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2023
JAPAN
INTERCHANGE
TOKYO | 10-11 JULY

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 Japan CDISC Coordinating Committee (J3C)

- Dr. Yuki Ando, PMDA (Ex-officio)
- Dr. Mihoko Okada, Institute of Health Data Infrastructure for All (Ex-officio)
- Dr. Hiroshi Masumoto, Daiichi Sankyo K.K (Ex-officio)
- Akira Soma, Oracle (Chair)
- Hidemi Hasegawa, Boehringer Ingelheim (Vice-Chair)
- Dr. Toshiki Saito, NHO Nagoya Medical Center (Vice-Chair)
- Hidetoshi Misawa, Pfizer (Past-Chair)
- Hideaki Kosaka, EPS Corporation
- Kaoru Matsumi, CMIC Co., Ltd.
- Yoshiteru Chiba, UMIN Center
- Dr. Hideto Yokoi, Kagawa University Hospital
- Takako Nozaki, Gilead Sciences
- Naoto Awaji, Chugai
- Daisuke Hisada, GlaxoSmithKline K.K.
- Megumi Kitayama, Wakayama Medical University
- Akira Mizuo, Intage Healthcare

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CRScube Clinical Research Solutions

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Thank You for Joining Us!

- First in-person event in Japan after the pandemic
- First Japan Interchange at a Host Location
- Support of sponsors and exhibitors – all spaces sold
- Cutting-edge topics; the latest on major CDISC initiatives

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

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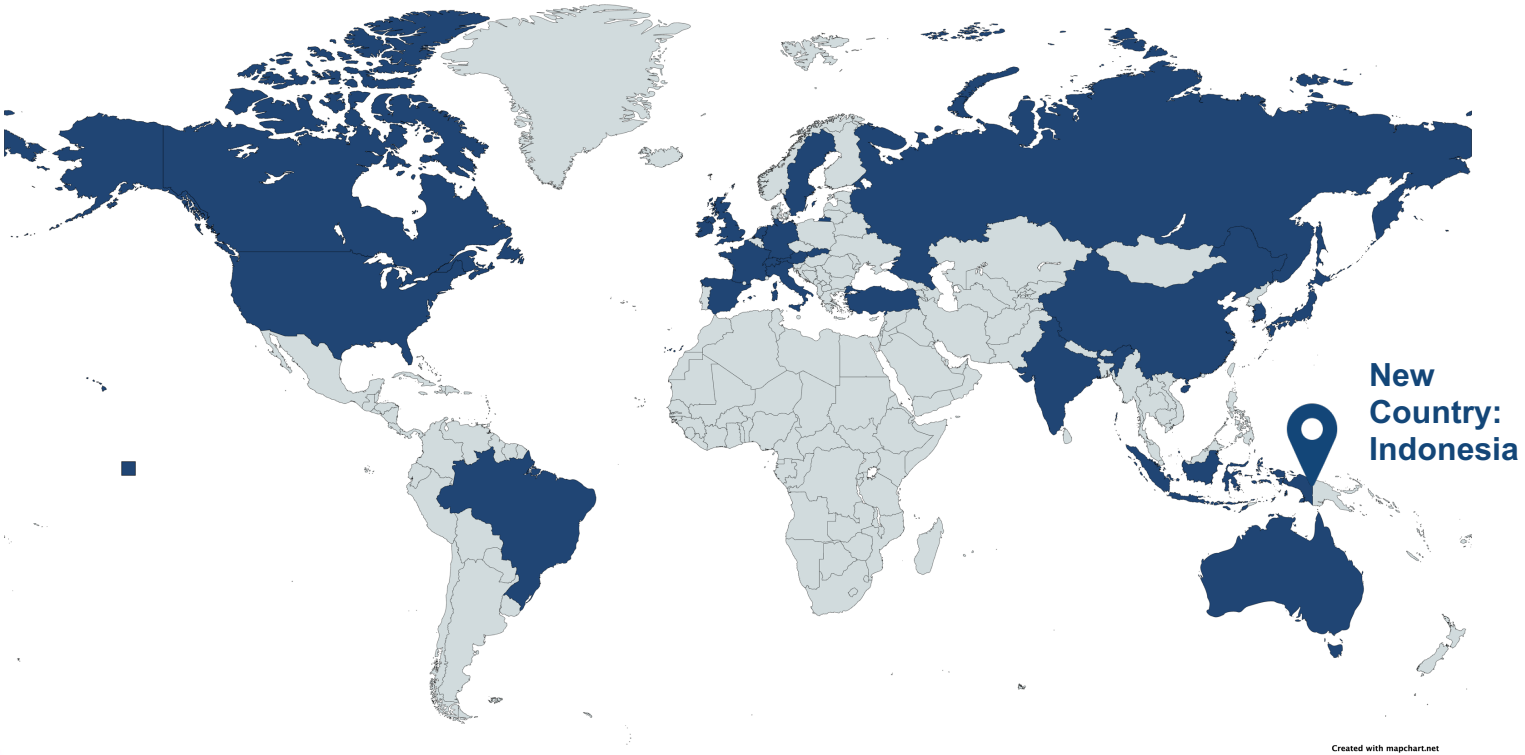
phuse

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 – 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

U.S	Japan	China	Germany	U.K	France	South Korea	Denmark	Canada	Belgium	Switzerland	Other Countries
48%	8%	6%	6%	5%	4%	3%	3%	3%	2%	2%	9%



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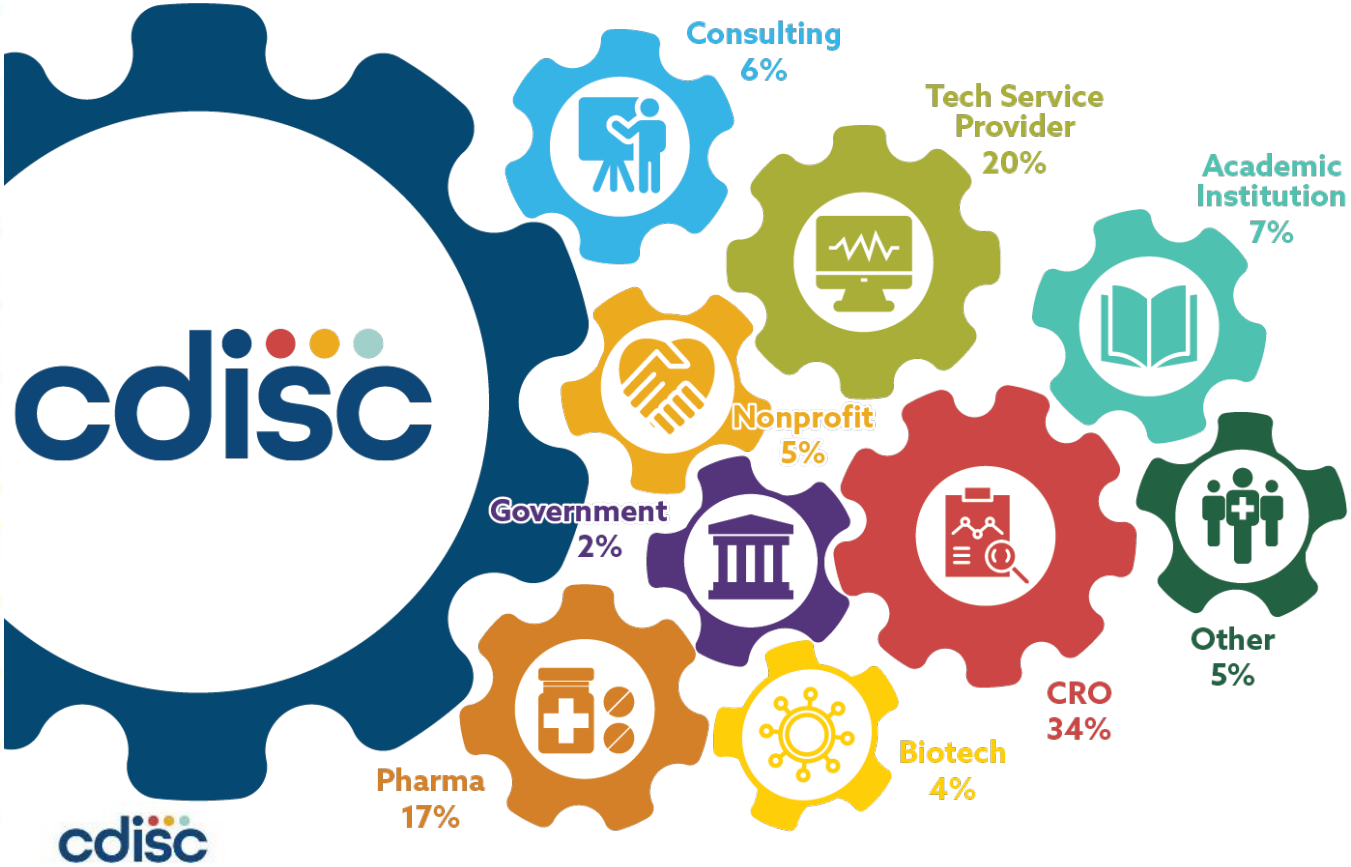
New Countries: Brazil, Indonesia, Turkey, Uganda

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*

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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*

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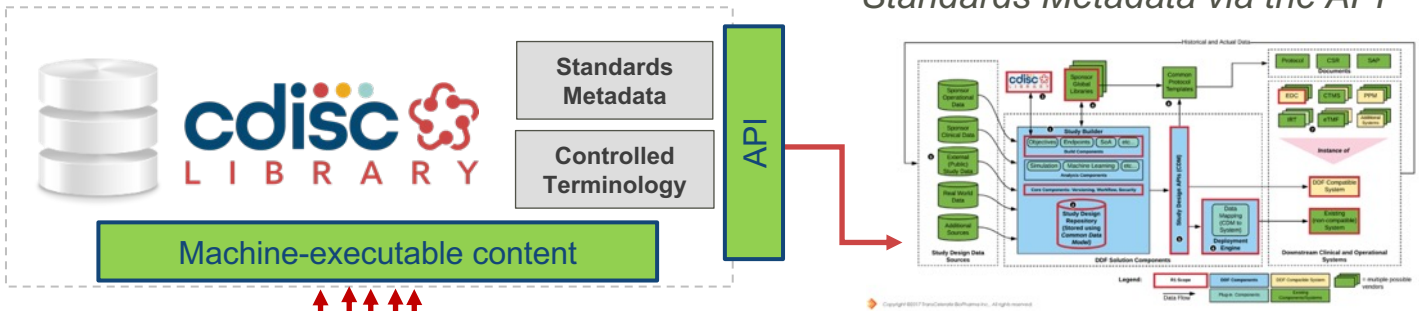
CDISC Library Provides the Foundation

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

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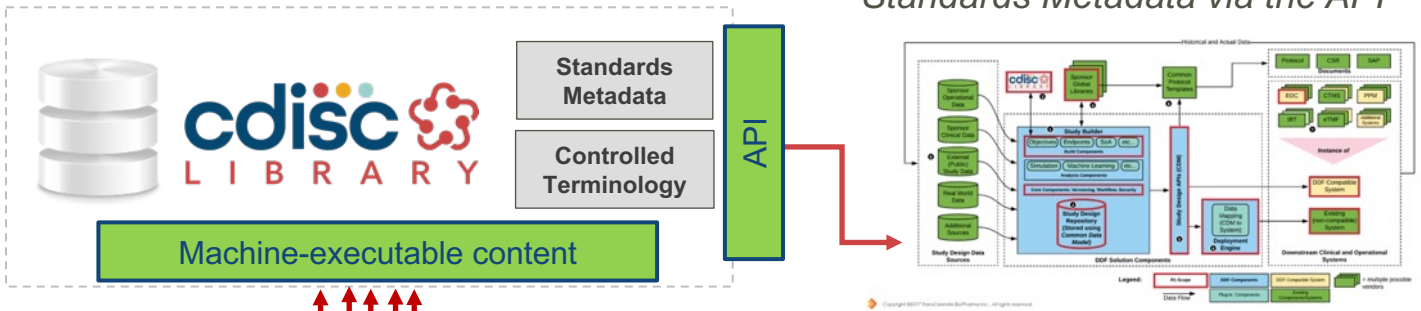

