

PhUSE Single Day Event



CDISC Data Flow Implementation Industry Case Stories

Copenhagen, 15th March 2010

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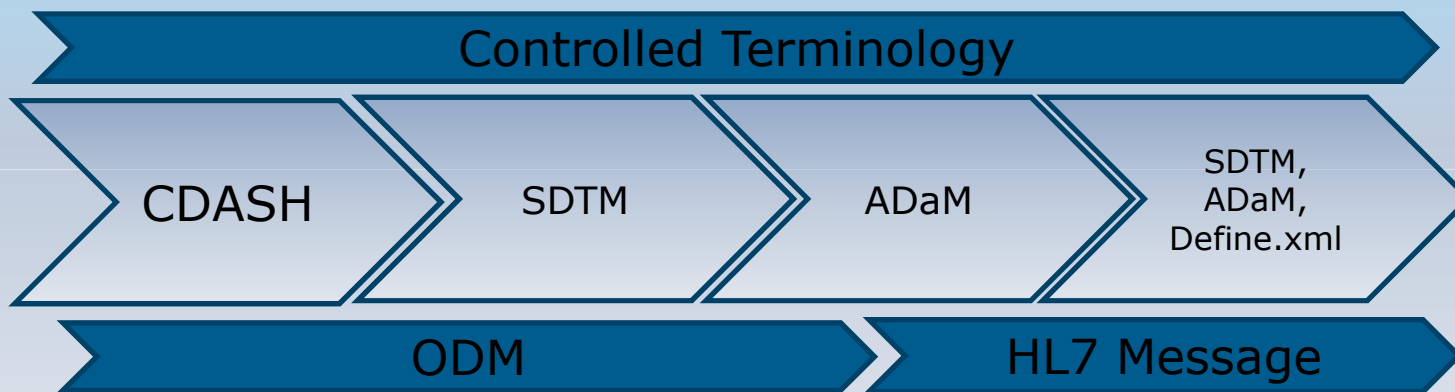


