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AstraZeneca's Path Towards End-to-end Clinical Data Standards

Presented by Brian Harris, Standards Developer, Senior Director, Clinical Data Standards, AstraZeneca

Meet the Speaker

Brian Harris

Title: Senior Director, Standards Developer

Organization: AstraZeneca

Brian has over 25 years of industry experience, primarily working as a biostatistician and, most recently, as a standards developer for clinical data standards (supporting standards for data collection, cleaning, tabulation, analysis, and reporting). He is currently leading projects within AstraZeneca's Redefining Clinical Data Flow Initiative.

Support within the CDISC ADaM team has included participation in the following sub-teams: ADaM Conformance, ADaM Questionnaire Supplements, and ADaM Implementation Guide versions 1.2 & 1.3. From January 2022 through the end of 2023, he is serving as ADaM Team Lead.

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.*
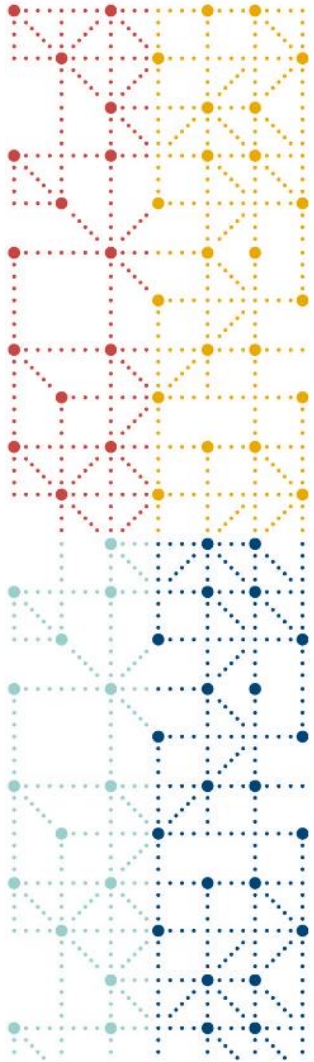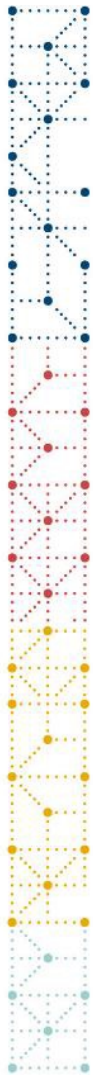
Agenda

1. Redefining Clinical Data Flow
2. Building a Foundation of End-to-end Clinical Data Standards
   - Streamlined and Robust Standards
   - Optimized Governance Process
   - "Linked" Standards Metadata Repository
3. Cross-industry Transformation
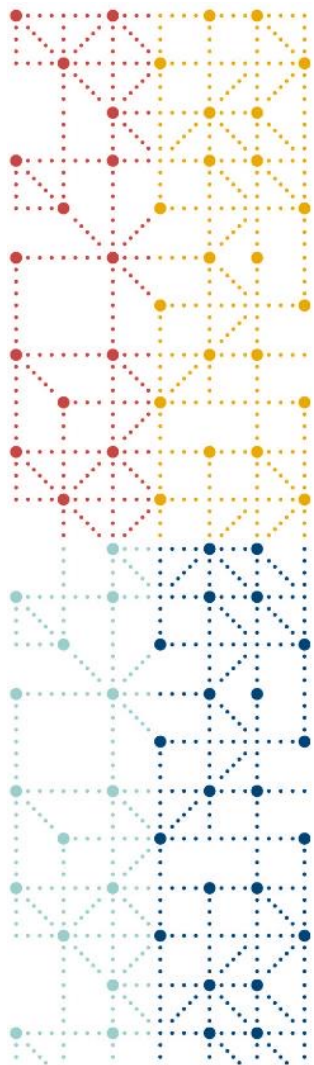
Redefining Clinical Data Flow

A Key Transformation Initiative within AstraZeneca

Redefining Clinical Data Flow

- Right-time foundational data flow – sustainable and agile
- Transformation of current approach to collection, access and management patient data
- New data sources and increasing volumes of data
- Tools and systems maximizing use of clinical data. Efficient, and effective work
- Overall goals: *simplify* ways of working, *improve* quality of deliverables, *increase* standardization and automation, *reduce time* to delivery.