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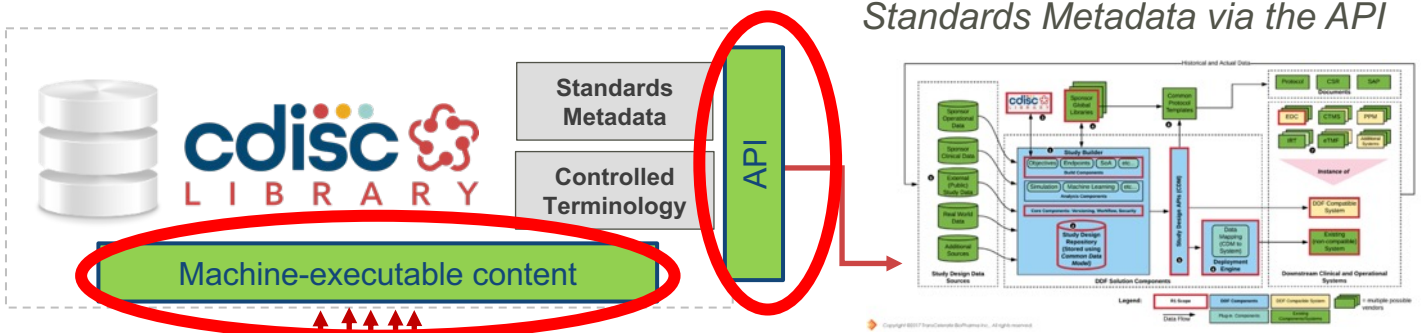

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CDISC Standards

Informative Content

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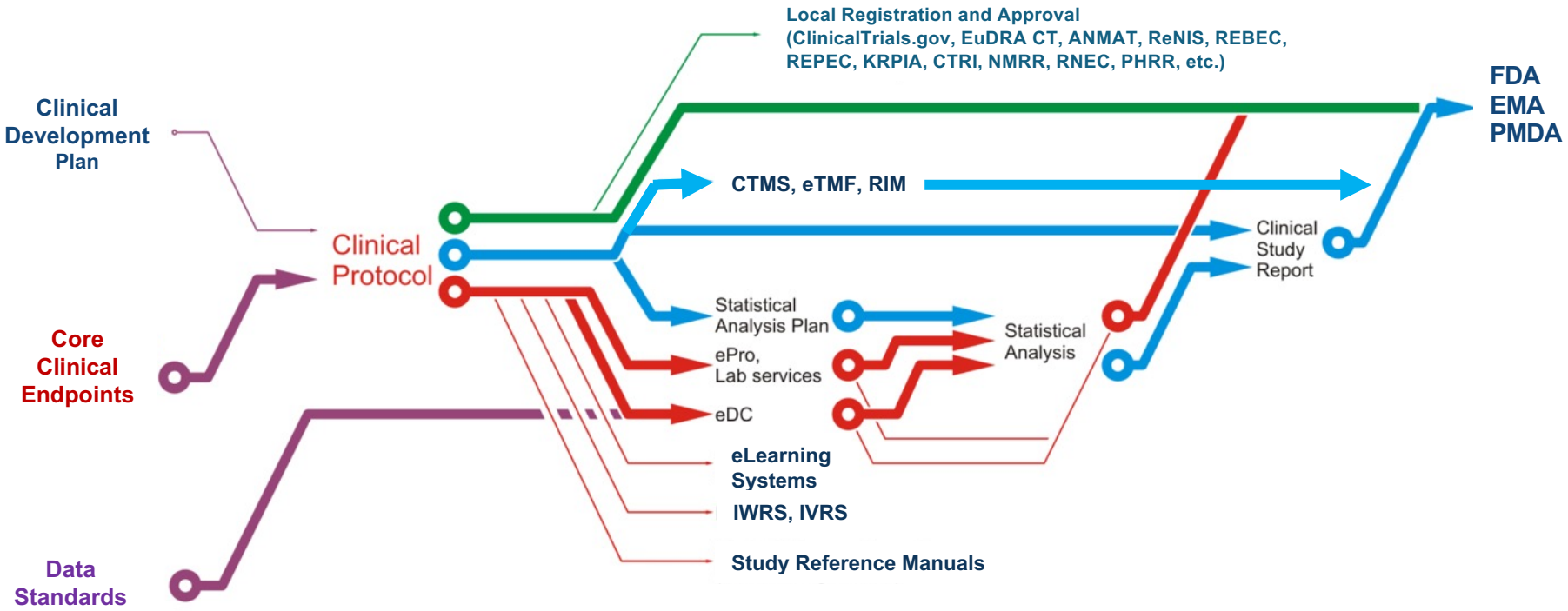

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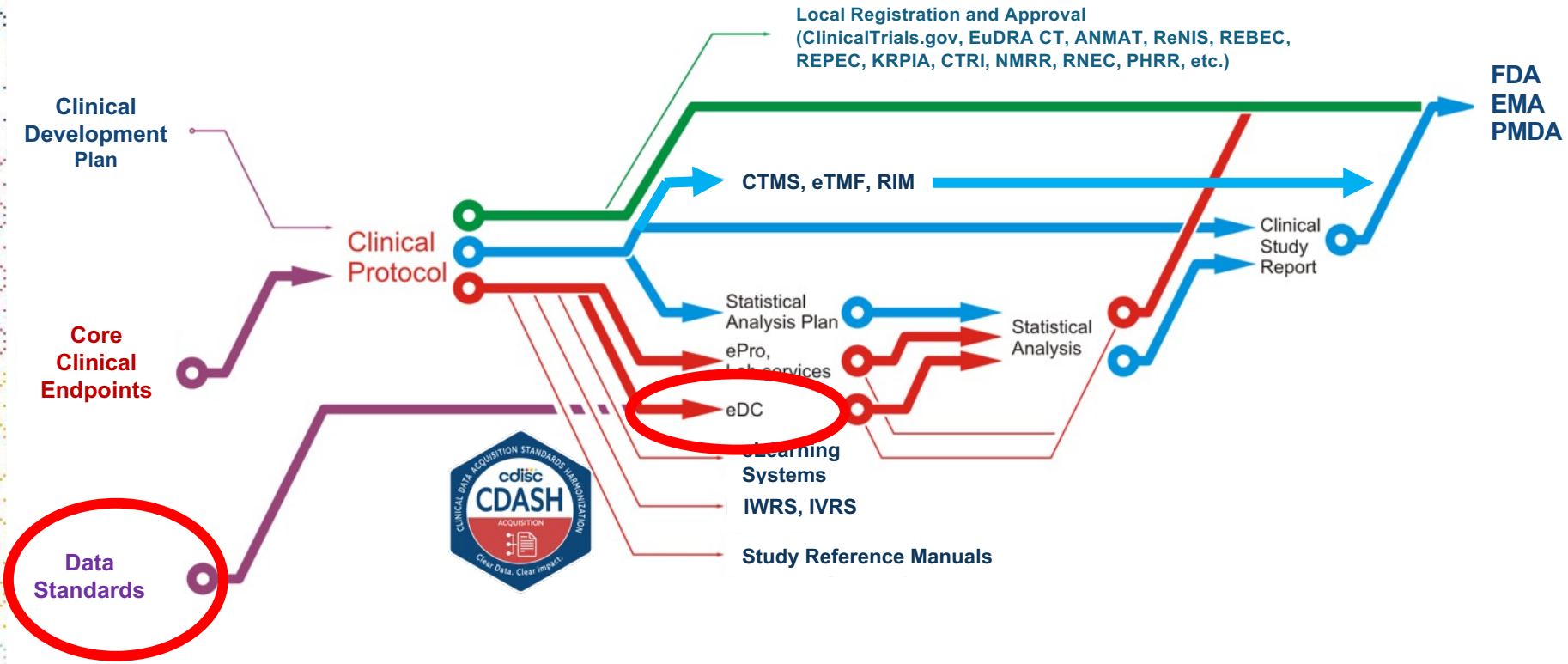

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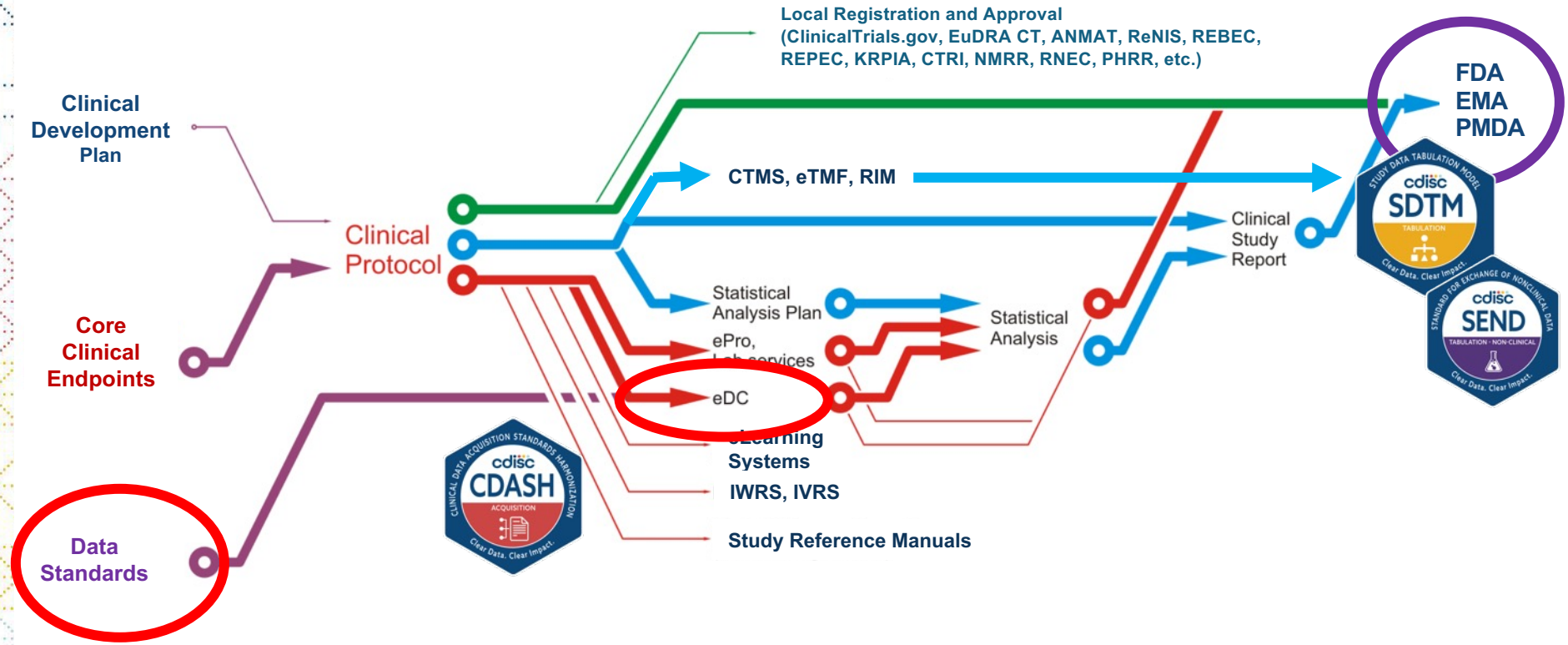

