Unanswered Questions: CDISC Public Webinar Series—Standards Updates and Additions (23 Oct 2014)
Agenda: SDTMIG Batch 2, Fred Wood (Accenture)

Q: when is the public review period for this batch?
A: Batch 2 is expected to be ready for review sometime next week.

Q: Are you thinking of CDISC/NCI Controlled Terminology for Role?
A: Answered online.
Q: I meant Controlled Terminology for the Role, not the added non-standard variable.
A: There is Controlled Terminology for Role, as described in the SDTM and SDTMIG. The focus of the CDISC CT Team and NCI terminology has been on data and not metadata. This is a question that could be addressed by this team, since I'm not involved in determining their scope.

Q: On Disease Milestones (slide 19): What if one has multiple milestones that would apply to the same Concomitant Medication?
A: It's considered extremely unlikely that a single dose of a concomitant medication would be relevant to two Milestones. As a result, this was not considered by the development team. More likely, there would be two CM records, one for each Milestone.

Q: With the new way to submit NSVs, where do we store the QEVAL information?
A: It would have to be handled as value-level metadata, just as the evaluator for any other standard variable would now have to be handled. There may be cases where this can be managed at the record level with the --EVAL variable in Events and Findings.

Q: If ADaM is not going away, why do we always add addtional variables to the collected/raw data?
A: --unanswered--
The SDTM has and will always contain tabulation (collected data). The only change in the handling of NSVs is that, instead of being submitted in SUPP-- datasets, they can be submitted in the parent domain.

Q: Not sure it is relevant for today TC but with regards to oncology domains (TU/TR/RS), I understood these have been generalized to eventually cover other TA (e.g. CV having similar concepts of lesiions). However for oncology they remain very specific to RECIST (so solid tumors). I was wondering when applied to other type of tumors, e.g. leukemia, where we still have the concept of tumor response but we do not have the concept of lesions (e.g. response driven by the hematoloy profile), if we could partially apply them? e.g. use on RS to store the response at each assessment but not the TU/TR. Also would you reccomed to use RS for prior therapies response or better to stored elsewhere e.g. SUPPXX
A: This question would have to be addressed by someone on the Oncology Team.