End-to-end Clinical Data Standards Fit Within Our Broader Vision of Redefining Clinical Data Flow
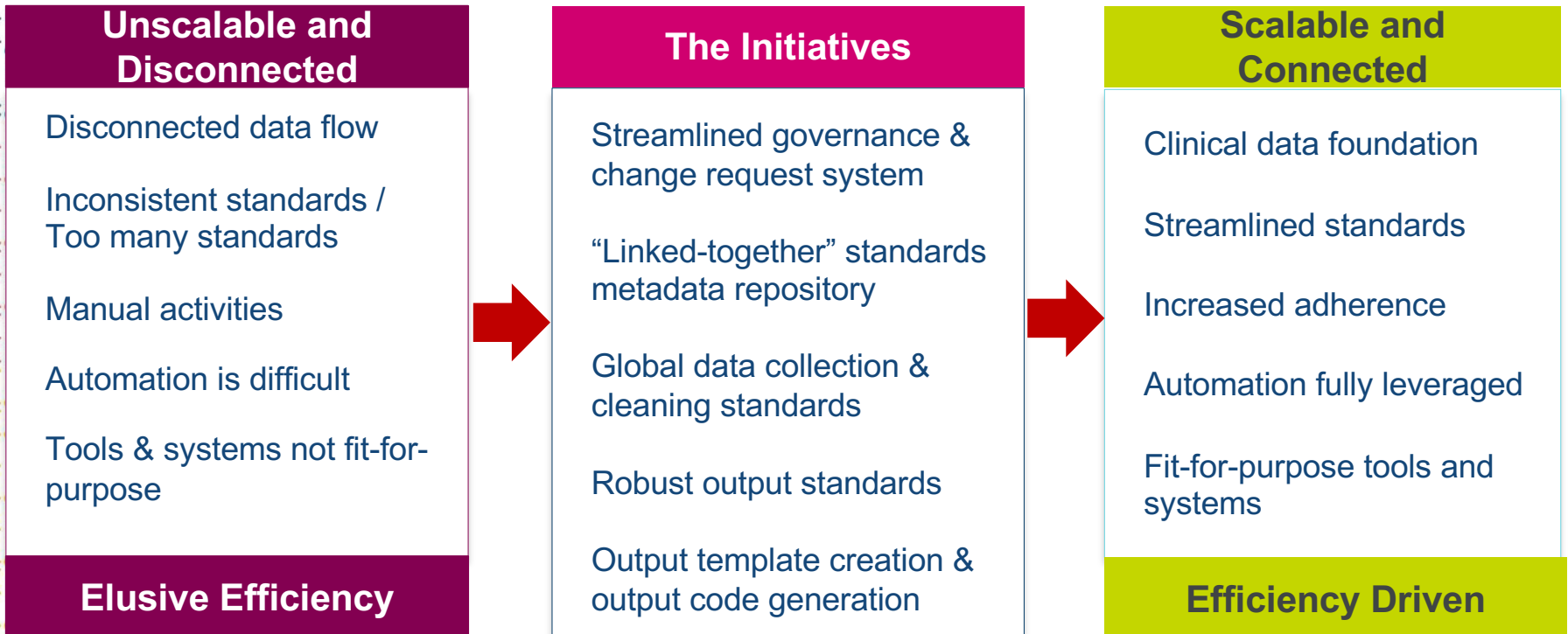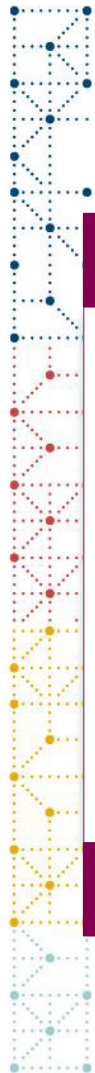
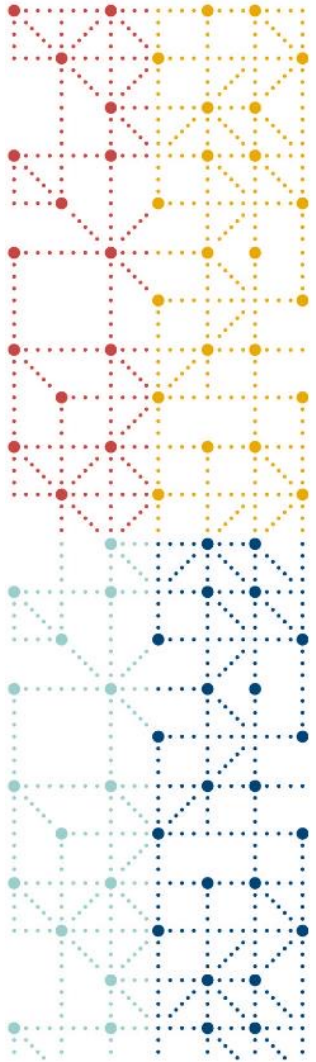**Redefining Clinical Data Flow at AstraZeneca**

