Time Travel for Librarians

PhUSE 2013
Brussels
Agenda

1. Clinical Data Standardization
2. Clinical Data Standards Platform
3. Time Travel for Librarians
4. Conclusion
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Clinical Data Standardization

Variety of Clinical Data Standards (CDS)

Intra-company CDS
- Increased competition, critical to achieve Operational Excellence

Inter-company CDS
- FDA requirement for submitting clinical data in a CDISC format.
  - Is evolving further ...

Business and Regulatory drivers
Overview of CDISC models

**PROTOCOL**
- PROTOCOL v.1.0 (JAN 2010)
- PRM TOOLSET v.1.0 (APR 2012)
- STANDARD PROTOCOL TOOLSET (JAN 2013)

**DEFINE.XML**
- DEFINE.XML v.1.0 (FEB 2005)
- DEFINE.XML v.2.0 (DEC 2012)

**CDASH**
- CDASH v.1.0 (OCT 2008)
- CDASH v.1.1 (JAN 2011)
- CDASH UG v.1.0 (APR 2012)
- CDASH v.1.2 (DEC 2012)

**SDTM**
- SDTM v.1.0 + SDTM IG v.3.1 (JUL 2004)
- SDTM v.1.1 + SDTM IG v.3.1.1 (AUG 2005)
- SDTM v.1.2 + SDTM IG v.3.1.2 (NOV 2008)
- SDTM IG v.3.1.2 AMENDMENT 1 (DEC 2011)
- SDTM v.1.3 + SDTM IG v.3.1.3 (JUL 2012)
- SDTM IG v.3.1.4 (DEC 2012)
- SDTM IG v.3.1.5 (JUN 2013)

**ADaM**
- ADaM v.2.0 (AUG 2006)
- ADaM v.2.1 + ADaM IG v.1.0 (DEC 2009)
- ADaM VALIDATION CHECKS v.1.0 (SEP 2010)
- ADaM VALIDATION CHECKS v.1.1 (JUL 2011)
- ADaM VALIDATION CHECKS v.1.2 (JUL 2012)
- ADaM IG v.1.1 (FEB 2013)

**ODM**
- ODM v.1.1 (APR 2002)
- ODM v.1.2 (JAN 2004)
- ODM v.1.2.1 (JAN 2005)
- ODM v.1.3 (DEC 2006)
- ODM v.1.3.1 (FEB 2012)

**THERAPEUTIC AREAS**
- ALZHEIMER v.1.0 (SEP 2011)
- PAIN (JUN 2012)
- TUBERCULOSIS (JUN 2012)
- DEVICES (SEP 2012)
- PARKINSON'S DISEASE (OCT 2012)
- VIROLOGY (NOV 2012)
- PKD (NOV 2012)
- ALZHEIMER v.1.1 (FEB 2013)
- CV IMAGING (CT MODALITY) (MAR 2013)
- SCHIZOPHRENIA (APR 2013)
- CV IMAGING (MAY 2013)

**SEND**
- SEND IG v.3.0 (MAY 2011)
- SEND IG v.3.1 (MAR 2013)

**SHARE**
- CDISC SHARE (DEC 2012)

**HEALTHCARE LINK** (DEC 2012)
CDISC models evolution over time

- **Content Standards**
- **Technical Standards**
- **Therapeutic Areas**

- Define.xml v2.0
- SDTM v3.2
- ADaM v3.1.2
- Alzheimer v1.0
- Parkinson’s Disease Devices
- CV Imaging
- Schizophrenia
- SEND v3.1
- SDTM.xml v1.0
- PRM Toolset v1.0
- CDASH UG v1.0
- SDTM IG v3.1.5
- ADaM IG v1.1
- ODM v1.2.1
- CDASH v1.0
- SDTM v3.1.3
- ADaM Val. Checks v1.1
- Define.xml v1.0

- BRIDG v3.3
- SDT v1.2
- SDTM IG v3.1
- BRIDG v2.1
- ADaM v2.1
- ODM v1.1
- BRIDG v1.1.1
- SDT v1.0
- CDASH v1.0
- ADaM Val. Checks v1.0
- BRIDG v2.2
- ODM v1.0
- CDASH v1.1
- Protocol Model
- BRIDG v3.0.1
- BRIDG v1.0
- BRIDG v2.0
- BRIDG v3.0
- SDT v1.1
- BRIDG v2.1
- ODM v1.3
- BRIDG v1.0
- Define.xml v1.0

- Pain
- Tuberculosis
- Cardiovascular
- Alzheimer
- Parkinson's Disease
- Devices

- 2002
- 2003
- 2004
- 2005
- 2006
- 2007
- 2008
- 2009
- 2010
- 2011
- 2012
- 2013
More complex and increasing challenges

- What is different compared to the legacy standards?
- How to update the legacy standards most efficiently?
- Etc.

- What standards version to use?
- What standards versions were used previously?
- What is the scope of the standardization?
- Etc.

