



Clinical Metadata
A complete metadata and project management solution.
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Agenda

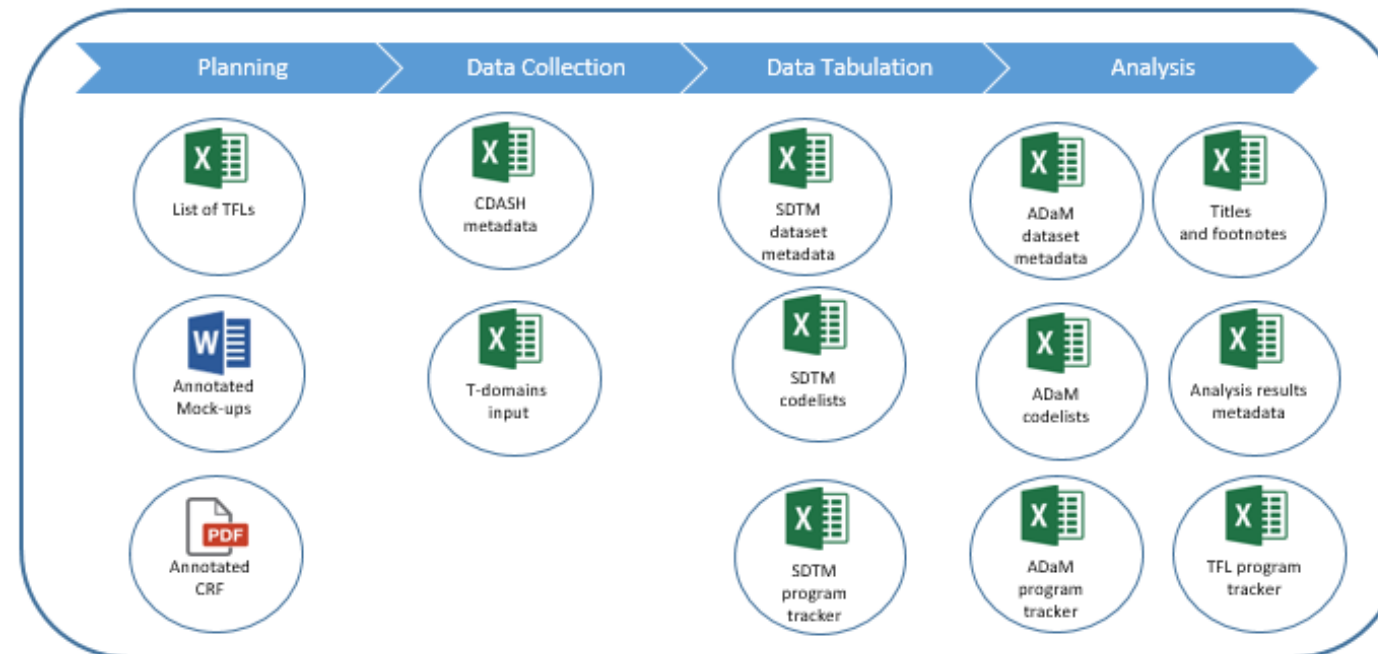
- How is metadata currently managed within the industry?
- Five key problems with current approaches.
- Introduction to the Clinical Metadata Product.
- How Clinical Metadata solves problems with existing approaches.
- Questions

Current approaches to CDISC

- CDISC formed in 1997
- Ever increasing number of foundational and therapeutic area standards.
- Conforming with CDISC standards now mandatory for submissions.
- CDISC business case describes a potential 50% reduction in analysis and reporting time (*Roswell et al 2009*)
- CDISC, data standardisation and metadata management potentially offer huge efficiency savings.
- The pharmaceutical industry has not realised these efficiencies because of inefficient systems and workflows.