Vision: Enabling efficient and quality delivery of data for primary and secondary use

Future innovations in Clinical Data Flow will be enabled by initiatives targeted to lay a foundation of a robust and agile end-to-end clinical data standards framework:

- **Facilitate automation & innovation** through a *streamlined & robust standards library* consisting of all components of clinical standards

- **Transform the standards mindset** through an *optimized governance process* and *change management program*

- **Enable a new approach to standards development,** accounting for the interconnectivity of the standards components, by putting in place a *new standards development platform and standards metadata repository*

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Creating a End-to-end Clinical Data Standards Foundation

Unscalable and Disconnected

Disconnected data flow

Inconsistent standards / Too many standards

Manual activities

Automation is difficult

Tools & systems not fit-for-purpose

Elusive Efficiency

The Initiatives

Streamlined governance & change request system

"Linked-together" standards metadata repository

Global data collection & cleaning standards

Robust output standards

Output template creation & output code generation

Scalable and Connected

Clinical data foundation

Streamlined standards

Increased adherence

Automation fully leveraged

Fit-for-purpose tools and systems

Efficiency Driven

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Streamlined and Robust Standards

Building the an end-to-end foundation

Why are Clinical Data Standards important?

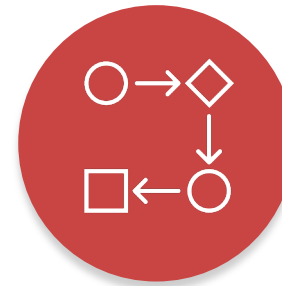**Standards enable data aggregation, traceability and reusability.**

