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How can effective Metadata Management improve speed and quality of CDISC-based clinical research

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Disclaimer

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Presenter Profile

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- 12 years in Fujitsu's Life Science solutions vertical
- Developer of tsClinical Define.xml generator tool
- Member of CJUG SDTM since 2013
- Actively researching OpenCDISC in CJUG SDTM
- Volunteer to CDISC SHARE team since 2014
  (not an active member yet though...)

Definition of Metadata

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In this presentation, Metadata refers to...

- Standard-level Metadata
  - CDISC Standards (e.g. SDTM, ADaM)
  - Controlled Terminology & External Dictionaries
  - Company standards and terminology
- Study-level Metadata
  - Database Specifications (i.e. EDC, Clinical Repository)
  - SDTM Mapping Specifications
  - ADaM Dataset Specifications

Main topics of this presentation

Value of CDISC – Theory

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CDISC Business Case (*summarized by the presenter)

- Improved Cost, Time and Efficiency
  - *"By using CDISC standards from the start, researchers can save 70-90% of time and resources during the Study Start Up stage (time to first patient enrolled) and ~ 75% of non-patient participation time during Study Conduct and Analysis*
    (Source: http://www.cdisc.org/business-case)
- Increase data quality
- Enable data integration, enhance reusability of data
- Facilitate data interchange
- Facilitate regulatory review

Reality - Challenges of Adopting CDISC

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- CDISC can be compared to very complex Building Blocks:

	Blocks	CDISC (SDTM)
Pieces	Thousands of pieces of blocks	Domain, Variable, CTs
Outcome	Castle	Study Datasets
Instructions	Sample Castle	Sample Datasets
Consequences	People make different castles	People use domains, variables, CTs differently

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Cost, Time and Quality depend on human experience.

Why is effective Metadata Management the key?

