2023
KOREA
INTERCHANGE
SEOUL | 11-14 DECEMBER

State of the Consortium

David A. Evans
President and CEO, CDISC
2023 Korea 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.

FROM YESTERYEAR TO TODAY

So what is true for life itself is no less true for the universe: knowing where you came from is no less important than knowing where you are going.
- Neil deGrasse Tyson

Think of these things, whence you came, where you are going, and to whom you must account.
- Benjamin Franklin

EARLY CDISC History – 1997 - 2000

1997

- **Founding Members**
  - Tom Tunstall, Bron Kisler, Becky Kush
- **Two volunteer Groups**
  - Nomenclature and Modeling
- **'CDISC' was Named**

1998

- Nomenclature – became Glossary Group
- Modeling – held numerous meetings

EARLY CDISC History (continued)

1999

- CDISC Volunteers offered assistance to incorporate non-profit organization
- Split Modeling Group into two teams
  - Submission (SDS)
  - Data
  - Acquisition (DAS→ODM)

2020

- CDISC is launched!

CDISC Is Officially Launched!

- **February 2000** – Business Case Presented
- **June 2000** – Charter Members
- **June 2000 –** Funding = $40,000
- **One first full-time employee hired**
- **Rebecca Kush, President**

CDISC Obtained Non-Profit Status

2000

CDISC registered as 501(c)(6) non-profit organization

2011

Status changed from 501(c)(6) to 501(c)(3) non-profit organization

CDISC Interchanges

First CDISC Interchanges held in the following countries:

- Europe – 2003 in Dublin
- Japan – 2003 in Tokyo
- USA – 2003 in Bethesda
- China – 2007 in Shanghai
- Korea – 2023 in Seoul

REGULATORS MANDATE

- FDA published Guidance on Standards Study Data in 2014 – all studies submitted in 2016 all studies that start in the year 2017 or later will be required to submit their data to the FDA in an electronic format i.e. CDISC.

- PMDA followed suit sharing timeline for implementation of electronic data submission using CDISC Standards in 2016

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U P D A T E !!!

October 2019 – NMPA ('National Medical Products Administration, new name for China FDA) recommended use of CDISC Standards – SDTM and ADaM for submission

How Far We have Come

- **Standards**
  - From Foundational Standards to **49** Therapeutic Area Standards
- **Training**
  - We started out with Public training, now we have Virtual training, Public and Private training, On-Demand Online training, in addition to webinars, workshops, licensed trainer instruction and more
- **Membership**
  - **18** Members in 2000, today we have over **500**
- **Revenue**
  - $40,000 in 2000 to over $11,000,000 in 2023
- **Employees**
  - 1.5 in 2000 to over 40 today

CDISC LOGOS THROUGH THE YEARS

CDISC - Who we are today

***Mission**: To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare*

- Global Non-profit Consensus-based Standards Development Organization
- 20+ Years of Regulatory Clinical Data Standards Development and Implementation
- Experienced Leadership Team and Dedicated Staff of 40+ Professionals and SMEs
- Volunteer Network of 1000+ Industry Experts
- 530+ Member Organizations
- Widely Adopted and Freely Available Clinical Research Data Standards
- Mature and Globally Accepted Standard Governance Processes
- Innovative Open-Source Technology for Standards Library and Metadata Management
- Involved in a wide range of emerging Industry Initiatives and Projects
- Collaborative Ecosystem of Relationships and Partnerships
  - Members, Regulators, Patient Foundations, Academia, SDOs and Industry

Alliances and Collaborations

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phuse

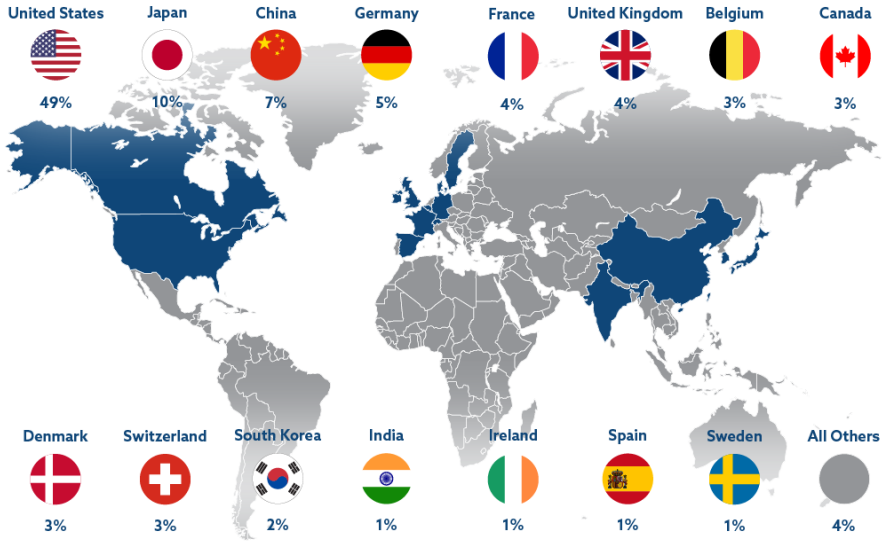
CDISC and PhUSE partner to further the mission of each organization collectively, with CDISC focusing on the development of global, platform-independent data standards, and PhUSE focusing on the implementation and use of the CDISC standards. The two organizations work to combine efforts on key initiatives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

CDISC Community

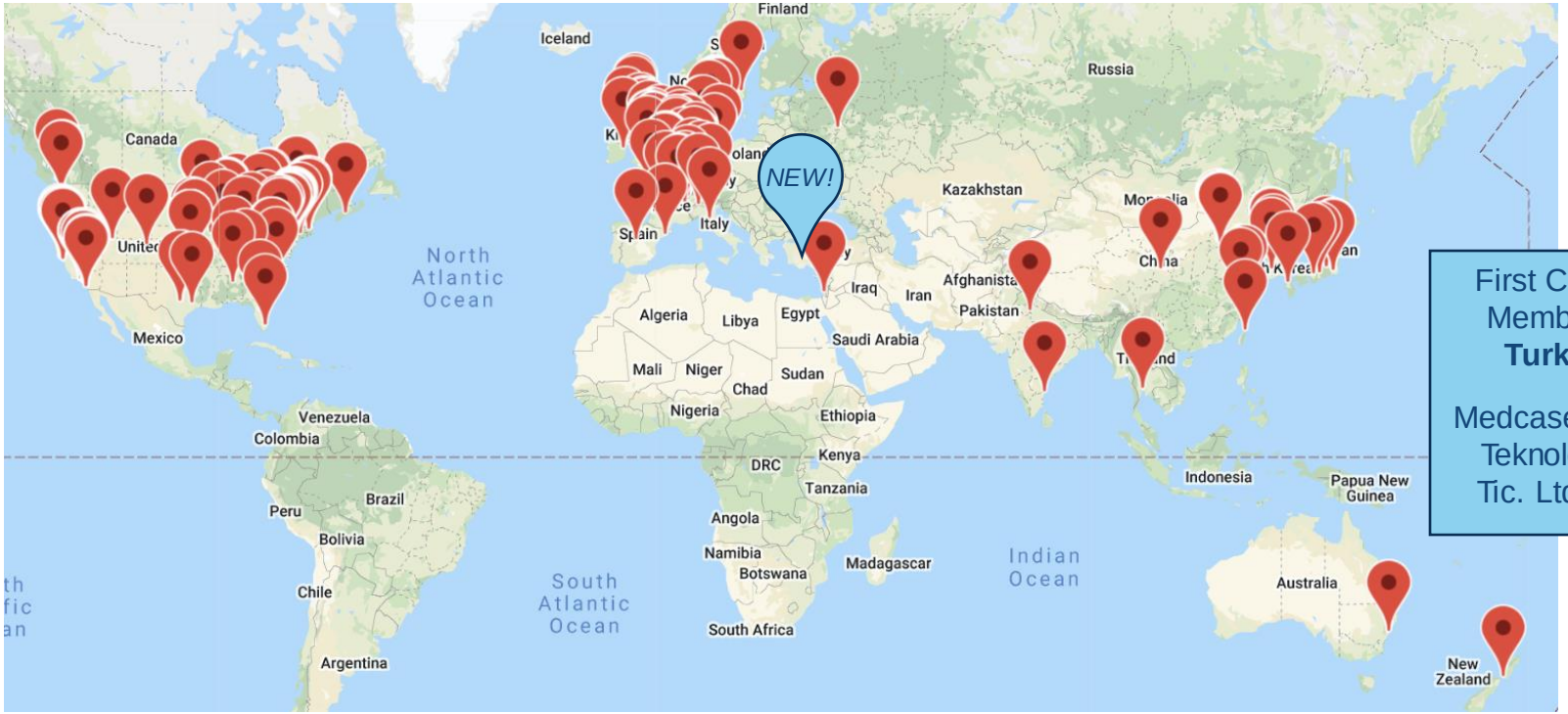
CDISC Members = Global Community

Members by Industry

Members by Location



CDISC Members Around the Globe



First CDISC Member in **Turkey!**

Medcase Yzilim Teknolojileri Tic. Ltd. Sti.

