



Implementing End-to-End Data Standards from a Metadata and Technology perspective

Gaithersburg
June 2nd, 2016

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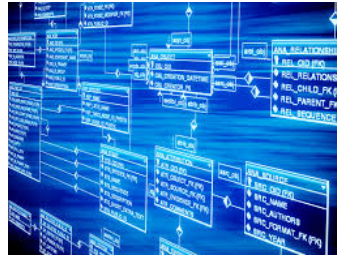


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OVERVIEW

Introduction

End to End Metadata



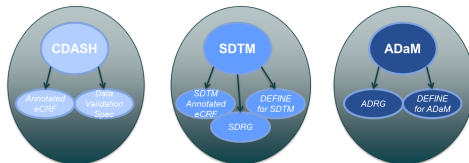
End to End Technology





END TO END FROM A METADATA PERSPECTIVE

“Classical approach”



- Data Standards (CDASH, SDTM, ADaM,..) maintained independently
- Mapping between data standards is managed manually (one by one)

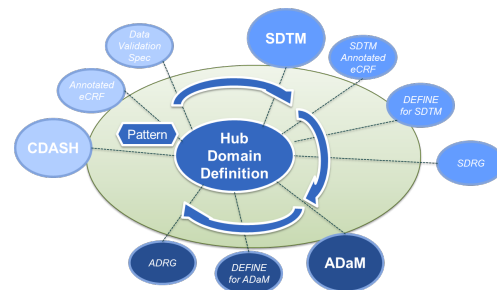
Benefit:

- Flexibility

Concerns:

- Risk of inconsistency in mapping for same type of variables across domains
- Workload to define the mapping
- Workload to generate mapping for studies
- More difficult E2E approach

“Hub & spoke” approach



- Data standards are maintained through a common Domain Definition “hub”
- Content and mapping generated semi-automatically through patterns

