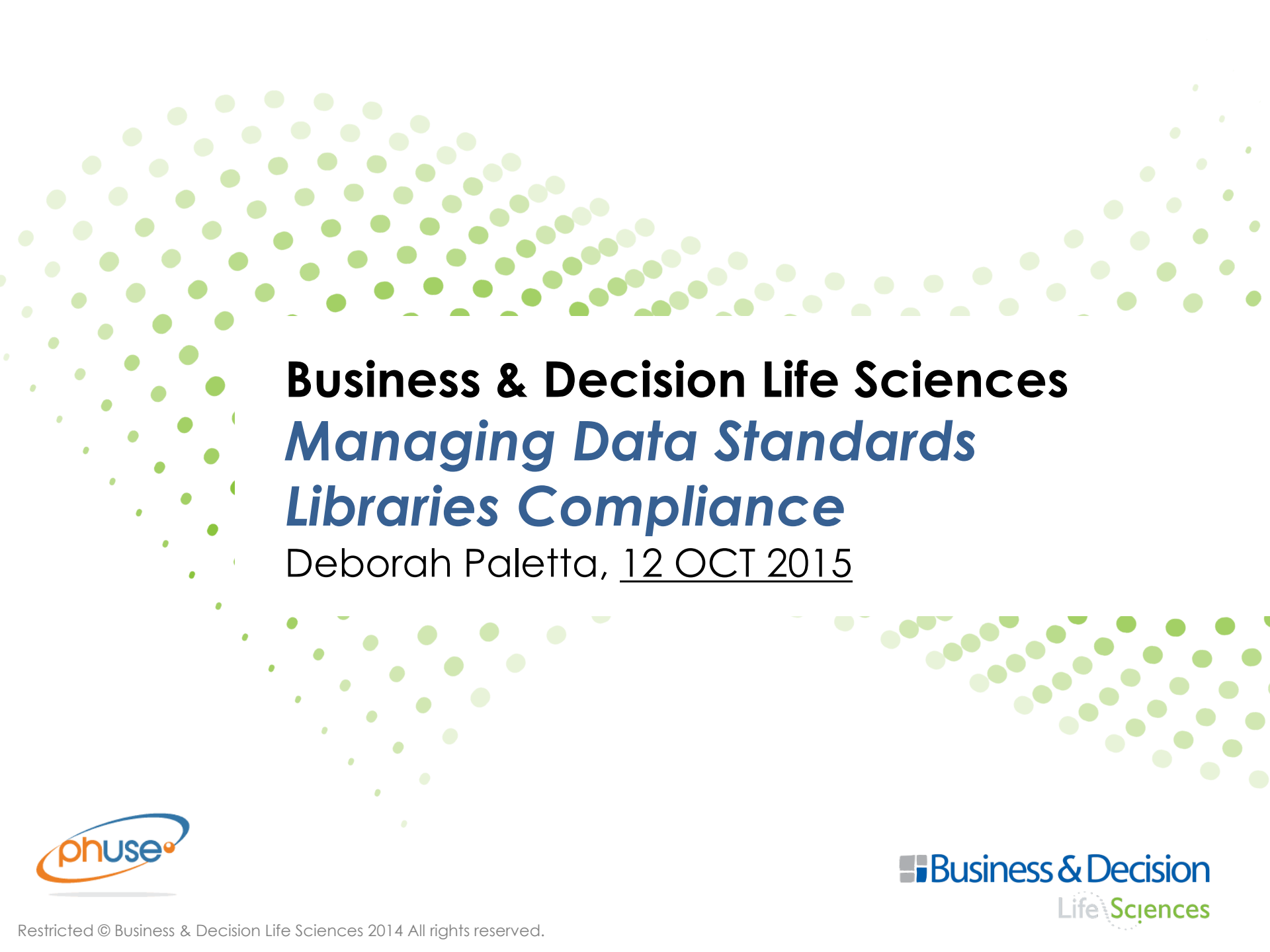




Business & Decision Life Sciences

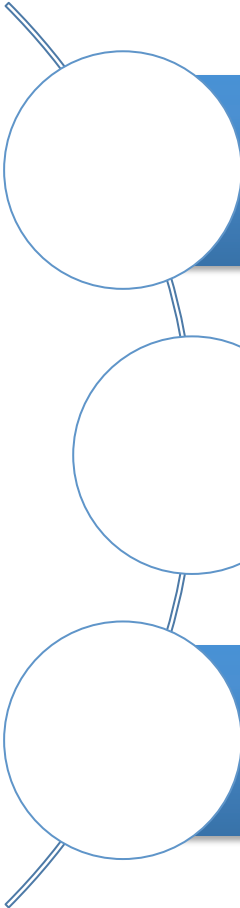
Managing Data Standards

Libraries Compliance

Deborah Paletta, 12 OCT 2015



Agenda