CDISC Members

CDISC COORDINATING COMMITTEES (3C)

Five CDISC Coordinating Committees in 2023:

- CDISC Europe (E3C) in 2001
- CDISC Japan (J3C) in 2002
- CDISC China (C3C) in 2007
- CDISC Korea (K3C) in 2017
- CDISC TMF (T3C) in 2023

CDISC KOREA COORDINATION COMMITTEE (K3C)

Organization Type	Organization Name	Member Name
Academic	DCUMC(Daegu Catholic University Medical Center)	Im-Hee Shin, Ph.D.(Maria)
		Sang-Gyu Kwak, Ph.D.
Academic	Dongguk University	Eon-Ho Kim, Ph.D.
		Hyun-Moon Kim
CRO(Non-clinical)	Biotoxtech, Inc.	Cheol-Beom Park, M.D.
CRO(Clinical)	LSK Global Pharma Services	Byeong-Kwan Park, Ph.D.
CRO(Clinical)	Symyoo, Inc.	Dong-Jin Yoo, M.D.
Government	Korea Institute Toxicology	Yong-Beom Kim, Ph.D
Pharmaceutical Company	Daewoong Pharmaceutical Co. Ltd.	Jee-Sun Lee, M.D, Ph.D.
Pharmaceutical Company	SK Chemicals	Hyun-Soo Lee
Technical Service Provider	Clupea, Inc.	Dong-Hoon Cho, Ph.D.
		Gi-Hwan Kim
Technical Service Provider	SAS Korea JMP	Chul-Hee Min

ROLE OF A 3C

Summary of Main Responsibilities of 3C

- **CDISC Standards**
  Promote and advocate the use of CDISC Standards
- **CDISC Events**
  Assist CDISC Events Team in organizing and promoting CDISC Interchanges
- **Training**
  Host/promote CDISC training and seminars
- **Translation**
  Help with translation of CDISC Standards and Training materials
- **Communication**
  - Provide update CDISC on activities
  - Support communication with Regulators

Announcing 2024 CDISC Interchanges

Thank You to Our Korea Interchange Sponsors

Diamond

Diamond

Ruby

Sapphire

Exhibitors

Thank You to the Organizing Team

CDISC TEAM

- Bernard Klinke
- Sheila Leaman
- Pearce O'Neal
- Andrea Vadakin

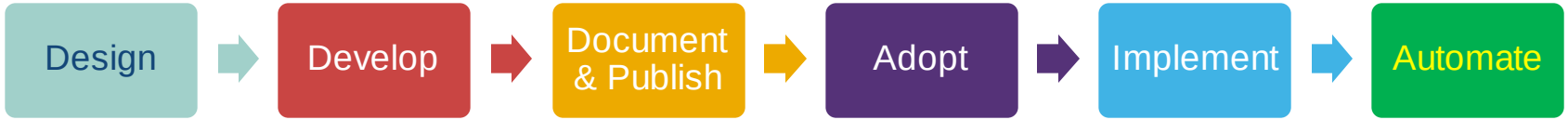
KOREA TEAM

- Dr. Im Hee Shin
- Gihwan Kim
- Jamie Kim

What is the next stage on the Clinical Information 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*

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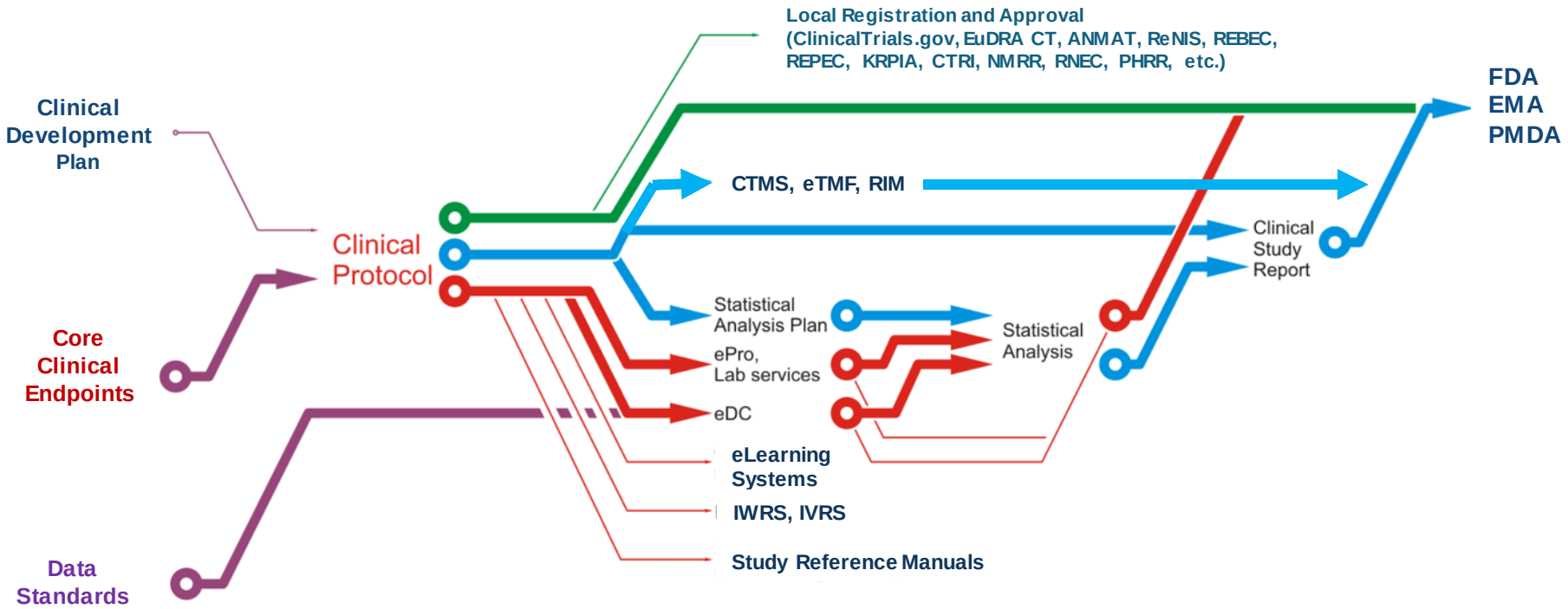
The Clinical Trial Information Flow



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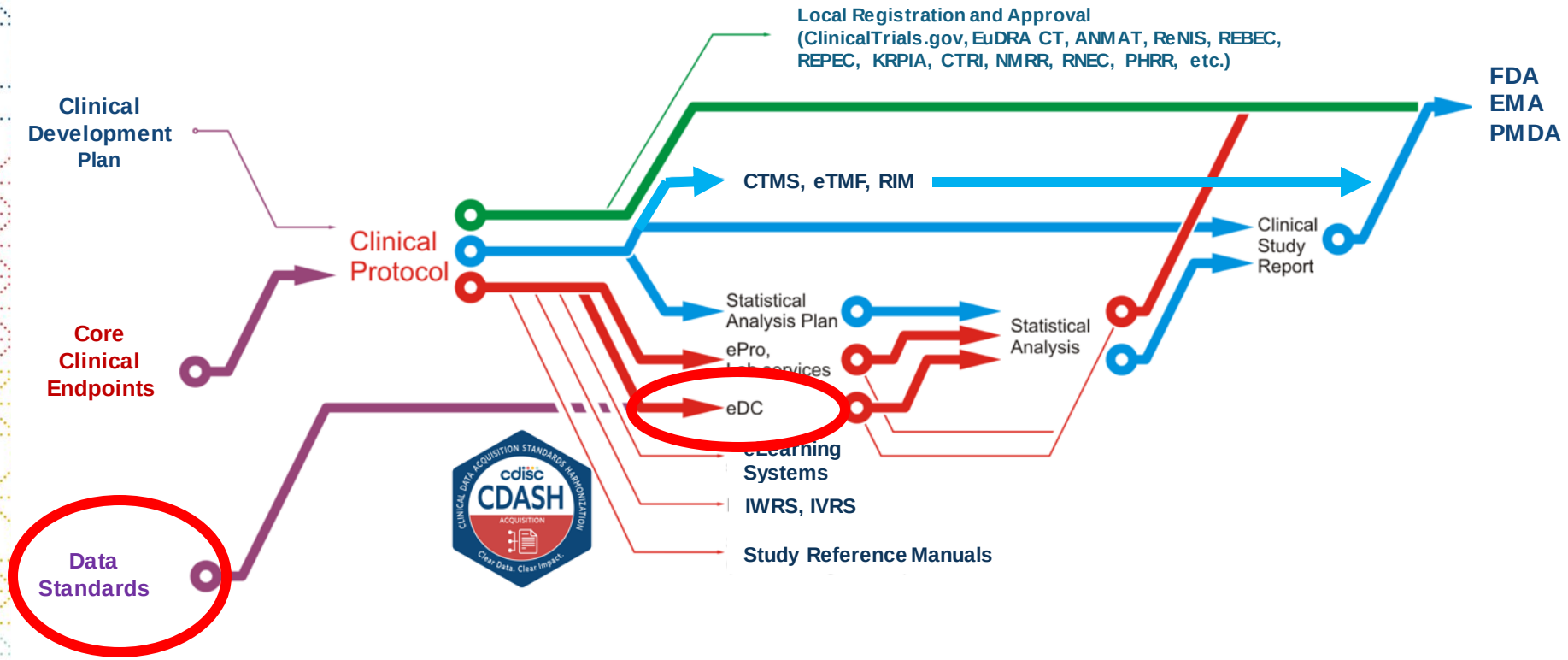

