

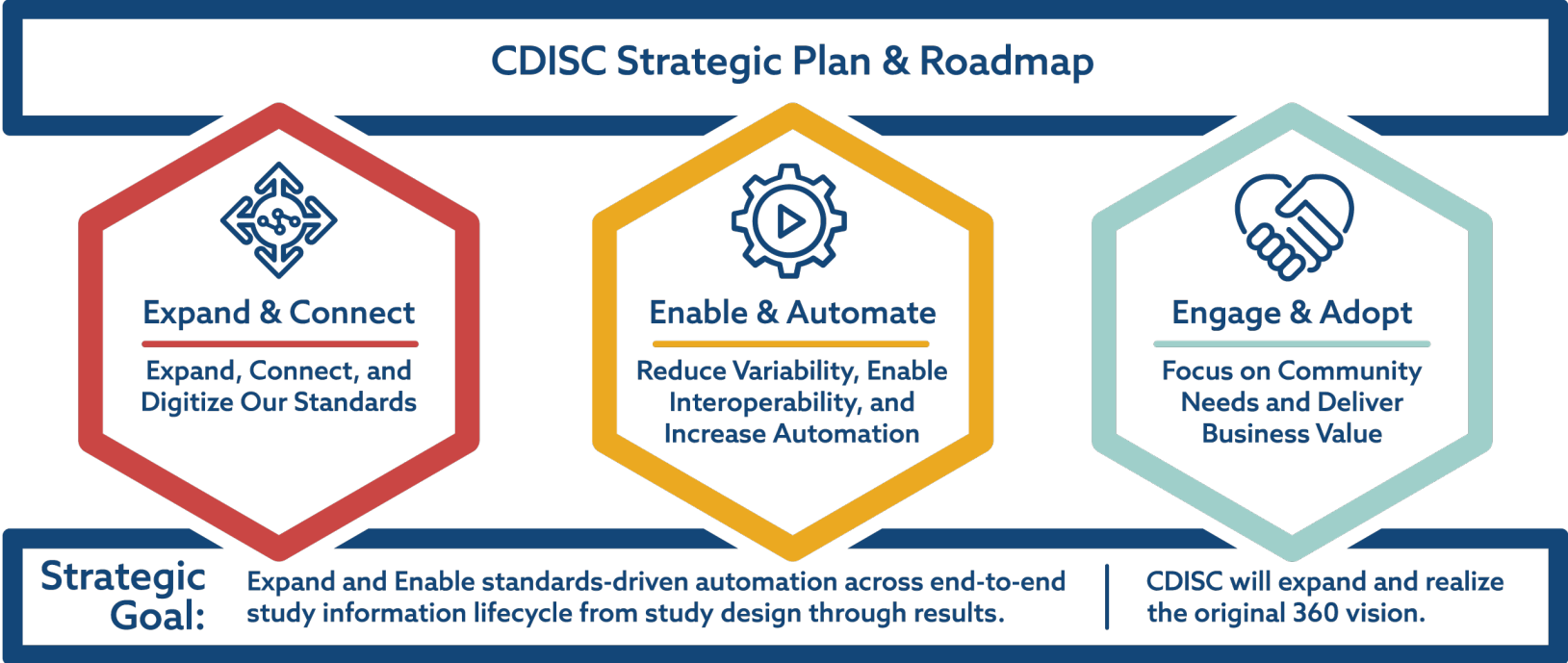


# CDISC Strategy and Roadmap

## Focus on Realizing the Long-Term Vision

**cdisc**

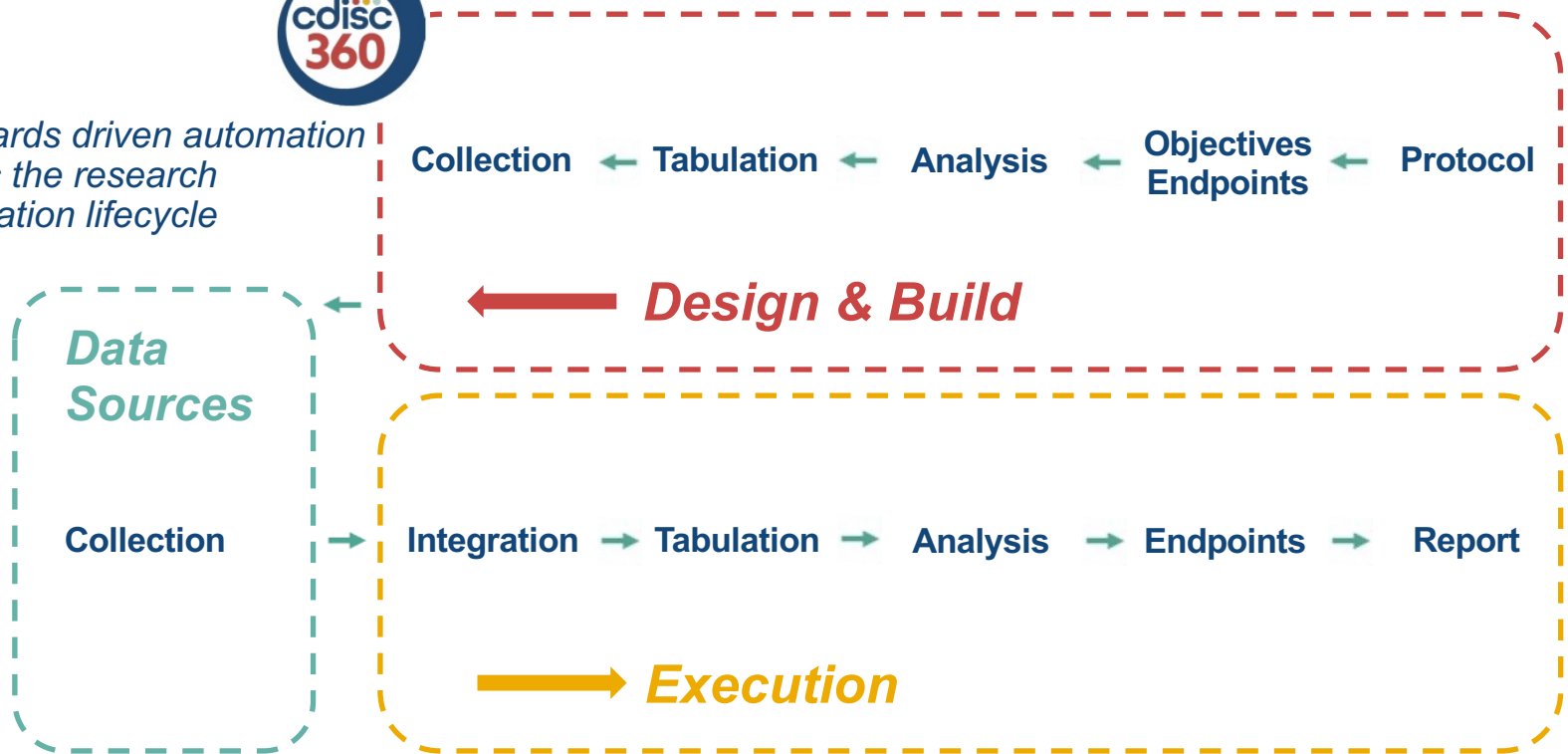
