



Protocol Representation Group (PRG) 2014 Team Charter

<p style="text-align: center;">Leadership Team</p> <p>David Gemzik (Medidata Solutions) – dgemzik@mdsol.com Dr. Stephan Bour (DigitalInfuzion) - stephanb@digitalinfuzion.com Melissa Cook (Accenture) - melissa.k.cook@accenture.com</p>	<p style="text-align: center;">Team Mission</p> <p>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.</p>		<p style="text-align: center;">Stakeholders/Constituency</p> <ul style="list-style-type: none"> ➤ 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
<p style="text-align: center;">Team Characteristics</p> <p>The PRG team is comprised of volunteer experts who can contribute to its various sub-teams with their technical or Therapeutic-based subject matter expertise.</p> <p>Volunteers Needed! Working knowledge of clinical study design and protocol content. Interest in leveraging structured protocol standards to facilitate subject recruitment, accelerate the clinical research process and improve review and analysis of research data.</p>	<p style="text-align: center;">History</p> <p>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.</p> <p>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.</p> <p>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 which 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/</p>		<p style="text-align: center;">Collaborations</p> <ul style="list-style-type: none"> • 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 <p style="text-align: center;">Team Dependencies</p> <p>Study Design (SDS sub team), BRIDG, Glossary, Terminology, ODM</p>
<p>The protocol standard must be both machine-readable and easily understood by its users, notably clinicians, medical writers, regulatory authorities, IRBs, statisticians, project managers, and site personnel. The machine-readable representation should be transparent to end-users listed above. Alignment with all CDISC standards through the BRIDG model and non-CDISC industry standards (where applicable) must be demonstrated.</p>	<p style="text-align: center;">Sub Teams</p> <ul style="list-style-type: none"> ➤ Study Design & Protocol Content Standards ➤ Structured Protocol Representation & Implementation ➤ Documentation (IG, UG, Use Cases) 	<p style="text-align: center;">2014 Deliverables</p> <ul style="list-style-type: none"> ➤ Protocol Content Concepts List and BRIDG Mapping – Q3 ➤ PRM “Protocol XML” – Q4 ➤ PRM Implementation and User Guide (with Use Cases) – Q3 with Iterative releases 	<p style="text-align: center;">Operating Model & Meetings</p> <p>Meeting every two weeks on Thursdays via telecon at +1 415 363 0833 / PIN 202675</p> <p>http://wiki.cdisc.org/display/PROT/Protocol+Representation+Group+Home</p> <p>http://portal.cdisc.org</p>