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2023
EUROPE
INTERCHANGE
COPENHAGEN | 26-27 APRIL

State of the CDISC Union

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 Europe CDISC Coordinating Committee (E3C)

- Nick De Donder, Co-Chair, Business & Decision Life Sciences
- Sujit Khune, Co-Chair, Novo Nordisk A/S
- Silvia Faini, Cytel
- Éanna Kiely, Alexion
- Simon Lundberg, AstraZeneca
- Eftychia-Eirini Psarelli, EMA
- Stijn Rogiers, Argenx
- Angelo Tinazzi, Cytel
- Johannes Ulander, data4knowledge ApS

Thank You for Joining Us!

- Highest number of Abstracts received for a Europe Interchange
- Highest Attendance on Record for a Europe Interchange
- Cutting-edge topics; the latest on major CDISC initiatives

CDISC Community

CDISC – State of the Organization

- Stable Staff with an Optimized Organization
  - 50+ Employees & FT Contractors
- Active Volunteer Network of 1000+ Industry Experts
- 550+ Member Organizations
- Widely Adopted Clinical Research Data Standards
- Mature Standard Governance Processes
- Growing Opportunity Pipeline and Backlog
- Active Innovative Standards & Technology Projects
- Active Involvement in Evolving Industry Initiatives and Projects
- Positive and Growing Relationships
  - Members, Regulators, Partners, Academia, SDOs and Industry

Alliances and Collaborations

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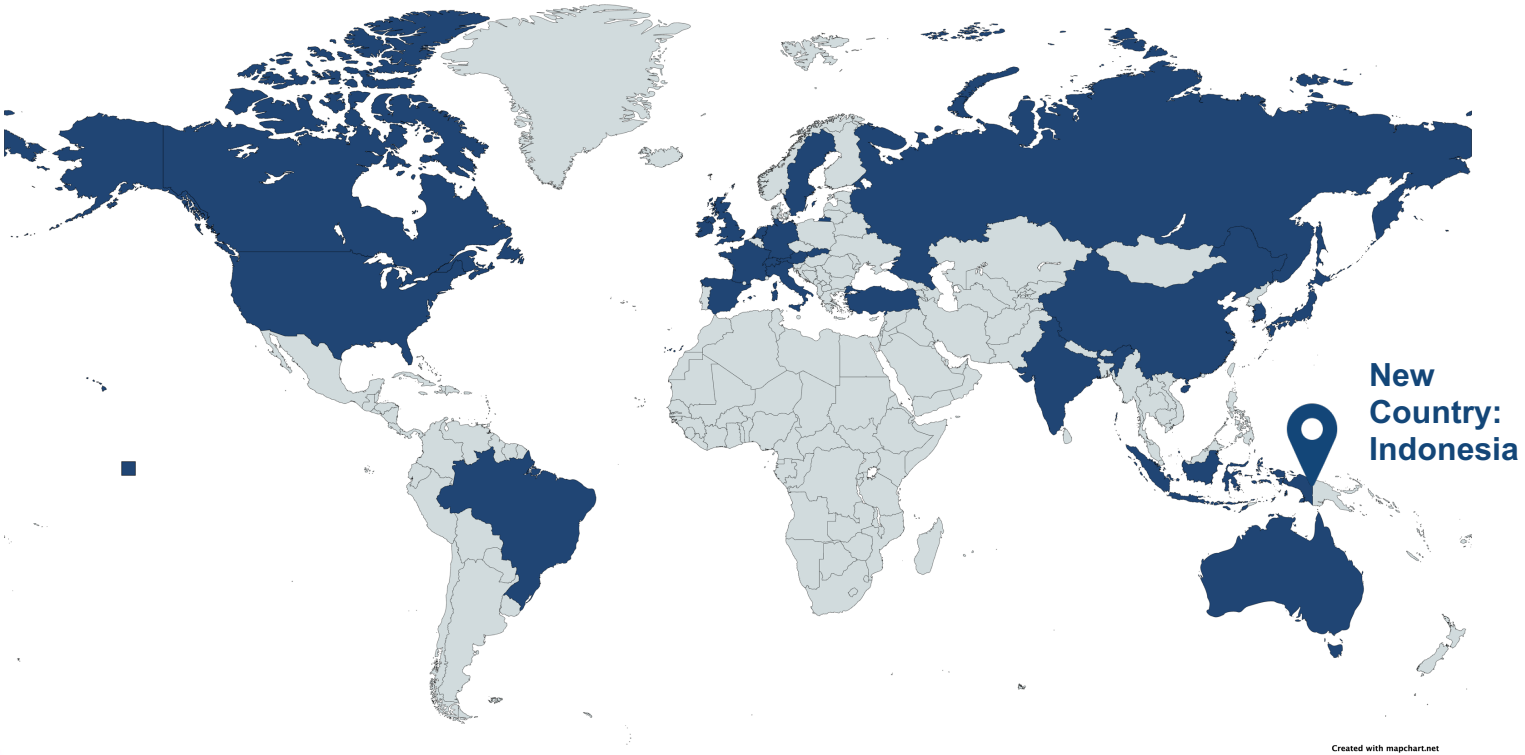
phuse