# Realizing the CDISC Mission



# End to End Study Information Lifecycle

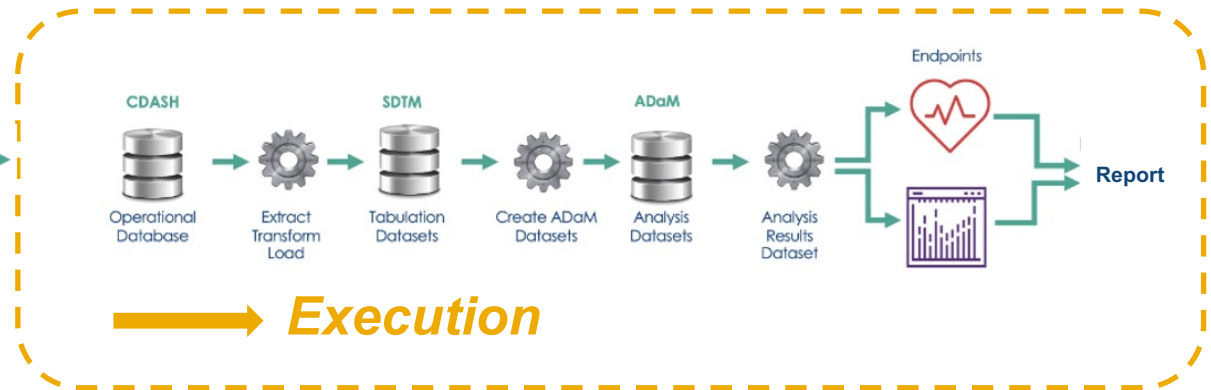