Current approaches to CDISC

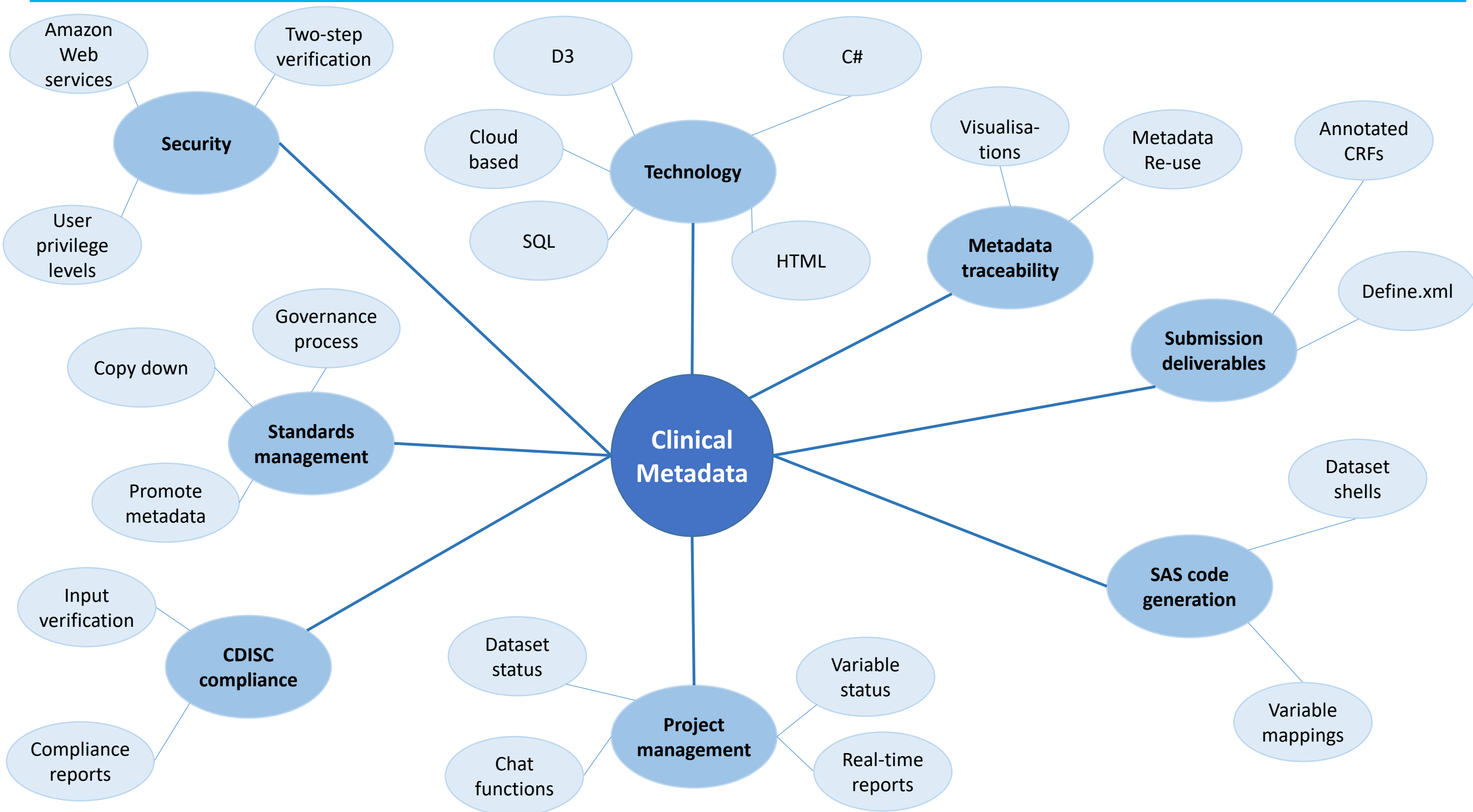
- Current implementations of CDISC consist of disconnected files.
- Consider a potential implementation of CDISC within a study.
- 12 spreadsheets, a word document and PDF.