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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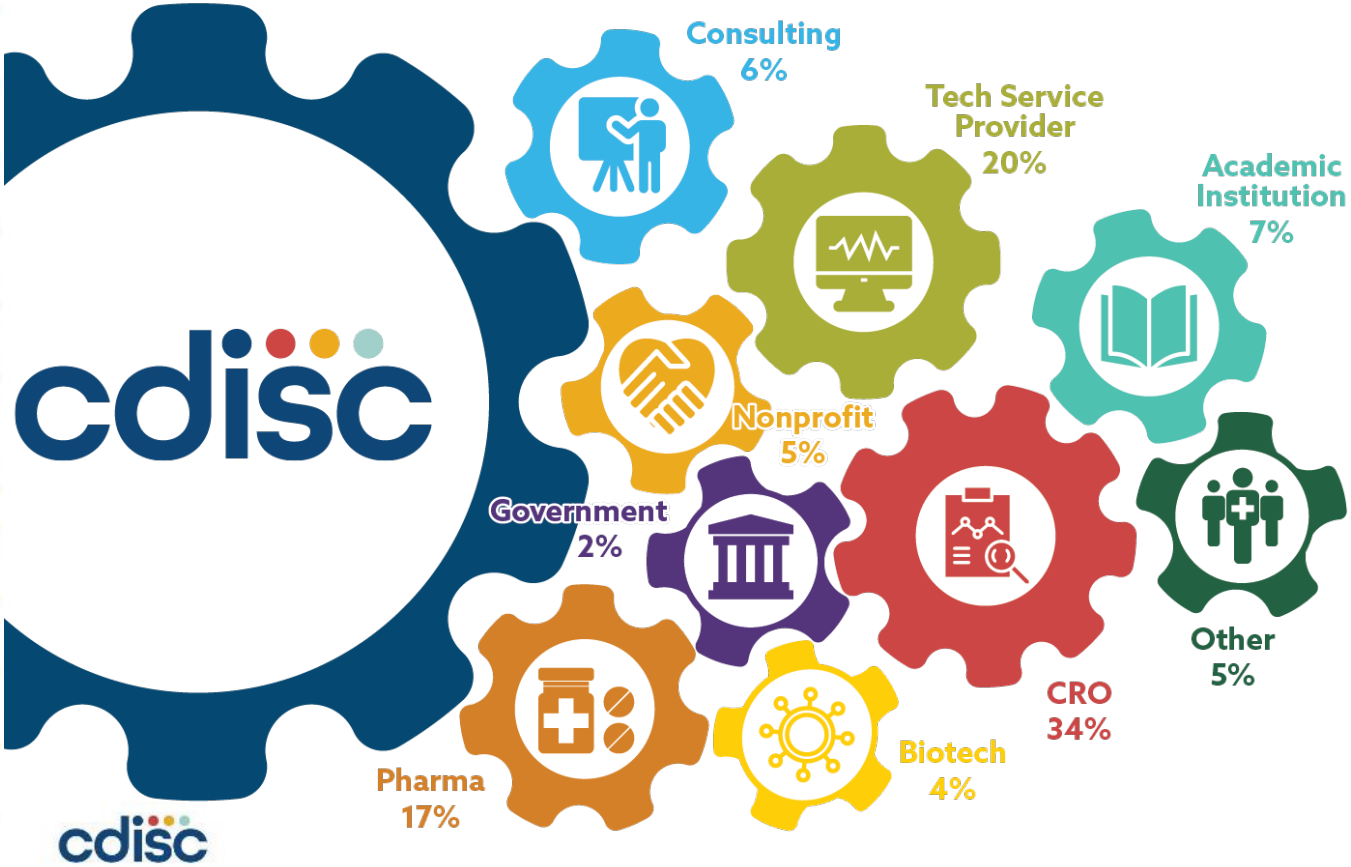
New Countries: Brazil, Indonesia, Turkey, Uganda

CDISC Members = Diverse Global Community



CDISC Membership

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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 (Anticipated)
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

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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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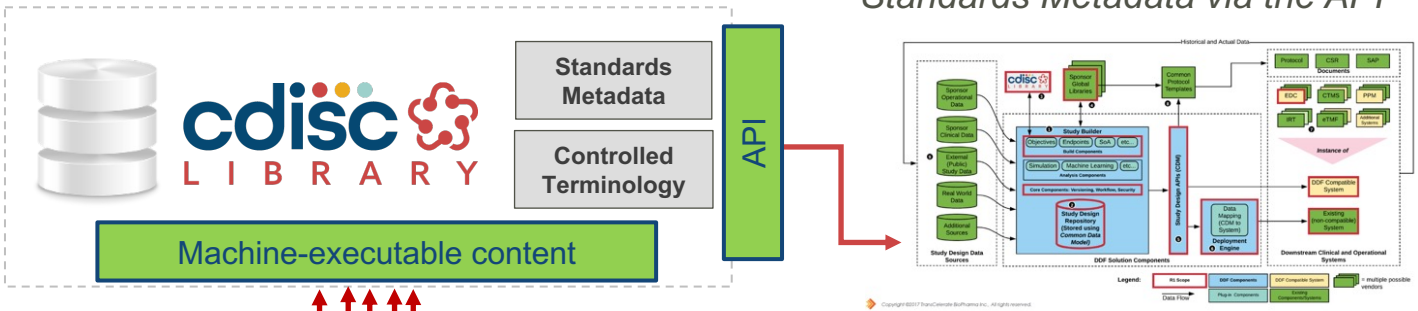
CDISC Library Provides the Foundation

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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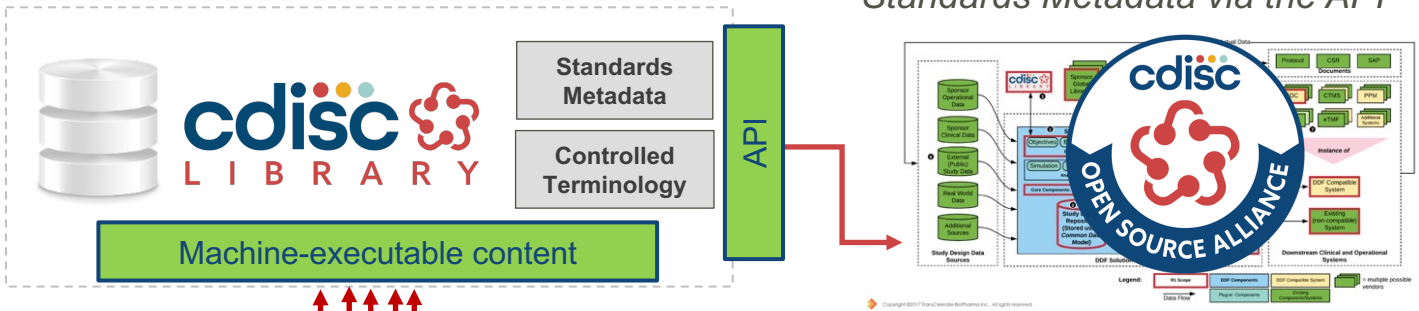