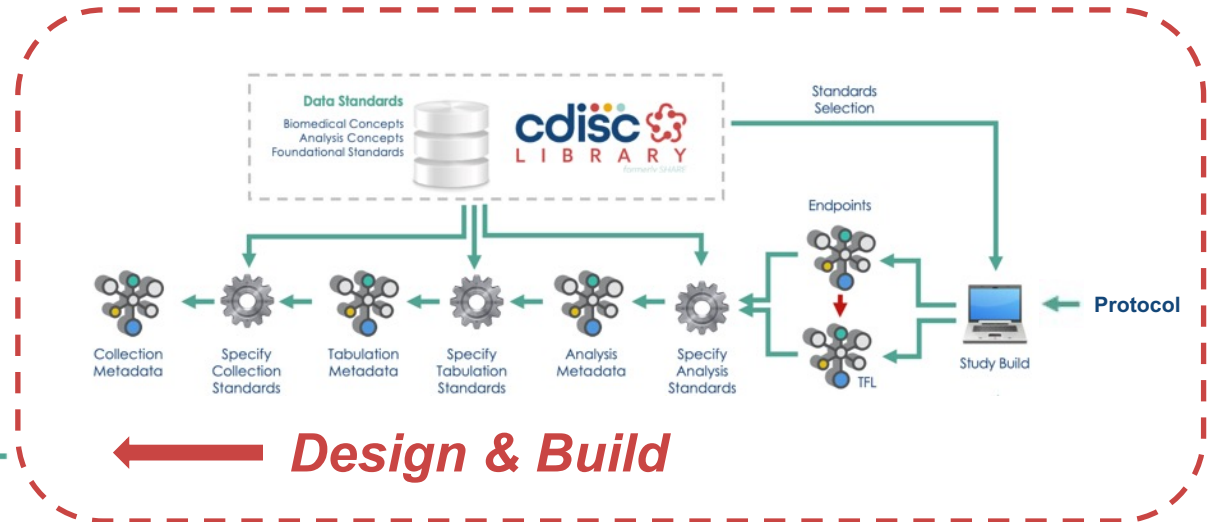


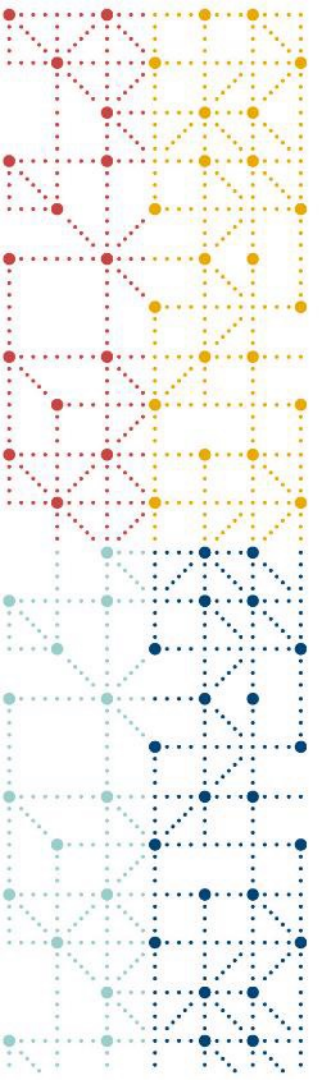
Standards driven automation  
across the research  
information lifecycle





