Notes from COSA OpenStudyBuilder workshop on EDC Integrations

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 API

- 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

OSB to data collection setup in EDC

Dynamic ODM.XML based

- Generate study level ODM.XML

Standard form reference

- Standard collection form aligned between OSB library and EDC library

Standard form + BC

- Include BC reference in standard form setup

Dynamic + Standard form + BC

- Combine both dynamic build of custom study form by ODM.XML + Standard form reference + BC relationship

Possible OSB Use cases linked to EDC + 360i

✓

Align on standard forms between MDR and EDC solutions

- Create standard forms in OSB or EDC system
- Include vendor specific extensions
- Import/export into/from EDC Library
- Add EDC specific capabilities in library forms
- Maintenance of changes between OSB and EDC libraries

Link standard forms to BCs to drive data flows

- Define standard form including BC reference
- Use standard forms with configuration for a study, including BC configuration
- Use configured BC to auto build source data structure mapping/linkage to target CDASH, SDTM data flows
- BC's links to study data contracts

eCOA links to BCs to drive data flows

- Standards for eCOA, but lack standards for data extracts and data flows
- Link eCOA to BCs and data flows
- Map to sponsor standards

How to apply cross skill areas in study setup and execution (CM focus)

Link standard forms to BCs to drive data flows

- Define standard forms including BC reference driving semantic definition and automation
- Add the semantic layer to the standard form definition linking it to BCs and variable definitions (study data contracts)
- Use standard forms with configuration for a study, including BC configuration
- Use configured BC to auto build source data structure mapping/linkage to target CDASH, SDTM data flows
  - BC's links to study Data Contracts (DC) can be a way to do this
  - So standard forms should have a reference to BCs and DCs, the DC id should then be included in data extracts

- Tooling is important
  - 'Middleware' is the key, this can be standards or OSB specific
- Training is important
  - Develop white papers, articles, videos,
- Standards development is important
  - Create UX framework for applying or developing BCs and use in standard forms
- Adoption is important
  - Link into new 360i and DDF as this will support community adoption

Next steps in OSB-COSA-EDC-360i use case

- "OSB-BC Standard Form" work group as part of 360i

- Demonstrate BC in action to show the value

- Get many stakeholders to take part in:

  - Input

  - Evaluations

  - Contribute

  - Adopt

- How can we develop concepts / prototypes so they can be used soon!

  - To get early return on investment…

  - But this is a big transformational change, difficult to get fast return…

SWOT: Link standard forms to BCs to drive data flows

Strengths

- Faster study build
- Easier to be in compliance with submission data requirements
- Reduced human errors in manual work processes

Weaknesses

- Variability in vendor acceptance and compatibility (leading to custom integrations)

Opportunities

- Link to BC must be shown as an annotation
  - This can be extended to annotation in any related standard (CDASH, SDTM, ADaM)
- Indicate clearly in standard forms
  - What is locked in the standard form
  - What can be disabled, enables, configured
  - What is selected options to CT (so you can change selections, but not change naming)

Threats

- Lack of adherence to standards in standard forms

- Vendor resistance

- Slow adoption