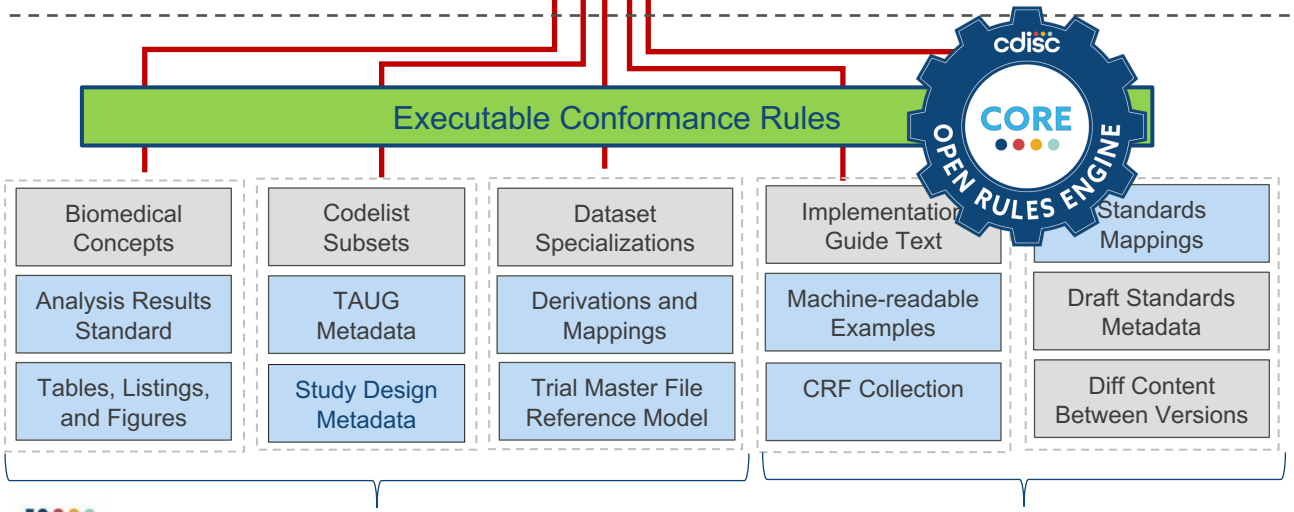

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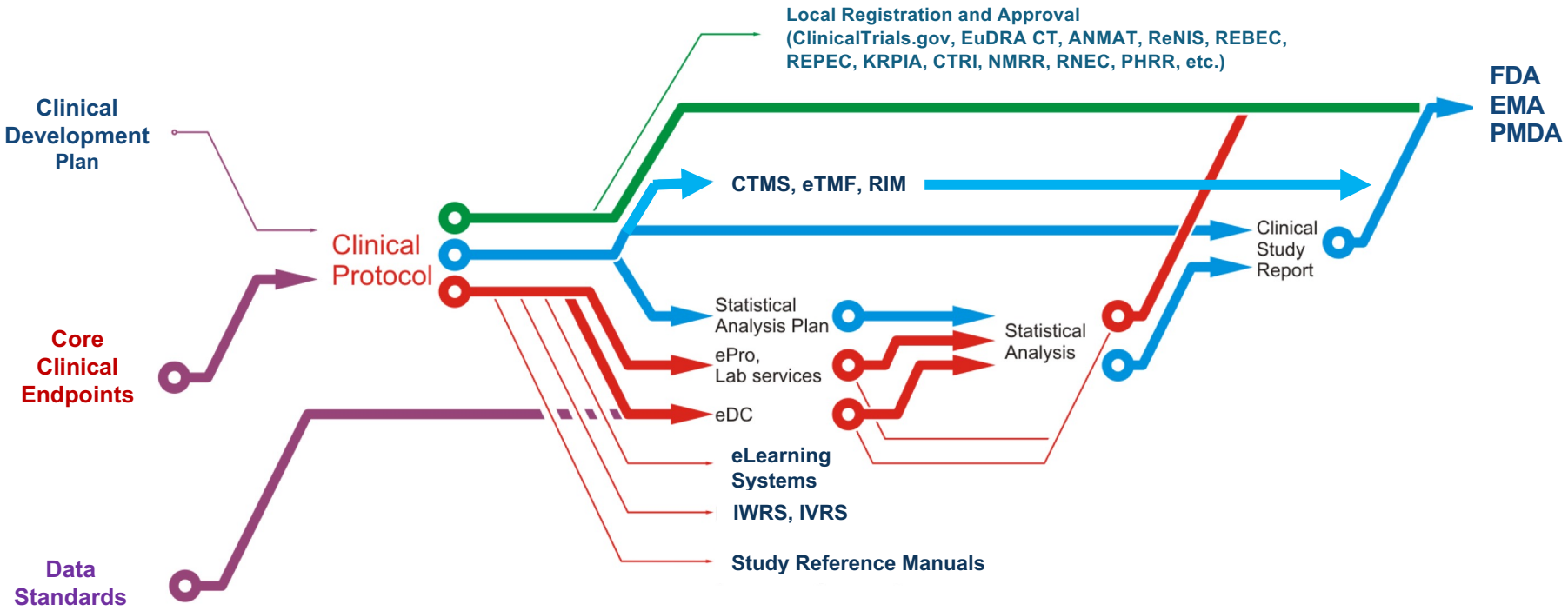
CDISC Standards

Informative Content

The Clinical Trial Information Flow



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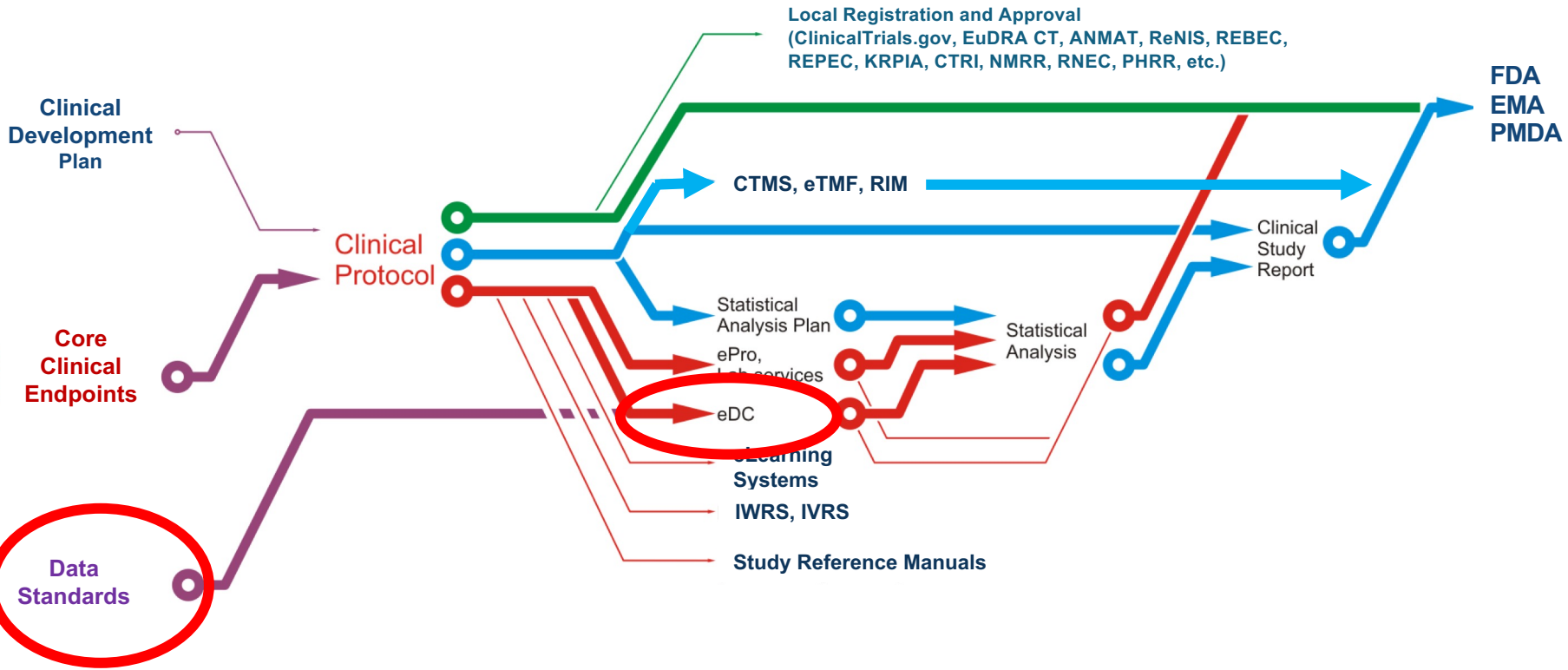

