



2023

CHINA

INTERCHANGE

BEIJING | 25-26 AUGUST



## Welcome Address: CDISC Strategy and the Future

David A. Evans, CDISC President and CEO



# 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.

# Thank you to our China CDISC Coordinating Committee

- Victor Wu, **Chair**, Beijing Data Science Express Consulting Co., Ltd.
- John Wang, **Vice-Chair**, Caidya CRO
- Ruiling Peng, **Vice-Chair**, Clin-nov Medical
- Zibao Zhang, **Past Chair**, LLC Ventures
- Wenjun Bao, JMP
- Hongwei Cai, The First Affiliated Hospital of Xi'an Jiaotong University
- Pamela Chen, Tigermed
- Yazhong Deng, Beijing Trust Medical Consulting Co. Ltd.
- Jingjing Han, CDE (Observer)
- Chao Wang, ClinChoice
- Simon Wang, F. Hoffmann-La Roche Ltd.
- Stanley Wei, Novartis Pharmaceuticals Corporation
- Zehuai Wen, Guangdong Provincial Hospital of Traditional Chinese Medicine
- Bryant Xiao, Hippocrates
- Billy Xin, EUCure (Beijing) Biopharma Co., Ltd.
- Lily Zhao, Innovent Biologics, Inc.
- Shenglin Zhang, JiXing Bio
- Haibo Wang, GCP Plus



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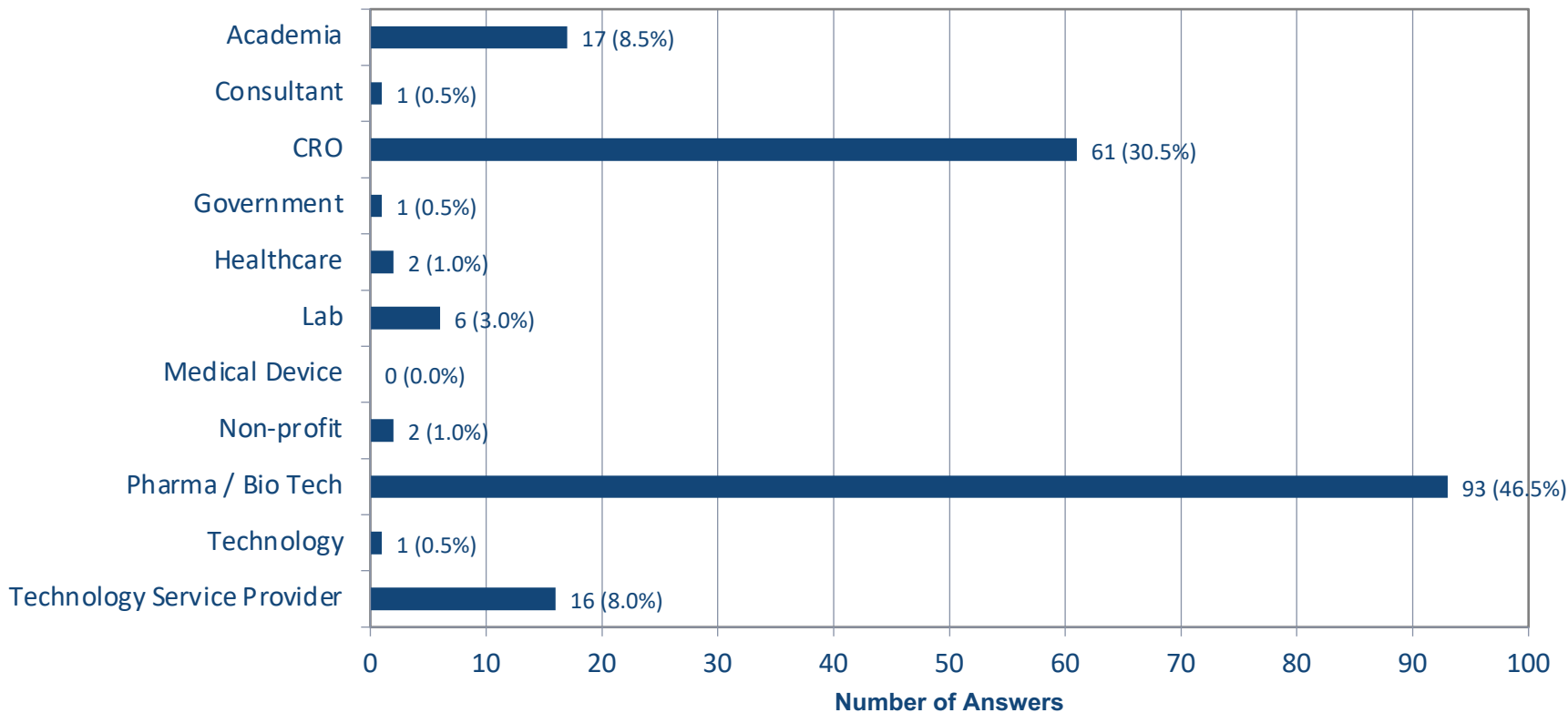


# Thank You for Joining Us!

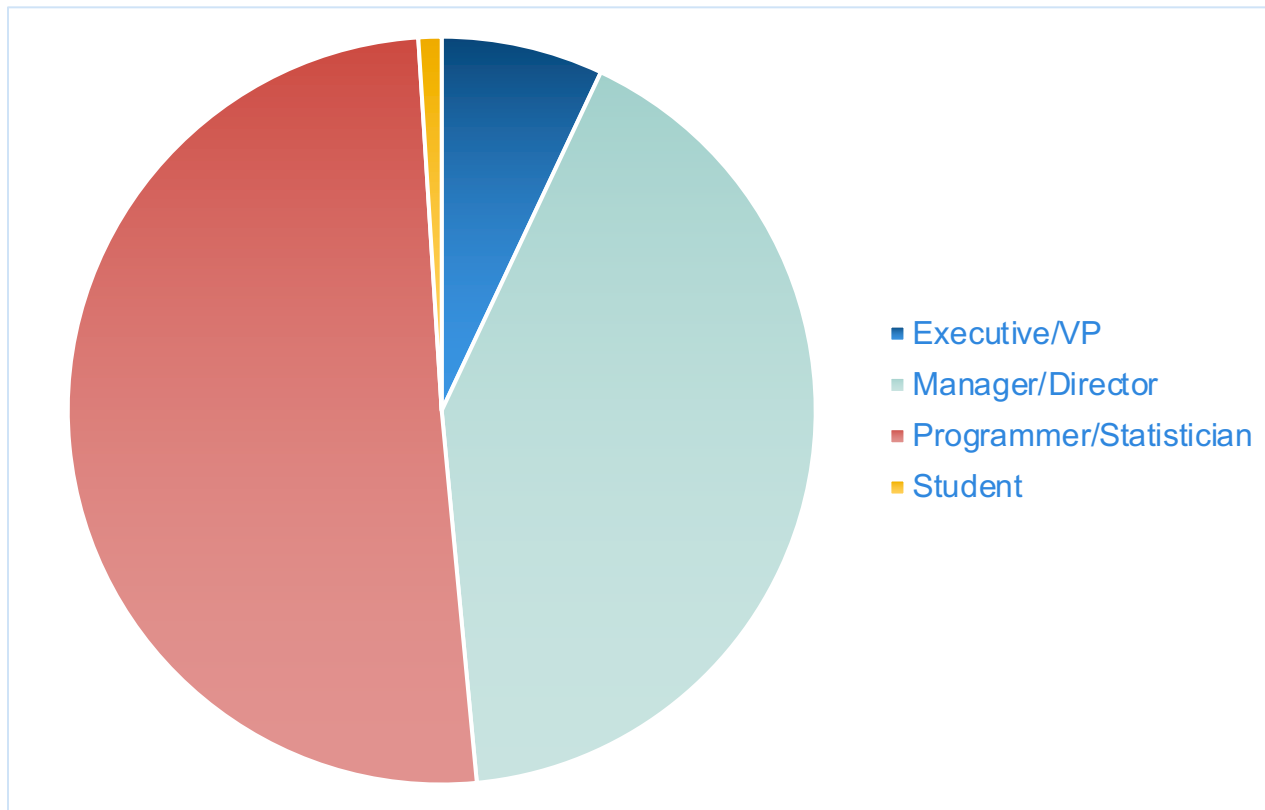
- First in-person event in China after the pandemic
- Highest in-person attendance
- Support of sponsors
- Cutting-edge topics; the latest on major CDISC initiatives

Year (In-Person)	Main Conference Attendance
2023	201
2019	176
2018	166
2017	123

# 2023 China Interchange Attendees by Industry Type



# 2023 China Interchange Attendees by Position





# CDISC Community







# 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
- 500+ 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

## CFAST & Therapeutic Area Partnerships

CDISC collaborates with many organizations to develop Therapeutic Area (TA) standards for multiple disease areas through the Coalition for Accelerating Standards and Therapies (CFAST) initiative, as well as other partnerships.



innovative medicines initiative



CRITICAL PATH INSTITUTE  
collaborate • innovate • accelerate



International Organization for Standardization



Leading healthcare terminology worldwide



Digital Imaging and Communications in Medicine



GS1



CHINA NMPA



harmonisation for better health

## Standards Development Organizations (SDO) Collaborations

CDISC collaborates with other SDOs to develop standards that are synergistic to support a learning health system based upon high quality research.

## Regulatory Collaborations

CDISC works closely with regulators around the world to ensure that CDISC standards will 1) streamline research from protocol/study design and trial registration through analysis and reporting; 2) facilitate the eSubmission review process; 3) ensure that clinical research is high quality; and 4) support the approvals of safe and efficacious medicines for patients.

Regulators also contribute to TA standards development

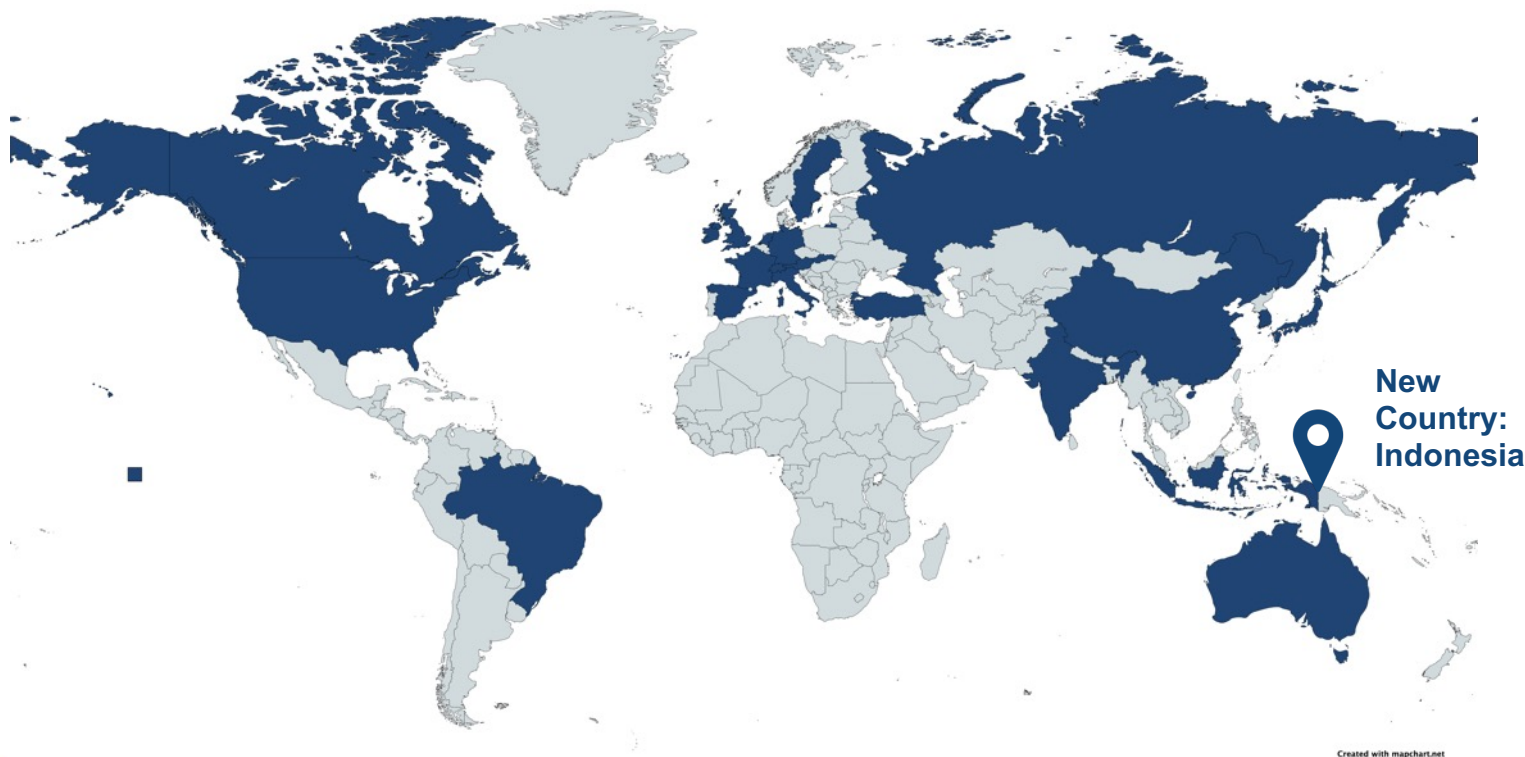
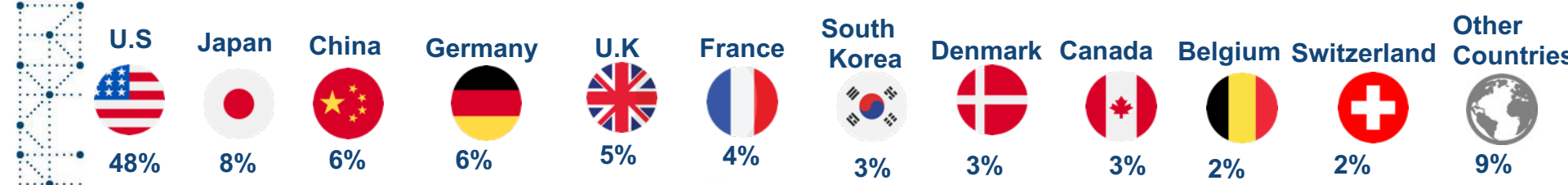


EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



## CDISC – a look into this year

- **Ongoing 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**

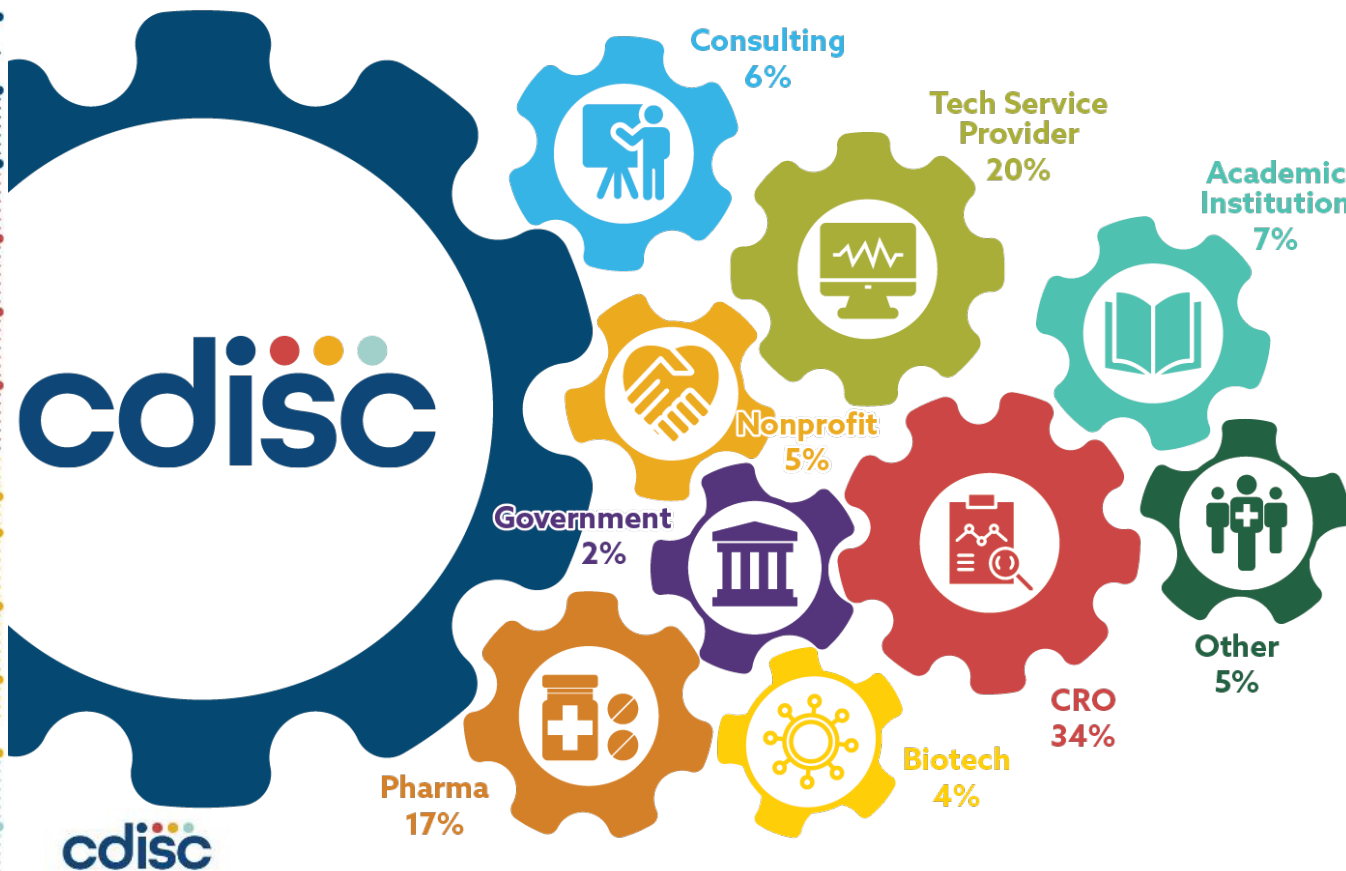


Created with mapchart.net



New Countries: Brazil, Indonesia, Turkey, Uganda

# CDISC Members = Diverse Global Community





# CDISC Membership



# 2023 On-Site Conferences

1



## Europe Interchange

Copenhagen, Denmark

24 – 25 April Education Courses & Workshops

26 – 27 April Main Conference

2



## Japan Interchange

Tokyo, Japan

10 – 11 July Main Conference (*Hosted by Oracle*)

12 – 13 July Education Courses (*Hosted by EPS Corporation*)

3



## China Interchange

Beijing, China

25 – 26 August Main Conference

4



## TMF Conference

Baltimore, Maryland

28 – 29 September Main Conference

27 September Workshop

5



## US Interchange

Washington, DC Area

16 – 17, 20 October Education Courses & Workshops

18 – 19 October Main Conference

6



## Korea Interchange

Seoul, South Korea

11 – 14 December Main Conference & Education Courses



# 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.*

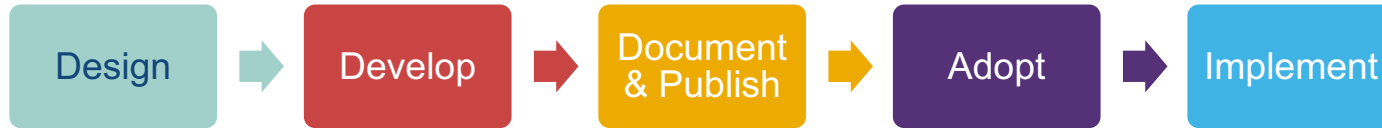
## CDISC Data Standards Lifecycle



# 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*

# What is the next stage on the CDISC Journey?

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## CDISC Data Standards Lifecycle



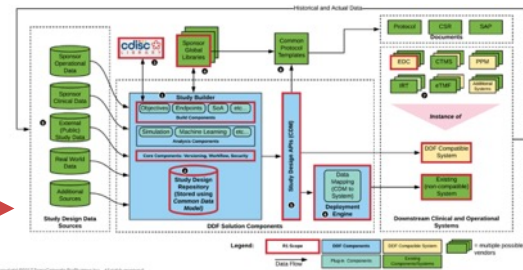
Automation requires:

