FDA/PhUSE CSS working groups and projects

Emerging Technologies Working Group

Introduction

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Objectives

- New challenges in regulatory science and drug, biologic, and device development provide new opportunities for recognizing and leveraging emerging technologies and computational tools.
- The FDA/PhUSE Computational Science Symposium (CSS) used the March, 2013 meeting as an opportunity to "launch" a new working group that provides a forum for determining interest in specific computational science topics, tools, technologies, and approaches.
- Topics include (but are not limited to) semantic web applications, analysis metadata, modeling, simulation, and "The Cloud".

http://www.phusewiki.org/wiki/index.php?title=Emerging_Technologies

Project Proposed

Project	Priority	Feasibility	Technology	Lead (FDA)	Lead (Industry)
Semantic web					
Data visualization					
Meta data definition					
Meta data E2E process					
Meta data: study level standard to BRIDG/JANUS					
Meta data: contextual data					
Meta data: versioning, upcoding, …					
CSV & multi-tenant cloud solutions					
Big data: definition & architecture					

Project Approved

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Semantic web					
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Meta data definition					
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Meta data: contextual data					
Meta data: versioning, upcoding, …					
CSV & multi-tenant cloud solutions					
Big data: definition & architecture					

Project 1. Semantic web

- Objective/Scope:
  - investigate how formal semantic standards can support the clinical trial data life cycle from protocol to submission
- Approach
  - Investigate Opportunities & challenges (barriers)
  - Identify use cases (inventory of what can be done)
    - ***Area 1: represent data standards (CDASH, SDTM, SEND, ADaM) in RDF***
    - Area 2: represent clinical trial data in RDF (more experimental – done by W3C)
    - Area 3: annotated TLFs with information on where the data came from (linked to traceability)
    - Area 4. modelling the protocol (try to understand what is feasible with what has already been done)
  - Linking with other "knowledge providers" (NCI, BRIDG, SNOMED, ..)
- Deliverable:
  - Readiness assessment – is semantic web technology useful or not - and what is the relationship with meta data ?
  - Catalogue & prioritization of uses cases
  - Identification, execution and experiment on high priority use case
- Status
  - Area 1 started with 4 separate sub working group (meeting every other week)
  - Done in collaboration with CDISC

Project 2. MetaData Definitions

- Objective/Scope: common definitions around metadata and related aspects across the industry
- Approach
  - Definition + example / short description of usage
  - Build/update on existing definition from FDA guidance's, CDISC glossary, check cross industry definition (e.g. Gartner)
  - To include
    - Metadata (structural & operational), data elements, attributes
    - Masterdata & master reference data
    - Controlled terminology, code systems, value sets, permissible values
    - Data pooling, data integration, data aggregation
    - Interoperability, semantic interoperability
- Deliverable: not only a glossary but a practical guide with example to ensure common understanding and usage
- Status
  - Started 1 month ago – first draft around metada – meeting every other week

Project 3. User guide for E2E use & implementation of metadata

- Objective/Scope:
  - practical guide on how to implement meta-data management (potentially with existing tools) within an organisation for a single trial
  - Gather key requirements for Metadata management tool that would fulfil the needs for an E2E process within an organisation , as well as supporting data consistency for cross trial analysis
- Approach
  - Main user needs (collect user stories) at different phases: protocol definition, system set-up, data visualization & monitoring, integration of collected data, analysis & reporting ..
  - Main process changes at different phases (basis of WI/SOP)
  - Link with data traceability project
  - Identify additional requirements related to Versioning, upcoding, …
  - Pilot with available tools
- Deliverable:
  - Draft user stories for MDR tool selection
  - Draft set of Work instruction to support MDR deployment
  - Pilot ?
- Status
  - To start in the coming weeks

Who to contact

Name	Role	Organization	E-mail
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Note: contacts for a specific project can be found in
http://www.phusewiki.org/wiki/index.php?title=Emerging_Technologies