Our work has started  
with CDISC 360





# CDISC Roadmap

# Roadmap Pillars and Objectives



## Expand & Connect

- Embrace and adopt digital study design
- Expand and connect standards across the clinical research information lifecycle
- Define clear pipeline for integration of new data sources



## Enable & Automate

- Develop ready to use implementation standards
- Create open-source technology enabled standards
- Establish and manage a conformance framework



## Engage & Adopt

- Establish a continuous feedback loop across the CDISC community
- Shift focus to producers/consumers needs and lower the barrier to use
- Prioritize communication to enable our stakeholders

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# Expand & Connect: Digital Study Design

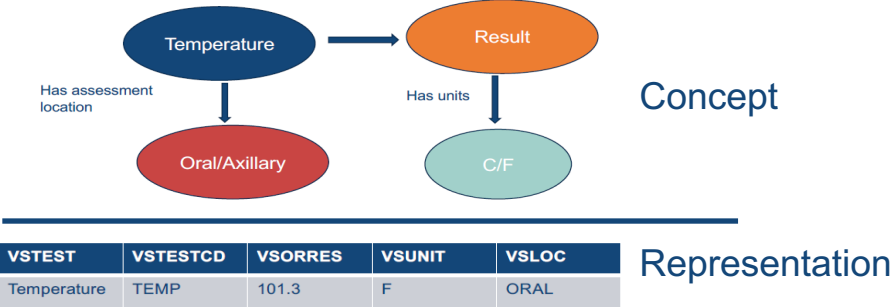
- Unified Study Definitions Model (USDM)
  - Holds many aspects of the study design
  - Facilitates interoperability between systems
  - Schedule of Activities = digital backbone of the protocol
    - Link Schedule of Activities to standard Concepts
  - Support study design activities
- ICH M11
  - Provide controlled terminology, aligned with USDM
  - Collaborate with ICH and Vulcan to create exchange mechanism
    - Utilizing Digital Protocol (UDP)
  - Support use cases and pilots (e.g. FDA PRISM)





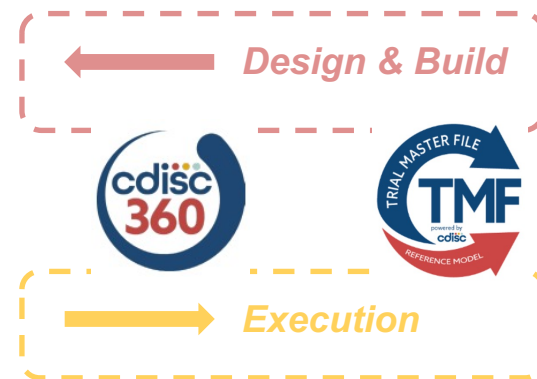
# Connect Design to Results

- Mapping data from various formats often breaks down
  - The meaning and terminology do not match (e.g. eHR to SDTM)
  - Mapping between common data models is only a part of the solution
- We need well defined Concepts
  - Standardize the meaning and semantics of data
  - Regardless of data representation
- Concepts will
  - Link to the **Schedule of Activities**
  - Provide consistent implementation
  - Facilitate automation
  - Prevent AI from hallucinating



# Close the gaps & Expand the standards

- Ensure standards can represent all data
  - Analysis Results Standards (launched March 2024)
  - Common electronic data transfers (to start)
  - Explore structures to represent objectives & endpoints (to start)
- TMF is now integrated with CDISC
  - Roll out from TMF standards development process
  - TMF Controlled Terminology (in progress)
- Digitalize Trial Master File
  - TMF Art of the Possible to TMF Roadmap
  - TMF systems will integrate digital protocol information
  - Enrich TMF with metadata to support automation



# Expand & Connect: Integrate Sources

- Study data is originating from many sources
  - Electronic Data Capture systems and eCRFs
  - Various Data Transfers such as eCOAs, ePROs, eHRs
  - Digital Health technologies
- Provide more standards to ingest data
- Digital Health Technologies initiative
  - Partnership with DiME – Library of digital endpoints
  - Link resources to concepts, device attributes, domains
  - Standardize analysis of DHTs where applicable



