
# Data Standards Governance, Challenges and MDR

Presented by Miho Hashio
Senior Director, Global Data Standards, GSK

# Meet the Speaker

## Miho Hashio

Title: Senior Director, Head of Global Data Standards

Organization: GSK

20+ years experience working for pharma industry. 10+ years experience working for Data Standards.

Global process owner, and business lead of end-to-end data standards for clinical trials at GSK.

# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

# Agenda

1. End-to-End (E2E) Data Standards Governance
2. Challenge
3. Metadata Repository/Architecture (MDR/MDA)
4. Conclusion

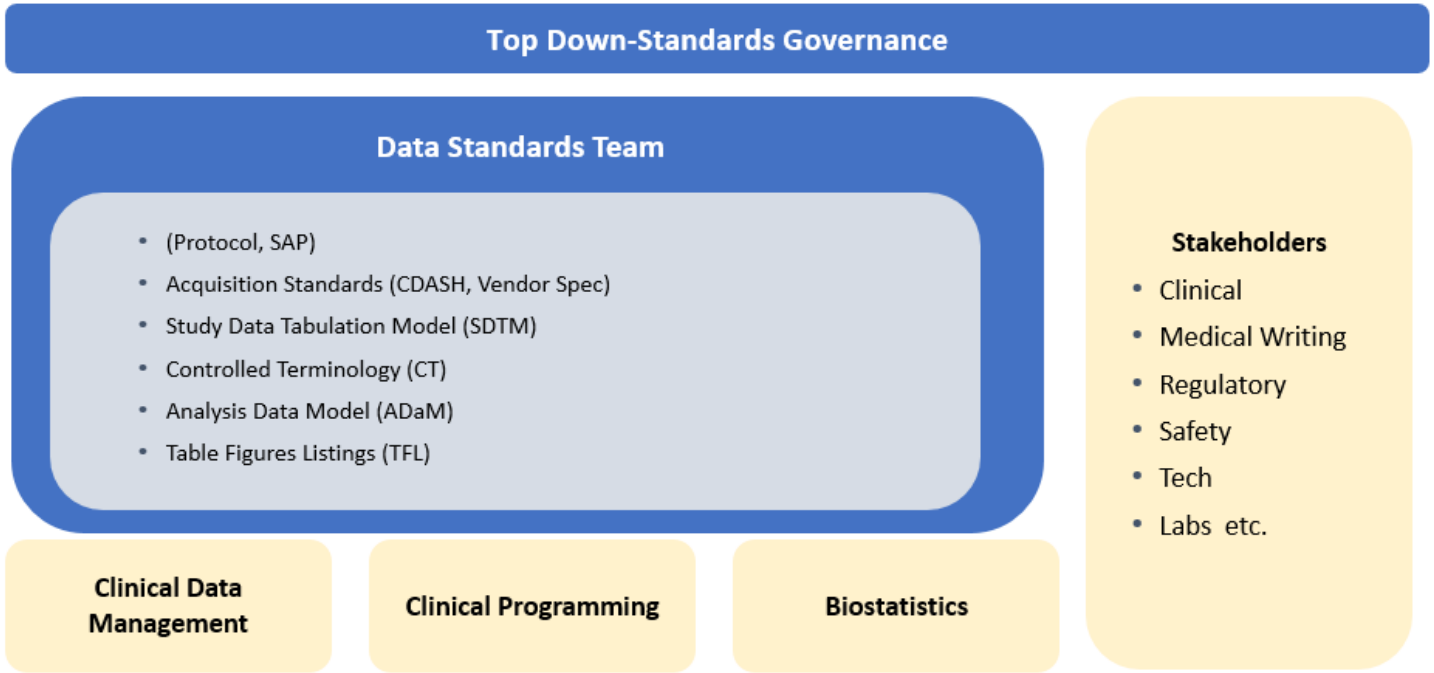
# End-to-End (E2E) Data Standards Governance

Vision and Example of Governance Model

# E2E Data Governance Vision

- Automation via E2E Metadata
- Harmonized Standards
- Commitment to Standards
- Simplify & Modernize
- Monitor Standards Impacts

