Implementing a Meta data Repository (MDR) using Functional Service Provider (FSP)
How does it work?

Carla Santillan, Chiltern International bvba, Belgium
Agenda

- Introduction
- Familiarization
- Transition of internal knowledge to the FSP
- Impact and scope of each change
- Governance
- Use of JIRA® software
- First study, theory versus reality
- What is next?
- Conclusions
- Questions
Introduction
Familiarization
Transition of internal knowledge to the FSP
Impact and scope of each change
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The sponsor developed an SDTM+ library, a centralized metadata model used since July 2015 and includes:
- SDTM+ metadata + user guide
- SDTM+ Standard CRF Library + user guide

- The SDTM+ metadata is administered within an MDR tool

Sponsor approach:
- Trial conduct and the creation of CDISC SDTM+ datasets are outsourced
- Maintenance and governance of the data standards is kept in-house
Introduction

Chiltern was selected as FSP to **maintain** the SDTM+ standard library and **review** key SDTM+ deliverables
- Annotated CRF
- Trial Design Domains (TDD)
- Metadata structure

Team: Clinical Programmers with SDTM experience
- MDR tool
- Sponsor SDTM+ library (what the ‘+’ was)

The implementation of MDR tool added new processes and modified existing ones
- Governance had to be defined for the tool users and reviewers

Tasks specific flow charts were created and implemented in JIRA
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Familiarization

- MDR tool and SDTM+ sponsor philosophy
- Series of trainings were scheduled by the sponsor:
  1. Sponsor SDTM+ library
     - SDTM+ metadata library (with SDTM+ user and administrator guide)
Familiarization

- **SDTM+ library:**

<table>
<thead>
<tr>
<th>Domain</th>
<th>Description</th>
<th>DB Requirement</th>
<th>Tabular Requirement</th>
<th>Custody</th>
<th>Class</th>
<th>Structure</th>
<th>Purpose</th>
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<tr>
<td>AE</td>
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<td>Mandatory</td>
<td>FDA Expected</td>
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<td>Events</td>
<td>One record per adverse event per subject</td>
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<td>Events</td>
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<td>No</td>
<td>Events</td>
<td>One record per medical history event per subject</td>
<td>Tabulation STUDY ID,U</td>
<td></td>
</tr>
</tbody>
</table>

- The “+” illustrates the sponsor vision of the CDISC SDTM
Familiarization

- MDR tool and SDTM+ sponsor philosophy
- Series of trainings were scheduled by the sponsor:
  1. Sponsor SDTM+ library
     - SDTM+ metadata library (with SDTM+ user and administrator guide)
     - Standard CRF library (with CRF library user guide)
- **CRF library:**

<table>
<thead>
<tr>
<th>[DM]</th>
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<th>Demography</th>
<th>SITEID</th>
<th>SUBJID</th>
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<tr>
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<td>Visit Name</td>
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<table>
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<table>
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<tr>
<td>Female</td>
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<table>
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<tr>
<td>Hispanic/Latino</td>
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</tr>
<tr>
<td>Not Hispanic/Latino</td>
<td></td>
</tr>
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</table>

Familiarization
Familiarization

● MDR tool and SDTM+ sponsor philosophy
● Series of trainings were scheduled by the sponsor:
  1. Sponsor SDTM+ library
     • SDTM+ metadata library (with SDTM+ user and administrator guide)
     • Standard CRF library (with CRF library user guide)
  2. Introduction to the MDR tool
  3. SDTM+ MDR tool process workshop
Familiarization

- MDR tool:
Familiarization

● MDR tool and SDTM+ sponsor philosophy

● Series of trainings were scheduled by the sponsor:
  1. Sponsor SDTM+ library
     • SDTM+ metadata library (with SDTM+ user and administrator guide)
     • Standard CRF library (with CRF library user guide)
  2. Introduction to the MDR tool
  3. SDTM+ MDR tool process workshop

● Training and a pilot practice were organised by Chiltern
  • JIRA® pilot practice was in place for a period of approximately 4 weeks
Familiarization

- **JIRA functionality:**

  **SDTM+ library Portal**

  **Introduction:**
  Welcome to the SDTM+ standard library maintenance and deliverable review task management system.
  Please use CREATE to create SDTM+ deliverable tasks or maintenance requests. Select the appropriate Project, task type and complete the required fields.
  Please provide as much information as you can. For further information please contact your Standards Library Team.

  **Favourite filters:**
  - Completed Tasks
  - Failed Tasks
  - Ready for Review
  - Unassigned Tasks
  - With issue for review
  - Work in Progress

  **Create filter** | **Manage filters**

  **Issues Calendar: Standards library requests**

  **Two Dimensional Filter Statistics: SDTM review tasks**

<table>
<thead>
<tr>
<th>Issue Type</th>
<th>Emma</th>
<th>Jason</th>
<th>Unassigned</th>
<th>T.</th>
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</thead>
<tbody>
<tr>
<td>eCRF review</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
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<tr>
<td>mock up CRF review</td>
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<td>2</td>
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<tr>
<td>SDTM+ database specification review</td>
<td>0</td>
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<td>2</td>
<td>2</td>
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<tr>
<td>Trial Design Dataset review</td>
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<td>2</td>
</tr>
</tbody>
</table>

  **Total Unique Issues:**
  - 1
  - 1
  - 7
  - 9

  Grouped by Assignee
  Showing 4 of 4 statistics.