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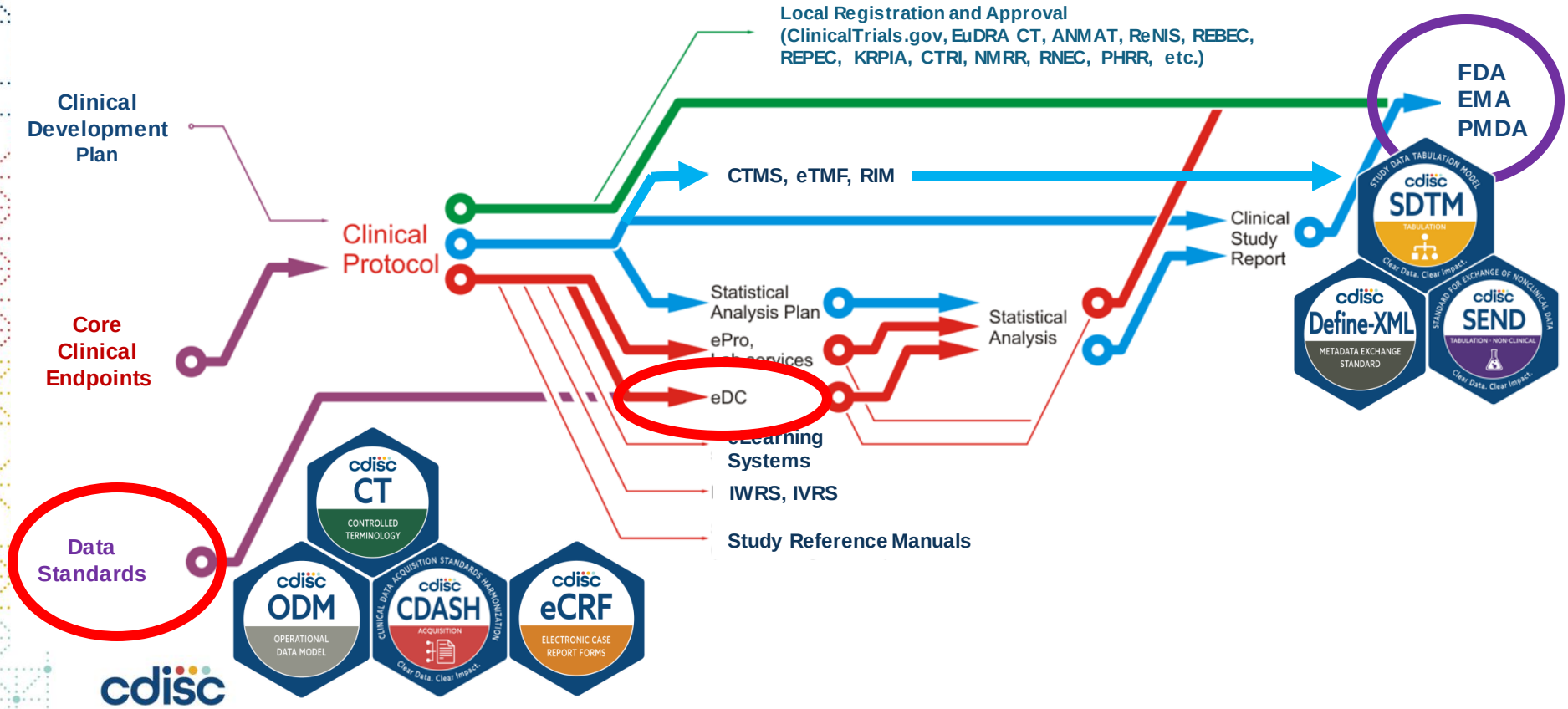

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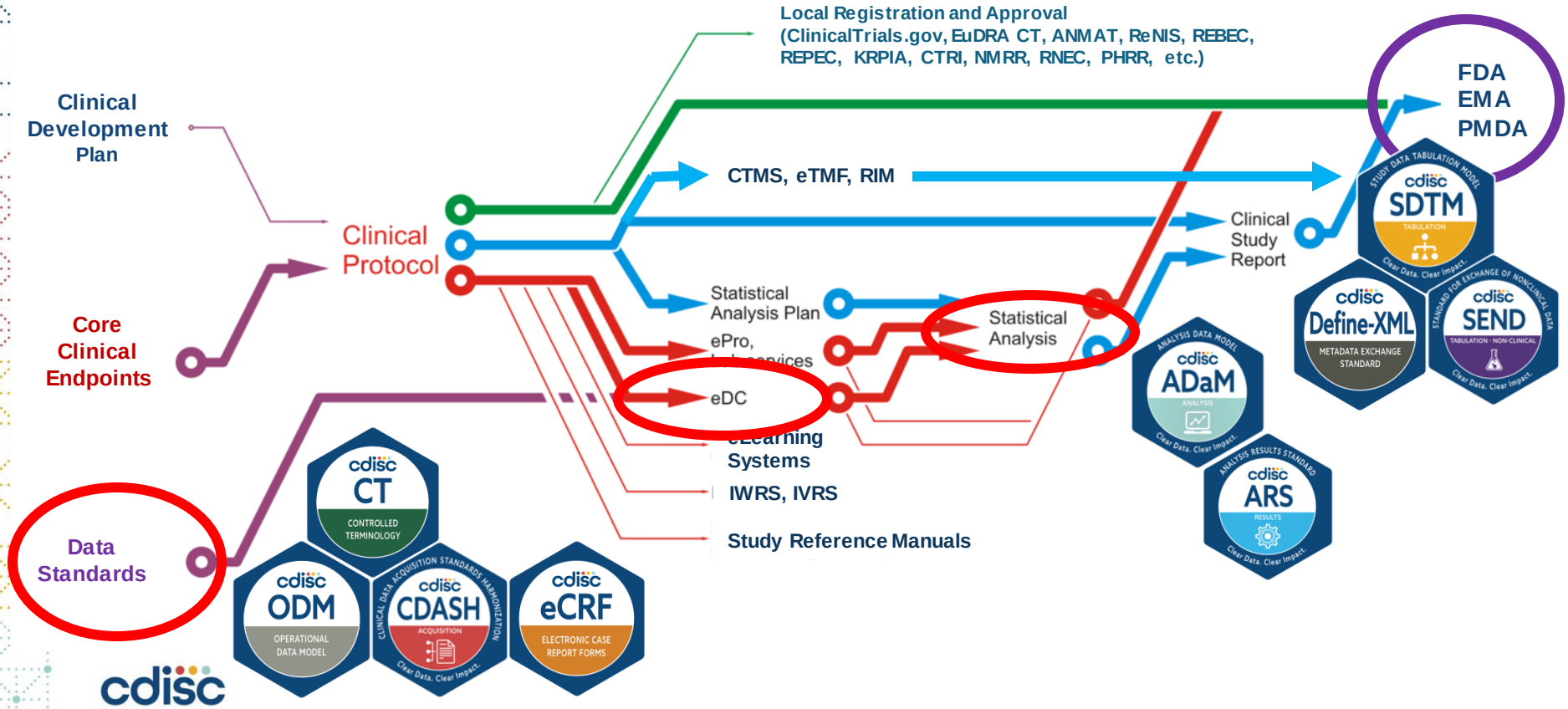