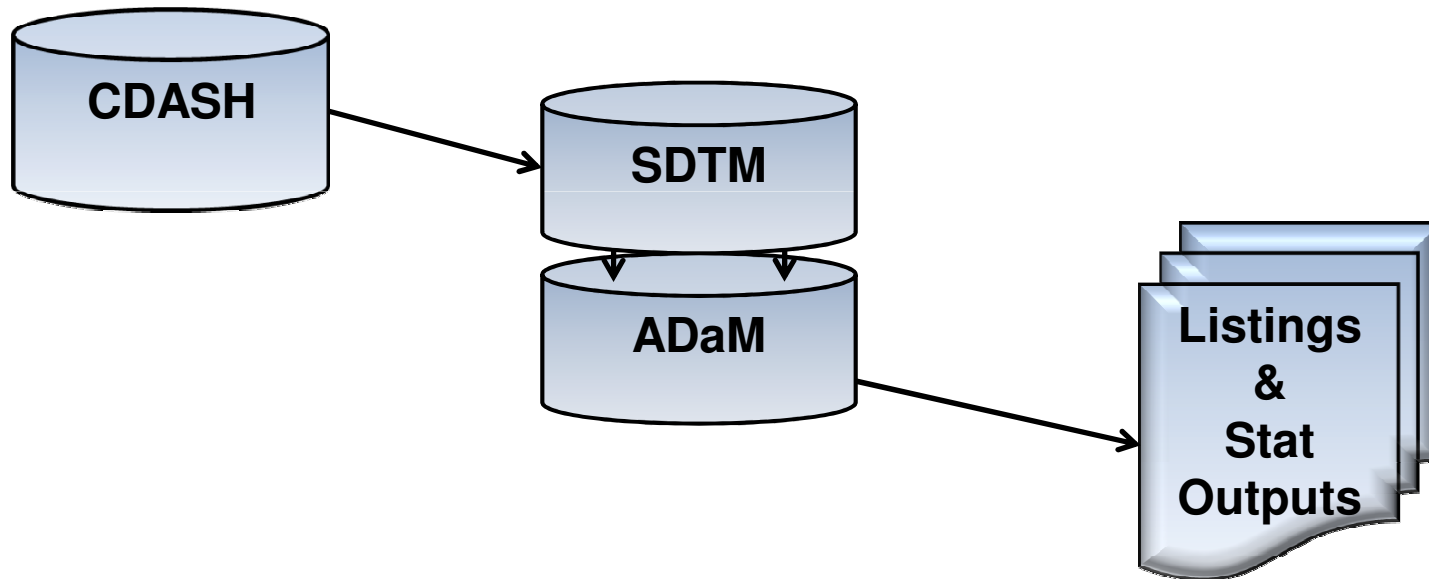


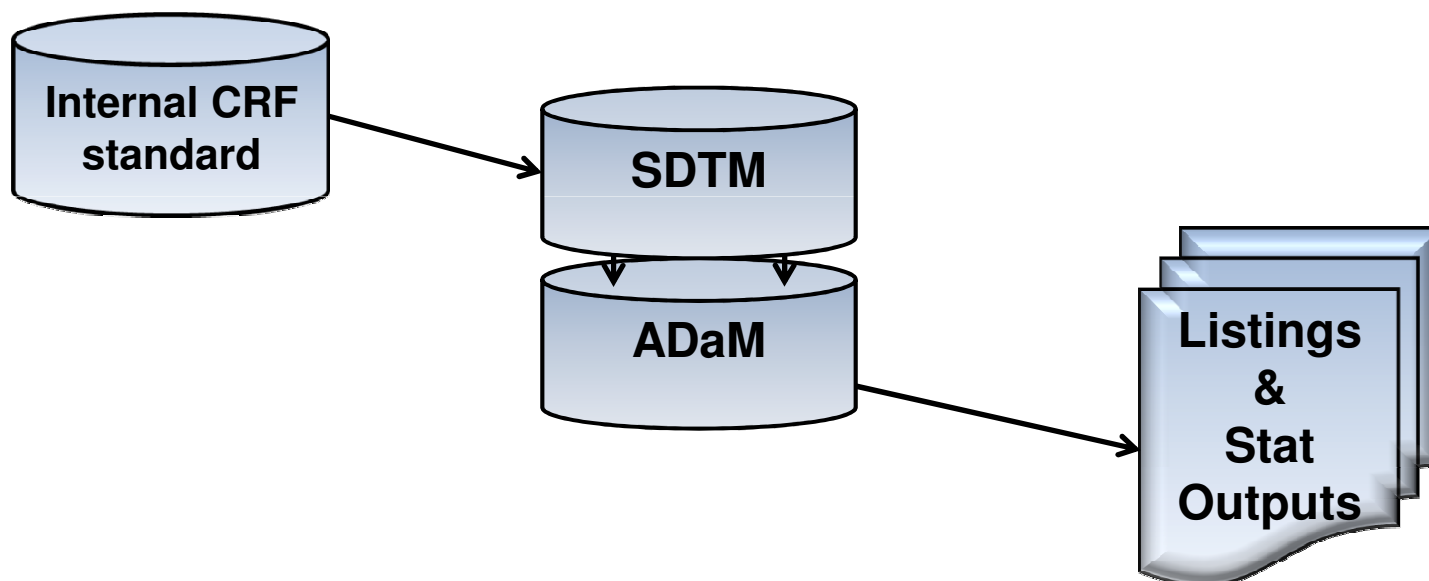
- Different implementations in different companies
- Examples of different priorities
- Use of benefit analysis for selecting optimal architecture
- Example of using benefit analysis in a concrete scenario
- Risks to be aware of when designing the dataflow