  **Two Dimensional Filter Statistics: Filter for library tasks**

<table>
<thead>
<tr>
<th>Status</th>
<th>eCRF review</th>
<th>Maintain user guide</th>
<th>mock up CRF review</th>
<th>SDTM+ object</th>
<th>New standard CRF page</th>
<th>Run QC modal checks</th>
<th>SDTM+ database specification review</th>
<th>Trial Design Dataset review</th>
<th>Update to CRF</th>
<th>Up to Exp Max</th>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Agenda

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- Familiarization
- **Transition of internal knowledge to the FSP**
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Transition of internal knowledge to the FSP

- Two months working hand in hand with the sponsor SDTM Specialist
  
  User (CDPM)                      SDTM Specialist                      Maintainers Chiltern Library Analysts (CLA)
  
- CLAs could focus on specific discussions, regarding the SDTM+ metadata, the CRF library or TDD and the use of the MDR tool
  
- The sponsor gained trust and CLA’s gained self-confidence, which had a direct positive impact on efficiency
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Impact and scope of each change

- The SDTM+ library elements:
  - SDTM+ Metadata
  - SDTM+ Standard CRF Library
The SDTM+ Metadata in MDR tool: follows the philosophy of define.xml Version 2.0 and is broken down into the following sections:

- Dataset Level
- Variable Level
- Controlled Terminology
- Value Level Metadata
- Computational Algorithm
- External Dictionary
- Standard Unit-Conversion Factors
Impact and scope of each change
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Governance

- First high level Study deliverable Review workflow

Diagram showing the workflow with tasks such as:
- Submit Review Task
- Submit Library Update Task
- CDFM creates mockup to CSD
- CDFM discusses new objects with Standards
- CDFM requests new objects via JIRA
- CDFM updates the mockup with new objects/comments from Stfs
- CDFM submits mockup to review
- CDA reviews the mockup
- CDA approves the mockup
- CDFM creates the db structure in XDMR
- CDFM loads the study data
- CDFM discusses any issues with Standards
- CDA approves the db structure in XDMR
- CDA builds out the model
- CDA reviews the DB specs (includes UCAP)
- CDFM submits db structure and design datasets for review
- CDA approves the db specs
- Final review
Governance

- One standard workflow for Mock up CRF review tasks
Governance

- CLAs tasks general flow chart
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Use of JIRA® software

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Create filter  Manage filters

Issues Calendar: Standards library requests

<table>
<thead>
<tr>
<th>Standards library requests (Due Date)</th>
<th>July 2016</th>
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<tbody>
<tr>
<td>Sun</td>
<td>Mon</td>
</tr>
<tr>
<td>26</td>
<td>27</td>
</tr>
<tr>
<td>Issues: 1</td>
<td>3</td>
</tr>
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Two Dimensional Filter Statistics: SDTM review tasks

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<tr>
<td>Trial Design Dataset review</td>
<td>1</td>
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<td>1</td>
<td>2</td>
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<tr>
<td>Total Unique Issues</td>
<td>1</td>
<td>1</td>
<td>7</td>
<td>9</td>
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</tbody>
</table>

Grouped by: Assignee
Showing 4 of 4 statistics.

Two Dimensional Filter Statistics: Filter for library tasks

<table>
<thead>
<tr>
<th>Status</th>
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</table>
Use of JIRA® software

Once ready to submit
Click start progress

Click edit to make changes
Once submitted no edits can be made

Add comments at any time

Include any attachments

Once submitted no edits can be made

CLA assigned to the task

Click here to watch a task

Task reference number
Use of JIRA® software

- Issues need to be **transitioned** from status to status
- Statuses are classified as To Do (**blue**), In Progress(**orange/yellow**), Done(**green**)
- Click on Transition buttons (in the task detail view) to move tasks through the workflow
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In a period of ten months we have worked on more than 350 JIRA® tickets related to changes to the SDTM+ and CRF libraries, with each ticket involving one or more change requests. We implemented 25 updates to user guides, and reviewed 14 studies.

Average study requires from 1 to 15 changes (cases with >50 changes)

Example report from JIRA®, filtered on one study number
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What is next?

- We are currently working on the updates needed to the SDTM+ library due to the latest version of CDISC controlled Terminology

- Can we relate the elements from the two libraries CRF and SDTM+ automatically? And from that can we then somehow automate the QC of study specific CRFs?
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Conclusions

- Providing valid standards and clear user guides for the sponsor is a need

- Working with an MDR tool keeps things aligned, the study cannot be conducted if it does not follow the SDTM+ metadata

- The use of FSP helps to test what is not working properly from an outsider point of view, as user, developer and admin.

- We value the use of JIRA an intuitive and easy to use tracking tool, it can be customised to specific tasks and roles. Allows to evaluate the amount of work done

- We understand the impact of our decisions, we try to automate and ensure consistency in each task, and keep ourselves constantly looking for possible improvements.
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