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Taming Rave: How to control data collection standards?

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Agenda

- Project Initiation
- How to:
  - Organize metadata
  - Structure metadata
  - Manage metadata
  - Check metadata
  - Present metadata
  - Map metadata
  - Set up environment
- Insights, Best Practices and Conclusions

Project initiation

- Project participants:
  - Mid-size pharmaceutical company
  - Vendor team (“virtual project team”)
- Project goals:
  - Implement metadata repository (MDR)
  - Manage data collection and SDTM metadata
  - Support global, project and study levels

How to organize standards?

- Configured hierarchy:
  - Levels: Global, project, study (as planned)
  - Studies are hierarchically managed in projects
  - Data elements and tables for most metadata
- Configured models:
  - Operational
    - Rave
    - External
  - "Post-processed"
  - SDTM (structure suitable for ADaM and SDTM+)
  - Controlled terminology

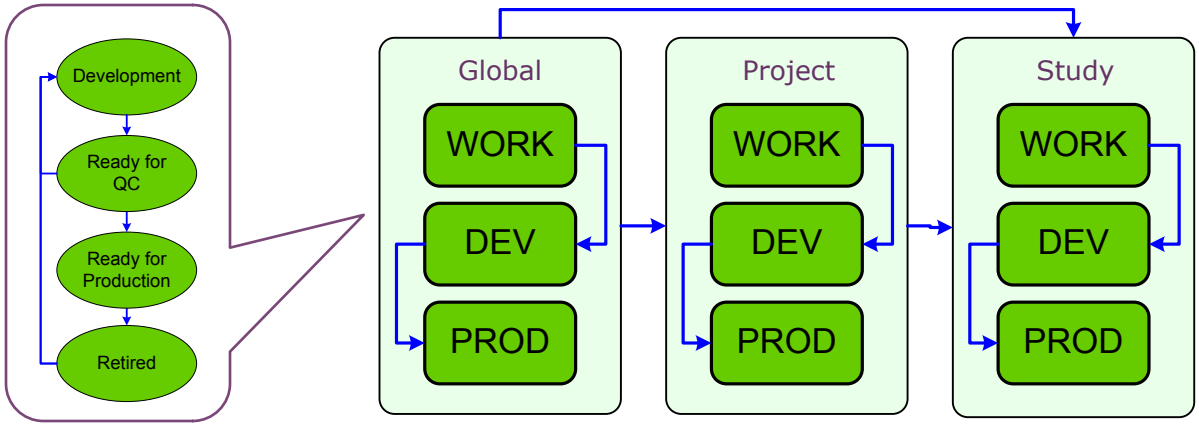
How to structure standards? ODM vs. ALS

- ODM:
  - Popular
  - Machine readable
  - Complex structure
  - Difficult to introduce at partners
- ALS:
  - Easy to understand
  - Easy to modify
  - Error-prone - validation checks required

The winner is ALS!

How to manage metadata? (1) Workflow

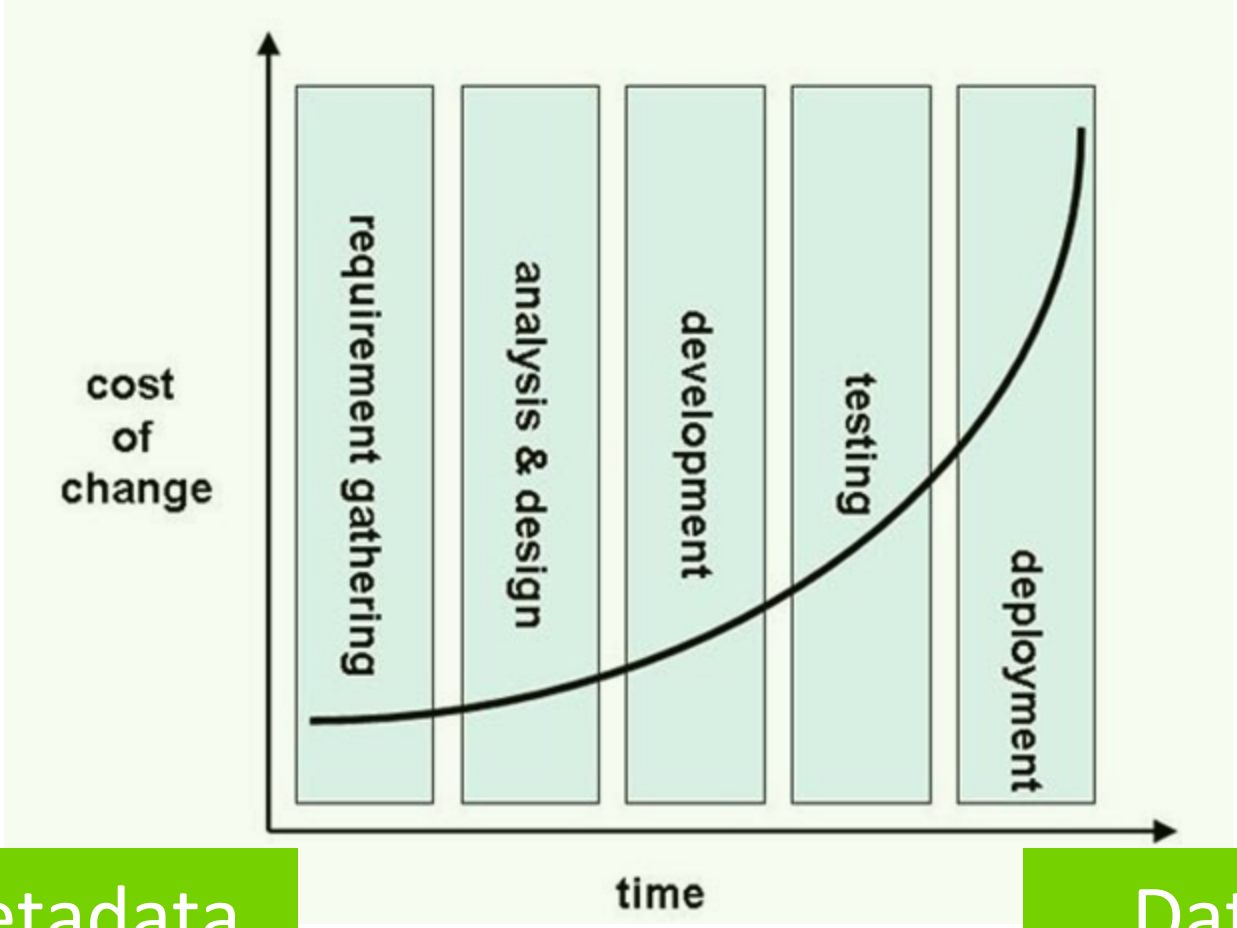
- ISO 11179:
  - Ambiguous (lifecycle mixed with workflow)
- Entimo's Best Practice:
  - Separate work/dev/prod areas
  - Status lifecycles in dev/prod areas