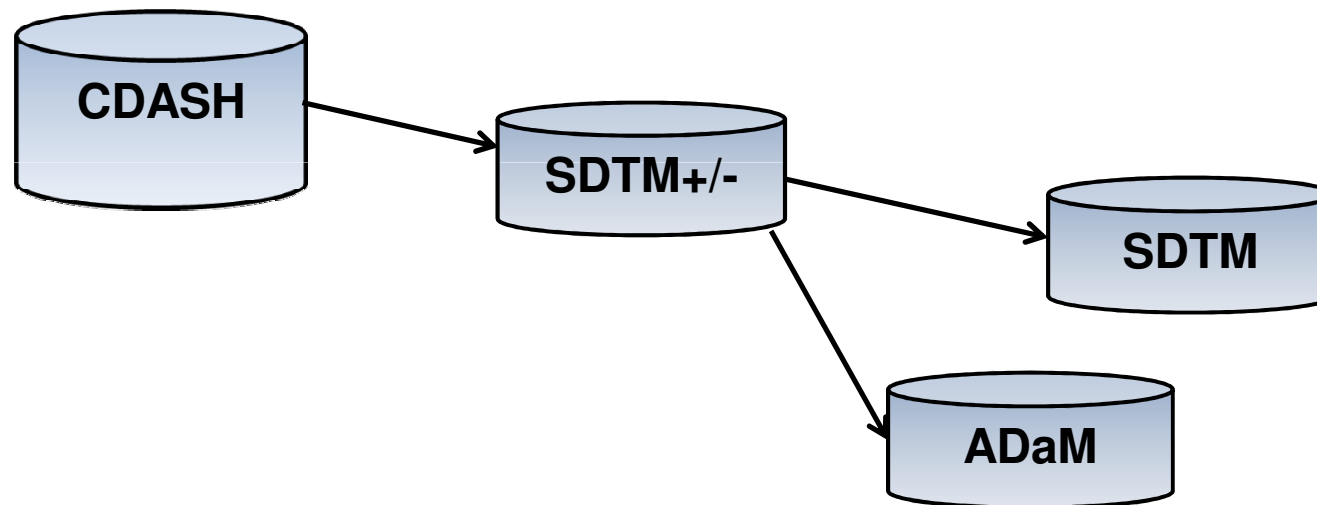


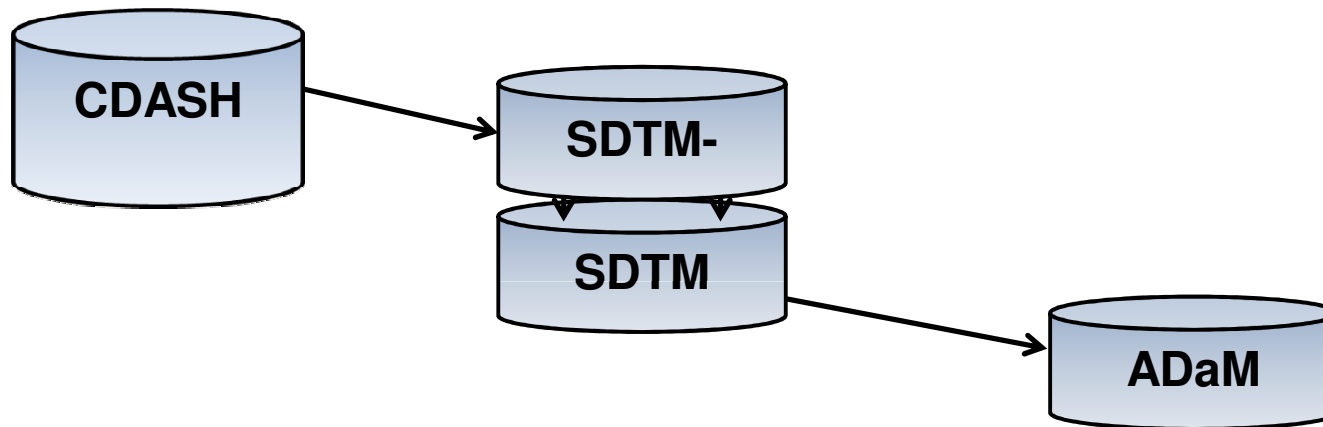
BRIDG & Electronic Protocol Representation



