Standards / Mapping Questions

- Rescreened Patients: multiple SUBJIDs?
- SE: sort order for SESTDTC?
- AETRTEM: residual effect period?
- SDSP (Study Data Standardization Plan): Status of implementation?
- Sponsor defined information for Tx set-up (eg oncology studies)

Standards / Mapping Questions
Rescreened Patients: multiple SUBJIDs?

Problem: According to the Study Data Technical Conformance Guide (published on 17. Dec 2014) re-screened patients should have different patient numbers assigned.
This is causing conflicts with the current SDTM standards (eg one line per USUBJID in DM only)

Question: Is there experience on how to handle re-screened patients which can be shared?

Solution: For the time being do not follow the FDA guidance in this case.

Standards / Mapping Questions
SE: sort order for SESTDTC?

Problem: In order to ensure the elements a patient actually passed through by are in the right order it is required to sort by SESTDTC.
There may be ambiguity due to partial/missing information or differing precision for elements to supposed to follow each other (eg 2015-03-03, and 2015-03-03T12:00).

Question: How to ensure proper order of elements considering these scenarios?

Solution: Sort by SESTDTC (date component only),
TAETORD,
SESTDTC (time component)
What else?

Standards / Mapping Questions
AETRTEM: residual effect period?

Question: Is there experience considering a residual effect period for assigning the AETRTEM flag?
If so, how is it implemented?

Solution: ?

Standards / Mapping Questions
SDSP: Status of implementation?

Problem: According to the Study Data Technical Conformance Guide (published on 17. Dec 2014) it is required to prepare an SDSP early on in the development program. As a minimum it should include:

1. List of the planned studies
2. Type of studies (e.g., phase I, II or III)
3. Study designs (e.g., parallel, cross-over, open-label extension)
4. Planned data standards, formats, and terminologies and their versions or a justification of studies that may not conform to the currently supported standards

Question: is there experience available which could be shared, regarding preparation of an SDSP?

Standards / Mapping Questions
Sponsor defined information for Tx set-up

Boehringer Ingelheim

Question: Are there options to add information to eg Tx available in the database so that it doesn‘t need to be re-generated in ADaM?

Example: Oncology – grouping together the visits comprising a course

Solution: So far visit name used (eg C1D1, C1D3, ….. , C2D1, C2D3…? Disadvantage is that there is limited control across studies to keep this consistent.

Ideally we could add a variable containing the course value.

Standards / Mapping Questions xxxxx?

Problem:?

Question:?

Solution: ?