

WebDCU and Data Management

Jodie Riley

Teldon Alford

Overview

- Common ESETT CRF data entry questions/tips
 - F501 Treatment Effect
 - F503 Secondary Outcomes
 - F117 Baseline Vital Signs
 - F101 Eligibility
 - F505 Demographics
- WebDCU Demo
 - Monitor visit site PI review
 - Enrollment summaries/charts
 - Data Management – DCRs, rules, alerts, data entry report

ESETT DATA ENTRY

Common questions/tips

Treatment Effect CRF

- 60 minute assessment FAQ:
 - The 60 minute assessment should reflect a clinical determination of the patient's condition at exactly 60 minutes regardless of when the assessment was performed.
 - For example, if the assessment was done at 70 minutes, the time of the assessment entered in WebDCU should reflect 70 minutes, but clinical judgment should be used to determine what was happening at 60 minutes based on all available information.

Secondary Outcomes CRF

- When any data point = Yes on the secondary outcomes CRF, a corresponding AE form should be submitted.

Secondary Outcomes CRF		AE CRF
Q01	Life-threatening hypotension within 60 minutes	→ Q30 = Life-threatening hypotension
Q02	Life-threatening cardiac arrhythmia within 60 minutes	→ Q30 = Life-threatening cardiac arrhythmia
Q03	Endotracheal intubation performed or attempted within 60 minutes	→ Q34 = Yes
Q04	Acute seizure recurrence between 60 minutes and 12 hours	→ Q30 = Acute seizure recurrence
Q05	Acute anaphylaxis within 6 hours	→ Q30 = Acute anaphylaxis

Baseline Vital Signs CRF

- Baseline vital signs are the vital signs collected closest and prior to the start of study drug infusion.
- If some vitals were collected before study drug infusion and others were collected after, enter ONLY the ones collected before study drug infusion into WebDCU.
- The vitals not collected before study drug infusion can be left blank on the CRF and warnings dismissed. Provide context in general comments as necessary.

Eligibility CRF

- Information may become available later that indicates the subject did not meet eligibility criteria at the time of enrollment. In this case, Eligibility CRF answers should be updated. This allows us to track eligibility deviations for analysis.
- The exception to this is for eligibility criteria that specify “known” in the question (e.g. “known liver disease”). These eligibility questions refer to what is known at the time of enrollment and they do not need to be updated later if more information becomes available.

Demographics CRF

- Years of education should be left missing if unknown, instead of entering '0'.
- If known to be zero, either respond to the warning or explain in general comments.

Q01	Ethnicity	<input checked="" type="radio"/> <i>Hispanic or Latino</i> <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Unknown	
Q02	Race <i>Check all that apply</i>	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input checked="" type="checkbox"/> <i>White</i> <input type="checkbox"/> Unknown	
Q04	Age at baseline <i>Derived from DOB on F101 Eligibility Form</i>	15 	
Q03	Number of years of education <i>If unknown, leave blank.</i>	0 	 <i>Based on the age, the subject should have some number of years of education. Leave blank if unknown, instead of putting 0.</i>

WEBDCU DEMO

Monitor Visit PI Review

- Principal Investigators can review monitoring visit reports in WebDCU and indicate in the system that they have reviewed.

Enrollment Summary

- Enrollment chart
 - By month
 - By week
 - By Hub
 - Cumulative
- Site enrollment summary

Data Management

- Review DCRs
- Review rule violations
- Monitor alerts
- CRF data entry report