



# Clinical Data Standards and Production of SDTMs. Are We Missing Important Points?

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PHUSE EU Connect 2022 – DS05  
2022-11-15



# What is needed for SDTM automation?



# Why are Clinical Data Standards important in AZ?

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



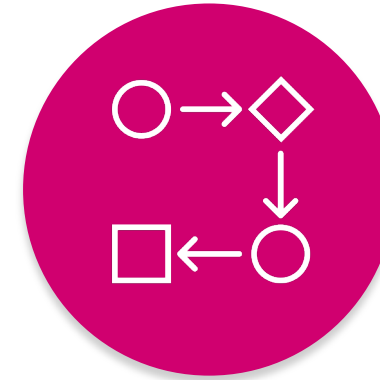
Alignment with  
industry and external  
standards



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



# Data Standards are essential to our ambition of achieving continuous data flow

## Data Standards progress at AstraZeneca

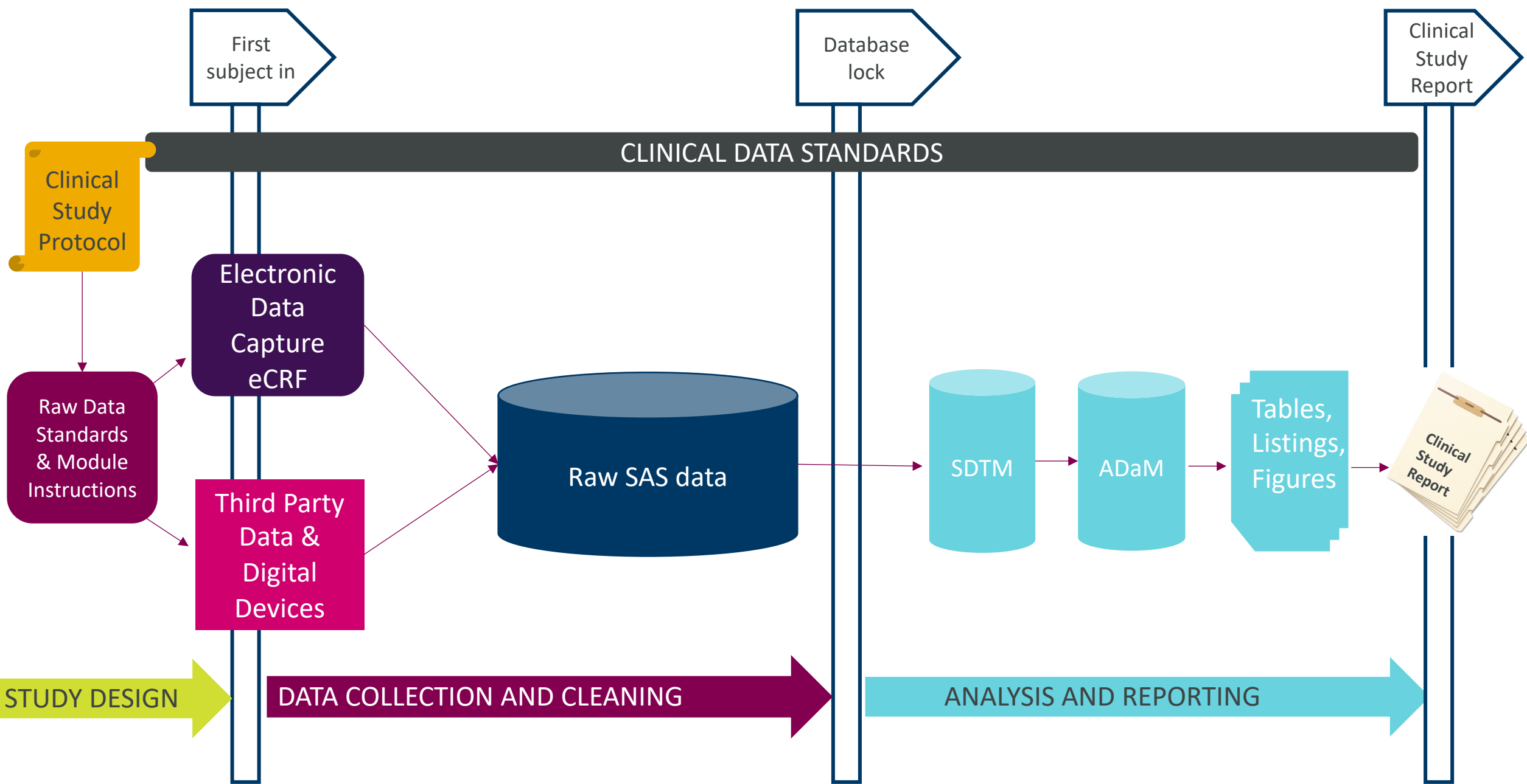
- Alignment of AZ Data Standards to industry standards
- Enabling first time right regulatory submissions
- Influencing direction of industry data standards
- Enabling data re-use