- *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*

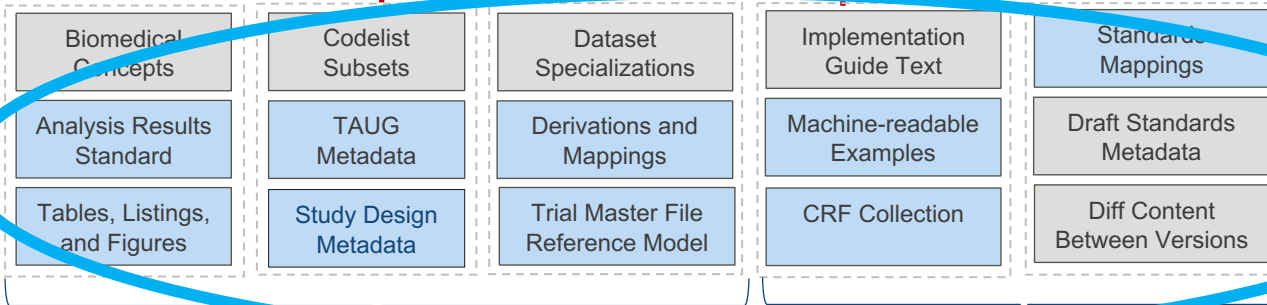


# CDISC Library Provides the Foundation

*Software Applications Consume Standards Metadata via the API*



## Executable Conformance Rules

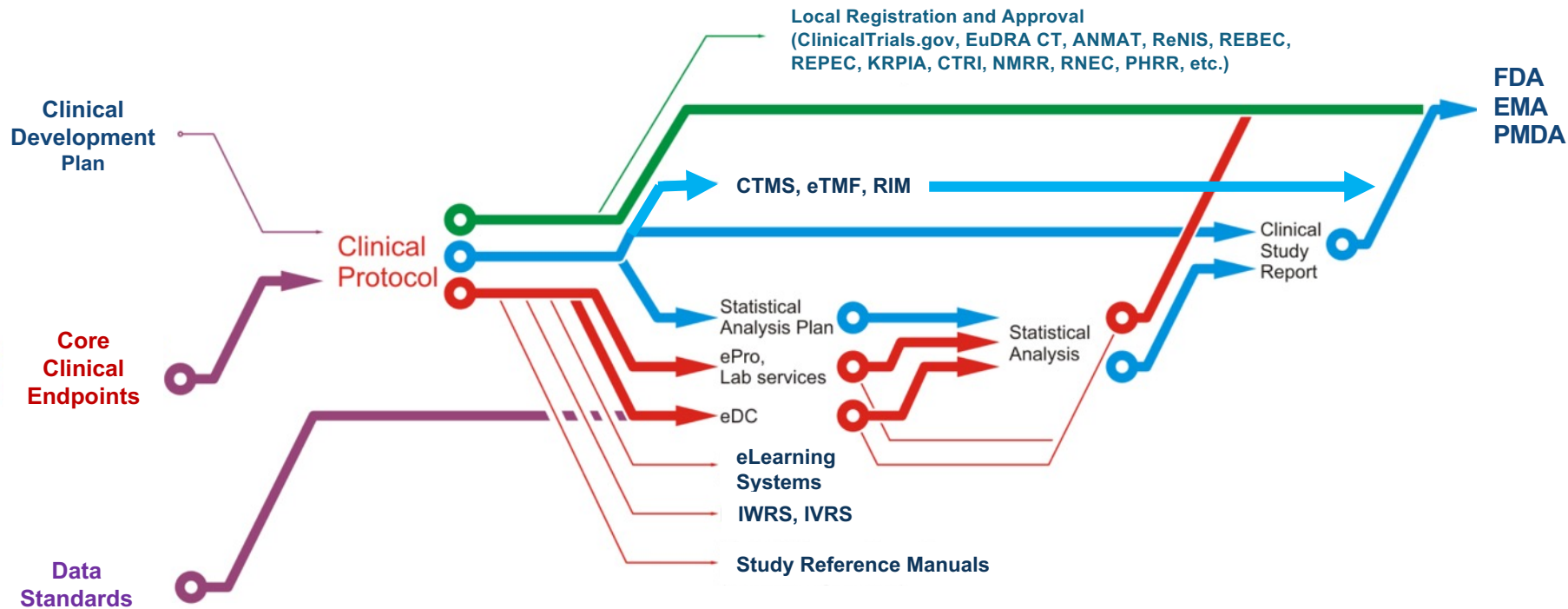


CDISC Standards

Informative Content

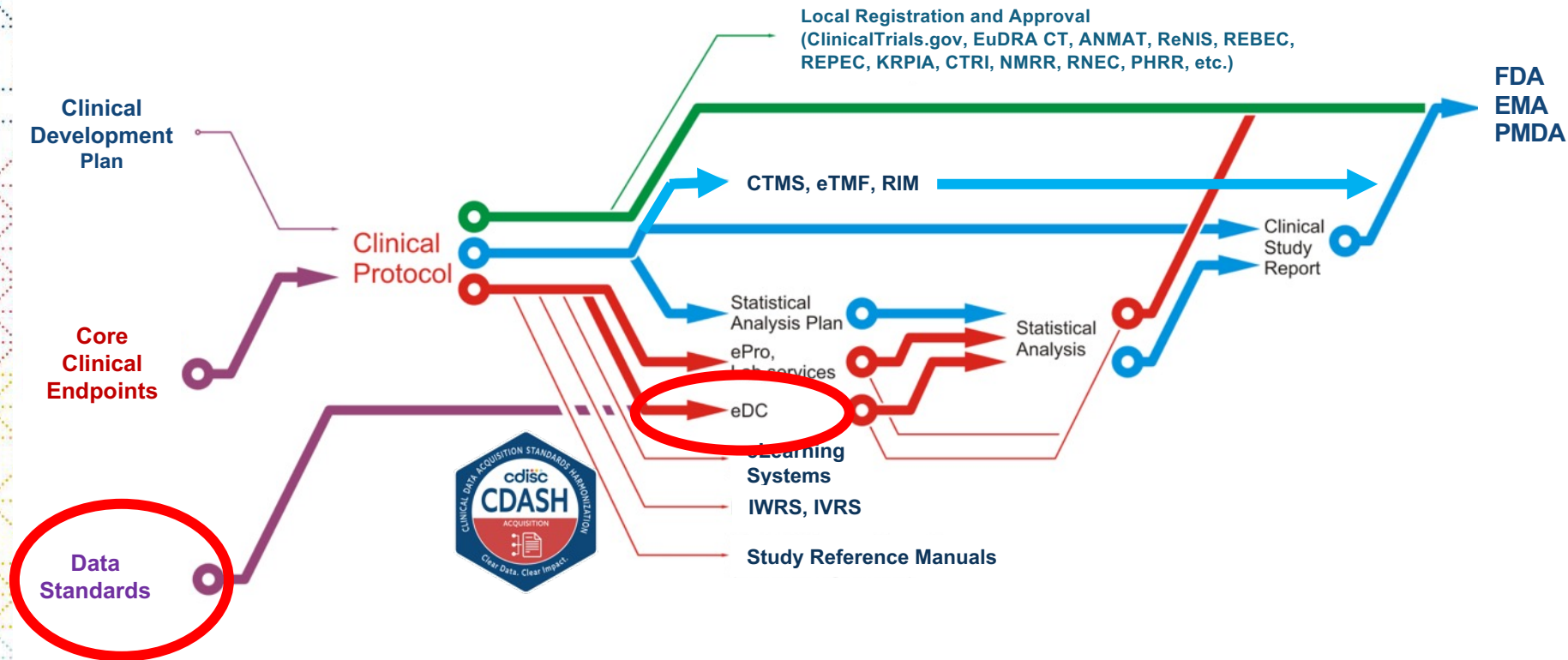


# The Clinical Trial Information Flow

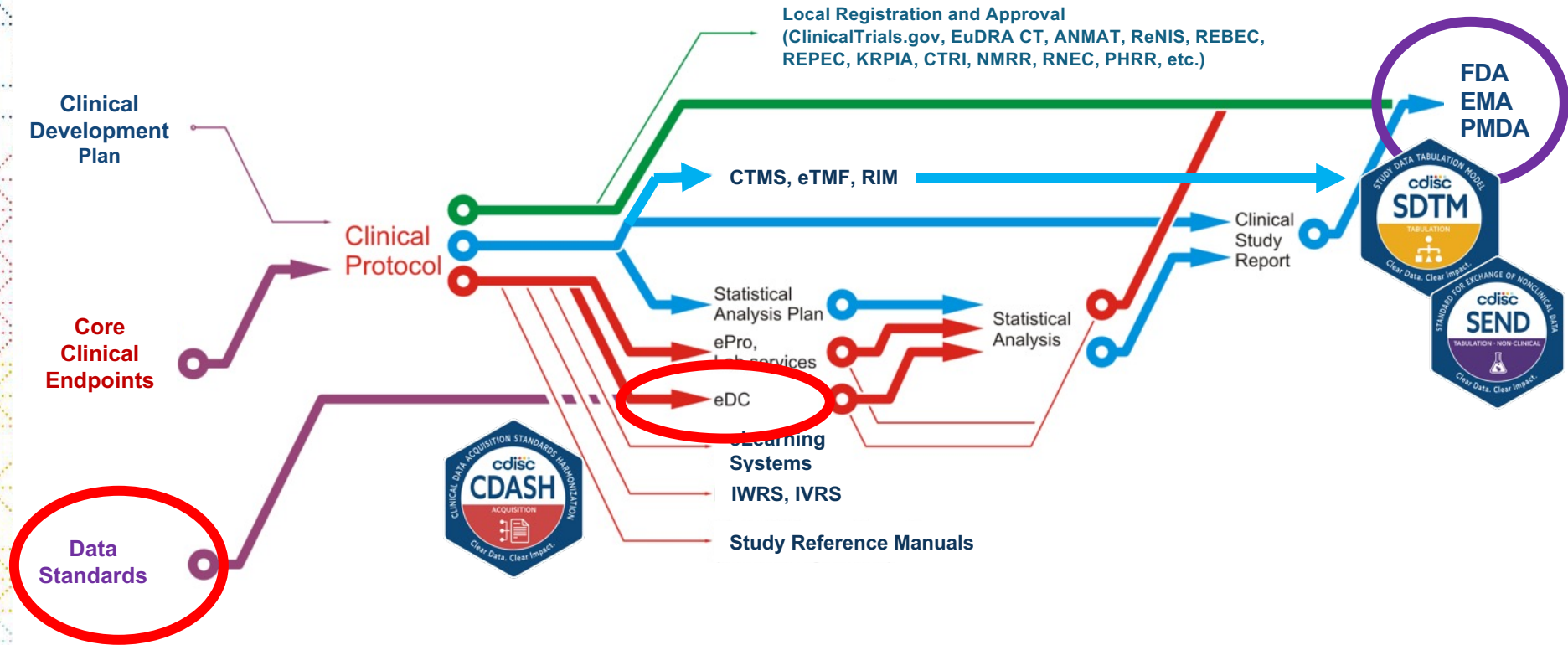




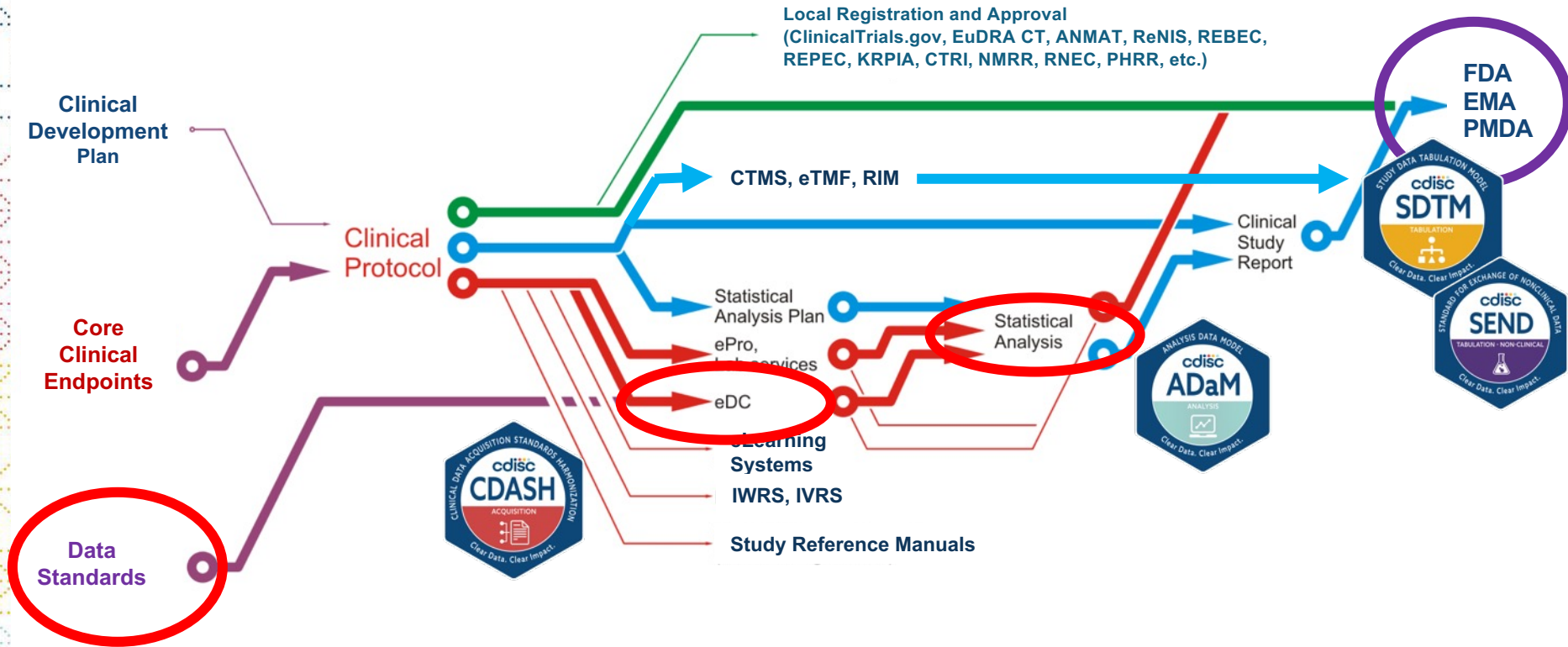
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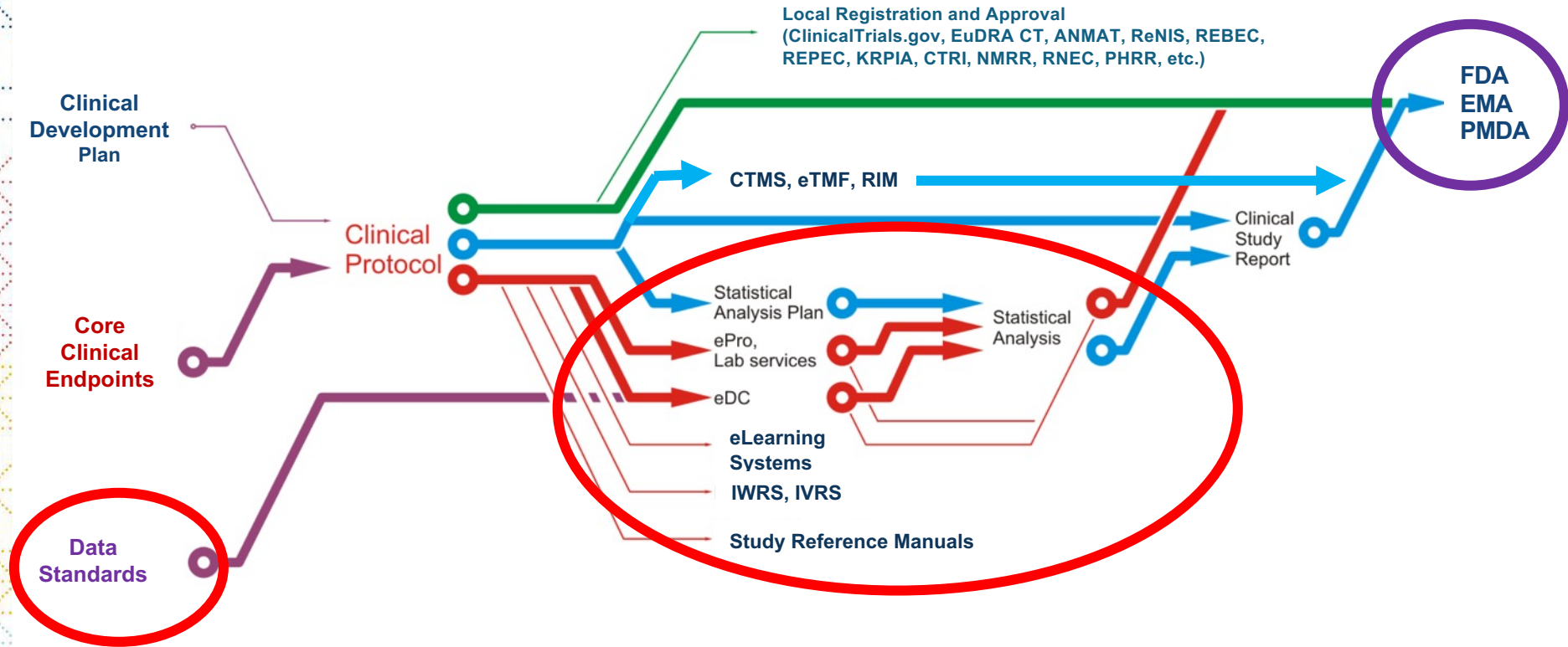
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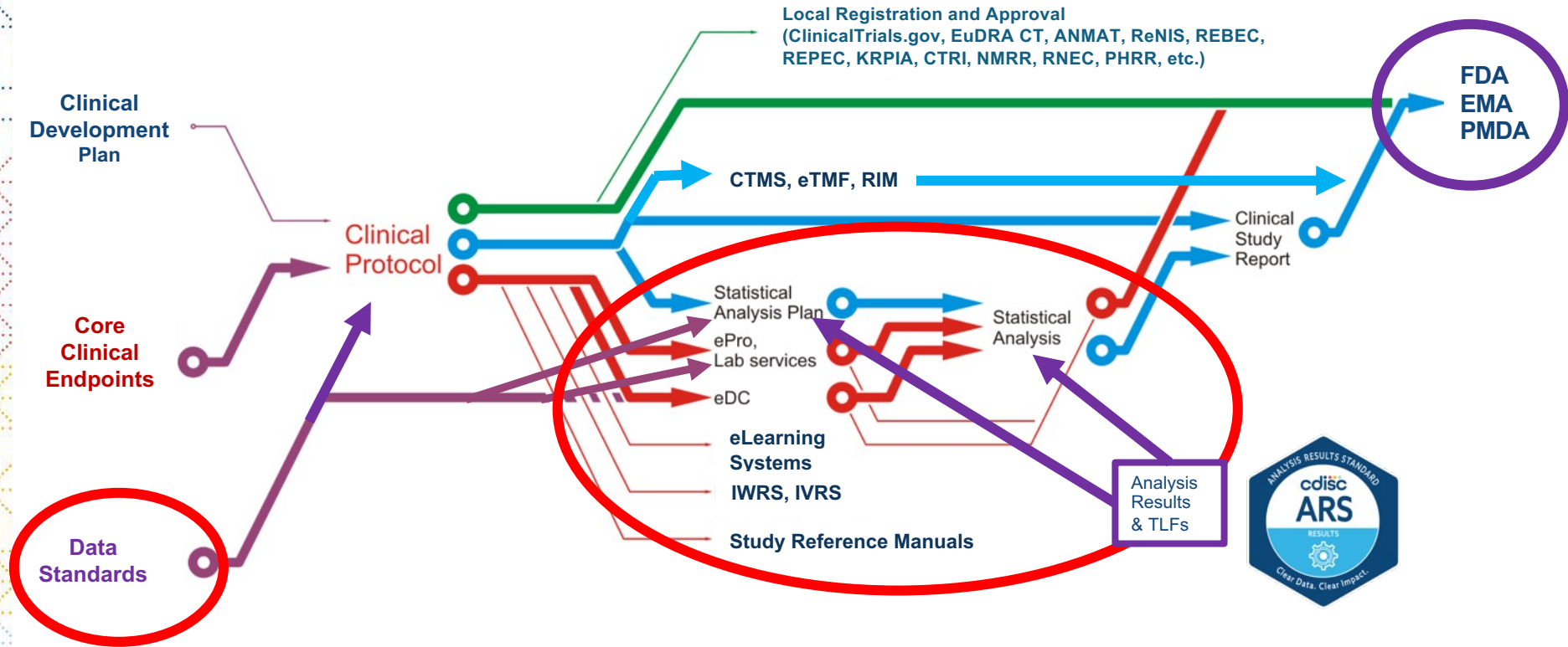
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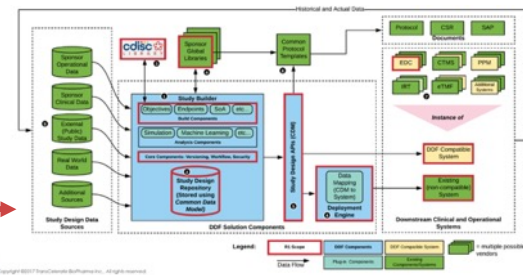


