CDISC

English Speaking User Group

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The ‘Metadatacentric’ approach – End to End demonstration and discussion

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SUPPORTED BY PhUSE

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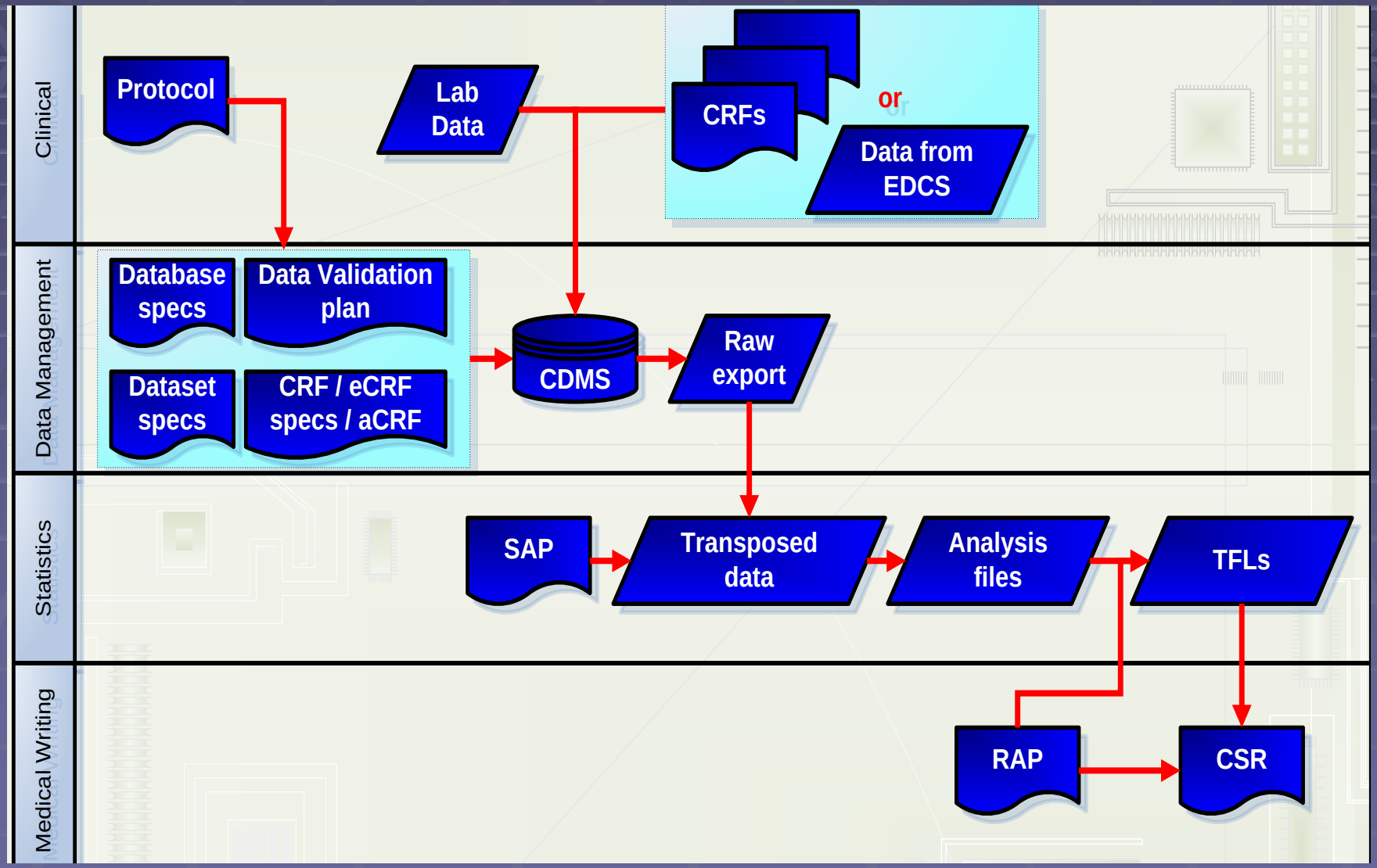
Special Thanks….