# Data Standards Governance Example



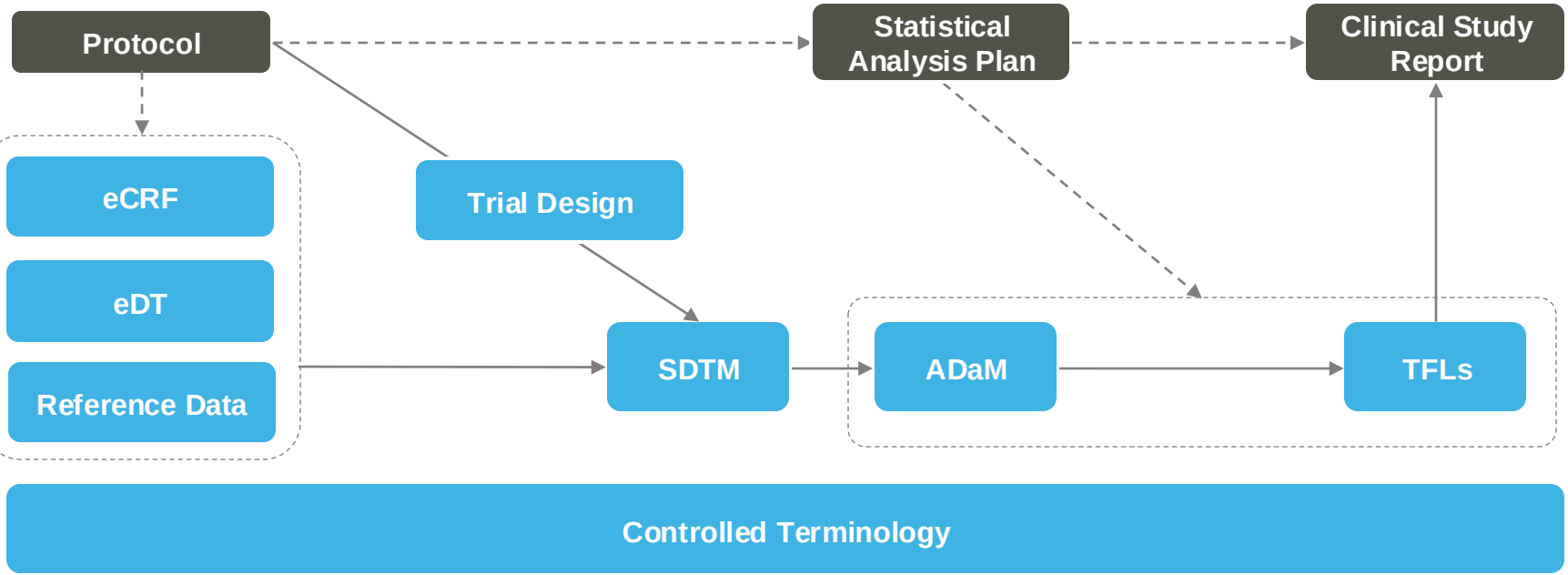
# Challenge

Current Reality of E2E Data Standards

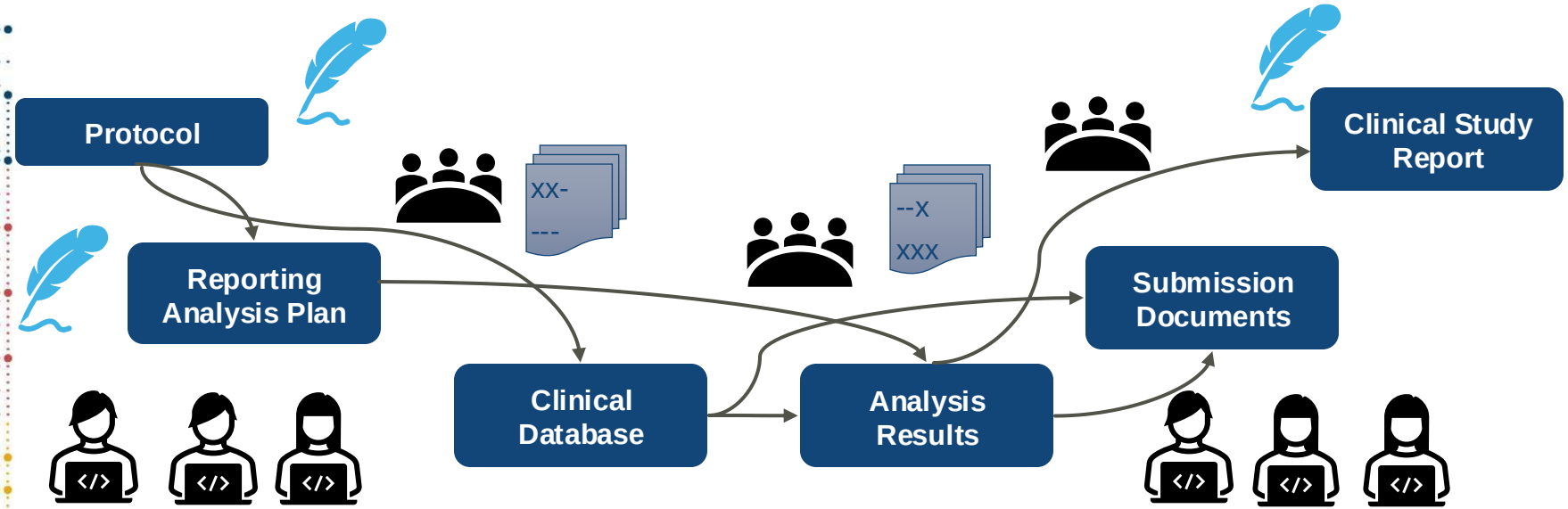
# E2E Data Governance Current Reality ?