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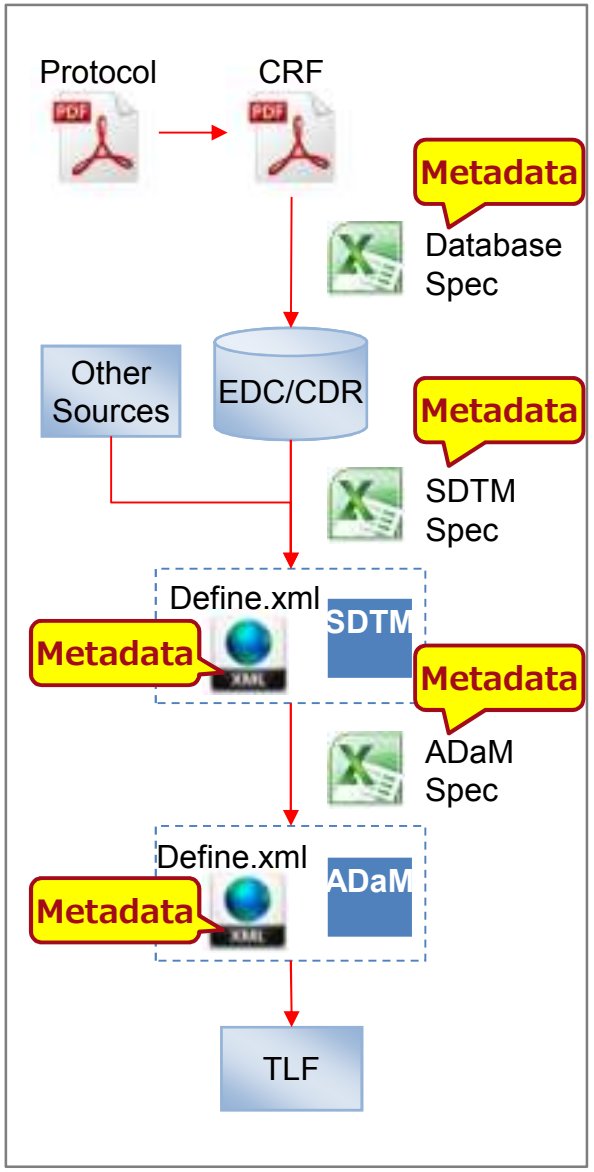
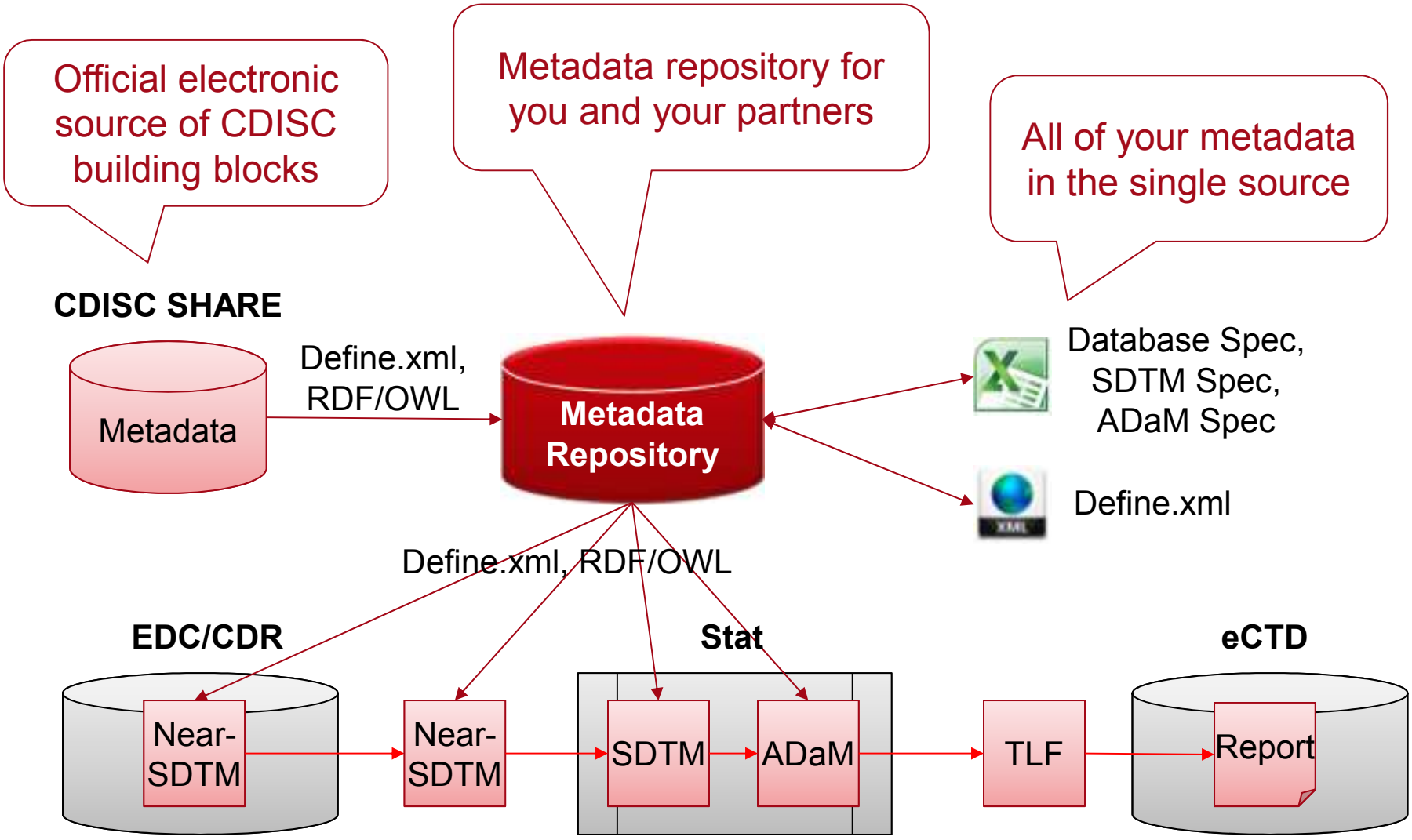
... because all of these “labor-intensive” processes are related to Metadata!!

- Reproduce building blocks of CDISC in your design documents
- Ensure SDTM/ADaM conformance of your study-level metadata
- Ensure everyone maps source data to SDTM in the same discipline
- Ensure metadata traceability (not data point traceability) between your EDC database, SDTM and ADaM
- Manage source information of Define.xml

All of these impact effectiveness and quality, and ability to integrate study data.



Proposed Metadata Management Framework



SHARE – Official Metadata Repository of CDISC

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- *"SHARE is a global electronic repository for developing, integrating and accessing CDISC standards metadata in electronic format."*

- *"A 2013 study conducted by a major pharmaceutical company has found that controlled use of a system such as SHARE (i.e. a standards and metadata repository) could save an estimated $240K per study."*

?