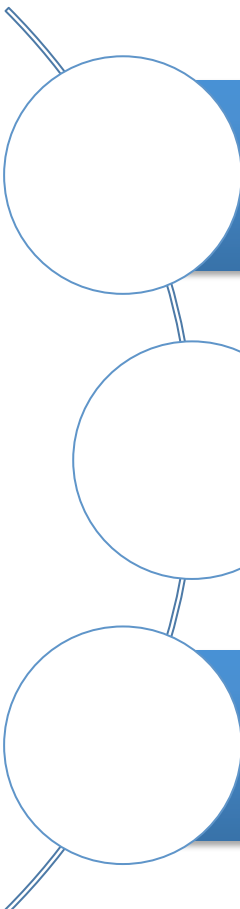


Creation of a Data Standards Library

CDISC Compliance:
Challenges & Considerations

Conclusion

Agenda



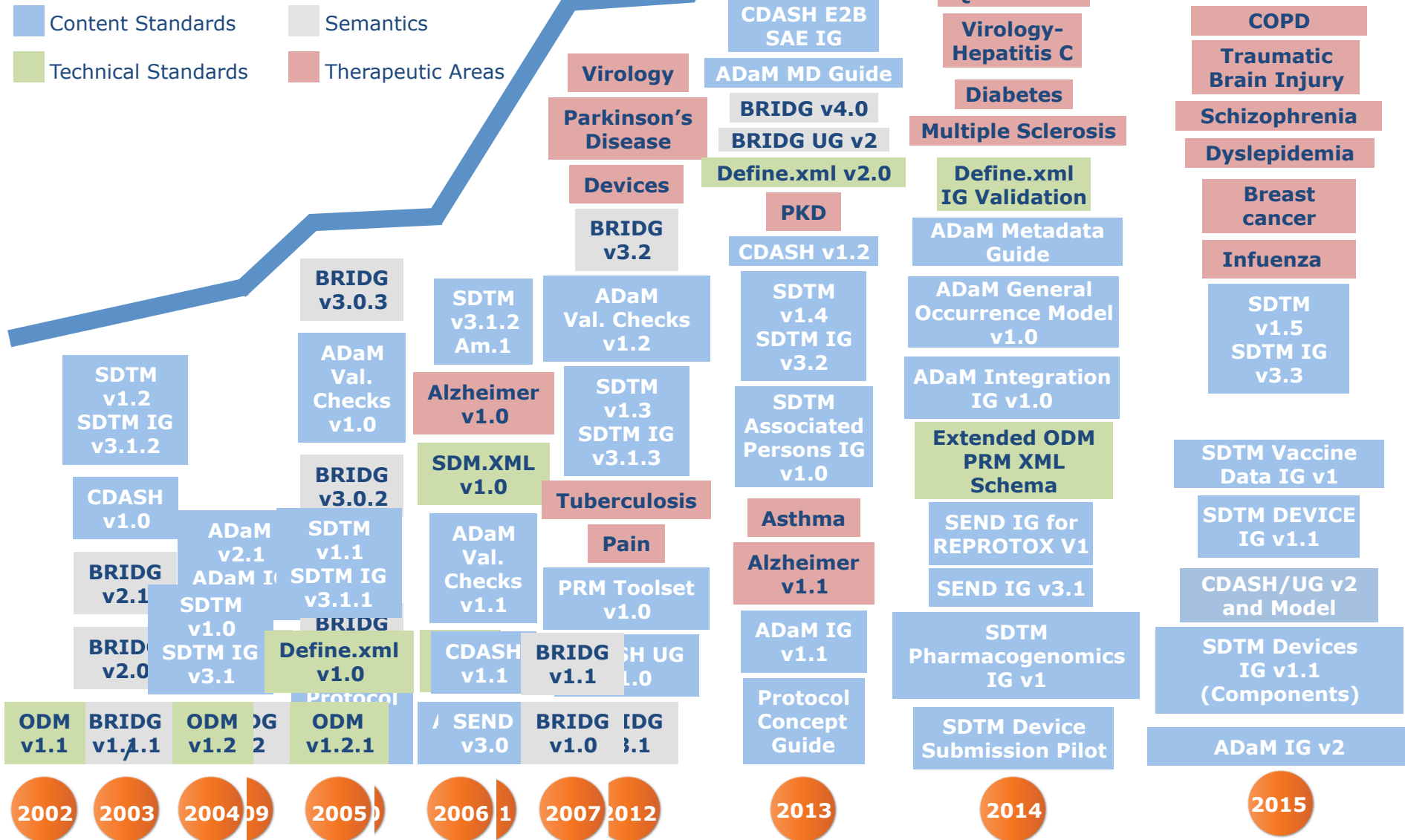
Creation of a Data Standards Library