#DataStandardsEasierLife



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





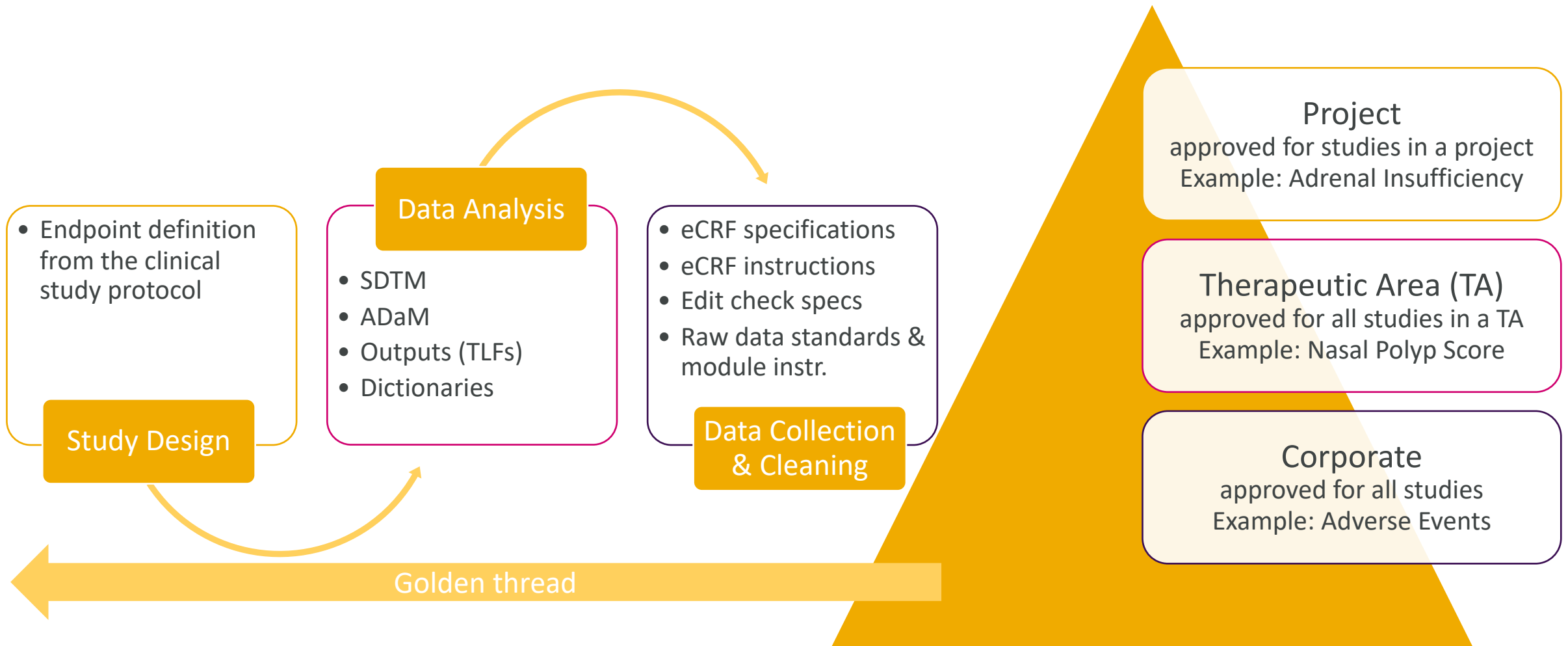
# RAW to SDTM mapping specification

- Mapping specification from RDS to SDTM for corporate and TA standards
- Also available Project specifications in separate files
- Defined structure and mapping elements included in specification enables automation
- Follows CDISC SDTM standards

| Source  |         |                   |                                                       |                                                       | SDTM    |          |                                     |      |
|---------|---------|-------------------|-------------------------------------------------------|-------------------------------------------------------|---------|----------|-------------------------------------|------|
| Library | Dataset | Variable          | Label                                                 | Map Definition                                        | Dataset | Variable | Label                               | Core |
| RAW     | AE      | STUDY             | Study Code                                            | Assign STUDYID from STUDY                             | AE      | STUDYID  | Study Identifier                    | Req  |
| RAW     | AE      |                   |                                                       | Assign DOMAIN with 'AE'                               | AE      | DOMAIN   | Domain Abbreviation                 | Req  |
| RAW     | AE      | STUDY<br>SUBJECT  | Study Code<br>Enrolment Code                          | Concatenate parts STUDY, '/', SUBJECT                 | AE      | USUBJID  | Unique Subject Identifier           | Req  |
| RAW     | AE      | AENO              | AE Number                                             | Assign AESPID with 'AE-'    strip(put(AENO, best.))   | AE      | AESPID   | Sponsor-Defined Identifier          | Perm |
| RAW     | AE      | AETERM            | Adverse Event Reported Term                           | Assign AETERM from AETERM                             | AE      | AETERM   | Reported Term for the Adverse Event | Req  |
| RAW     | AE      | LLT_NAME          | MedDRA Lowest Level Term Name                         | Assign AELLT from LLT_NAME                            | AE      | AELLT    | Lowest Level Term                   | Exp  |
| RAW     | AE      | LLT_CODE          | MedDRA Lowest Level Term Code                         | Assign AELLTCD from LLT_CODE                          | AE      | AELLTCD  | Lowest Level Term Code              | Exp  |