- Automation via E2E Metadata
- Harmonized Standards
- Commitment to Standards
- Simplify & Modernize
- Monitor Standards Impacts

# Traditional Metadata for Clinical Trials



# Automation via E2E Data Standards - Current Reality




**Study build**
- Multiple translation to study spec
- Build database use standards
- Programming, code build and QC/validation steps

- Increased focus on data insights
- Respond to evolving needs
- Quick delivery

**Study execution**
- Check/review all
- Many end points/ analysis results
- Asset level integration

# Metadata Repository/Architecture (MDR/MDA)

For E2E Data Standards Metadata Driven Automation

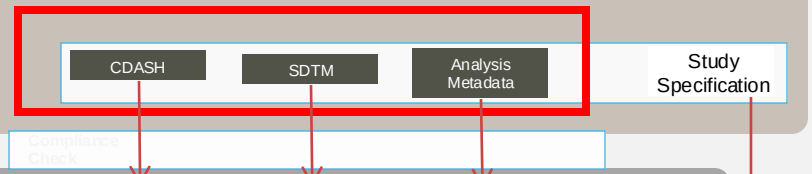
# E2E Standards Implementation in Systems as Standards and In Studies

Data Standards
"Metadata"

Standards
"Component"

**"Standards Layer"**
The Standards include the definitions of items (maintained in the MDR) and their implementation as re-usable object or component in a system.

**MDR Definition Library**:
Contains the system independent standard definitions of metadata in all data models, mappings & transformations and related information.
Resource competencies:
e2e metadata data flow, published /industry standards

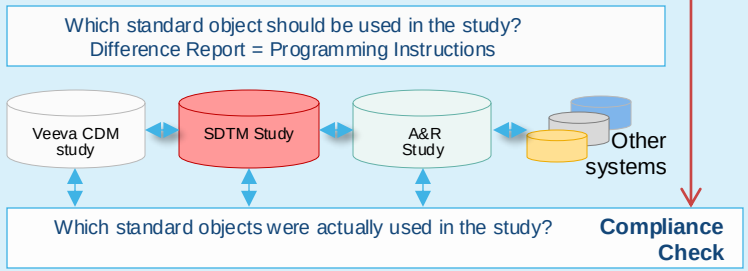



**Component Library**:
Contains the standard re-usable objects built in the respective system based on the definition provided by the MDR
Resource competencies:
system expertise, programming, spec implementation