CDISC Compliance:
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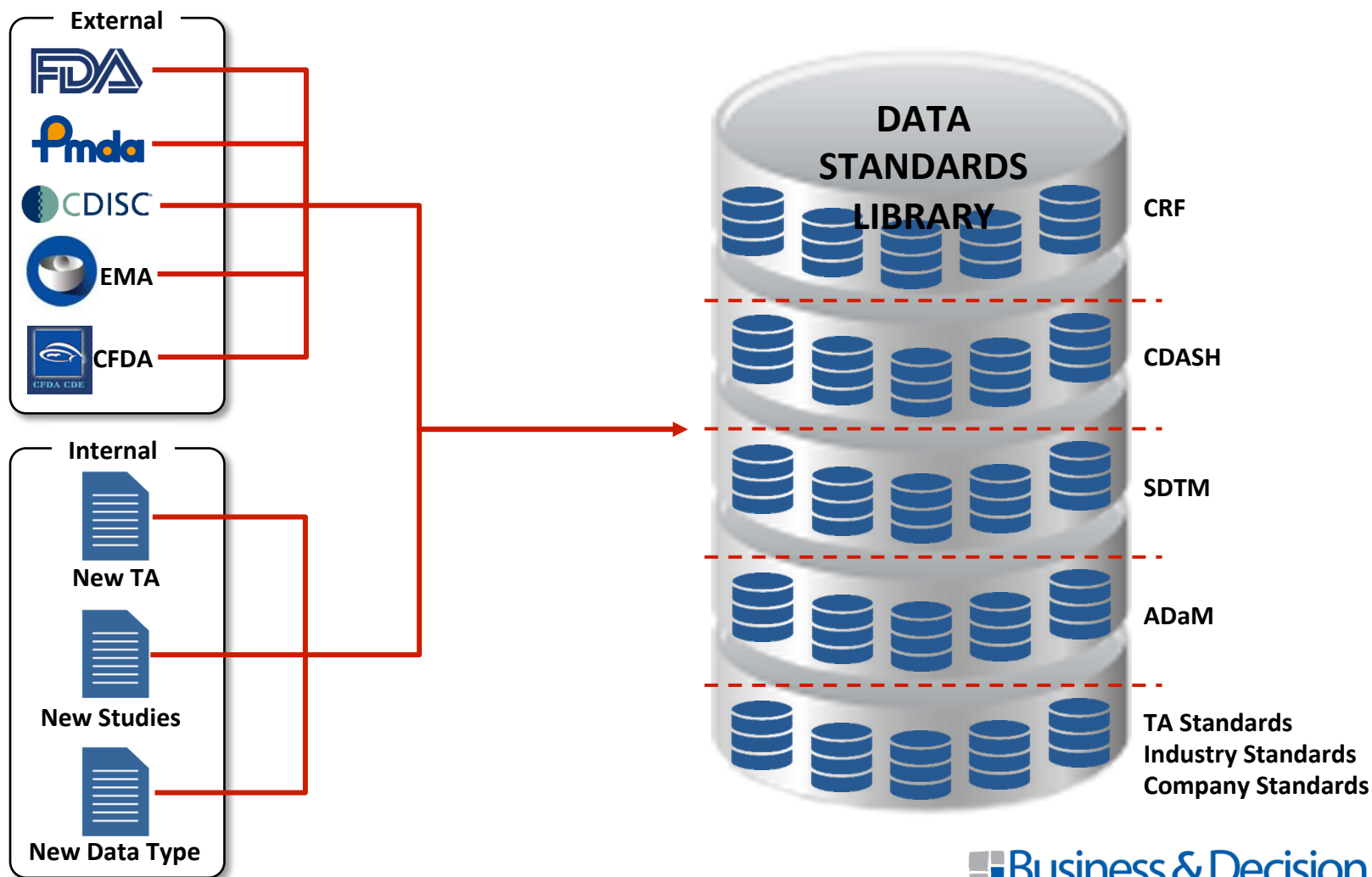
Conclusion

Updates over time

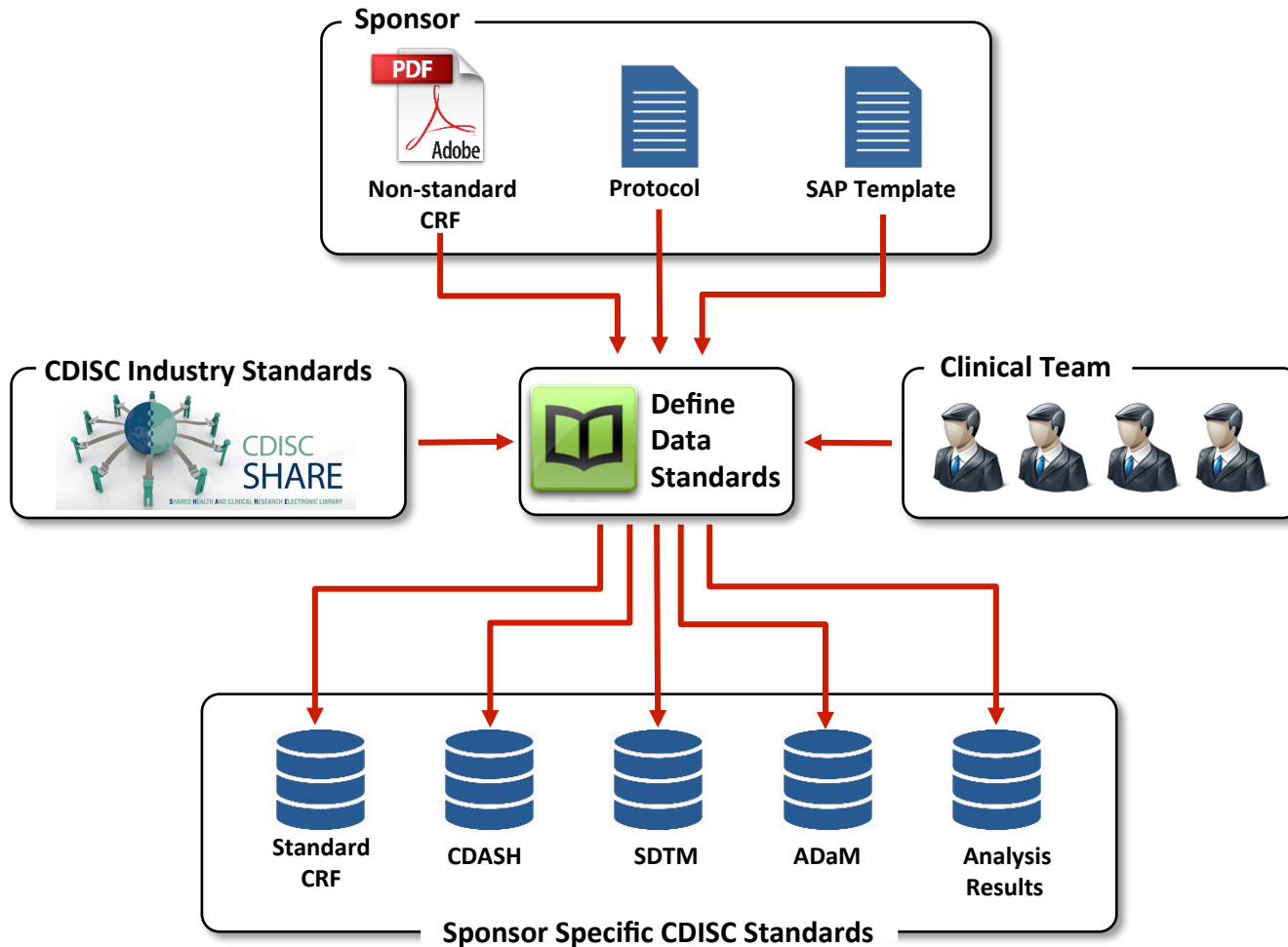
(SEP 2015)



