eSource to SDTM
Trade-offs and Pay-offs

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Overview

- Introduction
- Structural & Technical Trade-offs
- Structural & Technical Payoffs
- Two (e)Source Systems, One SDTM Database: a Case Study
- Conclusions
Introduction: What Is eSource?

- Electronic Data Capture
- Site Automation
- Digital Data Interface
Changes In The Data Flow

Paper → eCRF → eSource

Data Flow Diagram:
- **eSource** → transcription → eCRF
- SDV
- DM
  - transcription (double data entry) → CDMS
Technical & Structural Trade-offs

- To what extent should we change the data flows?
- Are individual tasks performed by the right people?
- Are our processes efficient and error-proof?
- How will we ensure SDTM compliance?
Reaping The Payoffs from The eSource Tradeoffs

- Access information in real-time
  - Fast, efficient and error-proof data flow
  - No SDV necessary

- Dedicated on site eSource design team
  - Much interaction with DM
  - Early SDTM awareness: forms, code list values,...
  - DM involved in review of eSource event/forms

- Integration in existing SDTM-based workflow
  - Time-proven DM tools reusable
The Standard SGS SDTM Workflow

Who?  What?  Where?

Site(s):
- Assessments eSource/ eCRF / paper source to eCRF

Local lab(s):
- Local Safety Lab results

Central lab(s):
- Blinded lab data PK/PD

Monitor, Data Manager:
- Protocol deviations entered in data entry application

Source database

Coding Tool

Lab database

Blinded Lab database

Secure data office database

DV database

Data Loader

Electronic Data conversion

SDTM database

SETUP QC LIVE SDTM SDTM SDTM

 WHEN YOU NEED TO BE SURE

SGS
The SGS SDTM Work Flow With eSource Systems

Who ?

Site(s): Local lab(s):
Assessments eSource/ eCRF / paper source to eCRF + Local Safety Lab results

Central lab(s):
Blinded lab data PK/PD

Monitor, Data Manager:
Protocol deviations entered in data entry application

What ?

Source database + Lab Database

Blinded Lab database

DV database

Where ?

Coding Tool

Data Loader

Electronic Data conversion

SDTM database

SETUP QC LIVE SDTM SDTM SDTM

Electronic Data conversion

WHEN YOU NEED TO BE SURE
Two (e)Source Systems, One SDTM: A Case Study

Why two (e)Source systems for a single study

- Study Design – SAD (Healthy Volunteers) & MAD (Subjects)
- Time Frame – Time between the conduct of SAD & MAD parts
- Sites – SAD (Single) & MAD (Multiple)
- Analysis – SAD results influencing MAD conduct
- Costs – Set up, Hosting & Transcribing costs
Two (e)Source Systems, One SDTM : A Case Study
Scenario A

Who?

- SGS CPU, Belgium:
  - Assessments eSource
  - eSource database

- Multiple sites:
  - Assessments paper source
  - Data transcription
  - Subjects - MAD
  - Data entry application/database

What?

- Electronic Data conversion
- Healthy volunteers - SAD

- Data conversion
- MAD SDTM database

Where?

- SAD SDTM database
- Merged SDTM database

WHEN YOU NEED TO BE SURE
Two (e)Source Systems, One SDTM: A Case Study
Scenario B


SGS CPU, Belgium:
- Assessments eSource
  - eSource database
  - Data transcription
    - Healthy volunteers - SAD

Multiple Sites:
- Assessments paper source
  - Data transcription
    - Subjects - MAD

Electronic Data conversion
Merged database

EDC / CRF Merged database

Merged SDTM database

WHEN YOU NEED TO BE SURE
Two (e)Source Systems, One SDTM: A Case Study

Scenario C

Who?  

SGS CPU, Belgium:
- Assessments eSource
- eSource database

Multiple Sites:
- Assessments paper source
- Data transcription
- Subjects - MAD
- EDC / CRF database

What?  

Electronic Data conversion
- Healthy volunteers - SAD
- SAD SDTM database

Electronic Data conversion
- MAD SDTM database

Where?  

Merged SDTM database

When you need to be sure

SGS
Conclusions

**Trade-offs**
- Task assignment
- Task execution
- Trial management
- Collaboration and Cooperation between departments

**Pay-offs**
- Increase in speed & efficiency of tasks
- Access to real time data
- High quality deliverables due to accurate and consistent data
- Ease of integration into the existing work flow
- Ability to process multi-source trials
eSource To SDTM: Trade-offs & Pay-offs

- It is not the end of the road
  - New generation eSource systems
Questions ?
Do meet us at the SGS booth 11