infant Assessments in OLE

- 48.9% of pregnancies have infant assessments completed on-time.

<table>
<thead>
<tr>
<th>Assessment Status</th>
<th>n</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed</td>
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<td>45</td>
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<tr>
<td>Missed</td>
<td>23</td>
<td>45</td>
<td>51.1</td>
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</table>

Figure 1: Distribution of Infant assessment completion status.
Infant Assessments- 48 weeks

Enrolled in Sub-study (4d) vs. Not Enrolled

<table>
<thead>
<tr>
<th>Assessment Status</th>
<th>Sub-study Status</th>
<th>n</th>
<th>Total</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Completed</td>
<td>Mother enrolled in Sub-Study</td>
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<td>Missed</td>
<td>Not enrolled in Sub-Study</td>
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<td>12</td>
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</table>

48wk assessment status:  
- **Completed**
- **Missed**
- **Pending**

**Count (mth)**

- **Mother enrolled in Sub-Study**
- **Not enrolled in Sub-Study**
Missing Infant Assessments

- Enrolled in sub-study (*n=11*)
  - Changed schedules prior to wk 48
  - Wk 48 done, but only have infant mortality completed
  - Participant “missed visit” for wk 48

- Not enrolled in sub-study (*n=12*)
  - There isn’t a OLE pregnancy visit schedule outside of 4d which has Infant Assessment form
  - No mechanism to date to “remind” sites

- Missing and discontinued from study (*n=14*)

  ➢ Moving forward sites will be queried ~48 weeks per live birth
• Update Pregnancy Outcome w Infant PTID

• Infant Assessments-
  • Ideally, capture as close to 48 weeks as possible
  • Source documentation ie road to health card
  • Forms should be completed to have 1:1 ratio of live birth to infant assessments

• Infant SAE collection- where applicable
  ➢ SCHARP will be issuing queries as reminders of the data entry
  ➢ Listings/ additional information can be provided
Database Updates
Add Event:
• Informed Consent- Version 5.0
• Step 6 visits:
  o 122.0 Week 104
  o 123.0 Week 112
Informed Consent V5.0

Add Event

- Report date of ICF
  - Must be on or before Wk 104 DOV
- Includes consent for ultrasound and infant assessments 48 weeks
Add Event:

• Pregnancy and Infant Sub-study:
  - Pregnancy 2 – V176
  - Pregnancy 3 – V276
  - Pregnancy 4 – V376
  - Pregnancy 5 – V476
  
  - Rave now assigns pregnancy number
Additional Details

- CCGs have been drafted
- CASI Directive:

The CASI survey does not have new Step 6 visit codes programmed yet. We request in the meantime to select visit code “59.0” when a participant completes the week 104 CASI. This will populate the appropriate questions for this visit. Once we migrate the CASI and add the new Step 6 visit codes, SCHARP will fix the visit codes on the back end.
Thank you for all your hard work!

Questions and/or comments?