| RAW     | AE      | PT_NAME           | MedDRA Preferred Term Name                            | Assign AEDECOD from PT_NAME                           | AE      | AEDECOD  | Dictionary-Derived Term             | Req  |
| RAW     | AE      | PT_CODE           | MedDRA Preferred Term Code                            | Assign AEPTCD from PT_CODE                            | AE      | AEPTCD   | Preferred Term Code                 | Exp  |
| RAW     | AE      | HLT_NAME          | MedDRA High Level Term Name                           | Assign AEHLT from HLT_NAME                            | AE      | AEHLT    | High Level Term                     | Exp  |
| RAW     | AE      | HLT_CODE          | MedDRA High Level Term Code                           | Assign AEHLTCD from HLT_CODE                          | AE      | AEHLTCD  | High Level Term Code                | Exp  |
| RAW     | AE      | HLGTNAME          | MedDRA High Level Group Term Name                     | Assign AEHLGT from HLGTNAME                           | AE      | AEHLGT   | High Level Group Term               | Exp  |
| RAW     | AE      | HLGTCODE          | MedDRA High Level Group Term Code                     | Assign AEHLGTCD from HLGTCODE                         | AE      | AEHLGTCD | High Level Group Term Code          | Exp  |
| RAW     | AE      | AECAT<br>AECATOCC | Category for Adverse Events<br>AE Category Occurrence | Assign AECAT with ifc(AECATOCC = 'C49488', AECAT, '') | AE      | AECAT    | Category for Adverse Event          | Perm |
| RAW     | AE      | SOC_NAME          | MedDRA System Organ Class Name                        | Assign AEBODSYS from SOC_NAME                         | AE      | AEBODSYS | Body System or Organ Class          | Exp  |
| RAW     | AE      | SOC_CODE          | MedDRA System Organ Class Code                        | Assign AEBDSYCD from SOC_CODE                         | AE      | AEBDSYCD | Body System or Organ Class Code     | Exp  |
| RAW     | AE      | SOC_NAME          | MedDRA System Organ Class Name                        | Assign AESOC from SOC_NAME                            | AE      | AESOC    | Primary System Organ Class          | Exp  |
| RAW     | AE      | SOC_CODE          | MedDRA System Organ Class Code                        | Assign AESOCCD from SOC_CODE                          | AE      | AESOCCD  | Primary System Organ Class Code     | Exp  |



