Dare to SHARE
CDISC International Interchange 2013
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Agenda

1. What is SHARE?
2. Why SHARE?
3. SHARE Content
4. SHARE Roadmap
5. Q&A
What is SHARE?
**Shared Health and Research Electronic Library (SHARE)**

**SHARE** is a global electronic repository for developing, integrating and accessing CDISC standards metadata in electronic format. SHARE is expected to dramatically improve the quality, reusability and integration among CDISC foundational and therapeutic area standards and controlled terminologies, and support greater interoperability with healthcare.

*SHARE is a requirement for standards-based automation, which is key to ROI from standards implementation*
Why SHARE?
Problems for TransCelerate and Regulators

• Slowness of content creation (e.g. TA data standards)

• Difficulty implementing standards
  ▪ Moved from separate companies developing their own standards to every company struggling to interpret & implement the same standard
  ▪ SDTM IG is 300-400 pages for 30 domains

• Clunky to access standards

• Increasing need to share data yet low data re-use capability
  ▪ Few relationships between objects – key to understanding data

Source: Dave Jordan, TCB
Moving from document-based standards to a Metadata Repository

Capturing metadata in documents starts simple….

But sophisticated metadata management gets complicated….

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<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No. of nuts in pile</td>
<td>No. of nuts after s/he eats 1</td>
<td>No. of nuts s/he leaves behind</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Squirrel 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Squirrel 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Squirrel 3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SHARE Content
CDISC SHARE Library Contents

• Metadata
  ▪ CDISC Therapeutic Area and Foundational Standards (Protocol, Trial Design, CDASH, SEND, SDTM, ADaM)
  ▪ BRIDG mappings, associations and relationships
  ▪ Value Level Metadata
  ▪ Definitions and annotations
  ▪ Datatypes (ISO 21090 and simple)
  ▪ Rules (conformance, implementation)
  ▪ Controlled Terminology

• Implementation instructions
• Research concepts
A Versioned Standard is comprised of a set of Operational Collections and associated variables and rules for a specific use case (e.g., SDTM, CDASH)

An Operational Collection is a grouping of Research Concepts. There may be additional rules between objects within the Operational Collection. An Operational Collection may be analogous with a SDTM Domain, a CRF, an ADaM data set, or a similar level of operational structure.

Basic elements that are the foundation for the content described in the SHARE repository. A Research Concept defines one or more related pieces of clinical data, which is developed using an Integrated BRIDG / ISO 21090 Template.

Integrated BRIDG / ISO 21090 Templates use BRIDG classes and relationships to fashion small re-usable patterns that are commonly needed in clinical research.

BRIDG is the foundation model for SHARE that provides classes, attributes and associations use to creates core building blocks.
SHARE Approach to TA Development: Concept Mapping
SHARE - Describes the Links between the Metadata

<table>
<thead>
<tr>
<th>USUBJID</th>
<th>VSSEQ</th>
<th>VSSTESTCD</th>
<th>VSTEST</th>
<th>VSPOS</th>
<th>VSLOC</th>
<th>VSORRES</th>
<th>VSORRESU</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC-001-001</td>
<td>12</td>
<td>SYSBP</td>
<td>Systolic Blood Pressure</td>
<td>SITTING</td>
<td>LEFT ARM</td>
<td>95</td>
<td>mmHg</td>
</tr>
<tr>
<td>ABC-001-001</td>
<td>13</td>
<td>DIABP</td>
<td>Diastolic Blood Pressure</td>
<td>SITTING</td>
<td>LEFT ARM</td>
<td>44</td>
<td>mmHg</td>
</tr>
</tbody>
</table>
Pre-SHARE CDISC Technical Blueprint
SHARE Roadmap
SHARE Road Map: Incremental Implementation

Major Versions: Releases 1 - 4

R1
Q1 2014

R2
Q4 2014

R3
Q4 2015

R4
Q4 2016
Incremental Development

• Each release will include incremental improvements in:
  ▪ Expanded breadth of standards content
  ▪ Standards quality & completeness
  ▪ Relationships between metadata
  ▪ Use of concepts to define standards and standards models
  ▪ Ease of use refinements
  ▪ New reports and metrics
  ▪ Standards development and governance workflows
  ▪ SHARE training and documentation
  ▪ Reducing the reliance on spreadsheets and other document formats for standards development and governance
  ▪ Efficiency in standards development and governance
R1: Machine-Readable Standards

- Initial load of CDISC standards into SHARE
  - SDTM 1.2 (IG 3.1.2) and 1.3 (IG 3.1.3)
  - CDASH 1.1
  - BRIDG 3.2 and ISO21090
  - All CDISC Terminologies
  - New versions (e.g. SDTM 3.1.4) will be added after the R1 release
- Export machine-readable standards (e.g. ODM, Define-XML)
- Initial Value Level Metadata
- Workflows (e.g. new requests, metadata governance)
- Version control & impact analysis
- Reporting (e.g. governance metrics)
R2: SHARE Concept Model

- Implementation of concept models into SHARE
- Load additional CDISC standards content (e.g. ADaM)
- Single, trusted source for all CDISC data standards
- Supports Therapeutic Area standards development
- Improved Controlled Terminology process integration
- Additional Value Level Metadata content (e.g. labs)
- Programmatic access to SHARE content
R3: End-to-End Standards Model

- SHARE model and content support an end-to-end standards model
  - From protocol through analysis results metadata
  - Relationships explicitly defined
  - Clinical research lifecycle explicitly captured in SHARE
  - Enhanced traceability
  - End-to-End standards content roadmap available
  - Validation rules explicitly represented

- Accelerated standards development
- Standards described completely within SHARE, and without need of additional documentation
R4: Multiple Concept Systems

- Support for linking CDISC standards to multiple concept systems
  - Research Concept Systems
  - Healthcare Concept Systems
- Improves support for semantic interoperability
SHARE R1 Licensed User Deployment Plan

Phase 1
Q1 2014

• Train initial SHARE Champions from content teams
• Cultivate a small group of experienced users
• All subscribers can download content

Phase 2
Q2 2014

• Still relatively small group of interactive users
• Champions will help support the next wave of users
• Increased use of SHARE workflows

Phase 3
Q3 2014

• Train users from other standards teams
• Train TA development teams

Full deployment anticipated in 2016

Licensed users work interactively within the SHARE software
Thanks!

Q & A
Strength *through collaboration.*