WITH STANDARDS – UNLOCK THE POWER OF DATA

cdisc

2022
CHINA
INTERCHANGE
29-30 JULY | VIRTUAL EVENT

# State of the Consortium

David A. Evans
President and CEO, CDISC
2022 Europe Interchange

# Meet the Speaker

## Dave Evans

Title: President and CEO

Organization: CDISC

Dave Evans is recognized industry-wide as a leading technology visionary for developing and implementing complex process and system solutions and as an expert in the areas of information standards, regulatory compliance and quality governance. He was the architect and developer of the first electronic drug submission to the FDA in 1985 and has been responsible for more than 100 electronic regulatory submissions and complex clinical data warehouse systems. He brings over 40 years' experience to CDISC, serving in various executive-level positions in software development, clinical research, regulatory and healthcare industries. Most recently, he was the Global Head of Quality Governance and Regulatory Compliance for Accenture Life Sciences. Prior to that, he was CIO of Octagon Research Solutions. He has also served on the CDISC Board and has chaired the CAC.

Dave received his MS in Biomedical Engineering from Drexel University and his BS in Biology from Ursinus College.

# State of the Consortium

# CDISC Community

# CDISC Today

- Staff of 40 Professionals with 40+ SME Contractors
- Volunteer Network of 1000+ Industry Experts
- 540+ Member Organizations
- Widely Adopted Clinical Research Data Standards
- Mature Standard Governance processes
- Healthy Financial Reserves
- Innovative Technology for Standards implementation
- Delivering on Innovative Industry Initiatives and Projects
- Positive Relationships
  - Members, Regulators, Partners, Academia, SDOs and Industry

# Alliances and Collaborations


phuse

CDISC and PhUSE partner to further the mission of each organization collectively, with CDISC focusing on the development of global, platform-independent data standards, and PhUSE focusing on the implementation and use of the CDISC standards. The two organizations work to combine efforts on key initiatives around end-to-end standards, TA standards, and semantics, strengthening an interdependent process.

cdisc

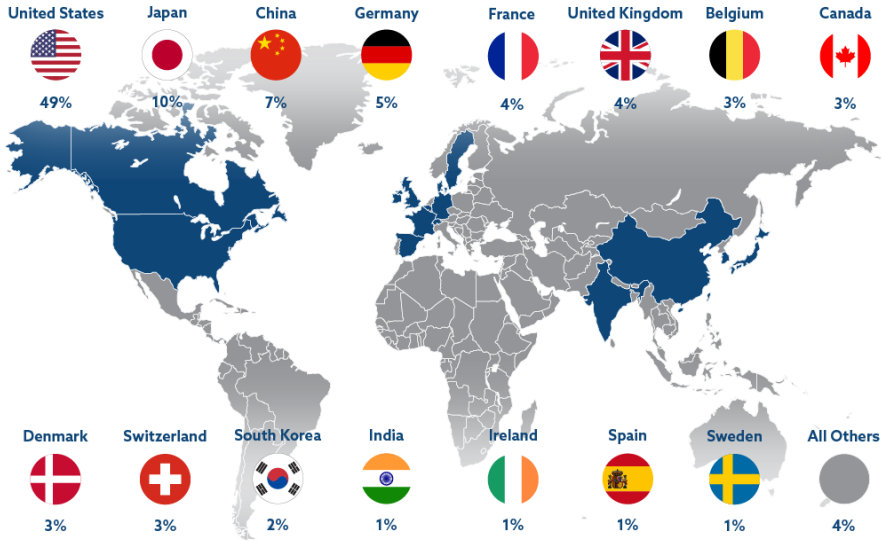
# CDISC – a look into this year

- Standards Initiatives from Regulatory Agencies
- Ongoing Therapeutic Area Projects
- Ongoing Activities and Projects on RWD/RWE & Data Sharing
- Standards Implementation for Registries and Academic Use
- New Industry Projects are on schedule for delivery
- Continue to build upon CDISC Library and Biomedical Concepts
- Continue to add content to eCRF Portal and QRS Library
- Collaboration with other SDOs on emerging Industry Initiatives
- Expansion into additional areas of Clinical Information Standards

