

HPTN 084: Pregnancy Data Requirements and Version 5.0 Updates

Stephanie Orme
SDMC, Clinical Data Management
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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

Page: Ultrasound - OLE - Interim Visit - OLE 68.1

1. Was an ultrasound exam performed? If yes, go to exam date. Yes

1a. Reason ultrasound not performed.

2 Exam Date 03 Oct 2022



3. Number of fetuses observed on ultrasound 1

#	Estimated gestational age - Weeks	Estimated gestational age - Days	Crown-rump length	Biparietal diameter	Biparietal diameter Not done/not collected	Femur length	Femur length Not done/not collected	Intracranial Result	If abnormal, please describe	Face/Lip Result	If abnormal, please describe	Spine Result	If abnormal, please describe	Thorax Result	If abnormal, please describe	Four-chamber heart Result	If abnormal, please describe	Stomach Result	If abnormal, please describe	Kidney Result
1	16	2	-	4	<input type="checkbox"/>	3	<input type="checkbox"/>	Normal	-	Normal	-	Normal	-	Normal	-	Normal	-	Normal	-	Normal

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*

Subject: 999384014
Page: Pregnancy Outcome Log - OLE - Delivery - OLE - V95

1. Date pregnancy reported	30 May 2023
1a. At what visit was the pregnancy reported?	V65.0 - Step 4c-TDF/FTC - Week 8
1a1. If 'Interim Visit' is chosen, provide interim visit code.	
1b. Did this pregnancy have an obtainable outcome?	Yes
1b1. If an outcome was not obtainable, please specify why:	
END OF FORM.	
2. How many pregnancy outcomes resulted from this reported pregnancy?	1
 Currently viewing line 1 of 1. Click here to return to "Complete View".	
3. Infant PTID	999612361 
4. Pregnancy outcome date	20 Oct 2023
5. Place of delivery/outcome	Hospital
5a. If other, specify:	
6. Pregnancy outcome	Premature term live birth (<37 weeks)

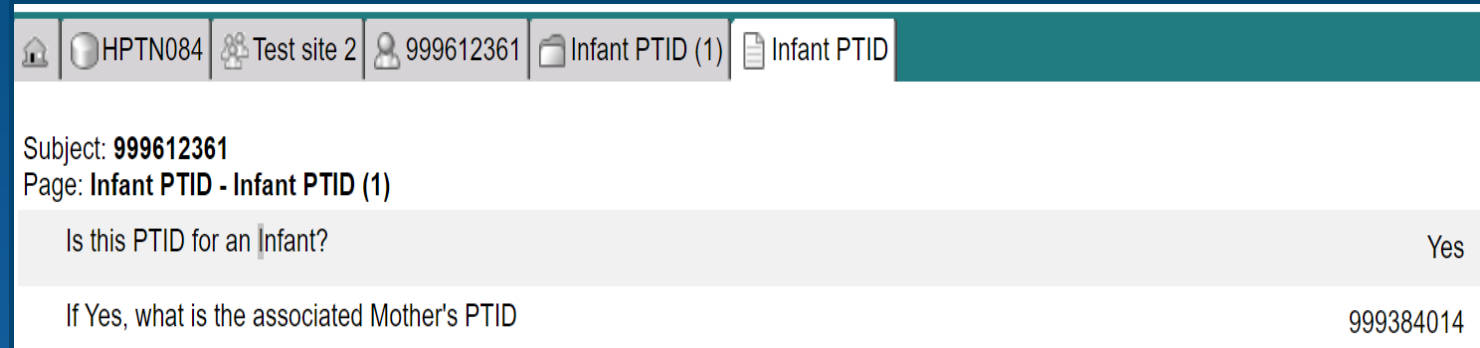
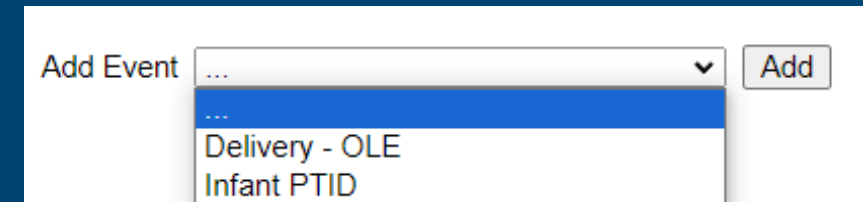
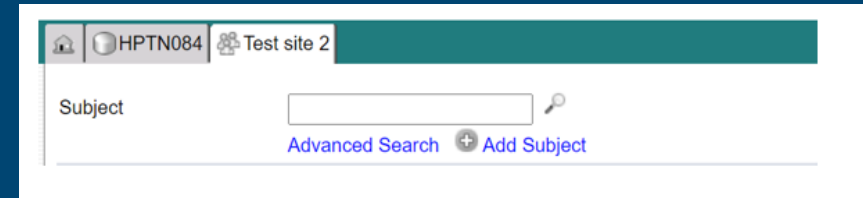
Infant PTID

