



Computational Science Symposium

March 15th–17th 2015

Silver Spring Civic Center | Silver Spring, Maryland, USA



CS Working Groups Overview

March, 2015

PhUSE Computational Science Collaboration Mission

To provide an open, **transparent** and collaborative forum in a **non-competitive** environment in which Academia, Regulators, Industry, and Technology Providers can address computational science needs in support of product development and regulatory review, ultimately bringing safe and effective products to those who need them

CS Working Group Framework



Optimizing the Use of Data Standards

Overview

Goal: Identify specific gaps that prevent FDA and industry from optimizing the use of data standards by collaborating to close these gaps

- Three (3) current projects , two (2) exploratory projects
 - Traceability and Data Flow
 - Best Practices for Data Standards Implementation
 - Study Data Standardization Plan (SDSP)
 - Open Round Table on FDA Guidance, Exploratory
 - Therapeutic Area User Guide (TAUG) eSHARE Metadata, Exploratory

Lead(s): Dhananjay (DJ) Chhatre, Jeffrey Conant

Optimizing the Use of Data Standards

2014 Accomplishments

- Traceability and Data Flow
 - Study Level Traceability in a Non Linear Data Flow
 - Best Practices for Basic Linear Data Flow (update)
 - Summary of Traceability References (update)
 - Legacy Data Conversion Plan Template
- Best Practices for Data Standards Implementation
 - Assigning VISITNUM to Unplanned Visits and Assigning EPOCH to Observations
 - Standardizing Lab Units
 - Ensuring USUBJID is Unique within an Application
- Study Data Standardization Plan (SDSP)
 - Draft SDSP Template

Optimizing the Use of Data Standards

2015 Plans for Conference

- Gather attendee feedback on deliverables published for review or under development
- Determine goals and potential deliverables for new projects
- Open Round Table Discussions on:
 - FDA Guidance
 - Therapeutics Area User Guide (TAUG) eSHARE Metadata (facilitated by CDISC)

Development of Standard Scripts for Analysis and Programming

Overview

Goal: Establish a platform for the collaborative development of program code to be used as analytical tools for clinical trial research, reporting, and analysis

Includes recommendations for analyses, tables, figures, and listings

Process and guidelines for documentation and management of scripts

Harness data standards whenever feasible

- Three Focus Areas, Six (6) active projects
 - Script Repository (4 projects)
 - White Papers on Analyses and Displays (1 project)
 - Communications (1 project)

Lead(s): Mary Nilsson, Hanming Tu

Development of Standard Scripts for Analysis and Programming

2014 Accomplishments

- Script Repository has been created
 - First contributed script from FDA added to the repository
 - 3 Script-athons, 27 scripts added to the repository, more to come
 - Naming convention and metadata tags for scripts developed
 - Process guidelines and Qualification guidelines developed
 - User-friendly script index page developed
- White Papers
 - Non-Compartmental Pharmacokinetics, finalized in March 2014
 - Demographics, Disposition, and Medications, finalized October 2014
 - Vital Signs, ECGs, Labs – Outliers/Shifts, almost final
 - Others (Adverse Events, Hepatotoxicity, TQT Studies, Questionnaire Data) in progress

Development of Standard Scripts for Analysis and Programming

2015 Plans for Conference

- Script-athon (Monday night, March 16th)
 - Focus on finalizing contributed scripts and “qualifying” them
- Repository: Qualification Process
- White Paper Content Discussions
 - Outlier/Shifts
 - “Cumulative” or “adjusted” percentages for integrated displays
 - Adverse Events
 - Defining the time period for treatment-emergence
 - Ideas for visual displays
 - “Cumulative” or “adjusted” percentages for integrated displays
 - Hepatotoxicity and TQT Studies
 - Gather initial impressions on first drafts

Non Clinical Roadmap and Implementation Overview

Goal: Improve nonclinical assessments and regulatory science

- by identifying key needs and challenges in the field and then establishing an innovative framework for addressing them in a collaborative manner*
 - using informatics approaches and standards for delivering ideas and solutions to nonclinical data challenges.*
- 6 active projects coming into 2015 CSS
 - 8 project(s) completed since 2014 CSS