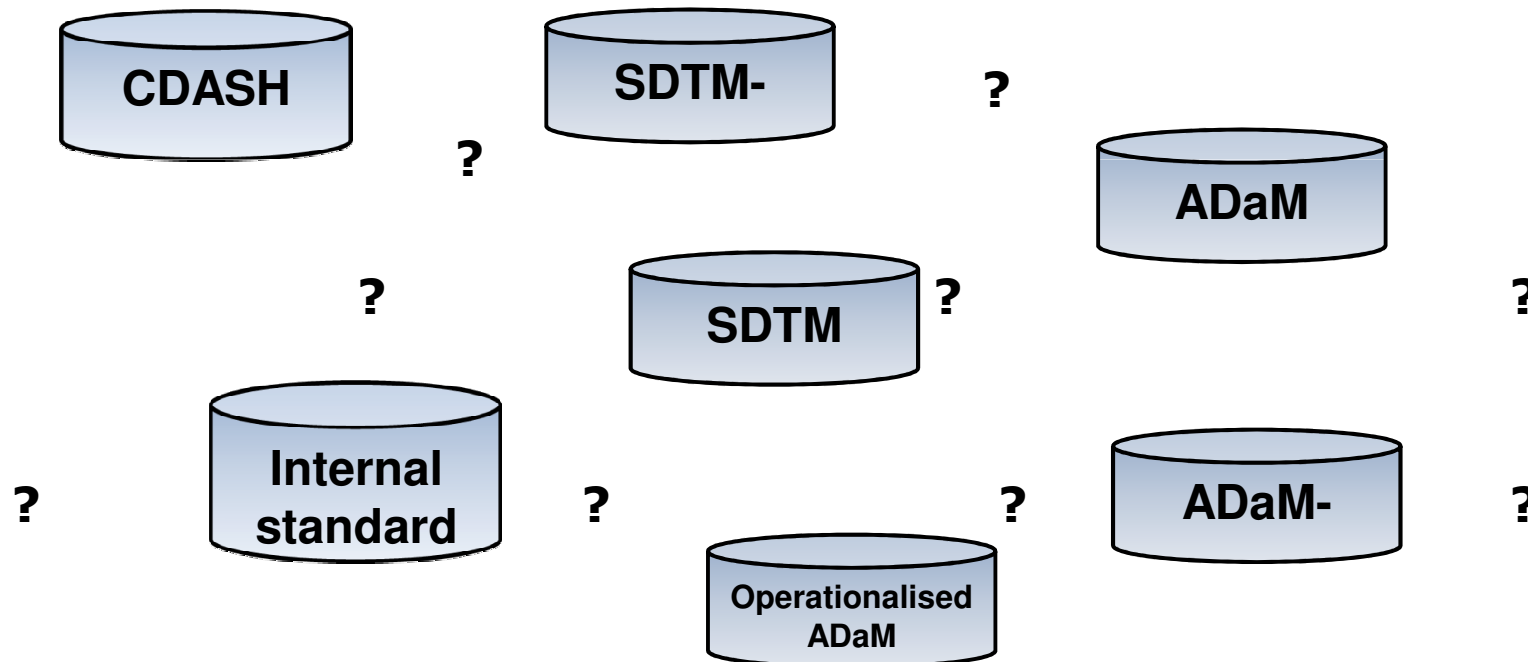




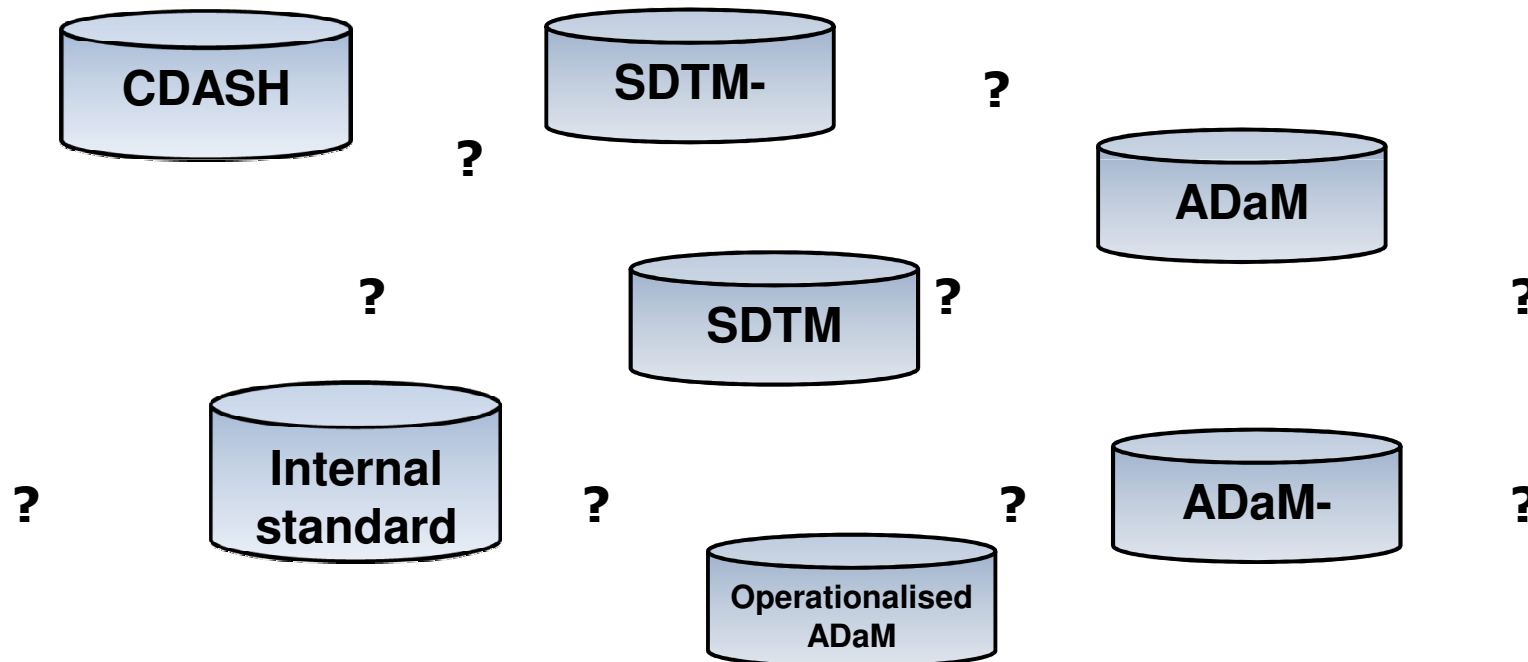




Why are there so many different implementations of the same standards to solve the same basic problem???



Because most companies are different and have different priorities...



Priority	Comment
Outsource-ability of ADaM production	Ability to outsource the production of ADaM datasets. The outsourcing of this would naturally be accompanied by outsourcing of the statistical analysis
Outsource-ability of SDTM production	Ability to outsource the production of SDTM datasets. The outsourcing of this would naturally be accompanied by outsourcing of creation of annotated CRF and define.xml
Transparency	Ability to make the creation of ADaM datasets transparent and ease traceability back to raw clinical data
Re-engineer processes	Ability to avoid or limit re-engineering of already existing processes and computer systems
SDTM resources	Limit resources used for creating SDTM for clinical trials that never reach submission
ADaM resources	Limit resources used for creating ADaM for clinical trials that never reach submission
Long term sustainability	It is a benefit if the chosen model is sustainable in the long term. Note that in many cases long term sustainability goes hand in hand with transparency

“Outsource-ability” of ADaM production:

Ability to outsource the production of ADaM datasets.

The outsourcing of this would naturally be accompanied by outsourcing of the statistical analysis.

Important for pharma companies with limited or no bio-statistical resources or with a general outsourcing strategy

“Outsource-ability” of SDTM production:

Ability to outsource the production of SDTM datasets.