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



Subject: 999612361	
Page: Infant PTID - Infant PTID (1)	
Is this PTID for an Infant?	Yes
If Yes, what is the associated Mother's PTID	999384014

Infant SAE collection- 48 wk follow up (*Not in Step 4d*)

- Record under mother and enter infant PTID
- Report SAEs as they become known

Subject: 999384014
Page: Adverse Event - Infant - Ongoing Logs (1)

#	Infant PTID	Date reported to site	Adverse Event (AE) ?	Onset Date	At which visit was this AE first reported?	If 'Interim Visit' is chosen, provide interim visit code.	Is the AE still ongoing?	Outcome Date	Toxicity (Severity) Grade	Relationship to Study Product	Alternate etiology	Action Taken with Study Product:	Other action(s) taken (Select "none" or all that apply) None	Medication(s) ?	Therapeutic procedure/surgery	Diagnostic procedure	Other	Specify other:	Status/Outcome	Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines? If "No", go to "Has or will this AE be reported as an EAE?". If "Yes", check all that apply.
1	999612361	19 Jan 2023	Neonatal Respiratory Distress Syndrome	1 Jan 2023	V73.0 - Step 5-TDF/FTC - Week 24	-	No	2 Jan 2023	Grade 4 (Potentially life-threatening)	Not Related	-	Not applicable	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	Recovered/resolved	Yes
2	-	-	-	-	-	-	-	-	-	-	-	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	-	-
3	999612361	19 Jan 2023	Neonatal Respiratory Distress Syndrome	2 Jan 2023	V73.0 - Step 5-TDF/FTC - Week 24	-	No	2 Jan 2023	Grade 5 (Death)	Not Related	-	Not applicable	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	Fatal	Yes

Add a new Log line Inactivate

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

Subject: 999384014
Page: Infant Assessment

1. How many live pregnancy outcomes had resulted from this pregnancy?
Complete one log line for each live outcome. 1

1a. Date pregnancy reported 30 May 2023

#	Infant PTID	Is the infant alive?	Was an infant assessment done? <i>If No, end of form.</i>	Date of assessment	Length	Weight	Head circumference	Abdominal circumference	Were any previously unreported fetal/infant congenital anomalies identified? <i>If "Yes", mark all that apply. If "No" or "Not assessed", end of form.</i>	Central nervous system, cranio-facial	Central nervous system, spinal	Cardiovascular	Renal	Gastrointestinal	Pulmonary	Musculoskeletal
1	999612361	No	No	19 Jan 2024 📅	–	–	–	–	–	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