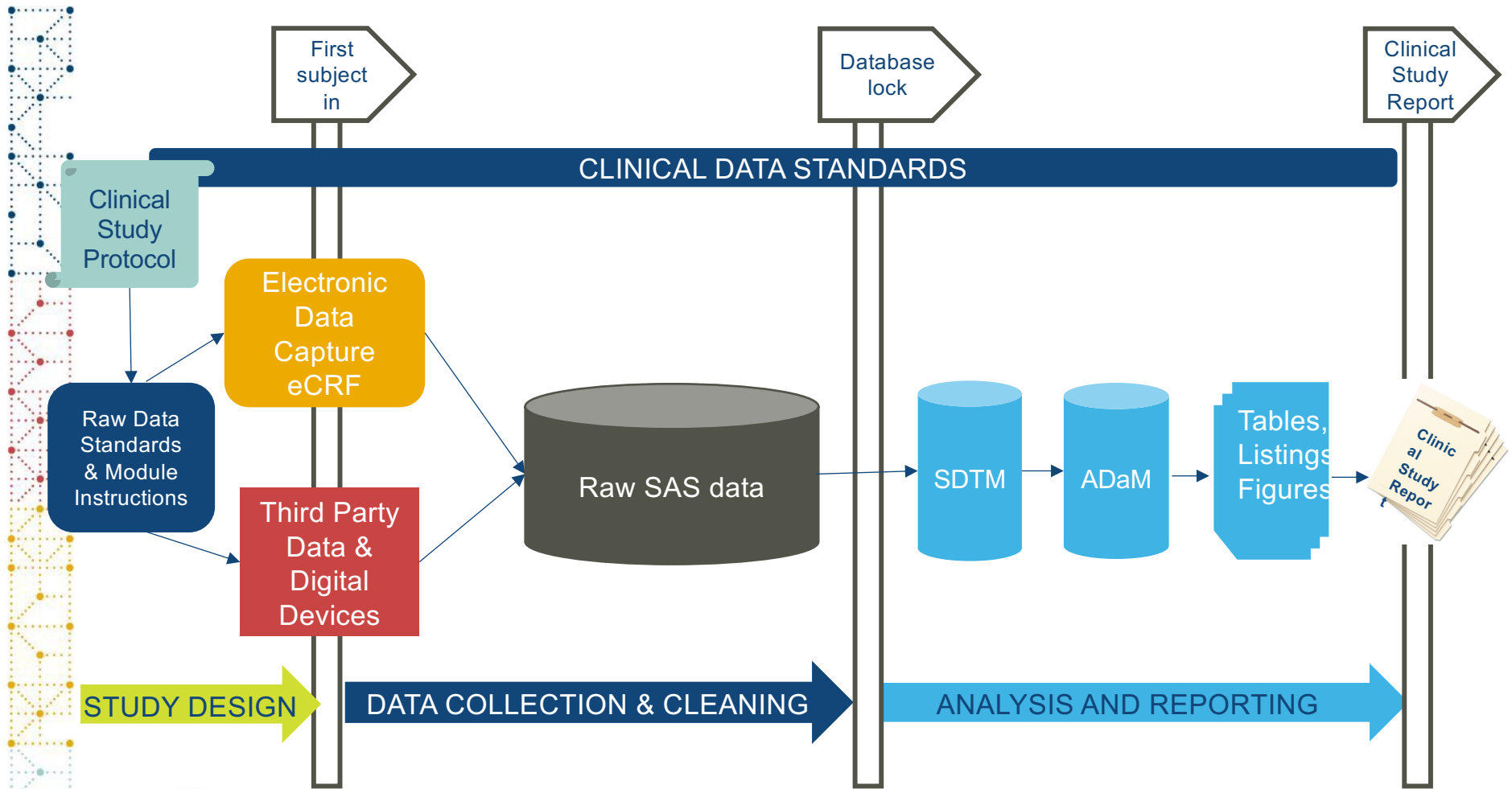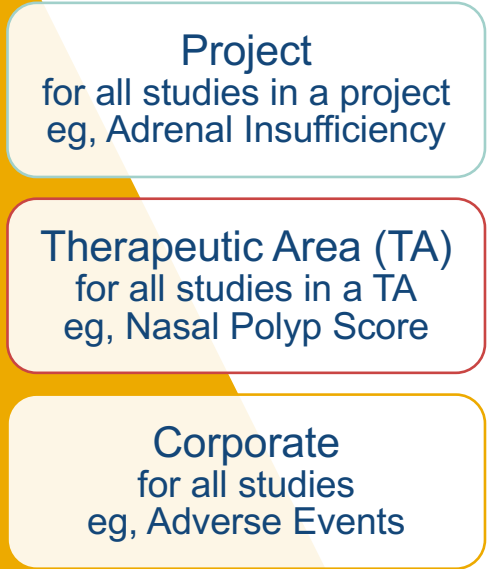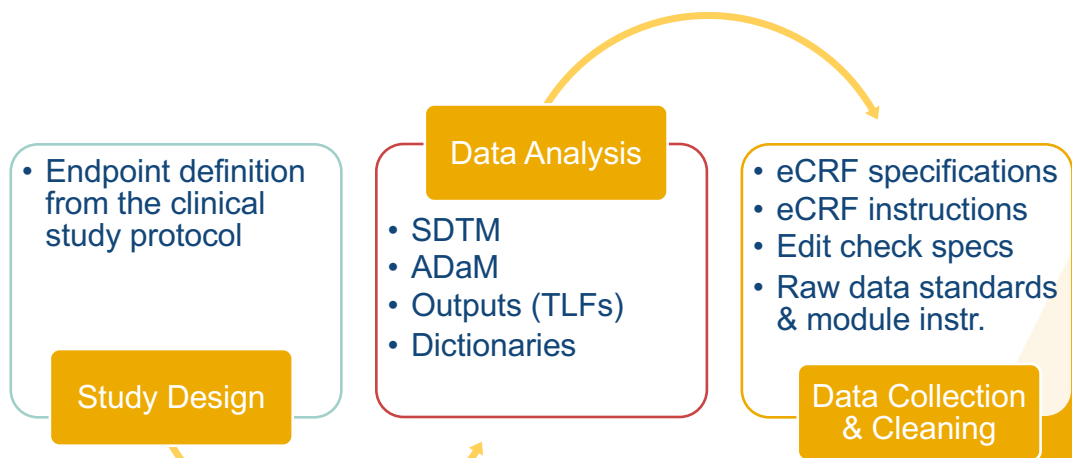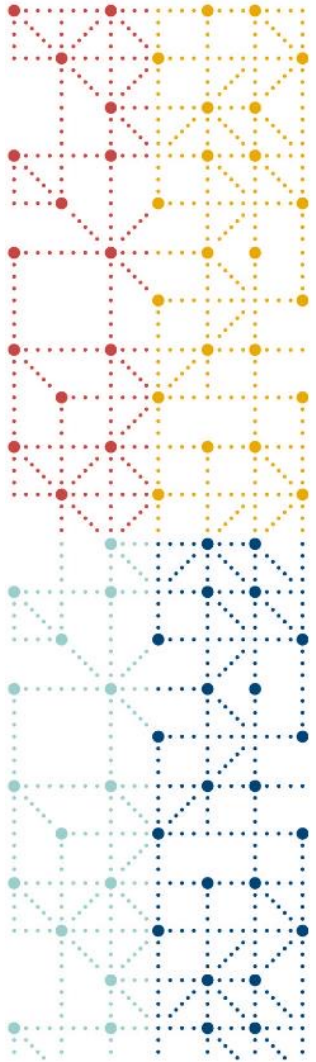| Alignment with industry and external standards | Support regulatory review | Drive process efficiency and quality enabling automation | Facilitate traceability of data across the lifecycle from collection to output | Enable data exchange and visualisation |