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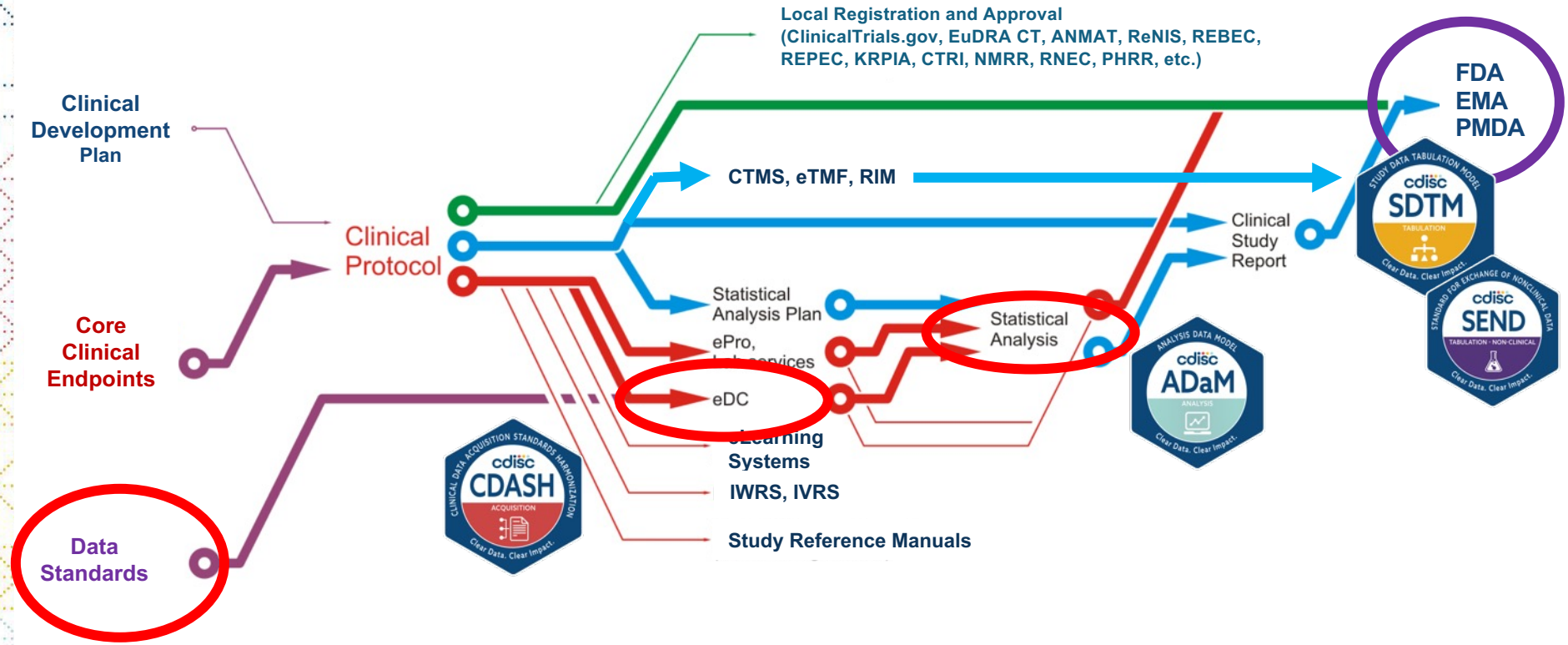

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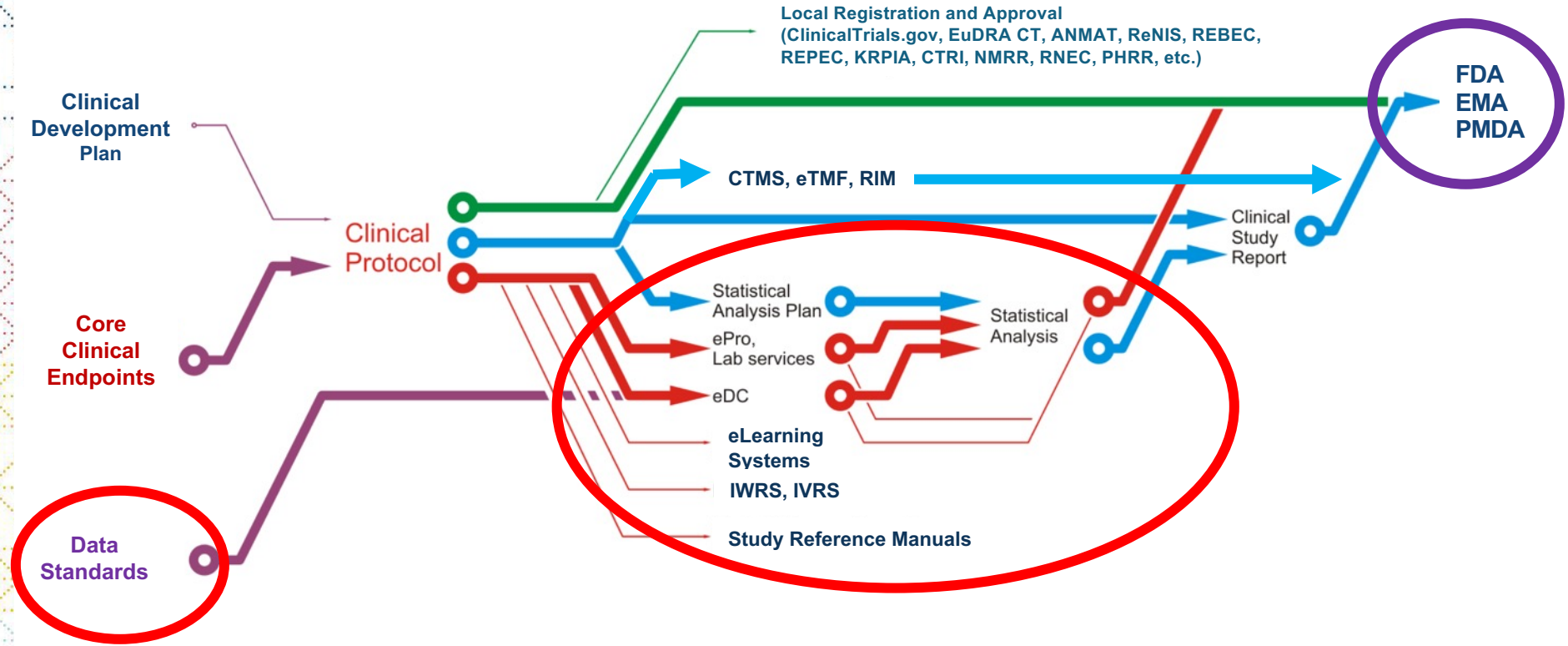

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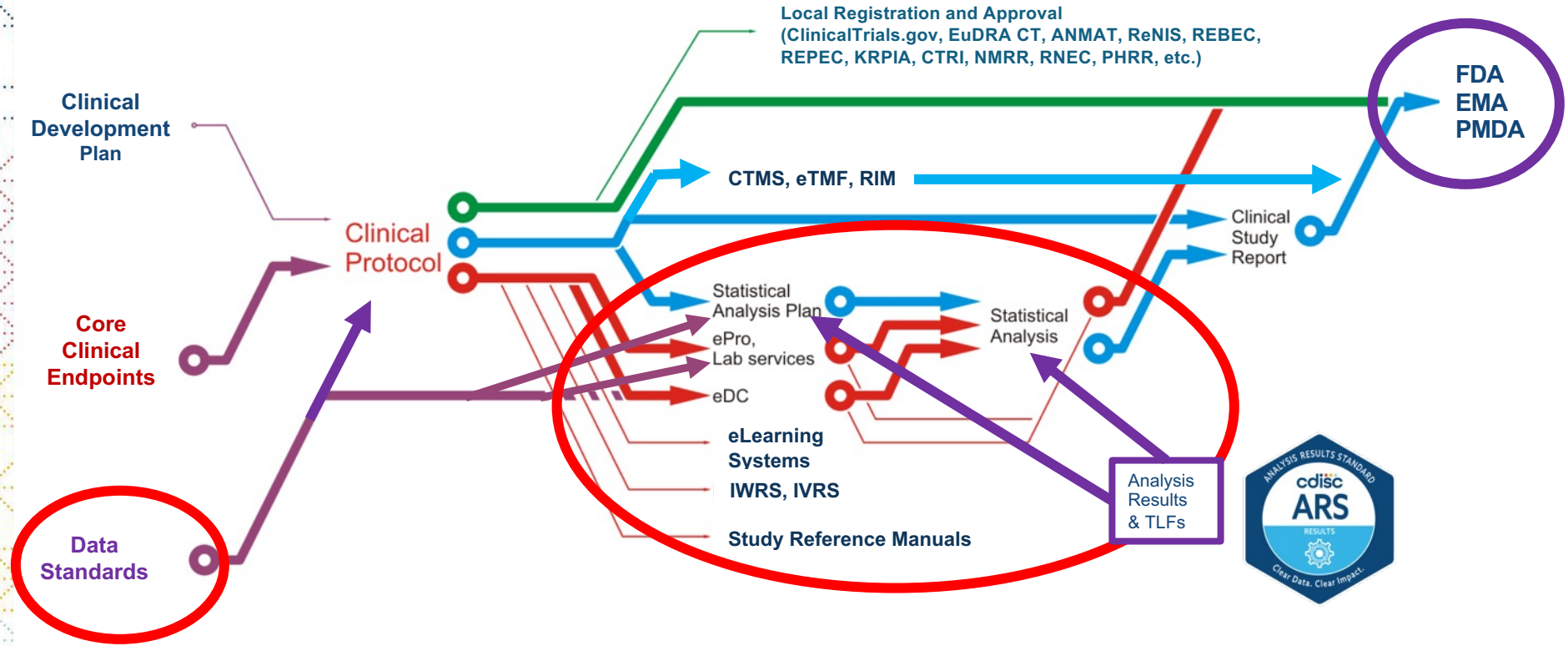

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CDISC Library Provides the Foundation

Software Applications Consume Standards Metadata via the API

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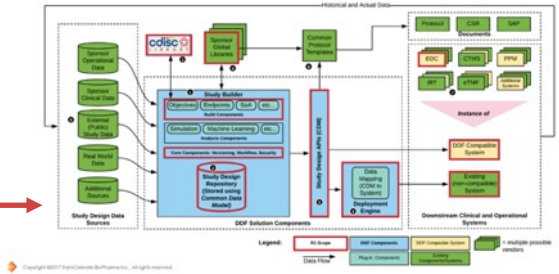
Standards Metadata