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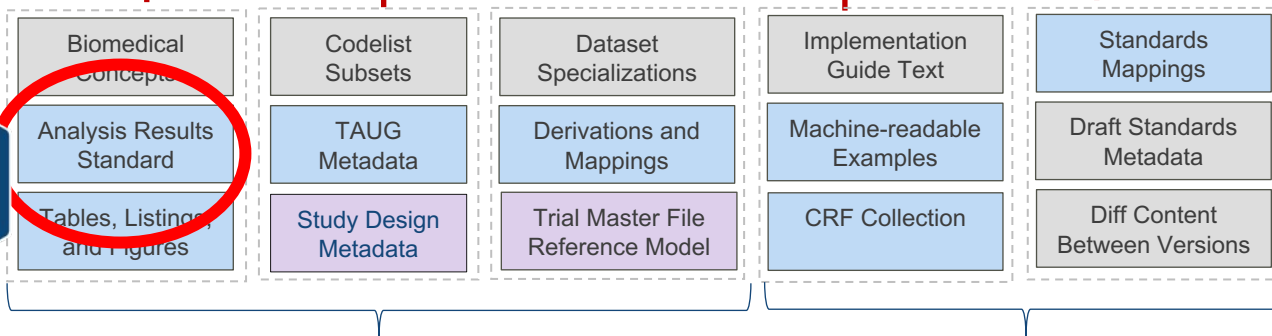


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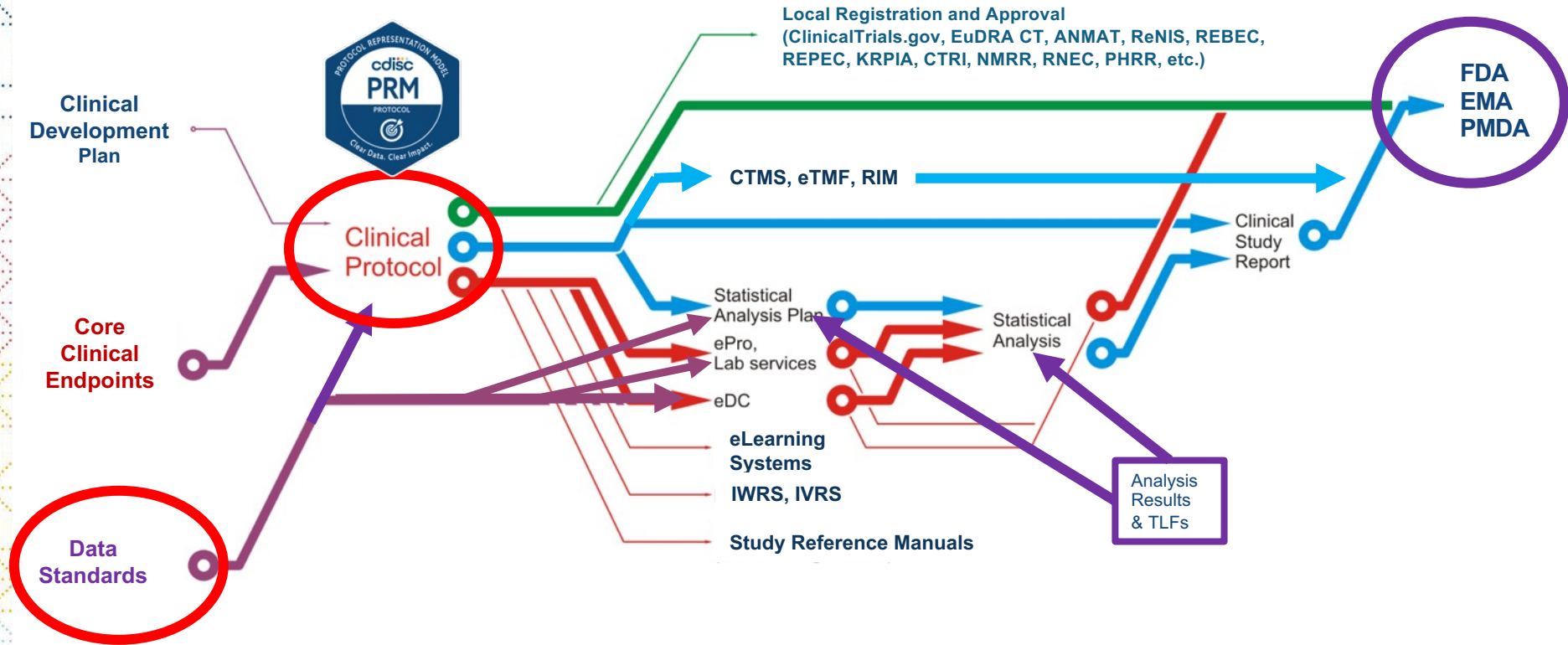
CDISC Standards

Informative Content



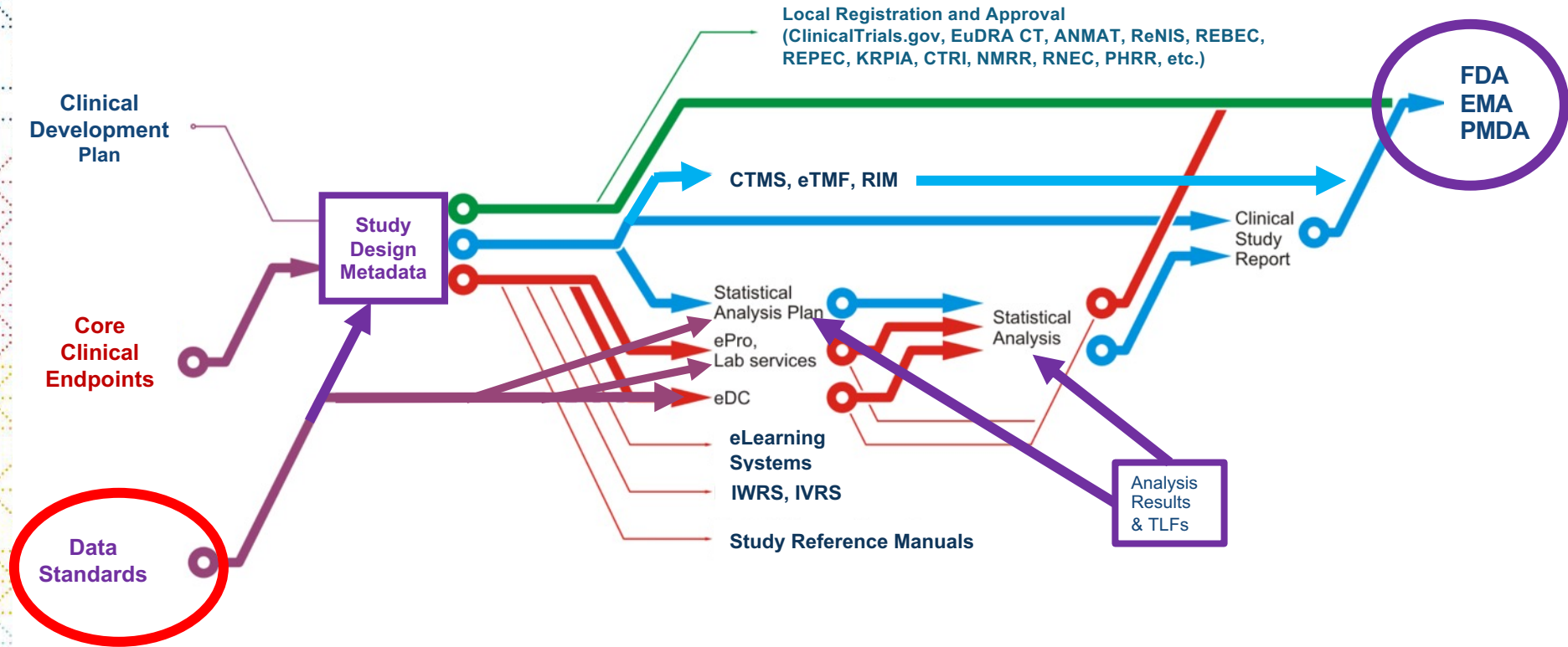


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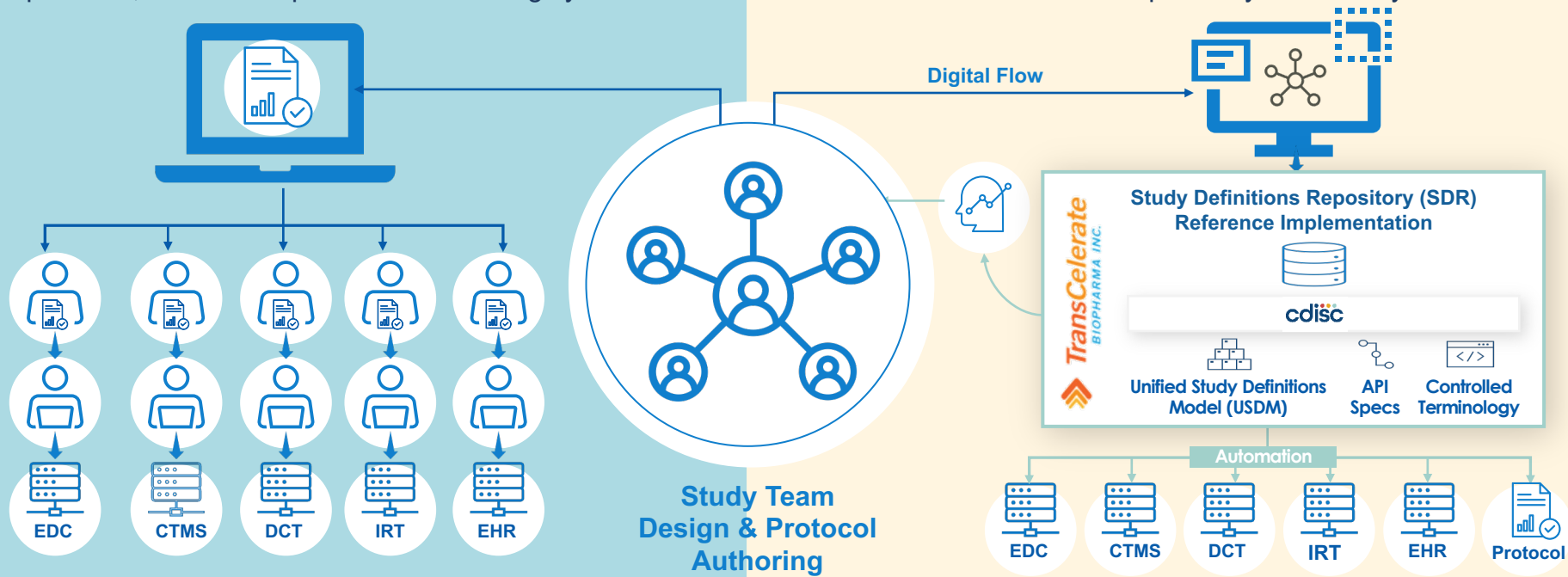