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CLINICAL DATA STANDARDS

First subject in

Database lock

Clinical Study Report

Clinical Study Protocol

Raw Data Standards & Module Instructions

Electronic Data Capture eCRF

Third Party Data & Digital Devices

Raw SAS data

SDTM

ADaM

Tables, Listings Figures

Clinical Study Report

STUDY DESIGN

DATA COLLECTION & CLEANING

ANALYSIS AND REPORTING

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End-to-end Clinical Data Standards

Hierarchy

- Endpoint definition from the clinical study protocol

Study Design

Data Analysis

- SDTM
- ADaM
- Outputs (TLFs)
- Dictionaries

- eCRF specifications
- eCRF instructions
- Edit check specs
- Raw data standards & module instr.

Data Collection & Cleaning

Project
for all studies in a project
eg, Adrenal Insufficiency

Therapeutic Area (TA)
for all studies in a TA
eg, Nasal Polyp Score

Corporate
for all studies
eg, Adverse Events

Golden thread

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Optimized Standards Governance

Strengthening the foundation

What are the benefits of Data Standards Governance?

Maintain the integrity of the standards, to ensure re-usability of data and facilitate automation

Ensure adherence to AZ standards principles and industry standards, when changes are requested

Ensure only essential data are collected and reported to minimise the burden on patients, sites and study teams
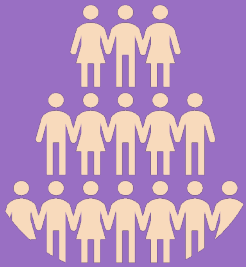
Provide expertise in use of standards, and offer alternative solutions rather than revising standards

Promote adoption of standards versus adapting, assisting automation; adopt versus adapt

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Optimisation of Governance Process