(Source: http://www.cdisc.org/business-case)

SHARE – iSHARE and eSHARE

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- iSHARE
  - Built on SOA Software's Semantic Manager
  - For Standards Development and Governance
- eSHARE
  - Accessible from CDISC web site (Platinum members only)
  - For distribution of standards in electronic formats (Excel, Define.xml)
  - RDF/OWL format may also be available in the future (draft version available on GitHub: https://github.com/phuse-org/rdf.cdisc.org)

DEMO1:

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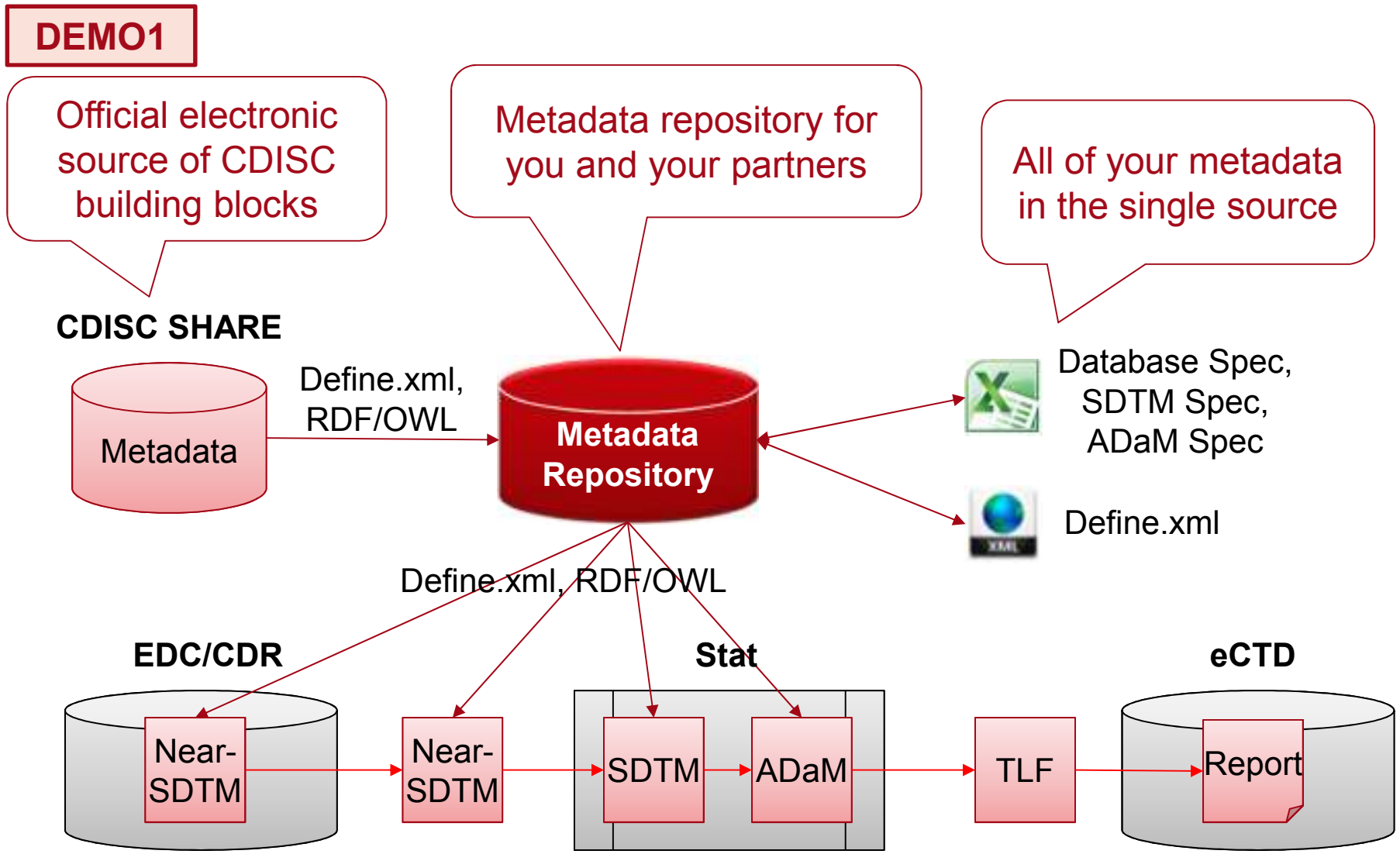
Enhanced functionality to use eSHARE data
in your own Metadata Repository