To SAS for hosting this event

Design/Setup			
	09:00	Jason Housley, Shire and E3C	Welcome and Context for the day
	09:15	Philippe Verplancke, XClinical and E3C	Overview of CDISC standards and use cases along the E2E data management process
	09:30	David Gemzik, Medidata Solutions	Structured Protocol writing and Trial design (PRM and TDM)
	09:50	Mark Wheeldon, Formedix	Study Startup: Database and CRF Design using ODM
			Study Startup: Dataset Design using Define.xml
	10:20	**Coffee Break**	
Execution			
	10:40	Philippe Verplancke, XClinical and E3C Mark Wheeldon, Formedix	Auto configuration of a CDMS. Loading CRF and Lab Data into CDMS and Sponsor Database using LAB and ODM. Moving CRF data from ODM into SDTM datasets (mapping)
	11:10	SAS	Importing CRF data and metadata into SAS
Analysis and Submission			
	11:30	SAS	Creation and Validation of SDTM datasets and checking against the define.xml. Producing ADaM Datasets from SDTM datasets, Analysis, Submission and Review
	12:00	**Lunch**	
	13:00	ALL	Group Discussion
	15:00	**Coffee Break**	
	15:15	Simon Bishop, GSK and CMDR	CDISC Metadata Data Repository (CMDR) - The vision moving forward
	15:45	Jason Housley, Shire and E3C	Meeting close out