Scope:
All parts of the organization use the same standards framework & governance process
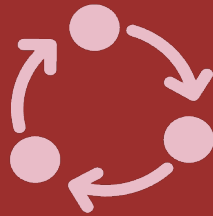
End to end approach:
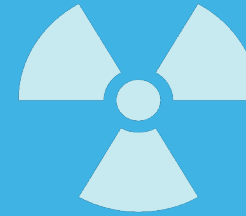All components impacted by a change should be considered and evaluated

Alignment:
Responsibilities aligned with most appropriate skill set (raw data standards prototype developed by data management)

Remove duplication:
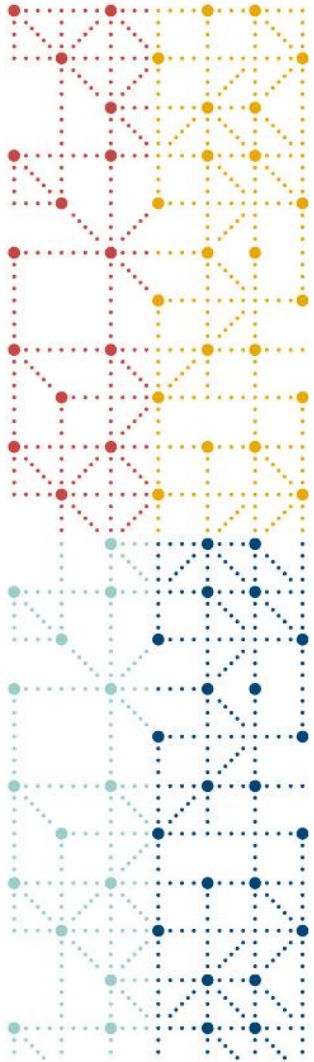Two step review process removed for corporate standard change requests

Risk based approach:
Reduced review for change requests with limited application

Maintenance of standards:
Maintenance led by central team, improvements led by subject matter experts

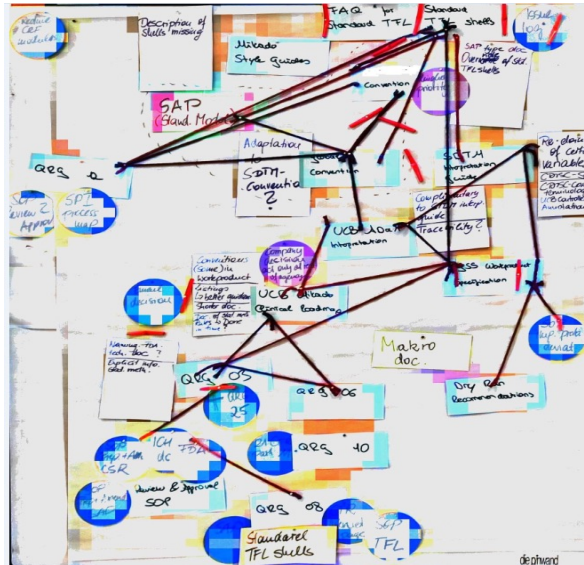One unified system to submit change requests to the governance teams

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Linked Standards Metadata Repository

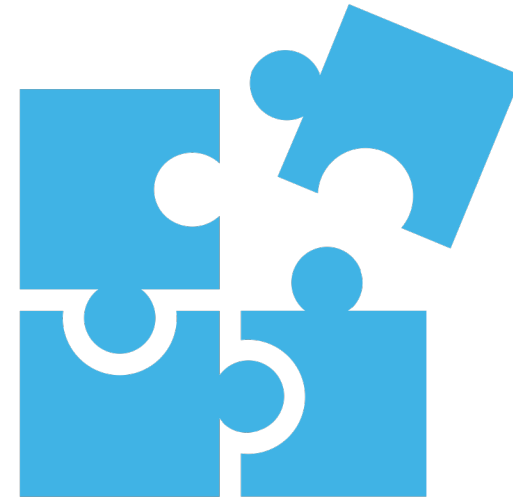Maintaining the foundation

# Linked Data Standards Enable Simplicity & Traceability

From

To

Planned improvements - Metadata Repository (MDR)

