

BRIDG Board of Directors Charter

Approved: May 2008; BRIDG mission updated November 2010; changed Semantic Coordination Committee to Semantic Coordination Committee November 2010

Vision: To be the unifying, global, information model for protocol-driven biomedical research

Mission: To engage stakeholders in an open, coordinated, and effective collaboration for developing and deploying a shared model of clinical research that advances data and information interoperability. This model is the domain model of HL7-RCRIM, and incorporates elements, requirements, and standards of stakeholder members.

Stakeholders: Organizations that use or contribute to BRIDG and commit to use the BRIDG Model in any new development requiring a clinical-research analysis model; over time, stakeholders are expected to use BRIDG in a preponderance of their use cases. Additionally, stakeholders are expected to submit local extensions or modifications to the SCC for harmonization. The founding stakeholders are: CDISC, FDA, HL7, and NCI.

BRIDG 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, subject characteristic, biologic, cosmetic, food 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.

By-Laws:

1. The BRIDG Board consists of 7-11 representatives of stakeholder organizations.
2. Board membership occurs in 2 ways:
 - a. Each founding stakeholder can appoint 1 member.
 - b. The remaining Board Members are elected by vote of the sitting Board members.
3. Appointed Board members serve as long as the appointing stakeholder desires. Elected Board members serve 3-year terms, which are renewable one time.
4. Elections are structured for staggered membership, with approximately one third of the membership elected each year.
5. A voting quorum consists of a simple majority of sitting members.
6. The Board Chair is elected by majority vote of sitting members for a term of one year; the Chair may not serve more than two consecutive terms.
7. Meetings of the Board are open to the public, with the exception of declared executive sessions when only Board members may attend.
8. The primary working extension of BRIDG is the Semantic Coordination Committee (SCC), comprised of stakeholder participants or their agents.
9. The Convener of the Semantic Coordination Committee holds an ex officio seat on the Board.
10. The Board may create other committees or task forces as it sees fit.
11. Changes to by-laws can be made by 2/3 affirmative vote of the Board membership present at any scheduled BRIDG Board meeting. Proposed changes must be published to the Board 30 days before the scheduled meeting.

Operating Procedures:

1. The Founding Stakeholders are encouraged to rotate their appointed membership.
2. The Board will have at least one face-to-face meeting each year. Attendance by electronic media constitutes presence, and qualifies for voting within the meeting.
3. Regular Board meetings will occur monthly by appropriate electronic media.
4. Voting procedures may be by electronic media.
5. A stakeholder member serves as the secretariat for the Board and the Semantic Coordination Committee. This may be the SCC Convener.
6. The Board will establish harmonization priorities for the SCC.
7. Technical products of BRIDG will be submitted for Committee Ballot by HL7-RCRIM.
8. Standard artifacts which pass HL7 Committee Ballot will be adopted by CDISC as a CDISC standard.
9. CDISC BRIDG standards will be submitted to ISO TC215 for adoption by reference, under ISO rules pertaining to Class A Liaison organizations.
10. Operating Procedures can be changed by a simple majority affirmative vote at any Board meeting.
11. A governance committee will be established for the election of Board members. The governance committee will publish a call for nominations and an election schedule.