The traditional process



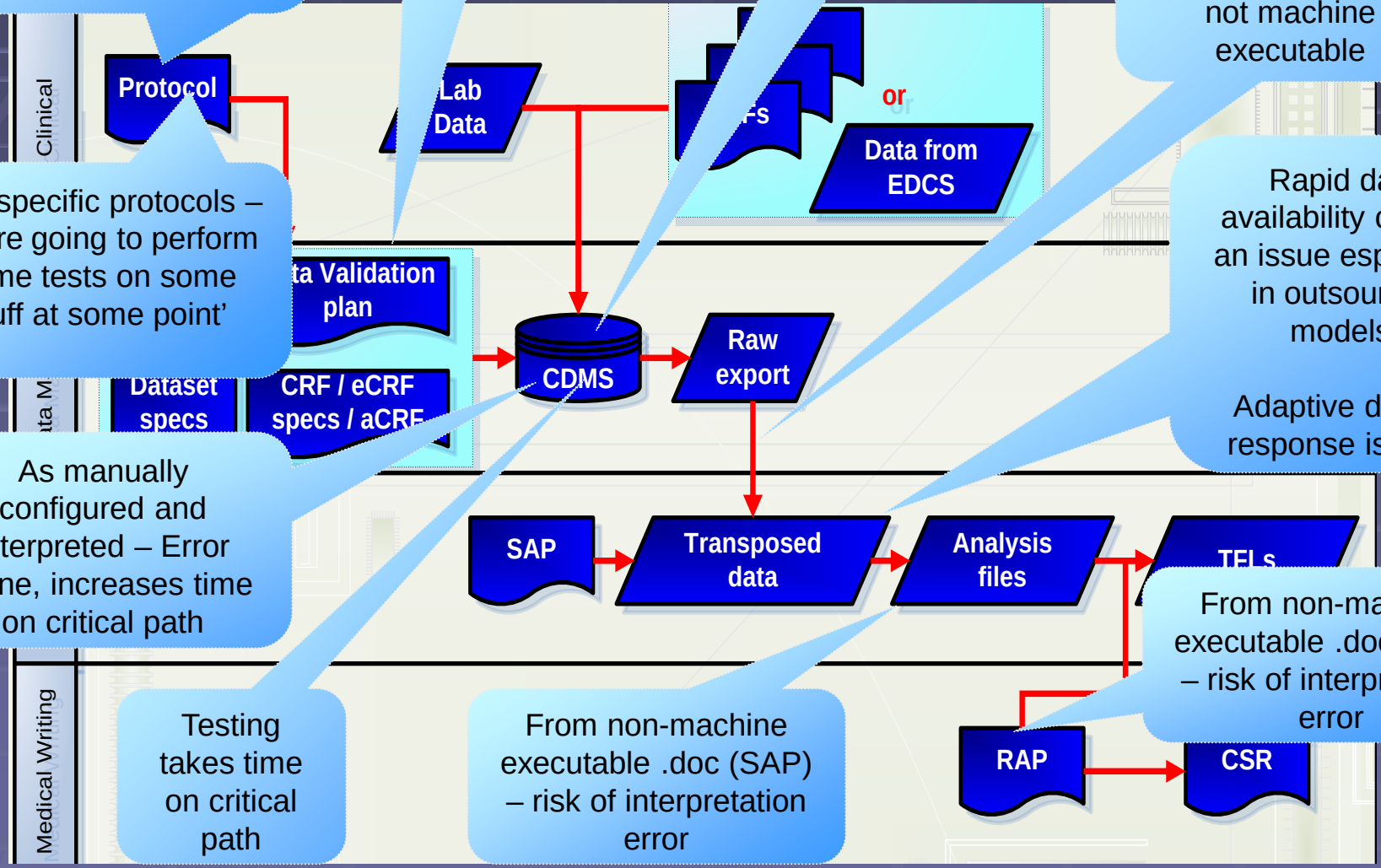
ap / Challenges

Protocols are manually generated – inconsistent. Protocol templates do not dovetail with end in mind (SDTM terminology for example)

Manually generated thus error prone / takes time on critical path

Interpretation / transcription errors in configuration a risk

Transposition specs manually written, non-standard and not machine executable



Non specific protocols – 'We're going to perform some tests on some stuff at some point'

Rapid data availability can be an issue especially in outsourced models.

Adaptive design response issues.

As manually configured and interpreted – Error prone, increases time on critical path