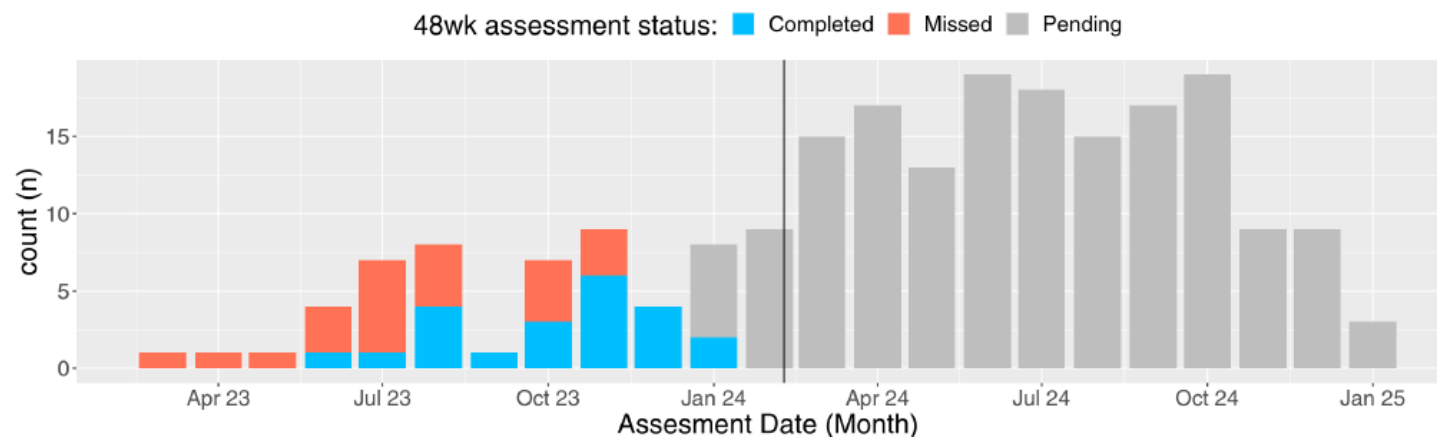
Infant Assessments- 48 weeks

Completion of Infant Assessments in OLE

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

Assessment Status	n	Total	%
Completed	22	45	48.9
Missed	23	45	51.1

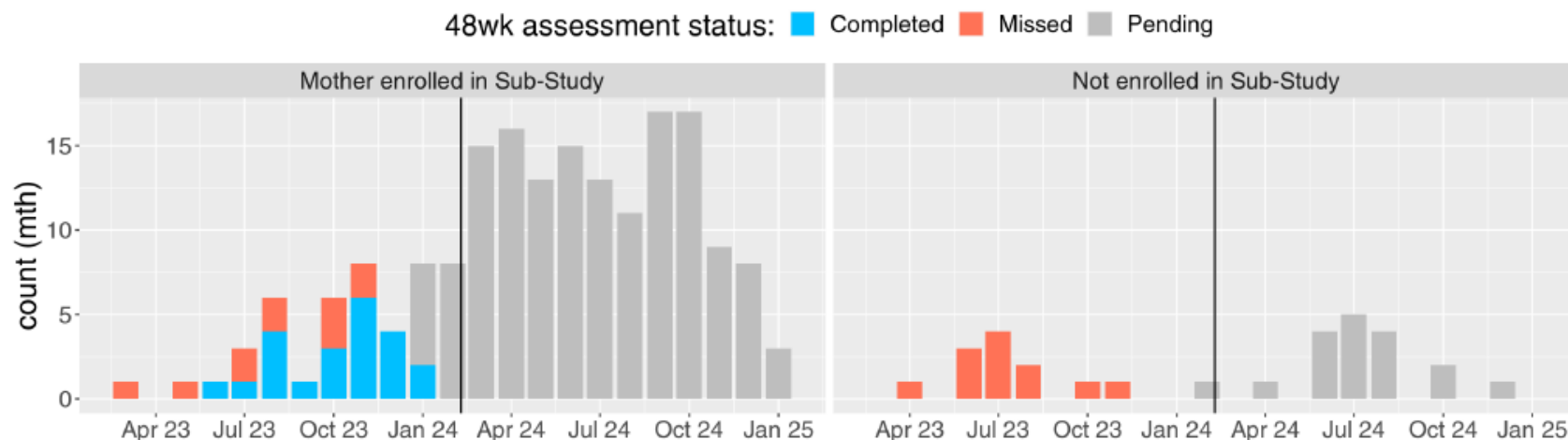
Figure 1: Distribution of Infant assessment completion status.