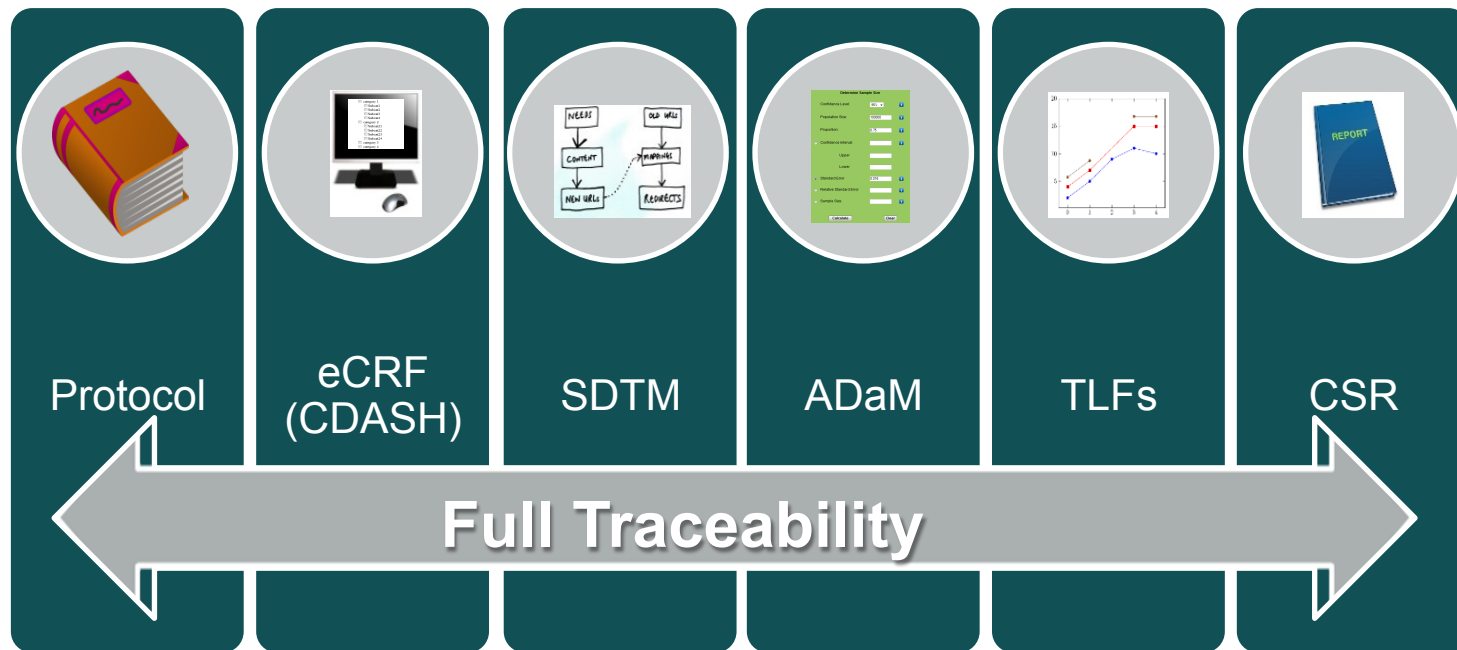
Benefit

- Consistency and quality in data standards (and underlying data)
- Efficiency in managing mapping across different standards and different versions of standards