From non-machine executable .doc (RAP) – risk of interpretation error

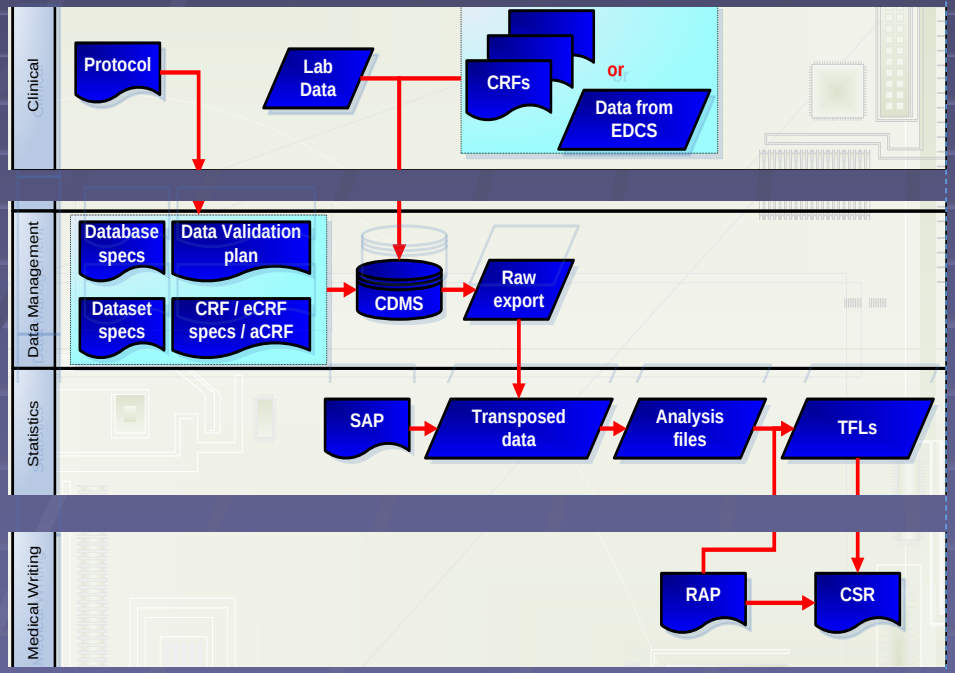
Testing takes time on critical path

From non-machine executable .doc (SAP) – risk of interpretation error

The outsourcing conundrum

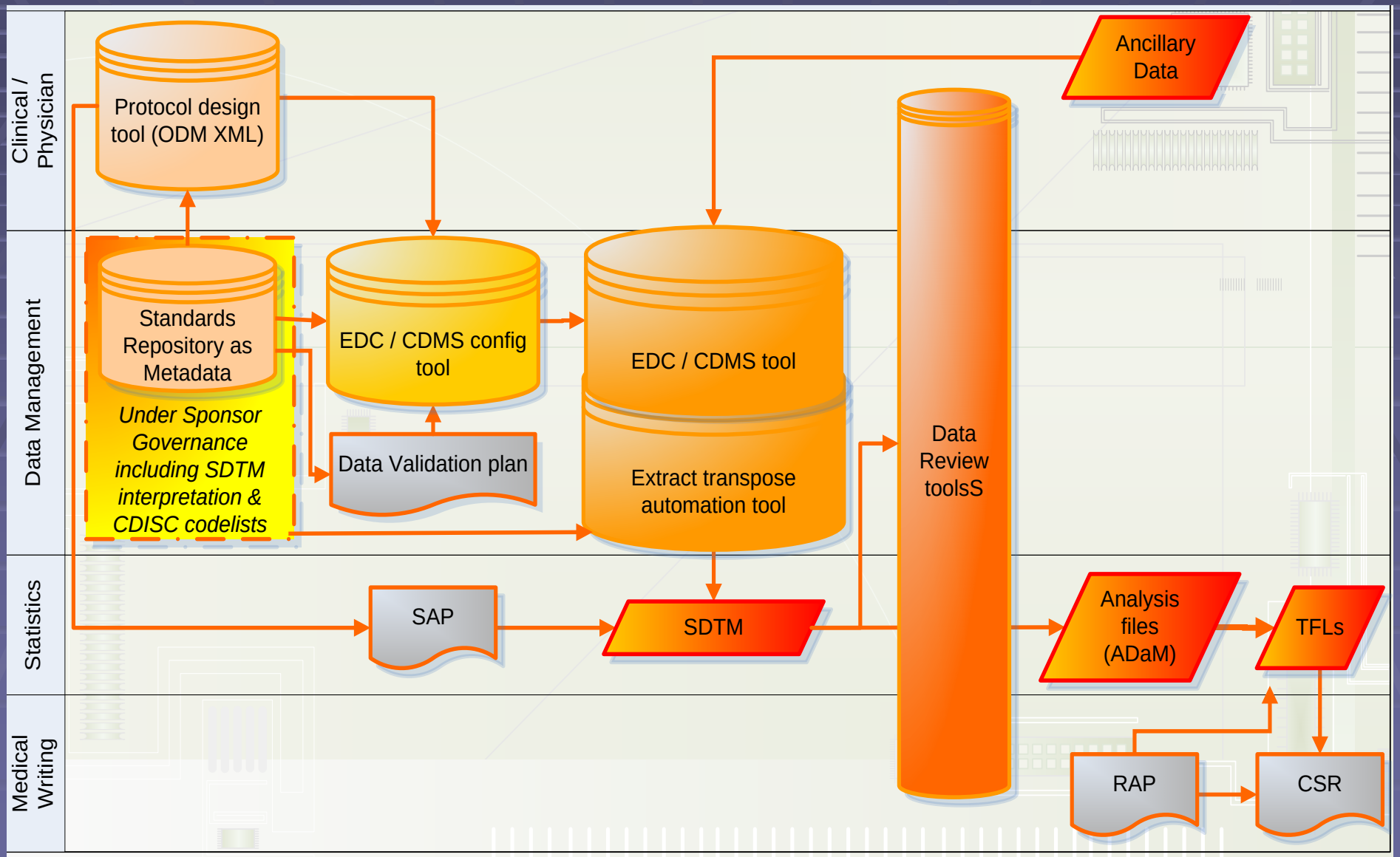
Sponsor

CRO

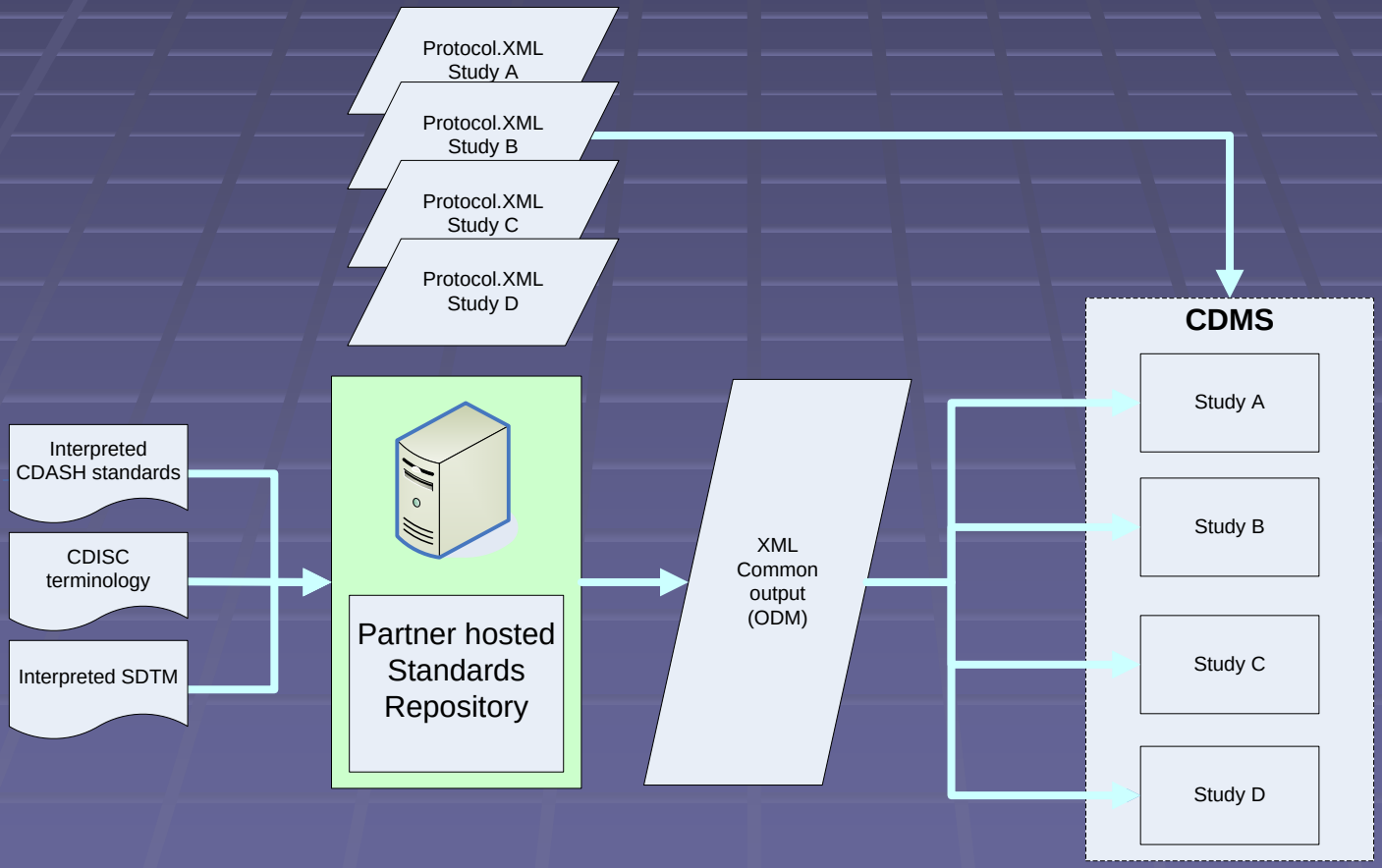


Interpretation issues further exacerbated

Future opportunities



How might that look in an outsourced scenario?



Future State - summary

- Standards underpin process improvement.
- *Machine executable* metadata is key to automation.

High Level Benefits

- CDISC business case (PhRMA-Gartner-CDISC) report projects:
  - ***~60% of the non-subject participation time***
  - ***~80% savings in the start-up stage***

Making it real…….

Over to:

- Philippe Verplancke – XClinical
- Andrew Newbigging – Medidata
- Douglas Bain – Medidata
- Mark Wheeldon – Formedix
- David Smith – SAS