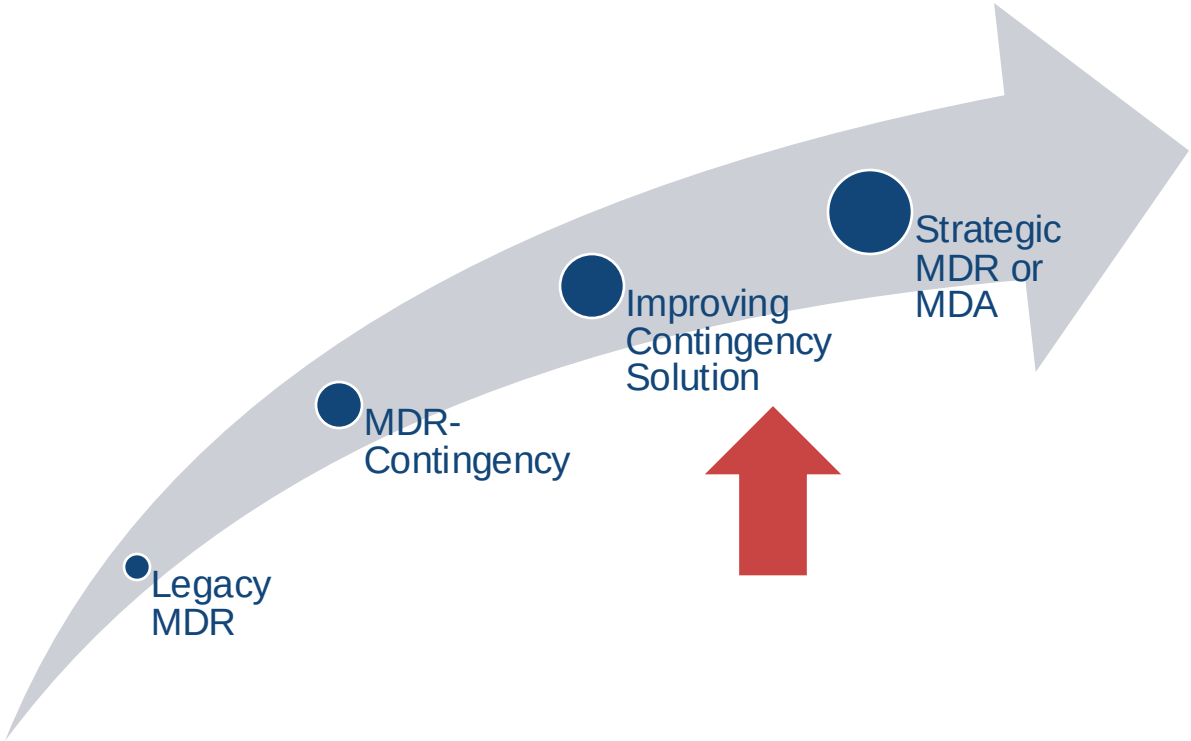
**Implementation in Study**

For an actual study, the Study Specification compiled in the MDR provides the definition of the objects to be used and thus the "pick list" for already available re-usable objects to be selected for the study.

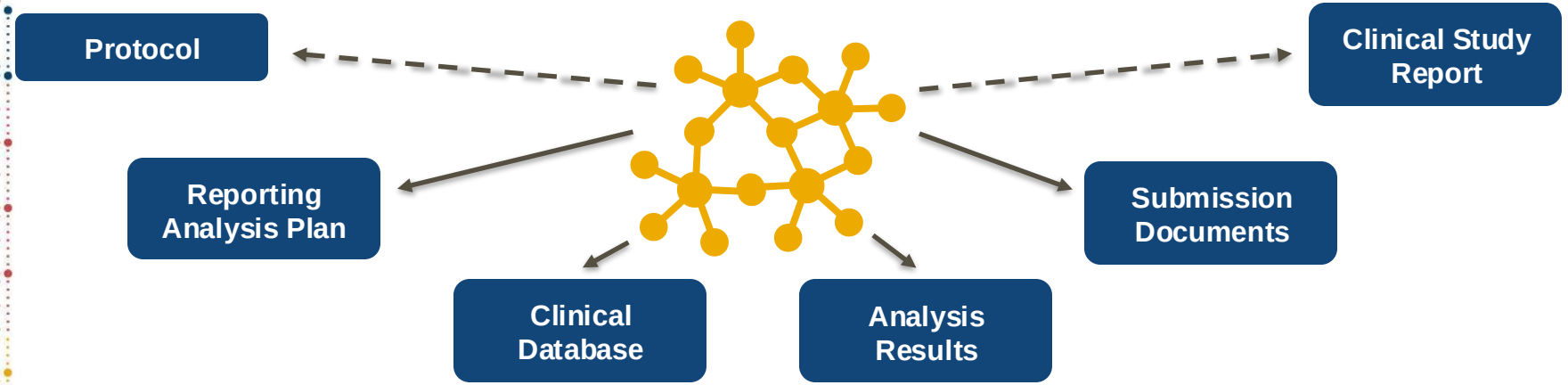
Prior to deployment of a study, a compliance check verifies that the correct objects were selected and the study complies with the specifications