Recap: Proposed Metadata Management Framework



What SHARE cannot do (at least currently)

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- SHARE currently manages **Standards-level Metadata** as defined in this presentation.
  - Not for Study-level Metadata
  - Does not allow “customizing” standards

Customizing Standards - Example Scenarios

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- Always add “model-permissible” variables
- Always add custom variables (SUPPQUAL)
- Add your own codelist in CDISC Controlled Terminology
- Add your own items to extensible codelist
- **Add company-defined synonyms to CDISC Controlled Terminology**

DEMO2:

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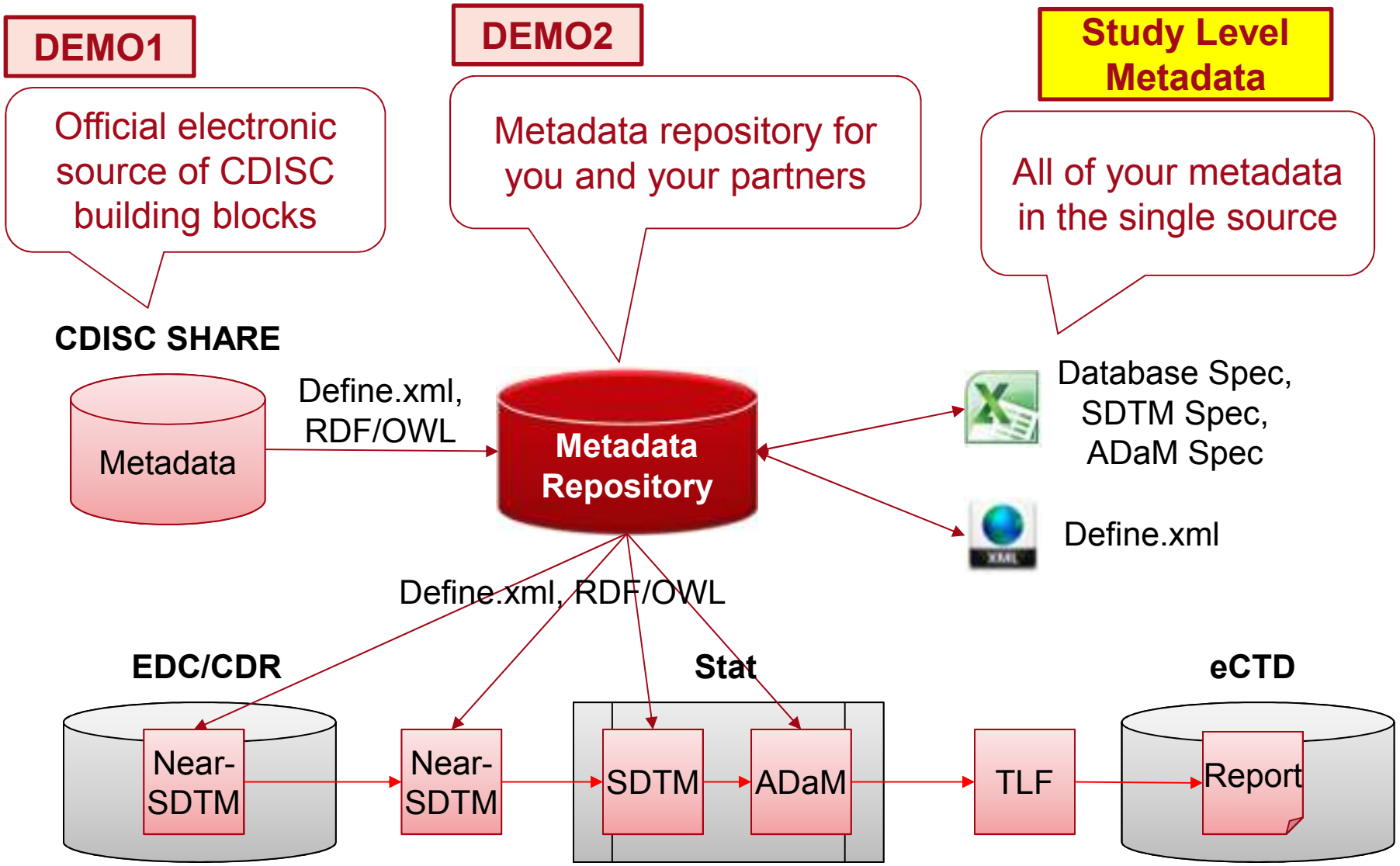
Search Controlled Terminology
using your own Synonyms