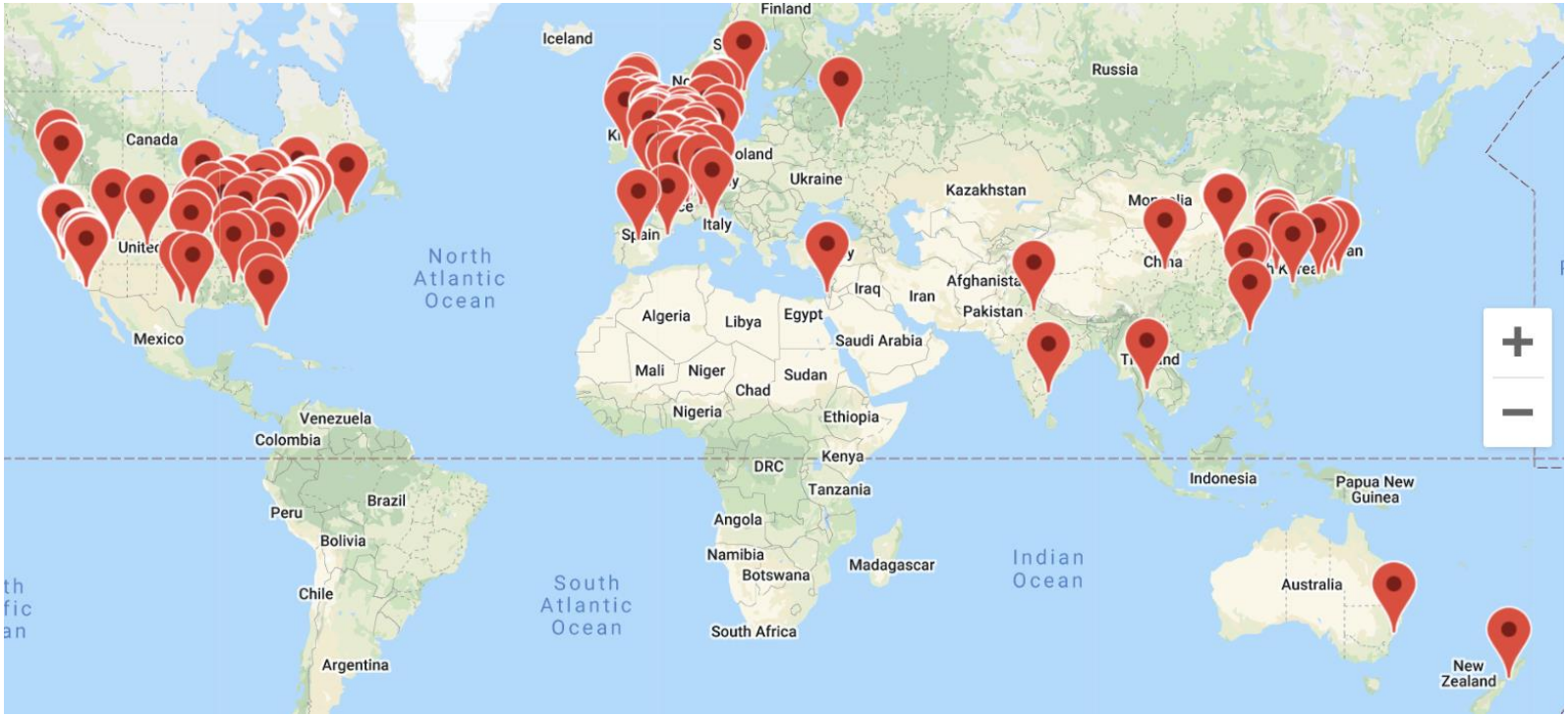
# CDISC Members = Global Community

## Members by Industry


## Members by Location



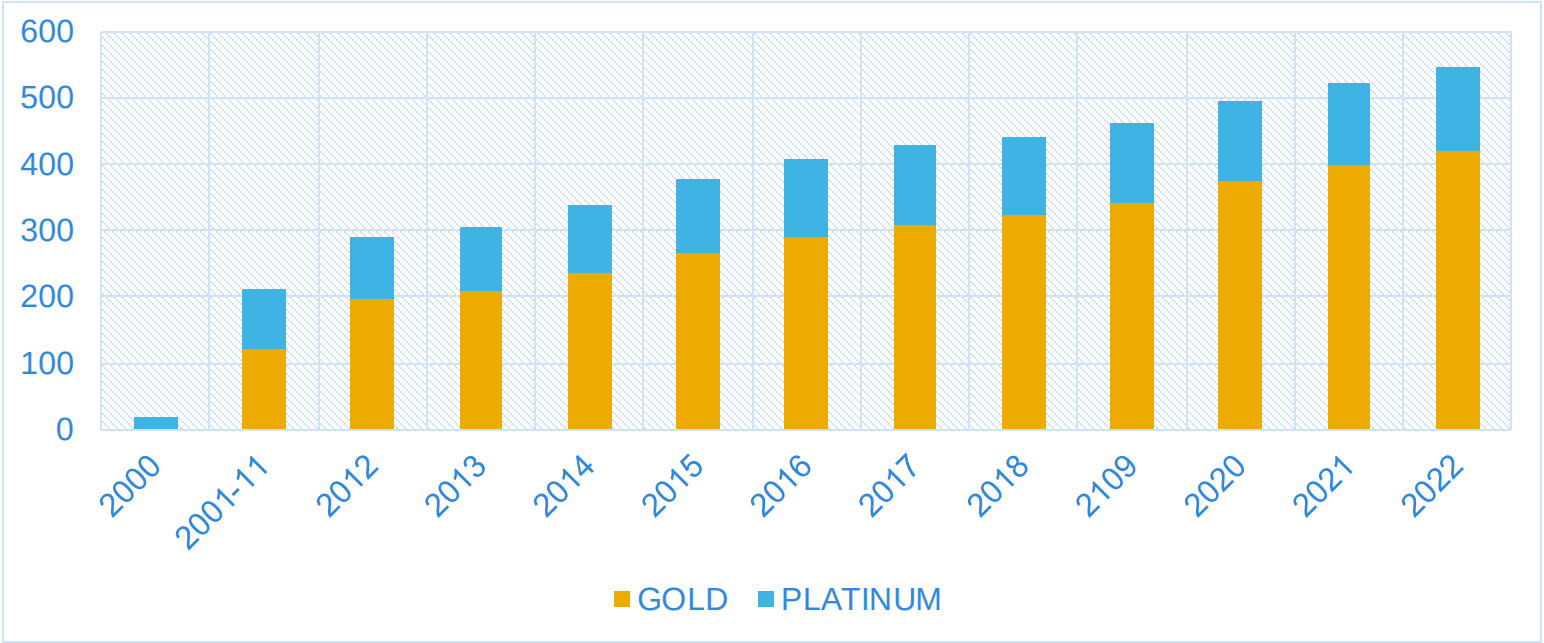
# CDISC Members Around the Globe



# CDISC Membership


cdisc

# Membership Trend, 2000-2022
## *548 Members as of 30 June 2022*




2000: **20 Platinum**

2022: **548 (11 new members in Q2)**

**8 Gold; 3 Platinum**

# CDISC Events, 2022 - 2023

**2022 Theme: With Standards – Unlock the Power of Data**

**2022 Europe Interchange**
27 – 28 April
Virtual
(*OpenStudyBuilder Workshop 29 April*)

**2022 Japan Interchange**
13 – 14 June
Virtual

**2022 China Interchange**
29 – 30 July
Virtual

**2022 US Interchange**
26 – 27 October
Austin, TX
USA

**2023 Europe Interchange**
26 – 27 April
Copenhagen
Denmark

**2023 Japan Interchange**
10 – 11 July
Tokyo
Japan

**2023 China Interchange**
25 – 26 August
Beijing
China

**2023 US Interchange**
October
Washington, DC
USA

# CDISC Events, 2023

# IN-PERSON US INTERCHANGE

UPDATE

# Journal of the Society of Clinical Data Management CDISC Focused Special Edition

Journal of the Society for Clinical Data Management

- 24 abstracts received
- FDA, PMDA, DMA represented
- Rolling publication
- Supplement publication: Q4 2022

# UPDATE

## Journal of the Society of Clinical Data Management CDISC Focused Special Edition


- 24 abstracts received
- FDA, PMDA, DMA represented
- Rolling publication
- Supplement publication: Q4 2022

# What is the next stage on the CDISC Journey?

*CDISC has always been an evolving transformational standards organization for information used in clinical research and regulatory submission.*

***CDISC Data Standards Lifecycle***

# What is the next stage on the CDISC Journey?

*CDISC has always been an evolving transformational standards organization for information used in clinical research and regulatory submission.*

## ***CDISC Data Standards Lifecycle***


Implementation requires:

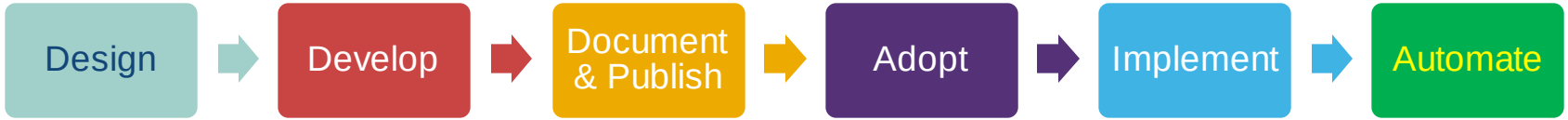
- *Standards expertise*
- *Standards conformance and verification*
- *Standards machinery and processes*

cdisc

# What is the next stage on the CDISC Journey?

*CDISC has always been an evolving transformational standards organization for information used in clinical research and regulatory submission.*

## ***CDISC Data Standards Lifecycle***



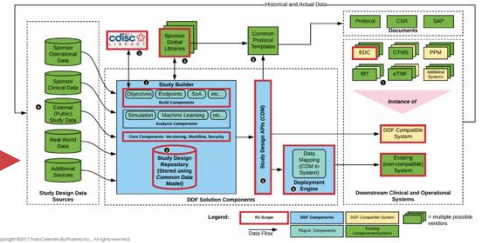

Automation requires:

- *Standard Machine-executable content for Useability*
- *Standard Technology Interfaces for Integration for Accessibility*
- *Standard Verification and Conformance Rules for Integrity*
- *Standard Trial Design Specifications for Total Automation of the Digital Data Flow*

cdisc

# CDISC Library

*Connect with Digital Data Processes through Open-API*



cdisc LIBRARY

Foundational Standards

Controlled Terminology

API

Machine-executable content

Executable Conformance Rules

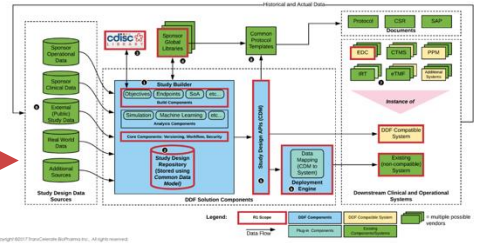
| | | | | |
|---|---|---|---|---|
| Biomedical Concepts | Codelist Subsets | Tables, Listings, and Figures | Implementation Guide Text | FHIR to CDISC Mappings |
| Analysis Concepts | TAUG Metadata | Derivations and Mappings | Machine-readable Examples | LOINC Code Mappings |
| Templates | Study Design Metadata | | CRF Collection | Diff Content Between Versions |