Infant Assessments- 48 weeks

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

Assessment Status	Sub-study Status	n	Total	%
Completed	Mother enrolled in Sub-Study	22	33	66.7
Missed	Mother enrolled in Sub-Study	11	33	33.3
Missed	Not enrolled in Sub-Study	12	12	100.0



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

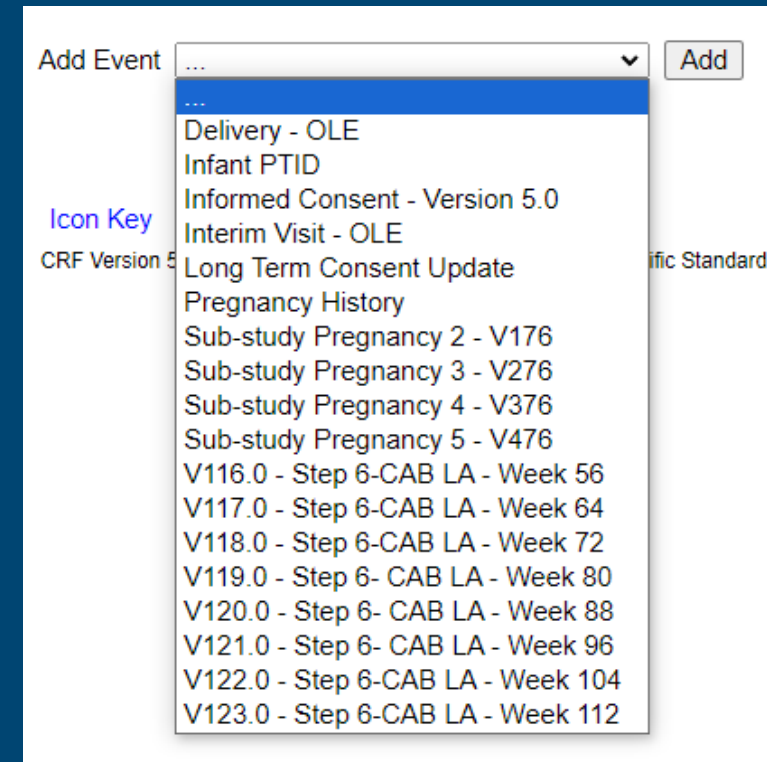
Pregnancy- Retrospective Data Collection in OLE

- 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:
 - 122.0 Week 104
 - 123.0 Week 112



The screenshot shows a web interface for adding events. At the top, there is a label 'Add Event' followed by a dropdown menu with a blue bar at the top and a downward arrow. To the right of the dropdown is an 'Add' button. Below the dropdown, a list of events is displayed. To the left of this list, there is a label 'Icon Key' in blue and 'CRF Version 5' in black. To the right, there is a label 'ific Standard T' in black. The list of events includes:

- Delivery - OLE
- Infant PTID
- Informed Consent - Version 5.0
- Interim Visit - OLE
- Long Term Consent Update
- Pregnancy History
- Sub-study Pregnancy 2 - V176
- Sub-study Pregnancy 3 - V276
- Sub-study Pregnancy 4 - V376
- Sub-study Pregnancy 5 - V476
- V116.0 - Step 6-CAB LA - Week 56
- V117.0 - Step 6-CAB LA - Week 64
- V118.0 - Step 6-CAB LA - Week 72
- V119.0 - Step 6- CAB LA - Week 80
- V120.0 - Step 6- CAB LA - Week 88
- V121.0 - Step 6- CAB LA - Week 96
- V122.0 - Step 6-CAB LA - Week 104
- V123.0 - Step 6-CAB LA - Week 112

