JIC Project Template
January 13, 2009

1. **Project Name:** Clinical Trial Registration and Results (CTRR)
2. **Project proposed**
    a. **Proposing organization:** HL7 and CDISC
    b. **Contact person with contacting information:**
    Tracy Beck - becktj@lilly.com
3. **Project Intent**
    a. **Informative – Technical Report**
    b. **Informative/normative – Technical Specification**
    c. **<DSTU(Draft Standard for Trial Use)>:** Target Date is September 2009
    d. **Normative – International Standard:** Target Date is May 2010
    e. **WHO may also be involved?**
4. **Project Purpose**
    a. **Why this project is needed – justification:**
    Public access to information concerning clinical trials and their outcomes has become an important and highly-visible global healthcare issue. In response, an increasing number of internet-based clinical trial registries and trial results databanks have been established or are being developed by national & regional health authorities and a variety of healthcare-related organizations. These publicly-accessible data repositories differ in their data requirements and in the scope of the information they present. As a result, they create a situation in which a given clinical trial may be represented in multiple repositories, in multiple native languages, and in differing presentation formats. Trial sponsors are facing increasing challenges in providing this information to the growing number of mandatory and voluntary repositories in a consistent fashion. At present, there is currently no consensus-based data exchange standard to support either the sponsor-to-repository or repository-to-repository information flow required to facilitate a harmonized approach to providing this data.
    b. **Why this project should be JIC:**
    Clinical trial transparency is viewed as a global public health issue. As a result, requirements for clinical trial registration and trial results reporting are being established in many regions and countries. The development of a global standard for this purpose provides a consistent mechanism to meet varying requirements.
    c. **What is the market need for this standard?:**
    Sponsors of clinical trials are the primary beneficiaries of the development of this data standard. Establishment of a global data standard for this purpose will enable process efficiencies in the preparation and review of this data before it is externally provided. In addition, repository owners also benefit from the development of this standard as it will help to promote data consistency and data quality. Finally, the public benefits from the development of this standard as it will help ensure that trials are consistently represented across multiple repositories (data integrity).
5. **Project Scope**

a. **What will be covered in this project:**
The development of a data exchange standard to provide the information required to register clinical trials in trial registries and report clinical trial outcomes in trial results databases as defined by global requirements.

b. **What will not be covered in this project:**
The registration or reporting of health outcomes related to the care of individual patients within clinical trials.

6. **Participating SDOs: for each SDO (usually more than one)**
   a. **Name of SDO:** HL7 and CDISC and TC 215
   b. **Name and ID of project:** Clinical Trial Registration and Results (CTRR), HL7 Project Insight # 372
   c. **Date project approved for harmonization effort by the sponsoring SDO:** December 200**8**
   d. **Is the SDO already working on this specific project?:** Yes
   e. **Lead within each SDO:**
   HL7 (RCRIM) – Scott Getzin, Kris Spahr
   CDISC – David Iberson-Hurst, Becky Kush
   f. **Approximate number of persons from SDO working on project**
   HL7 – 15
   CDISC - 4
7. **Host SDO:** HL7 (RCRIM) – See below
8. **Project Objectives and deliverables (commitment levels)**
   - Develop an initial data exchange standard to meet the current global requirements for trial registration and basic results reporting
   - Extend the initial standard to meet the requirements of expanded results reporting as these requirements become known
   - Utilize the RCRIM BRIDG model in the analysis process and extend, as needed, to meet trial registry and result database requirements
   - Establish a roadmap for evolving the standard into an ISO-approved, global exchange standard
   a. **Time line:**
   <DSTU(Draft Standard for Trial Use)> : DSTU – September 2009
   Normative – International Standard: May 2010
   b. **Where work will be done (primarily) in HOST SDO or combined SDO WG?:** HOST SDO – HL7
9. **Project dependencies**
   a. **Other documents/standards:** BRIDG – Domain Analysis Model (Clinical Trial Registry Portion)
   b. **Other groups, including liaisons:**
   National Cancer Institute, FDA, National Library of Medicine – Clinical Trials.gov, Clinical Translational Science Center, WHO, EMEA and Pharmaceutical Companies
   c. **Volunteer or funded:** Volunteer
10. **Comments**
11. **Date of JIC approval**

Background Information:

RCRIM - Regulated Clinical Research Information Management (HL7 Working Group)

- Formed as SIG in 2001, as TC in 2002 (joint effort between CDISC, FDA, and pharma industry)
- Mission:
    - This committee supports the HL7 mission to create and promote its standards by developing standards to improve or enhance information management during research and regulatory evaluation of the safety and efficacy of therapeutic products or procedures worldwide.

BRIDG - http://www.bridgmodel.org/

The BRIDG Model is a collaborative effort of stakeholders from the Clinical Data Interchange Standards Consortium (CDISC), the HL7 Regulated Clinical Research Information Management Working Group (RCRIM), the National Cancer Institute (NCI), and the US Food and Drug Administration (FDA) to produce a shared view of the dynamic and static semantics that collectively define a shared domain-of-interest, i.e. the domain of clinical and pre-clinical protocol-driven research and its associated regulatory artifacts.

The BRIDG model is an instance of a Domain Analysis Model (DAM). As such, it depicts a shared representation of the dynamic and static semantics of a particular domain-of-interest. In the case of the BRIDG model, the domain is defined as:

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 biologic subject or substance plus all associated regulatory artifacts required for or derived from this effort.