# Digital Data Flow (DDF) Initiative

*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

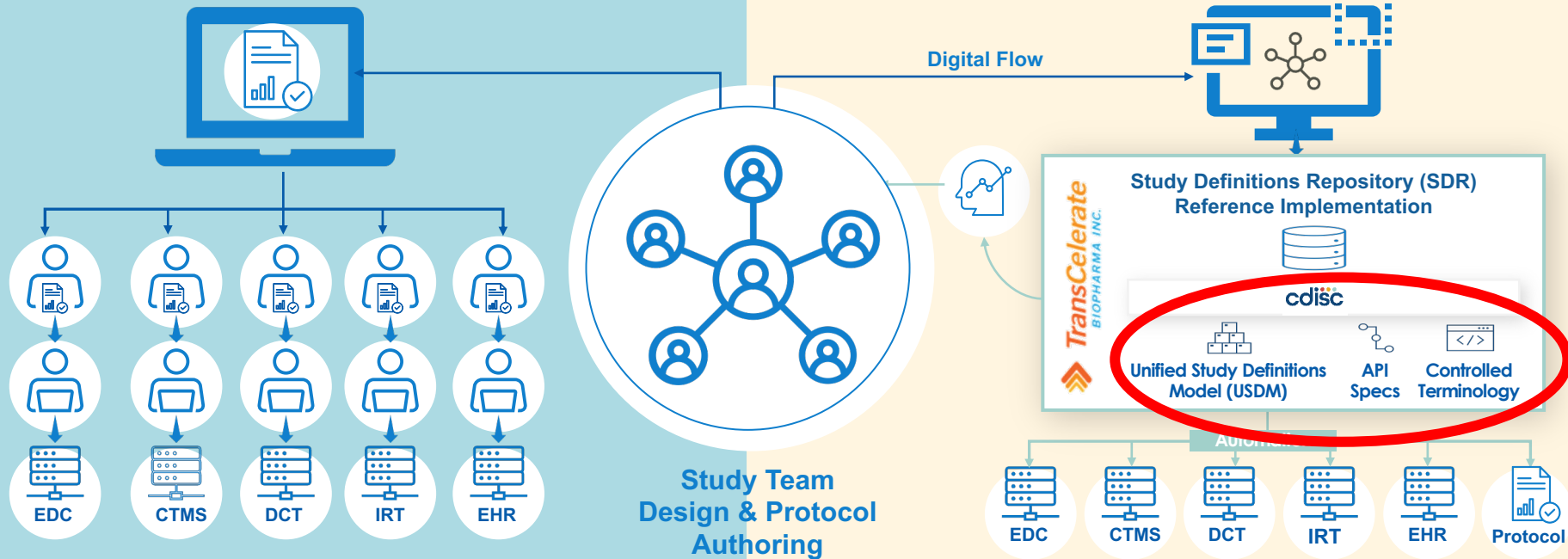


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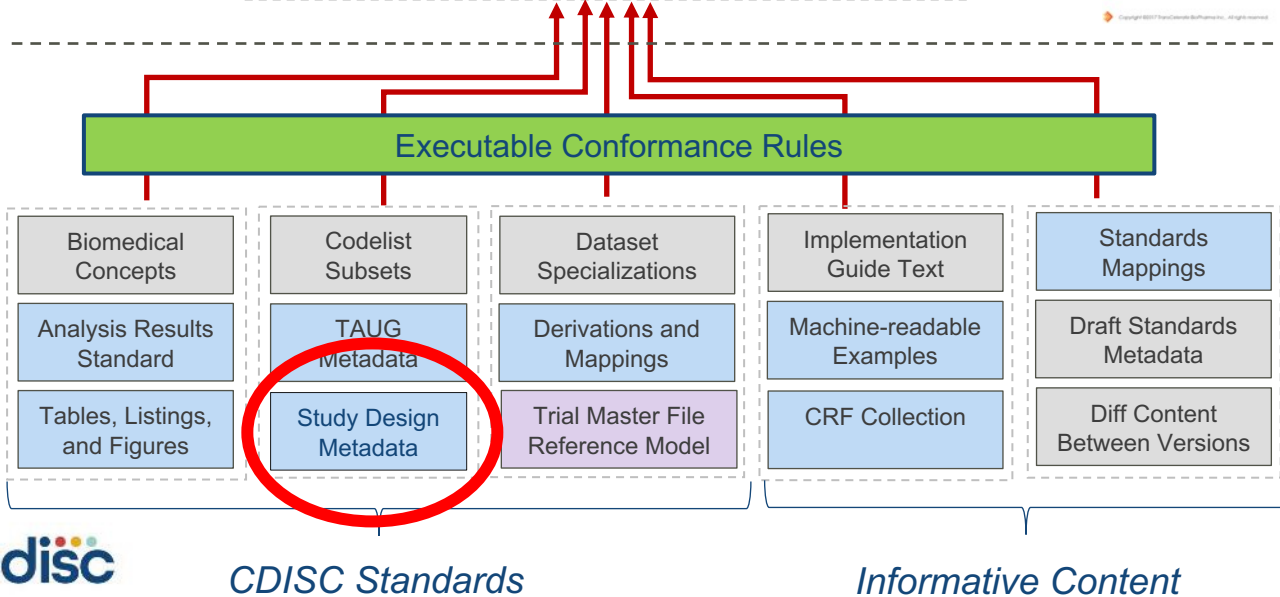
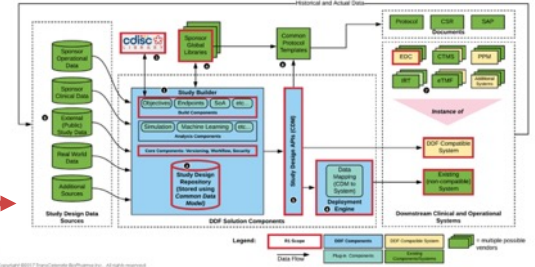
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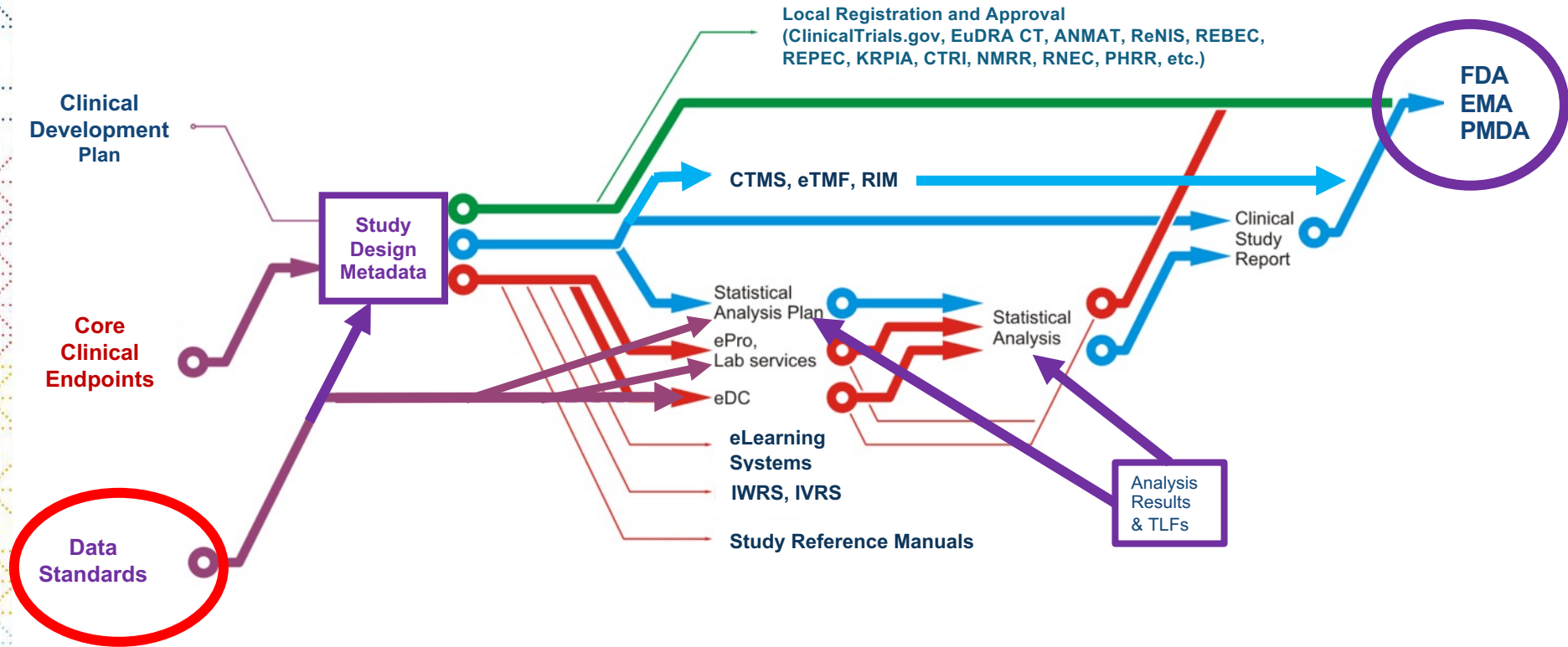


# CDISC Library Provides the Foundation

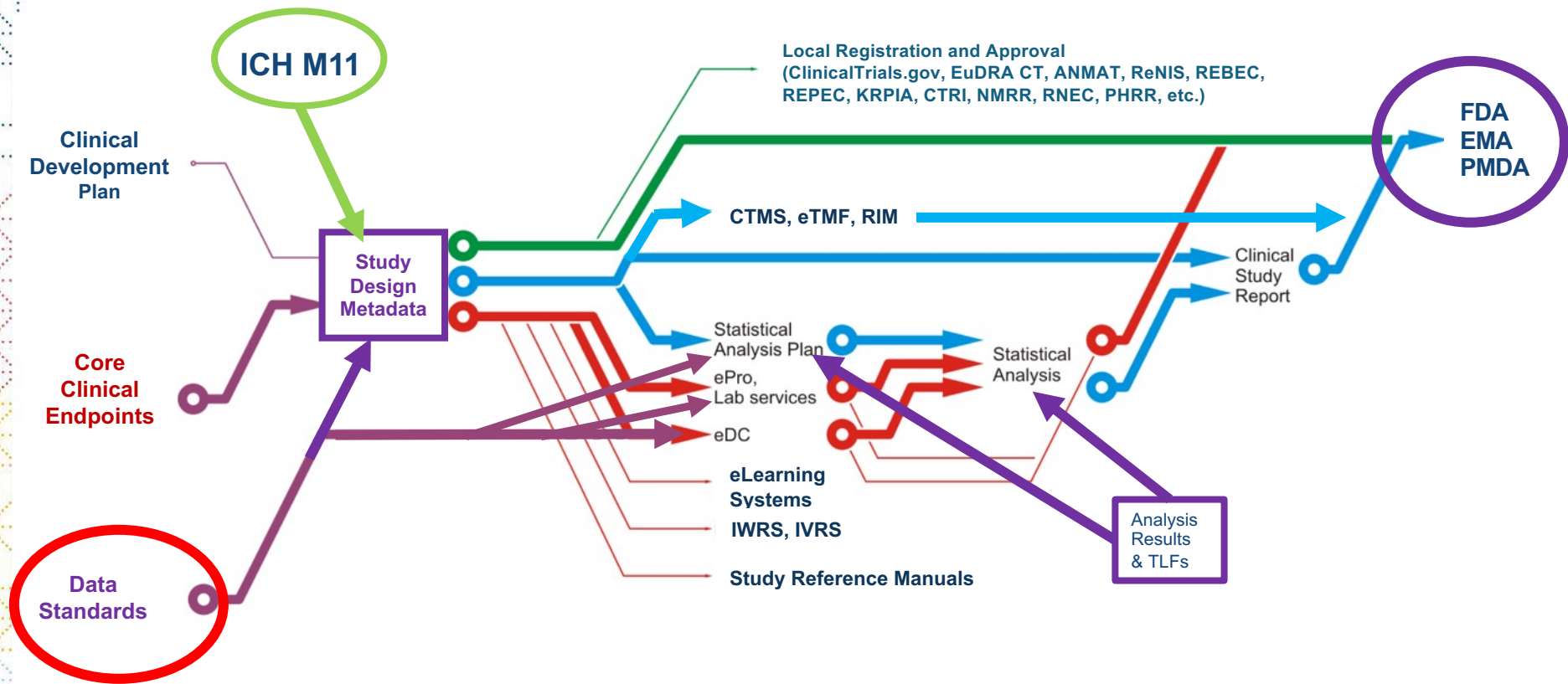
*Software Applications Consume Standards Metadata via the API*



# The Clinical Trial Information Flow



# The Clinical Trial Information Flow



# ICH M11: Clinical Electronic Structured Harmonised Protocol Components

The **Technical Specification** presents the conformance, cardinality, and other technical attributes that enable the interoperable electronic exchange of protocol content



The **Template** presents the format and structure of the protocol, including the table of contents, common headers, and contents



