BRIDG Release 3.2 Now Available

The Clinical Data Interchange Standards Consortium (CDISC), Health Level Seven (HL7), the U.S. Food and Drug Administration (FDA) and the U.S. National Cancer Institute (NCI) are pleased to announce the release of version 3.2 of the Biomedical Research Integrated Domain Group (BRIDG) model of the semantics of protocol-driven clinical research. Release 3.2 of the model is available for download at: http://bridgmodel.nci.nih.gov/download_model

The changes represented in Release 3.2 are largely due to the harmonization of several projects:

- **CDISC Statistical Analysis Domain Analysis Model** - The Statistical Analysis Domain Analysis Model includes concepts describing the planning and performance of the statistical analysis of data collected during clinical trial research and their relationships. This sub-domain will eventually include the semantics for the entire Statistical Analysis lifecycle. For BRIDG 3.2, only the Statistical Analysis Plan semantics are included.

- **Hematopoietic Cell Transplant (HCT) Database** – This project is designed to produce a BRIDG-compatible model and database (with associated Common Data Elements (CDEs)) covering the scope of federally-mandated data submission from all transplant centers to the Stem Cell Transplant Outcomes Database (SCTOD). In association with integration engines to be developed in tandem but outside the scope of this project, the application will support direct connection between center databases of varying types and the SCTOD. The feasibility of this design has already been demonstrated at MD Anderson using a non-BRIDG compatible data model but caDSR-curated CDEs. Successful implementation will demonstrate high-volume clinical data transmission using the GRID for sharing of center-generated standardized clinical outcome data. It will also support intra-center data exchange and transmission of data to the CTRP and the .gov databases without data transcription. The harmonization of the HCT concepts has occurred in phases, the first of which was included in release 3.1 and covered concepts related to donor and recipient information. The second phase harmonized HCT concepts that are related to product processing and storage. Because HCT is an emerging field, we anticipate further changes to BRIDG to harmonize that content in later releases.

- **NCI Case Report Form (CRF) Harmonization and Standardization Initiative**: This project is an NCI Clinical Trial Work Group initiative focused on the improvement of enterprise clinical trials through the use of a library of harmonized data collection forms (Case Report Forms, aka CRFs) created through stakeholder consensus. Running since 2006, this effort is projected to run through an estimated five consecutive rounds of community review and consensus-building to produce a set of wider community vetted and approved variables that will be used to create Standard CRF modules that will be used to build CRF collection instruments. The core set of elements and associated forms will be registered in the cancer data standards registry and repository for public
The main concepts covered in the harmonization of the NCI CRFs include Concomitant Medication, End of Form, Footer, Header, Prior/Post Therapy Agents, Staging/Extent of Disease, and Study Agent Administration. The NCI CRF project is taking a phased approach so additional concepts will be harmonized in subsequent releases of BRIDG.

- **FDA Clinical Trials Repository (CTR)/Janus**: The Clinical Trial Repository (CTR) is a standards-based repository of subject level clinical trial data to support regulatory review and patient centered outcomes research. The conceptual model captures FDA's requirements for clinical trial data. The model is informed by the Biomedical Research Integrated Domain Group (BRIDG) Domain Model and is designed to receive data in CDISC SDTM format and emerging HL7 v3 study data exchange standards.

- **HL7 Clinical Trial Registration and Results (CTRR)** - This effort is focused on the development and maintenance of a Health Level 7 (HL7) V3 message in support of the information requirements brought about by the increasing number of national, regional and global clinical trial registries and trial results databases. In doing so, this project will provide an important element in the electronic exchange of both the protocol-related descriptive information needed to register a clinical trial, as well as a capability to define the exchange of information summarizing trial result outcomes. The project is intended to address the exchange of clinical trial summary-level data and will not be used to transport individual patient-related data.

- **NCI Clinical Trials Reporting Program (CTRP)**: NCI's Clinical Trials Reporting Program (CTRP) is a web-based program that is designed to serve as a single, definitive source of information on all NCI-supported cancer-related clinical trials. The CTRP system receives submissions and updates from hospitals and cancer centers and from systems maintained within the Cancer Therapy Evaluation Program (CTEP), the Division of Cancer Prevention (DCP) and the Center for Cancer Research (CCR). CTRP captures information covering all key aspects of a clinical trial -- including study design, sponsors, investigators, participating sites, eligibility criteria, trial status, and accrual. The data collected in CTRP is used by NCI to coordinate research efforts and facilitate effective clinical trial prioritization. To learn more about CTRP, please visit the NCI Wiki: [https://wiki.nci.nih.gov/display/CTRP](https://wiki.nci.nih.gov/display/CTRP).

- **FDA HL7 Study Design Structured Document (partial)** - The Study Design Structured Document specification describes a research study protocol. This specification will transport the human-readable protocol and machine-readable trial design and eligibility criteria information in a standardized format, with particular emphasis on communicating the following as structured items: arms, epochs, subject assignment, planned encounters (visits), planned interventions, planned observations (assessments), eligibility criteria and other study characteristics. Release 3.2 contains a subset of the semantics of this project. The remaining semantics are expected to be included in a future release of BRIDG.

Other major changes in BRIDG R3.2 include:

- **Inclusion of the OWL Perspective** – The BRIDG SCC has now committed to publishing a representation of BRIDG semantics in OWL. For this release, the scope of the OWL content is limited to the information found in the BRIDG UML model.
• **Addition of an html representation of the BRIDG Model** – The BRIDG SCC is providing the html version of the BRIDG model from the new website.

• **Addition of new instance diagrams** – These new instance diagrams should help BRIDG users understand how to use BRIDG semantics to represent:
  
  o Contingent Eligibility Criteria, e.g., asking an eligibility criteria question that is contingent on the answer to one or more previous eligibility criteria questions.
  o Hematopoietic Stem Cell Transplant concepts, e.g., how various CDEs are linked to one another through a series of commonly referenced complex activities.

• **Removal of the SME perspective subdomain models from the BRIDG release package** – Because the content of these subdomain diagrams do not differ significantly from the comprehensive domain diagrams and there was no known use of these subdomains, these files have been removed from the release package.

In addition to the changes in the BRIDG model, the BRIDG web site has been updated to provide easier access to BRIDG related content. In the past, this content has been available in documentation accessed through Project SVN, BRIDG website and GForge site. This new website has consolidated all that information. The BRIDG SCC has also provided some additional content, such as the html version of all BRIDG releases, upcoming BRIDG SCC plans, etc. To see the new updated website, please visit www.bridgmodel.org.