Controlled Terminology

API

Machine-executable content



Executable Conformance Rules

Biomedical Concepts

Analysis Results Standard

Tables, Listings and Figures

Codelist Subsets

TAUG Metadata

Study Design Metadata

Dataset Specializations

Derivations and Mappings

Trial Master File Reference Model

Implementation Guide Text

Machine-readable Examples

CRF Collection

Standards Mappings

Draft Standards Metadata

Diff Content Between Versions

CDISC Standards

Informative Content

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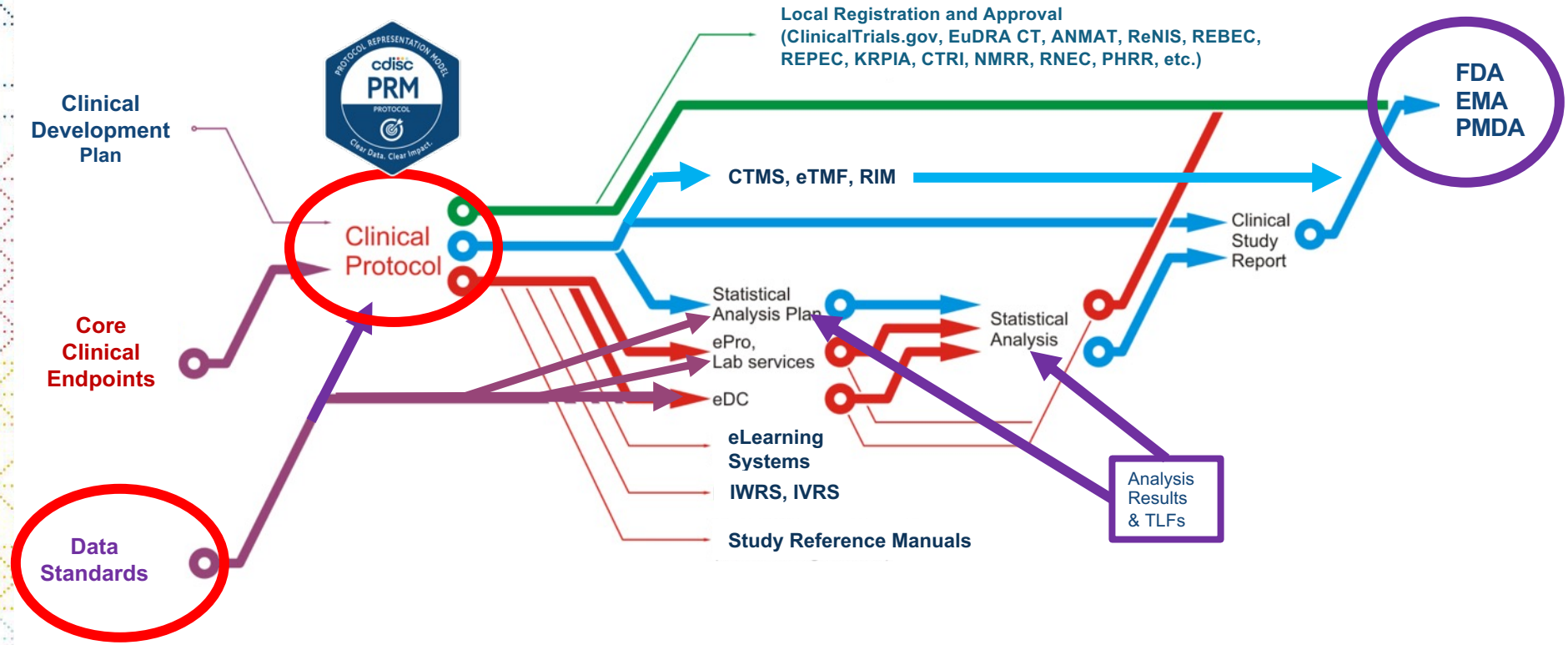

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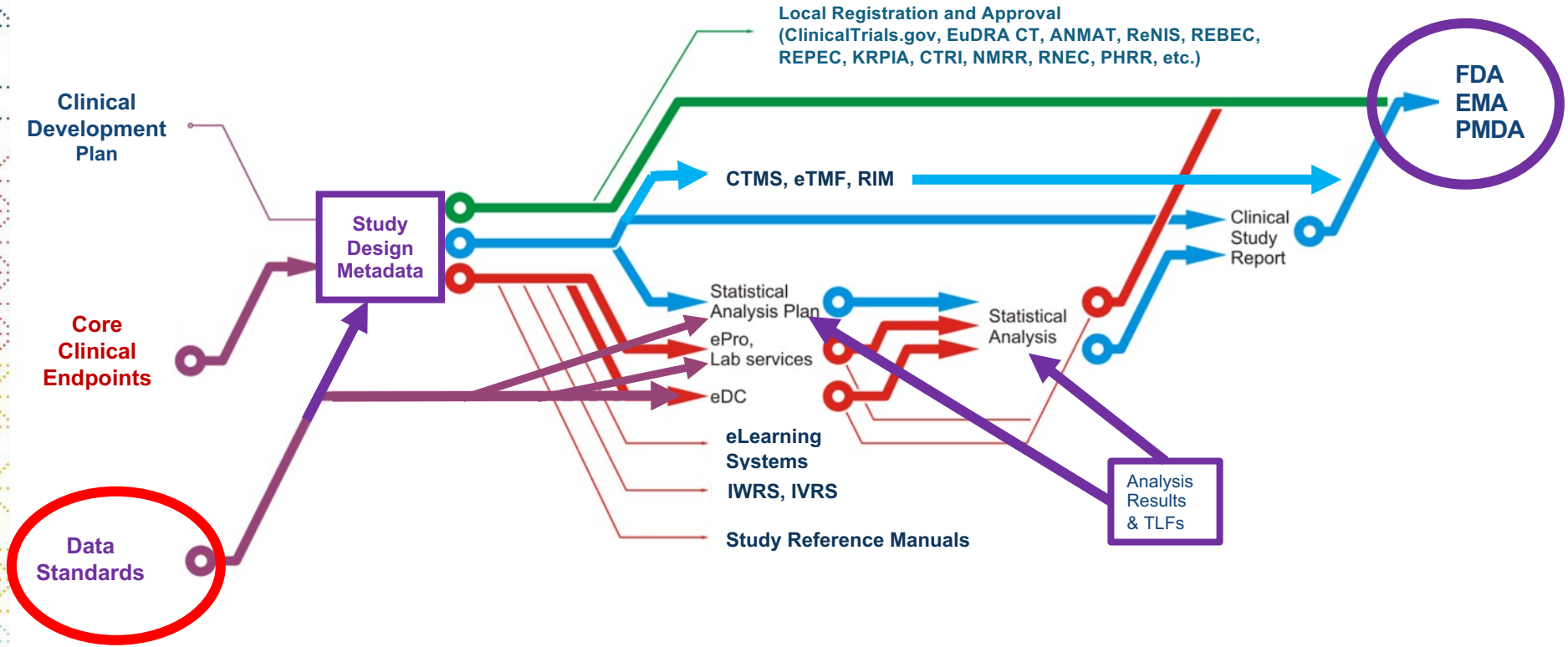

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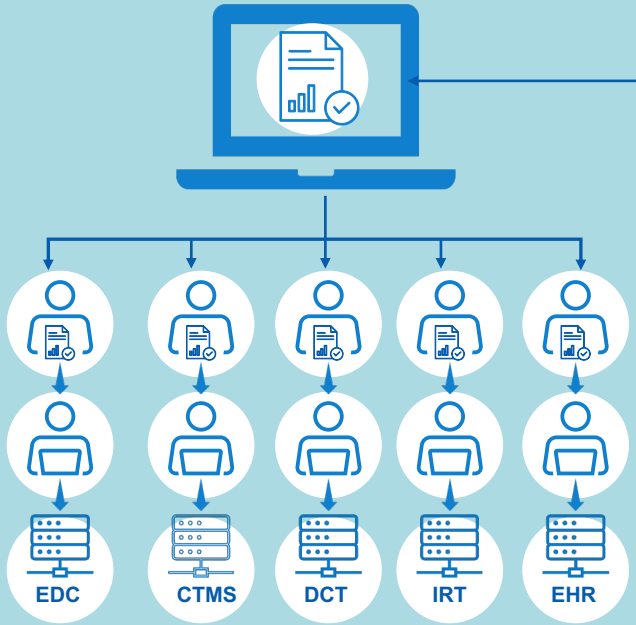
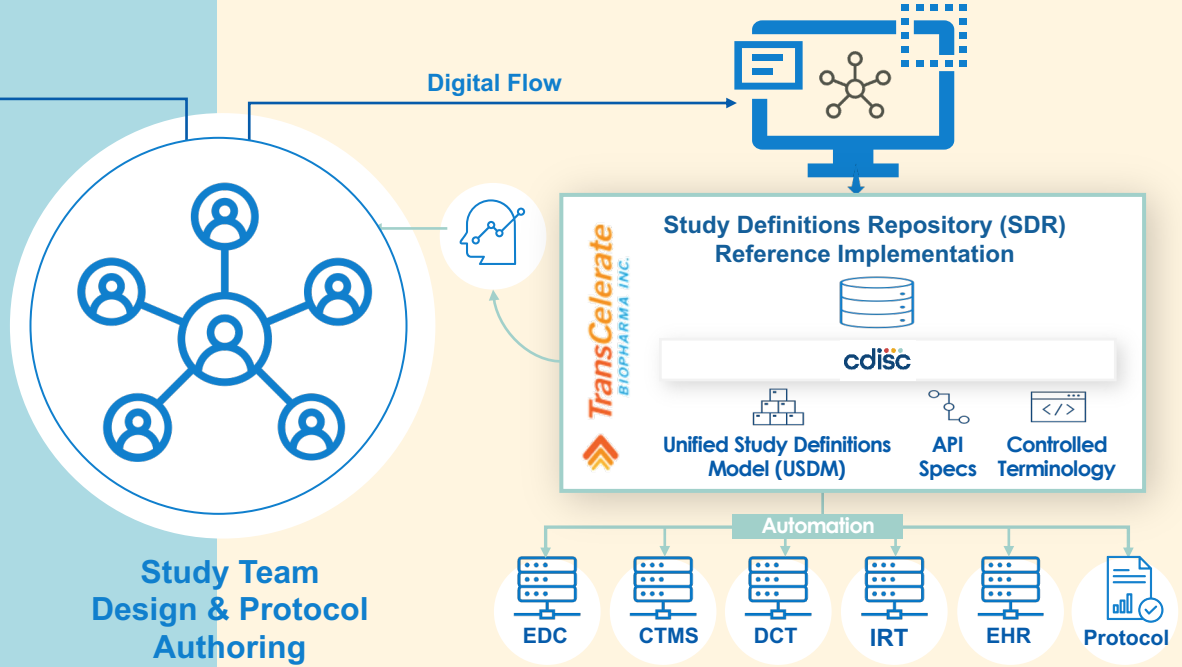
Digital Data Flow (DDF) Initiative

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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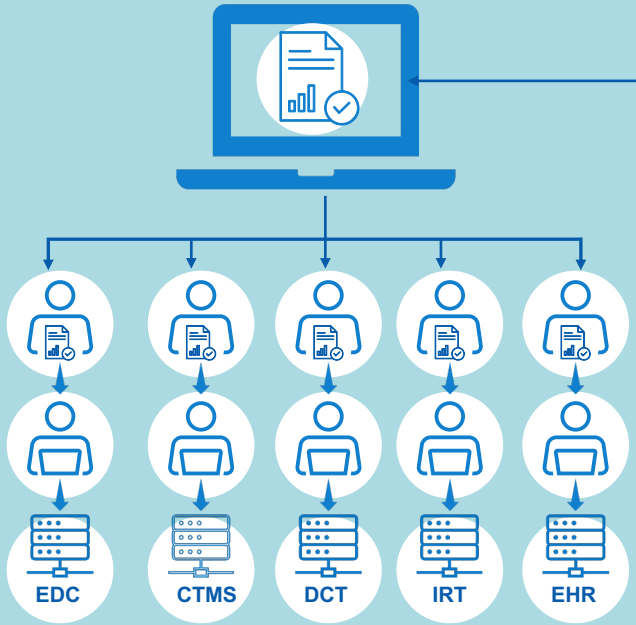