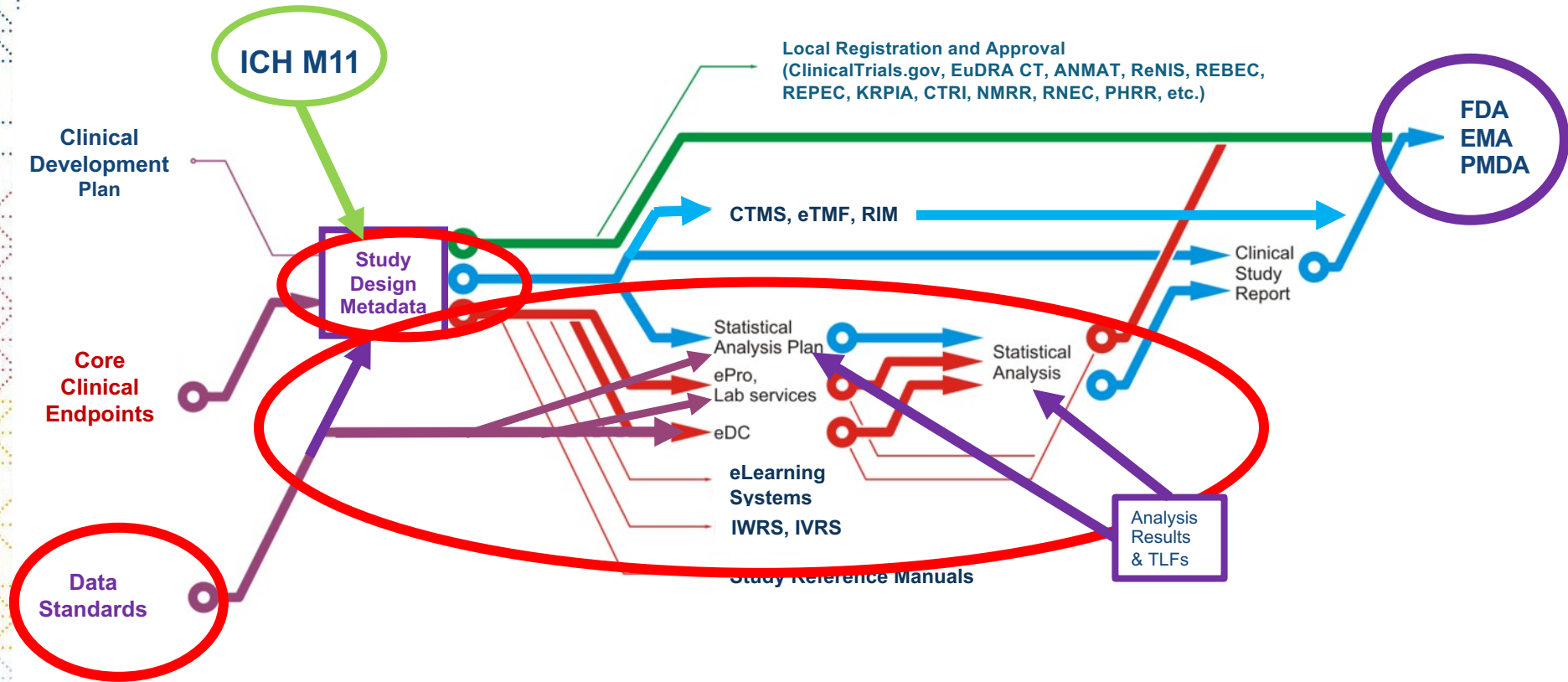


# ICH M11

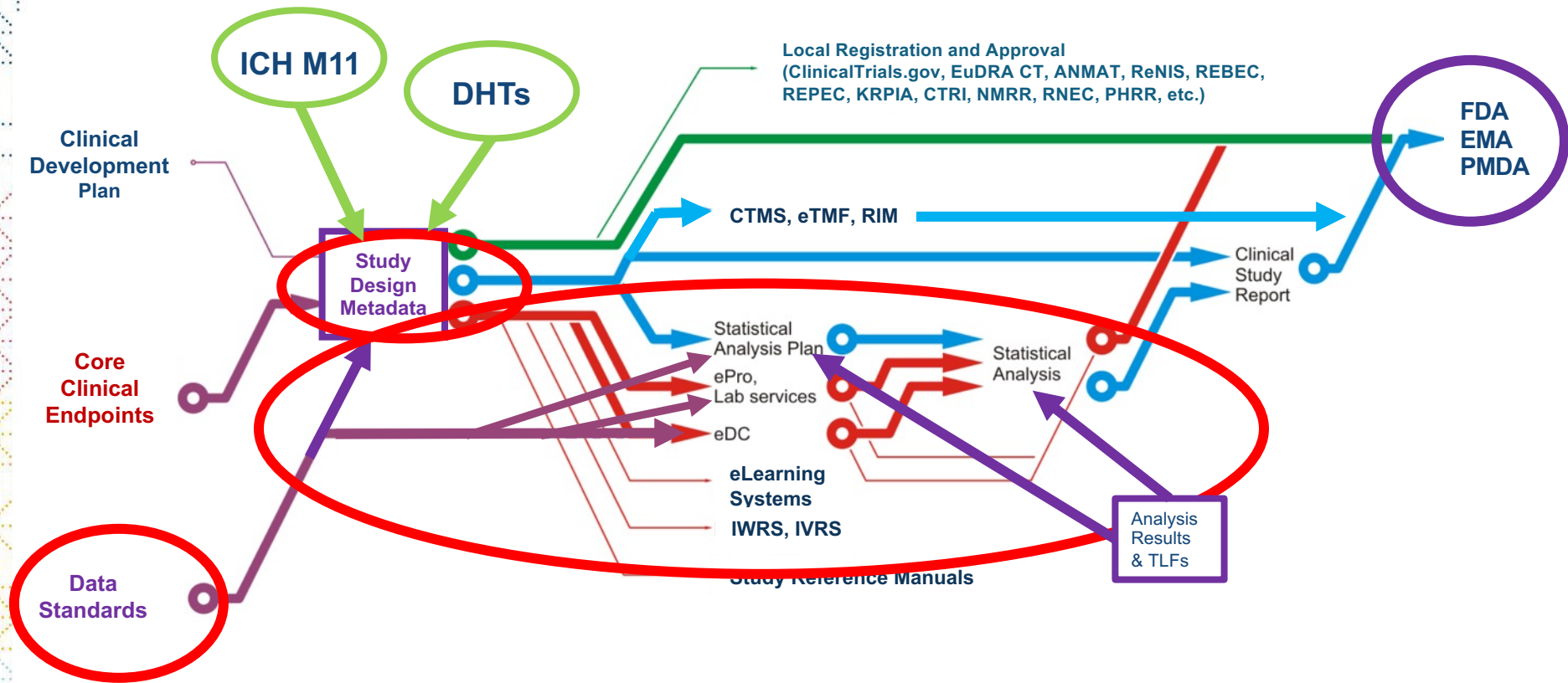
## Clinical Electronic Structured Harmonized Protocol

**CDISC** (<https://www.cdisc.org/about>) and **HL 7 Vulcan** (<https://www.hl7.org/vulcan/>) are announcing a project that will deliver an electronic exchange standard for the **ICH M11 Clinical electronic Structured Harmonised Protocol (CeSharP)**. HL 7 is a not-for-profit organization focused on providing standards for the exchange, integration, sharing and retrieval of health information. CDISC is a nonprofit standards development organization that develops standards that support acquisition, exchange, submission, and archive of biopharmaceutical data. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (<https://www.ich.org/>) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals and develop ICH Guidelines. M11's deliverables include a guideline, a clinical protocol template, and an electronic exchange standard.

# The Clinical Trial Information Flow



# The Clinical Trial Information Flow



# Increased Regulatory Focus on Digital Health Technologies

FDA | CDER | Small Business and Industry Assistance

## INDUSTRY NEWS

### **FDA to Host Digital Health Technologies for Drugs Public Workshop**

The U.S. Food and Drug Administration is hosting the virtual public workshop “Understanding Priorities for the Development of Digital Health Technologies to Support Clinical Trials for Drug Development and Review” on March 28th and 29th, 2023. The workshop will focus on understanding the priorities and challenges of developing Digital Health Technologies (DHTs) to support clinical drug trials.

The workshop will be convened by the Robert J. Margolis, MD, Center for Health Policy at Duke University under a cooperative agreement with FDA.

For more information on the Digital Health Technologies virtual public workshop and to register, please visit [FDA’s Meeting’s, Conferences & Workshops \(Drugs\)](#).

# CDISC Digital Health Technologies (DHT) Team



## Scoping

Team kick-off

Scoping from June -  
August



## Development

Standards development  
begins September



## Deliverables

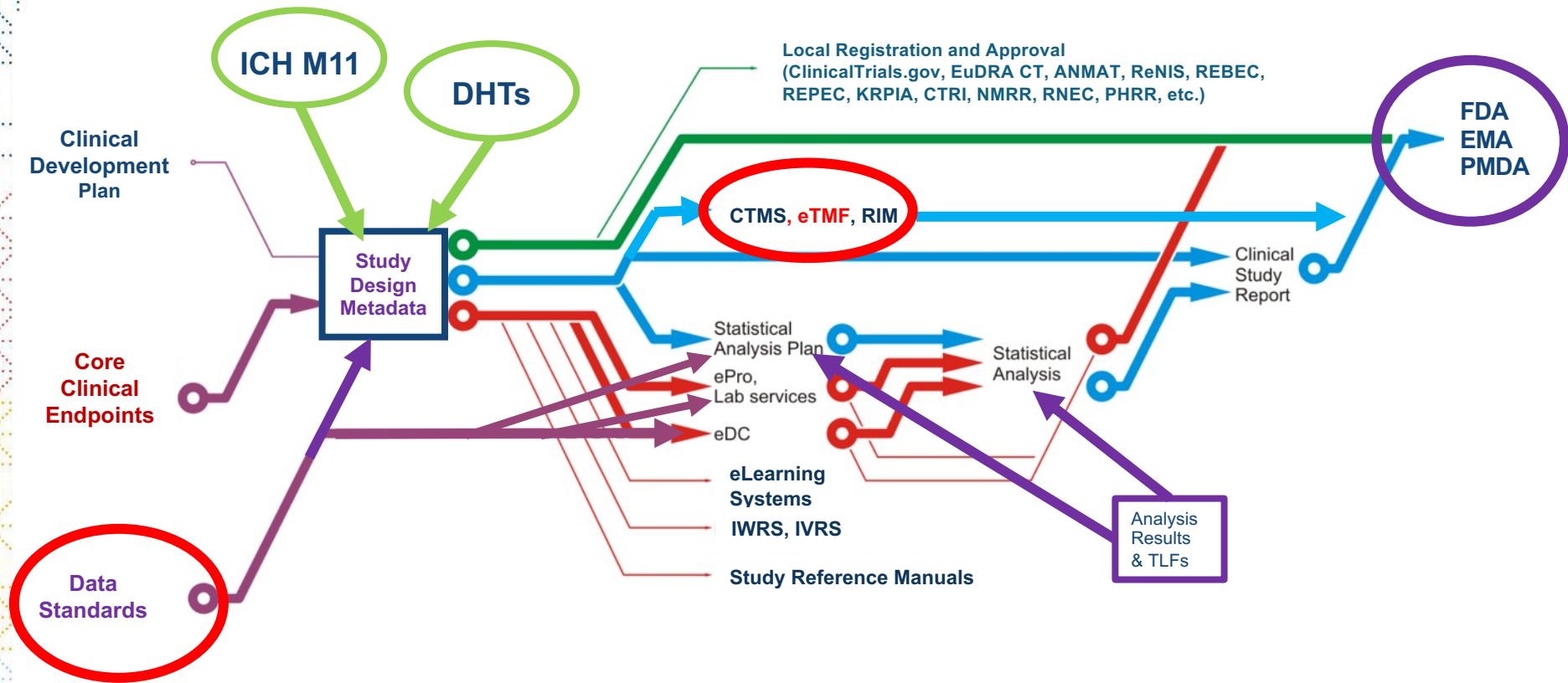
Deliverables completed  
by Q4 2024

Staged releases  
preferred

### Under consideration:

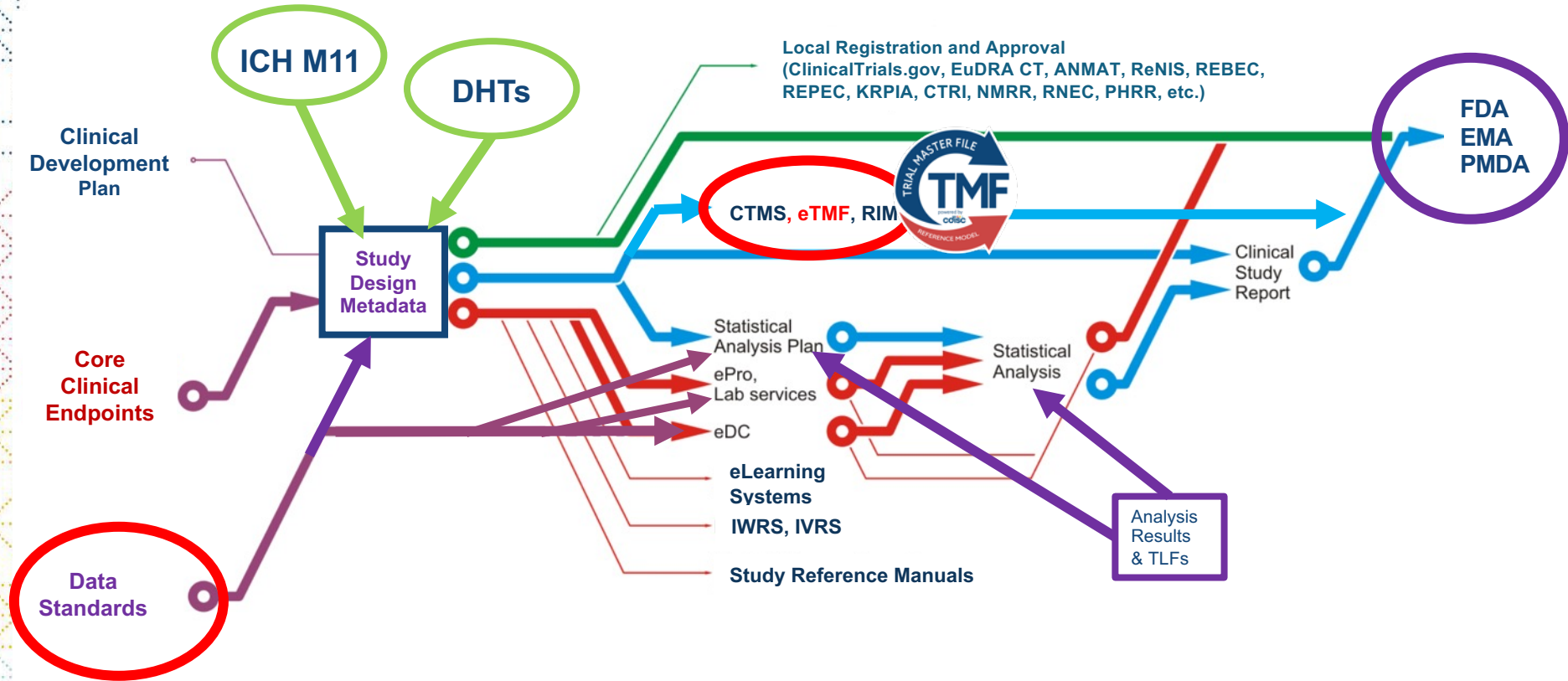
- Enhancements to the SDTM and other foundational standards
- Controlled Terminologies and Codetable Mapping Files for digital endpoints
- Deliverables for release after Q4 2024!