Co-Lead(s): Bob Dorsam, Sue DeHaven

Non Clinical Roadmap and Implementation

2014 Accomplishments

1. *Published*: Interconnectivity of disparate nonclinical data silos for drug discovery and development.
2. *Completed* : Nonclinical SDRG Template and Template User Guide
3. *Completed*: Survey of industry SEND data from Small/Medium Service Providers: How prepared are they to supply data in SEND format?
4. *Completed*: Template to Facilitate Creating PC Domain nonclinical datasets
5. *Opened* : a SEND Forum, where users can go for Q&A discussion. Over 100 Comments in 10 months!
6. *Maintained* the SEND Wiki, where users can go for how-to guides, FAQs. Over 90 common questions answered in 11 categories
7. *Validated* : “How to build a Custom Domain” process, with step by step instructions and associated conformance rules
8. *Completed*: Online search tool using Semantic data model/Resource Description Framework (RDF) of the IGs

Non Clinical Roadmap and Implementation

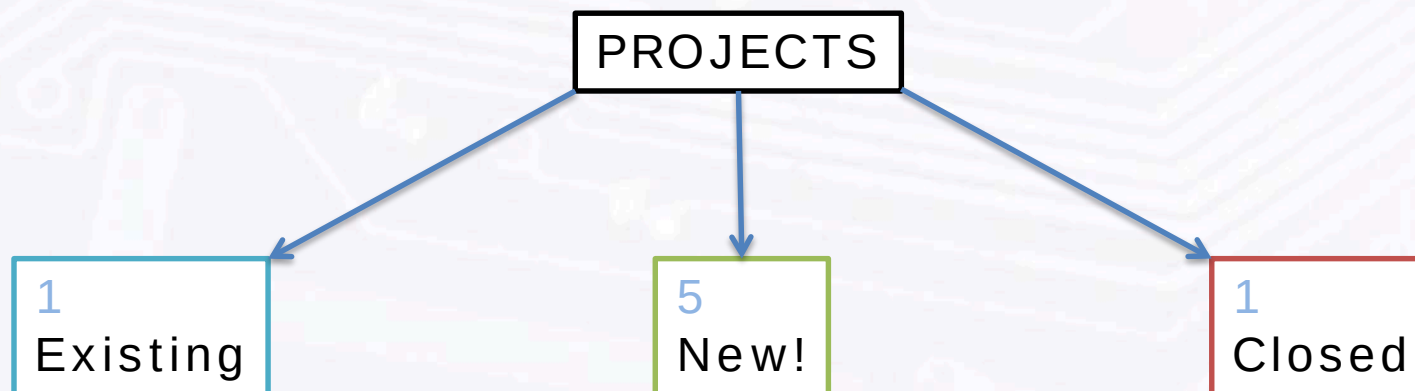
2015 Plans for Conference

- Day 1 – Nonclinical WG Opportunities and Accomplishments
 - Presentation/forum on areas for collaboration on data challenges
 - Past Year Project deliverable presentations from each project
 - New Project Candidates Presentations
- Day 2 – Decisions and Planning for Coming CSS Year
 - New project prioritization and selection
 - Selected project refinement and team building
 - Wrap-up and communication plan for 2015

Emerging Technologies Overview

Goal: New challenges in regulatory science and drug, biologic, and device development provide new opportunities for recognizing and leveraging new or emerging technologies and computational tools or under-utilized existing technologies. The Emerging Technologies Working Group provides a forum for determining interest in specific computational science topics, tools, technologies

Co-Leads: Dave Handelsman and Geoff Low



Emerging Technologies 2014 Accomplishments

- Lowering Barriers to Cloud Adoption (Existing)
 - Framework document delivered and commented
- Metadata Management (Closed)
 - Metadata Definitions document delivered and available for Public Review
 - Feedback to FDA Guidance for consistent use of metadata definitions, submitted directly to the FDA Registry
 - Presentations at PhUSE Conferences
- Breakout of Semantics Technologies Group