How to manage metadata? (2) Access rights and roles

- Challenges:
  - How many roles are required?
  - Who is allowed to access what in which area?
  - Who is allowed to modify what at what level? (e.g. some global fields are not allowed to be modified in studies)
  - Who does QC?
  - What is QCed – data elements or tables?

Cost of Change Curve



Metadata

Data

How to check metadata? (1) Integrity

- Challenge:
  - How to keep metadata consistent (within one area/level)?
- Solutions:
  - Checks of mandatory variables
  - Key checks
  - Checks of attribute types
  - Cross-table checks (e.g. referenced forms, linked dictionaries, controls and dependencies)
  - Content checks (e.g. FieldOID vs VariableOID)

How to check metadata? (2) Comparisons

- Challenges:
  - Are all critical attributes from Global the same as at lower levels in the MDR?
  - Is delivered study build from the MDR equal to the EDC export (DEV/UAT/PROD)?
  - *Flexibility to support different keys and to exclude variables depending on comparison level required!*
- Solutions:
  - Comparison tool - **major QC tool in the MDR!!!**
  - Rules and keys change based on selected settings:
    - Area parameters (global, project, study levels)
    - Comparison type (e.g. inbound vs. outbound for studies, project to global standards)

How to present metadata? Visualization

- Challenges (“metadata dilemma”):
  - Metadata is useful, but complex
  - How much metadata is needed to make decisions?
- Solutions:
  - Tabular metadata view – metadata centered
  - CRF preview – form centered
  - Error tracking for CRF visualization

How to map standards?

- Challenges:
  - RAVE delivers extracts (not equal to ALS)
  - How to ensure consistency between ALS and extract definitions?
  - Relations are more complex than 1:1
  - Logical vs functional mapping

- Solutions (few examples):
  - Extract structures are generated from ALS
  - Extract metadata are mapped to down-stream data models

How to set up environment?

- Challenges:
  - Hosted externally vs. in-house hosting?
  - How to integrate with the internal world?
- Solution (this project):
  - Hosted
  - Virtualized
  - Shared drives mapped

Project insights

- Complexity of the MDR world and of the processes involved is very high
- “Agile” approach has two coin sides
- Process definition takes longer than usually anticipated

- Iterations are necessary (revision of process parts and process relations)
- Stable, motivated team which represents all processes needed

Best practices

- Plan maturation time
- Plan multiple review workshops / iterations
- Introduce automation, e.g.:
  - Extract metadata generated from ALS
  - Comparison of all study build parts at once
- Use metadata templates as subsets (e.g. for different study phases)
- *Buy ice cream for project meetings!* ☺

Conclusions

- Project goals (phase 1) have been fulfilled:
  - MDR configured
  - DEV/VAL/PROD environments installed
  - UAT accomplished
  - Productive pilot is going to start
- Metadata QC has crucial importance
- Motivated, diverse team is everything!

End or Beginning?

Thank you for your attention!

Questions?

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