Informed Consent V5.0

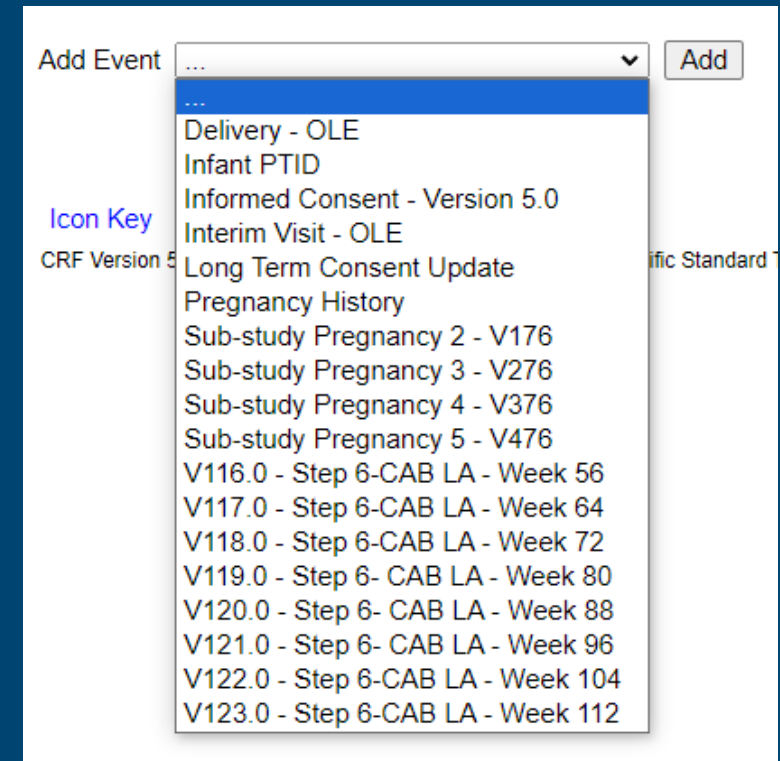
Add Event

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

Subject: 999779567					
Page: Informed Consent - Version 5.0 - Informed Consent - Version 5.0 (1)					
Did the participant consent for Protocol Version 5.0? <input checked="" type="radio"/> Yes <input type="radio"/> No					
If Yes, Date of Informed Consent <input type="text" value="12"/> <input type="text" value="Feb"/> <input type="text" value="2024"/>					
If she becomes pregnant, did she consent for prenatal ultrasound and infant assessments including safety for a year? <input checked="" type="radio"/> Yes <input type="radio"/> No					

Add Event:

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



The screenshot shows a web interface for adding events. At the top, there is a label 'Add Event' followed by a dropdown menu and an 'Add' button. The dropdown menu is open, displaying a list of event options. To the left of the dropdown, there is a blue 'Icon Key' and a label 'CRF Version 5'. To the right, a partial label 'ific Standard T' is visible. The dropdown list includes the following items: Delivery - OLE, Infant PTID, Informed Consent - Version 5.0, Interim Visit - OLE, Long Term Consent Update, Pregnancy History, Sub-study Pregnancy 2 - V176, Sub-study Pregnancy 3 - V276, Sub-study Pregnancy 4 - V376, Sub-study Pregnancy 5 - V476, V116.0 - Step 6-CAB LA - Week 56, V117.0 - Step 6-CAB LA - Week 64, V118.0 - Step 6-CAB LA - Week 72, V119.0 - Step 6- CAB LA - Week 80, V120.0 - Step 6- CAB LA - Week 88, V121.0 - Step 6- CAB LA - Week 96, V122.0 - Step 6-CAB LA - Week 104, and V123.0 - Step 6-CAB LA - Week 112.

- 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?