# 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.

## Regulatory Submission

Common Technical Document (CTD)

Trial Master File (TMF)

Investigator Site Files (ISF)

# 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

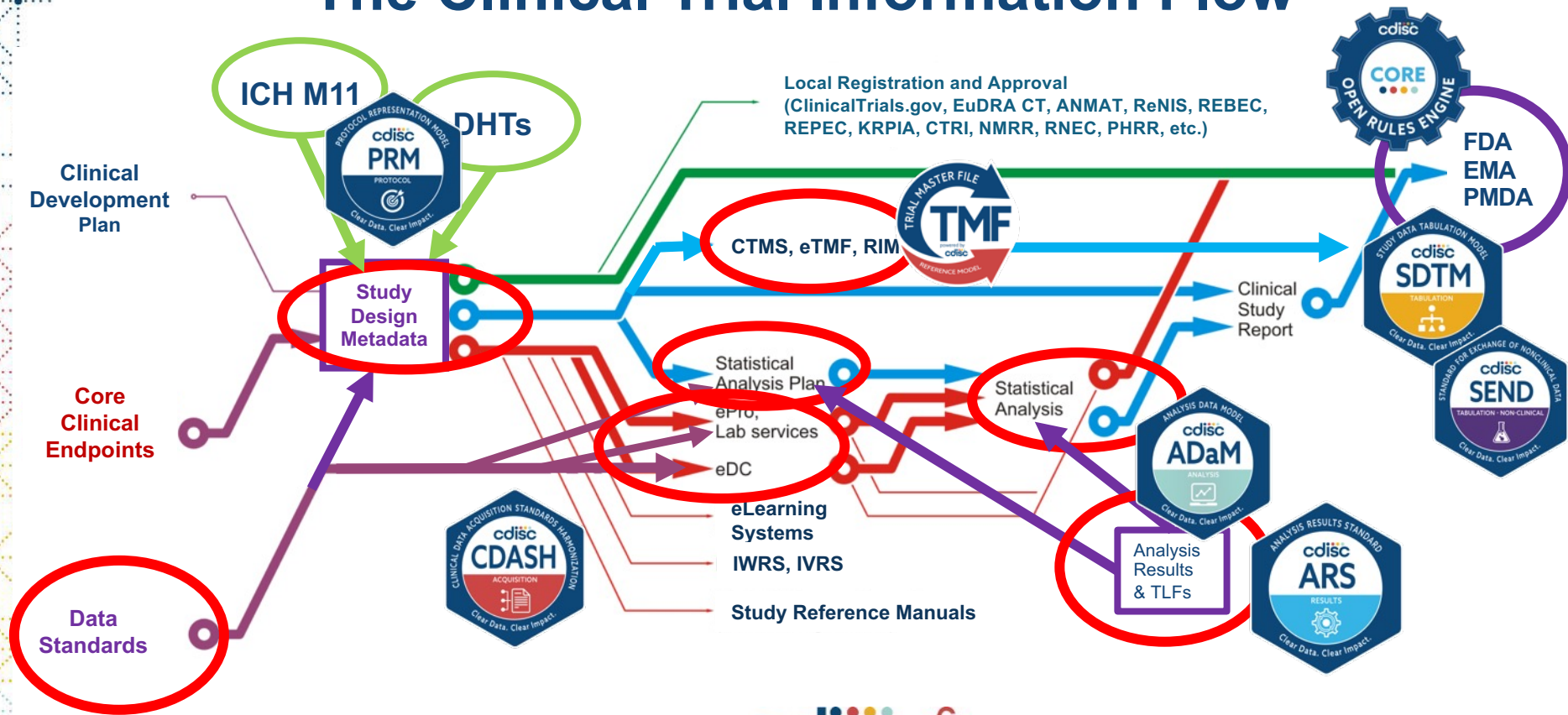
- Based on ICH E6 R2 Sect. 8 & industry-accepted terminology

## Standard Metadata

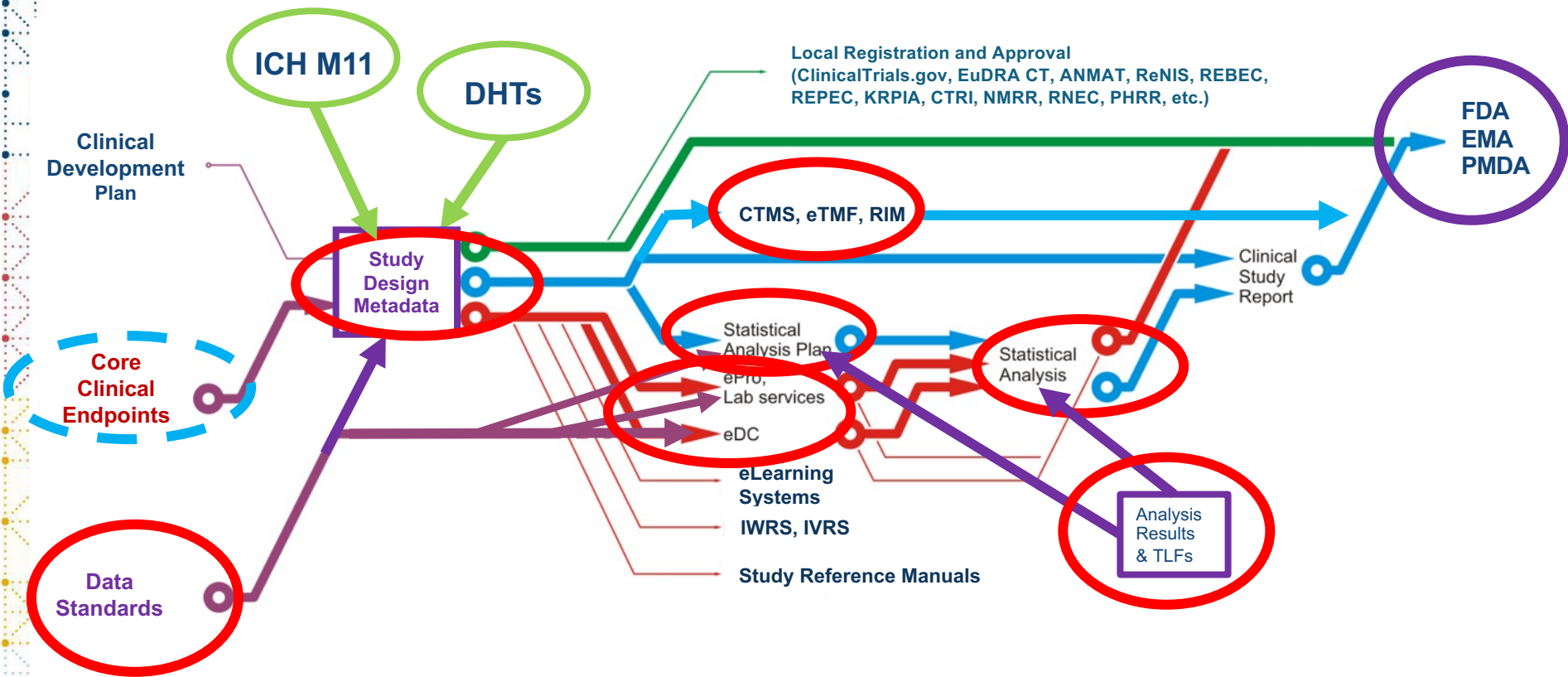
- Recommended minimum metadata at system and artifact level



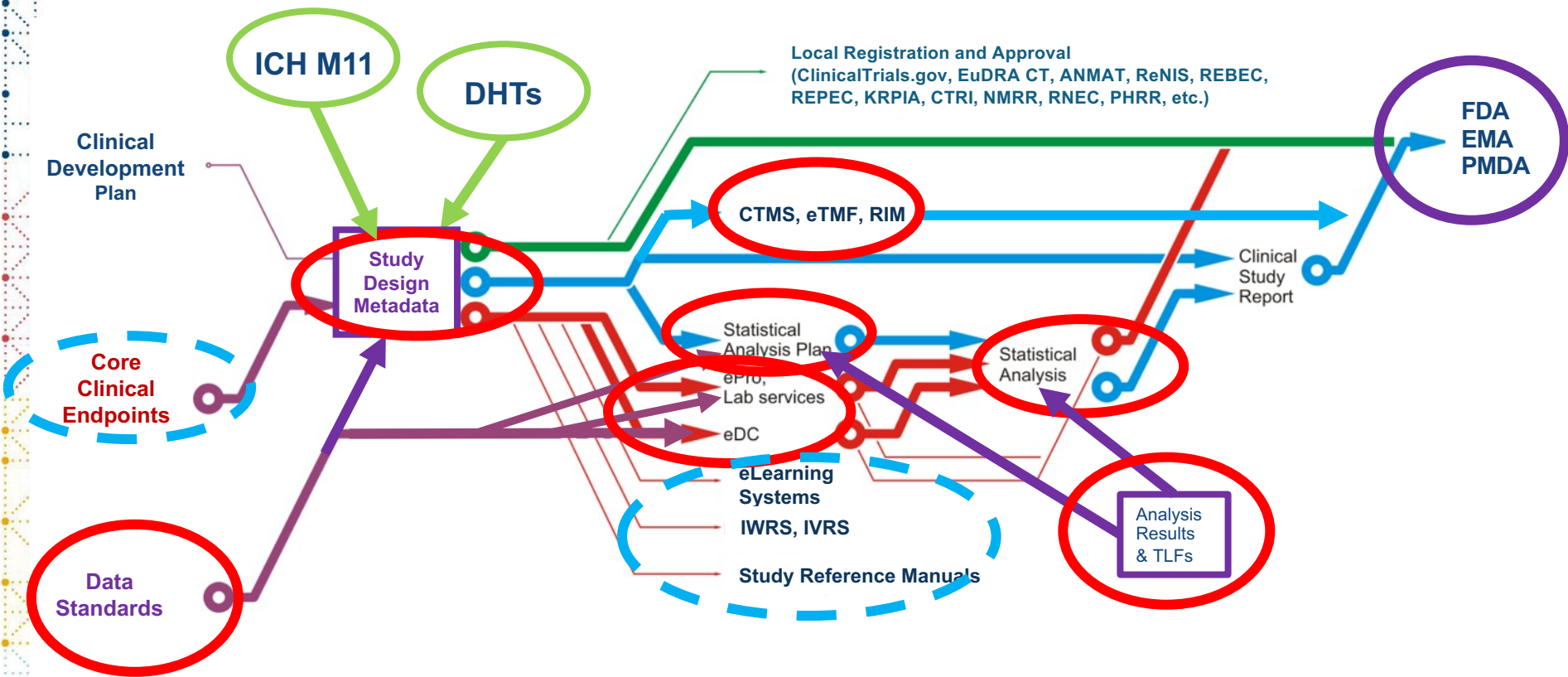
# The Clinical Trial Information Flow



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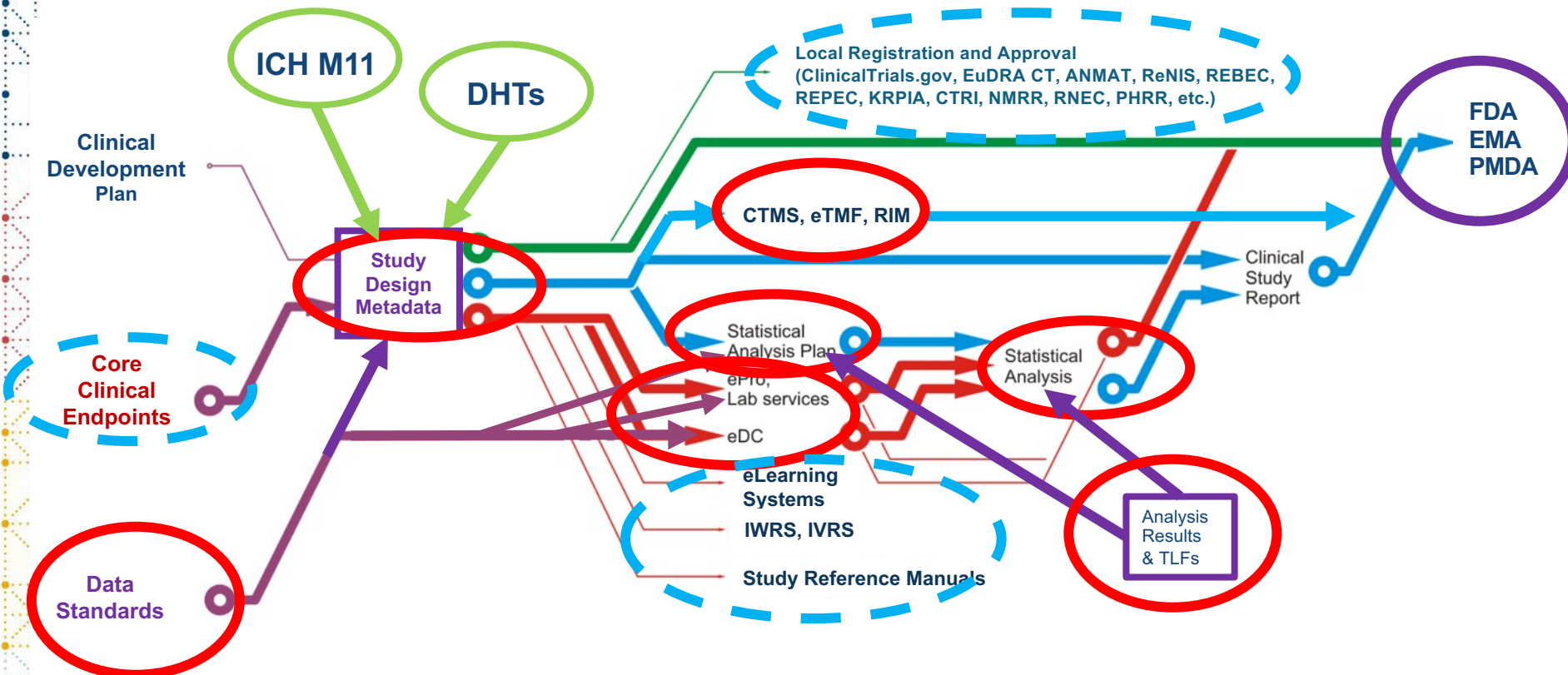