Data Standards Governance



Library Creation Process



Data Standards Solution Overview



- An integrated solution with six components:



Data Standards
Library
Management



Study
Specification



Study
Metadata



Study
Validation



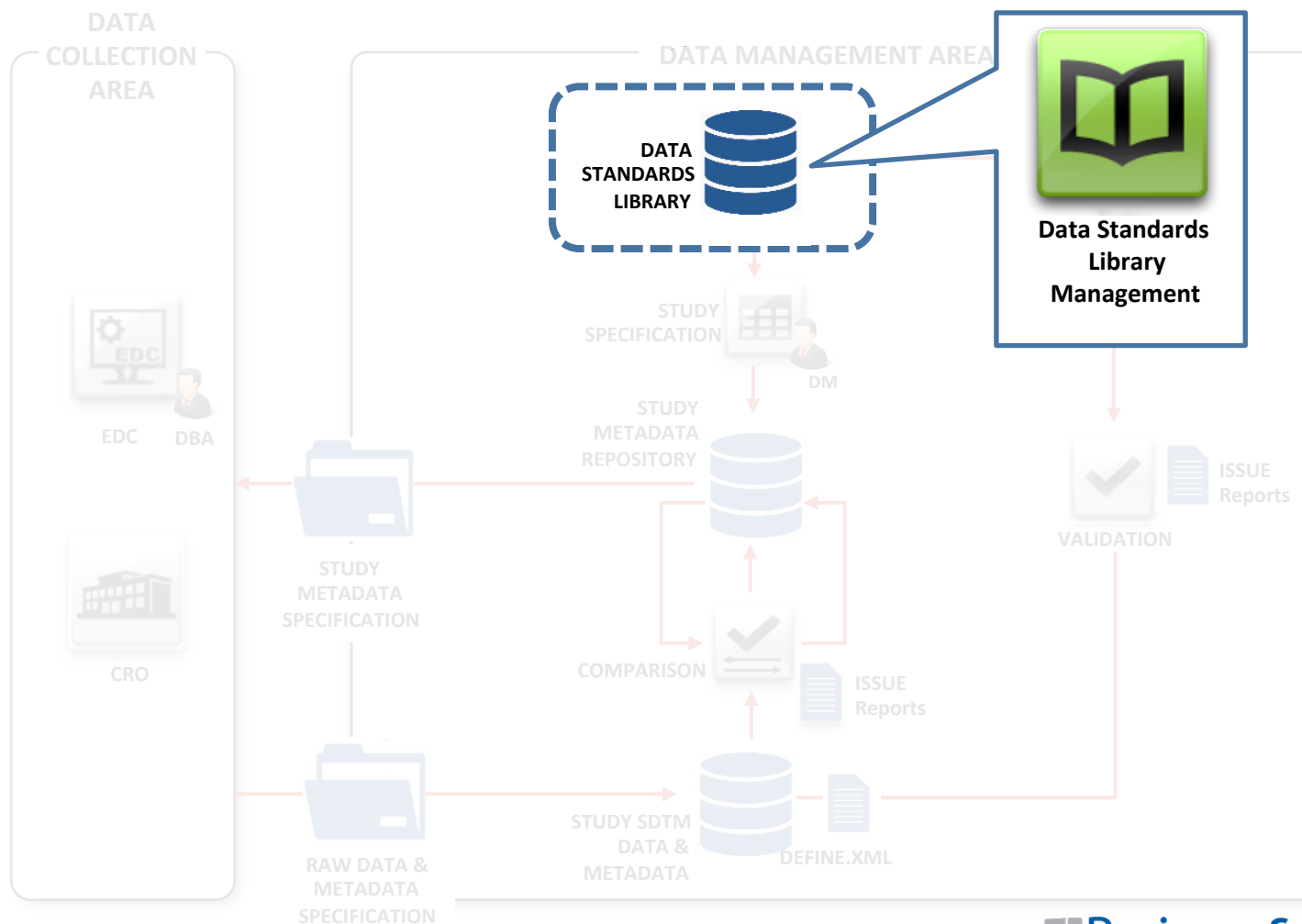
Issue
Management



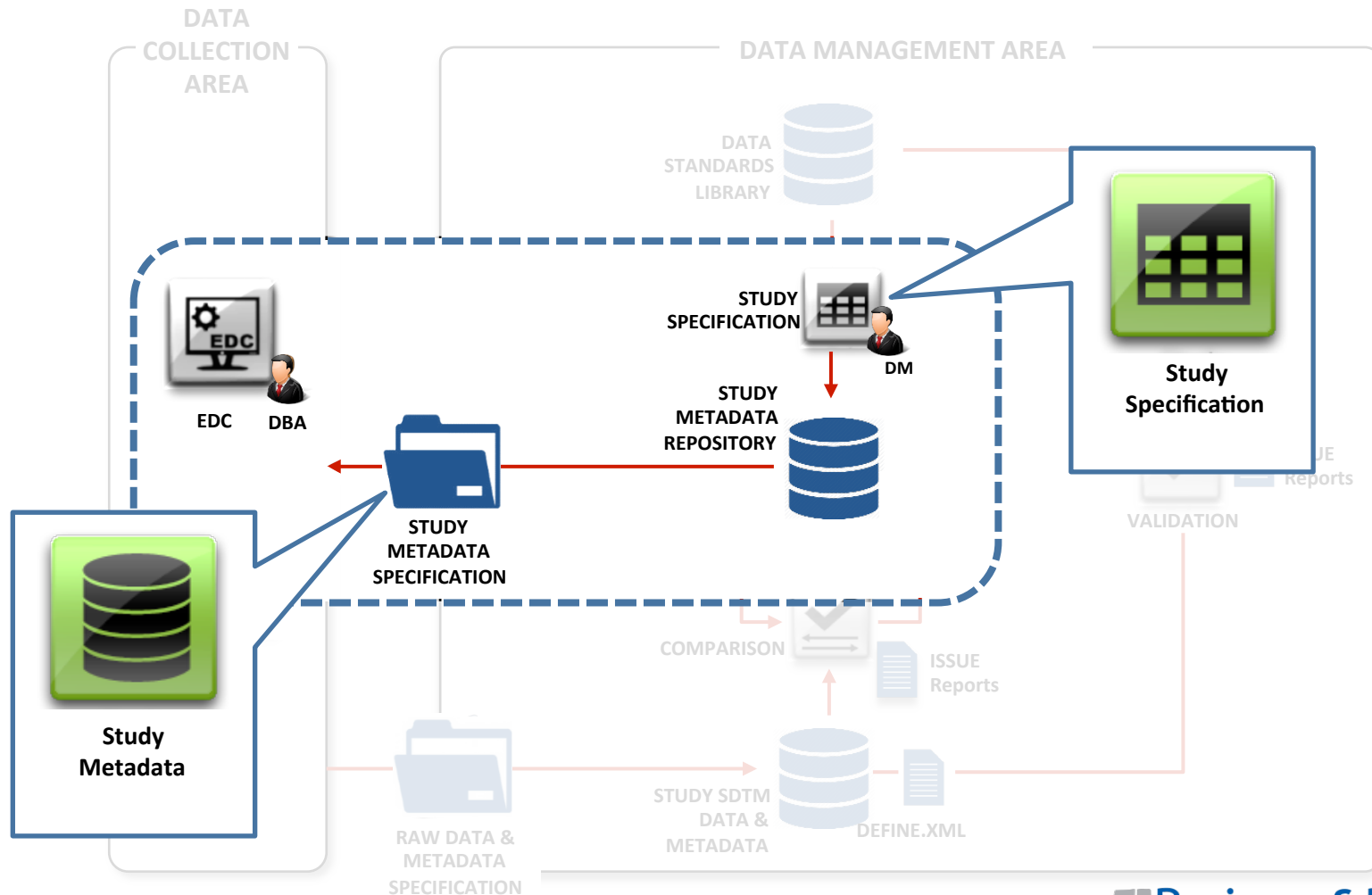
Administration



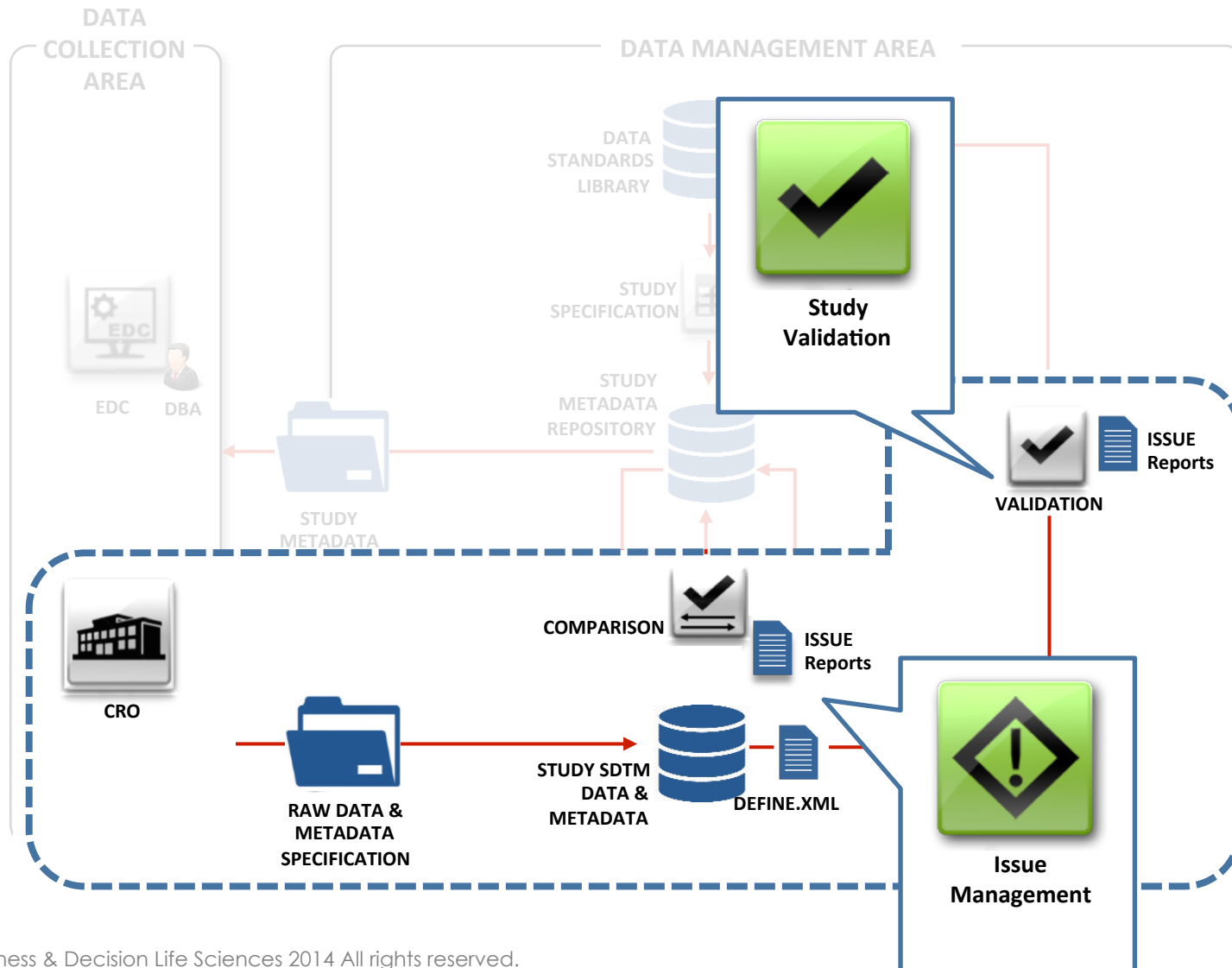
Library Management



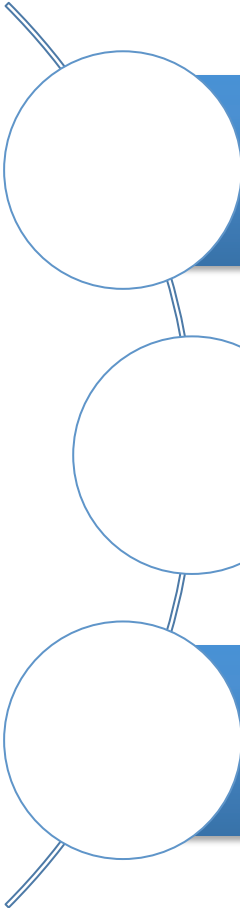
Study Specification – Study Metadata



Study Validation – Issue Management



Agenda

