Feedback from break-out groups in OpenStudyBuilder <-> EDC integrations

COSA Workshop 23. April 2024

23rd April 2024

OpenStudyBuilder EDC use cases

EDC ODM.XML based OSB integration

- The Marvin case
- Advantages & Disadvantages of ODM integrations
- Reality vs. Standards vision
- ODM Extensions

EDC integration to native OSB utilising API generated ODM.XML

- The Oracle Clinical One case
- Can use all EDC attributes for the integration, using vendor + OSB extension
  - Enabling a complete integration and automation

OSB integration to native EDC API

- The Veeva EDC case
- Will only use selected ‘core’ EDC attributes for the integration, only using core OSB extensions (limited vendor extension)
  - Enabling a partly integration focusing on the need for data retrieval and down steam usage
  - Will require a vendor specific set-up in the EDC solution, using the EDC controlled library

SWOT- Break-out 1 (ODM.XML)

Strengths

- Opportunity to give feedback to CDISC what's lacking to get standard ODM and API standard (ODM Evolution)
- ODM structure matches majority of study concept (concepts for cycles/events driven like in Oncology)
- Data import due to defined structure autoflow option
- OSB as acceleration tool to get information
- ODM.xml and define.xml linkage
- Migration from EDC to another
- Low memory and storage (easy format)
- Transformable format (stylesheets)
- Extensions to be flexible according requirements (user friendliness, …)

Weaknesses

- ODMv1.3 missing trial design
- Workflow is missing in ODM completely
  - Dynamics, automatic checks, notifications etc.
  - ODM lacking behind EDC (worksflow)
- Formats is too open "what is date"
- File-based approach -> no tracking, what changed, what impact in EDC system (do they stick to standards?)
- Migration ODMv1.3 to 2.0
- XML format issues for read/process by users
- EDC and lab missing adoption for ODM
- Mission to bring standards forward as transfer method is in reality rarely been used (lab & other)
- Extensions are very flexible and differ for vendors

Opportunities

- Standardization of additional attributes
- Workflow standard definitions
- Alignment of ODM and SDTM
- Industry focus on ODM/standardization lead to more ODM adoption

Threats

- CDISC Versioning change like ODMv2 (no item groups), but systems use item groups
- Resource constraints to adopt to ODM.xml
- Vendors developing "vendor standards" instead of using industry

SWOT- Break-out 2 – OSB <-> EDC / API

Strengths

- **Already working as demonstrated by Oracle One / EvidentIQ**
- **Many API endpoints**

Wishes

- **Many endpoints but lack of granularity**
- **Have a generic way of adding more data (budget info, cdash,…) in every part of the OSB**
- **Improve the API endpoint for the CRF with Test data automatically generated for validation**
- **Have a way to integrate an agnostic protocol template**
- **Have some API endpoints to load legacy metadata**
- **OSB Vendor extensions to be integrated into the CDISC Library**
- **Have some system reports providing the % of Standard versus Sponsor metadata**

SWOT Break-out 3 - OSB <-> native EDC API (1)

Strengths

- Hold the core data specification needed for the down-stream data flows – not holding all details needed for data collection
  - Limit dependencies between systems, drive innovation
  - Focus on what is needed to drive clinical data flows
- Possibility to ensure sync between the MDR/SDR OSB versus the EDC system using shared uid reference keys for building blocks to be synced between MDR-EDC, including process for governance & maintenance
- You define the data specification for a study in one place/system, use it in many places, different EDC, ePROs, Labs, etc.
- OSB support a granular level of versioning, enabling sync with the EDC library is important
- Reduced number of API calls to define an EDC collection instrument
- Annotated CRF will come out of the MDR – as this is part of data spec and a submission deliverable
- It will have a manifest 'contract' that will help the machine to understand and read successfully the file for sync

Weaknesses

- CDISC exchange formats is for exchange – including extensions – but some of the needed '25' core attributes are missing, these need to be added as 'CDISC Standard' extensions
- Differences in data types between systems that are not sufficiently captured in the core MDR definitions.
- Another system to learn if we have the general specifications included in MDR (OCM work)

SWOT Break-out 3 - OSB <-> native EDC API (2)

Opportunities

- The core ‘data specification’ to ‘submission delivery specification’
- Improve insight into actual data collection use of data standards, study specific use, a bottom-up approach for standard governance and standard development
- OSB can provide a ‘digitally enabled study specification’ for data collection systems, where the receiving system can utilise the parts they support
- Some OSB definitions simply is ‘structured’ instructions for manual study build in EDC
- ePRO and EDC communication, standards that go across systems setup un StudyBuilder – source agnostic data flows

Threats

- Do not boil the ocean in the MDR, focus on the core integration
- Many MDR solutions have failed due to incomplete coverage for the study set-up in the MDR<->EDC/ePRO – due to the vision of a complete coverage – solution is to limit the integration to the core parts
- How to drive adoption in the organisation to be used across skill areas
- Standards are different across companies
- OSB and EDC systems have different versioning approaches

Actions and next step

The NN OSB <-> Veeva EDC experiments

- Will focus on the NN needs
- Veeva will build API's for their solution, will be made public
- NN will build OSB integration using Veeva APIs
- We will share these for collaboration

Other OSB EDC experiments

- Can focus on anyone's need

CDISC COSA collaboration

- Presentations at:
  - Webinars
  - Videos
  - Workshops
  - Conferences (EU + US)
  - DDF/USDM
  - COSMoS

Follow up

- Newsletter (linkedIn)
- Project homepage (openstudybuilder.com)

OpenStudyBuilder
Feedback & Feature Requests

- Mail: OpenStudyBuilder@gmail.com
- Slack / LinkedIn
- OpenStudyBuilder community meetings (next 6.6.)