Protocol Representation Toolkit – Beta Testing Period

Comments Requested

The leader of the CDISC Protocol Representation Group (PRG) presented via an online webinar on 18 December 2012 where more than 200 attendees joined the webcast from various regions of the world. The PRG has worked for the past decade under an overall charter and a primary objective for standardizing and structuring the content of the Research Protocol document. The Protocol Representation Model (PRM) v1.0 was published in 2010. A more recent objective of this CDISC team is to facilitate the use of this standard by creating tools around using these standardized concepts. Furthermore, the relationship between the PRM and SDTM is extremely important to the PRG. The tool and this relationship were the primary topic for this webinar.

The PRG has ensured alignment of the PRM with the CDISC BRIDG model while releasing the initial tool, which is based around Study Online Concepts (including standards concepts and standard document layout). In addition, the Protocol team continues work to create the standard list of concepts for the entire Protocol; this comprehensive set of concepts is an activity for this team in 2013.

The Study Outline Web-Wizard Tool: This tool is an online web-based accessible tool available on the CDISC website for all CDISC members: http://www.cdisc.org/extranet/index.php. Click here for further information on the CDISC PRM Toolset Version 1.0: https://cdiscprm-sandbox.imedidata.net/.

We have the benefit of the standardization, but we need to know how to apply these standards in the business process (for clinicians and medical writers and other protocol authors and users). Therefore, the purpose of this tool is to facilitate the standards implementation process; it is an example of how to use the standards.
The team will continue to publish iterations on the Protocol Standard, the Study Outline Web-Wizard tool and on program concepts in 2013. The current Protocol v1 Standard provides standard-content in a domain analysis concept, based upon the BRIDG model; the tool shows how to use the standard within any work environment.

**Further Objectives of the PRG Team:** One of the objectives of the Protocol team is to move the data downstream and to find a way to transfer that information into the system; hence, to successfully enable that interchange of information. For this purpose, the team did something similar to the IODM (SDM ODM extension).

The PRG is focusing on standardizing the complete list of Protocol Concepts in 2013, to supplement the previously release Protocol Outline Concepts (2012). Once the Concepts are finalized, they will be harmonized with both BRIDG and applicable SDTM Elements. The next step is to release a standard ODM with Extensions to include the Protocol Concepts, including reference to the SDM ODM Extensions.

**Brief Introduction for the Study Outline Web-Wizard**

**Beta release:** This is a test-period where the Study Outline Web-wizard tool application is made available to allow for comments and feedback, which will be used for production purposes. The team will release the production version in 2013.

The web interface focuses on the Study Outline document. For example, if one creates the core concepts of a study (Pre-Protocol after clinical development plan) within this Web-Wizard, one can develop the study synopsis and obtain a brief of the study along with the final Protocol. The tool will also generate the SDTM Trial Summary Datasets along with the information that has been entered and then maps directly to the Study Outline Standard. It also shows how to map to SDTM and how to interact and use the standard on a practical basis.

**Output of the Tool:** Generating a PDF of the Study Outline document.

Below is an example of the tool: Upon signing-in to the website, one will see an explanation of this tool and how it operates, then can hit “start” to view the tool. By walking through the study outline concept as defined in the standard, one will see the high-level defined grouping as in the blue bars below, and can view the general information trial objective and purposes. This information can be saved in PDF format.
The figure above shows information populated from the CDISC Controlled Terminology. If one looks at the figure above, one will notice values for “Yes” or “No” (and some concepts have multiple values). In addition, one has the ability to add as many values as needed. And at the end of the process, one can create the PDF-export which is laid out in
the standard format. Furthermore, the SDTM trial summary (inclusion/exclusion) are also exported from the tool and those files can be saved to one’s computer as well.

The current site provides for a Beta test period. The Protocol team welcomes any feedback and comments that help in improving and releasing further iterations of the tool.

**Information about the Protocol Representation Model Group/Team:** The Protocol team meets bi-weekly, every other Thursday at 10:30 AM EST, they will meet next on 24 January 2013. Information on the CDISC Protocol Standard can be obtained from the CDISC website, Protocol area: [http://www.cdisc.org/protocol](http://www.cdisc.org/protocol). Any further details on the Protocol tool will be posted on the website soon, stay tuned to [www.cdisc.org](http://www.cdisc.org).

**Last but not least, volunteers are always welcome! Click here to volunteer:** [http://cdisc.wufoo.com/forms/z7p9r7/0](http://cdisc.wufoo.com/forms/z7p9r7/0). Please do not hesitate to provide us with your feedback. The standards can be used in practice on a daily basis across the industry. Comments and input around the standards and the Web-Wizard Tool are also welcome at anytime.

See also the related article in this eNews by Julie Evans.

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