**Leadership Team**

The BRIDG Advisory Panel, a new governance structure sponsored by the NCI, is in place starting in 2013.

BRIDG Advisory Panel:
- Ed Helton – Sponsor Project Officer, NCI
- Becky Kush – Chair, Subject Matter Expert
- Diane Wold – Subject Matter Expert, GSK
- Ed Hammond – Subject Matter Expert, Duke University, HL7
- Bob Milius – Subject Matter Expert, National Marrow Donor Program
- Lauren Becnel – Subject Matter Expert, Baylor College of Medicine
- Mary Ann Slack – Subject Matter Expert, FDA

The BRIDG Advisory Panel currently has an NCI hosted site at: [https://wiki.nci.nih.gov/display/BRIDG/BRIDG+Governance](https://wiki.nci.nih.gov/display/BRIDG/BRIDG+Governance)

**Team Mission**

The mission of the CDISC Biomedical Research Integrated Domain Group (BRIDG) Project is to support the goal of semantic interoperability within the CDISC standards and with healthcare by providing CDISC standards semantics to the BRIDG model. BRIDG Release 1 was issued in June 2007 with a total of 12 releases issued to date. The current release is BRIDG Release 3.2.

BRIDG is a kind of information model called a Domain Analysis Model (DAM), which represents a shared view of the concepts of protocol-driven clinical research. This structured information model is being used to support development of data interchange standards and technology solutions that will enable semantic (meaning-based) interoperability within the biomedical/clinical research arena and between research and the healthcare arena.

The BRIDG model is a conceptual UML model from which detailed design level artifacts can be built. Interoperability with healthcare is based on mapping to the HL7 Reference Information Mode (RIM), which is available as a series of Visio diagrams.

**Scope**

General Scope: Protocol-driven research and its associated regulatory artifacts: i.e. the data, organization, resources, rules, and processes involved in the formal assessment of the utility, impact, or other pharmacological, physiological, or psychological effects of a drug, procedure, process, or device on a human, animal, or other subject or substance plus all associated regulatory artifacts required for or derived from this effort, including data specifically associated with post-marketing adverse event reporting.

CDISC Scope: BRIDG is being used as the reference model for both the Therapeutic Area development process as well as the SHARE metadata repository.

The BRIDG SCC is currently being funded by CDISC and TransCelerate Biopharma, Inc.

**2014 Deliverables**

- List of gaps between Therapeutic Areas (TAs) and BRIDG – These deliverables will be available within 2 months after each TA User Guide is published for Public Comment.
- User’s Guide Update – Q4
- Release 4.0 – Q4 – Will include the NCI Life Sciences Domain Analysis Model (LSDAM).
- BRIDG ISO Ballot – To be determined

**Stakeholders/Constituency**

- National Cancer Institute
- FDA
- HL7
- Pharmaceutical Sponsors
- Software Application Builders
- Medical Devices, Diagnostics Sponsors
- Contract Research Organizations & Consultants

**Collaborations**

- NCI, FDA, HL7, ISO

**Operating Model & Meetings**

The BRIDG Advisory Panel is currently meeting on an ad hoc basis. The FDA and NCI have participated from 2006 - 2013 and are currently reviewing their level of participation for 2014.

The BRIDG SCC is currently meeting when projects are funded for harmonization.

Since BRIDG is a collaborative project, the NCI has provided the website for BRIDG at [www.bridgmodel.org](http://www.bridgmodel.org).


**Team Characteristics**

**Therapeutic Area Teams**

BRIDG Modelers review each TA User Guide to identify new semantics for BRIDG.

**BRIDG Semantic Coordination Committee**

This team typically comes together when a project is funded for BRIDG harmonization. The team members are clinical research information scientists that enter new semantics into BRIDG based on projects submitted by stakeholders.