*CDISC Standards*

*Informative Content*

# CDISC Library

*Connect with Digital Data Processes through Open-API*



cdisc LIBRARY

Foundational Standards

Controlled Terminology

API

Machine-executable content

Executable Conformance Rules

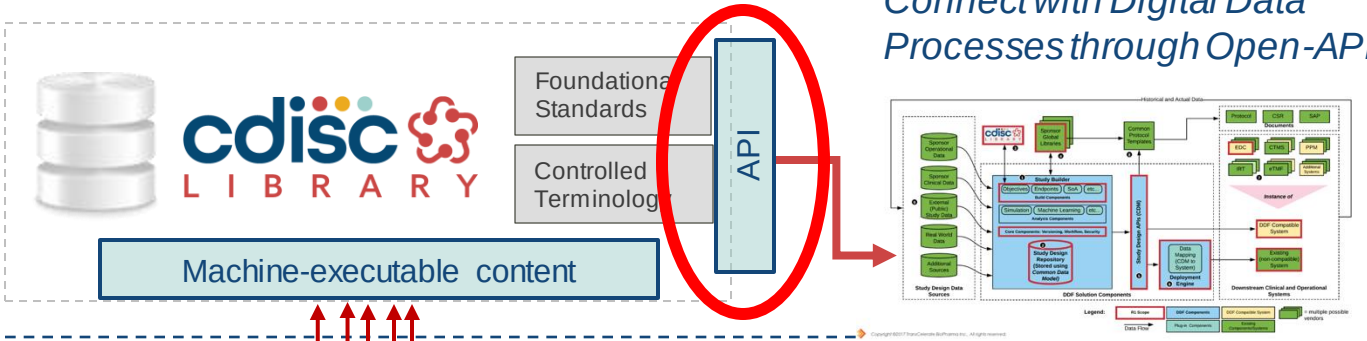
| | | | | |
|---|---|---|---|---|
| Biomedical Concepts | Codelist Subsets | Tables, Listings, and Figures | Implementation Guide Text | FHIR to CDISC Mappings |
| Analysis Concepts | TAUG Metadata | Derivations and Mappings | Machine-readable Examples | LOINC Code Mappings |
| Templates | Study Design Metadata | | CRF Collection | Diff Content Between Versions |

*CDISC Standards*

*Informative Content*

# CDISC Library

*Connect with Digital Data Processes through Open-API*




Executable Conformance Rules

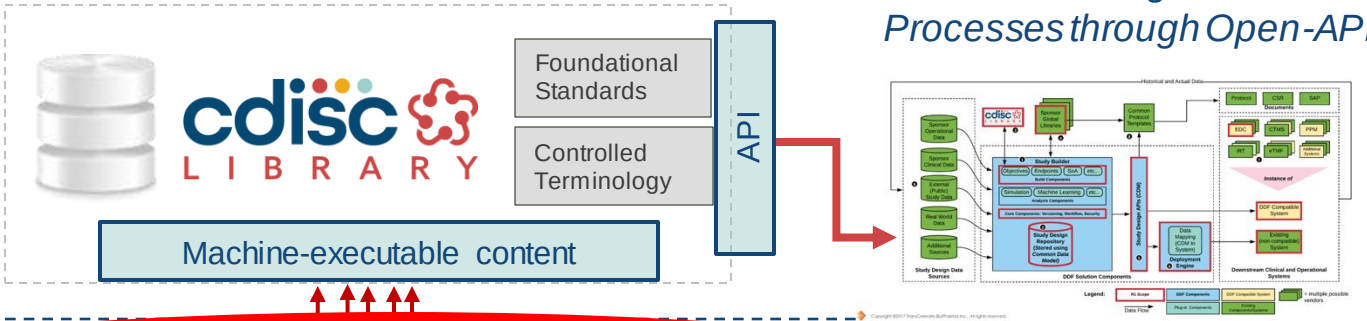
| | | | | |
|---|---|---|---|---|
| Biomedical Concepts | Codelist Subsets | Tables, Listings, and Figures | Implementation Guide Text | FHIR to CDISC Mappings |
| Analysis Concepts | TAUG Metadata | Derivations and Mappings | Machine-readable Examples | LOINC Code Mappings |
| Templates | Study Design Metadata | | CRF Collection | Diff Content Between Versions |

*CDISC Standards*

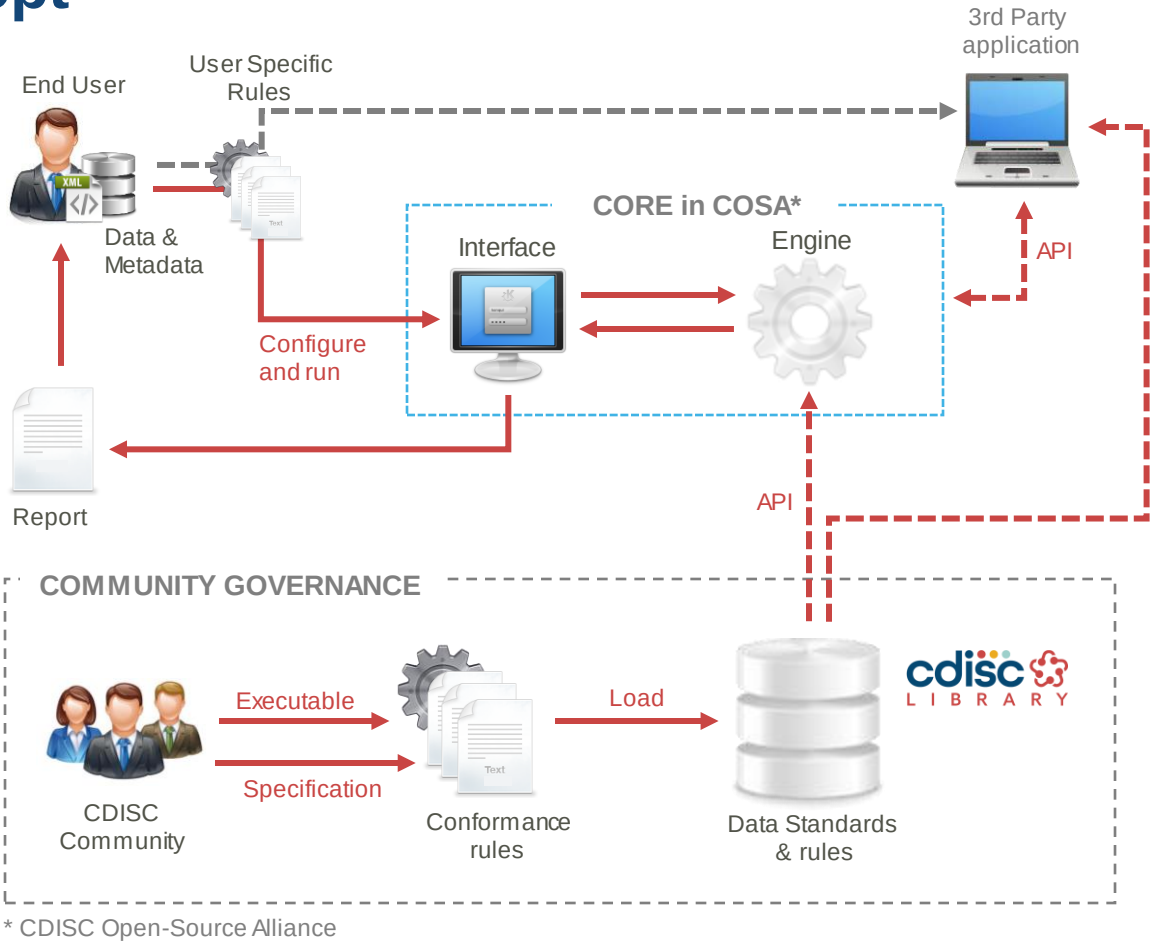
*Informative Content*

# CDISC Library

*Connect with Digital Data Processes through Open-API*



# CORE Concept




* CDISC Open-Source Alliance

# Why is CDISC doing CORE?

- Ensure each standard has a set of unambiguous, executable Conformance Rules
- Ensure consistency across Conformance Rule implementations
- Expedite the availability of executable Conformance Rules for new Foundational Standards
- Create executable Conformance Rules vetted by the CDISC standards development teams
- Develop an open-source engine that serves as a Reference Implementation
- Publish the Rules in the CDISC Library and the engine under the CDISC Open Source Alliance (COSA)