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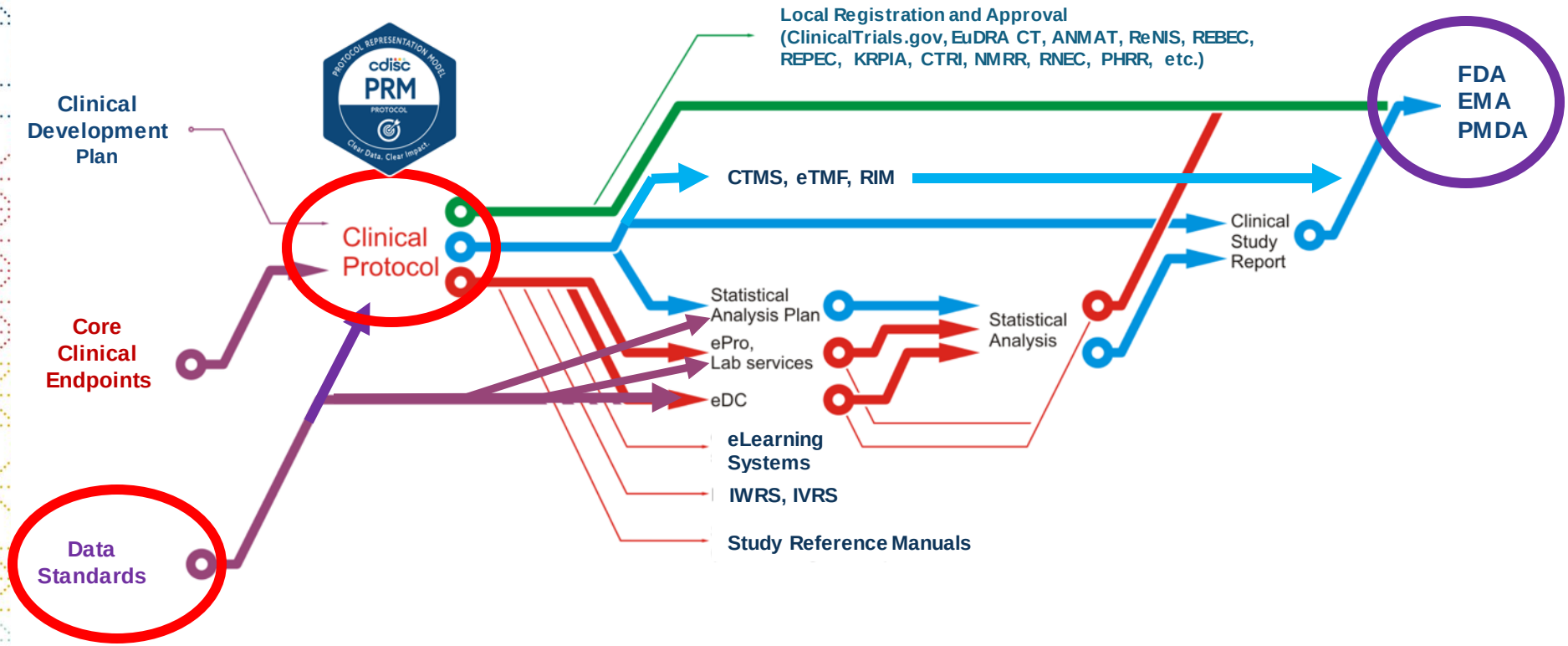

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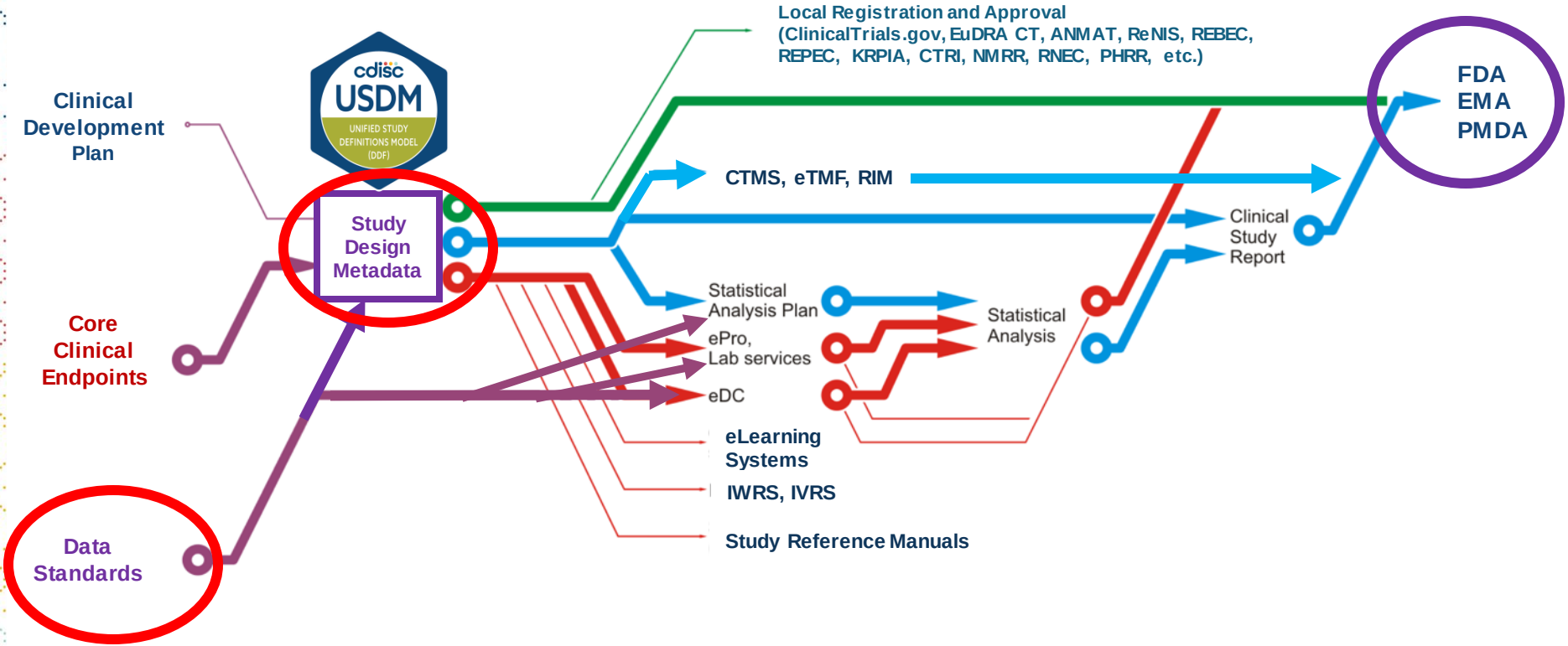

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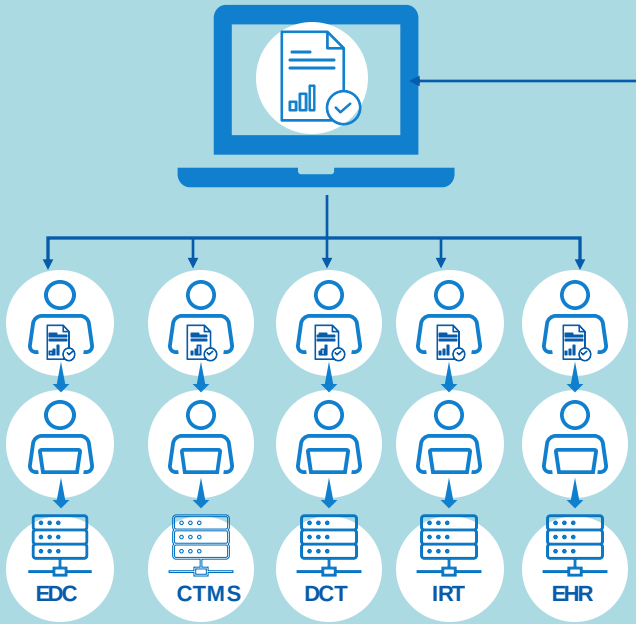
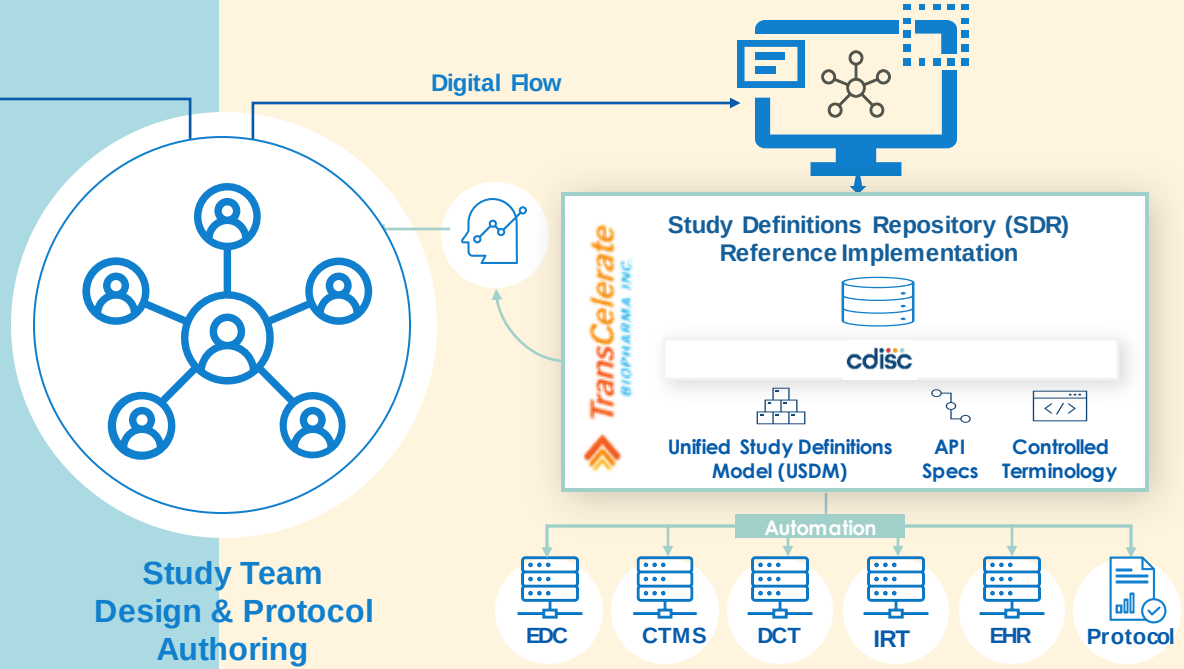
Digital Data Flow (DDF) Initiative