Concerns

- Requires definition of “Hub” concept and mapping patterns

END TO END FROM A METADATA PERSPECTIVE



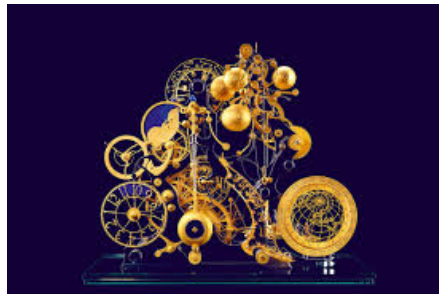
- **Traceability can help in:**

- Audit situations
- Error detection
- Cross-functional process flow

End to End

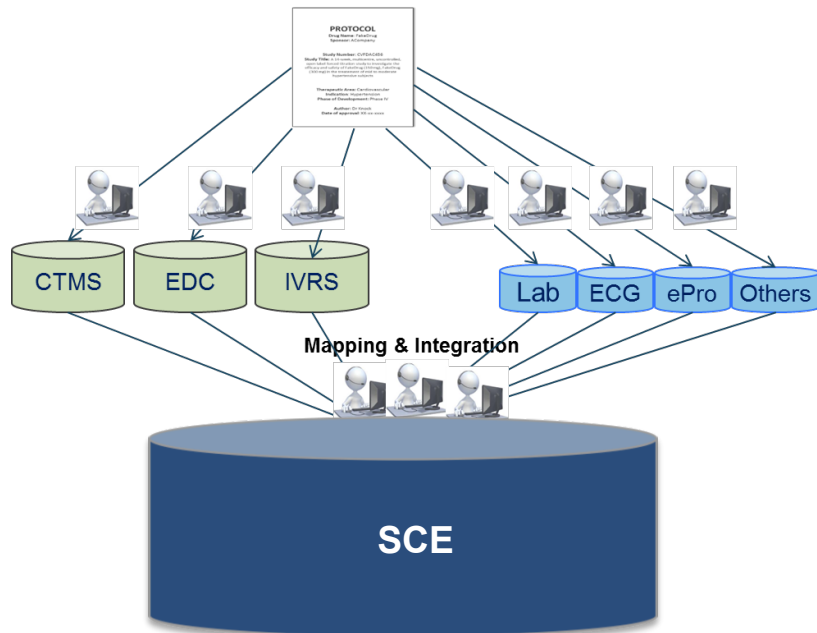


From a Technology perspective

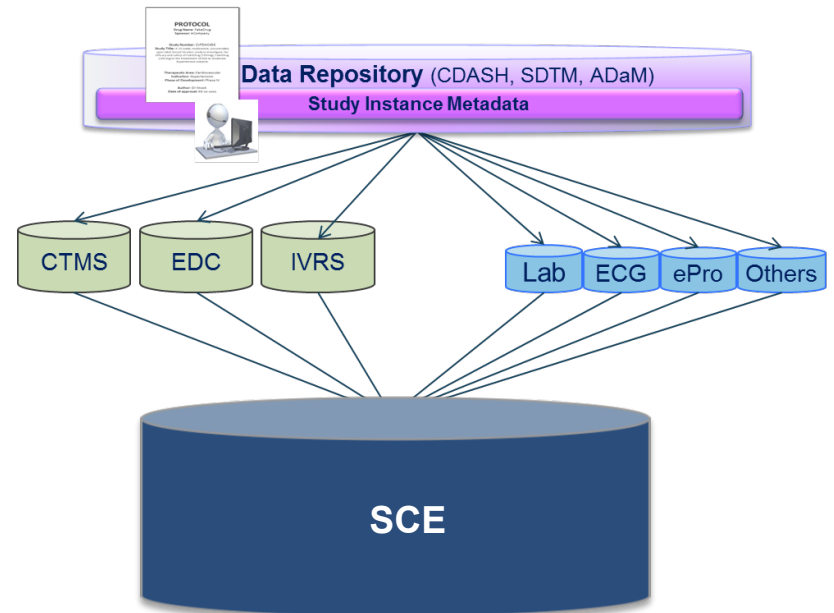


WHY DO WE NEED AN MDR ?

