Webinar: ADaMIG v1.1 & OCCDS v1.0

Date: May 19 2016

Time: 10:00-11:30 AM CT

Presenter: John Troxell and Sandra Minjoe, Accenture.

1. Can we use OCCDS class in current version of OpenCDISC (Pinnacle 21) data validation? Have the OpenCDISC validation rules been updated to reflect ADaMIG v1.1?

The CDISC ADaM Team is currently working on ADaM Team-specified validation checks for these new CDISC ADaM documents (ADaMIG v1.1 and OCCDS v1.0).

2. What is the plan for the next iteration of ADaMIG release? Would it include OCCDS model? Would it include integrated analysis model?

Work on the next ADaMIG release is underway, but that release will not attempt to combine documents. CDISC is investigating how best to combine documents in the future.

3. Can we create two variables TRTDUR and TRTDURU instead of one variable TRTDURD/M/Y?

The ADaM Team determined that there were cases when more than one unit would be useful in a single study (such as treatment duration in days and treatment duration in months). For that reason, variables TRTDURD, TRTDURM, and TRTDURY were all included as variables, so we can include more than one of these when needed.

4. If the lab data is analyzed both as findings data (change from baseline etc.) as well as NCI/CTC criteria, do we map lab data to both BDS and OCCDS structure and create two datasets?

The choice of data structure is dependent on analysis needs. If you need to analyze change from baseline, then BDS is the appropriate structure. If you need to analyze lab event occurrences, then OCCDS is the appropriate structure.

5. Can BDS structure be used for ADAE while using ADaMIG v1.1 during transition

There isn't a standard ADAE dataset specified by any ADaM standard documents.