Angelo Tinazzi

Subject: CDISC Italian User Network TC - SAVE THE DATE

Start: mer. 28/11/2018 12:00
End: mer. 28/11/2018 13:30
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: Angelo Tinazzi
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Update con Webex info

CDISC Italia UN

Wednesday 28 November 2018

12:00 | Europe Time (Paris, GMT+01:00) | 1 hr 30 mins

Meeting number (access code): 795 057 266

Host key: 704803

Meeting password: CDISC

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Buongiorno a tutti,

Scusandoci per la lunga assenza riprendiamo questo mese con le nostre TC regolari (piu' o meno).
Abbiamo allocato per questa TC 90 minuti invece dei 60 minuti usuali.

Questa dovrebbe essere l'agenda di massima :

- CDISC e Data Submission What's New
- CDISC e Data Submission topic dall'ultimo PhUSE di Francoforte
- Come Gestire 'Multiple Enrolment' e 'Multiple screen Failure' in SDTM e.g. USUBJID. Stato dell'arte da CDISC, PhUSE Working Group e Guidance FDA
- CDISC e Machine Learning. Stato dell'arte emerso da presentazioni CDISC Interchange e PhUSE
- Varie ed Eventuali

Vi manderemo al piu' presto i dettagli WEBEX.

Vi segnaliamo infine che FDA ha rilasciato la versione di ottobre della study data technical conformance guidance (la trovate in attachment).

Qui di seguito un sommario dei cambiamenti rispetto alla versiona di marzo. Il sommario è in inglese perchè è preso da un email che ho inviato qualche giorno fa internamente a Cytel (…..troppo pigro che tradurlo, scusate….)-

As most of you should know (or must), there are special requirements when submitting data to FDA using standards e.g. CDISC.
Among the guidance they have released, the Study Data Technical Conformance Guide is the one containing more technical details, thus everyone should be familiar with its content.

The October 2018 version has been just released, and you can find it in attachment.
For your information FDA plans to release two versions per year, one in March and one in October.

I had a quick look at the new version and in particular at the changes documented in the document revision history section.

October 2018	4.2	Section 3.3.5 (Special Characters: Variables and Datasets) – Added clarification text Section 4.1.1.3 (SDTM Domain Specifications) – Additional text and table under DM and Trial Design Model sections, added DV Domain section Section 4.1.2.10 (Software Programs) – Clarified text Section 4.1.3.2 (General Considerations) – Updated text Section 4.1.3.3 (SEND Domain Specification) – Added Lab Test Results, Body Weight, and Comments domains, updated Pharmacokinetics Concentrations Domain and Trial Design Model sections Section 4.1.4.1 (Variables in SDTM and SEND: Required, Expected, and Permissible) – Update Section 5.2 (Supported Therapeutic Areas) –Added TA sections Section 6.6.1.1 (General Considerations) – Updated text Section 7.1 (eCTD Specifications) – Updated text Section 8.2.2 (Support on Data Validation Rules) – Updated text Appendix B, C, D, E, F, G - Added

Clarification of use of Special Characters in datasets (in the content/values)

With this version of the guidance, FDA has clarified that the restriction on the use of special characters applies to data as well and not just metadata e.g. dataset names, variables names and labels.

UTF-8 for extended characters is not recommend, meaning that only *printable value below ASCII 128* should be uses, so ASCII characters between 32 and 127 (ASCII below 32 are not printable characters e.g. carriage return).

So once again always check in the datasets you receive.

How to handle Screen Failure and multiple enrolment / screening in SDTM DM

The way screen failure should be identified in DM is one of the few instance where FDA "contradict" a CDISC rule.
While the CDISC Ig suggest to represent screen failure with ARMCD/ACTARMCD = "SCRNFAIL" / ARM/ARMCD = "Screen Failure", FDA requires all this fields to be left Null.
This was already a requirement in previous version, what has been clarified in the text below in the October release is that the requirement is same for ARMCD, ACTARM and ACTARMCD.

DM Domain (Demographics)
In the DM domain, each subject should have only one single record per study.

Screen failures, when provided, should be included as a record in DM with the ARM, ARMCD, ACTARM, and ACTARMCD field left blank. For subjects who are randomized in treatment group but not treated, the planned arm variables (ARM and ARMCD) should be populated, but actual treatment arm variables (ACTARM and ACTARMCD) should be left blank.[25]

Also for multiple enrolments, the following text clarify how FDA would like to handle multiple enrolment or multiple screenings.
In few words DM will contain the main enrolment / main screening and all other instances of enrolment screening in a sponsor domain with similar structure to DM. The question might be how to name it and if we can consider as Special Purpose Domain in define.xml like for DM! This has to be to clarified.

For subjects with multiple enrollments within a single study, the primary enrollment should be submitted in DM. Additional enrollments should be included in a custom domain with a similar structure to DM. Clarifying statements in the RG would be helpful.

For subjects with multiple screenings and no subsequent enrollment, include the primary screening in DM with additional screenings in a custom domain with a structure similar to DM.

For subjects with multiple screenings and subsequent enrollment, include the enrollment in DM with screenings in a custom domain with a structure similar to DM.

The recommendation here for your studies is to check sponsor preferences, if any.

SDTM DV (Protocol Deviations)

This is a new section where FDA requires the submission of Protocol Deviations SDTM dataset (DV).

More Clarification for SDTM TS (Trial Summary)

They clarify the need of submitting a simplified version of TS when submitting legacy data e.g. data not in standard format (CDISC).

They also propose some parameters to add in TS datasets to specify the SDTM Ig / model used (up to now only available in the reviewer guide) and any other guidance e.g. therapeutic area guidance, you might have used in your SDTM datasets.

Moreover there is a new Appendix containing a list of recommend parameters for both complete and simplified TS version.

New Appendixes B, C, D, E, F, G

In particular:

- appendix B and C are for TS (see above)
- appendix E contains example of eCTD folder structure for datasets

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A presto

Silvia e Angelo