Leadership Team
David Gemzik (Medidata Solutions) – dgemzik@mdsol.com
Melissa Cook (Accenture) - melissa.k.cook@accenture.com

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 standands-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/

Stakeholders/Constituency
- Clinical Operations and Medical Writing
- Standards Development Organizations
- Pharmaceutical sponsors
- Medical devices, diagnostics
- Contract Research Organizations, technology providers & consultants
- Academic researchers
- Regulatory Agencies
- Protocol Content Consumers including IRBs, Registries, Investigators

Collaborations
- HL7 RCRIM Study Data team - Stage II
- SPIRIT (SPIRIT Initiative (Standard Protocol Items: Recommendations for Interventional Trials) – developing guidelines for core content of clinical trial protocols)
- FDA
- PhUSE Emerging Technologies workgroup
- TransCelerate BioPharm Common Protocol Template initiative

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

Operating Model & Meetings
Meeting every two weeks on Thursdays via telecon at +1 415 363 0833 / PIN 202675.
Contact dgemzik@mdsol.com for calendar invitation

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