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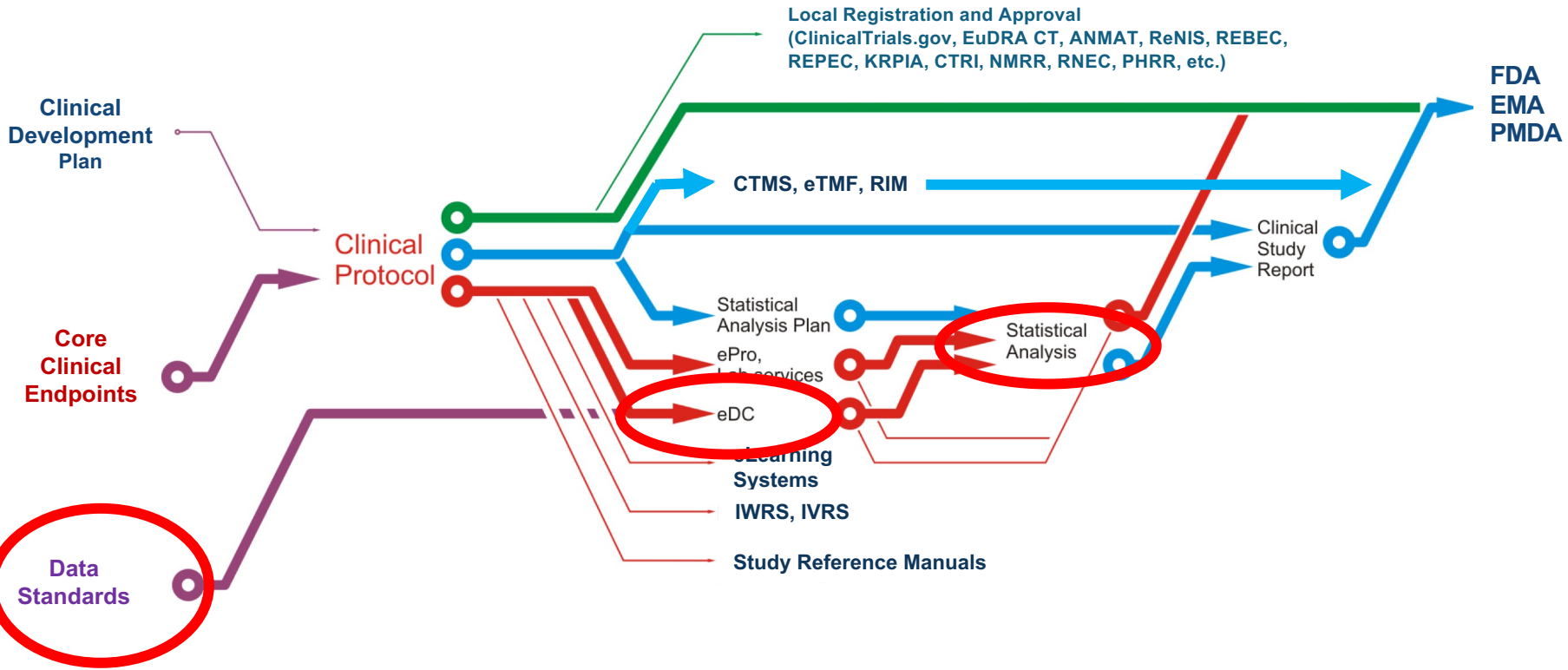

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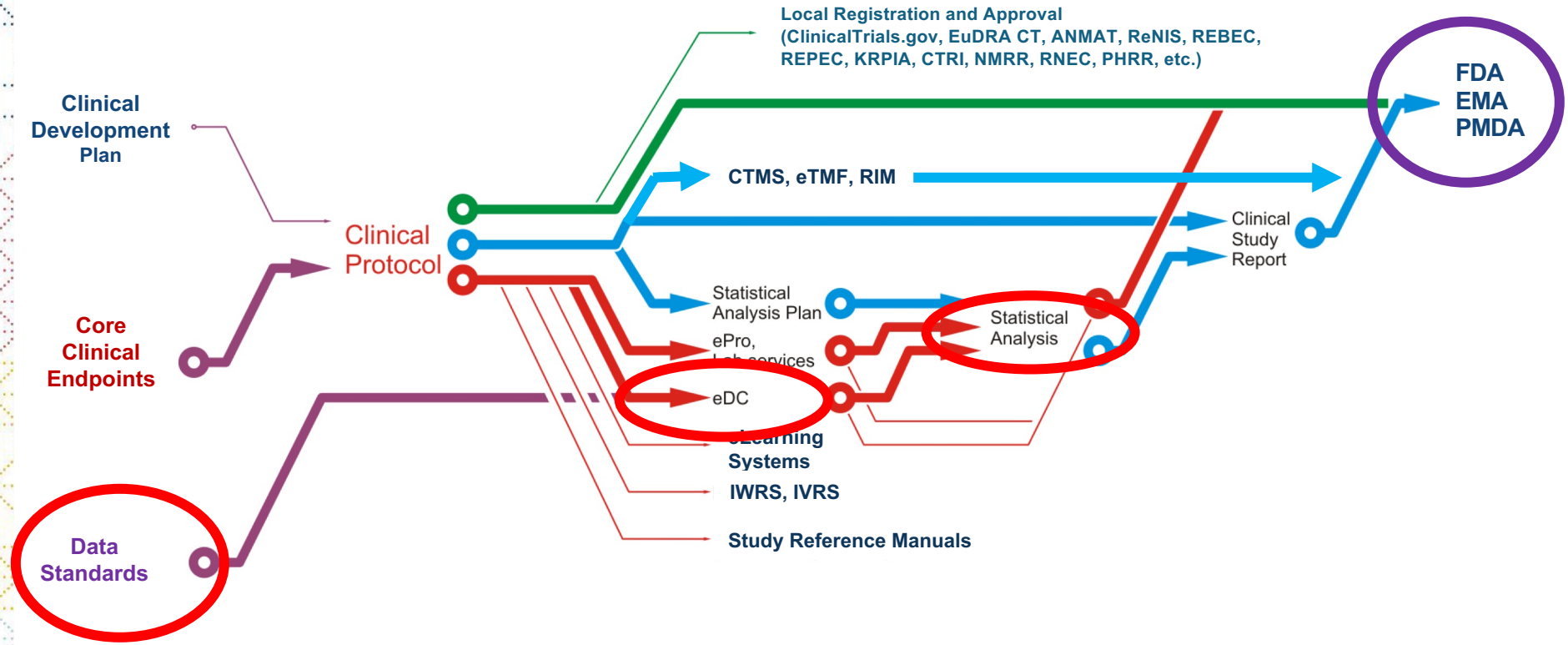