Key problems with current approaches

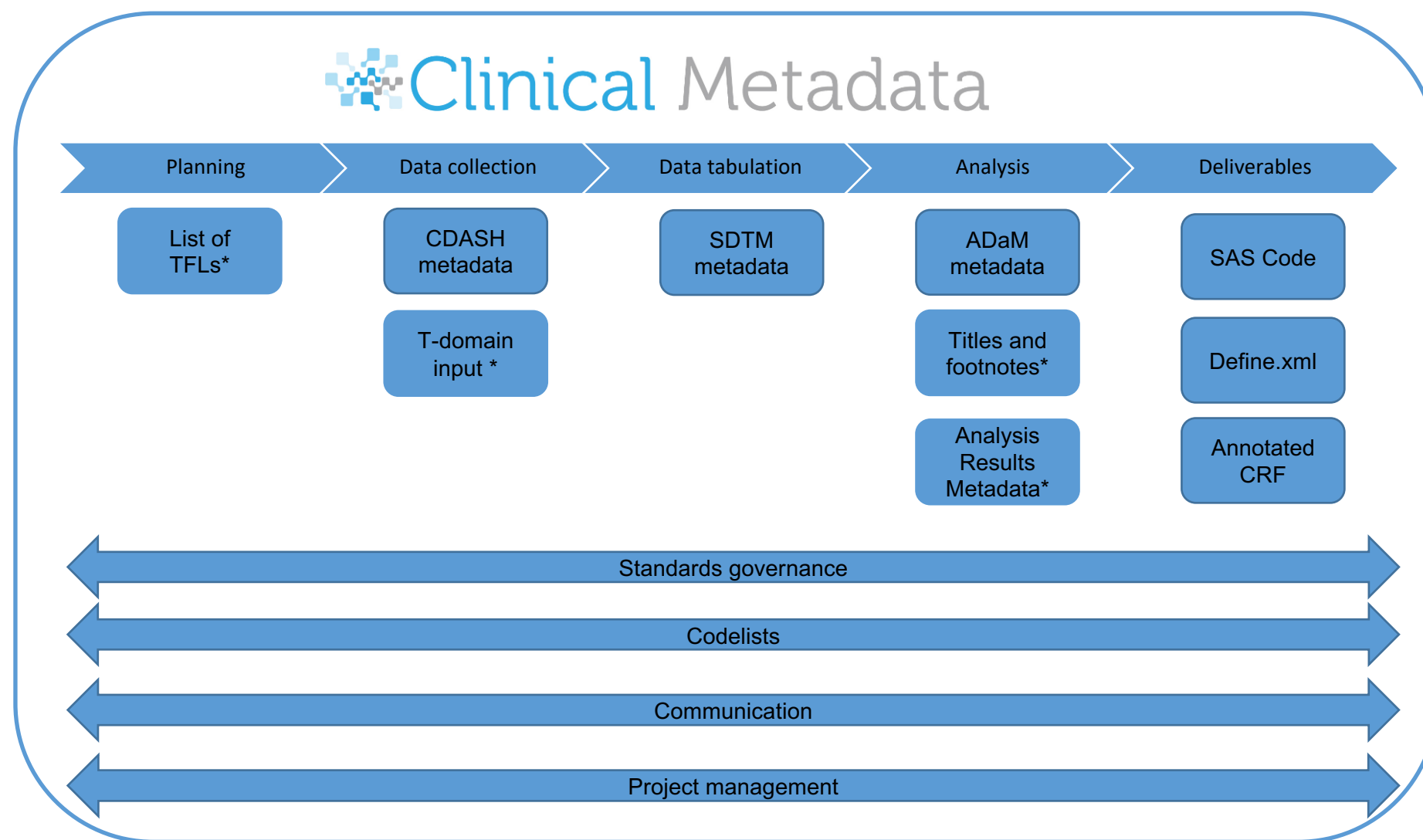
1. Study metadata consists of disconnected metadata silos.
2. Difficult to understand the relationships between metadata elements.
3. Reading and writing information directly from the metadata is complicated.
4. Difficult for multiple users to collaborate.
5. Additional tools outside system needed to manage standards and check CDISC compliance.

