METADATA REPOSITORY CONCEPT

20th February 2018, German CDSIC User Network
Christian Geretzki
AGENDA

• WHY AND HOW TO USE STANDARDS
• HIERACHY IN THE REPOSITORY
• STANDARDS IN MDR
• CDASH AS OVERLAY IN MDR

About Me:

Christian Geretzki
Principal Data Standards Analyst

Member of Data Standards Governance Team responsible for seamless integration between MDR Standards and EDC systems
WHY DO WE NEED STANDARDS

Database Programmer:

• It’s working fine as it is.
• We are all experts and know how to setup studies.

Working with Standards leads to:

• Additional departments are involved.
• They never fit what we need.
• We need to work around restrictions.
• So is a time consuming job.
METADATA STANDARDS HIERARCHY

ORGANIZATIONS
COMPANIES, THERAPEUTIC AREAS, OTHERS

STANDARDS
METADATA CONCEPT COLLECTION (MCC)

SIM CATALOG
APPROVED STUDIES (SIMS)

STUDIES
STUDY INSTANCE METADATA (SIM)
METADATA STANDARDS CONTENT

STANDARDS
FORMS, FIELDS, CODELISTS, MAPPINGS
EDIT CHECKS

STUDY INSTANCE METADATA (SIM)
+EPOCHS, VISITS, MATRICES, STUDY PARAMETER

EDC BUILD
METADATA STANDARDS MANAGEMENT – CORE METADATA AND EXTENDED METADATA

STANDARDS (MCC)

CORE PARAMETER

OVERLAY AREA

CDASH /GLOBAL
SAS LABEL / QUESTION TEXT / DOMAIN

- SAS LABEL
- QUESTION TEXT
- DOMAIN
- DISPLAY OPTION

- SAS LABEL
- QUESTION TEXT
- DOMAIN
- DATASOURCE

- SAS LABEL
- QUESTION TEXT
- DOMAIN
- COLLAPSIBLE
MANAGING CORE AND OVERLAY METADATA

Manage Core and Overlay metadata in one spreadsheet with each item as a single record.

<table>
<thead>
<tr>
<th>A</th>
<th>Name</th>
<th>Form (Name), Area (Name)</th>
<th>Length</th>
<th>Value Set (ID)</th>
<th>Descriptions</th>
<th>Questions</th>
<th>Required</th>
<th>CDASH/Q #</th>
<th>CDASH Question Text</th>
<th>CDASH Short Prompt</th>
<th>Sponsor Text</th>
<th>SAS Label</th>
<th>CDASH HS Core</th>
<th>CDASH HS Parexel</th>
<th>CRM Completion Instruction</th>
<th>Short Mage Name</th>
<th>Displayed Option</th>
<th>Short Prompt</th>
<th>Source</th>
<th>Model</th>
<th>Model Edit</th>
<th>Model Value</th>
<th>Model Scope</th>
<th>DataMapping</th>
<th>Rename</th>
<th>FieldID</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>AE PR</td>
<td>Adverse Events Diary 1</td>
<td>128</td>
<td>4292_C_14F</td>
<td>Administration and倫理</td>
<td>1</td>
<td>Another adverse event? AdminD</td>
<td>Admin D</td>
<td>Admin D</td>
<td>Adverse Event Diary 1 Admin D</td>
<td>Administration and倫理</td>
<td>Another adverse event?</td>
<td>Admin D</td>
<td>Admin D</td>
<td>Admin D</td>
<td>Admin D</td>
<td>Another adverse event?</td>
<td>Admin D</td>
<td>Admin D</td>
<td>Admin D</td>
<td>Admin D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>AE PR</td>
<td>Adverse Events Diary 2</td>
<td>128</td>
<td>4292_C_14F</td>
<td>Administration and倫理</td>
<td>1</td>
<td>Another adverse event? AdminD</td>
<td>Admin D</td>
<td>Admin D</td>
<td>Adverse Event Diary 2 Admin D</td>
<td>Administration and倫理</td>
<td>Another adverse event?</td>
<td>Admin D</td>
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<td>Admin D</td>
<td>Another adverse event?</td>
<td>Admin D</td>
<td>Admin D</td>
<td>Admin D</td>
<td>Admin D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Once imported, the core and overlay metadata become part of the standard MCC and are copied into each SIM along with the standard.
CDASH/GLOBAL OVERLAYS

On Forms:

CDASH
Domain Class: Findings
Domain: LB
Data Collection Scenario: LB-Local Processing

Domain Class options:

On Itemgroups:

CDASH
Category
Hematology
Sub Category
**CDASH/GLOBAL OVERLAY**

On Items:

<table>
<thead>
<tr>
<th>LBTESTCD_CHEM</th>
<th>Laboratory Test Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>K</td>
<td>Potassium Measurement</td>
</tr>
<tr>
<td>SODIUM</td>
<td>Sodium Measurement</td>
</tr>
<tr>
<td>UREAN</td>
<td>Urea Nitrogen Measurement</td>
</tr>
<tr>
<td>PROT</td>
<td>Total Protein Measurement</td>
</tr>
<tr>
<td>ALB</td>
<td>Albumin Measurement</td>
</tr>
<tr>
<td>CREAT</td>
<td>Creatinine Measurement</td>
</tr>
<tr>
<td>BILDIR</td>
<td>Direct Bilirubin Measurement</td>
</tr>
<tr>
<td>BILI</td>
<td>Total Bilirubin Measurement</td>
</tr>
<tr>
<td>ALT</td>
<td>Alanine Aminotransferase Measurement</td>
</tr>
<tr>
<td>AST</td>
<td>Aspartate Aminotransferase Measurement</td>
</tr>
<tr>
<td>GLUC</td>
<td>Glucose Measurement</td>
</tr>
<tr>
<td>PHOS</td>
<td>Phosphate Measurement</td>
</tr>
<tr>
<td>ALP</td>
<td>Alkaline Phosphatase Measurement</td>
</tr>
<tr>
<td>UREA</td>
<td>Urea Measurement</td>
</tr>
<tr>
<td>CA</td>
<td>Calcium Measurement</td>
</tr>
<tr>
<td>MG</td>
<td>Magnesium Measurement</td>
</tr>
<tr>
<td>CL</td>
<td>Chloride Measurement</td>
</tr>
<tr>
<td>BICARB</td>
<td>Bicarbonate Measurement</td>
</tr>
<tr>
<td>LDH</td>
<td>Lactate Dehydrogenase Measurement</td>
</tr>
<tr>
<td>CRP</td>
<td>C-Reactive Protein Measurement</td>
</tr>
<tr>
<td>T3</td>
<td>Triiodothyronine Measurement</td>
</tr>
<tr>
<td>T4FR</td>
<td>Free Thyroxine Measurement</td>
</tr>
<tr>
<td>TSH</td>
<td>Thyrotropin Measurement</td>
</tr>
</tbody>
</table>

**CDASH**

CDASH Question Text: What was the lab test code?

CDASH Short Prompt: Lab Test Code

PXL Text: Parameter

PXL SAS Label: Lab Test Code

CDASH IG Core: Req (SDTM)

CDASH Definition:
Terminology used for laboratory test codes of the CD ISC Study Data Tabulation Model.

PXL Justification:

CRF Completion Instructions:
Record the name of the Lab measurement or finding, if not pre-printed on the CRF. If collected on the CRF, the sponsor may provide additional instructions to ensure the data is entered as intended.

PXL Completion Instructions:

Notes:
# CDASH/Global Overlay

## On Codelists / ValueSets:

<table>
<thead>
<tr>
<th>Laboratory Test Code_C_LB_Chem</th>
<th>K</th>
<th>Potassium Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SODIUM</td>
<td>Sodium Measurement</td>
</tr>
<tr>
<td></td>
<td>UREAN</td>
<td>Urea Nitrogen Measurement</td>
</tr>
<tr>
<td></td>
<td>PROT</td>
<td>Total Protein Measurement</td>
</tr>
<tr>
<td></td>
<td>ALB</td>
<td>Albumin Measurement</td>
</tr>
<tr>
<td></td>
<td>CREAT</td>
<td>Creatinine Measurement</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>CA</td>
<td>Calcium Measurement</td>
</tr>
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<td></td>
<td>MG</td>
<td>Magnesium Measurement</td>
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<td></td>
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<td>Triiodothyronine Measurement</td>
</tr>
<tr>
<td></td>
<td>T4FR</td>
<td>Free Thyroxine Measurement</td>
</tr>
<tr>
<td></td>
<td>TSH</td>
<td>Thyrotropin Measurement</td>
</tr>
</tbody>
</table>

### Value Set Properties
- **Items:** 23
- **Name:** Laboratory Test Code_C_LB_Chem
- **Synonym:** Laboratory Test Code
- **Extensible:** true
- **Submission value:** LBTESTCD_LB_CHEM