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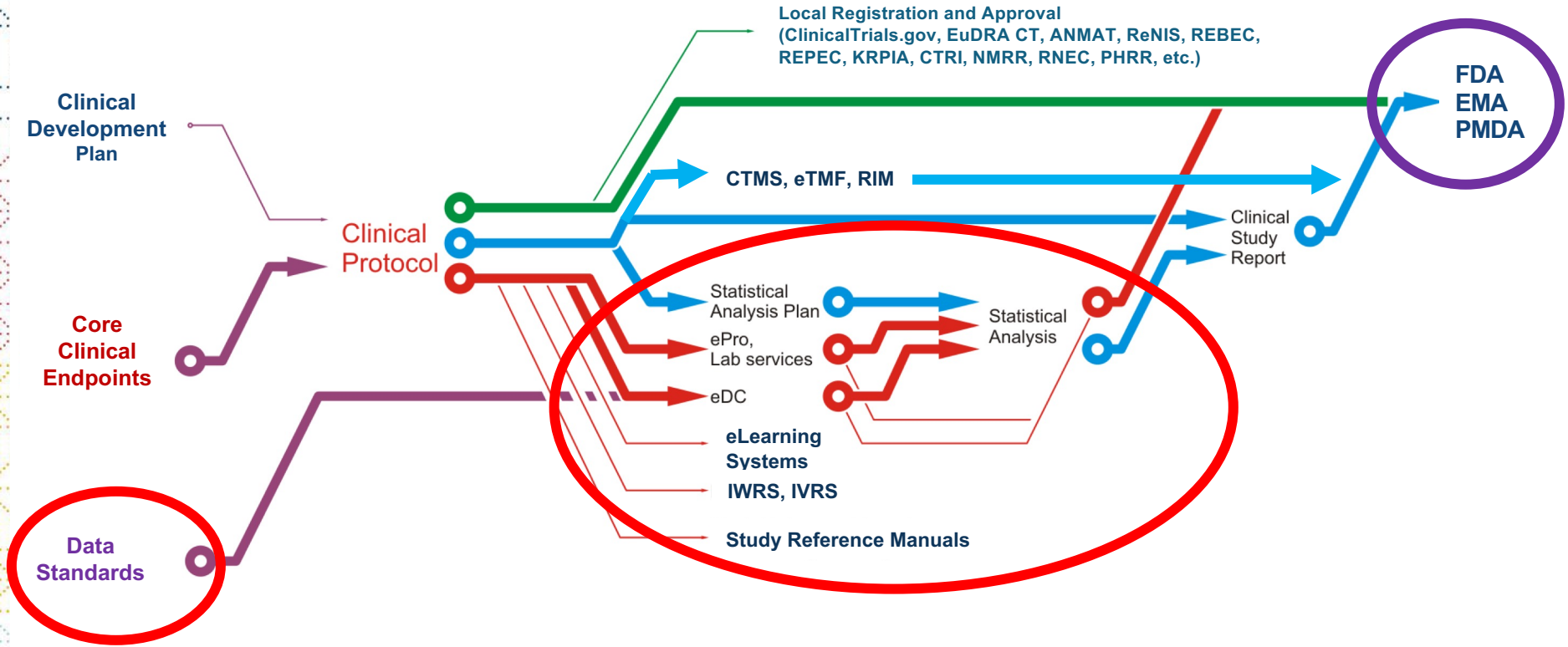

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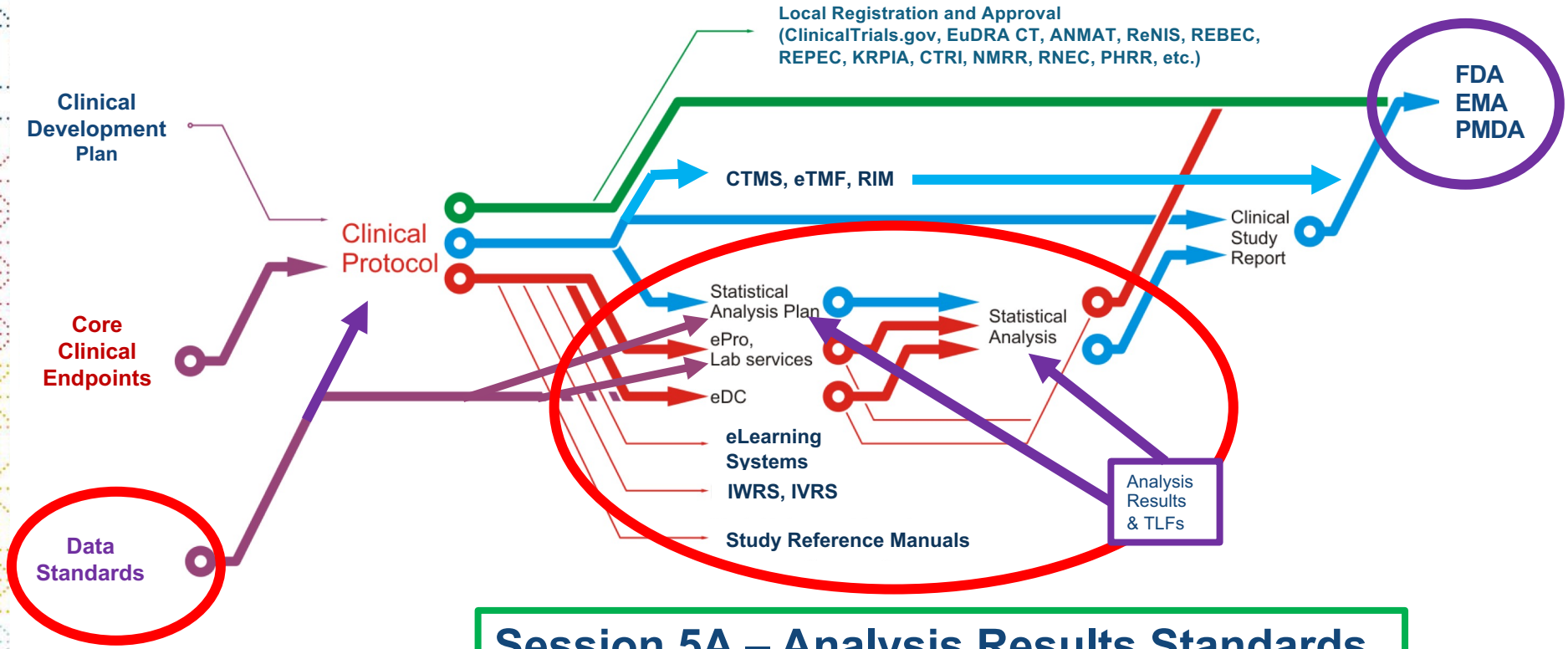

