An Overview of SHARE, CDISC’s Clinical Research Standards Metadata Repository

AHIMA call
June 23, 2016

Lauren Becnel, Ph.D.
Senior Director, Biomedical Informatics & Alliances
End-to-End CDISC Standards

Clinical Data Acquisition (CRF) Standards Harmonization CDASH Protocol Metadata

Study Data Tabulation Model SDTM for clinical studies, including medical devices

Analysis Data Model ADaM

Controlled Terminology CT

Standard for the Exchange of Non-Clinical Data SEND (Based on SDTM)
Why a Metadata Repository?

Updates over time (JAN 2016)

Content Standards
Technical Standards
Semantics
Therapeutic Areas

This & next slide with permission from Peter Van Reusel, 2016 CDISC European Interchange
Updates over time (JAN 2016)

Content Standards
- ODM v1.3.1
- BRIDG v3.0.3
- BRIDG v3.0.1
- BRIDG v3.0.2
- ADaM Val. Checks v1.0
- Protocol Model v1.0

Technical Standards
- SDM.XML v1.0
- Alzheimer v1.0
- BRIDG v3.2
- SDT v3.1.2 Am.1
- ADaM Val. Checks v1.1
- CDASH v1.1
- SEND v3.0

Semantics
- Pain
- Devices
- Alzheimer v1.1
- BRIDG v4.0
- ADaM IG 2.0
- ADaM OCCDS V1.0
- ADaM Validation Checks V1.3

Therapeutic Areas
- Parkinson’s Disease
- Virology v1.0
- CDASH v1.2
- SDT v3.1.3
- SDT v3.4
- SDT v2.0
- SDT Pharmacogenomics IG v1.0

- Tuberculosis
- Define.xml v2.0
- PRM Toolset v1.0
- Associated Persons IG v1.0
- PROTOCOL.XML 1.0

- ADaM Val. Checks v1.2
- CDASH UG v1.0
- CDASH E2B SAE IG
- SEND IG v3.1
- SAE IG

- PKD
- ODM v1.3.2
- Define.xml v2.0
- ADaM IG v1.2
- ADaM IG v1.1
- ADaM OCCDS V1.0
- ADaM Validation Checks V1.3

- Influenza
- Diabetes
- QT Studies
- Analysis Results Metadata v1.0
- SDTM v1.5
- SDTM Device Submission Pilot
- ADaM Validation Checks V1.3

- Cardiovascular
- Multiple Sclerosis
- Dataset-xml v1.0
- SDTM v1.3 Batch 1
- SEND IG v3.1
- SEND IG v3.4
- SEND IG v2.0

- Pain
- Devices
- Alzheimer v1.1
- BRIDG v4.0
- ADaM IG 2.0
- ADaM IG v1.2
- ADaM IG v2.0

- Alzheimer v1.1
- BRIDG v3.2
- SDT v3.1.3
- SDT v3.4
- SDT v2.0
- SDT Pharmacogenomics IG v1.0

- Pain
- Devices
- Alzheimer v1.1
- BRIDG v4.0
- ADaM IG 2.0
- ADaM IG v1.2
- ADaM IG v2.0
SHARE Overview

SHARE provides access to *curated, machine-readable* CDISC Standards to:

- Support reuse and management of standards
- Implement standards in real time or as packages
- Meaningfully exchange health research data
- Over time, reduce costs
- Maintain compliance of data submission to FDA, PMDA
The Pillars of SHARE

- Foundational Standards
- Semantics
- Therapeutic Area Standards
- Biomedical Concepts
Current CDISC Standards in SHARE

CDASH
- CDASH v1.0 (OCT 2008)
- CDASH v1.1 (JAN 2011)
- CDASH UG v1.0 (APR 2012)
- CDASH E2B SAE IG (NOV 2013)

CDASH Terms
- CDASH Terms (DEC 2013)
- CDASH Terms (MAR 2014)
- CDASH Terms (SEP 2014)
- CDASH Terms (MAR 2015)
- CDASH Terms (MAR 2016)
- CDASH v1.1 to SDTM 3.1.2 Map

SDTM
- SDTM v1.0 + SDTM IG v3.1 (JUL 2004)
- SDTM v1.2 + SDTM IG v3.1.2 (JUN 2014)
- SDTM v1.3 + SDTM IG v3.1.3 (AUG 2014)
- SDTM MEDICAL DEVICES v1.0 (NOV 2014)
- SDTM v1.4 + SDTM IG v3.2 (AUG 2014)
- SDTM IG 3.1.3 to 3.2 DIFF (FEB 2014)
- SDTM v1.5 + SDTM IG v3.3 Drafts (JUL 2015)
- SDTM IG 3.1.3 to 3.2 DIFF (FEB 2014)
- SDTM PHARMACOGENOMICS IG v1.0 (MAY 2016)

