Access to CDISC SHARE Metadata:

A la carte, prix fixe, or table d'hôte?

Ken Stoltzfus
12 October, 2015
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- CDISC SHARE 101
- Metadata Use Cases
- CDISC SHARE API Pilot
- Q&A
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CDISC SHARE 101

Metadata Use Cases

CDISC SHARE API Pilot

Q&A
CDISC SHARE in the Industry

CDISC Existing Standards

CDISC / CFAST / CPATH Standards Development Teams

Sponsor A

Sponsor B

Sponsor C

Sponsor D

Sponsor E

Sponsor F

Standards Metadata

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Standards Metadata
New Opportunities for Standardized Metadata to Improve Interoperability

- Foundational Standards Metadata
- Controlled Terminology
- Therapeutic Areas
- Research Concepts
- Value-level Metadata
- Process Metadata
- Validation Rules
- Codelist Subsets
- End-to-end Metadata

Slide Courtesy of: Sam Hume, CDISC, VP SHARE Technology & Services
The interactive tool used by the CDISC standards development community for developing, governing, and publishing the standards. It is the source for content that is available for export in eSHARE.

The eSHARE website maintains executable, downloadable links for each of the standards metadata published from iSHARE, including exports in multiple formats as well as multiple versions of the standards.
eSHARE Access

- CDISC eSHARE website
- Pre-defined logical sets of standards metadata
  - SDTM IG 3.2, 3.1.3, etc.
  - TA UG Virology, Devices, etc.
- Export files:
  - XML
  - Excel
  - RDF
- Manual processing of SHARE export files
SHARE: Patterns of Metadata Use

New metadata products to support new patterns of use

- Diff files – process the updates
- Bundles – process related content together
- Metadata + Examples + Test Data
- Normative + Non-normative
- New formats – XML & RDF
Hard decisions!

- Regardless of the exact nature of the standards metadata

✓ CDISC SHARE metadata can help
Version Control with SHARE metadata

```xml
<xml version="1.0" encoding="UTF-8">
    <SourceSystemVersion>1.0 (6.6.1006)</SourceSystemVersion>
    <SourceSystem>SHARE</SourceSystem>
    <Originator>CDISC</Originator>
    <ODMVersion>1.3.2</ODMVersion>
    <FileType>Snapshot</FileType>
    <FileDestName>StudySDTM.MDES_3.2</FileDestName>
    <GlobalVariables>
      <GlobalVariable Name="AE" def="StructuredEvent">
        <Description>Events</Description>
        <Repeating>Yes</Repeating>
        <Type>StructuredEvent</Type>
        <ItemOID>IT.MDE.STUDYID.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.DOMAIN.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.USUBJID.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.AESEQ.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.AEGRPID.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.AEREFID.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.AEOPT.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.AEREF.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.AEDCOD.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.AELTT.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.AETCD.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.AETDE.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.AERTEC.[SDTM_AE]_MDE_1</ItemOID>
        <ItemOID>IT.MDE.AERTEC.[SDTM_AE]_MDE_2</ItemOID>
        <ItemOID>IT.MDE.AERTEC.[SDTM_AE]_MDE_3</ItemOID>
        <ItemOID>IT.MDE.AERTEC.[SDTM_AE]_MDE_4</ItemOID>
      </GlobalVariable>
    </GlobalVariables>
  </ODM>
</xml>
```
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CDISC SHARE 101

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Q&A
Emerging Regulatory Requirements

**European Medicines Agency**
Publication and access to clinical-trial data (EMA/240810/2013)
“In future, CDISC shall be the required standard.”

**Food and Drug Administration**
Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act
*This legislation gives the FDA the ability to enforce CDISC standards*

Providing Regulatory Submissions in Electronic Format — Standardized Study Data
*Clinical and non-clinical studies that start after December 17, 2016 must use the CDISC standards in the Data Standards Catalog*

**Pharmaceuticals Medical Devices Agency**
Basic Principles on Electronic Submission of Study Data for New Drug Applications
*Will require electronic clinical study data conforming to the CDISC SDTM and ADaM format from J-FY2016 with a transitional period*
Metadata Use Case #1

Adverse1 EDC extract

S_AE.SAS

AE SDTM domain

A_ADAE.SAS

ADAE ADaM dataset

XML

SAS

SDTM

ADaM

MDR
Metadata Use Case #2

- ADAE
  - ADaM dataset

- XML
  - T_ADAE.SAS
  - F_ADAE.SAS

- Macro Parameters
  - ADaM dataset

- MDR

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**Metadata Use Case #3**

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### Study Design: Adverse Events (AE_UseCase1) [AE_UseCase1]

**Event Experienced** [igAE_UseCase1_YN]

1. Were any adverse events experienced? [Any AEs?]
   - [AEYN] [A:N] No
   - [A:Y] Yes

---

### Event Term Entry [igAE_UseCase1_H]

1. AE Group ID
2. Adverse Event

---

### Event Details Entry [igAE_UseCase1_D]

1. AE Identifier [read-only]
   - [AE SPID] N4

2. What is the date the adverse event started? [Start Date]
   - [AE SDATE] Req / Req/Unk / Req (2012-2014)

3. Is the adverse event still ongoing? [Ongoing]
   - [AEONGO] [A:N] No
   - [AEENDAT] End Date
   - [A:Y] Yes

4. What is the toxicity grade of the adverse event? [Toxicity Grade]
   - [AE TOXGR] [CITOXGR]
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CDISC SHARE 101

Metadata Use Cases

CDISC SHARE API Pilot

Q&A
SHARE Access - Future

MDR to MDR

Application Programming Interface (API)
• Direct automated interaction between CDISC Share Repository and Sponsor MDR
SHARE: Application Programming Interface

- iSHARE
- eSHARE
- SHARE Repository
- SHARE Metadata Services Bus
  - Batch Load
  - SHARE API
  - Export

Web Clients
- External Terminologies & Models
- EDC Products
- Open CDISC, Tools
- External Repositories
- Sponsor MDR

AWS EC2 Cloud

Slide Courtesy of: Sam Hume, CDISC, VP SHARE Technology & Services
CDISC SHARE API Pilot

Details:

- RFI published - April 2015
- Started – August 2015
- Anticipated end - Q4 2015
- Participant organizations:
  - CDISC
  - Accenture
  - Business and Decisions
  - Cambridge Semantics
  - Entimo
  - eTriks
  - Fujitsu
- Committal of a dedicated resource (~ 0.25 FTE)
- Participation fee
CDISC SHARE API Pilot

- **Goals**
  - Enable automated programmatic access to SHARE content
  - Develop use cases
  - Enhance design aspects
  - Review and test the Web API features

- ★ Final specification for the API will be delivered during the pilot
  - Draft specification currently exists
SHARE Access - Future

API access yields opportunities:

- Sets of standard metadata or specified components
  - Domains
  - Variables

- Update packages (changes between versions)

- Lookup capabilities:
  - Test names associated with Test codes
  - Available supplemental qualifiers
  - Validation rules

- Mapping data for variables (e.g.: CDASH to SDTM)

- Research concepts

- Value--level metadata
SHARE Interoperability Benefits

- Increases process automation opportunities
- Increases metadata quality
- Improves data quality through standardization
- Improves data quality through semantics
- Encourages data re-use
- Facilitates data aggregation
- Improves data exchange across organizations
- Improves end-to-end data lifecycle efficiency

Slide Courtesy of: Sam Hume, CDISC, VP SHARE Technology & Services
Feel free to visit the Accenture booth for more information on Accenture's solutions.
Q&A