Session 5A – Analysis Results Standards

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CDISC Library Provides the Foundation

Software Applications Consume Standards Metadata via the API

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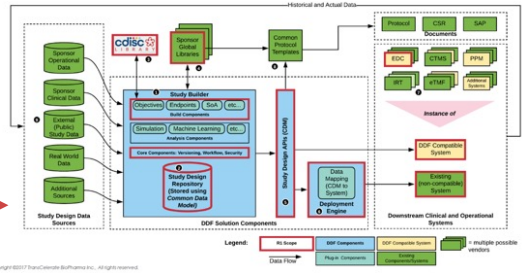
Standards Metadata

Controlled Terminology

API

Machine-executable content



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CDISC Standards

Informative Content

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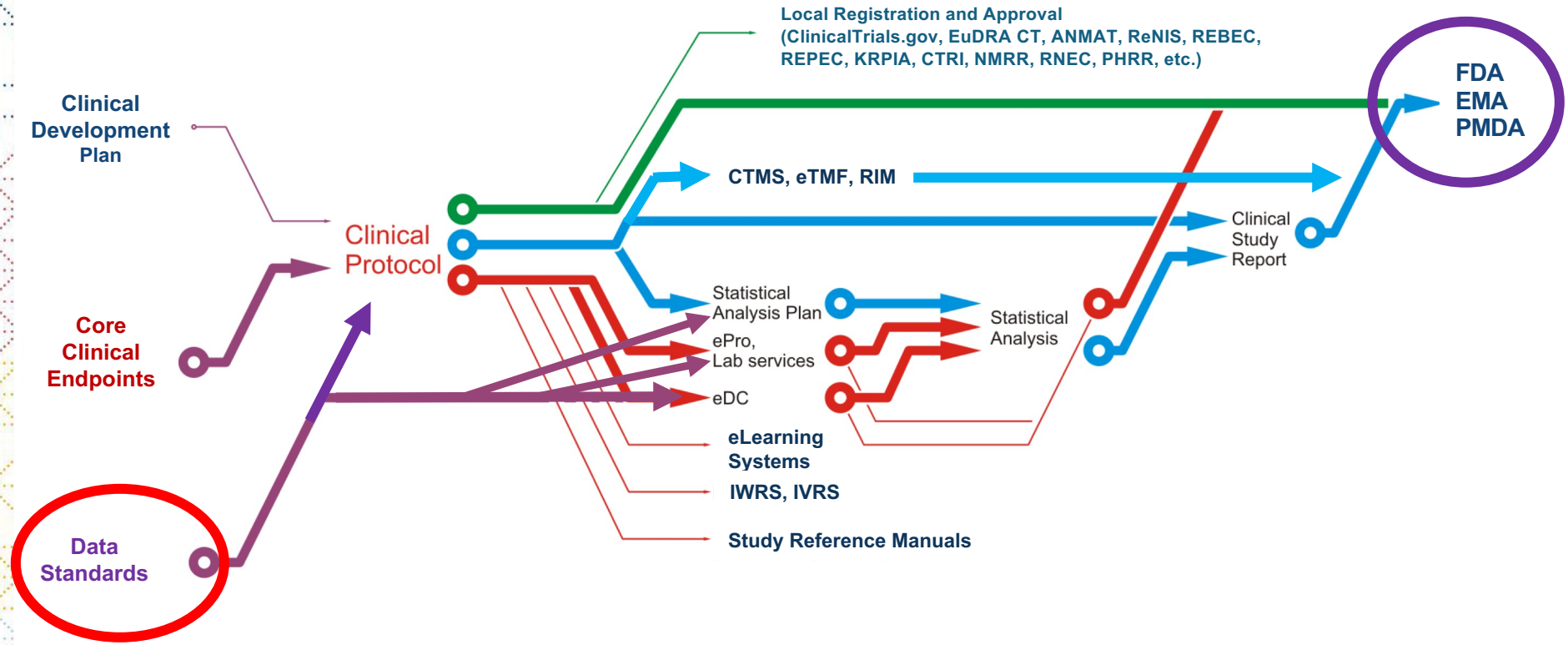