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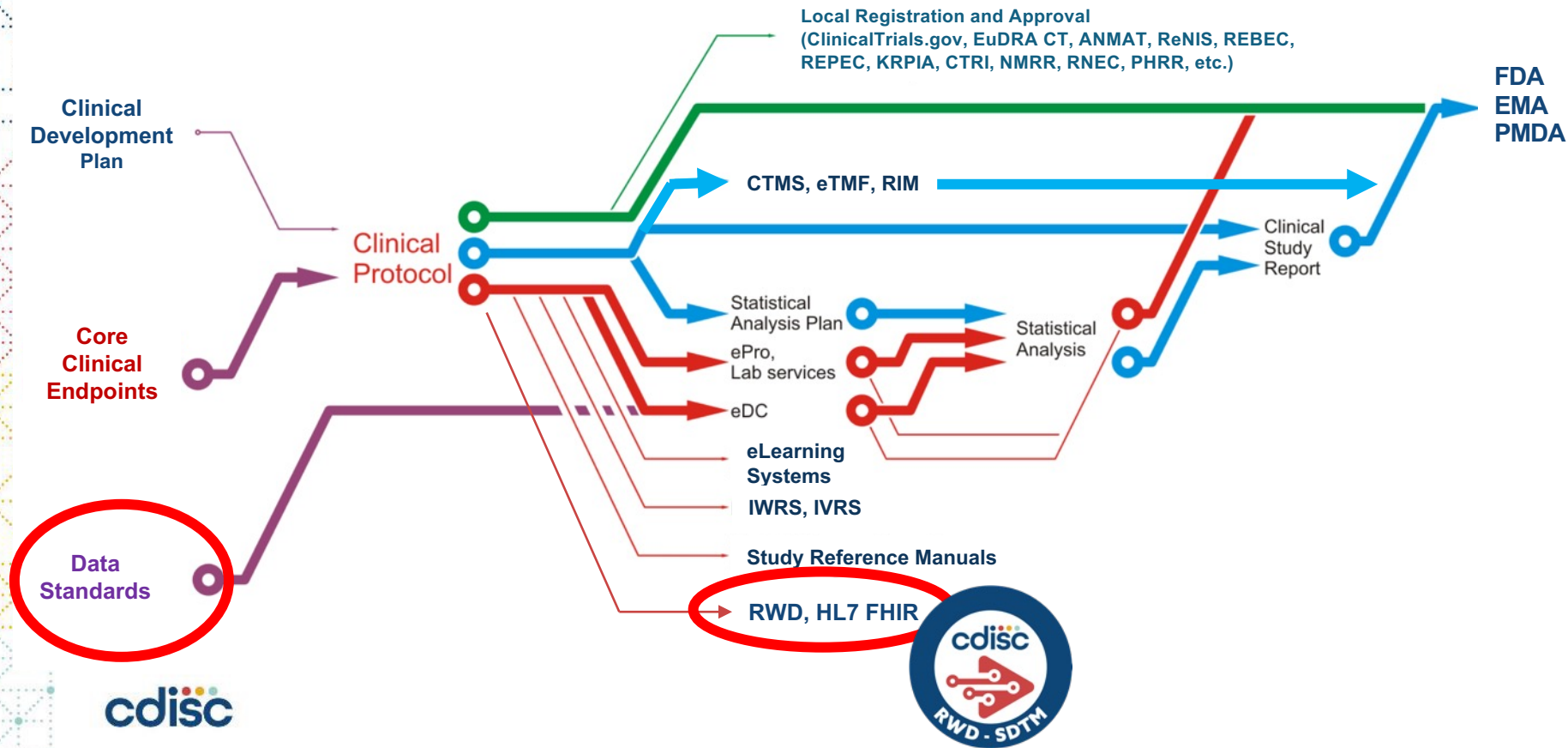




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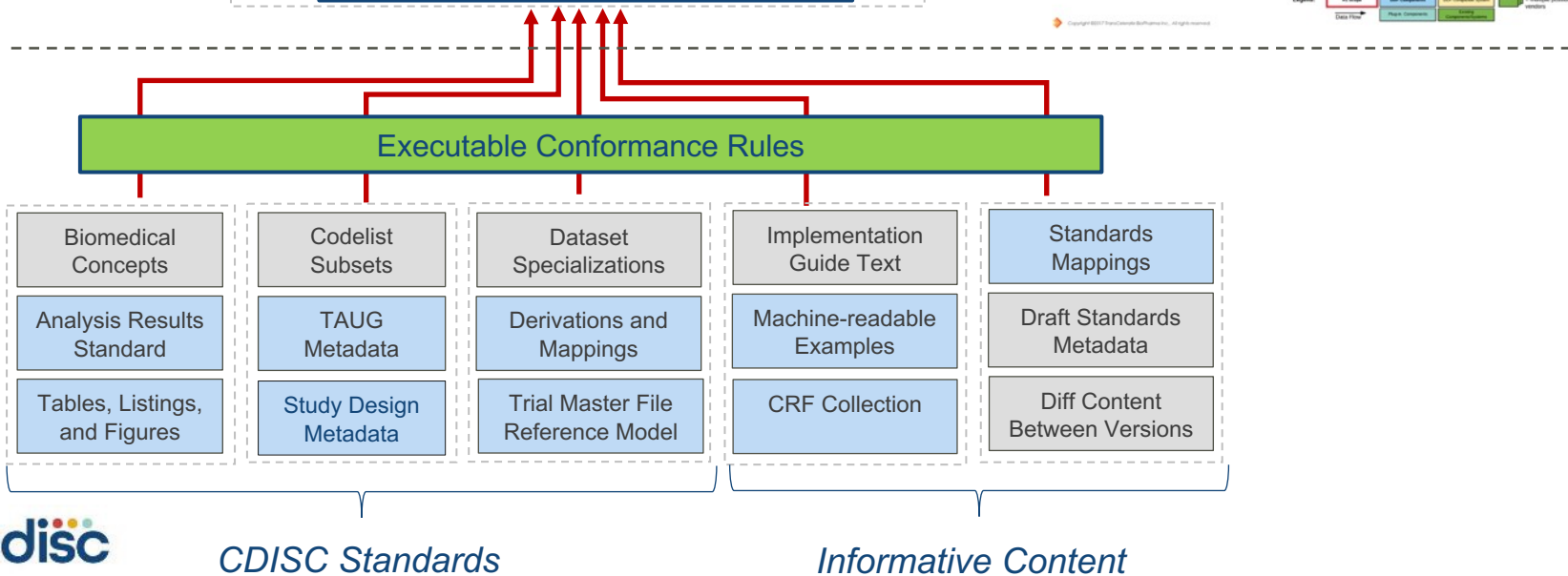
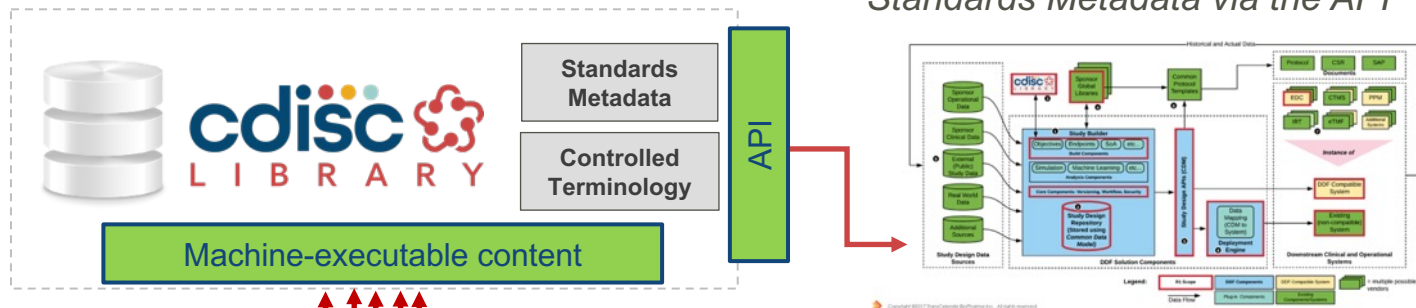


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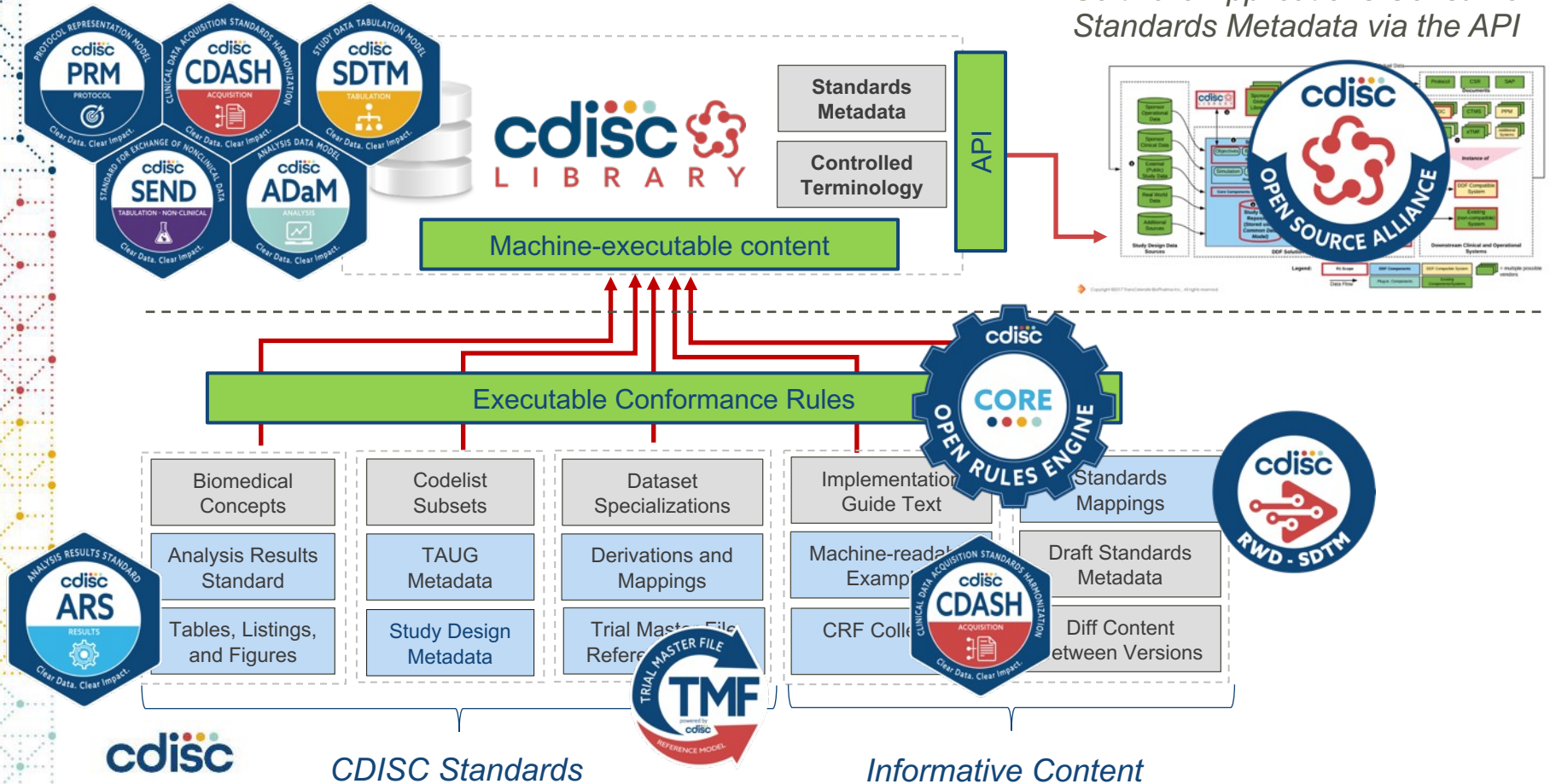
# CDISC Library Provides the Foundation

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# Benefits for the Clinical Research Community

- Expansion of scope of clinical information standards to protocol, trial design, trial administration, clinical operations, regulatory documentation.
- CDISC serves as the hub for cross-industry standards initiatives with TMF RM, M11, DDF being 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. CDISC will collaborate with industry initiatives to support interoperability.
- 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.*





Thank You CDISC Community!

*Dave Evans – President & CEO, CDISC*  
*[devans@cdisc.org](mailto:devans@cdisc.org)*