SDTM Terms
- SDTM Terms 2013-12 (DEC 2012)
- SDTM Terms 2014-03 (OCT 2014)
- SDTM Terms 2014-06 (OCT 2014)
- SDTM Terms 2014-12 (APR 2015)
- SDTM Terms 2015-03 (APR 2015)
- SDTM Terms 2015-06 (DEC 2015)
- SDTM Terms 2015-12 (FEB 2016)
- SDTM Terms 2016-03 (MAY 2016)

SDTM Terms 2
- QRS Terms 2013-12 (JUN 2014)
- QRS Terms 2014-03 (OCT 2014)
- QRS FT Terms 2014-06 (OCT 2014)
- QRS FT Terms 2014-09 (OCT 2014)
- COA Terms 2014-12 (APR 2015)
- COA Terms 2015-04 (APR 2015)
- QRS Terms 2015-06 (SEP 2015)
- QRS Terms 2015-06 (DEC 2015)
- SDTM Variable Codelist Mapping (JAN 2016)
- Multiple SDTM + CT Bundles

SDTM Terms 2
- SDTM Terms 2014-03 (OCT 2014)
- SDTM Terms 2014-06 (OCT 2014)
- SDTM Terms 2014-12 (APR 2015)
- SDTM Terms 2015-03 (APR 2015)
- SDTM Terms 2015-06 (SEP 2015)
- SDTM Terms 2015-06 (FEB 2016)
- SDTM Terms 2016-06 (MAY 2016)

ADaM
- ADaM v2.1 (FEB 2015)
- ADaM VALIDATION CHECKS v1.0 (SEP 2010)

ADaM Terms
- ADaM Terms 2013-12 (JUN 2014)
- ADaM Terms 2014-09 (OCT 2014)
- ADaM Terms 2015-12 (FEB 2016)
- ADaM Terms 2016-03 (MAY 2016)

SEND
- SEND IG v3.0 (OCT 2014)
- SEND IG v3.1 Draft (APR 2015)
- SEND IG v3.0 – 3.1 DIFF (OCT 2015)

SEND Terms
- SEND Terms 2014-03 (OCT 2014)
- SEND Terms 2014-06 (OCT 2014)
- SEND Terms 2014-09 (OCT 2014)
- SEND Terms 2014-12 (APR 2015)
- SEND Terms 2015-03 (APR 2015)
- SEND Terms 2015-06 (SEP 2015)
- SEND Terms 2015-09 (DEC 2015)
- SEND Terms 2015-12 (FEB 2016)
- SEND Terms 2016-03 (MAY 2016)

SEND Terms
- SEND Terms 2014-03 (OCT 2014)
- SEND Terms 2014-06 (OCT 2014)
- SEND Terms 2014-09 (OCT 2014)
- SEND Terms 2014-12 (APR 2015)
- SEND Terms 2015-03 (APR 2015)
- SEND Terms 2015-06 (SEP 2015)
- SEND Terms 2015-09 (DEC 2015)
- SEND Terms 2015-12 (FEB 2016)
- SEND Terms 2016-03 (MAY 2016)

THERAPEUTIC AREAS
- CHRONIC HEP C VIRUS (SEP 2015)
- QT STUDIES v1.0 (JUL 2015)
- MULTIPLE SCLEROSIS (JUN 2015)
- INFLUENZA v1.0 (JUN 2015)
- DIABETES (MAY 2015)
- CARDIOVASCULAR v1.0 (MAY 2015)
- SDTM UG BUNDLE (APR 2015)
- ALZHEIMER (APR 2015)
- PAIN (JUN 2012)
- TUBERCULOSIS (JUN 2012)
- PARKINSON’S DISEASE (OCT 2012)
- VIROLOGY v1.0 (NOV 2012)
- DEVICES (DEC 2012)
- PKD (FEB 2013)
- ASTHMA v1.0 (APR 2015)
- DISLIPIDEMIA v1.0 (JUN 2015)
- SCHIZOPHRENIA v1.0 (JUN 2015)
- VIROLOGY v2.0 (SEP 2015)
- BREAST CANCER v1.0 Draft (Q1 2016)

BRIDG
- BRIDG v3.0 (OCT 2009)
- BRIDG v3.0.1 (FEB 2010)
- BRIDG v3.1.2 (AUG 2010)
- BRIDG v3.1.3 (DEC 2010)
- BRIDG v3.1 (FEB 2012)
- BRIDG v3.2 (SEP 2012)

Controlled Terminologies
- Miscellaneous CT Packages (Recurring)
Which standards are available in eSHARE?