The outsourcing of this would naturally be accompanied by outsourcing of creation of define.xml and annotated CRF.

Important for pharma companies without data transformation resources or with a general outsourcing strategy



Examples of Priorities

Transparency:

Ability to maintain good transparency all the way from raw data to submission deliverables.

There is an ever increasing demand for transparent data-flows from the authorities.

Of importance for all pharma companies submitting data.



Examples of Priorities

Re-Engineering processes:

Ability to avoid or limit changing existing processes/systems

Important for any company that has good systems, standards or processes in place already



Examples of Priorities

SDTM resources:

Ability to limit resources used for creating SDTM for clinical trials that never reach submission.

Important when running drug projects with a low probability of reaching submission or for medium and small size pharma companies that use their resources in a targeted fashion

ADaM resources:

Ability to limit resources used for creating SDTM for clinical trials that never reach submission.

Important when running drug projects with a low probability of reaching submission or for medium and small size pharma companies that use their resources in a targeted fashion

Please note:

- 1) As of Feb 2010 there is no explicit guidance to submit analysis data as ADaM
- 2) In many cases analysis data is only submitted for some of the studies in a submission



Examples of Priorities

Long term sustainability:

Ability to design an architecture that is sustainable in the long term.

In many cases this is equivalent to making the flow transparent, but also need to consider how global data standards are expected to evolve in the future and what future regulatory requirements are expected to be.

Examples of Priorities

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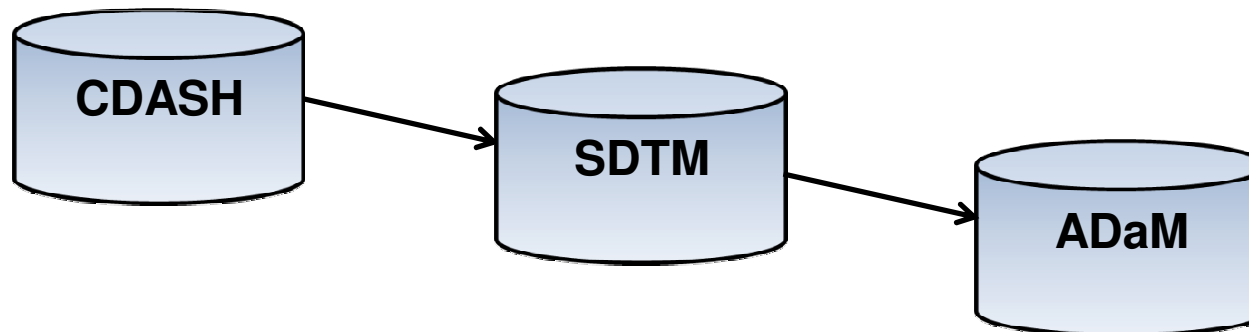


Analysis Example

Model for SDTM and ADaM - Linear, Parallel, Retrospective or Hybrid?

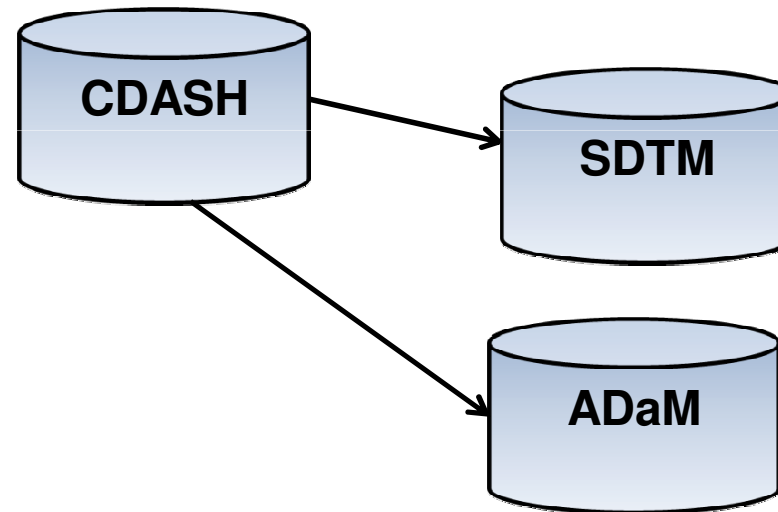
Model for SDTM and ADaM - Linear, Parallel, Retrospective or Hybrid?