A metadata and project management solution



#1 No more metadata silos

- Clinical Metadata provides an end-to-end solution



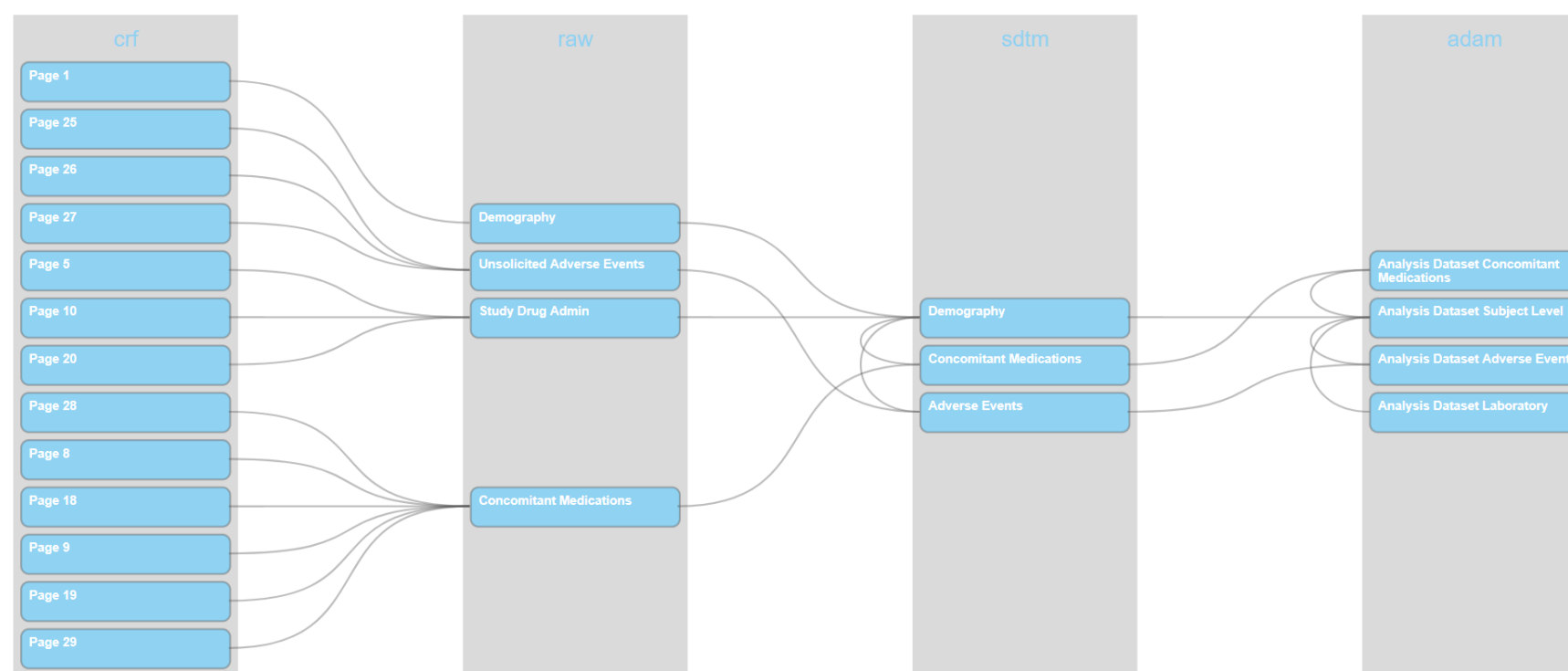
#1 No more metadata silos

- Variables are often repeated in both SDTM and ADaM
- Traditional system
 - SDTM and ADaM metadata stored in separate spreadsheets
 - Manually copy SDTM variables into ADaM
- Clinical Metadata
 - Use a point and click system to indicate that the ADaM variable is a direct copy of the SDTM variable.
 - Establish a permanent link between variables

#2 Understanding metadata relationships

- Clinical Metadata utilises the latest visualisation tools
- Traditional system:
 - Metadata exists in a series of disconnected flatfiles
 - Hard to understand the relationship between elements.
 - Important information lost within free text fields.
- Clinical Metadata:
 - Interactive visualisations explain the metadata flow.
 - Establish a permanent link between variables

