

eSource to SDTM

Trade-offs and Pay-offs

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WHEN YOU NEED TO BE SURE



Overview

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

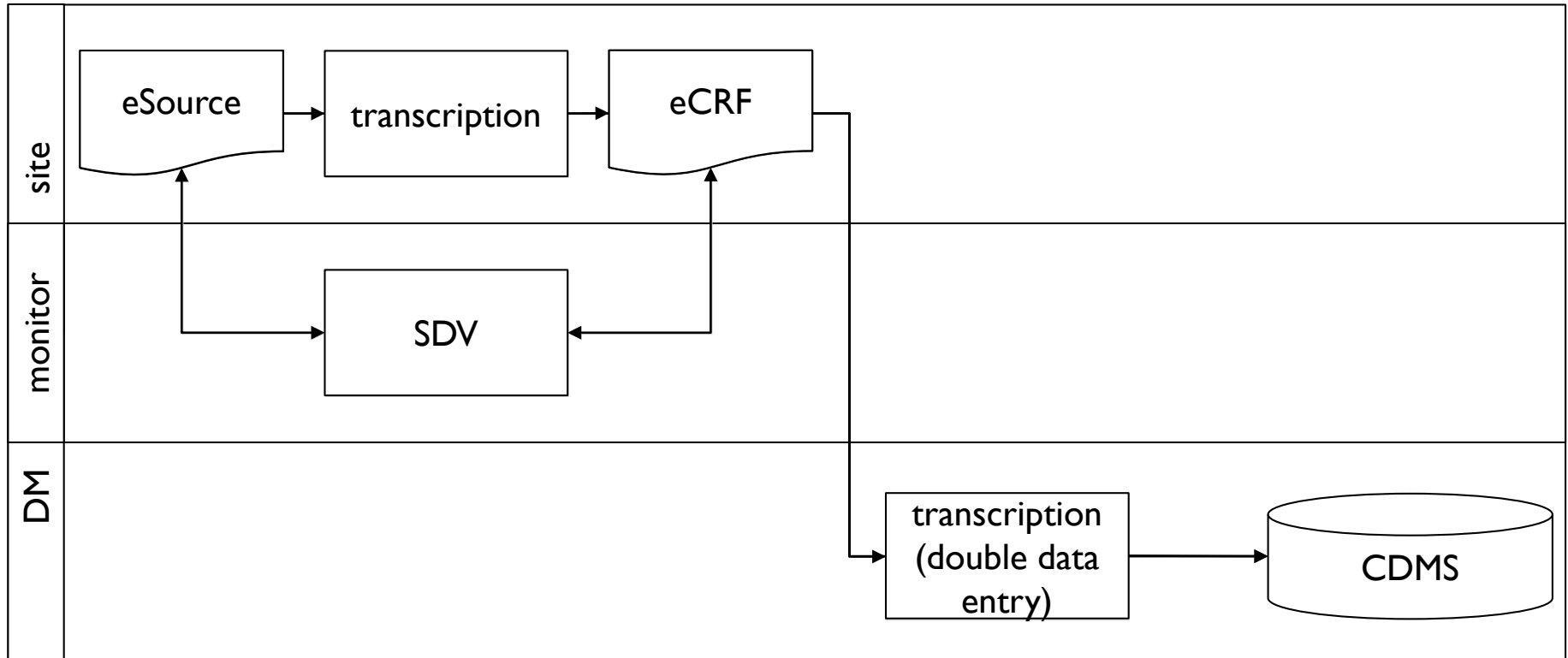


Introduction: What Is eSource?

- Electronic Data Capture
- Site Automation
- Digital Data Interface



Changes In The Data Flow

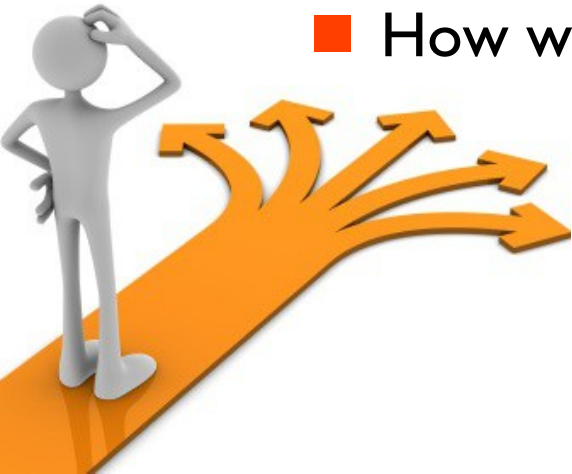


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Technical & Structural Trade-offs

- 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



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The Standard SGS SDTM Workflow

Who ?

What ?