### Value Set Item Properties
- **Code / Submission Value:** CREAT
- **Decode / Synonym:** Creatinine Measurement
- **Description:**
  A measurement of the creatinine in a biological specimen.
- **Preferred Term:** Creatinine Measurement
- **Global Unique ID (C Code):** C65047
- **OID:** CLI.6.C65047_C_LB_CHEM:9285f042-aa68-4914-8eec-4c6e5e90aab2.C65047
- **Required:** false

### DataLabs
- **Data Entry Prefix:**

### CDASH
- **Display Text:** Creatinine
OVERLAY WAKE UP

DATA STANDARD FORMS & FIELDS

STUDY INSTANCE METADATA (SIM)

INFORMATION LEVEL:

1. MDR CORE INFORMATION
2. STANDARD OVERLAY
3. EDC SPECIFIC OVERLAY
STUDY INSTANCE MEATADATA (SIM)

- NAME
- DATA TYPE
- LENGTH
- DISPLAY TEXT

FIXED IN THE MDR
DATABASE STRUCTURE

Item Properties
Name: COMPDATE
Oid: 4136e0d2-2491-4449-9562-da31b75e102c:a790347e-9fb8-45ad-a0c0-47f15162f6ea5
Data Type: date
Description: Completion Date (This item is intended for EDC purpose only)
Question: Completed Date:
Length: 11
Mandatory: false
Required: false
OVERLAY WAKE UP

STANDARD OVERLAY = CDASH

- DOMAIN
- DATA COLLECTION SCENARIO
- CDASH DEFINITION
- SAS LABEL
- PXL TEXT (JUSTIFICATION)

CDASH INFORMATION
NOT RELATED TO A SPECIFIC EDC-SYSTEM
OVERLAY WAKE UP

EDC SPECIFIC OVERLAYS

- Control Type
- Form/Field Identifier
- Double Data Entry
- Ident level
- Headertext
- Helpertext / Links
- Default Value
- Is Required?
- Field Edit Checks
- Security Settings (e.g. Blinded-Unblinded)
OVERLAY DRESS UP

 CORE

 CDASH

 RAVE

 Core

 Standard CDASH

 EDC System
<table>
<thead>
<tr>
<th>CORE</th>
<th>NAME:</th>
<th>AETERM</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDASH</td>
<td>SAS Label:</td>
<td>Adverse Event</td>
</tr>
<tr>
<td></td>
<td>CRF Completion:</td>
<td>Record only one dia...</td>
</tr>
<tr>
<td>RAVE</td>
<td>FieldOID:</td>
<td>AETERMCOD</td>
</tr>
<tr>
<td></td>
<td>DraftFieldName:</td>
<td>AETERM</td>
</tr>
<tr>
<td></td>
<td>Helpertext:</td>
<td>Adverse Event</td>
</tr>
<tr>
<td></td>
<td>SAS Label:</td>
<td>Record only one dia...</td>
</tr>
</tbody>
</table>

EDC TOOLBOX

RESULT

<p>| FieldOID: | AETERM |
| VariableOID: | AETERM |
| DraftFieldName: | AETERMCOD |
| SAS Label: | Adverse Event |
| Helpertext: | Record only one dia... |</p>
<table>
<thead>
<tr>
<th>Item Group</th>
<th>Item</th>
<th>Repeating</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORE</td>
<td>Item</td>
<td>= true</td>
</tr>
<tr>
<td>CDASH</td>
<td>Item</td>
<td>= HEM</td>
</tr>
<tr>
<td>RAVE</td>
<td>FieldOID</td>
<td>IsLogLine:</td>
</tr>
<tr>
<td>RESULT</td>
<td>FieldOID</td>
<td>LBTESTCD_HEM</td>
</tr>
<tr>
<td></td>
<td>IsLogLine</td>
<td>true</td>
</tr>
</tbody>
</table>
CHECK OUTFIT

PAREXEL® CLINICAL MDR

Using WEB-API

EDC TOOLBOX
- Combine Overlay Information
- Apply all the Business Rules
- Check the Study Build
- Provide Target output format

SANITY CHECKS
- Dataformat and Datatype doesn’t match
- Form not assigned to any visit
- Controltype doesn’t fit
- SAS Label exceed 40char
- Fieldlength doesn’t match ValueSet Items
- Same Fieldname but different Datatype
- Field hidden without any default value
EDC TOOLBOX

- Combine Overlay Information
- Apply all the Business Rules
- Check the Study Build
- Provide Target output format

Using WEB-API

PAREXEL® CLINICAL MDR

RAVE - ALS
RAVE - WEB SERVICE
DATALABS SDR/DVS
DATALABS XML
INFORM ODM
INFORM CSML
PAREXEL DATALAKE
THANK YOU

again