PhUSE CSS Semantic Technology Working Group

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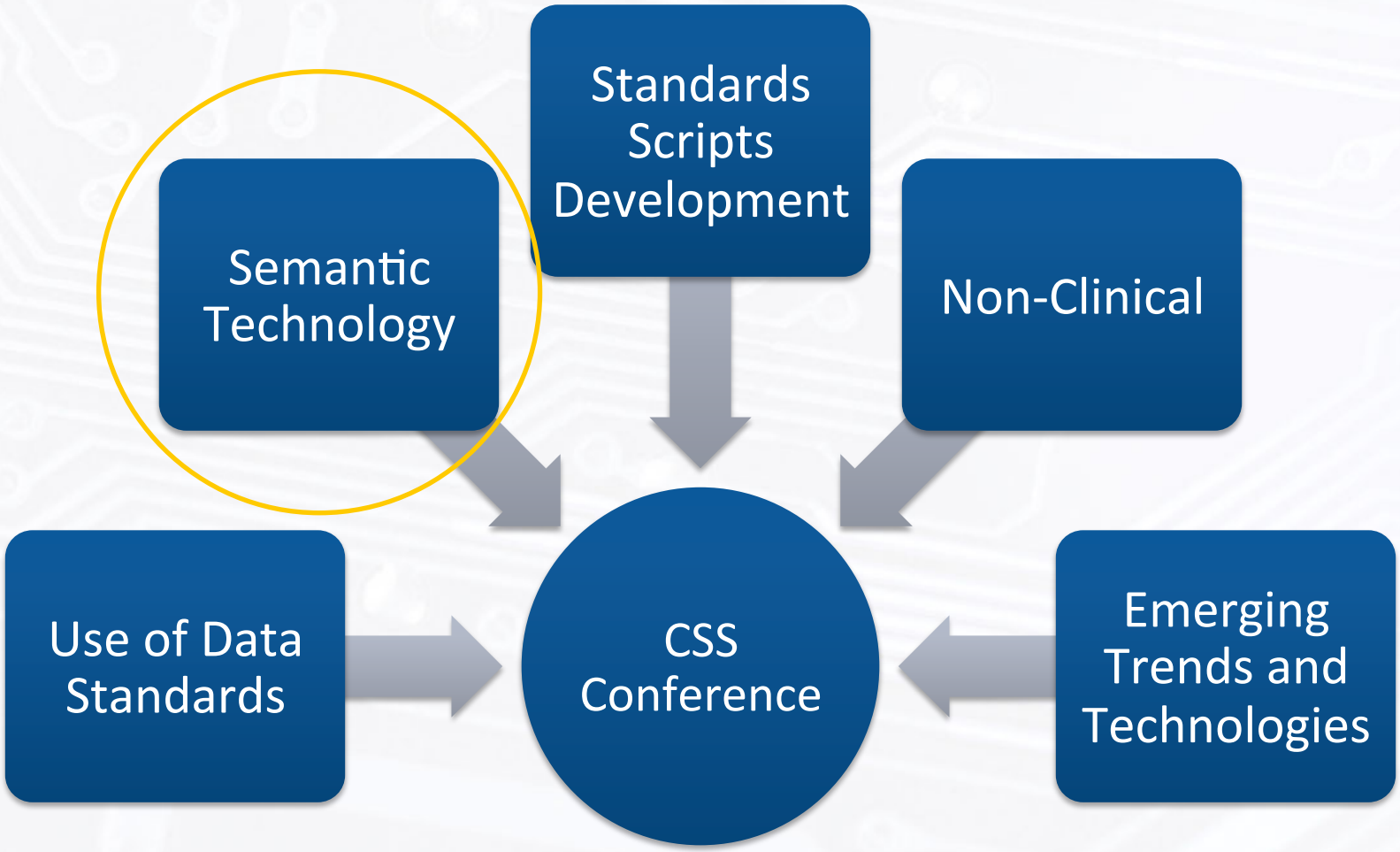
The CSS Working Groups