# Expand & Connect: Integrate Sources

- Real-world data provides valuable insights but...
- Concerns about
  - Data quality
  - Data integration issues (fidelity)
  - Traceability
- RWD Lineage
  - Exchange mechanism to represent lineage, traceability and quality
  - Together with the data
- Continue partnering with NIH, IMI and other SDOs
  - Define core data elements



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## Enable & Automate

- Develop **ready to use** implementation standards
- Create **open-source technology** enabled standards
- Establish and manage a **conformance** framework



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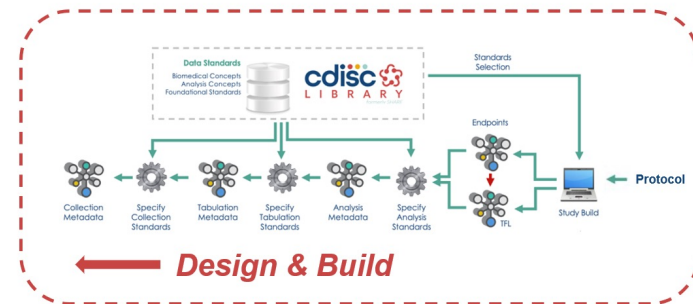
# Enable & Automate: Ready to Use Standards

- Provide rich resources and examples
  - normative standards with informative content
  - 'easy' to implement and understand
- eCRF portal
  - <https://www.cdisc.org/kb>
  - 70 eCRF resources and growing
  - Ready to download and use in eDC systems
- eTLF portal
  - Based on the Analysis Results Standard
  - Analysis concept + ADaM metadata + ARS metadata + TFL example
  - Ready to download and implement

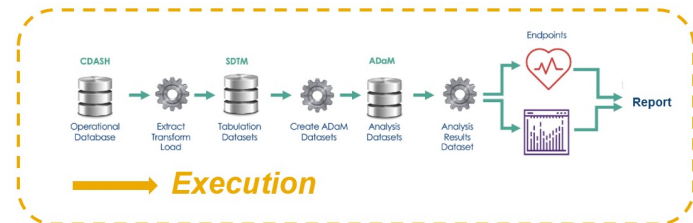


# Enable & Automate: Preconfigured example study

- Complete preconfigured example study
  - Include all components from design to submission
  - Understand the normative gaps between standards



- Demonstrate and test the example study
  - Set-up Connectathon events with technology providers



- Collaborate with Regulatory to define use cases
  - Enabling better use of standards for review

# Enable & Automate: Open-Source

- Consider technology and automation upfront
- CDISC Open Source Alliance
  - Support and promote development of open-source software
  - Drive innovation
- Examples
  - Oak Initiative: automate SDTM generation
  - Open Study Builder
  - CDISC Open Rules Engine
  - CDISC Rule Editor





# Enable & Automate: Technology Enables Automation

- Modernize data transport: Dataset JSON
  - Technology friendly, future proof
- Standards with logical models
  - Both USDM and ARS are published with logical models
  - Enables technical implementation, demonstrate use cases
  - Includes API specifications
- CDISC Library
  - Relevant standards are digitally available via APIs
  - Source for tools and automation





# Enable & Automate: Conformance Rules

- Complete conformance rules for all relevant foundational standards
  - SDTM, ADaM, SEND, ARS, ...
- Expand to regulatory business rules
  - Current collaboration with FDA, other agencies to follow
- Expand to industry quality rules
  - Quality rules beyond standard conformance
  - Creating conformance rules for USDM to ensure compliance with USDM framework
    - This will enable checking conformance with M11 transport standard
- Going forward
  - Establish rules for all CDISC standards

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## Engage & Adopt

- Establish a continuous **feedback** loop across the CDISC **community**
- Shift **focus** to **user needs** and lower the barrier to use
- Prioritize **communication** to enable our stakeholders

# Engage & Adopt: Feedback

- Ensure we are **solving the right problems**
  - Understand the needs of end-users
- Establish a transparent feedback framework
- Reform the CDISC Advisory Council
  - Member input