Write Once, Read Many

TODAY: Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems



TOMORROW: Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



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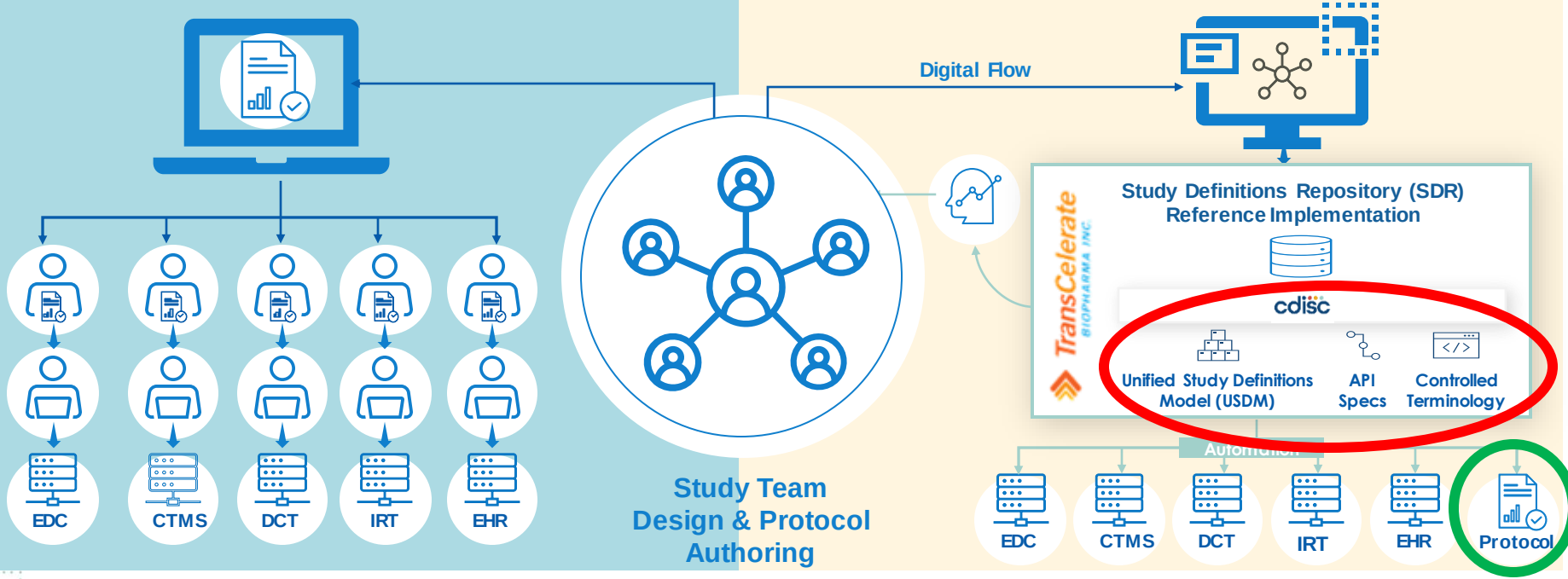

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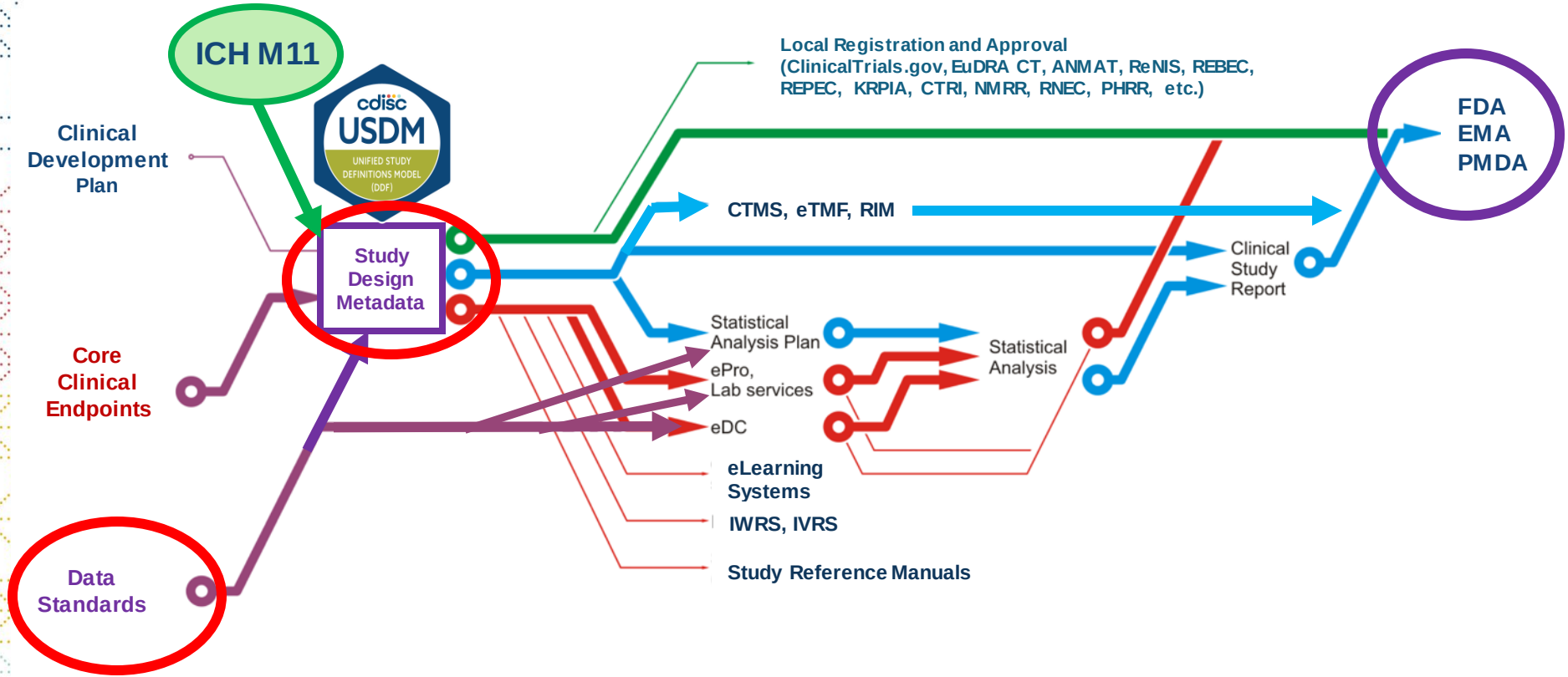

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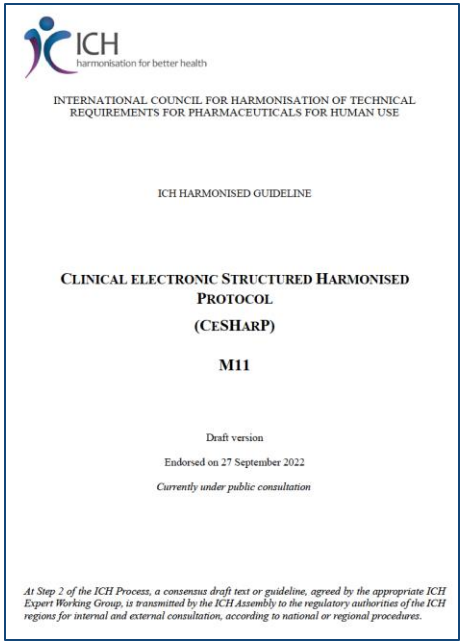
M11 Is …

ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

https://www.ich.org/page/multidisciplinary-guidelines



ICH harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11

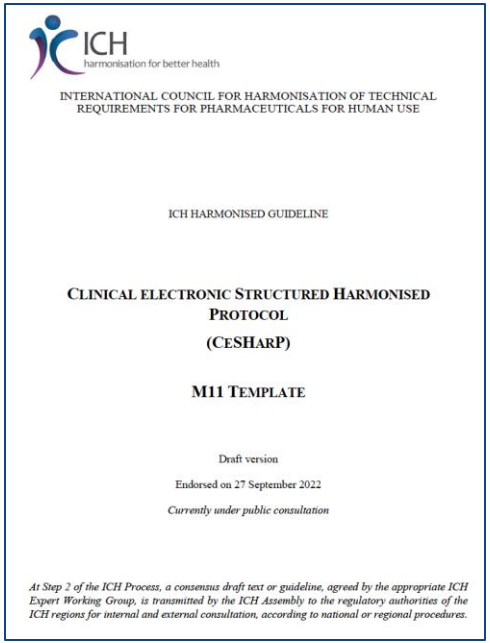
Draft version

Endorsed on 27 September 2022

Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

Provides background, purpose, and scope as a guideline



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(CESHARP)

M11 TEMPLATE

Draft version

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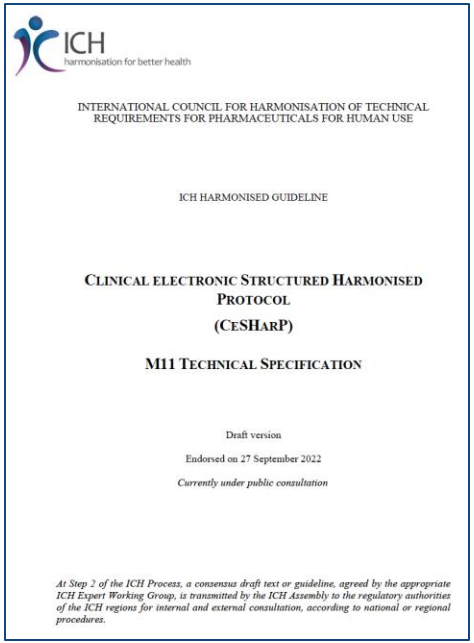
Provides the written format for the Interventional Clinical Trial Protocol Template



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(CESHARP)

M11 TECHNICAL SPECIFICATION

Draft version

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Provides the technical representation aligned with the guideline and protocol template

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Template for Description of Trial Design

4.1 Description of Trial Design

Describe the trial intervention model (for example, single group, parallel group, cross-over, factorial, sequential), the expected number of participants, and the control method (for example, placebo, active comparator, low dose, historical, standard of care, sham procedure, or none [uncontrolled]).

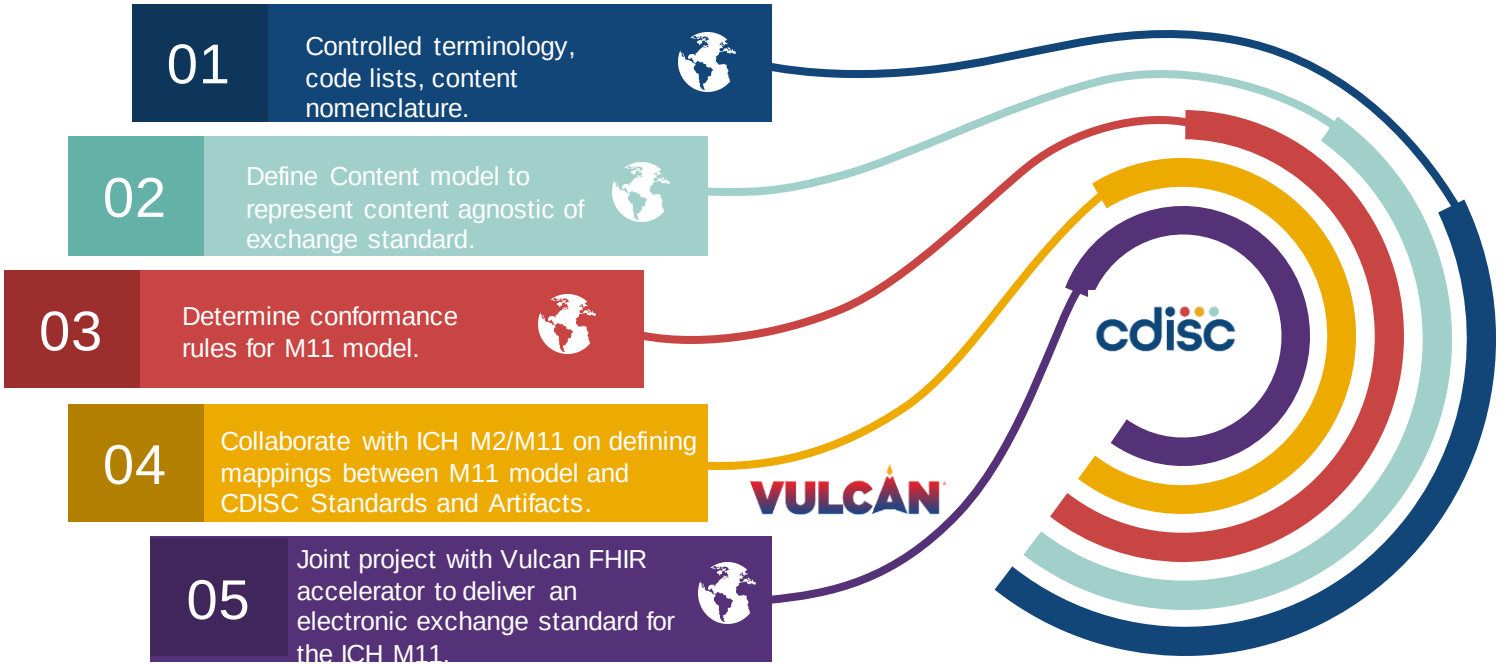
If applicable, indicate the type of trial (for example, superiority, non-inferiority, dose escalation, or equivalence).

Technical Specification for Description of Trial Design

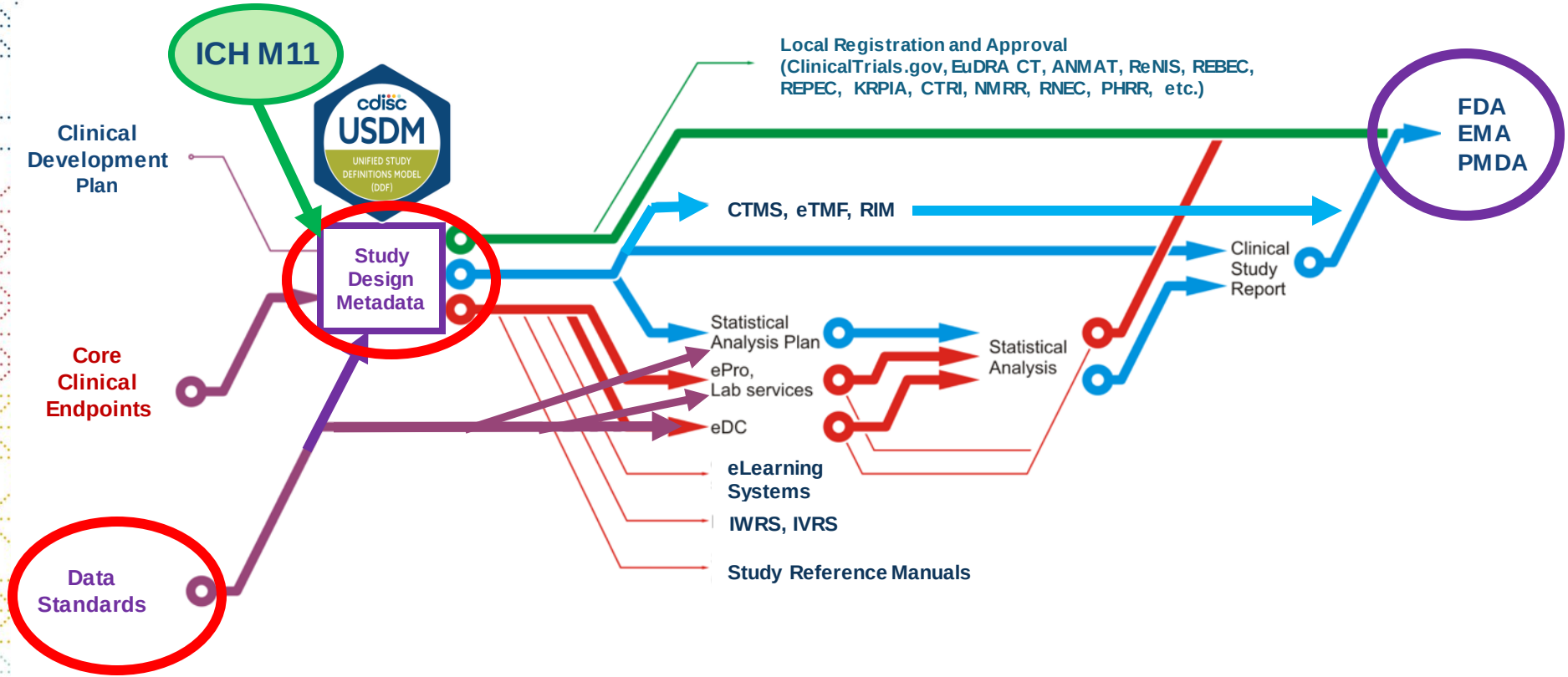
Term (Variable)	Type of Trial
Data Type	List
Topic, Value or Header	D
Definition	
User Guidance	
Conformance	Required
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Trial Design
Relationship (reference to high level conceptual model)	
Value	Superiority, non-inferiority, dose escalation, or equivalence
Business rules	**Value Allowed:** Yes **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