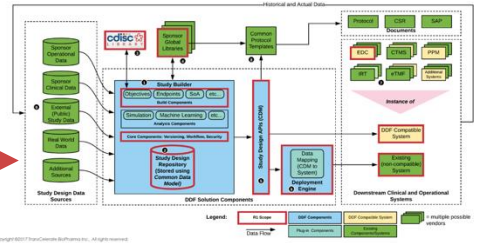

https://www.cdisc.org/core


https://cosa.cdisc.org/

cdisc

# CDISC Library

*Connect with Digital Data Processes through Open-API*



cdisc LIBRARY

Foundational Standards

Controlled Terminology

API

Machine-executable content

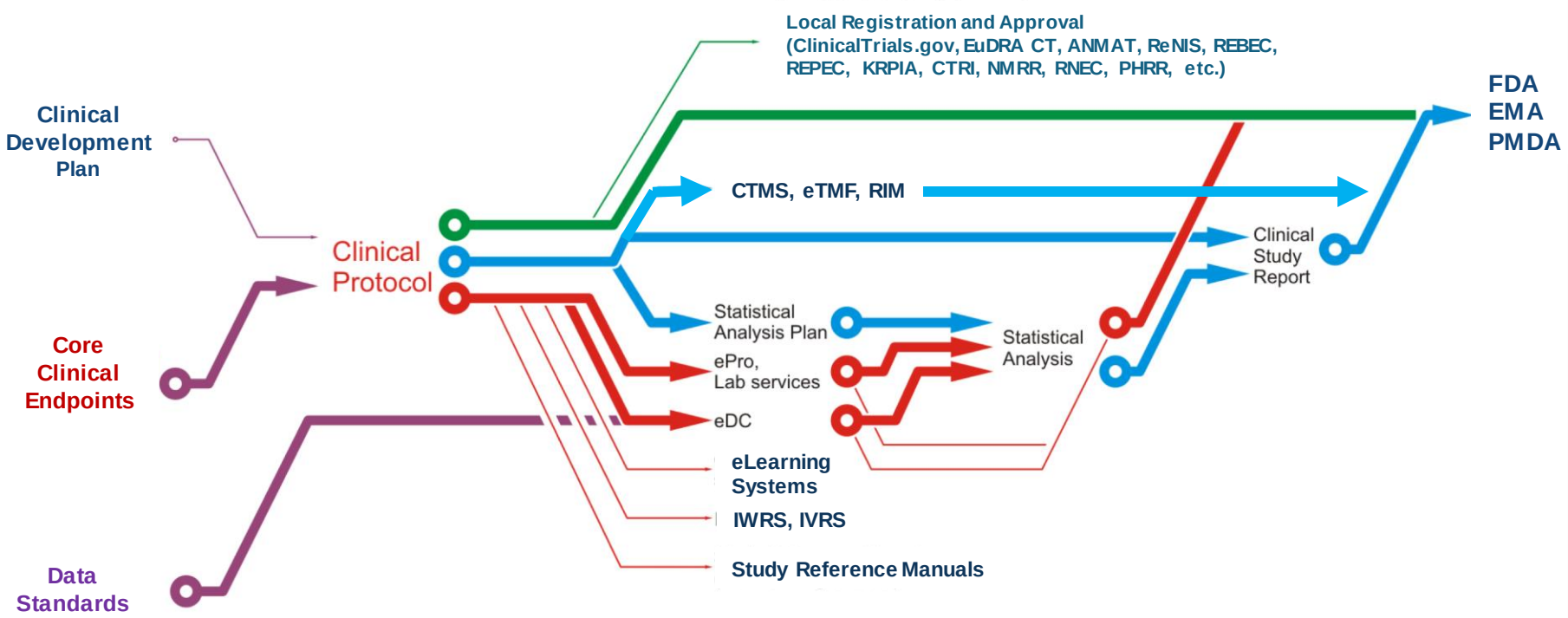
Executable Conformance Rules

| | | | | |
|---|---|---|---|---|
| Biomedical Concepts | Codelist Subsets | Tables, Listings, and Figures | Implementation Guide Text | FHIR to CDISC Mappings |
| Analysis Concepts | TAUG Metadata | Derivations and Mappings | Machine-readable Examples | LOINC Code Mappings |
| Templates | Study Design Metadata | | CRF Collection | Diff Content Between Versions |