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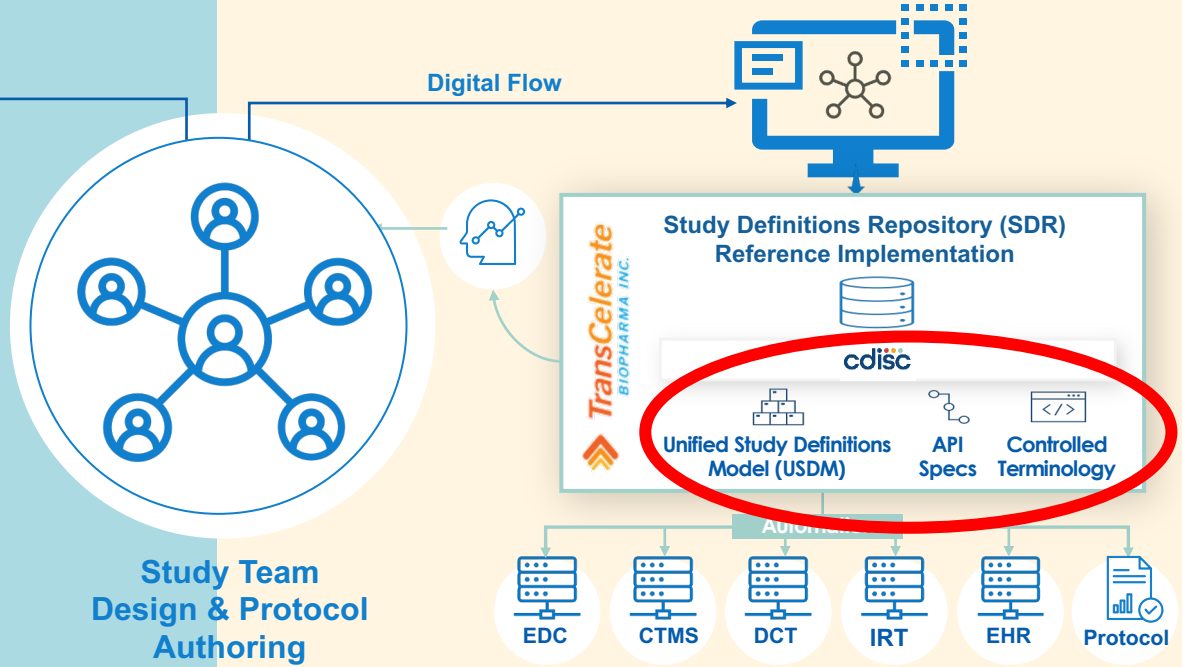
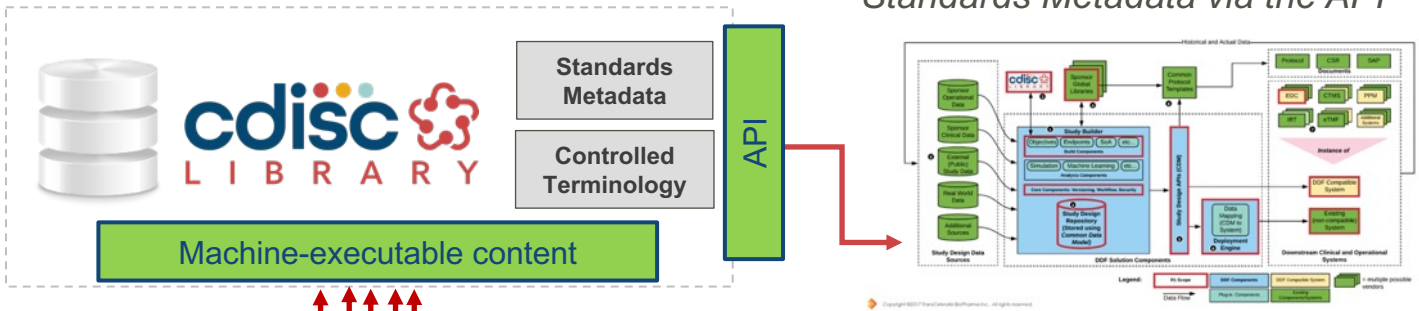


CDISC Library Provides the Foundation

Software Applications Consume Standards Metadata via the API



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CDISC Standards

Informative Content

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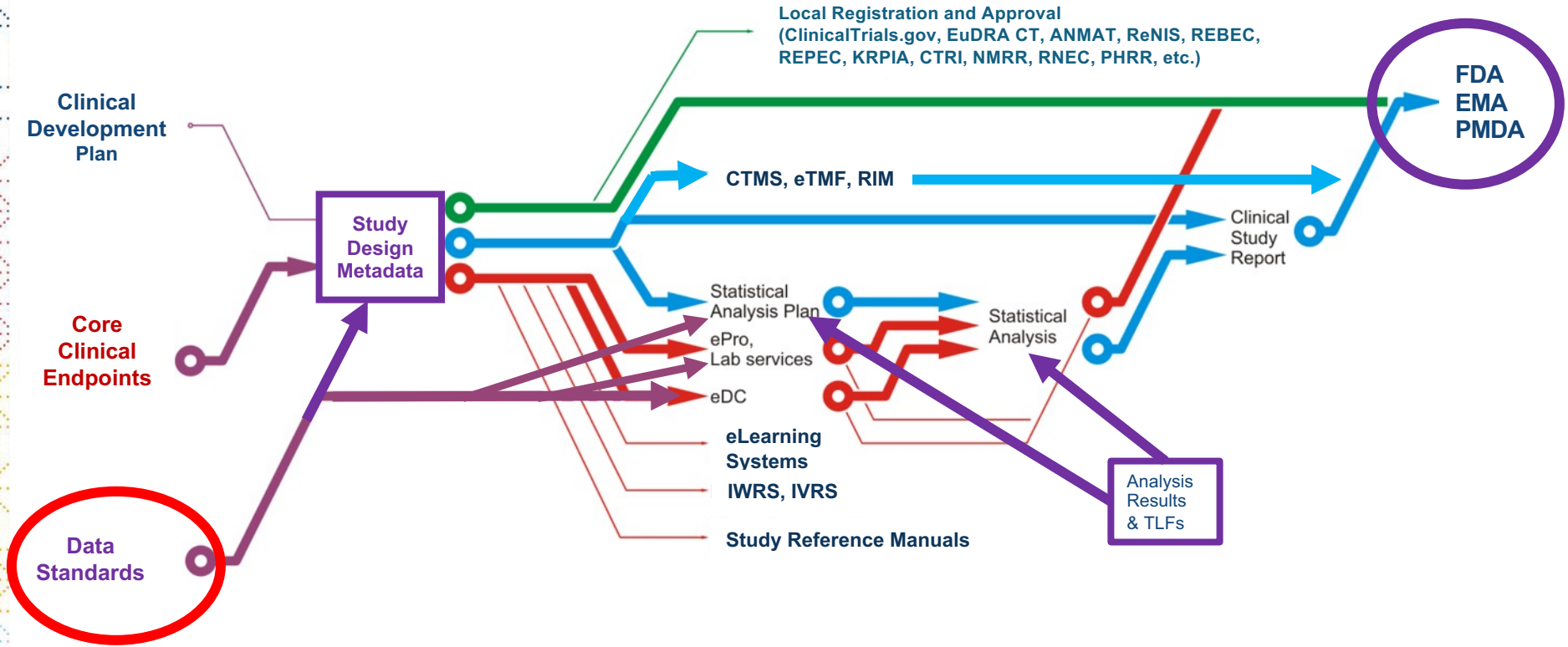

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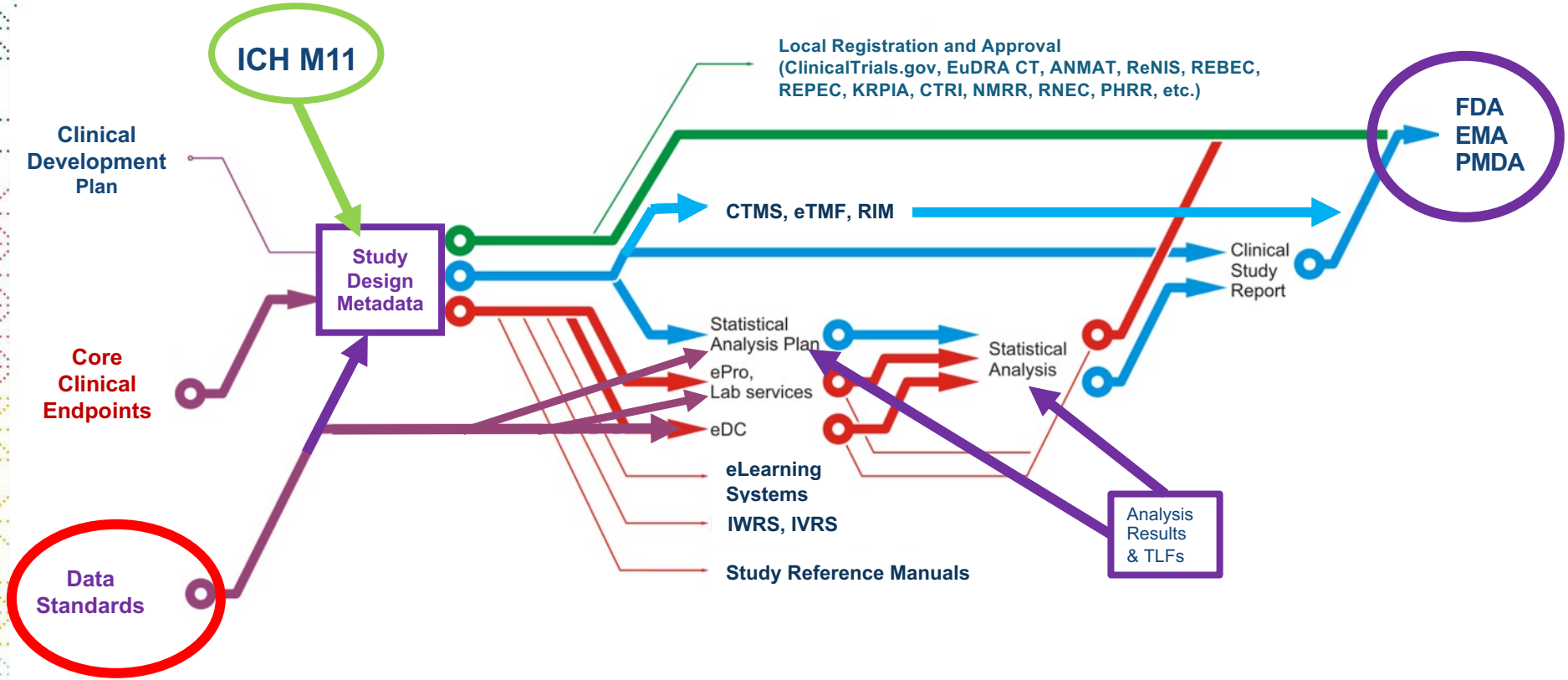
The Clinical Trial Information Flow



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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


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 TECHNICAL SPECIFICATION

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


ICH
harmonisation for better health

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M11 TEMPLATE

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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.*