# End to End Clinical Data Standards and Hierarchy



# What are the benefits of Data Standards Governance?



Maintain integrity



Ensure adherence



Essential data



Provide expertise



Promote adoption



# Standards Governance - Clinical Data Standards team

## ***DATA COLLECTION STANDARDS (DCS)***

- Raw Data Standards (RDS)
- Module Instructions (MI)
- eCRF specifications
- eCRF instructions
- Edit check specifications (ECS)
- Global Library (RAVE)

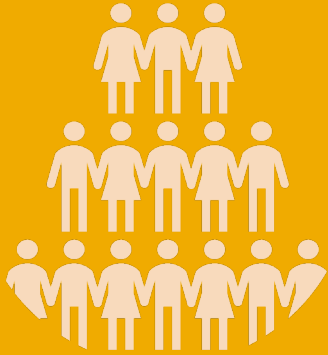
## ***DATA ANALYSIS & REPORTING STANDARDS (DARS)***

- Study Data Tabulation Model (SDTM)
- Analysis Data Model (ADaM)
- Tables, listings and figures templates (TLFs)
- Endpoint Definitions
- Clinical Dictionaries

Standards Review Team (SRT)  
Therapy Area Standards Definition Team (TASDT)

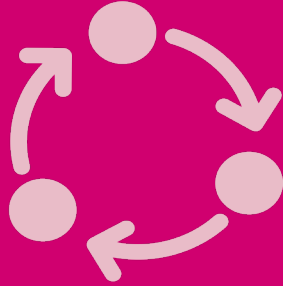


# Optimisation of Governance Process



## Scope:

All parts of the organisation use the same standards framework



## End to end approach:

All components impacted by a change should be considered and evaluated



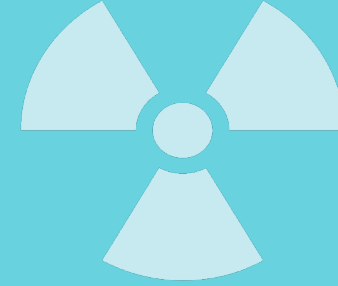
## Alignment:

Responsibilities aligned with most appropriate skill set



## Remove duplication:

Two step review process removed for corporate standard change requests



## Risk based approach:

Reduced review for change requests with limited application



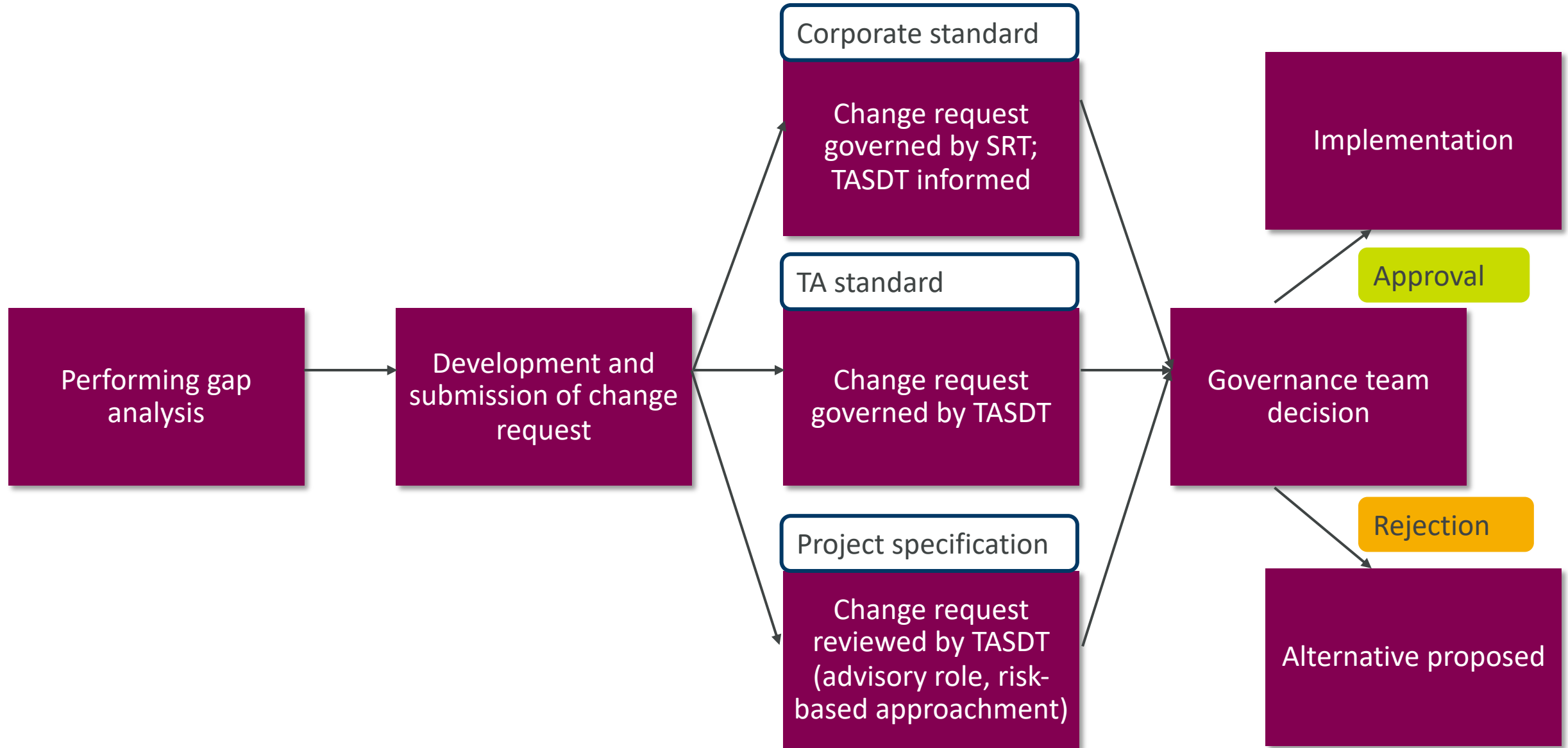
## Maintenance of standards:

Maintenance led by central team, improvements led by subject matter experts

One unified system to submit change requests to governance teams



# Clinical Data Standards Governance



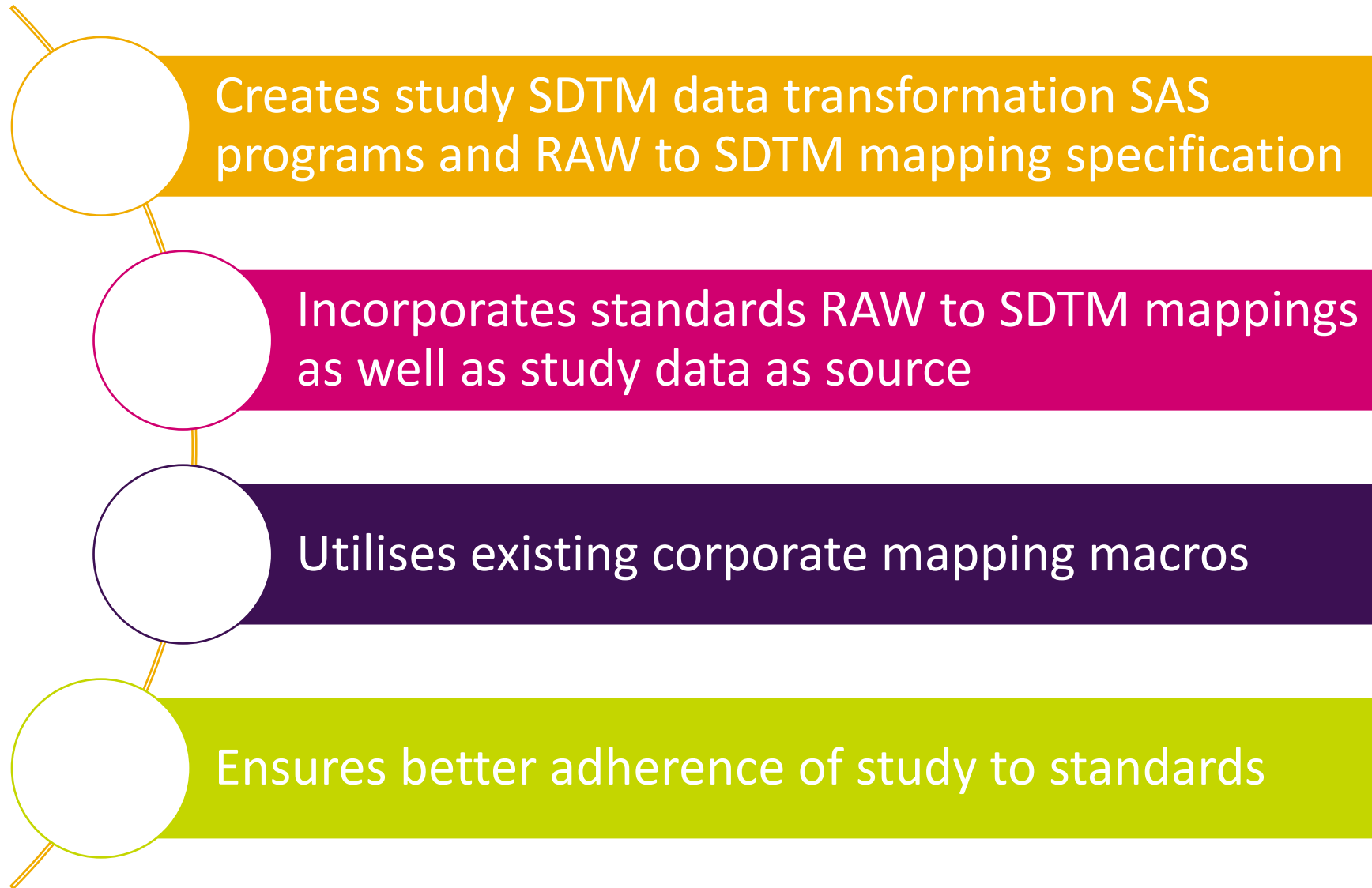
# Improved System for Standard Change Requests

- ✓ Applicable for all components of end-to-end clinical data standards
- ✓ Provides a landing page for users presenting current status of their ongoing requests
- ✓ Allows easy search of previous and current requests
- ✓ Includes functionality for governance teams
- ✓ Generates metrics on the governance process

„A responsive and robust standards framework requires a user-friendly change request system”

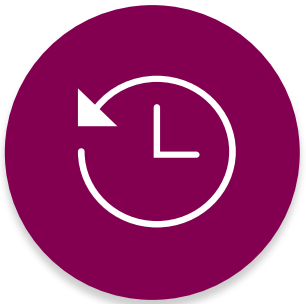


# SDTM Automation Program Builder



# Metadata Repository (MDR) Improvements

The purpose of the Standards Platform is to create, maintain, promote, and retire Clinical Data Standards for AZ sponsored Clinical Studies as well as to 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



THANK YOU