Linear:



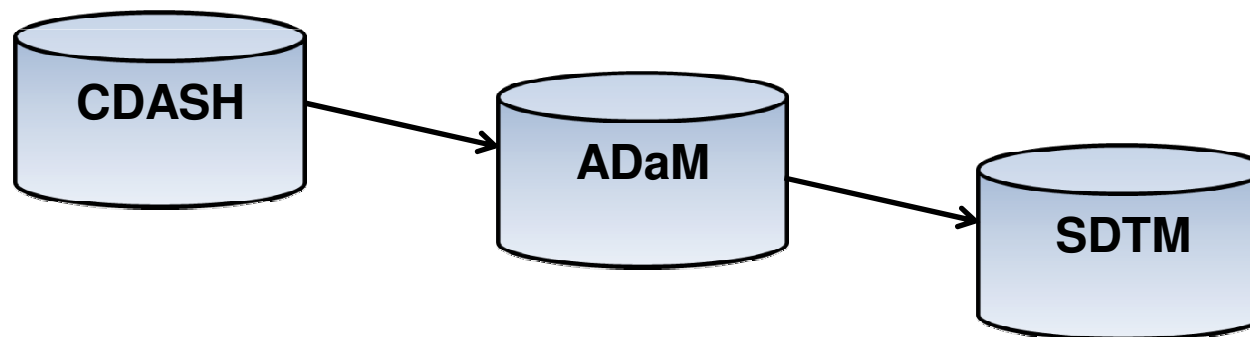
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Parallel:



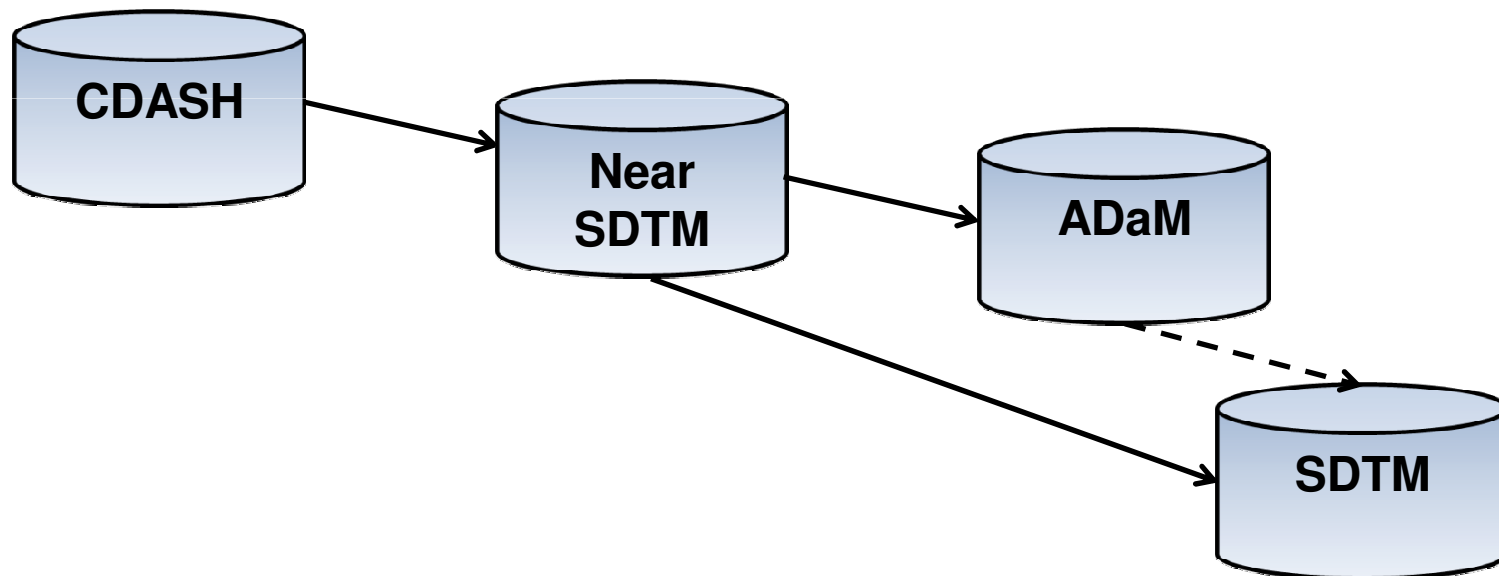
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Retrospective:



Model for SDTM and ADaM - Linear, Parallel, Retrospective or Hybrid?

Hybrid:





Analysis Example

Model for SDTM and ADaM - Linear, Parallel, Retrospective or Hybrid?

- **Linear**
- **Parallel**
- **Retrospective**
- **Hybrid**

Model for SDTM and ADaM - Linear, Parallel, Retrospective or Hybrid?

- Linear
- Parallel
- Retrospective
- Hybrid

Eliminated to simplify the example as they are solutions without long term sustainability

Method	Wins	Losses	Neutral
Parallel			
Linear			





Analysis Example

Method	Wins	Losses	Neutral
Parallel	Outsource ability of ADaM Outsource ability of SDTM		
Linear			Outsource ability of ADaM Outsource ability of SDTM



Method	Wins	Losses	Neutral
Parallel	Outsource ability of ADaM Outsource ability of SDTM	Transparency	
Linear	Transparency		Outsource ability of ADaM Outsource ability of SDTM



Method	Wins	Losses	Neutral
Parallel	Outsource ability of ADaM Outsource ability of SDTM SDTM resources	Transparency	
Linear	Transparency	SDTM resources	Outsource ability of ADaM Outsource ability of SDTM