#2 Understanding metadata relationships



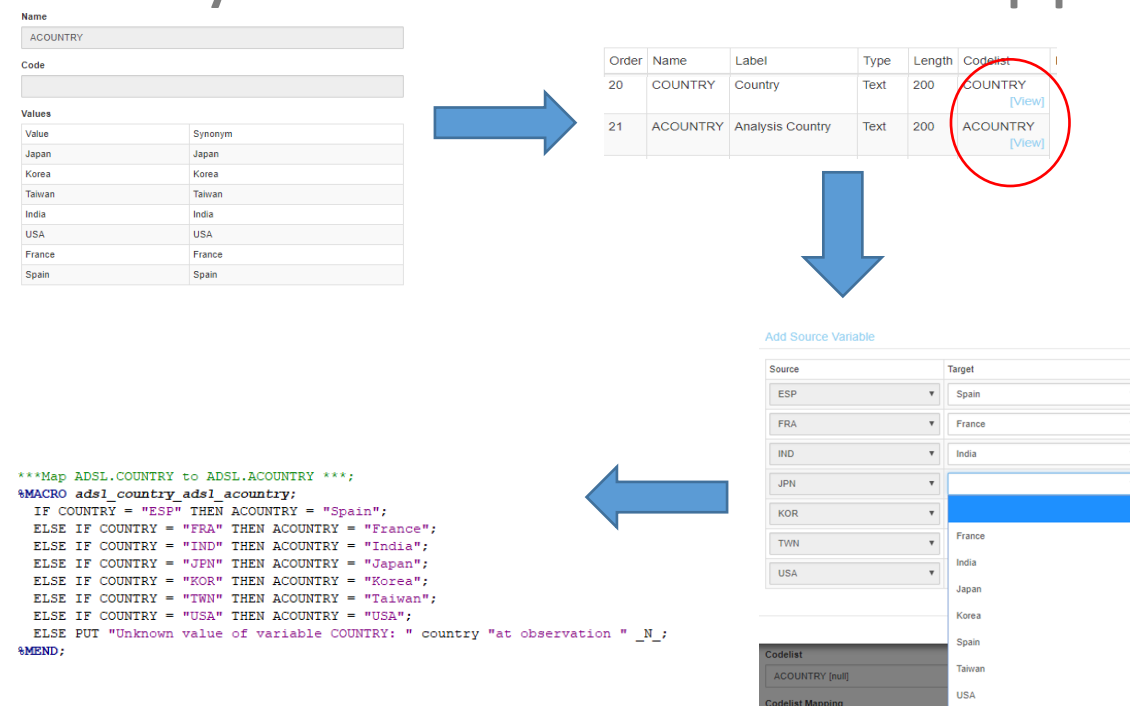
#3 Making programmatic use of metadata

- Clinical Metadata generates SAS code and submission deliverables directly from the metadata.
- Example: Map from ADSL.COUNTRY to ADSL.ACOUNTRY
- Traditional system
 1. Manually created the COUNTRY codelist
 2. Manually created the ACOUNTRY codelist
 3. Manually created the metadata for the ADSL.COUNTRY variable.
 4. Manually created the metadata for the ADSL.ACOUNTRY variable, as well as defined a pseudocode derivation rule.
 5. Manually created the SAS code required to perform the mapping.

#3 Making programmatic use of metadata

■ Clinical Metadata

1. Imports the COUNTRY variable from SDTM.DM.
2. Imports the AOUNTRY variable from a project library.
3. Creates the AOUNTRY codelist.
4. Uses a point and click system to define the mapping.



#4 Facilitating collaboration between users

- Traditional systems:
 - Information fragmented across multiple documents.
 - Users at different stages do not understand each others work.

- Clinical Metadata
 - All users always access the latest version of the specifications.
 - In-built communication tools
 - Project management utilities so that users can clearly understand the status of each stage of the project.

#4 Facilitating collaboration between users

- An example: Information exchange
- Clinical Metadata
 - Uses inbuilt chat function.
 - The status of each metadata element is captured within the system and summary level information is available for managers.