A diagram consisting of three white circles with blue outlines, arranged vertically and connected by thin blue lines. The top circle is slightly offset to the left, the middle one is centered, and the bottom one is slightly offset to the right.

Creation of a Data Standards Library

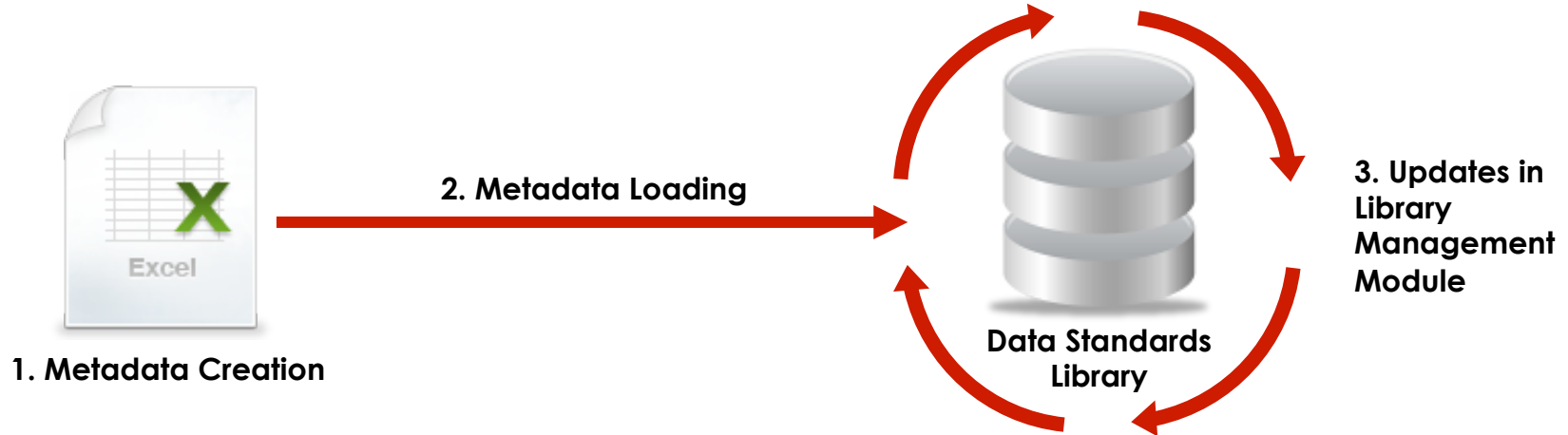
**CDISC Compliance:
Challenges & Considerations**

Conclusion

Challenges related to CDISC-Compliance



■ Three main areas



1. Creation of Metadata



■ Challenges

- Alignment of vision of different team players
- Divergent viewpoints on the requirements, priorities and understanding of standards
- Development of EDC System independent standard CRFs

1. Creation of Metadata



Considerations

- Streamlined vision
- Define objectives and processes
- Agree/Enforce DS Library design principles

2. Loading of Metadata



■ Challenges

- Although BDLS-defined validation rules are available in the Library Management (LM) module, CDISC validation rules are not available at this level
- Risk of loading non-CDISC compliant metadata into Data Standards (DS) Library

2. Loading of Metadata



■ Considerations

- Set of external QC tools to check for compliance between the metadata created and:
 - *CDISC CDASH UG*
 - *CDISC SDTM IG*
 - *Controlled Terminology*



