2015 CDISC Strategic Goals

• Promote and support the continued global **adoption** of **harmonized** data standards throughout the clinical research **lifecycle** by engaging regulatory agencies, research sponsors, academia and other **stakeholders** through education, advocacy and collaboration.

• Implement clinical research standards that are **compatible** with standards in the broader **healthcare ecosystem** and thus **add value** for clinical researchers, healthcare providers and patients.

• **Leverage** the Shared Health And Research Electronic Library (SHARE) and other **tools** to further **expedite** the development and facilitate the **implementation** of **harmonized** standards for clinical research.
Foundational Products Released in 2014-2015:
• Dataset-XML v1 Final
• SDTMIG 3.3 Batch 1 (7 draft domains)
• SDTMIG 3.3 Batch 2 (Milestones, 2 Domains)
• Pharmacogenomics SDTMIG v1 Draft
• SEND v3.1 Draft
• ADaM Occurrence Data Structure v1 Draft
• ADaM IG v1.1 Draft
• ADaM Results Metadata Spec for Define-XML
• ADaM Data Structure for Integration (ADSL)
• ADaM v1.3 Validation Checks
• CDISC in RDF Reference Guide (PhUSE)
• Periodic Terminology and COA Packages
• Updated COP and Process Docs
• BRIDG v4

Upcoming Major New Drafts for Comment:
• ADaM Data Structure for Integration (ADSL)
• SEND DART (Reproductive Toxicology)
• CTReg XML Schema
• SDTMIG Batch 3, SDTM v1.5
• Protocol Concepts
• Define-XML IG, v2.1
Program Overview – March 2015
Approved Therapeutic Area Standards Projects

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Coordinating Organizations/Project Manager</th>
<th>Proposal Approval Date</th>
<th>Stage 0 Scoping &amp; Planning</th>
<th>Stage 1 Concept Modeling</th>
<th>Stage 2 Standards Development</th>
<th>Stage 3c Internal Review</th>
<th>*Stage 3b Public Review</th>
<th>*Stage 3c Projected Publication</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Traumatic Brain Injury v1</td>
<td>CDISC Rhonda Facile</td>
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</tbody>
</table>

TAUGs released in 2014-2015:
- Multiple Sclerosis
- Diabetes
- Cardiovascular
- Influenza
- QT Studies
- Schizophrenia
- Dyslipidemia

Upcoming:
- Chronic Hep-C
- Diabetes ADaM Supplement
- Traumatic Brain Injury

Key: 🟢 Stage completed  🟡 Stage ongoing  All months reflect when stage s, or is projected to be, completed.

*The Stage 3b concludes at the end of the 38-day review period and Stage 3c concludes when all tasks have been completed and the standard is publicly available.
**Specific projected publication dates to be added to the notes section at the conclusion of Stage 3b.
## 2015 Technical Plan

<table>
<thead>
<tr>
<th>Team</th>
<th>Project</th>
<th>Description</th>
<th>Req Date</th>
<th>State</th>
<th>Target Date</th>
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<tr>
<td>PRG</td>
<td>Protocol Concepts</td>
<td>Protocol Concepts V1.0 spreadsheet release for review and collaboration with TransCelerate Common Protocol Template project (concept mapping to Template)</td>
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<td>Draft</td>
<td>Q2</td>
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<td>CDASH</td>
<td>CDASHIG v2</td>
<td>CDASH Model, new domains (PR, HO, SR, DD, MI, MO, RP, PC, PP, FA, QS) to correspond to newer SDTMIG v3.2 domains.</td>
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<td>SDTM</td>
<td>SDTM v1.5</td>
<td>New variables, domain-specific variable class, disease milestones, new special purpose domains to support SEND, PGx, Devices, Human Clinical Trials.</td>
<td>2013</td>
<td>Draft</td>
<td>Q2</td>
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</table>
| SDS    | SDTMIG v3.3   | • New Intervention domains: Procedure Agents (AG) and Meal (ML)  
• New Physiology Findings domains: Respiratory (RE), Nervous System (NV), Ophthalmology (OE), Urinary (UR), Cardiovascular (CV)  
• Broadening TU, TR, and RS domains to handle non-tumor lesions  
• Use of "Non-Standard Variables" in parent domains rather than as supplemental qualifiers  
• Disease Milestones | 2013     | Final | Q3          |
2015 CDISC Winter IntraChange

Learn, Meet, Interact

wkubick@cdisc.org
2015 Guiding Themes for Standards Development

• Improve transparency
  ▪ Share requirements and plans in advance; invite feedback
  ▪ Make it easier for global participants to get more involved

• Be more agile - Apply Scrum for standards development
  ▪ Expand use of collaboration tools to work more efficiently
  ▪ Smaller teams, with scrum and sprints, all coordinated through SHARE and JIRA
  ▪ Get content into SHARE early – as soon as its stable
  ▪ Rollout SHARE collaborative curation initiative – to rapidly expand and expedite filling gaps in content
  ▪ Engage a second class of Fellows

• Focus and Execution
  ▪ Do what’s necessary so industry and regulatory authorities get what they need when they need it to better realize the benefits of CDISC standards
“In a nutshell, Scrum is a simple organizational framework based on three ideas:

1. **divide and conquer** the complex into the simple
   - break complicated work into simple pieces
   - break organizations into small teams
   - break time into short cycles

2. **Inspect and adapt** your process and your plan
   - revisit plans and assumptions regularly
   - optimize the value delivered by the product
   - continuously improve your process

3. **Create transparency** because people make better decisions with all the information”
CDISC Technical Roadmap - 2015

Foundational Standards
- PROTOCOL
- SDS/SDTM Products
- CDASH
- SEND
- ADAM
- Others
- XML Technologies

Semantics
- Controlled Terminology
- BRIDG
- CDISC SHARE
  - R1
  - R2
  - R3

Therapeutic Areas (CFAST)
- Track 1 Projects
- Track 2 Projects
- Track 3 Projects

Health Care Interoperability

Data Exchange Layer
- XML, RDF, …

Semantic Layer
- BRIDG/Terminologies/SHARE

Functional Layer
- SDTM, SEND, ADaM, CDASH …

Implementation Layer
- Therapeutic Area Guides,
  Questionnaire Guides
- Healthcare Interoperability
  Kits

The Roadmap depicts evolution from siloed standards to an integrated stack based on BRIDG and SHARE.
Strength *through collaboration.*