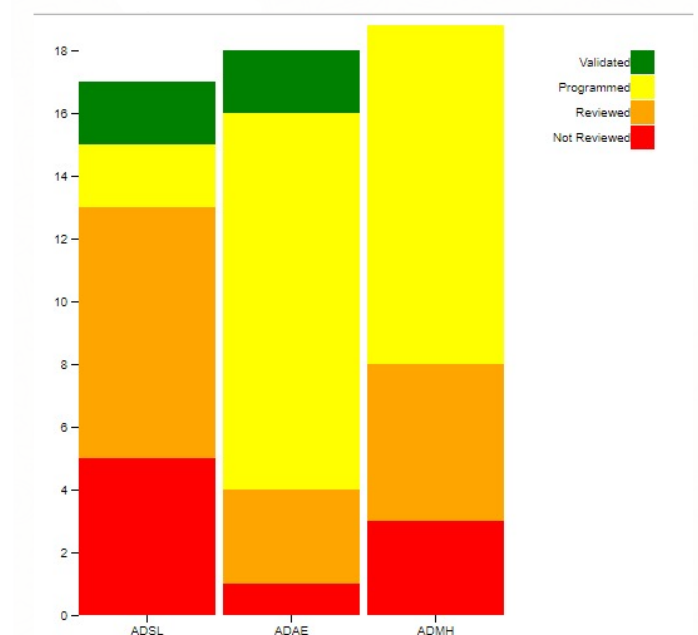
Dataset ADSL - Comments

Add Comment

Save

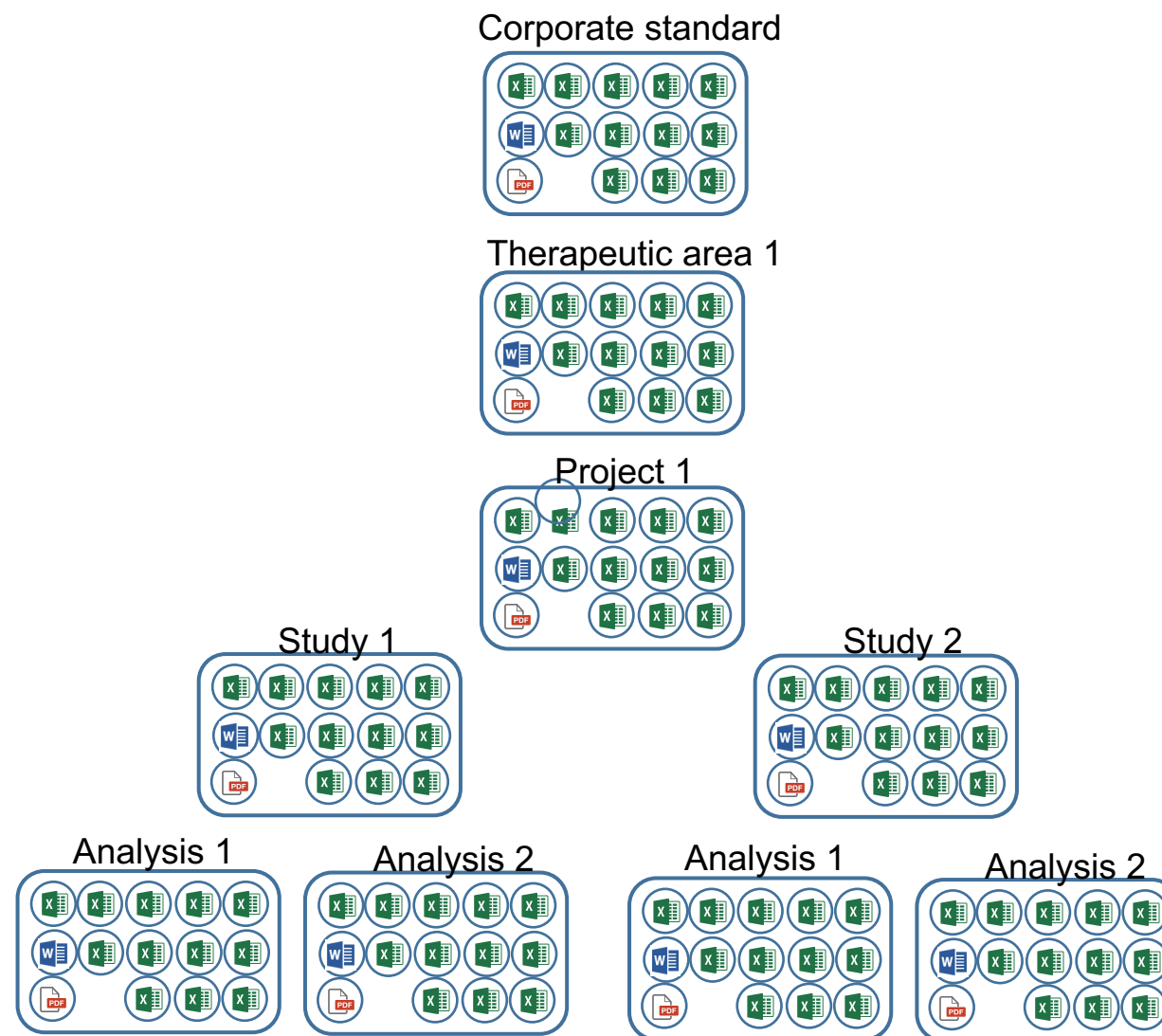
User	Comment	Timestamp	
andy	This is the final reply in this stream	21/08/17 22:56	Delete
andy	This is a reply to the first comment.	21/08/17 22:16	Delete
andy	This is a comment attached at the dataset level.	21/08/17 22:16	Delete