Method	Wins	Losses	Neutral
Parallel	Outsource ability of ADaM Outsource ability of SDTM SDTM resources ADaM resources	Transparency	
Linear	Transparency ADaM resources	SDTM resources	Outsource ability of ADaM Outsource ability of SDTM



Method	Wins	Losses	Neutral
Parallel	Outsource ability of ADaM Outsource ability of SDTM SDTM resources ADaM resources	Transparency Long term sustainability	
Linear	Transparency ADaM resources Long term sustainability	SDTM resources	Outsource ability of ADaM Outsource ability of SDTM



Method	Wins	Losses	Neutral
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Linear	Transparency ADaM resources Long term sustainability	SDTM resources	Outsource ability of ADaM Outsource ability of SDTM

Re-engineering of processes not considered as even though important, is also very company specific





Analysis Example

Method	Wins	Losses	Neutral
Parallel	FLEXIBILITY		
Linear	TRANSPARENCY		



Method	Wins	Losses	Neutral
Parallel	FLEXIBILITY		
Linear	TRANSPARENCY		



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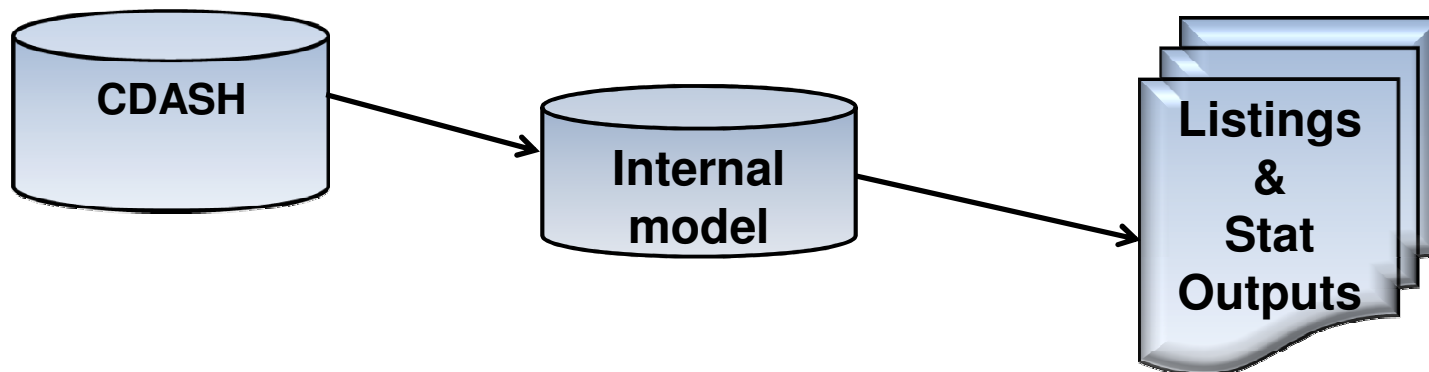


Analysis Example

In the current example the parallel approach was chosen.

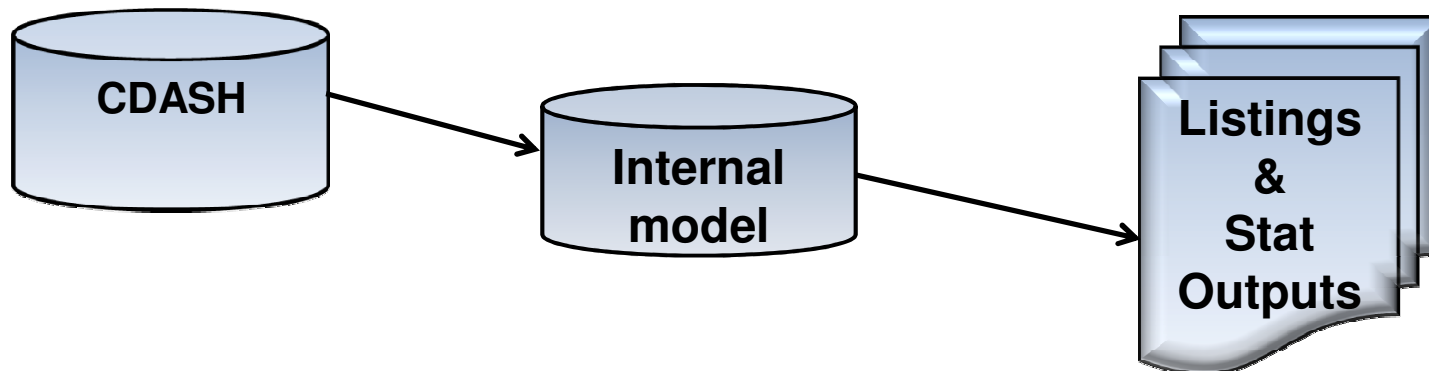
The company was a medium-sized pharma company with a strong outsourcing strategy.

Another example:



Led to an unusual mapping from CDISC standard to internal standard.