Semantic Technology Working Group Leads

- Scott Bahlavooni, PhUSE
- Geoff Low, Medidata
- Frederik Malfait, IMOS Consulting
- Mitra Rocca, FDA , CDER, OTS

Working Group Objective

Investigate how formal semantic standards can support the clinical and non-clinical trial data life cycle from protocol to submission

Standards driven

- CDISC clinical trial standards
- ISO 11179 metadata standards
- W3C semantic standards Resource Description Framework (RDF)

Working Group Projects

Phase I (Completed):

- CDISC Foundational Standards in RDF
- KeyCRF (EHR Link)

Phase II (Current):

- Protocols in RDF (Prior and Current Work)
- Analysis Results Metadata in RDF
- Clinical Program Design in RDF (New)
- Representation of Regulations in RDF (New)

CDISC Foundational Standards in RDF

- 2014 deliverables
  - CDASH, SDTM, SEND, ADaM representations in RDF
  - Controlled terminology in RDF
  - User Guide and Reviewer Guide
  - CDISC public review
- 2015 activities ongoing

KeyCRF – EHR Link

- Goal: Creation of a semantically annotated electronic Case Report Form (eCRF) that can enable the pre-population of the eCRF from linked data elements in an EHR summary document, HL7's Continuity of Care Document (CCD).
- The project Leverages:
  - RDF representation of the CDISC CDASH standard.
  - IHE Data Element Exchange (DEX) specification to create the annotated eCRF,
  - Metadata from a metadata repository (MDR) such as CDISC's SHARE or the SALUS MDR.
  - HL7 CCD Standard

Protocol in RDF – Prior Work

- Developed a RDF model for the Schedule of Activities
  - Currently in Draft and available on the PhUSE Github Repository for anyone to review
- Worked on 'other' Protocol components
  - Limited progress, except for the Eligibility which is a current activity
  - Utilized similar modeling approaches from Foundational Standards in RDF work

Protocol in RDF – Current

- Team lead: Geoff Low
- Three main topics
  - Eligibility
    - Evaluating models for Protocol Inclusion/Exclusion Criteria (RDF and not-RDF)
  - Structured Document Representation in RDF
    - Looking to define a RDF model for structured documents (such as a Protocol)
    - Evaluating existing standards (eg DocBook and DITA)
    - Aiming to use Document Representation to model the Transcelerate Common Protocol Template (CPT)
  - End to End standards
    - Evaluating any current models for representing the end-to-end of a clinical study
    - Including Protocol, Clinical Trial Registration, etc.

Analysis Results Metadata in RDF

- Team leads: Marc J. Andersen, Ian Fleming
- Work packages
  - Release of R package
  - RDF ontology for analysis results
  - White paper: Analysis Reults Metadata in RDF
- Breakout topics
  - Rationale for using the W3C RDF data cube standard
  - Workflow from ADAM over TFLs to results as RDF
  - Graphical presentation of RDF
  - R package using CDISC RDF creating RDF data cubes
  - Rationale for presenting analysis results from RDF
  - Plan for deliverables in 2015 including White Paper

Clinical Program Design in RDF

- Team leads: Laszlo Vasko, Mary Banach
- Objective: To develop a reference RDF information model to capture and share clinical program design information
  - Design inputs such as claims, target product profile, development plans etc.
  - Design elements such as objectives, endpoints, treatments, patient population etc.
  - Options and rationale for each design decision
  - Trial and program prototypes and options
- Benefits
  - Facilitate information sharing between all stakeholders
  - Reference & link agency guidance to design decision
  - Share best practices and facilitate collaboration
- Alignment with the Protocol and Study Design in RDF team

Representation of Regulations in RDF

New

- Team leads: Mitra Rocca, Frederik Malfait, Lin Yu, Rashedul Hasan
- Objective: Evaluate the feasibility of representing regulations and guidance documents in RDF
- Benefits
  - Representing the regulations and guidance documents in RDF enables the linking of said documents to RDF sources
- Deliverables:
  - Identify regulations and guidance documents referenced in CDISC standards
  - Represent regulations and guidance documents in RDF.
  - Link the RDF representations to CDISC standards represented in RDF