The purpose of the Standards Platform is to create, maintain, promote, and retire Clinical Data Standards for AZ sponsored Clinical Studies as well as be used to facilitate the clinical standards-based study setup in the EDC (data collection), A&R (analysis and reporting) and other downstream systems.
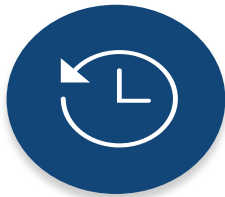
Reduce timelines for end-to-end metadata management

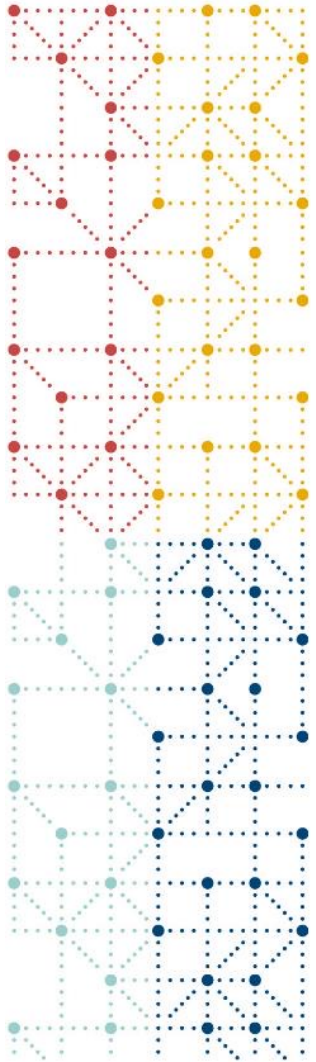Improve quality of deliverables by reducing manual updates & providing automated checks

User friendly system allowing a broader user base

Provides metadata for Master Data repository in AZ

Enables machine readable standards for study delivery and reuse for science

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Cross Industry Transformation

End-to-end Standards connection to Automation

Essential to our ambition of achieving continuous data flow

#DataStandardsEasierLife

Data Standards progress at AstraZeneca

- ➢ Alignment of AZ data Standards to industry standards
- ➢ One of the leading Pharma companies in adoption and use of industry standards
- ➢ Enabling first time right regulatory submissions
- ➢ Influencing direction of industry data standards
- ➢ Enabling data re-use

E2E standards are foundational to automation to simplify & achieve efficient data flow

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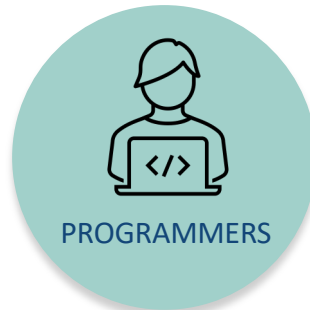# Benefactors of Robust End-to-end Clinical Data Standards

Data Managers

STATISTICIANS

MEDICAL COMMS, CLINICAL SCIENTISTS, CLINICIANS

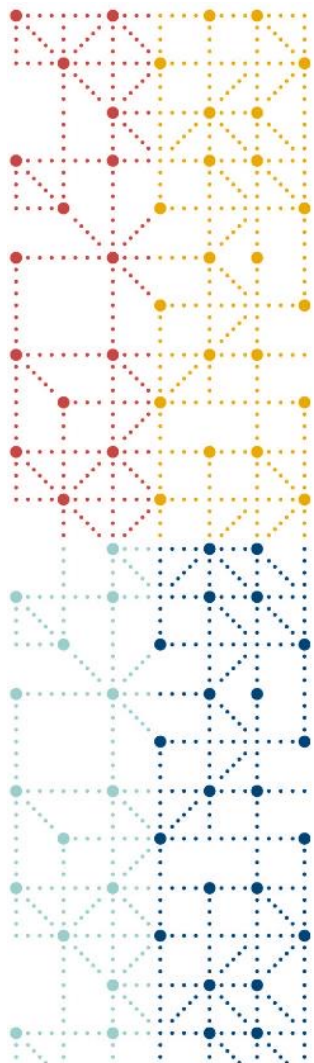ALLIANCE MANAGERS (& SUPPLIERS)

PROGRAMMERS

(PATIENT SAFETY) PHYSICIANS

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Thank You!