## Continuous Feedback

Define and manage community feedback loop to ensure understanding of needs

# Engage & Adopt: User Focus

- Focus to enhance and accelerate standards adoption
  - A standard is only successful when used
- Include impact assessment to significant standard changes
  - Provide a rationale and value for the change
  - Provide implementation considerations where possible
- CDISC education
  - Shift from theory to hands-on experience trainings
  - I do, we do, you do



## User Focus

Shift from development to user needs to enhance and accelerate standards adoption

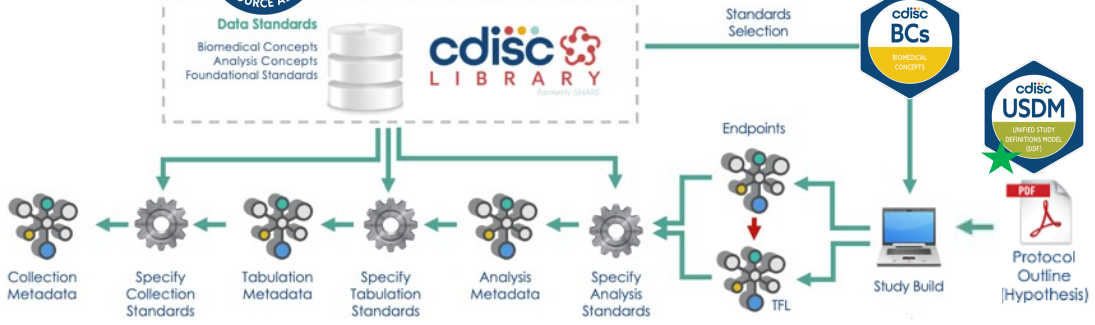
# Engage & Adopt: Communication

- Evaluate on how we make content and information available
  - Website, Social Media, Github, CDISC Library
- Publish and maintain a dashboard with current CDISC activities and progress
- Publish the Annual Report
  - Summarize progress on strategic objectives
  - How is CDISC using membership fees to create value



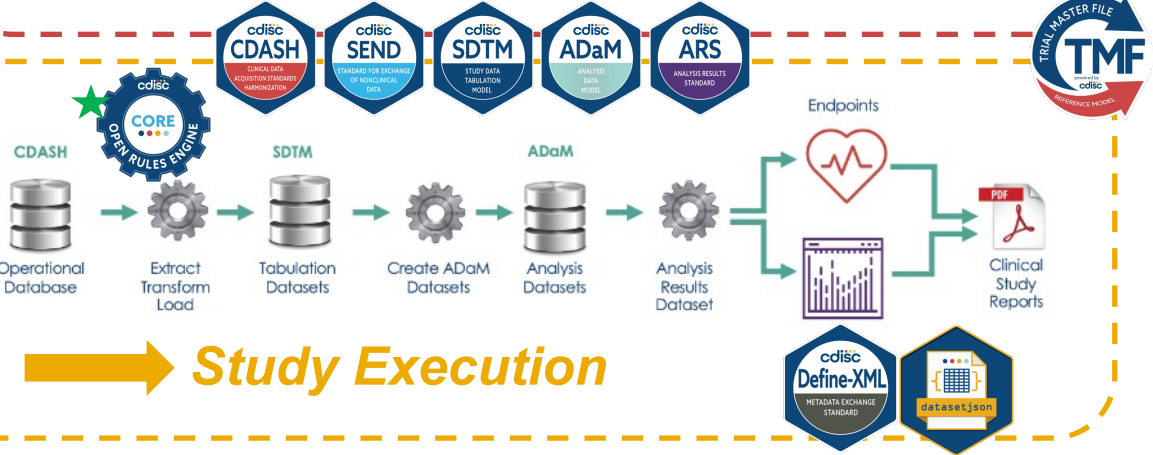
## **Prioritize Communication**

Create frequent and accessible information for CDISC and community alignment



## Study Design & Build

## Data Sources



## Study Execution



# We Want Your Feedback!

## Opportunities:

- Contact CDISC leadership team
- Survey with QR Code
- Social post to share message with broader CDISC community