Where ?

Site(s):

Assessments eSource/ eCRF /
paper source to eCRF

Local lab(s):

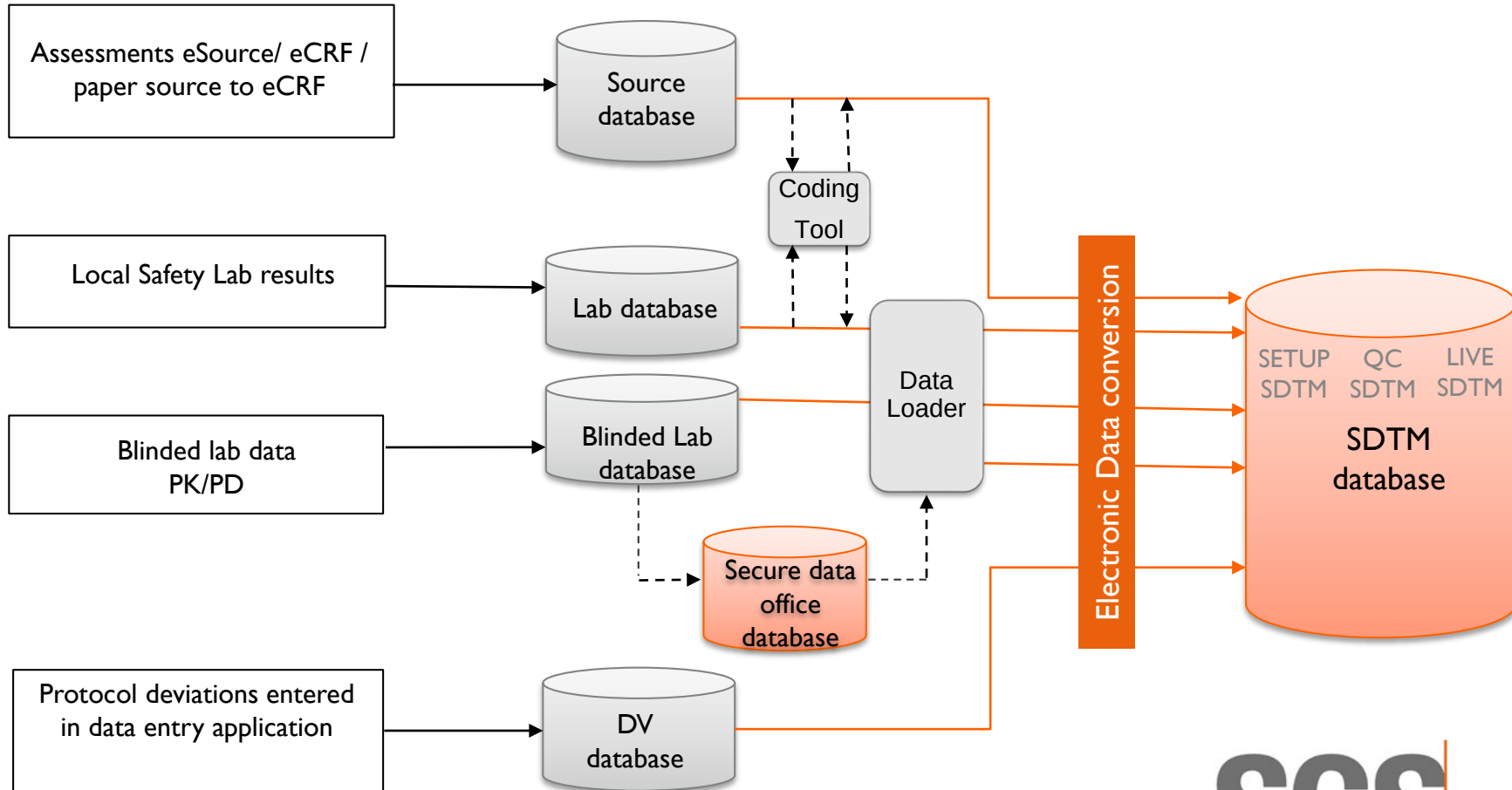
Local Safety Lab results

Central lab(s):

Blinded lab data
PK/PD

**Monitor,
Data
Manager:**

Protocol deviations entered
in data entry application



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The SGS SDTM Work Flow With eSource Systems

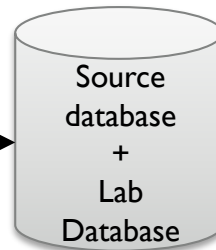
Who ?

What ?

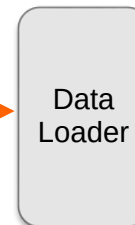
Where ?