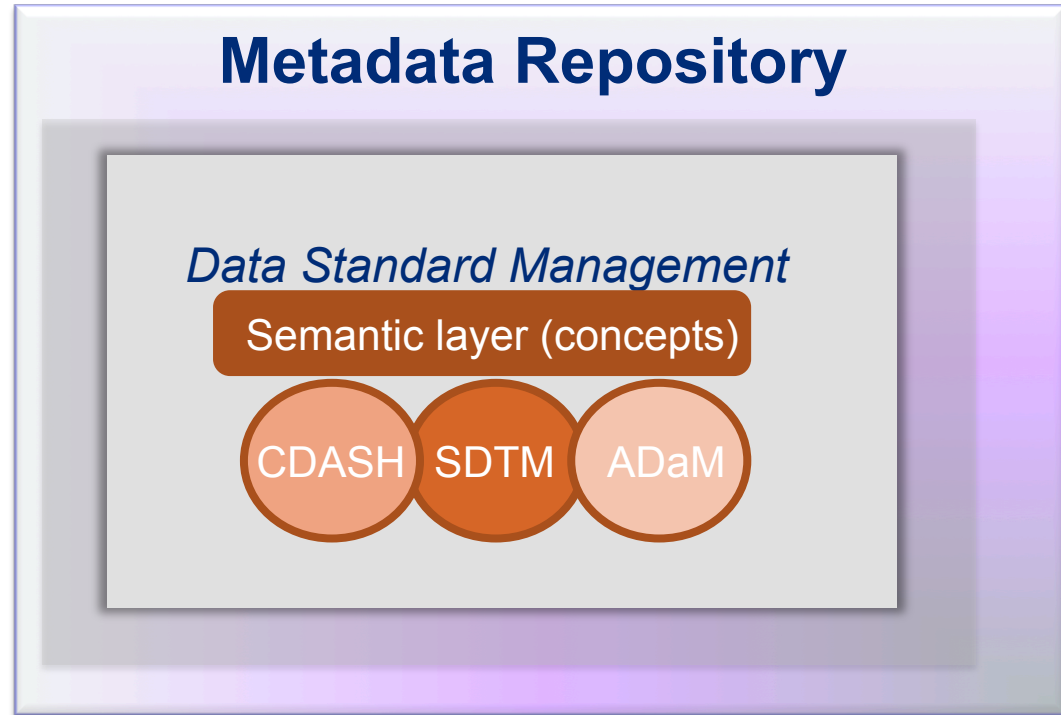
Retroactive Approach



Proactive Approach

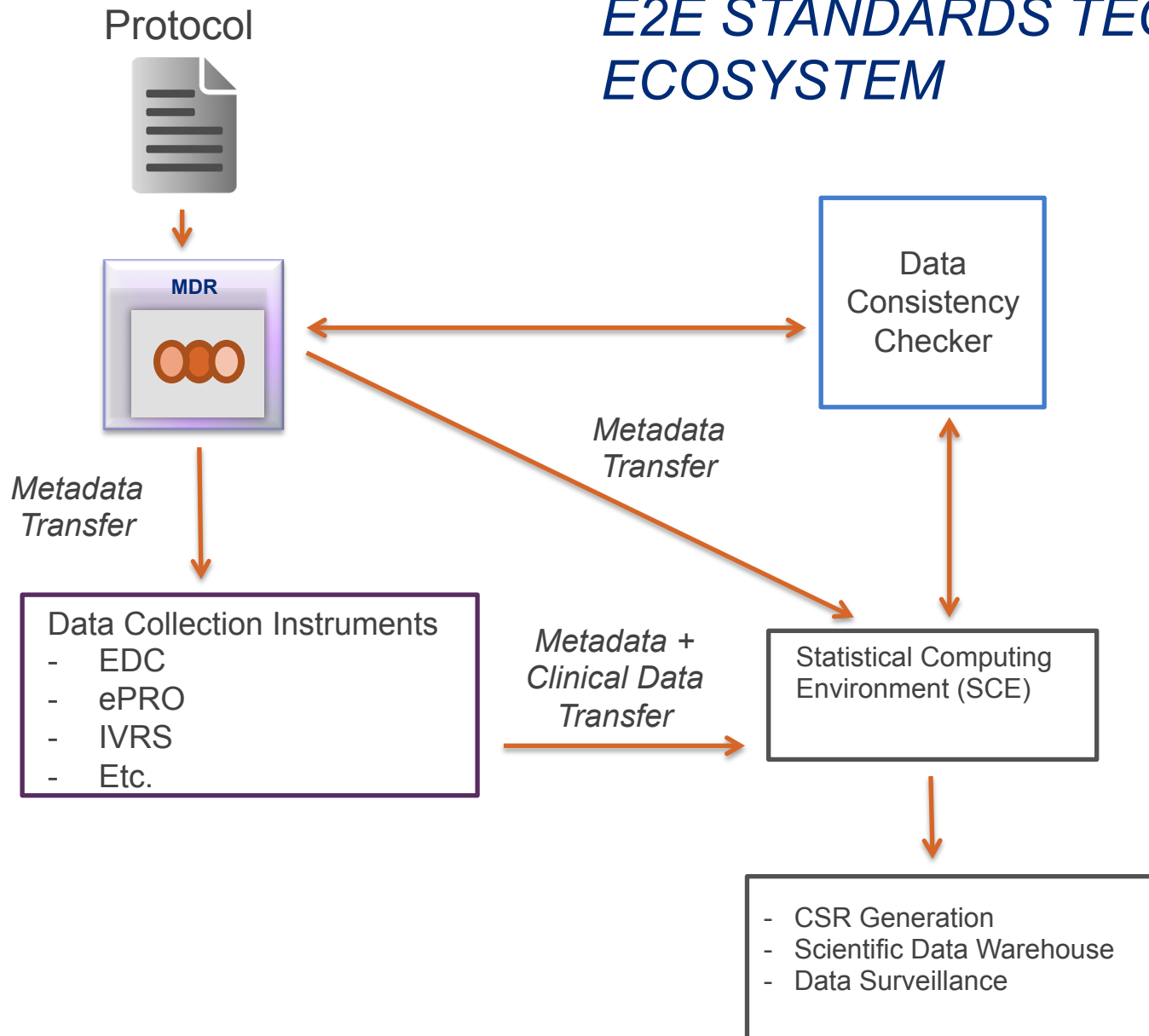


MDR FUNCTIONALITY



- **Workflow management**
- **Embedded Data Standards Governance Process**
- **Search / Import / Export Functionality**
- **Version control**
- **System agnostic**

E2E STANDARDS TECHNOLOGY ECOSYSTEM



GOVERNANCE

- **End to End Metadata + Technology will not be enough**
- **Need for Data Standards Governance**
 - How do we enforce the use of standards (in a global environment) ?
- **Culture change**
 - How do we engage all employees / functions ?
- **Track efficiencies**



SUMMARY

- **Breaking the CDISC silos**
- **Embed SDTM and ADaM into your everyday-process and not as an afterthought**
- **Ensure to cover all data elements for a clinical study (not just the once collected in EDC)**
- **MDR can be more than just a repository**
- **Standards Technology does not end with an MDR**
- **Ensure Governance structure is in place**



Q & A



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