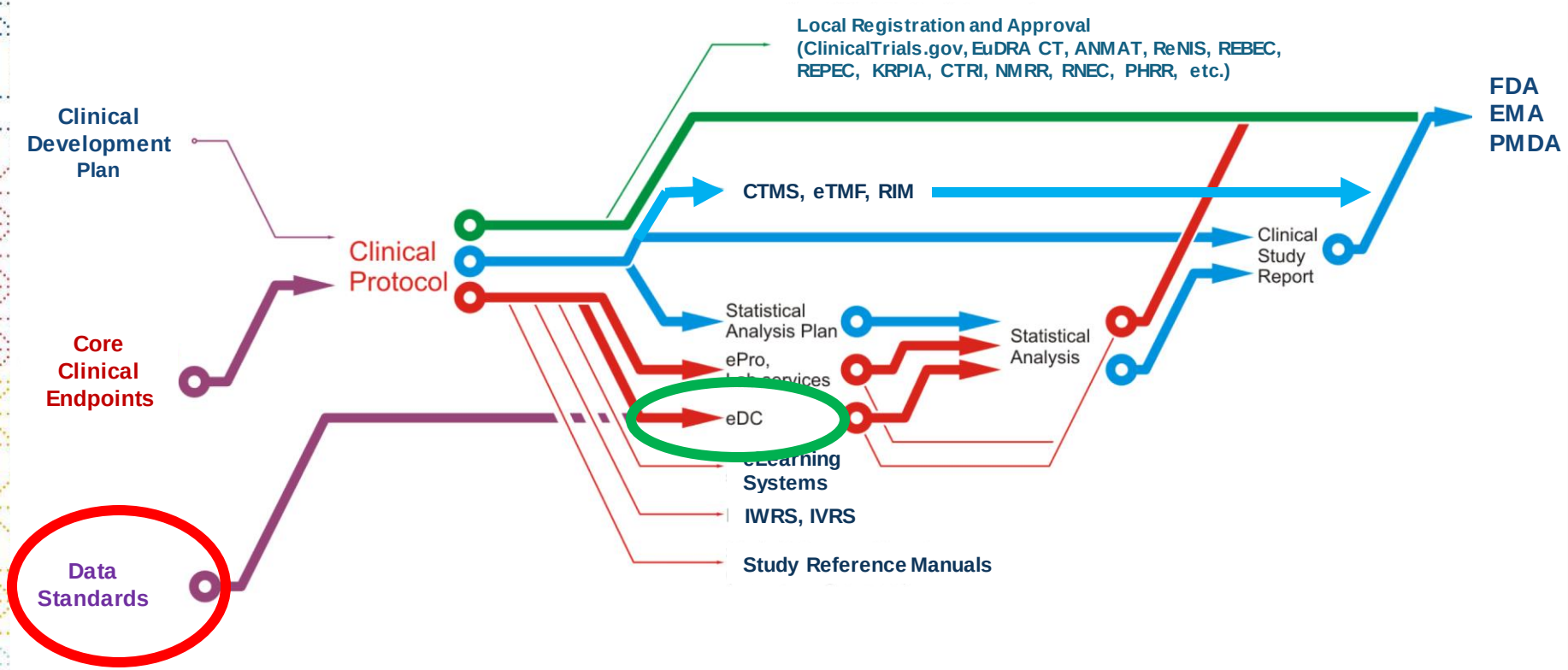
*CDISC Standards*

*Informative Content*

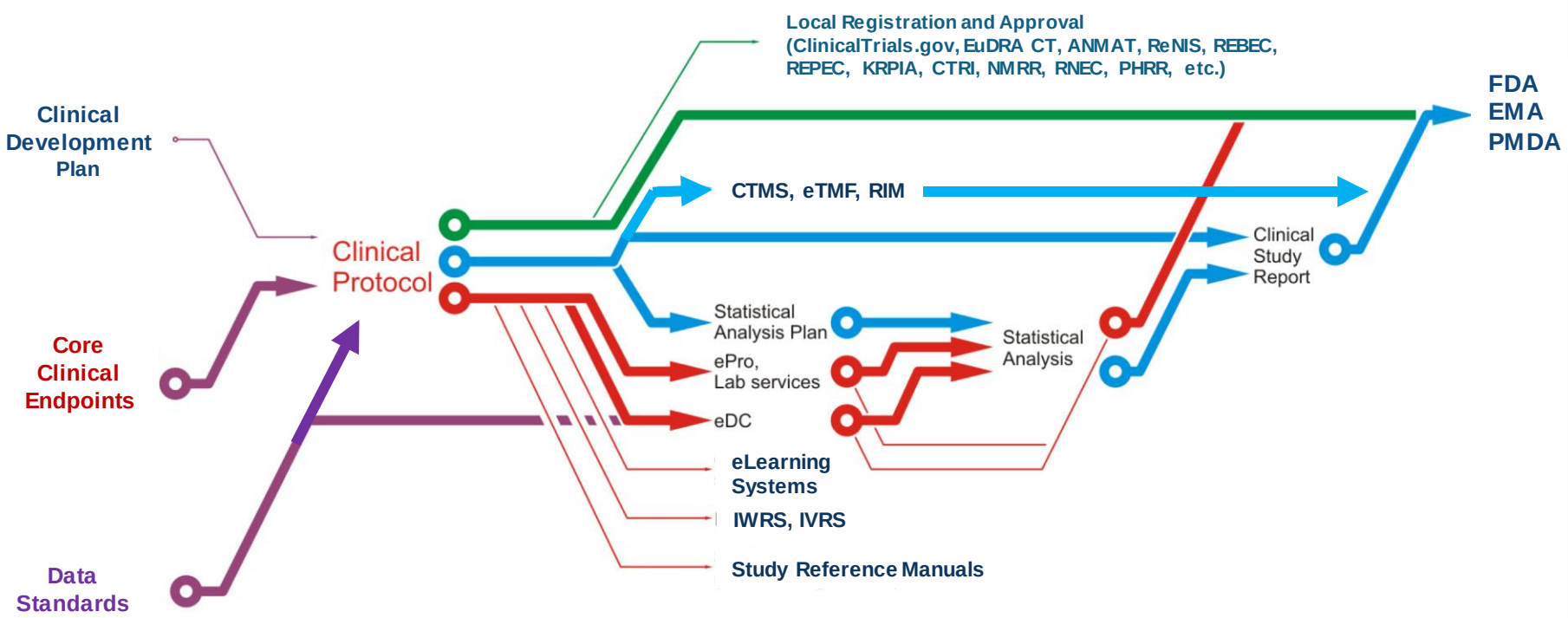
# The Clinical Trial Information Flow



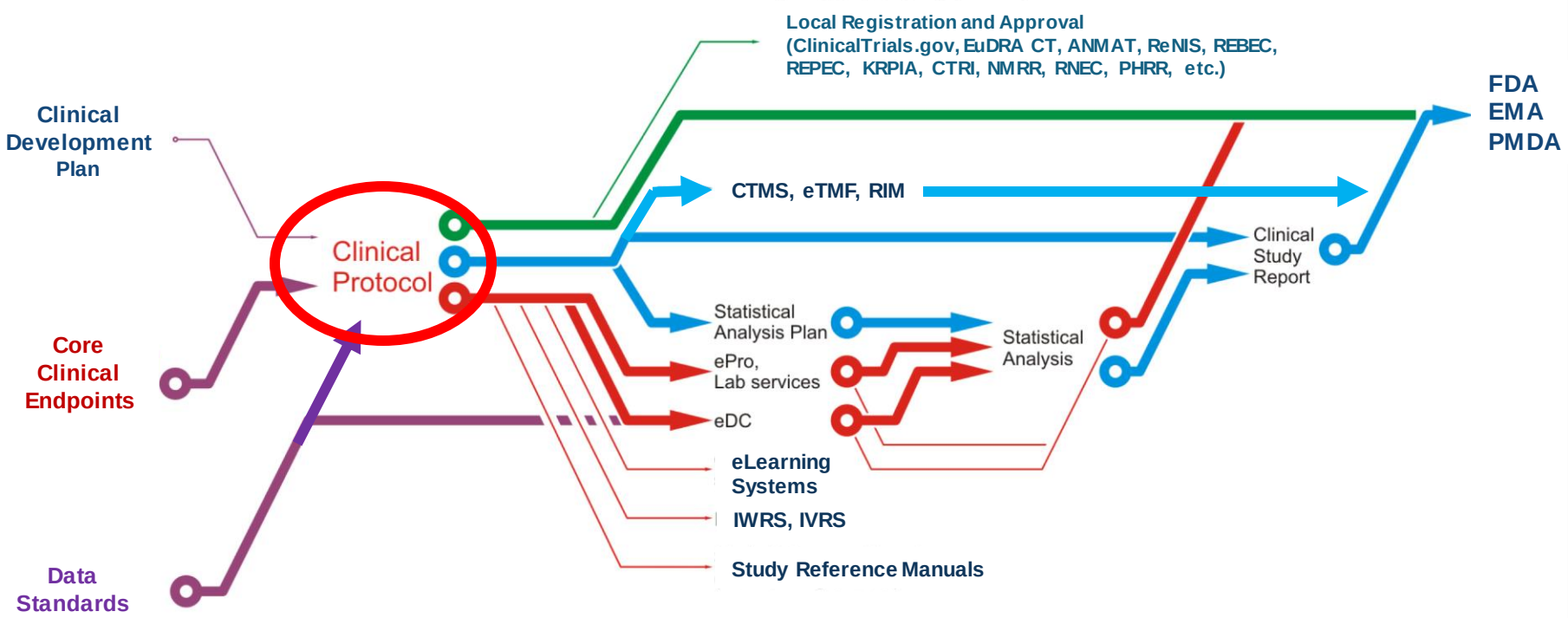
# The Clinical Trial Information Flow



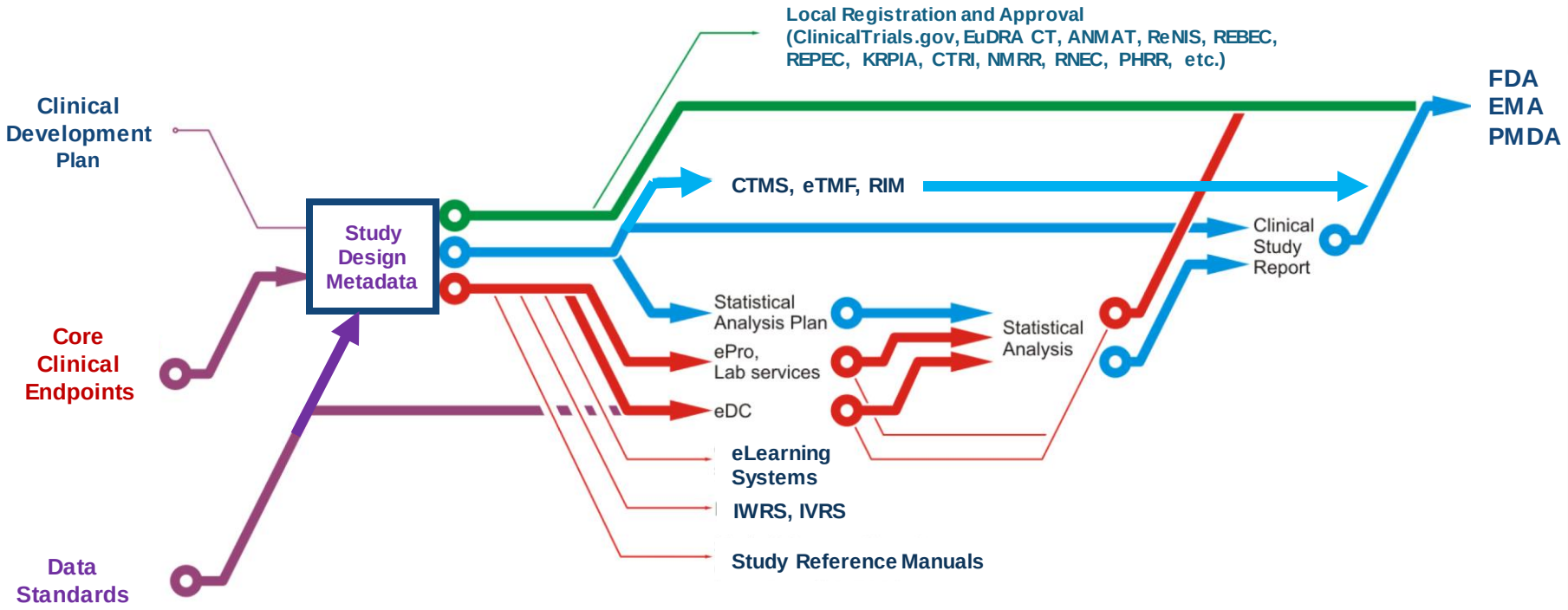
# The Clinical Trial Information Flow



# The Clinical Trial Information Flow

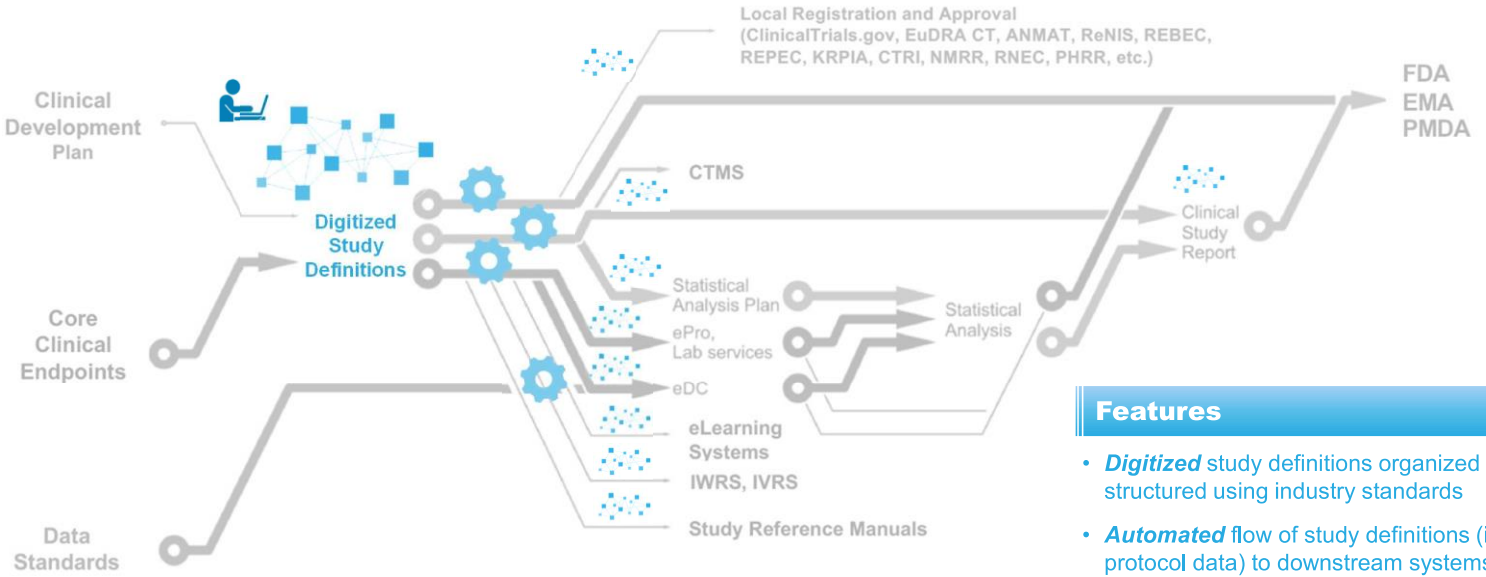


# The Clinical Trial Information Flow



# Future Vision for DDF

*Digitized, Automated & Dynamic*



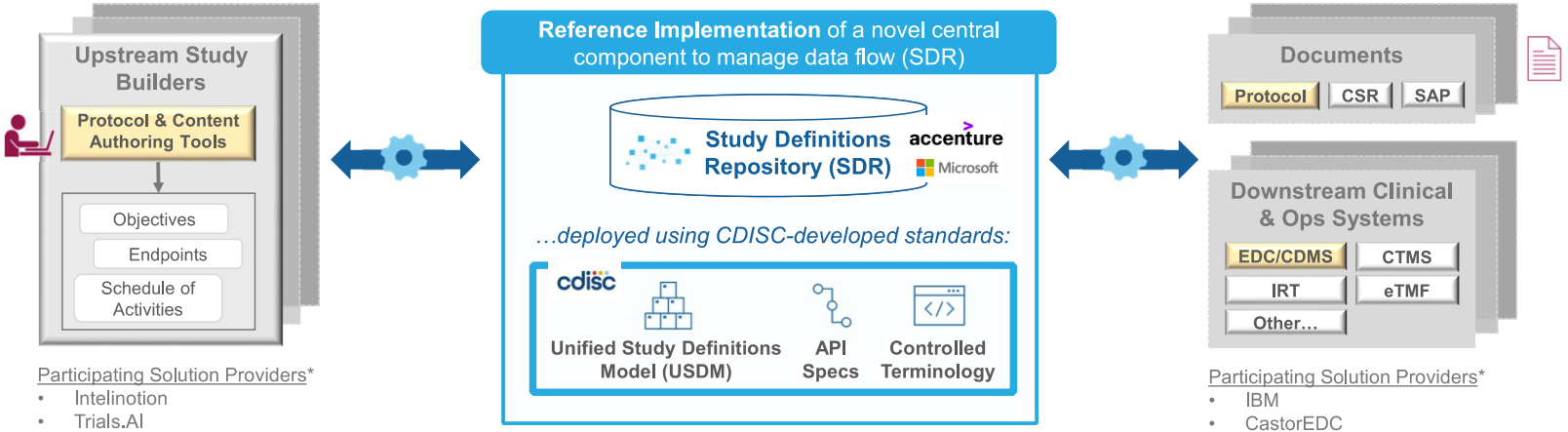

## Features

- ***Digitized*** study definitions organized & structured using industry standards
- ***Automated*** flow of study definitions (i.e. protocol data) to downstream systems