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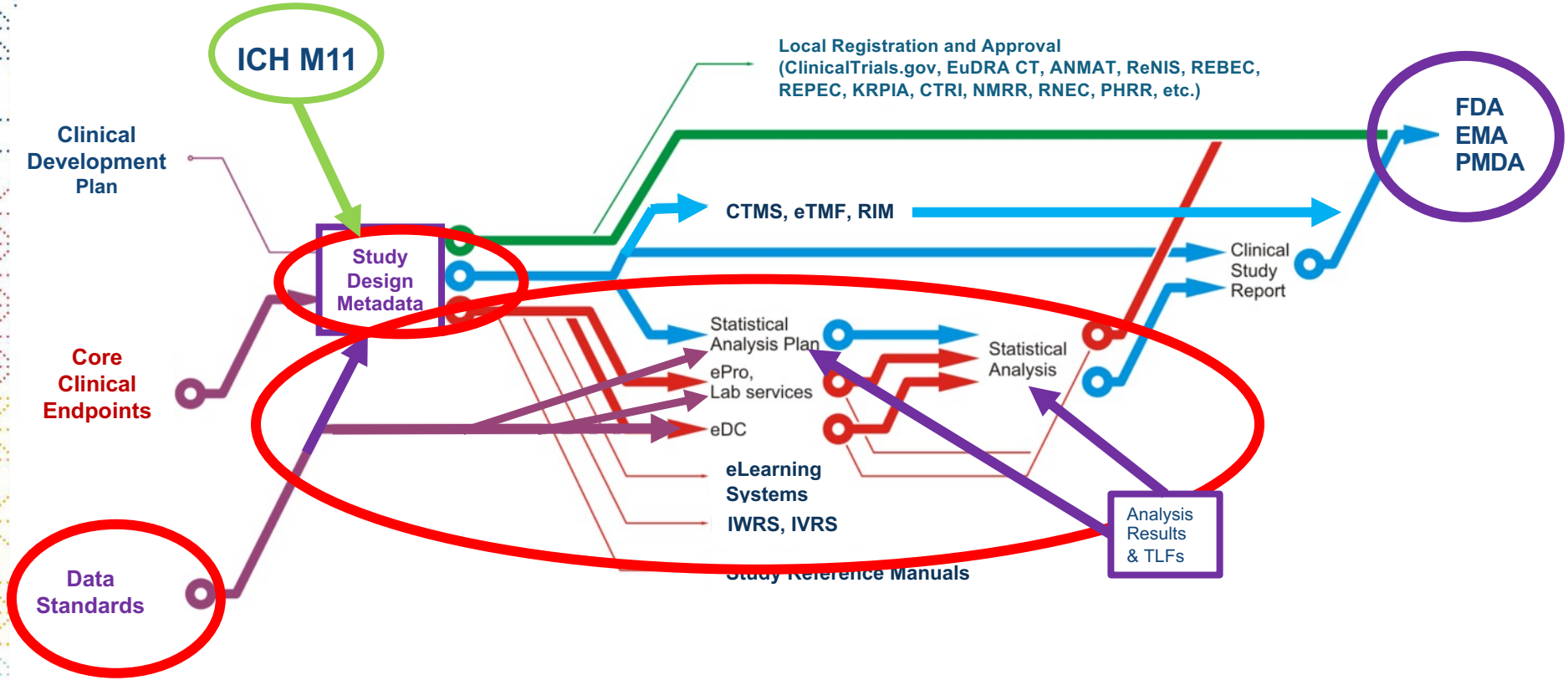
The Clinical Trial Information Flow



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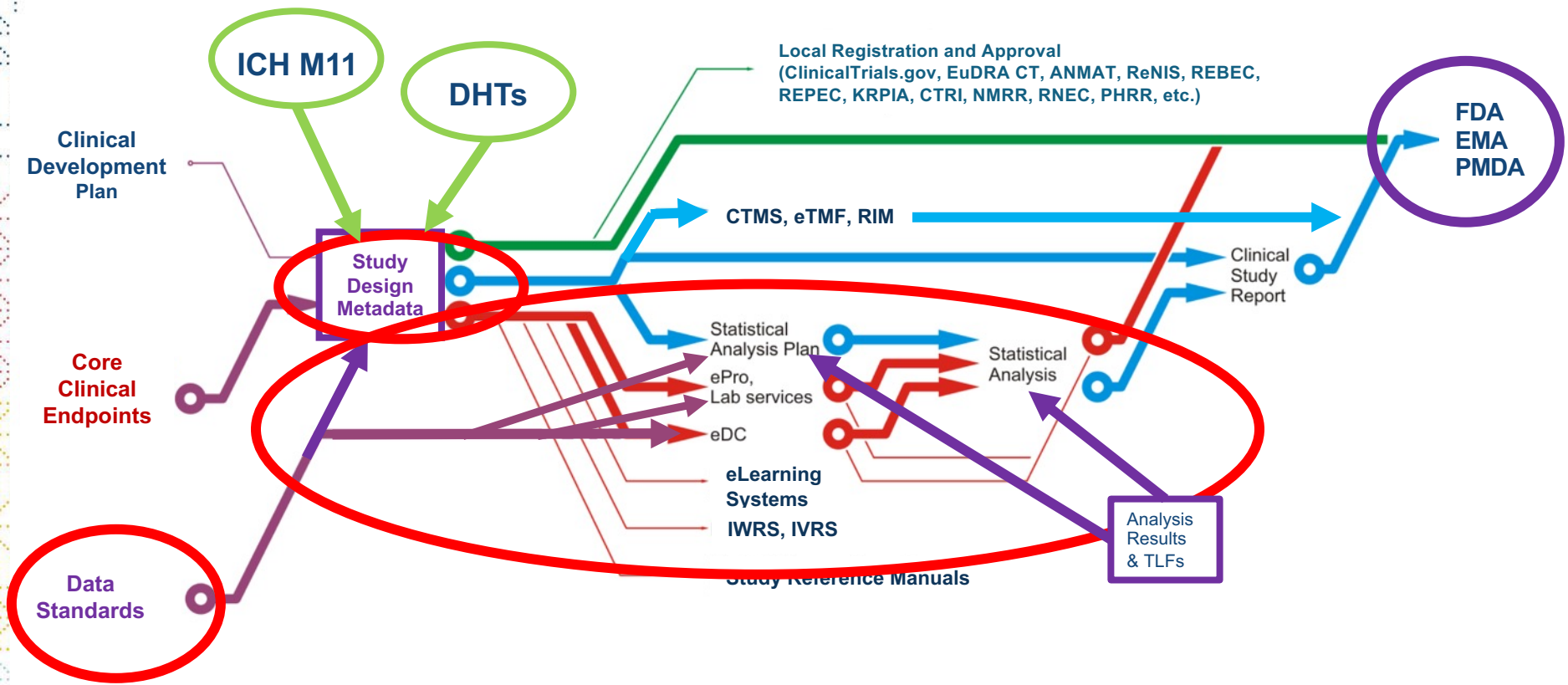


Increased Regulatory Focus on Digital Health Technologies

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

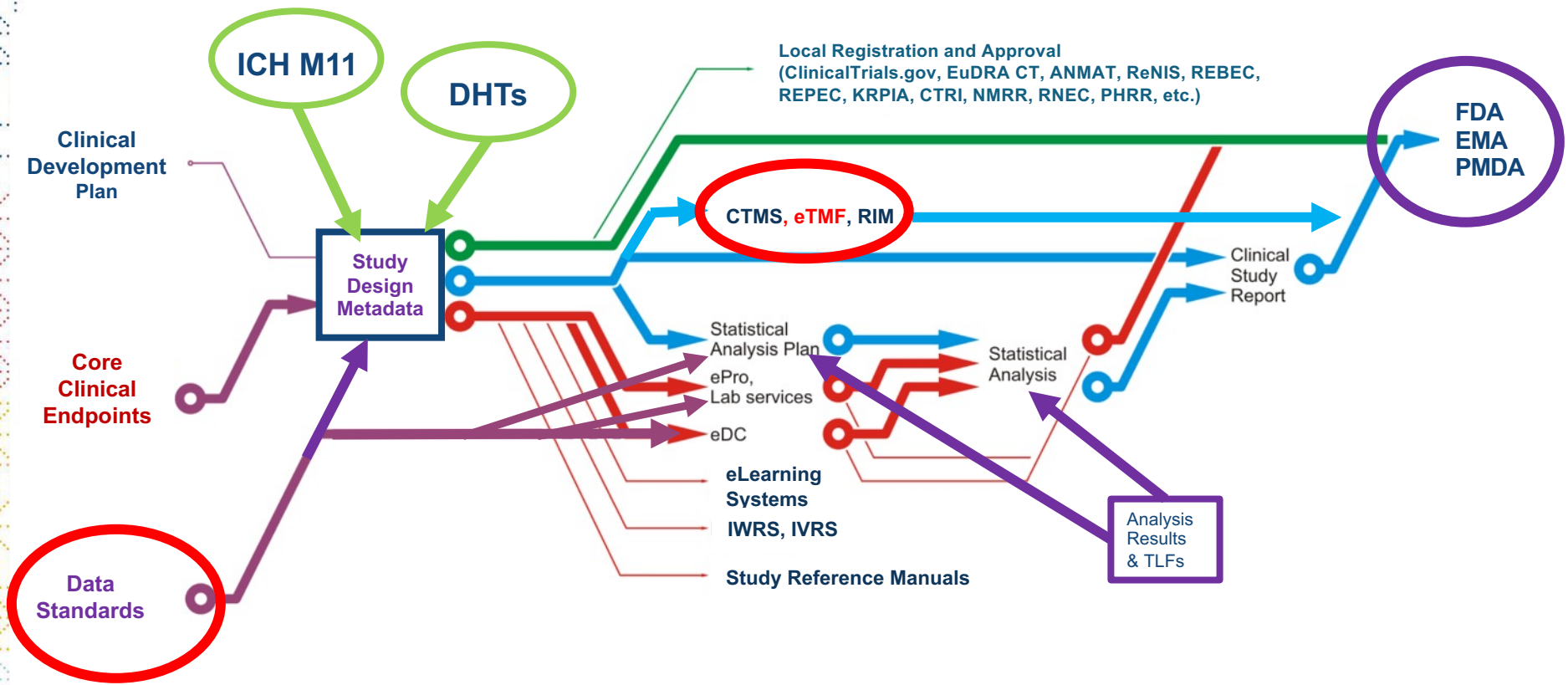
Deliverables completed by Q4 2024

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



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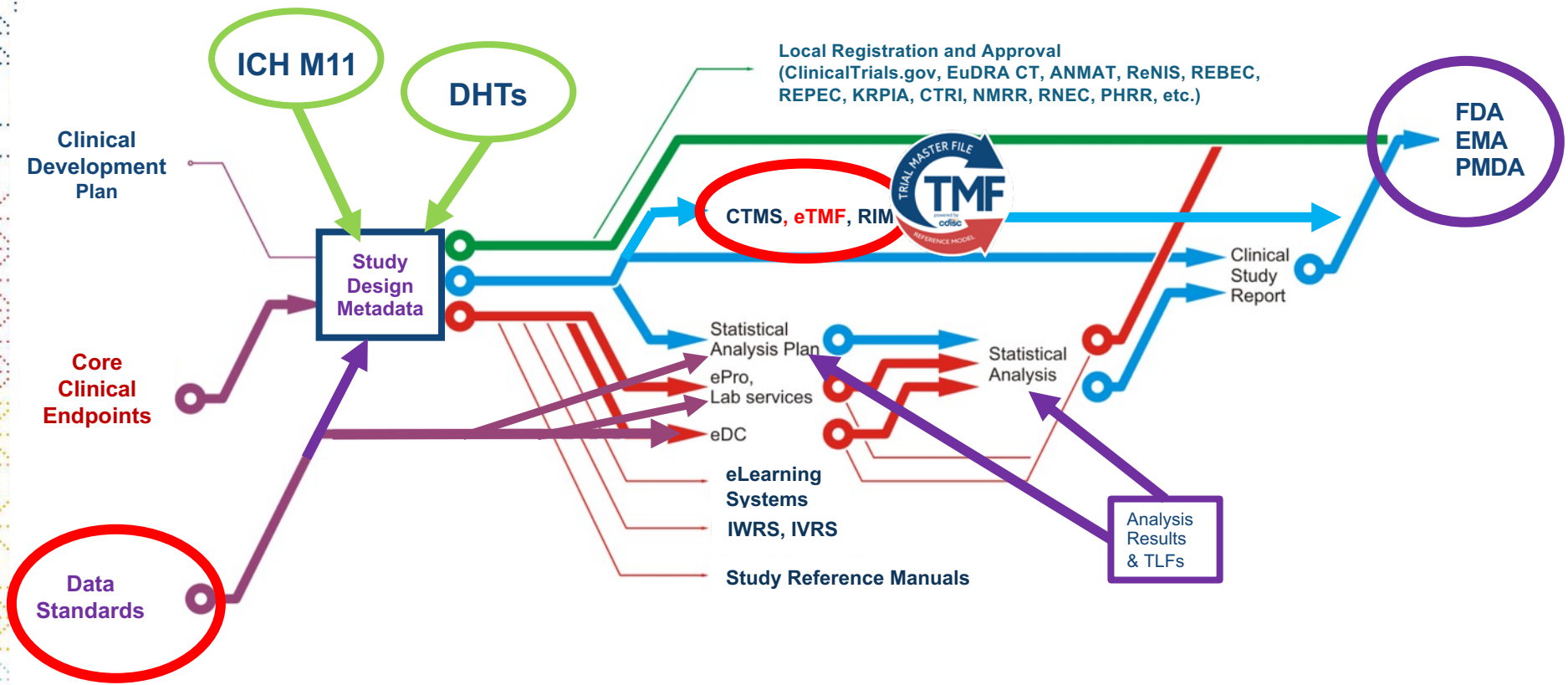