# An example of MDR/MDA Journey



# Linked/Connected Standards

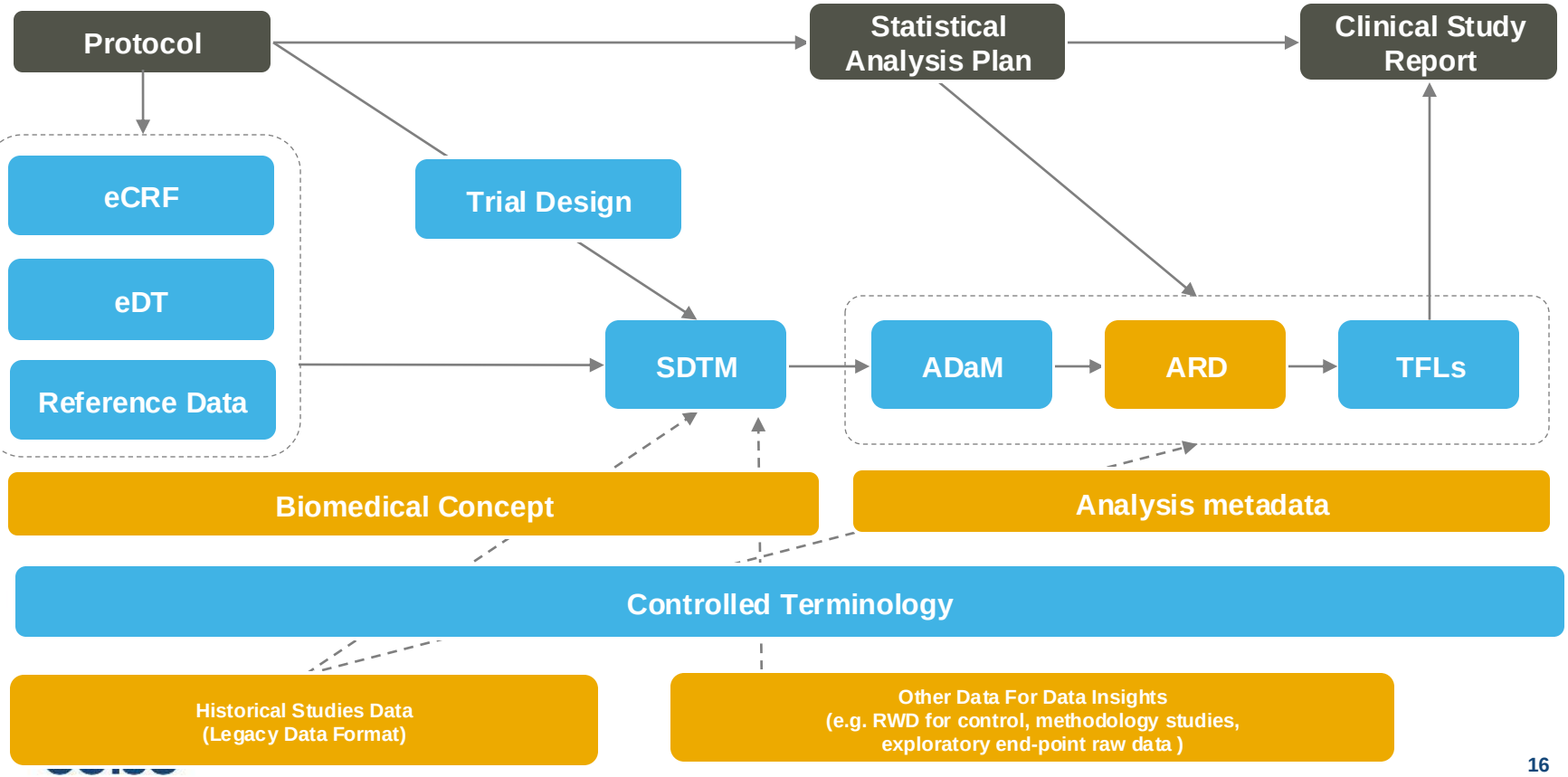



**Efficient study build**
- Fit for purpose and easy to adopt
- Proactive impact analysis
- Increased consistency

- Increased focus on data insights
- Respond to evolving needs
- Quick delivery

**Efficient study execution**
- Quality by design
- Reusable analysis results
- Simpler integration

# Linked/Connected Metadata for Clinical Trials Enable Automation & Use/Re-Use



# Conclusion

# Conclusion

- Top-down data driven governance is required to implement of E2E Data Standards efficiently
- Foundational data standards are getting matured, but evolving
- Connected standards is a game changer for metadata driven automation
- Metadata Repository/Metadata Architecture should be agile and interoperable for collaboration and adoption of new technologies
- Collaboration across the industry with embracing new technologies is key for success

# Thank You!