- ***Dynamic readiness*** enabled by faster cycle times & quality data from a single source

# Minimum Viable Product (MVP) Development Complete

April 2022 Release

Open Source | Vendor Agnostic | Agile Development | Dynamic Alignment to Standards




Participating Solution Providers*

- Intelinotion
- Trials.AI
- Nurocor

Participating Solution Providers*

- IBM
- CastorEDC
- RedCap Cloud
- Oracle

KEY

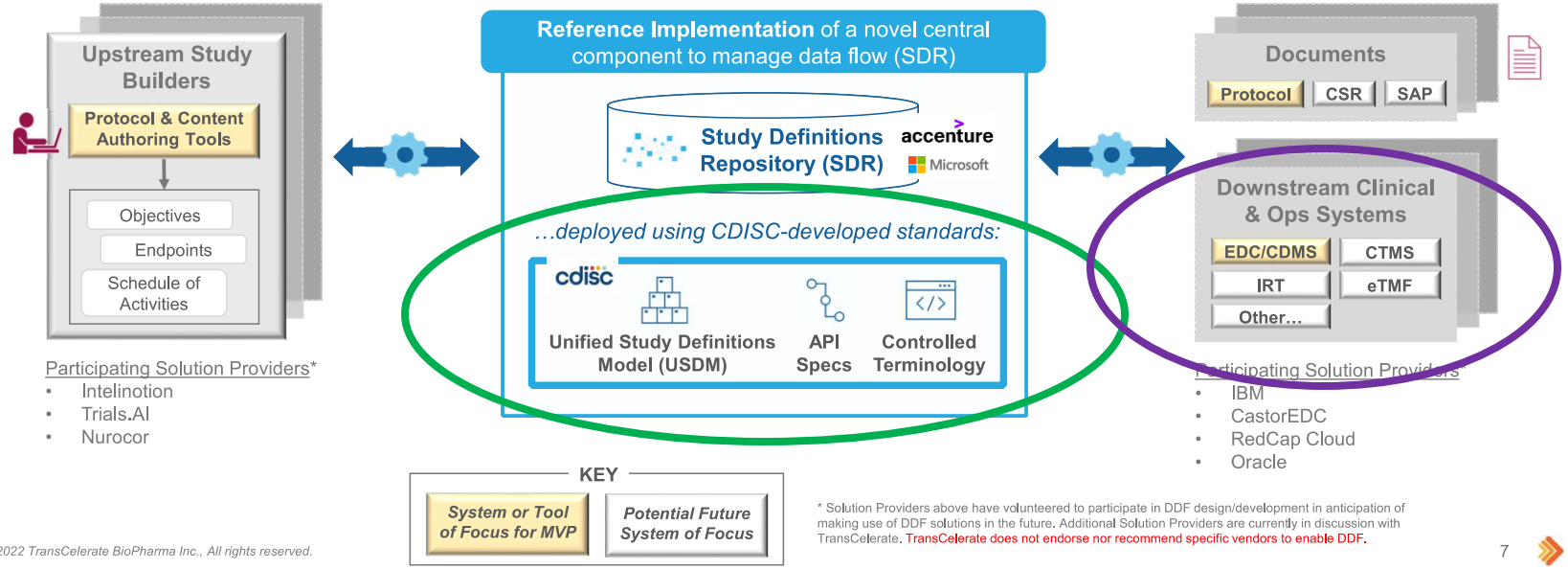
*System or Tool of Focus for MVP* | *Potential Future System of Focus*

* Solution Providers above have volunteered to participate in DDF design/development in anticipation of making use of DDF solutions in the future. Additional Solution Providers are currently in discussion with TransCelerate. TransCelerate does not endorse nor recommend specific vendors to enable DDF.