Close



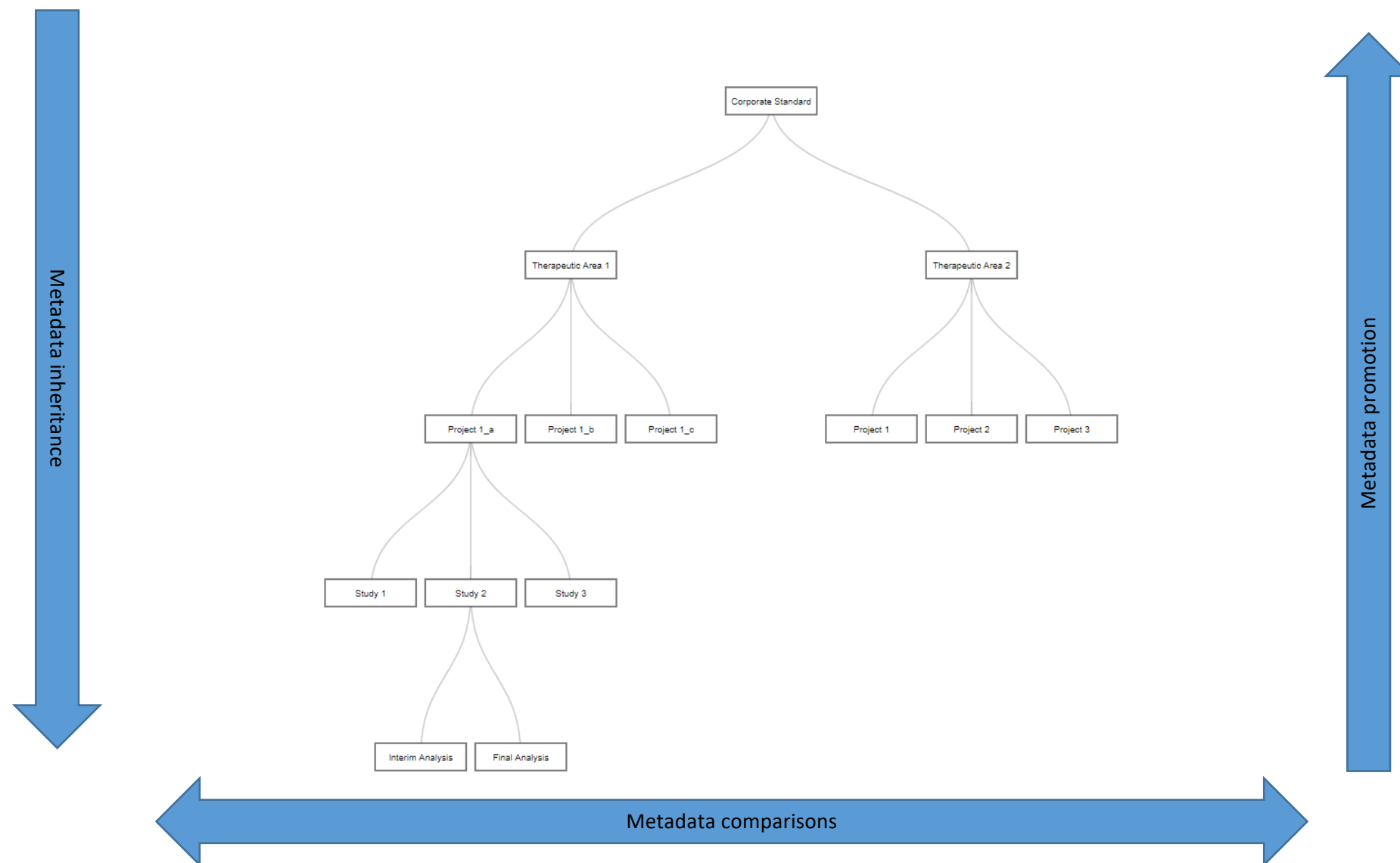
#5 Managing standards and CDISC compliance

■ Traditional systems:



#5 Managing standards and CDISC compliance

■ Clinical Metadata



Summary

- Clinical Metadata is an end-to-end metadata and project management solution.
- It uses the latest visualisation tools to help users understand their metadata.
- Metadata should be created once and re-used many times.
- Generates SAS code and submission deliverables.
- Steers users towards CDISC compliance.

Questions