- Variables
- Concept/Terminology
- Code lists
- Conformance

CDISC M2/M11 Engagement



The Clinical Trial Information Flow



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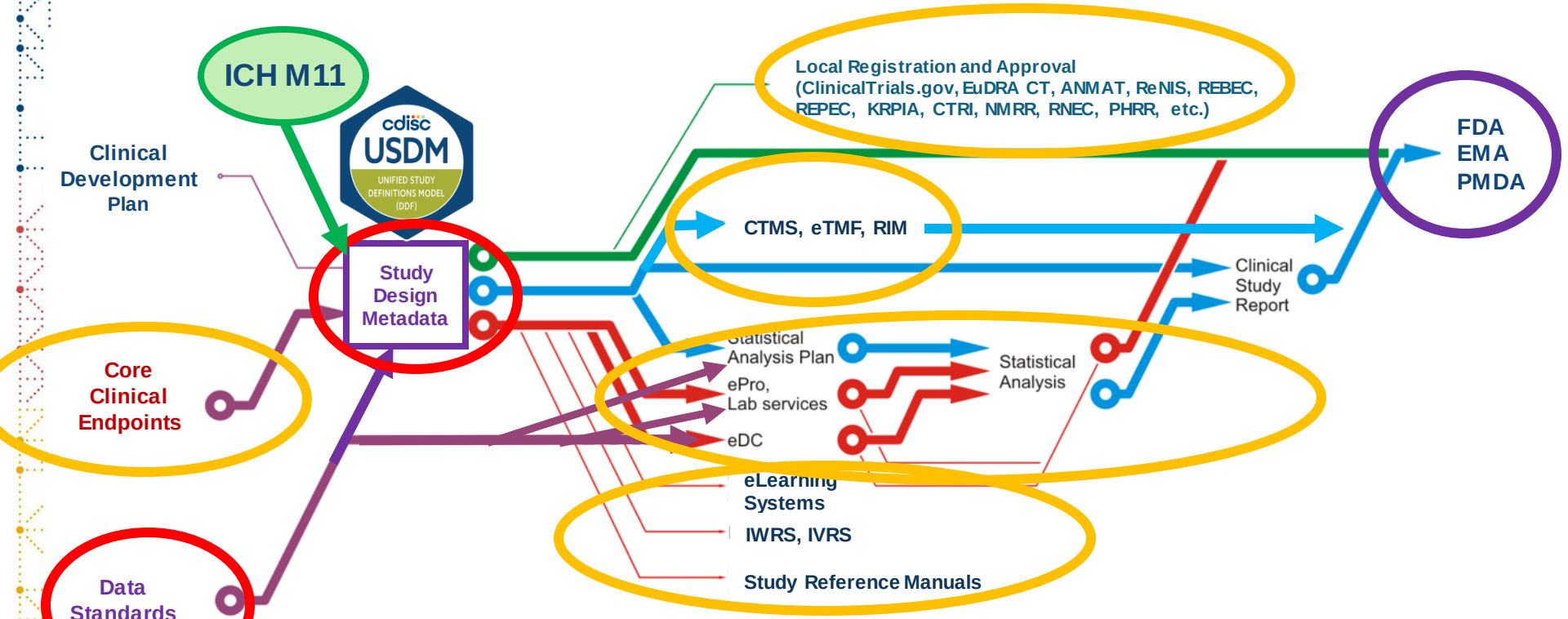

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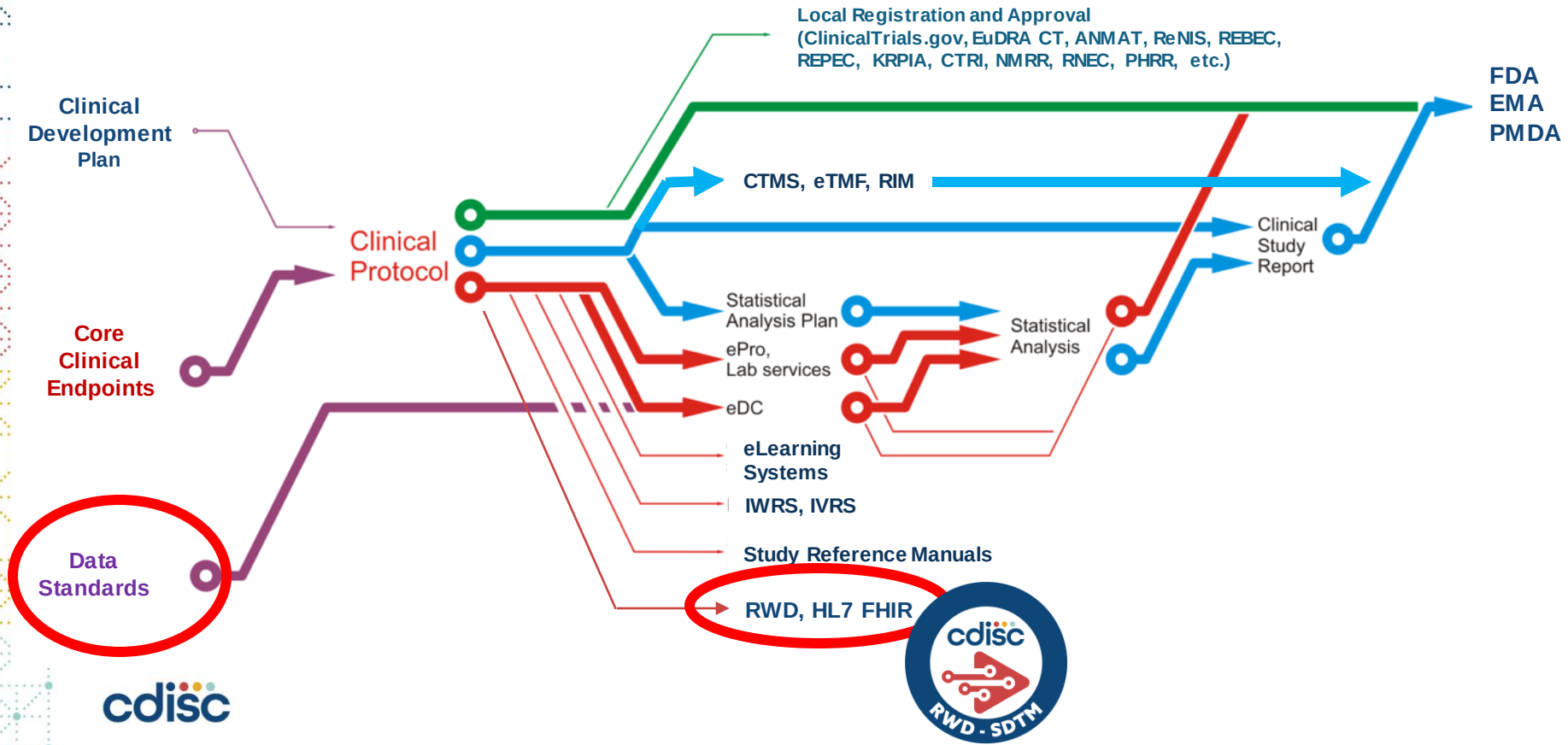