Recap: Proposed Metadata Management Framework



Managing Study-level Metadata

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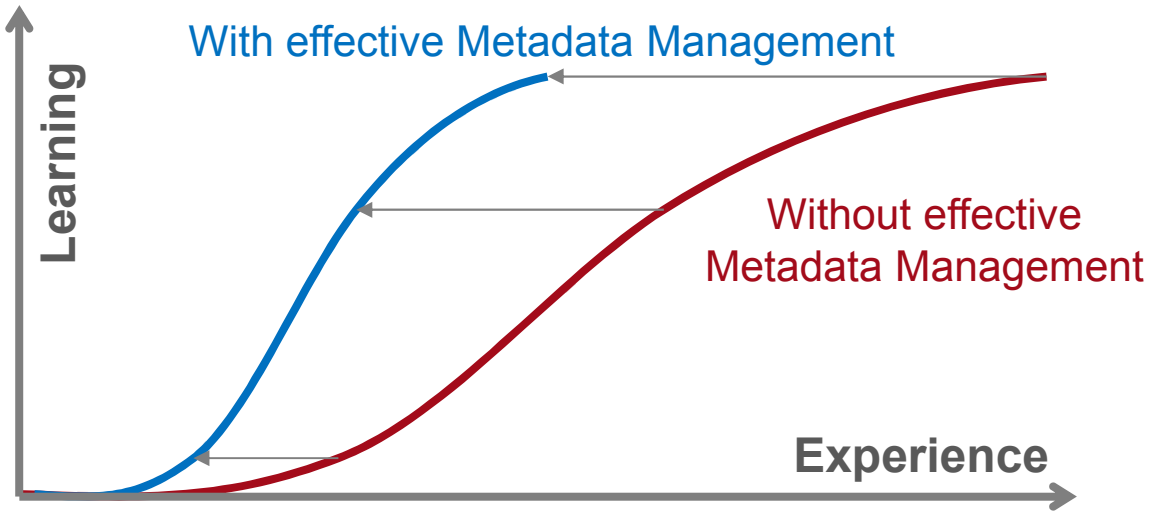
- Effective metadata repository should have the following capability to manage Study-level Metadata:
  - Allow users to design SDTM Spec based on Database Spec, and ADaM Spec based on SDTM Spec to ensure metadata traceability.
  - Reuse metadata of previous studies for a new study
  - Facilitate everyone maps source data to SDTM in the same discipline
  - Validate SDTM/ADaM metadata for IG conformance
  - Generate Define.xml from metadata repository
  - Share study-metadata with your partners

Key Messages

- With enhanced functionality, data distributed from eSHARE tells more about IG and CT.
- If used effectively, synonyms are powerful tool to enable consistent CRF-CT mapping.
- Your own Metadata Repository effectively implemented can dramatically raise learning curve.



Contact

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Thank you for listening!

Please feel free to send your questions to:

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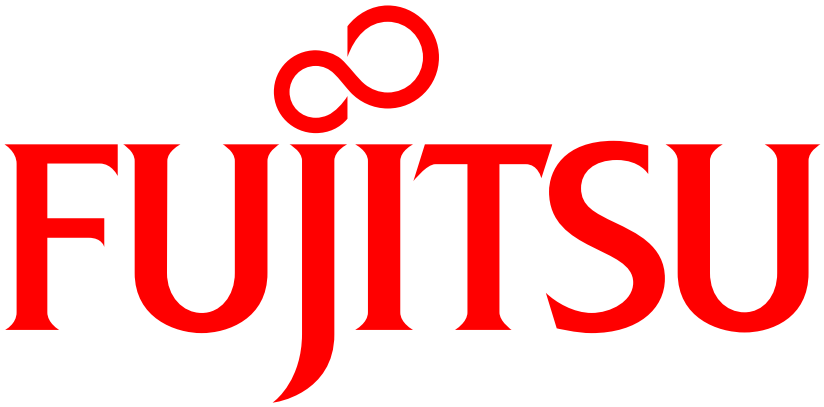

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