

Biomedical Research and Regulation



Quick Start

Conference Calls and Minutes

Regular conference calls take place every Tuesday between Working Group Meetings from 16:00-17:00 Eastern time.

To join a call click on the following link: <https://zoom.us/j/94348388165>

You can download and import an [iCalendar](#) (.ics) files to your calendar system.

To get a local phone number go to: <https://zoom.us/u/aeYKKVpETd>

If you ever need it this is the Meeting ID: 943 4838 8165

There is a [Tip Sheet for Zoom here](#)

All active participants **and** other interested individuals are invited to join us for this call.

Conference call agendas and minutes are posted [here on Confluence](#) - see the tree on the left of the page

Work Products and Contributions to HL7 Processes

The BR&R performs the bulk of its work through projects with a clear line of sight to its scope. Examples include BRIDG (domain analysis model supporting research) and RPS (exchange message supporting medical product application submissions to regulators).

This Work Group will facilitate the development of common standards and the maintenance and enhancement of the research-focused domain analysis model for clinical research information management across a variety of organizations, including national and international government agencies and regulatory bodies, private researchers and research organizations, sponsored research, CROs and other interested entities. A shared semantic view is essential if the clinical research community, both for itself and as part of the larger Healthcare and life sciences communities, is to achieve computable semantic interoperability.

The BR&R will seek to assure that related or supportive standards produced by other HL7 groups are robust enough to accommodate their use in regulated clinical research through participation as appropriate, including ballots. The group will also monitor information interchange standards developed outside of HL7, and attempt harmonization of information content and representation of such standards with the HL7 content and representation.

The BR&R's charge includes the maintenance of BR&R-produced standards until their useful life has been exceeded, either through discontinuance of use or through supersession by later versions of the standard. The portfolio of standards will be reviewed annually for active use, obsolescence, and potential need for change. When a standard is identified for withdrawal, the BR&R will make efforts to communicate to users or potential users of that standard well in advance of any withdrawal action.

The BR&R will develop specifications using the principles and language of the Services Aware Interoperability Framework (SAIF) Canonical Definition (CD) and the restrictions and specializations of the HL7 SAIF Implementation Guide (IG) to ensure traceability from conceptual to logical to implementable specifications.

The term "regulated" or "regulation" refers to human and animal medical products and foods regulation.

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Formal Relationships with Other HL7 Groups

Clinical Genomics Clinical Interoperability Council Clinical Quality Information Electronic Health Record Emergency Care FHIR Health Care Devices Orders and Observations Patient Care Patient Safety Pharmacy Public Health and Emergency Response Structured Documents

Formal Relationships with Groups Outside of HL7

The BR&R maintains liaison relationships with appropriate national and international standard bodies subject to the approval of the HL7 Board, including at minimum CDISC and ISO TC 215 (and by reference, CEN TC 251).

BR&R BRIDG Re-architecture and Usability Subgroup

The objective of this BR&R subgroup is to develop a plan to improve the usability of the BRIDG UML model.

Deliverables:

- List of key usage scenarios supported by BRIDG
 1. Submission of study data to a central repository
 2. Clinical trial participant registration, and submission of the registration data to [ClinicalTrials.gov](#) and other international registries
 3. Submitting data to research repositories, such as oncology data for the SEER Registry
 4. Submit subject lab data to CRO and/or sponsor (similar to TCB Use case 3)
 5. Study setup, management, and site network management
 6. Sharing protocol and CRF metadata and subject data among trial stakeholders
 7. Adverse Event reporting
- Updated [ResearchStudy](#) and [ResearchSubject](#) resources (using BRIDG as the semantic basis for these resources)
- List of key BRIDG re-architecture recommendations