Emerging Technologies Plans for Conference

- Lowering Barriers to Cloud Adoption
- Statistical Computing Environments (SCE)
- Two New Topics (Selected based on Popularity)
 - Data Visualizations – toolbox for standard views
 - Framework for mHealth – mobile health adoption
 - Text Analytics for Clinical Research
 - Value of Big Data
- Determine champions to lead new groups
- Determine steps for other topics - open to motivated volunteers

Semantic Technology Overview

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

Standards driven:

- W3C Semantic Standards
 - Resource Description Framework (RDF)
 - CDISC Standards
 - ISO 11179 Metadata Registry
-
- Four (4) active projects
 - One (1) project completed since 2014 CSS

Co-Lead(s): Frederik Malfait, Scott Bahlavooni, Geoff Low, Mitra Rocca

CS WG: Semantic Technology

2014 Accomplishments

- **CDISC Foundational Standards in RDF**
 - Completed CDASH, SDTM, SEND, ADaM plus CT representations in RDF; User Guide and Reviewer Guide
 - CDISC Public Review of the work package ended 20-Feb-2015
- **Protocol and Study Design in RDF**
 - Completed draft representation of a protocol Schedule of Activities in RDF
- **Analysis Results Metadata in RDF**
 - Release R package
 - Completed an RDF ontology for analysis results metadata
 - Completed a white paper: Analysis Results Metadata in RDF
- **keyCRF**
 - Completed a prototype for pre-populating a CRF from an EHR
 - Developed a video demonstrating the capabilities

CS WG: Semantic Technology

2015 Plans for Conference

- **Protocol and Study Design Model in RDF – Breakout Topics**
 - Modeling Eligibility, Endpoints, Study Outcomes and Objectives
 - Discussing alignment with TransCelerate CPT activities and other CS WGs
- **Data Analysis Results in RDF – Breakout Topics**
 - Rationale for using the W3C RDF data cube standard and presenting analysis results from RDF
 - Workflow from ADaM over TFLs to results as RDF
 - R package using CDISC RDF creating RDF data cubes
 - Plan for deliverables in 2015 including new white papers
- **Clinical Program Design in RDF (New) – Breakout Topics**
 - Project kickoff!!!
 - Align on project objectives



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Thank You

Steering Committee

Industry

- Chris Decker – Industry PM, d-Wise
- Scott Bahlavooni, Biogen Idec
- Anne Russotto, Celgene
- Michael Brennan, ArborSys
- DJ Chhattre– Optimizing Standards Liaison, Booz Allen Hamilton
- Susan DeHaven – Non-Clinical Liaison – Sanofi
- Mary Nilsson – Standard Scripts Liaison – Eli Lilly
- Frederik Malfait – Emerging Technologies Liaison – IMOS Consulting

FDA

- Jade Nguyen – FDA PM
- Crystal Allard
- Armando Olivia
- Steve Wilson
- Chekesha Clingman

Planning Committee

- Stephen Bamford, Business & Decision Life Sciences
- Kevin Lee, Accenture
- Marcelina Hungria, Dcore Group
- Maureen Rossi, Roche
- Grace Lu, AstraZeneca
- Michael Rubison, Capish
- Suhas Sanjee, Novartis
- Chris Hurley, MMS Holdings
- Trish Koussis, FDA Liaison
- Tora Whitworth, PhUSE Office