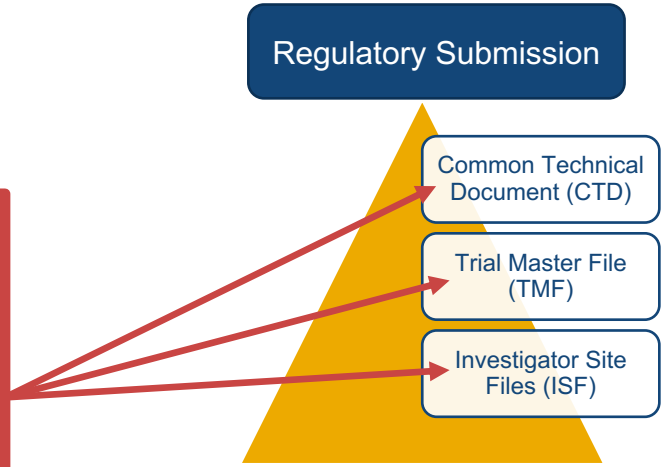
What is a Trial Master File?

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

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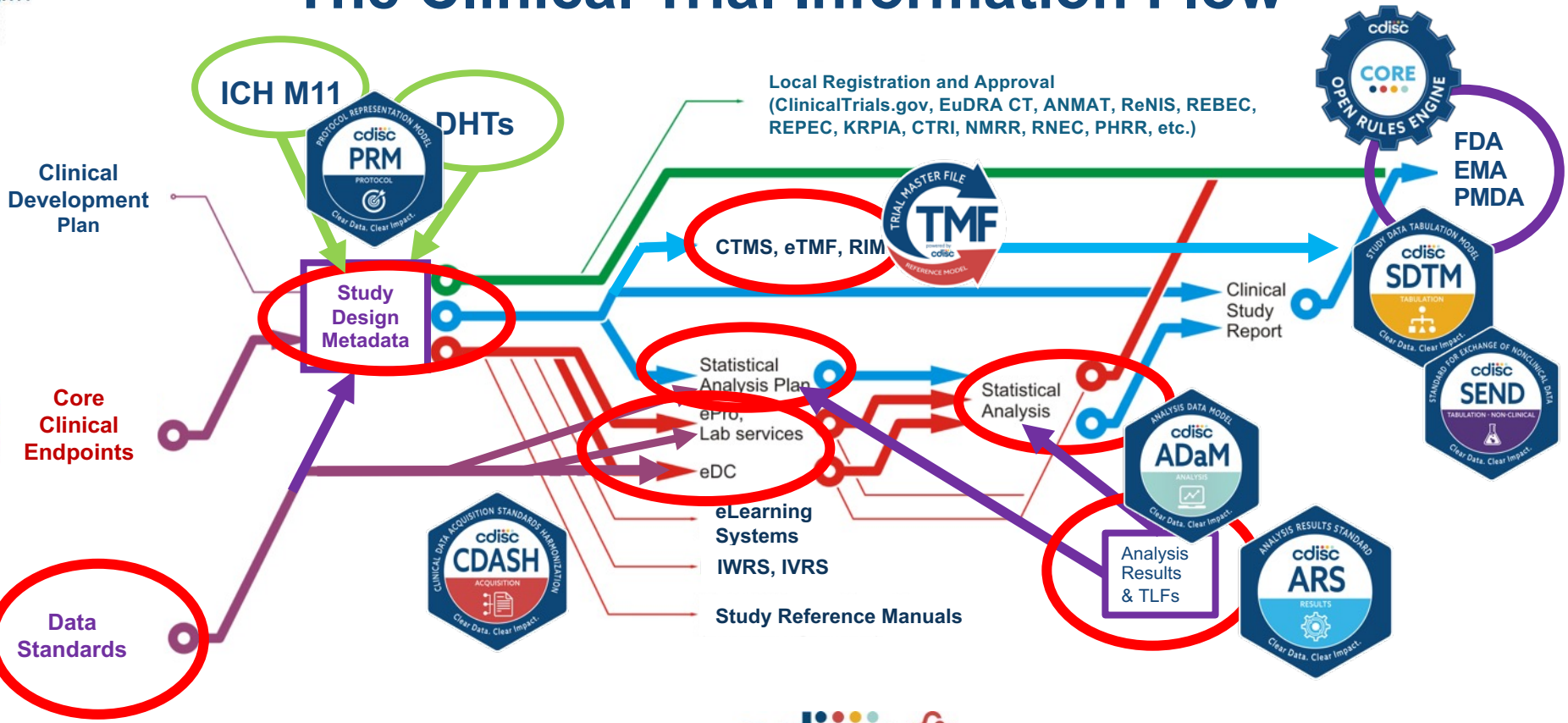
The Clinical Trial Information Flow



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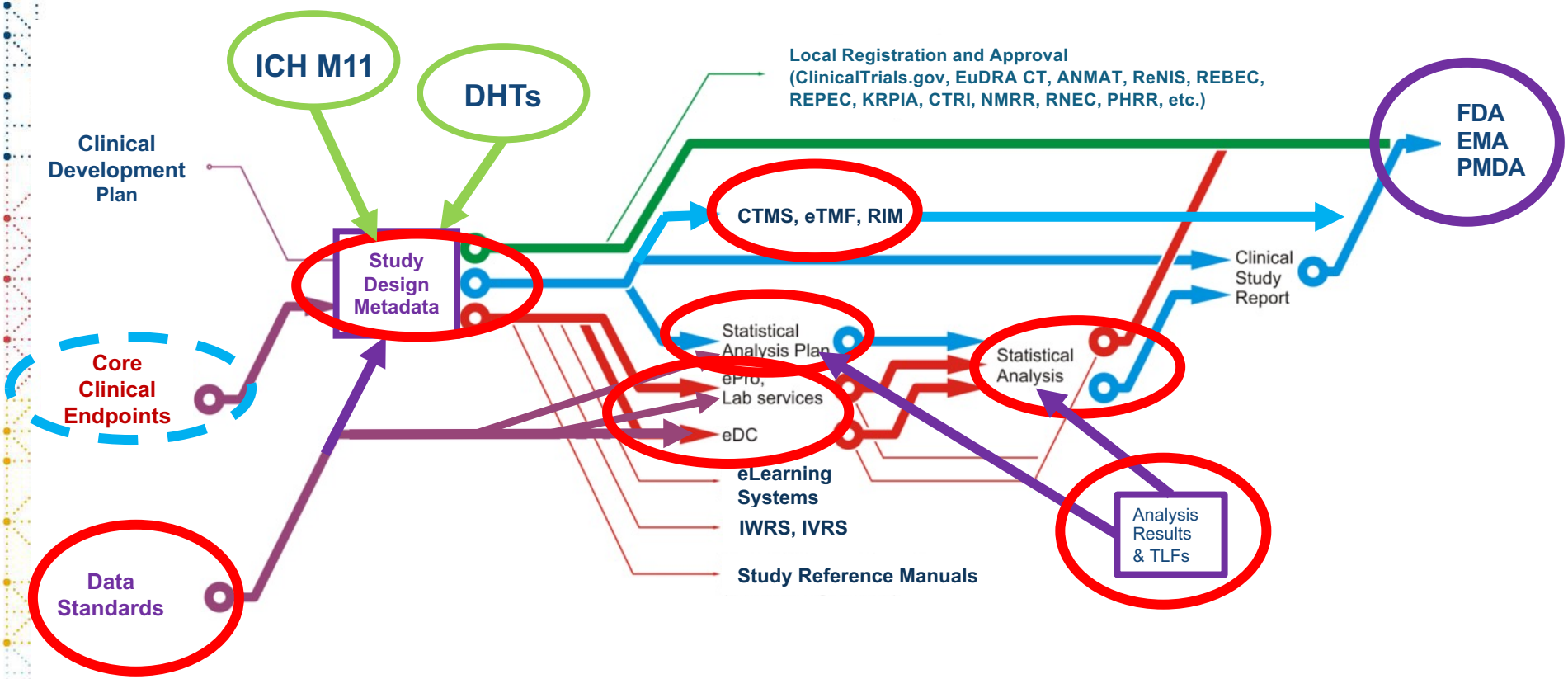

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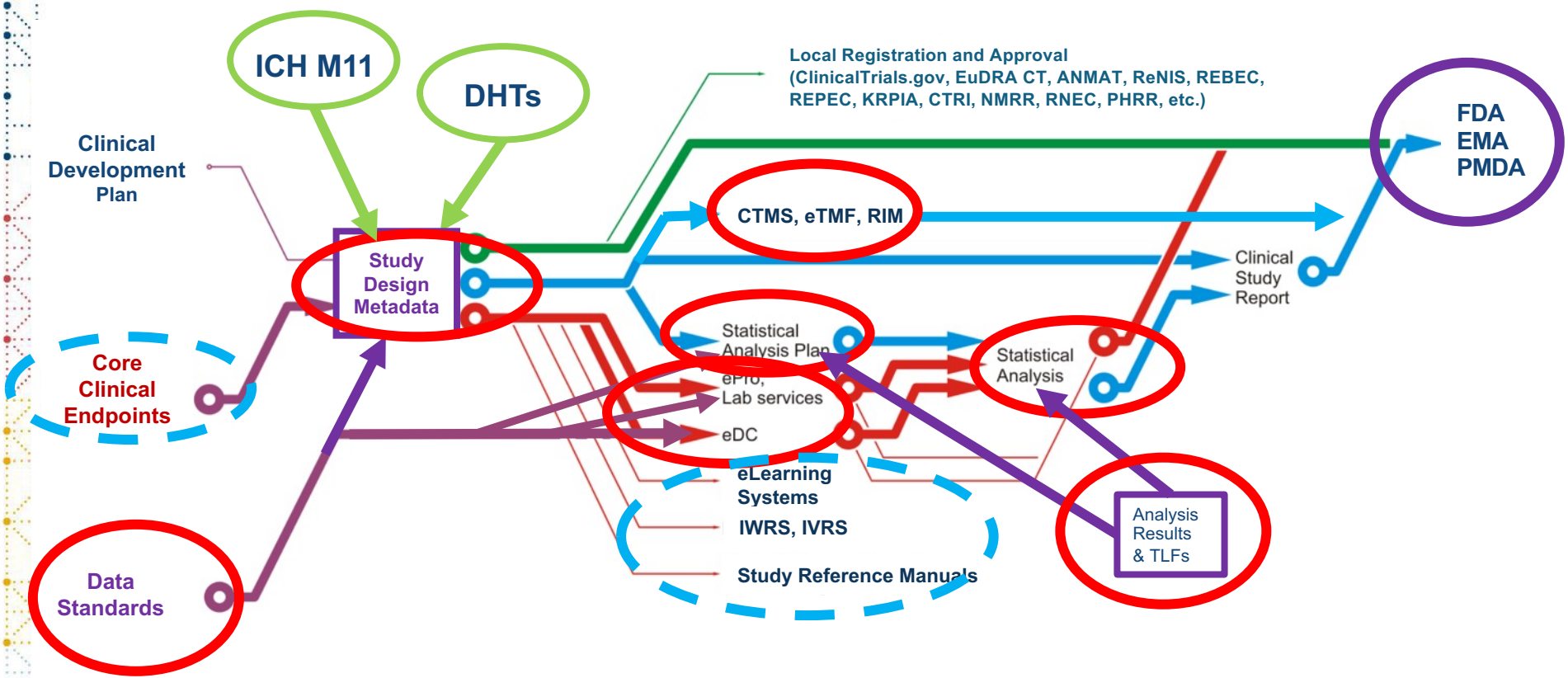

