2015 CDISC Winter IntraChange
Mar. 18-20, Silver Spring Civic Center
Draft Agenda

8:30-5:30pm Wednesday and Thursday
5:30pm Thursday Happy Hour at McGinty’s Pub
8:30-3:00pm Friday (no Q4 on Friday)

General session plan:

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>8:30-10:30</td>
<td>Q1 Plenary (Presentations and Training)</td>
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<tr>
<td></td>
<td>• Day 1: Overview, Plans, Tools (Wayne Kubick)</td>
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<td>• Day 2: Standards Development with SHARE (Sam Hume)</td>
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<td>• Day 3: Optimizing Foundational and Therapeutic Area Standards Development and How Education fits into the Standards Development Process (Rhonda Facile)</td>
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<td>10:30-11:00</td>
<td>Break</td>
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<td>11:00-12:30</td>
<td>Q2 Individual Team Meetings</td>
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<td>12:30-1:30</td>
<td>Lunch</td>
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<td>1:30-3:00</td>
<td>Q3 Individual Team Meetings</td>
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<td>3:00-3:30</td>
<td>Break</td>
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<tr>
<td>3:30-5:30</td>
<td>Q4 Cross-Team Breakout Sessions</td>
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Planned Q2 and Q3 Individual Team Meeting Topics (Days 1-3):
Each team will review charter, plans and key challenges and issues for 2015 Day 1. COA will meet Day 1 only. All other teams will meet each day.

ADaM (Nate Freimark)
• Work on finalizing ADaMIG v1.1
• Review status of ADaMIG v1.2
• Plan topics for ADaMIG v2.0
• TAUGs

CDASH (Trisha Simpson, Lorraine Spencer)
• Both Wednesday & Thursday: CDASH v2.0

CFAST PM Meeting (Day 3 only) (Rhonda Facile)
• Project Status Reports
• Modeling issues and maintaining consistency across the TAUGs
• Metadata Development Tools
• Review of lessons learned from completed projects
• Process review and identification of areas for improvement.
• Education process discussion

COAs (QS, FT, CC) (Day 1 only) (Steve Kopko, Gary Cunningham)
• COA Level Metadata Review
• COA Section of SDTMIG (include QS, FT, CC domains)
• COA Process Flows

Education (all CDISC instructors and Education staff) (Kit Howard, Shannon Labout)
(Lunch meeting, Day 1 only)
• Get to Know the Education In-house and Instructor Team
• Online Training Development Goals
• Classroom Training Development Goals
• Instructor Recruiting Process/Requirements
• Instructor Enrichment
• The Future of CDISC Training/Education

**Medical Devices** (Kit Howard, Carey Smoak, Fred Wood)
*(Will have a real/virtual combo meeting, 2 quarters, Day 2 only)*
- Integrated example incorporating all domains and structures defined in the IG
- Review new domain-specific examples

**SDS** (Dan Godoy, Barrie Nelson)
- SDTMIG v3.3
- Provisional Domains
  - Versioning of the Domains
- Filling gaps in SDTMIG
  - LOC variables (Test and Result)
  - Supplemental Qualifiers used in the TAUGs
  - Concept Maps for SDTMIG Domains
  - Supplemental Qualifiers vs. Findings About
  - Proposed New General Observation Class
- SDS Subteam meetings
- SDTM Governance Team Update
- FDA Discussion Topics

**XML Technologies** (Sam Hume, Sally Cassells)
- Define-XML v2.1 working sessions
- Protocol and Registry

**Planned Q4 Cross-Team Breakout Session Topics (Day 1 and 2):**

**#1 Optimizing CDISC Submission Standards** (Dan Godoy, Barrie Nelson, Nate Freimark)
- Discussion of Final FDA Guidance
- Using multiple submission standards on studies: SDTMIG, Devices, PGx, ADaM, TAs, Terminology
- Relevant features of SHARE

**#2 Realizing CDISC Standards End-to-End** (Sam Hume)
- Protocol through ADaM
- Defining and using value-level metadata
- Relevant features of SHARE
- Therapeutic Area Standards

**#3: Coordinating Therapeutic Area Standards Development with Foundational Teams - Status, process review and discussion, plans for 2015 and review of ongoing projects** (TBI, DKD, TB, RA, CV Imaging, etc.) (Rhonda Facile)
- TA Projects and ADaM
- TA Projects and SDTM
- TA Projects and Terminology
- TA Projects and COAs/QS