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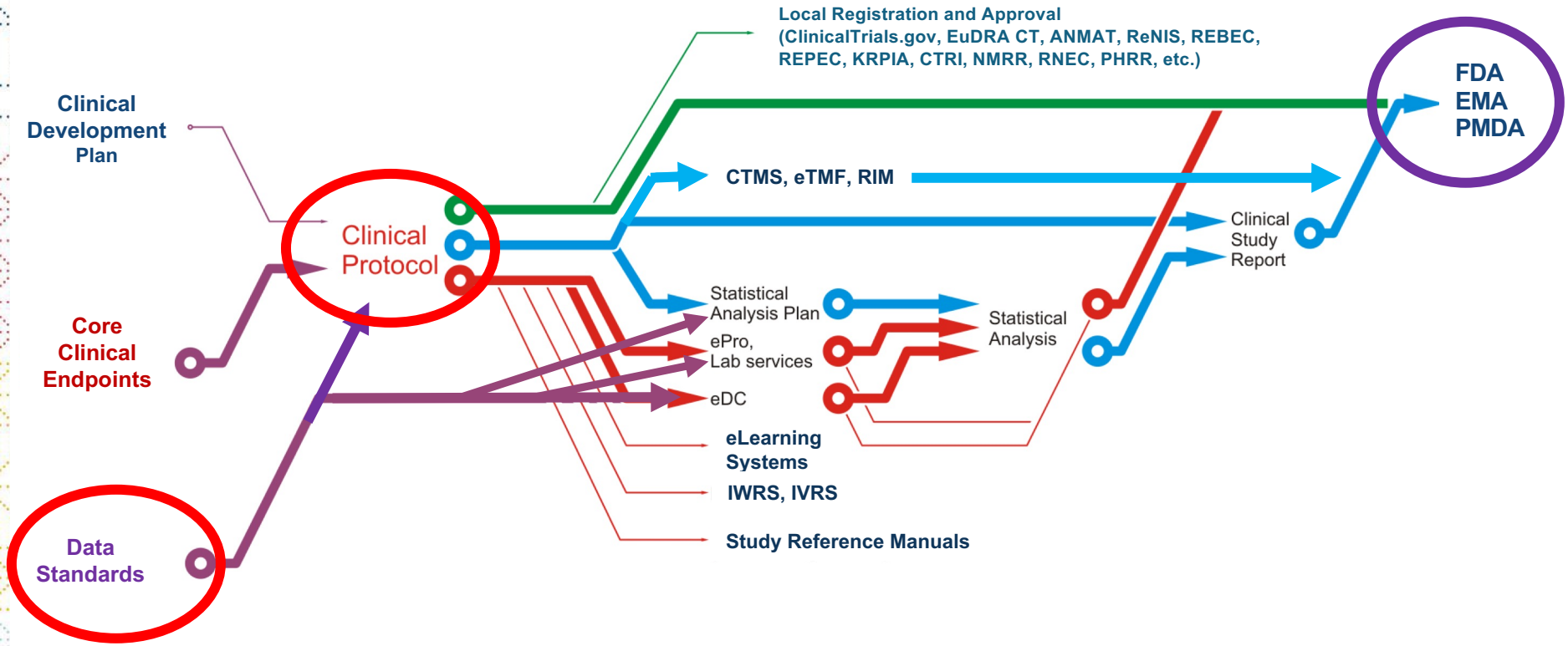

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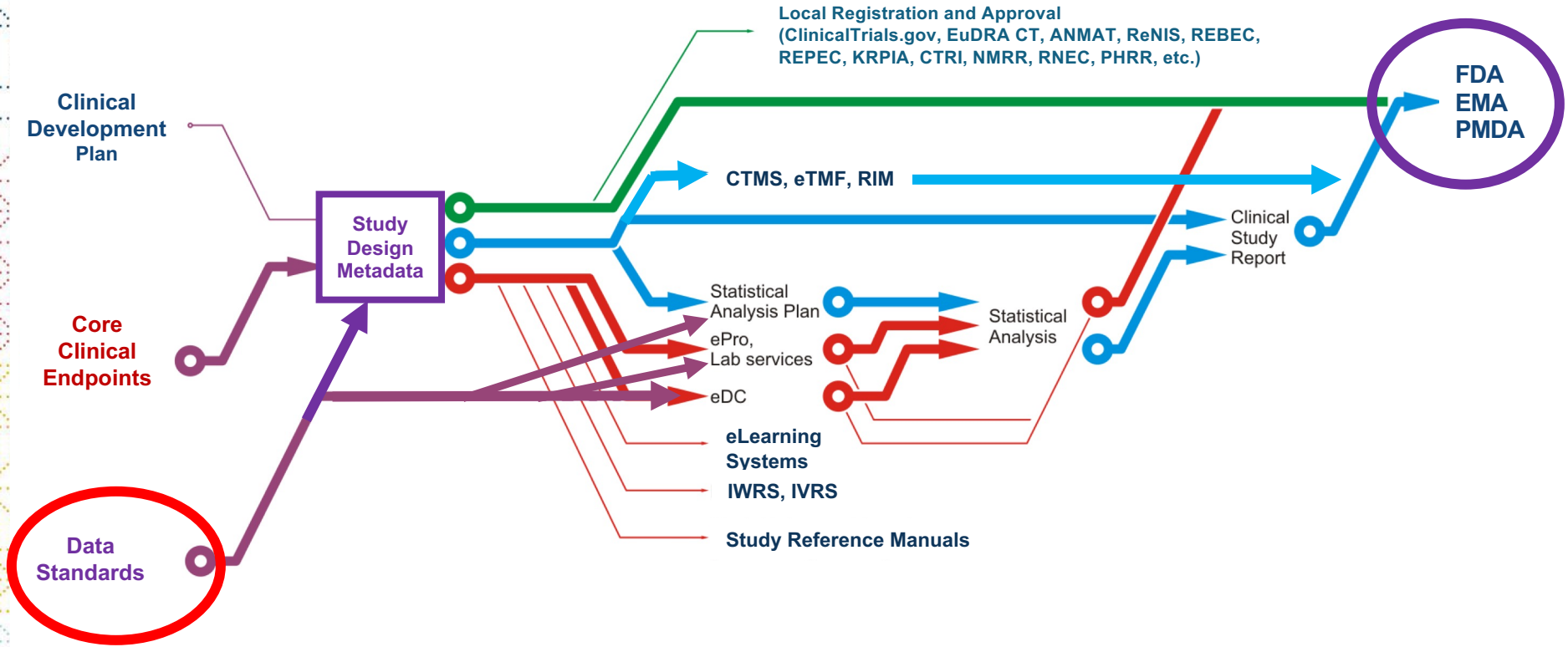