Chosen to avoid re-engineering:







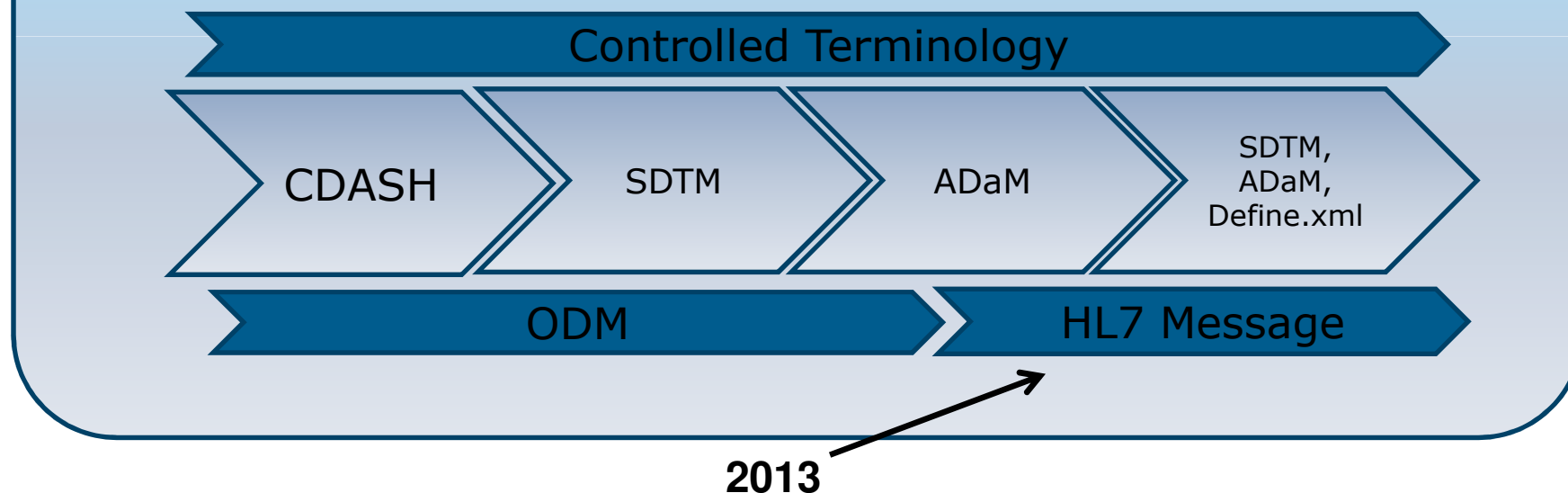
Risks

CDISC Trial Design Domains are currently not matured enough to use in metadata driven environment.

May change as electronic protocol standard matures.

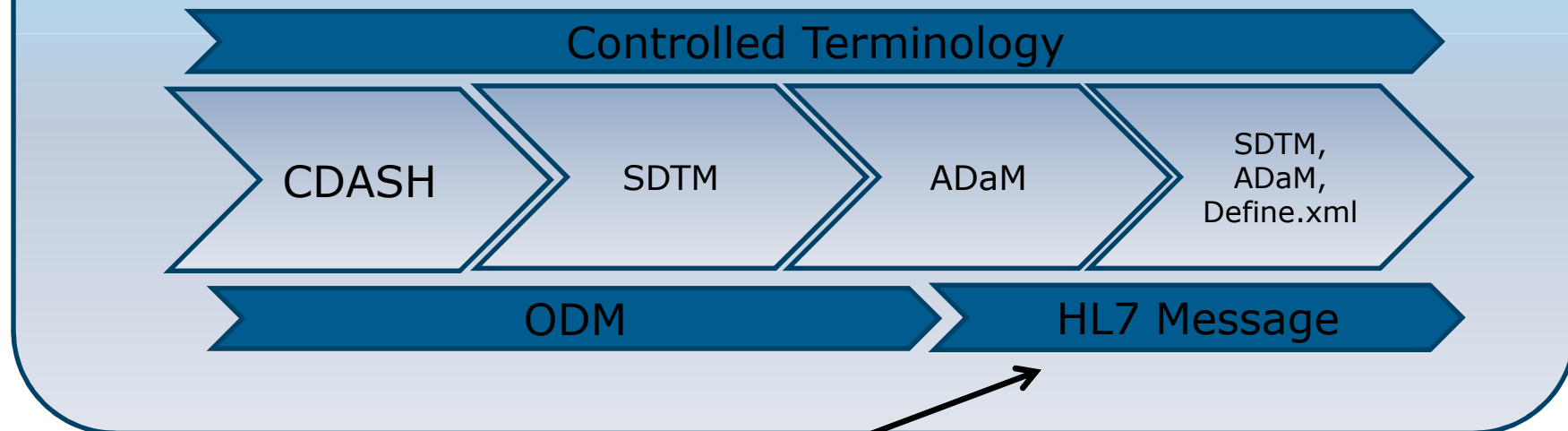


BRIDG & Electronic Protocol Representation





BRIDG & Electronic Protocol Representation



FDA has officially stated that the introduction of HL7 standards as a transport vehicle will not happen in the near future