3. Updates in Data Standards Library



Challenges

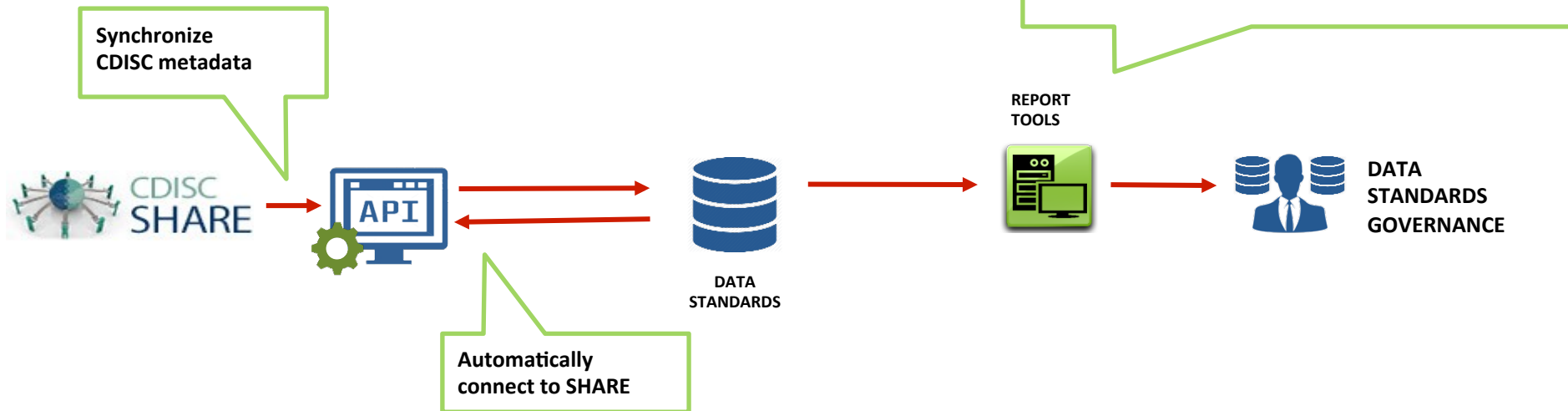
- No CDISC validation rules available at the LM module level
- Non-CDISC-compliant library objects could be created when working in the Data Standards Library in the LM Module

3. Updates in Data Standards Library

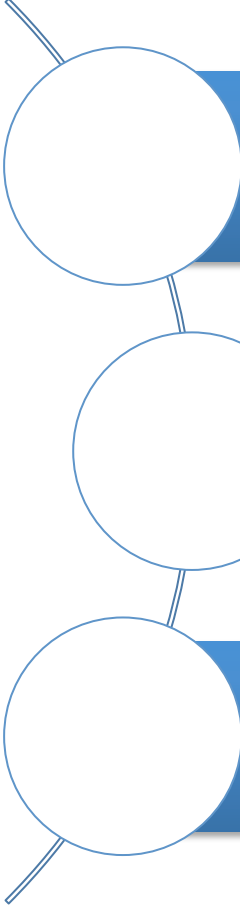


■ Considerations

- eShare API Integration
- CDISC eSHARE DS Library in LM
- Reporting Tool in LM



Agenda



Creation of a Data Standards Library

CDISC Compliance:
Challenges & Considerations

Conclusion

When creating a Data Standards Library

Alignment team vision:

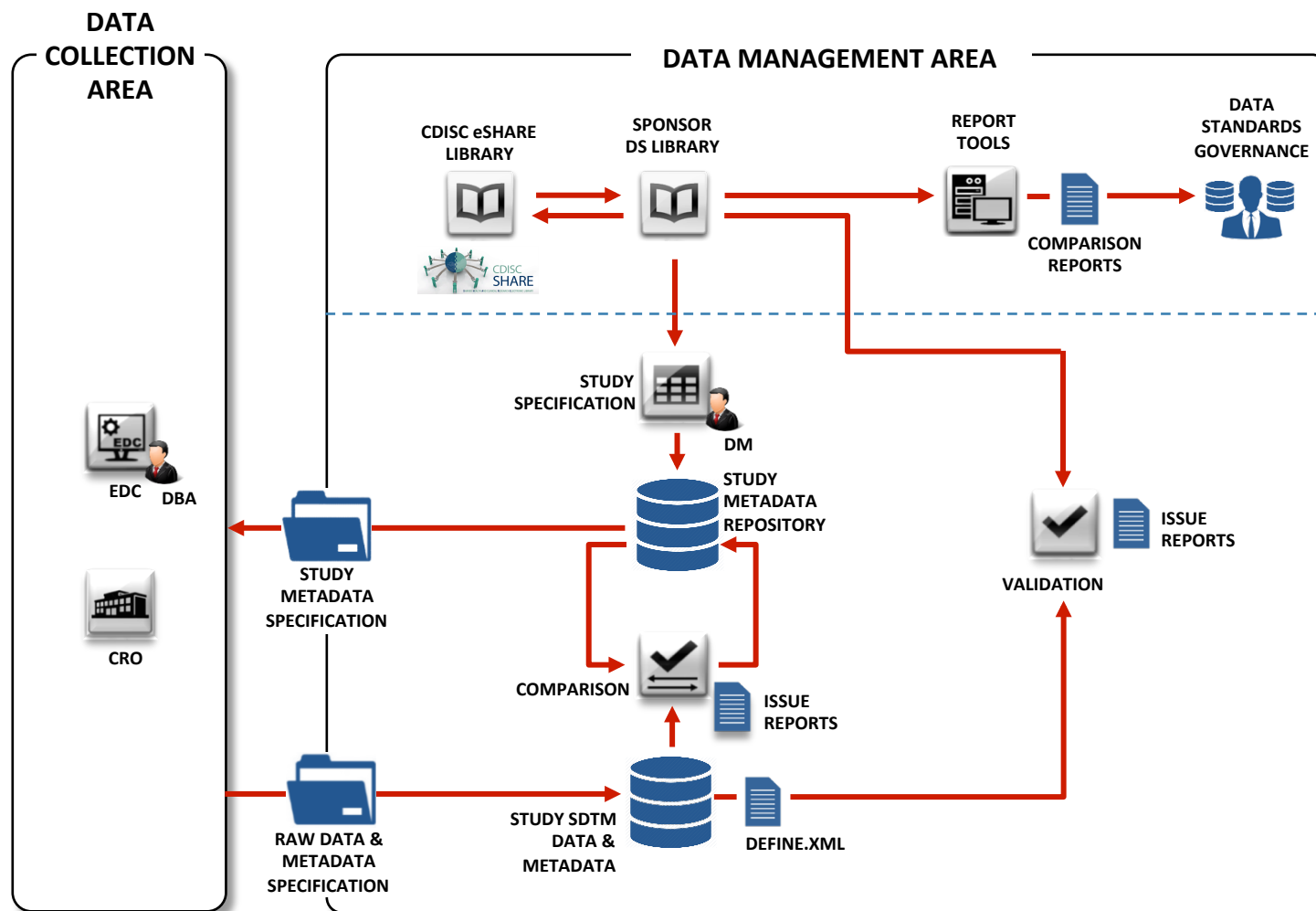
- Define objectives and processes
- Agree/Enforce DS Library design principles