**Site(s):
Local lab(s):**

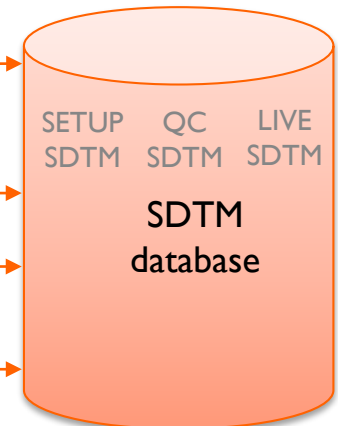
Assessments eSource/ eCRF /
paper source to eCRF
+
Local Safety Lab results



Coding
Tool



Electronic Data conversion



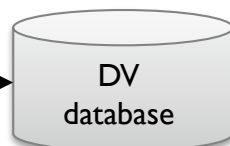
Central lab(s):

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**Monitor,
Data
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Protocol deviations entered
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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

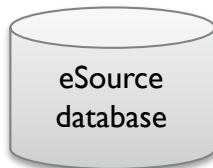
Who ?

What ?

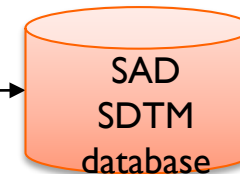
Where ?

**SGS CPU,
Belgium:**

Assessments
eSource



Electronic Data conversion
Healthy volunteers - SAD



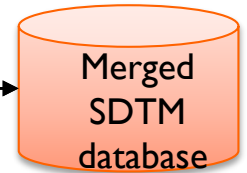
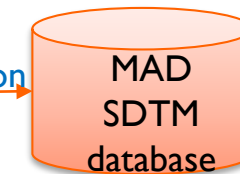
Multiple sites:

Assessments
paper source

Data transcription
Subjects - MAD



Electronic
Data conversion
MAD



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Two (e)Source Systems, One SDTM: A Case Study

Scenario B

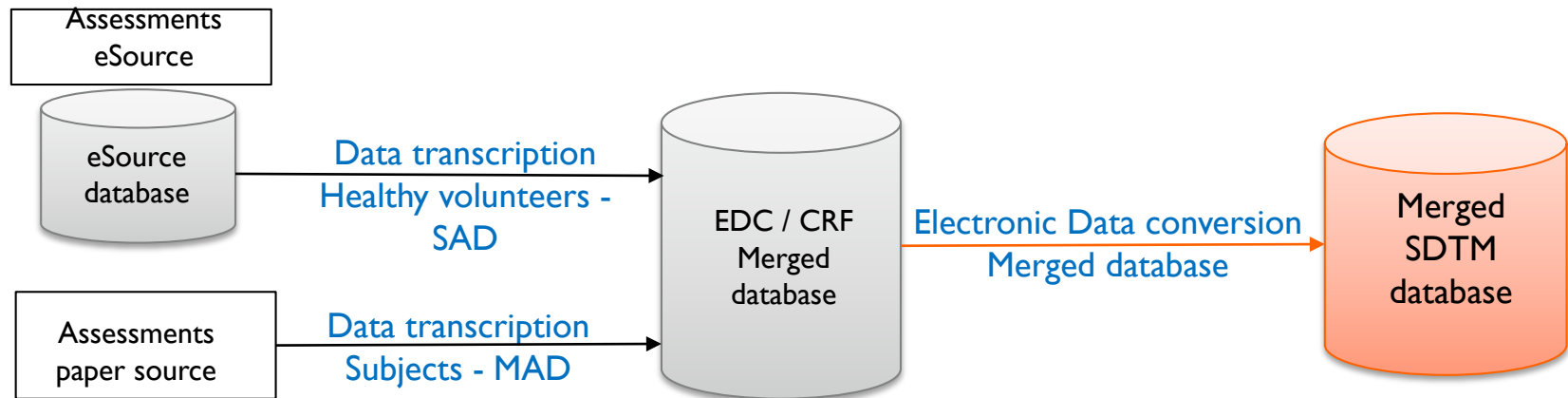
Who ?

What ?

Where ?

**SGS CPU,
Belgium:**

Multiple Sites:



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Two (e)Source Systems, One SDTM : A Case Study Scenario C

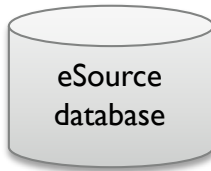
Who ?

What ?

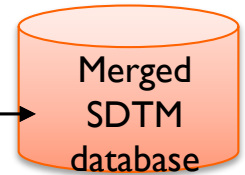
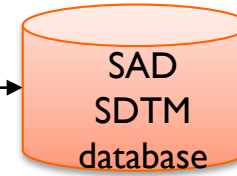
Where ?