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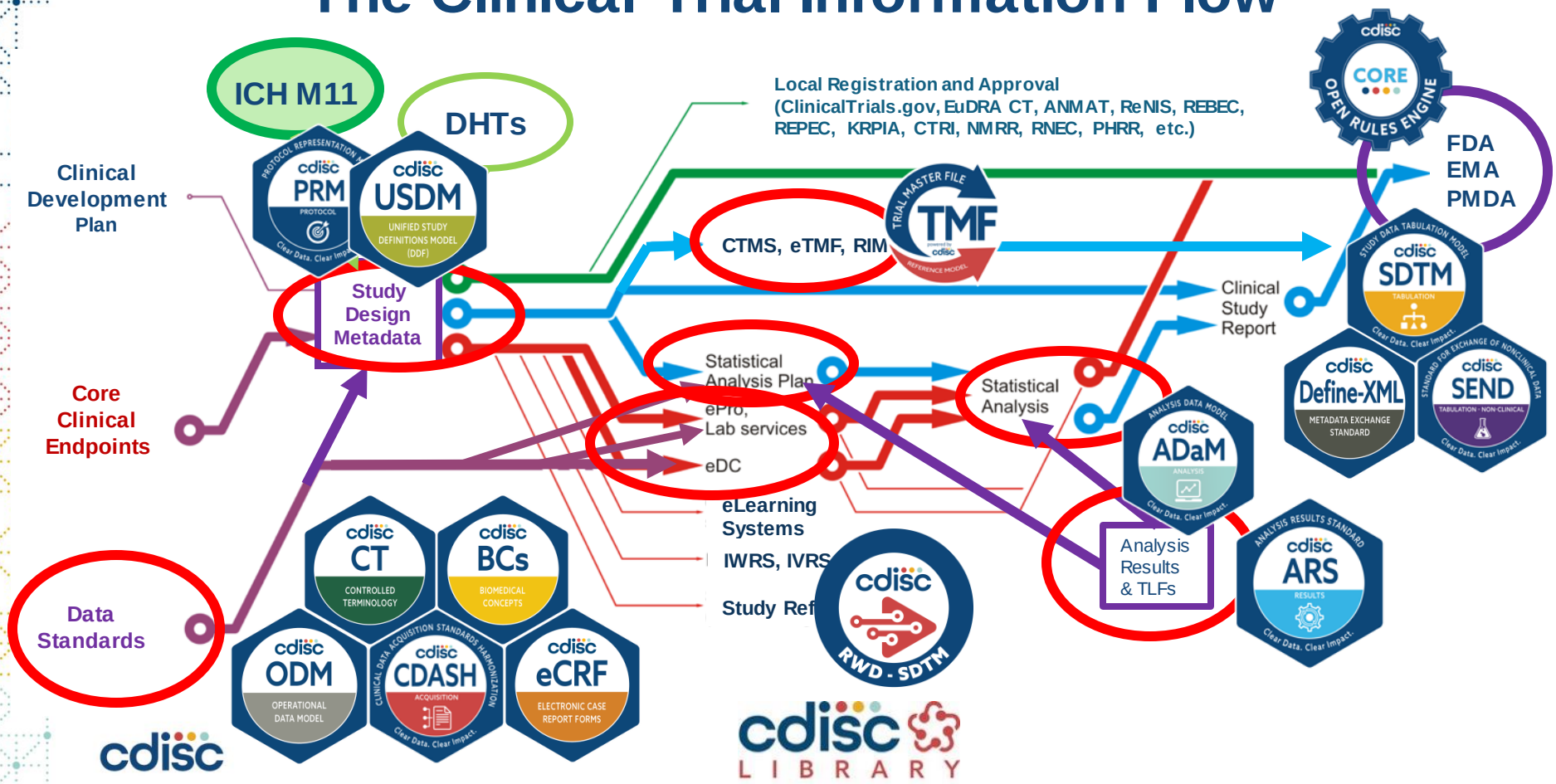
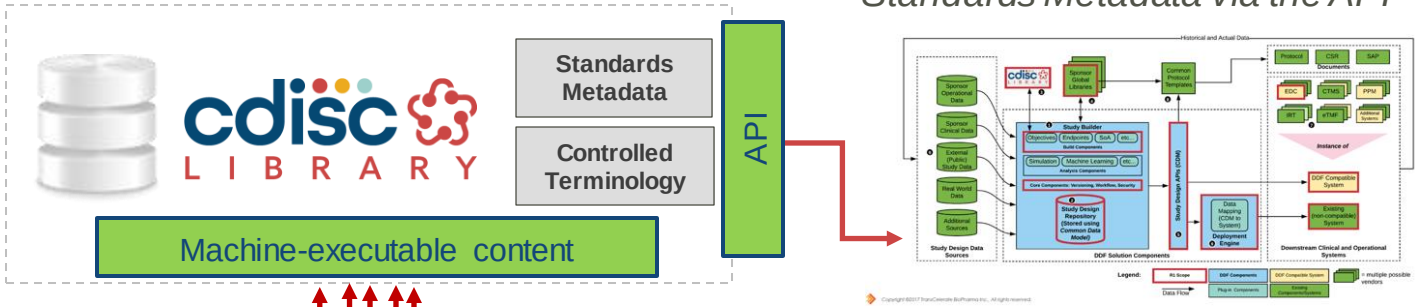


CDISC Library Provides the Foundation

Software Applications Consume Standards Metadata via the API



Executable Conformance Rules

Biomedical Concepts	Codelist Subsets	Dataset Specializations	Implementation Guide Text	Standards Mappings
Analysis Results Standard	TAUG Metadata	Derivations and Mappings	Machine-readable Examples	Draft Standards Metadata
Tables, Listings, and Figures	Study Design Metadata	Trial Master File Reference Model	CRF Collection	Diff Content Between Versions

CDISC Standards *Informative Content*

CDISC Library Provides the Foundation

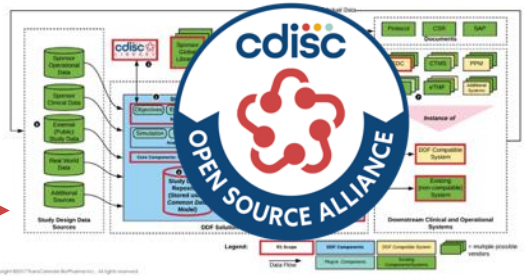
Software Applications Consume Standards Metadata via the API

cdisc LIBRARY

Standards Metadata

Controlled Terminology

API



Machine-executable content

Executable Conformance Rules

CORE OPEN RULES ENGINE

Biomedical Concepts	Codelist Subsets	Dataset Specializations	Implementation Guide Text	Standards Mappings
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Tables, Listings, and Figures	Study Design Metadata	Trial Master File Reference	CRF Collection	Diff Content between Versions

ARS

CDASH

TMF

RWD - SDTM

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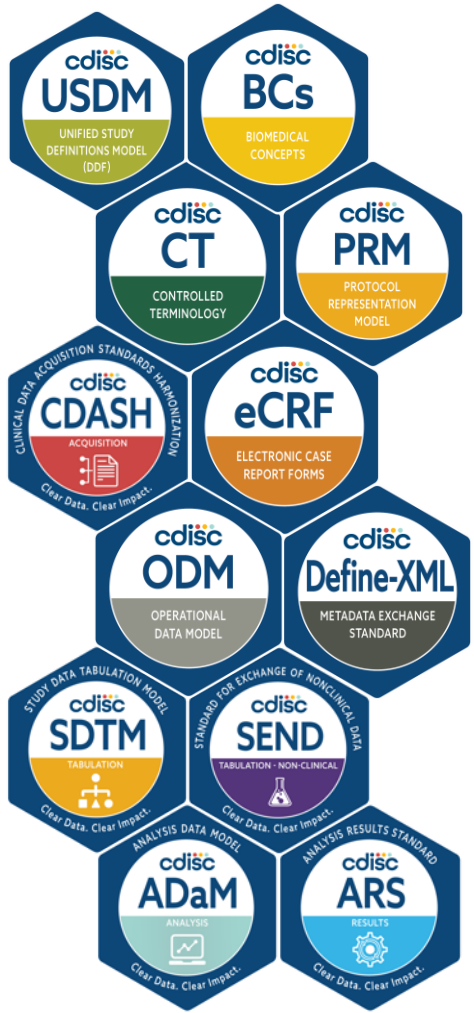
CDISC Standards

Informative Content

Thank You!

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



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cdisc CORE OPEN RULES ENGINE

cdisc OPEN SOURCE ALLIANCE

TRIAL MASTER FILE TMF powered by cdisc REFERENCE MODEL

cdisc LIBRARY

cdisc CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

See You Next Year in Daegu in September!

감사합니다!