Implementation of CDISC validation rules and sponsor-specific business rules

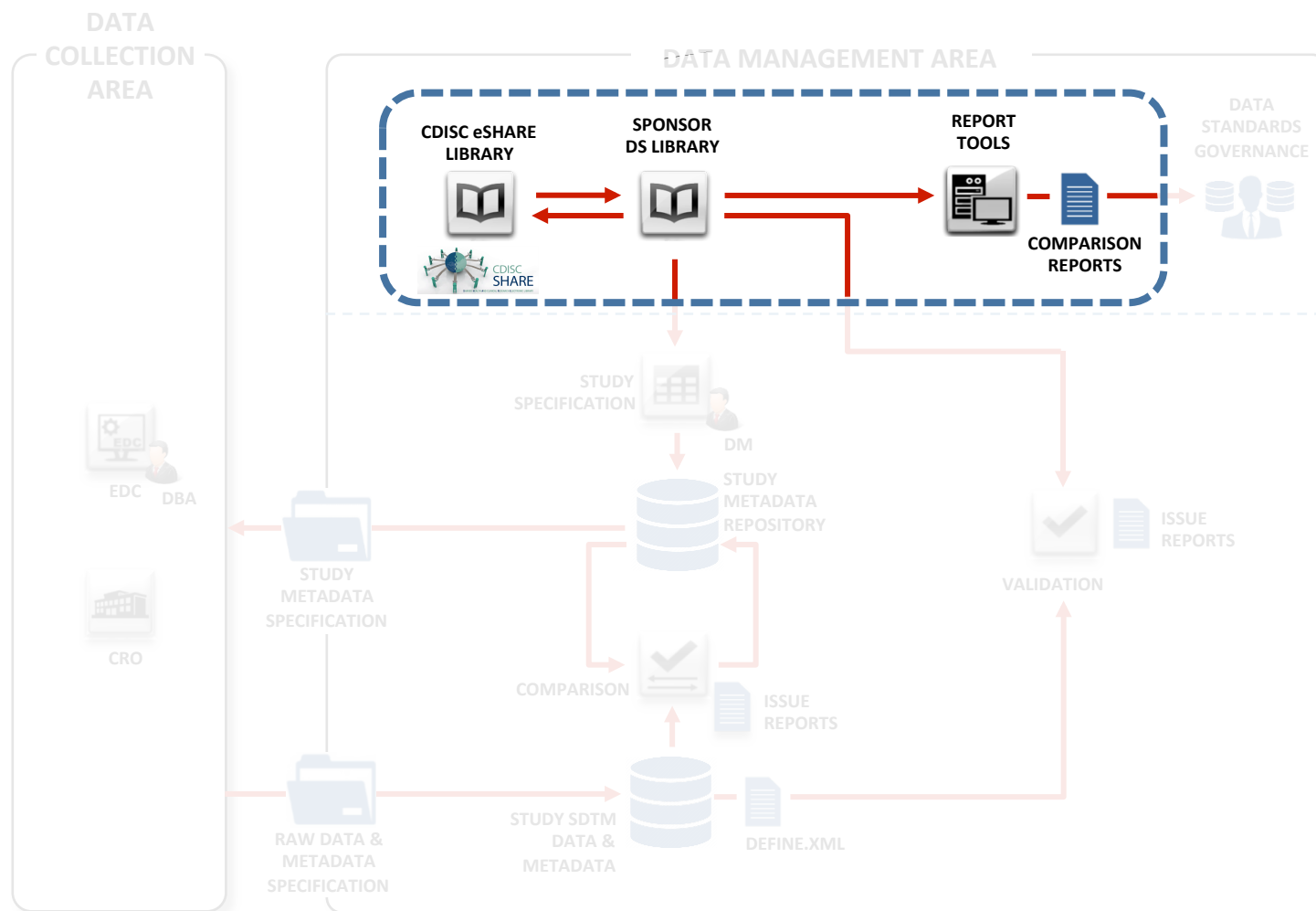
Implement a CDISC eSHARE DS Library that allows

- Promoting CDISC compliant metadata to repository
- Generating CDISC compliant study specifications
- Compare study data to sponsor-specific DS Library
- Compare study data to a specific standard version in the CDISC eSHARE DS Library

Data Standards Extended Solution



Data Standards Extended Solution



Benefits of a CDISC compliant Data Standards Library



- **Eliminate data inconsistencies, improves quality** and ensures full CDISC (CDASH/SDTM/ADaM) compliance resulting in a reference for internal stakeholders.
- Drive the streamlining of internal processes and ensures **Regulatory compliance**.
- Allow **traceability** of data, more data trustworthiness and **tighter data governance**.
- Can be **automated** by integrating in a fully automated platform, the CDISC **Data Standards Library solution** of Business and Decision Life Sciences (CDmation).
- Reduce timelines, allows fewer resources and produces '**ready for submission**' data.
- Enable control and **cooperation** with **partners** and vendors.

Thank you for your attention.
Vienna, Austria, 12 OCT 2015





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