- Foundational standards
  - SDTM
  - CDASH
  - ADaM
  - SEND
  - Medical Devices
  - PGx
  - Questionnaires
- Therapeutic Areas
- Mappings
- CT Packages
- Diff files

<table>
<thead>
<tr>
<th>CDASH</th>
<th>eSHARE Standards Catalog</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Posted</td>
<td>Content</td>
</tr>
<tr>
<td>2014-06-02</td>
<td>CDASH</td>
</tr>
<tr>
<td>2014-06-02</td>
<td>CDASH + CT</td>
</tr>
<tr>
<td>2014-06-02</td>
<td>CDASH</td>
</tr>
<tr>
<td>2014-06-02</td>
<td>CDASH UG</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CDASH Terminology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Posted</td>
</tr>
<tr>
<td>2015-04-10</td>
</tr>
<tr>
<td>2014-10-17</td>
</tr>
<tr>
<td>2014-10-17</td>
</tr>
<tr>
<td>2014-06-02</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CDASH To SDTM Map</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Posted</td>
</tr>
<tr>
<td>2015-02-02</td>
</tr>
</tbody>
</table>

eSHARE exports are free to members & academics via eSHARE.
Coming Soon: SHARE API

The SHARE API will provide programmatic access to SHARE. A business model is being developed to support its continued development and maintenance.
SHARE in Learning Health System

- Will support Healthcare Link, make better use of existing health data for regulated research

Assessing SHARE on FHIR® from HL7® to couple healthcare syntax with CDISC’s biomedical semantics
Questions?

Check the CDISC website for:

- eSHARE
- Volunteer opportunities
- Educational materials
  - In-person training schedules
  - Interchange Workshop
- Signing up for email blasts/newsletters
- Upcoming meetings
- News
- Other resources

Contact:
Ibecnel@cdisc.org
SHARE API v1.0

Introduction to the SHARE API
June 23, 2016
Sam Hume
The SHARE Application Programming Interfaces (API) provides programmatic access to machine-readable SHARE content for Metadata Repositories (MDR) and other software tools.
Sponsor MDRs use SHARE API-aware MDR products to automatically access the latest CDISC standards content.
Importance of the SHARE API

• The SHARE API...
  ▪ is the most efficient way to deliver standards metadata
  ▪ enables the next step in standards-based process automation
  ▪ enables enhanced innovation opportunities
  ▪ enables higher levels of standards metadata quality
  ▪ represents a modern method for accessing information
The SHARE API Pilot Project

• The purpose of the pilot is to partner with industry technology leaders to design and implement the SHARE API
  ▪ The partnership includes each partner building and testing an interface to SHARE using the API

• The goal is to deliver the first release of the SHARE API with software tools capable of using the interface
  ▪ A secondary goal is to start a SHARE API roadmap to outline future development opportunities
A quick look at the API

• RESTful API: uses HTTP requests to Get standards metadata
  ▪ http://{system-endpoint}/{context-root}/rest/semantics/{library-name}/{rest-api-name}/{rest-api-parameter}?{query-parameters}

• Standards metadata returned in the following formats:
  ▪ SHARE-XML
    • Extended ODM v1.3.2 XML
    • Extended Define-XML v2.0
  ▪ RDF (only available for top-level standards)
    • rdf-xml
    • turtle
    • n-triples
  ▪ JSON (experimental)
A quick look at the API

- Get Standards API - Example
  - https://smpoc3.akana.com/sm/rest/semantics/CDISCAPI/standards?user-id=bus_user&encoding=identity&lifecycle-status=Approved%20Final

```xml
<MetaDataVersion Name="CDISCAPI" OID="MDV.28.1.getStandards" mdr:ShareXMLVersion="1.0.0">
  <ItemGroupDef Name="CDASH (MDES 1.1)" OID="1.0_13910561168727094932" Purpose="Data Collection" Repeating="No" mdr:DSTO="10" mdr:Status="Approved Final">
    <TranslatedText xml:lang="en">
      Clinical Data Acquisition Standards Harmonization (CDASH) v1.1
    </TranslatedText>
  </ItemGroupDef>
  <ItemGroupDef Name="SDTM (MDES 3.1.2)" OID="1.0_1391054074081152706575" Purpose="Data Tabulations" Repeating="No" mdr:DatePublished="2016-03-10" mdr:Status="Approved Final">
    <TranslatedText xml:lang="en">
      Study Data Tabulation Model (SDTM) 1.2, SDTM IG 3.1.2
    </TranslatedText>
  </ItemGroupDef>
  <ItemGroupDef Name="SDTM (MDES 3.1.3)" OID="1.0_13969030352051659917782" Purpose="Data Tabulations" Repeating="No" mdr:DatePublished="2016-03-10" mdr:Status="Approved Final">
    <TranslatedText xml:lang="en">
      Study Data Tabulation Model (SDTM) 1.3, SDTM IG 3.1.3
    </TranslatedText>
  </ItemGroupDef>
</MetaDataVersion>
```
RDF and SHARE-XML Exports

• SHARE API and Exports use the same code base

• RDF exports have recently completed testing

• SHARE-XML offers additional metadata available in SHARE as an extension to ODM or Define-XML
  ▪ Can easily re-create the metadata spreadsheets from the XML
  ▪ Includes additional information not available in the spreadsheets

• Coming to eSHARE soon
SHARE API Next Steps

• Setup the SHARE API production environment
• Deploy the API to the production environment
• Develop a SHARE API licensing model
• Launch the SHARE API
Strength *through collaboration.*