# Minimum Viable Product (MVP) Development Complete

April 2022 Release

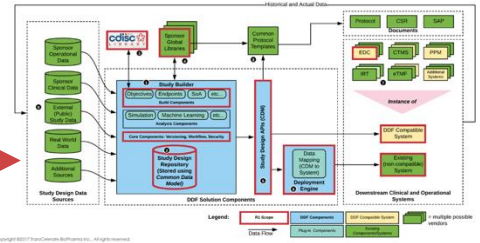
Open Source | Vendor Agnostic | Agile Development | Dynamic Alignment to Standards




* Solution Providers above have volunteered to participate in DDF design/development in anticipation of making use of DDF solutions in the future. Additional Solution Providers are currently in discussion with TransCelerate. TransCelerate does not endorse nor recommend specific vendors to enable DDF.

# CDISC Library

*Connect with Digital Data Processes through Open-API*



cdisc LIBRARY

Foundational Standards

Controlled Terminology

API

Machine-executable content

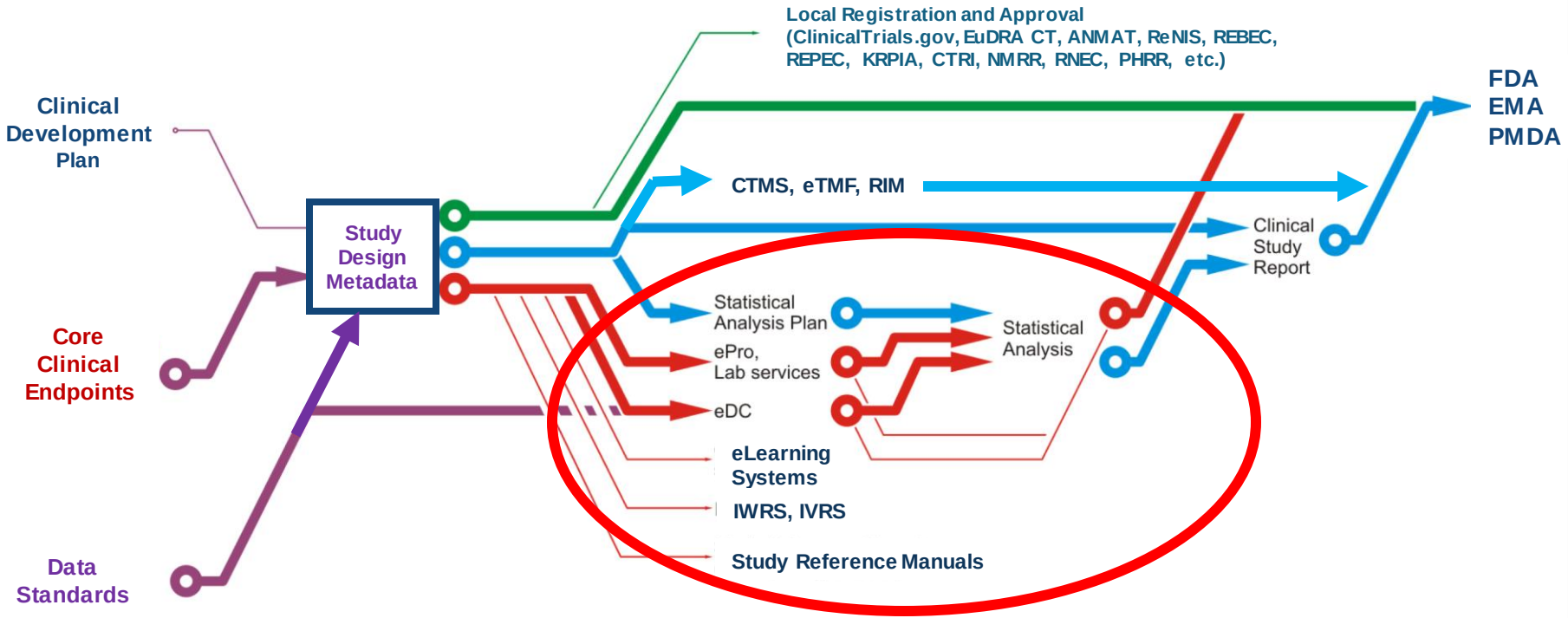
Executable Conformance Rules

| | | | | |
|---|---|---|---|---|
| Biomedical Concepts | Codelist Subsets | Tables, Listings, and Figures | Implementation Guide Text | FHIR to CDISC Mappings |
| Analysis Concepts | TAUG Metadata | Derivations and Mappings | Machine-readable Examples | LOINC Code Mappings |
| Templates | Study Design Metadata | | CRF Collection | Diff Content Between Versions |