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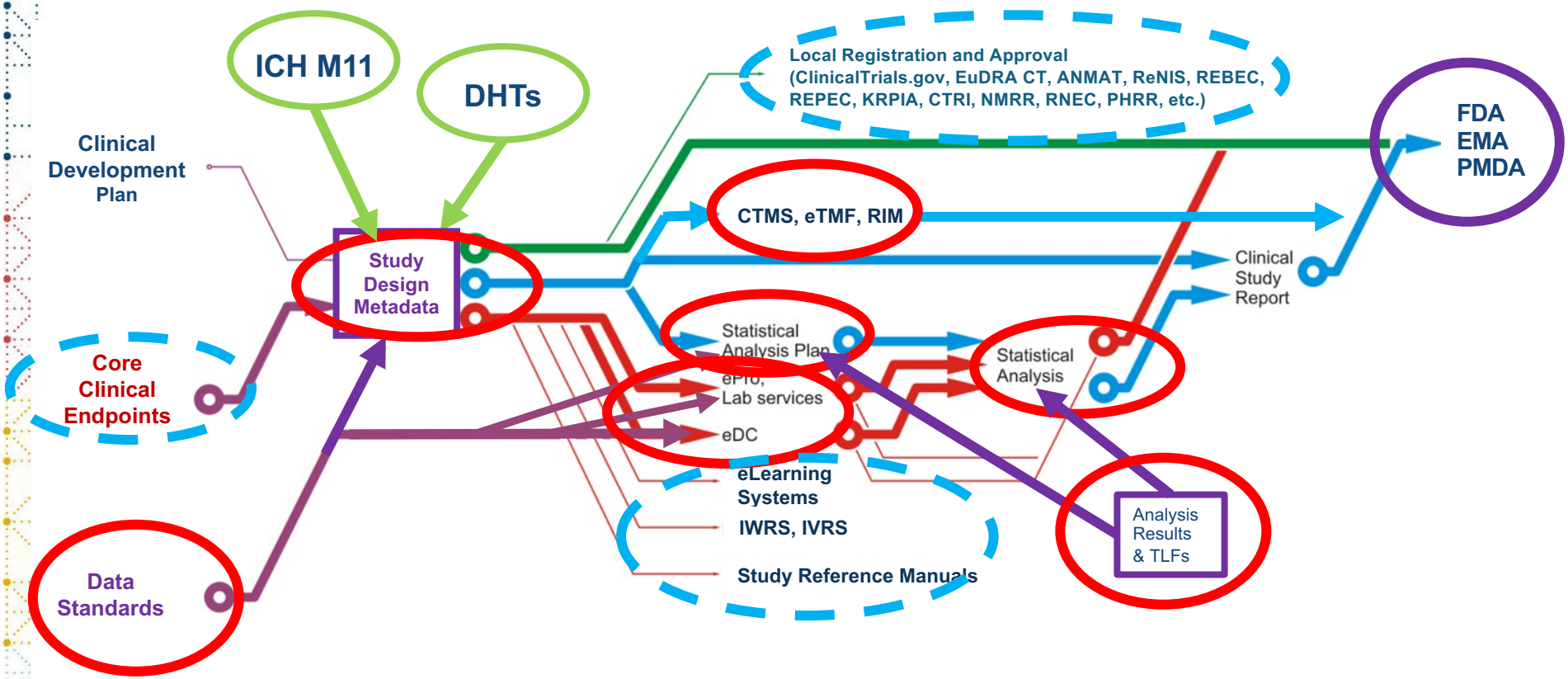

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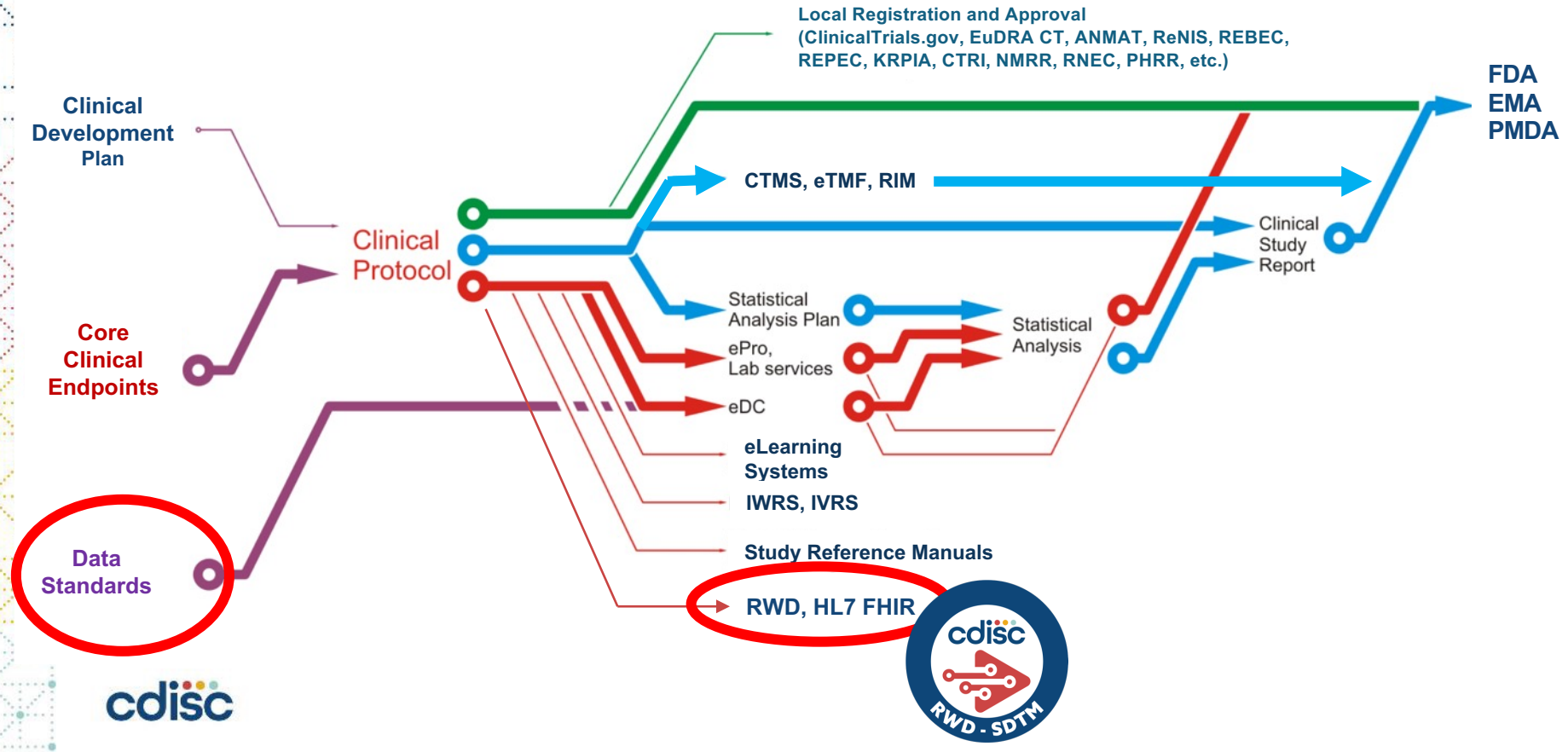
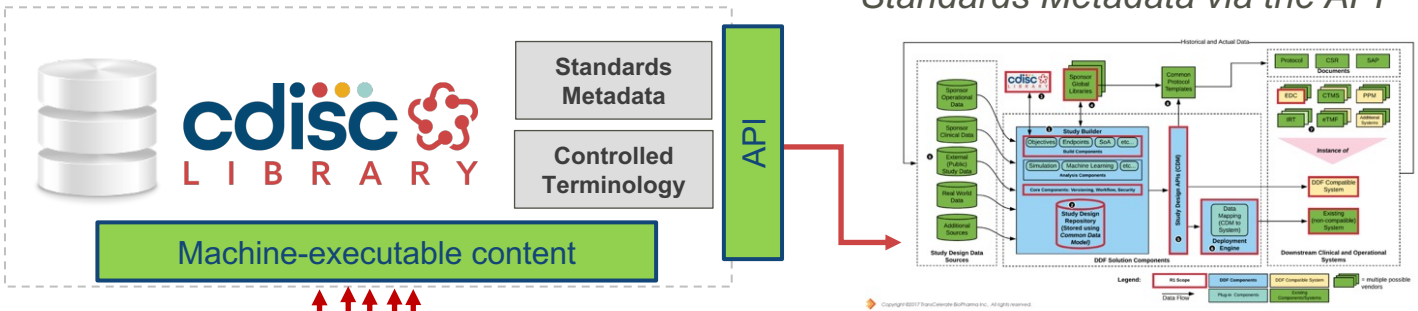


CDISC Library Provides the Foundation

Software Applications Consume Standards Metadata via the API



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CDISC Standards *Informative Content*

CDISC Library Provides the Foundation

Software Applications Consume Standards Metadata via the API

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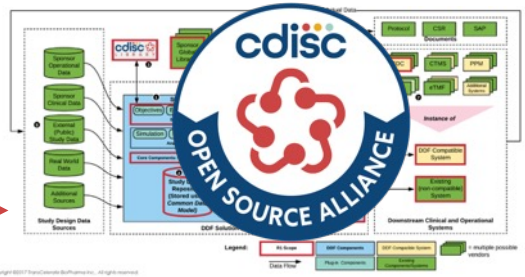
Standards Metadata

Controlled Terminology

API



Machine-executable content

Executable Conformance Rules

cdisc CORE OPEN RULES ENGINE

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	CRF Collection	Diff Content between Versions

cdisc ARS RESULTS

cdisc CDASH ACQUISITION

cdisc RWD - SDTM

TRIAL MASTER FILE TMF REFERENCE MODEL

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CDISC Standards

Informative Content

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.*

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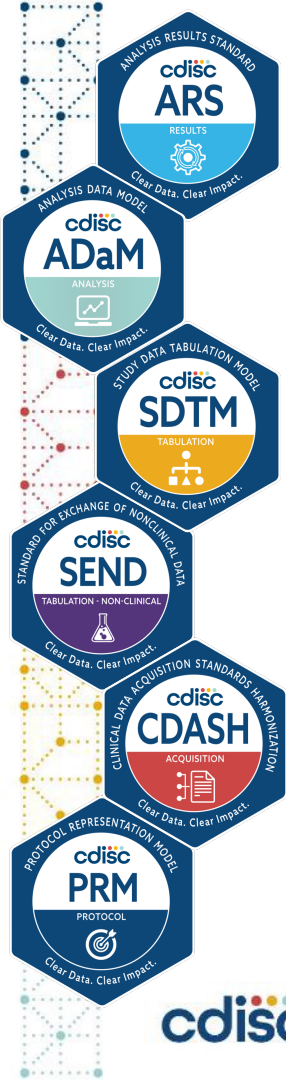

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Thank You CDISC Community!

Dave Evans – President & CEO, CDISC

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