The Protocol Representation Model

Version 1.0 Notes

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Section 1.   Protocol Representation Model Version 1.0

The CDISC Protocol Representation Model Version 1.0 View is intended for those involved in the planning and design of a research protocol. The majority of business requirements have come from those involved in clinical trial protocols. It focuses on the characteristics of a study and the definition and association of activities within the protocols, including "arms" and "epochs". It also includes the definitions of the roles that participate in those activities.

The scope of this view includes Trial Design, Eligibility Criteria, and the requirements from the ClinicalTrials.gov and World Health Organization (WHO) registries.

This view is based on the BRIDG Release 3.0 Protocol Representation sub-domain. It includes all classes in the BRIDG Protocol Representation sub-domain plus some classes from other BRIDG sub-domians, generally classes required for ClinicalTrials.gov and the WHO registries.

Section 2.   Files in the PRM V1.0 Package

The PRM V1.0 Package includes all materials collected and published as a formal release of the PRM. These items are gathered in a single package (ZIP file) and posted on the CDISC website at http://www.cdisc.org/protocol. The files in the package are:

- **PRM V1.0 Document**

  The PRM V1.0 document introduces the PRM, provides a brief explanation of how to read UML, and includes a report of all the model contents.

  The specific file name in the Version Package in this category is:

  o   Protocol Representation Model Version 1.0.pdf.

- **PRM V1.0 Model in Enterprise Architect**

  The UML representation of the PRM is represented in Enterprise Architect from Sparx Systems (which is an .EAP file). A UML modeling tool such as Enterprise Architect supports the development of a model as a collection of dynamic and static semantics which are represented in multiple views (e.g. Class, Instance, and State Diagrams) as described above.

  o   NOTE: A viewer which enables full traversal and inspection of the PRM V1.0 view of BRIDG model and the complete BRIDG model can be downloaded from the Sparx Systems website (http://www.sparxsystems.com.au/).

  The specific file name in the Version Package in this category is:

  o   BRIDG with PRM V1.0 View.EAP.

- **PRM V1.0 Model Diagram in Excel**

  The PRM diagram is difficult to read in a pdf document, so this file is provided for those who would like to view the diagram without using the Enterprise Architect tool.

  The specific file name in the Version Package in this category is:

  o PRM V1.0 Diagram.xls.

- **PRM V1.0 Review Comments and Responses**

  During 2009, the CDISC PRG published the PRM for review and comment. The PRG then reviewed each comment and provided a response. In many cases, the model was updated as a result of the comment. The comments and responses are documented in this file.

  The specific file name in the Version Package in this category is:

  o PRM V1.0 Review Comments and Responses.xls.

- **PRM V1.0 Version Notes (this file)**

  This file provided a description of this version and a list of files included.

  The specific file names in the Release Package in this category are:

  o PRM V1.0 Version Notes.pdf

Section 3.   How to Comment on PRM V1.0

You can post comments, suggestions, and questions in the CDISC Discussion Forum on the CDISC website at http://www.cdisc.org/public-discussion-forum under the Protocol Representation Model V1.0 topic.

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