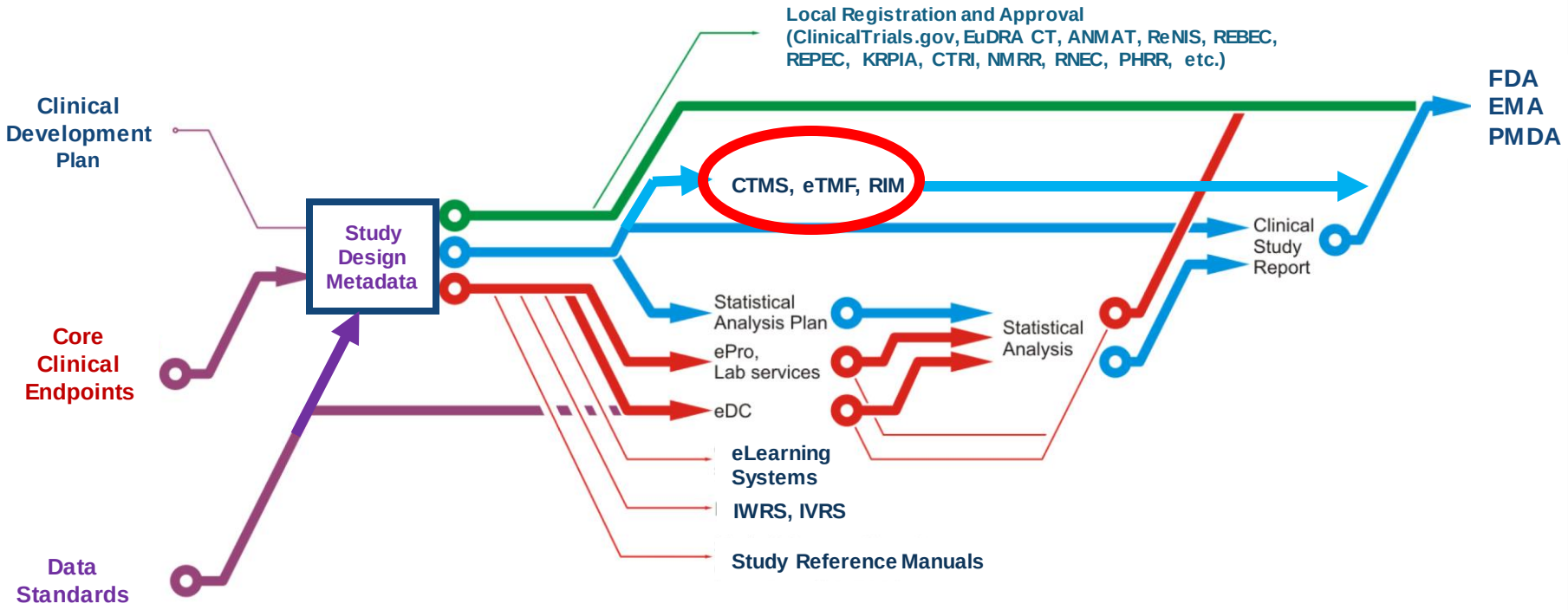
*CDISC Standards*

*Informative Content*

# The Clinical Trial Information Flow



# The Clinical Trial Information Flow



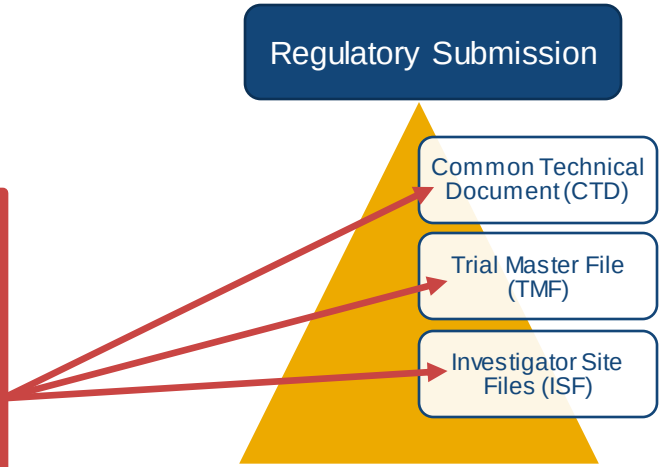
# What is a Trial Master File?

The sponsor and the investigator shall keep a clinical **trial master file**. The clinical trial master file shall at all times contain the **essential documents** relating to that clinical trial which allow verification of the conduct of a clinical trial and the quality of the data generated […]. It shall be readily available, and directly accessible upon request, to the Member States. [EU Regulation 536/2014]

"The minimum list of essential documents that has been developed....." [ICH GCP Section 8.2 – 8.4]

Essential Documents examples:

- CV
- 1572
- Protocol
- IRB approval
- IRB approved Informed Consent
- IRB correspondence
- Lab normal ranges
- Investigational Product tracking
- Etc.



# Purpose of the TMF Reference Model

## Standard Contents

- Industry opinion on what is kept in a TMF

## Standard Structure

- To support paper and electronic systems

## Standard Naming

- Based on ICH E6 R2 Sect. 8 & industry-accepted terminology

## Standard Metadata

- Recommended minimum metadata at system and artifact level


Website => tmfrefmodel.com

cdisc

# Benefits Gained by Implementation of eTMF RM Standards

- Standardizes company content and structure and limits company customization
  - We all follow the same regulatory requirements
  - Inspectors are the same across companies
  - Company-specific requirements are often driven by tradition, legacy or personal opinion
- Simplifies engagement of CROs and other third parties
- Simplifies consolidation of disparate documents into a single TMF structure (in real time, at defined trial events and/or at study end)

cdisc

TRIAL MASTER FILE TMF powered by cdisc REFERENCE MODEL

# Development of the TMF Reference Model

2009 to 2010

Initial meeting in 2009 with first version being released in 2010

2011 to 2013

Multiple releases including Regulator feedback, Investigator Site Files, Devices, Process based metadata. Workgroups established

Separated from DIA

2014 to 2021

Formalization with a Steering Committee. **Release of the Exchange Mechanism Specification** and Version 3

2022 onwards

cdisc

***The Future as a Standard!***

TRIAL MASTER FILE TMF powered by cdisc REFERENCE MODEL

cdisc

# Why Affiliate with CDISC?

GLOBAL NON-PROFIT CLINICAL RESEARCH STANDARDS DEVELOPMENT ORGANIZATION

PROMOTE INTEROPERABILITY

ABILITY TO EXTEND THE TMF METADATA AND PROVIDE IN MACHINE READABLE FORMAT

DEVELOPS GUIDANCE AND IMPLEMENTATION DOCUMENTS

STANDARDS EDUCATION ON IMPLEMENTATION

STANDARDS TO REMAIN FREELY AVAILABLE

cdisc

TRIAL MASTER FILE TMF powered by cdisc REFERENCE MODEL

# Benefits for the Clinical Research Community

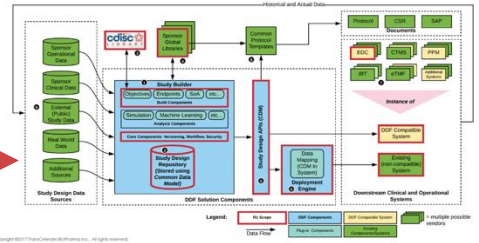
- Expansion of scope of clinical information standards to trial design, trial administration, clinical operations, regulatory documentation
- CDISC serves as the hub for cross-industry standards initiatives and the TMF RM will be part of that direction
- Strategically, there is a natural progression to the development and governance of standards, so why reinvent the wheel when so much work has already been done
- Evolution organizationally to embrace governance of clinical research information standards, not just the clinical data from where it originated.
- Broadening the harmonization of clinical research information standardization.

cdisc

TRIAL MASTER FILE TMF powered by cdisc REFERENCE MODEL

# CDISC Library

*Connect with Digital Data Processes through Open-API*



cdisc LIBRARY

Foundational Standards

Controlled Terminology

API

Machine-executable content

Executable Conformance Rules

| | | | | |
|---|---|---|---|---|
| Biomedical Concepts | Codelist Subsets | Tables, Listings, and Figures | Implementation Guide Text | FHIR to CDISC Mappings |
| Analysis Concepts | TAUG Metadata | Derivations and Mappings | Machine-readable Examples | LOINC Code Mappings |
| Templates | Study Design Metadata | TRIAL MASTER FILE TMF REFERENCE MODEL | CRF Collection | Diff Content Between Versions |

*CDISC Standards*

*Informative Content*

# We welcome the TMF RM Community to the CDISC Consortium of Clinical Research Standards


TRIAL MASTER FILE
TMF
powered by cdisc
REFERENCE MODEL

cdisc

# 2020 AND BEYOND

- Data Modernization and Governance
  - Areas of Focus
    - § Data Management and Governance Maturity Assessment and Gap Analysis

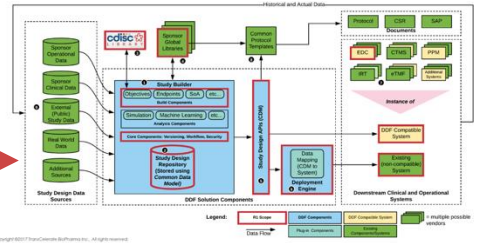
      Establish a baseline, conduct a gap analysis and generate documentation that outlines a schedule for implementation of data governance policies and procedures for all CTP data systems and processes
    - § Data Management Framework Implementation

      Develop a recommended roadmap for the modernization of our existing data architecture in accordance with recommended Data Management and Data Governance policies and procedures. This roadmap will delineate strategic priorities and outline a recommended approach to attain a desired Data Management Framework as dictated by the Data Management needs of CTP
    - § Data Governance Framework Implementation

      Implement the Data Governance Framework in accordance with the outcomes from the data management framework implementation plan.

# CDISC Library

*Connect with Digital Data Processes through Open-API*



cdisc LIBRARY

Foundational Standards

Controlled Terminology

API

Machine-executable content

Executable Conformance Rules

| | | | | |
|---|---|---|---|---|
| Biomedical Concepts | Codelist Subsets | Tables, Listings, and Figures | Implementation Guide Text | FHIR to CDISC Mappings |
| Analysis Concepts | TAUG Metadata | Derivations and Mappings | Machine-readable Examples | LOINC Code Mappings |
| Templates | Study Design Metadata | TRIAL MASTER FILE TMF REFERENCE MODEL | CRF Collection | Diff Content Between Versions |

*CDISC Standards*

*Informative Content*

# Thank You CDISC Community!

*Dave Evans – President & CEO, CDISC*
*devans@cdisc.org*