### Leadership Team

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<tr>
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### Team Mission

Development and publication of standard, structured, protocol concepts and content that will enable interchange and reuse of protocol-required data and metadata among systems, stakeholders, and operations staff throughout the lifecycle of the study.

### History

The team was initiated in 2002 and first explored ICH E3, E6 and E9 and other global protocol requirements. Next, the team developed a spreadsheet containing an outline, hierarchy and elements that are common across protocols that were harmonized into the BRIDG domain analysis model. This established a framework for conducting end-to-end protocol-driven clinical research in a standards-based environment and support semantic consistency and interoperability.

PRM V1.0 was released in January 2010 as a set of BRIDG classes and attributes related to study and protocol design. PRM elements and standard templates are harmonized with the BRIDG model to ensure semantic consistency and support interoperability with other accepted standards.

In 2012, the PRG team released the PRM Toolset V1.0 targeting the Clinical Study Outline content and standard implementation. The Toolset included a set of study outline concepts mapped to BRIDG and SDTM, a Document Template representing a presentation of the standard concepts, and the Protocol Wizard Demonstration Tool. The Protocol Wizard is a web-based tool that allows users to create a standard Study Outline document as well as export the TS and TI SDTM tabulations from a single web interface. It is freely available at https://cdiscprm-sandbox.imedidata.net/

### Sub Teams

- Study Design & Protocol Content Standards
- Structured Protocol Representation & Implementation
- Documentation (IG, UG, Use Cases)

### 2014 Deliverables

- Protocol Content Concepts List and BRIDG Mapping – V1.0 draft Q1 2015
- PRM “Protocol XML” – Q4 2015
- PRM Implementation and User Guide (with Use Cases) – Q3 2015 with iterative releases