Protocol – PRIMe

The need for an implementable standard that comprehensively covers Protocol has been an imperative for many years and this standard is one of the last essential pieces in the CDISC standards suite. By way of a brief history the PRG (Protocol Representation Group) was initiated in 2002 and first explored ICH E3, E6 and E9 and other global protocol requirements. The team 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. 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://cdisc cprmsandbox.imedidata.net/. In the last year TransCelerate and CDISC have been working towards better defining protocol elements already which will provide an input into the project and it is envisaged that the TransCelerate Common Protocol Template would be able to utilize the PRIMe and CTR2 standards. PhUSE also have been working on automating protocol and results elements and this project will also look to collaborate with the PhUSE teams and the existing efforts of the CDISC PRG. The participation of all key players will be essential in seizing this opportune moment to agree these requirements and to create an international Protocol standard for the benefit of the global stakeholders.

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 the end-users listed above. Alignment with all CDISC standards through the BRIDG model and non-CDISC industry standards (where applicable) must be demonstrated.

Registration and Results – CTR2

Recently NIH, EMA and WHO have put out requests for comments on draft proposals for clinical trial registration systems and for the presentation of results. The CDISC CTR has just finished public review and will be published q1 of 2016, this ODM based XML schema allows for the generation of partially harmonized messages to WHO ICTRP, and the Clinical Trials.gov and EudraCT registries. Increasing the harmonization of global clinical trial registries will be a core driver of this project and the stakeholder list will include Chinese and Japanese registries.

Trying to harmonise requirements across international jurisdictions is always a challenge but CDISC standards, including CDISC CTR, already support an extensive superset of clinical trial data elements so an excellent foundation exists already. If CDISC can create a standard using structured clinical trial elements then registries could effortlessly and accurately populate their systems so the public and researchers will have greater confidence in the data they are looking at. Project ‘Optimus’ will invite a dialogue between the registries, industry and regulators to try to reach some consistency and some agreement on results and registration metrics.

It isn’t expected that international registries will harmonize fully due to jurisdictional stipulations but by creating and evolving an agreed global standard to cover registration and summary results it will mean that clinical trial registrations could be harmonized to a greater extent, creating efficiencies and consistent and higher quality information within the world’s registries. Also as clinical trial complexity increases the CTR team, working with the CDISC SDTM team, can agree subsequent forward integrated versions of the standard.