Using CDISC Standards and Semantic Technology to Drive the Automation of Study Database Build

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1 – Infrastructure

The Global Data Standards Repository (GDSR) is a Metadata Repository (MDR) based on semantic technology and the ISO 11179 MDR standard. The infrastructure supporting Roche’s Global Data Standards has been extended to also store metadata relating to individual studies.

2 – Roche RDF Model Extensions for SoA

Roche extensions, where necessary, have been added to RDF model for the Protocol Schedule of Activities (SoA) developed by the Semantic Technology Computational Science Working Group to allow a link between the SoA and internal Data Collection Standards.

3 – The Study Builder Application

Starting Point for users is the study design represented as a grid of arms and epochs plus a special “epoch” to allow studies to indicate what data should be collected at unscheduled visits.

TP – Timepoints: Where data is collected multiple times at a single study event (visit) the user can define the time points used in the study.

A schedule needs to be defined for each study cell. Where schedules are identical or similar within an epoch the user has the ability to link or copy.

Activities have sub-activities that relate to questions on the CRF. These can be grouped both by CRF pages and by biomedical concepts. All activities and sub-activities have associated content required to build the study within Roche’s EDC system, Medidata Rave.

4 – Generation of eCRF

Architect Loader Spreadsheet (ALS) generated from the Study Builder
Used to build study in Rave

Planned Future Enhancements (2016+)

- Protocol SoA
- Generation of specifications for non-EDC data
- Submission-ready SDTM annotated CRFs
- SDTM Code Generator
- Interfaces with other internal systems