Working Group Co-Leads

- Dhananjay (DJ) Chhatre, Jeffrey Conant
- Bob Dorsam, Sue DeHaven
- Geoff Low, Dave Handelsman
- Mary Nilsson, Hanming Tu
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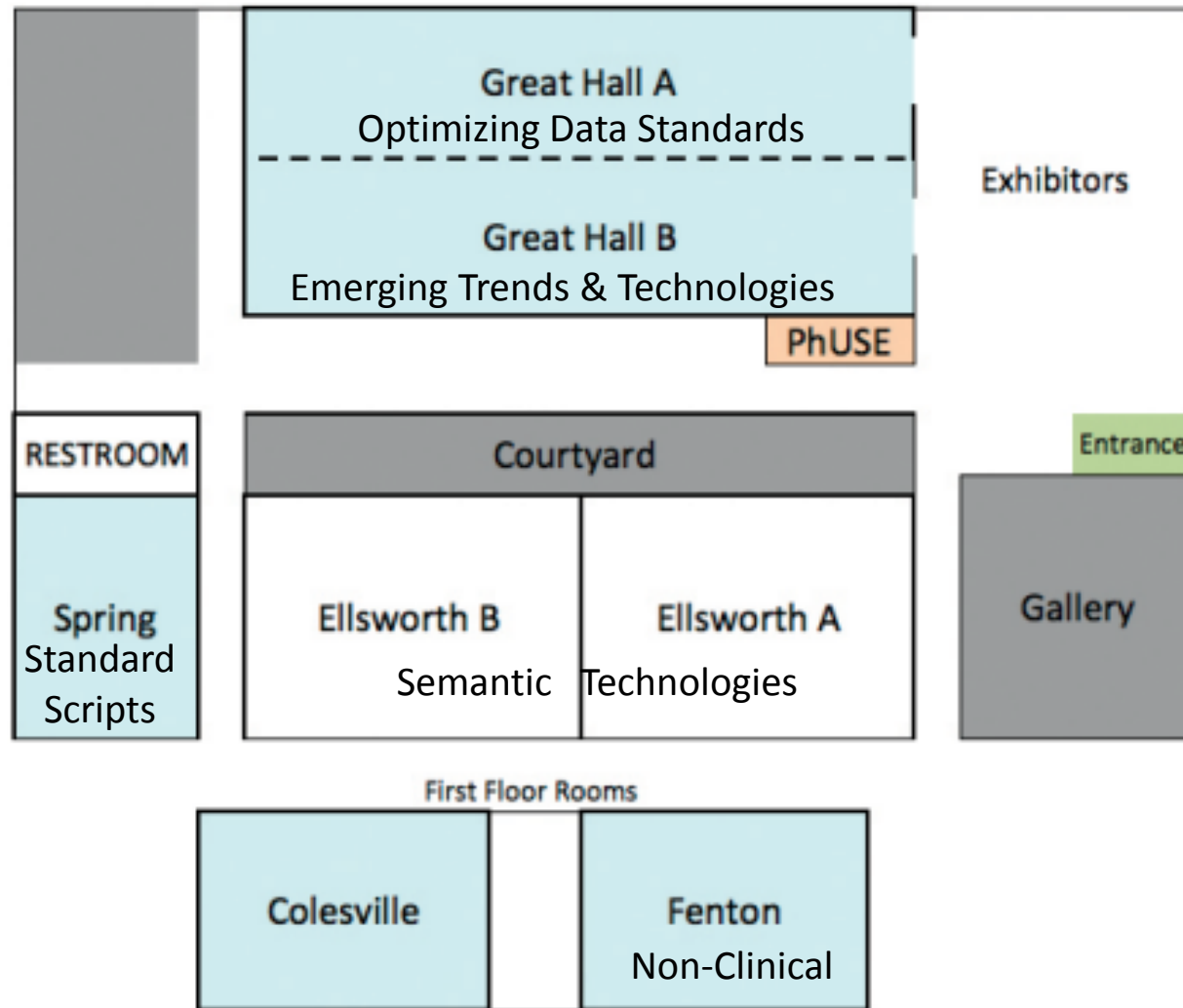


Logistics

Agenda

- Monday:
 - 11-12 pm; 1:30-4:30 PM: Working Group Breakout Sessions
 - 12:30-1:30: Guidance Roundtable Discussion
 - 5-6:30 Poster Session
- Tuesday:
 - 8:30-12 pm, 1-2 pm: Working Group Breakout Sessions and Wrap Up
 - 2:30-3:30: FDA Panel
 - 3:30-4:00: Poster Awards and Wrap Up

Civic Center Layout



General Notes

- #phusecss
- Civic Center Wi-Fi – MCGGUEST– no access code required
- Exhibitor Card and Prize
- Wear your name badges throughout and return at the end – we will recycle
- Turn off cell phones or set to vibrate
- Please deposit all trash
- Unseasonably Warm

Thoughts

- “Change is the essential process of all existence” — Spock
- “If you want something new, you have to stop doing something old” — Peter F. Drucker
- “Change is impossible without industry-wide collaboration, cooperation and consensus” – Simon Mainwaring