- How to evaluate overall CDISC compliance?
- How can we compare easily between studies?
- Etc.
Agenda

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Clinical Data Standards Platform

- Performance management and CPI
- Data Standards Governance
- Robust Technical platform
Define Strategic and Operational Objectives, KPIs, KPI targets and Initiatives for improving Clinical Data Standards management
Technical Platform - high level flow

DATA COLLECTION AREA
- DBA
- EDC
- CRO

DATA MANAGEMENT AREA
- DATA STANDARDS LIBRARY
- STUDY SPECIFICATION
- STUDY METADATA REPOSITORY
- COMPARISON
- ISSUE REPORTS
- STUDY SDTM DATA & METADATA
- DEFINE.XML

DATA AREA
- SD04: “An Integrated Platform for Standards Management and Study Conduct”
- DH10: “Time Travel for Librarians: Versioning Complex Library Metadata for Past, Present or Future Retrieval”
- CD14: “Is your Library a Success: Manage and Measure Conformance Across Partners and Projects”
- TS06: “Developing an Integrated Platform, Getting the Best out of Several Technologies”
- SD05: “Data Validation, Getting Full Control over your Data Standards Compliance and Data Flow”
- CC06: “Dynamic SAS Programming with XML Templates”
The Data Standards Library contains:

- **Data Collection Modules:**
  - using CDASH metadata
  - with clustered SDTM metadata
  - annotated for CDASH
  - annotated for SDTM

- **Metadata Definitions:**
  - SDTM Standards
  - Therapeutic Area Standards
Data Collection Modules - CDASH

DATA COLLECTION MODULES LIBRARY

Vital Signs

<table>
<thead>
<tr>
<th>Vital signs</th>
<th>VSDAT</th>
<th>VSTIM</th>
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<td>Date and time</td>
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<tr>
<td>VSTIM</td>
<td>dd</td>
<td>hh</td>
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<tr>
<td>mmm</td>
<td>mm</td>
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<tr>
<td>yy</td>
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<td>(24 h time clock)</td>
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<th>VSORRESU</th>
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<td>kg</td>
<td>cm</td>
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</thead>
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<td>VSORRESU</td>
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<td>beats/min</td>
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<table>
<thead>
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<th>VSTEST</th>
<th>VSORRESU</th>
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<td>VSORRESU</td>
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<tr>
<td>Supine</td>
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<td>Standing</td>
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<td>VSTESTCD</td>
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<tr>
<td>VSTESTCD</td>
<td></td>
</tr>
</tbody>
</table>

Collected CDASH Variables | CRF Prompt | Codelist | Preprinted values |
--------------------------|------------|----------|-------------------|
VSDAT                     | Date       |          |                   |
VSTIM                     | Time       |          |                   |
VSPOS                     | Position   | POSITION |                   |
VSTEST                    | Test       | VSTESTCD | Height            |
VSTEST                    | Test       | VSTESTCD | Weight            |
VSTEST                    | Test       | VSTESTCD | Pulse             |
VSTEST                    | Test       | VSTESTCD | Systolic Blood Pressure |
VSTEST                    | Test       | VSTESTCD | Diastolic Blood Pressure |
VSORRESU                  | Unit       | VSRESU   | cm                |
VSORRESU                  | Unit       | VSRESU   | kg                |
VSORRESU                  | Unit       | VSRESU   | beats/min         |
VSORRESU                  | Unit       | VSRESU   | mmHg              |
Data Collection Modules - SDTM

DATA COLLECTION MODULES LIBRARY

Value Level Metadata (ValueList.VS.VSTESTCD)

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<tr>
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<td>WEIGHT</td>
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<td>CRF</td>
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</table>
Build within a controlled environment

- Version control
- Search for Library Objects
- Integrity and Consistency checks
- Groups, Roles & Privileges
- Change Request Reasons
- Audit Trails
Versioning of Library Objects: principle

- **Versioning through date fields**

  - Each record in the library contains an “Active From” and “Active To” field

  - There can be no overlap of dates
  - The “Active From” date
    - No date in the past permitted
    - > than today if the record is already created prior to release
  - The “Active To” date can remain blank if expected to be used indefinitely
  - There can never be more than one “version” of an object active at any point in time
Versioning through date fields

An example for a Code List record
Versioning of Library Objects: example

**CV3a:**
- Active From: 01 JAN 2013
- Active To: 01 OCT 2013

**CV3b:**
- 02 OCT 2013
Versioning of Library Objects: example

- PAST
- PRESENT
- FUTURE

Code List

- Code Value 1
- Code Value 2
- Code Value 3
- Code Value 4
- Code Value 5
Allowing Time Travel for Librarians ...

**DCM Domain**

**CDASH metadata**

**SDTM metadata**

**Code Lists**

**Code Value**

**VLM Name**

**VLM Value**

**Computational Algorithm**

**Data Validation Rule**
Data Standards Library comparisons

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<th>Label</th>
<th>Type</th>
<th>Default Value</th>
<th>Check</th>
<th>Name</th>
<th>Description</th>
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</table>
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Conclusion

• Increased and complex Clinical Data Standards challenges

• Clinical Data Standards Platform requires:
  – Data Standards Governance,
  – Robust Technical platform,
  – Performance Management

• Version control with Active From an To dates allows **TIME TRAVEL** for librarians

• Ensures:
  – Increased CDISC clinical data standards adaptability
  – Better collaboration and easier regulatory submissions
  – Continuous Process Improvement
  – ...
Thank you for your attention