**SGS CPU,
Belgium:**

Assessments
eSource



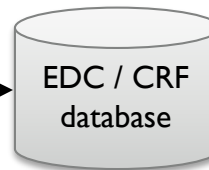
Electronic Data conversion
Healthy volunteers - SAD



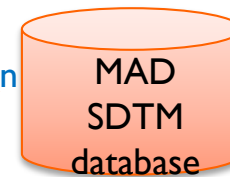
Multiple Sites:

Assessments
paper source

Data transcription
Subjects - MAD



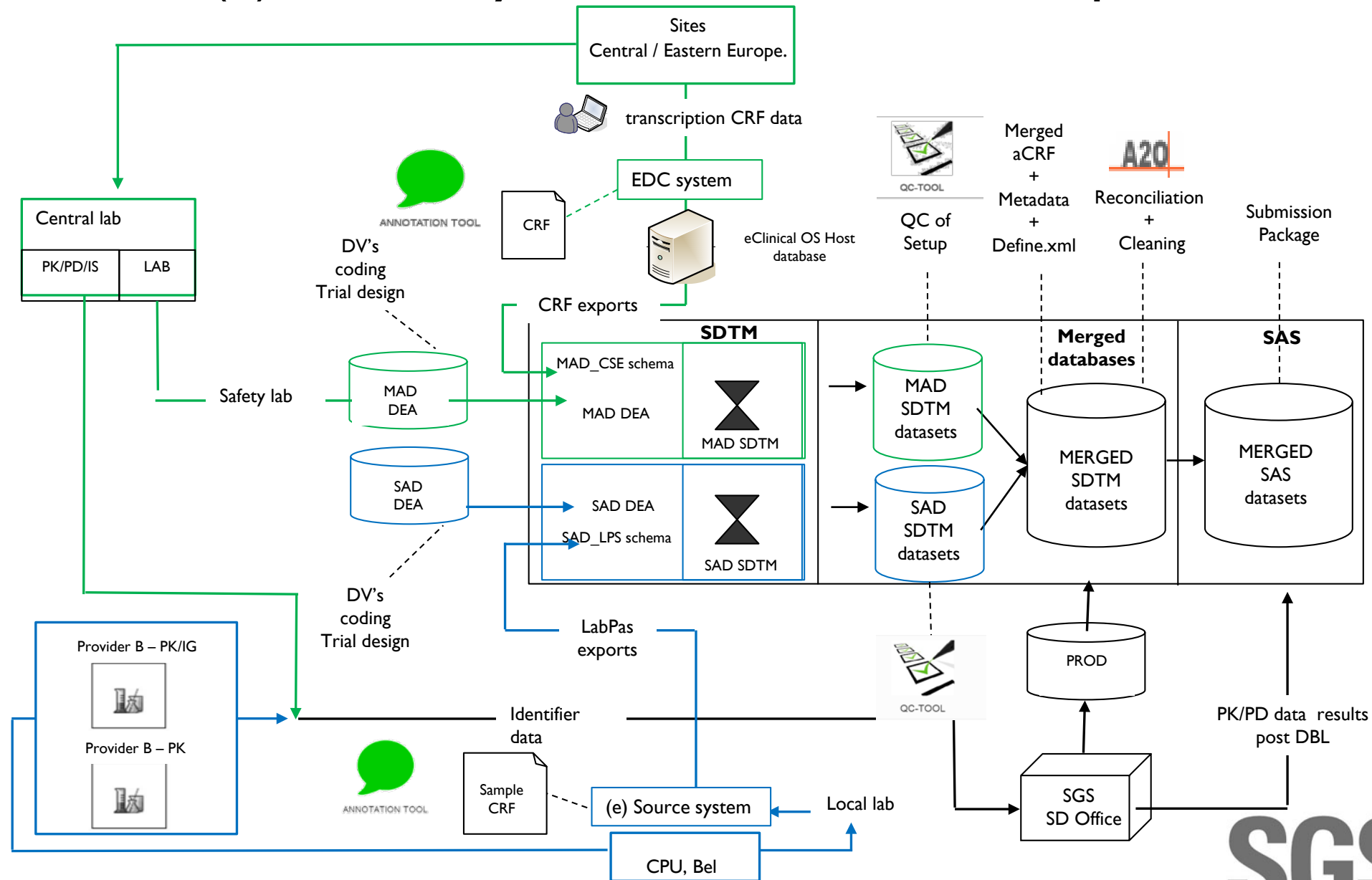
Electronic
Data conversion
MAD



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Two (e)Source Systems, One SDTM : Implementation



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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 ?





BROAD CLINICAL RESEARCH SOLUTIONS



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