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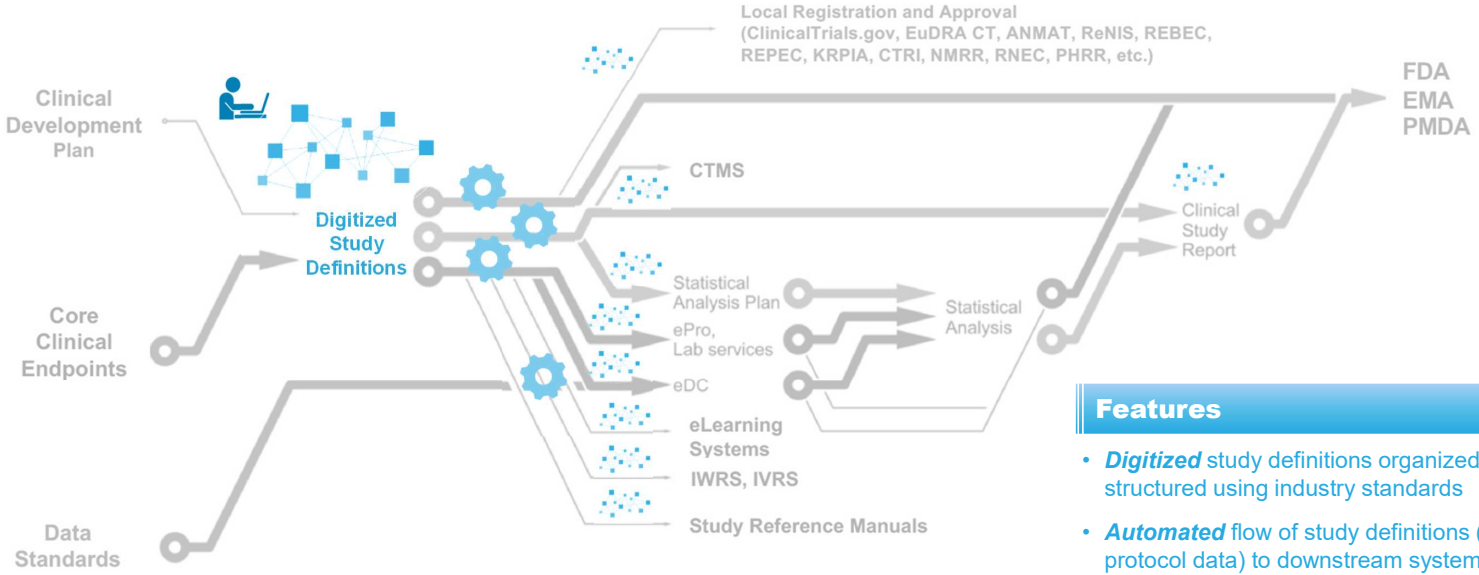
TransCelerate Digital Data Flow (DDF)

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

Session 7 – Digital Data Flow

CDISC Library Provides the Foundation

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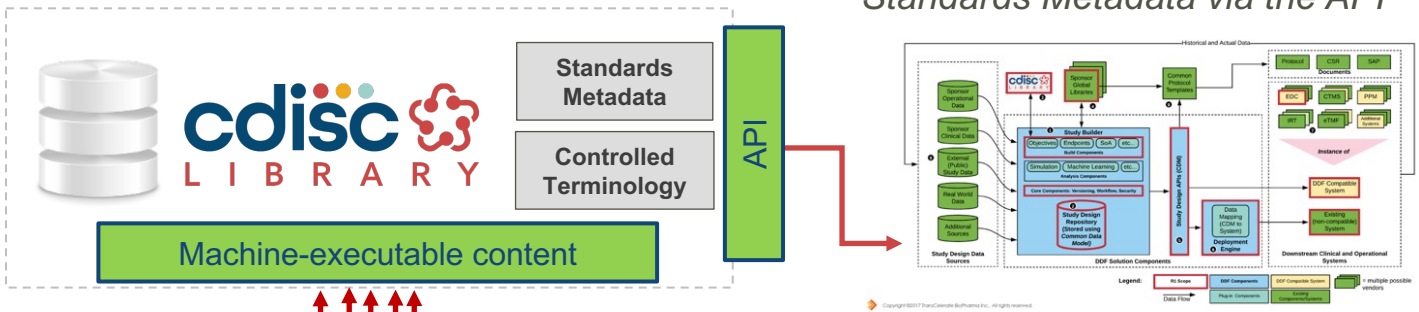

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CDISC Standards

Informative Content

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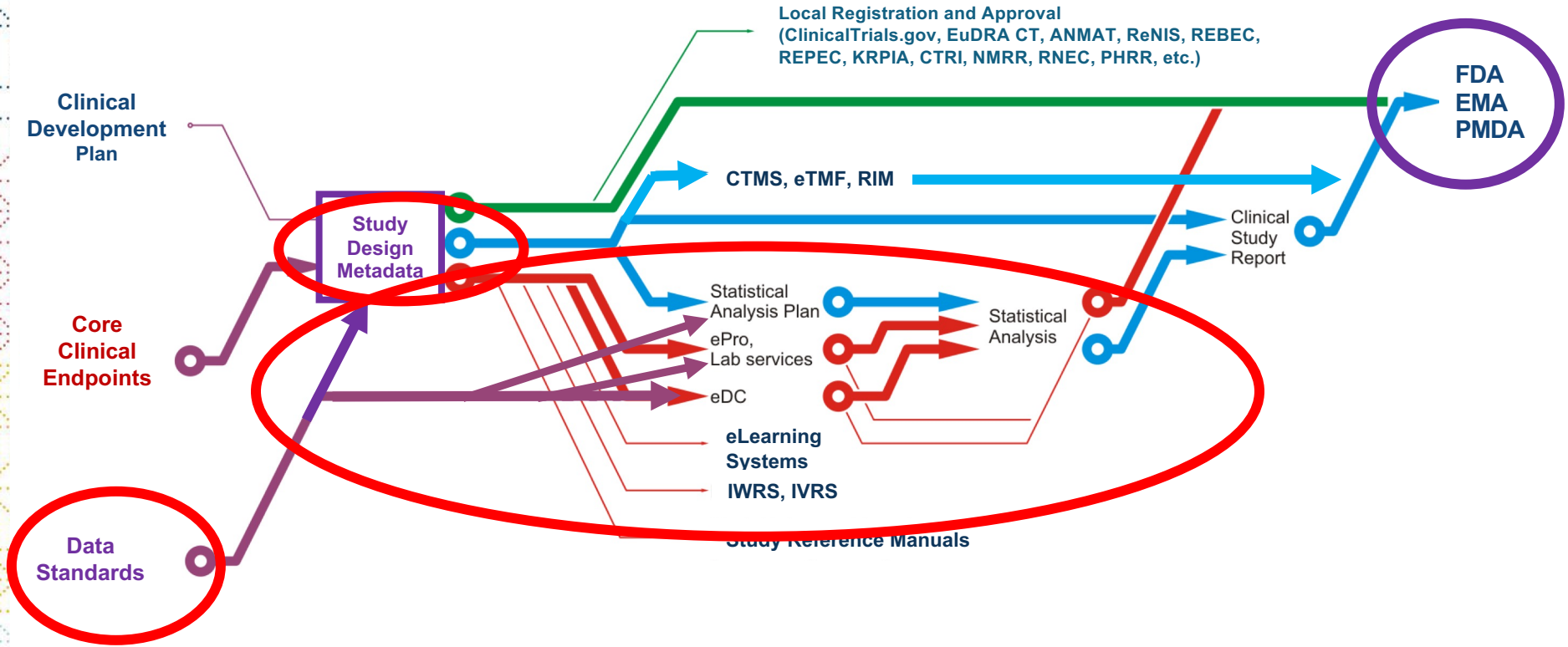

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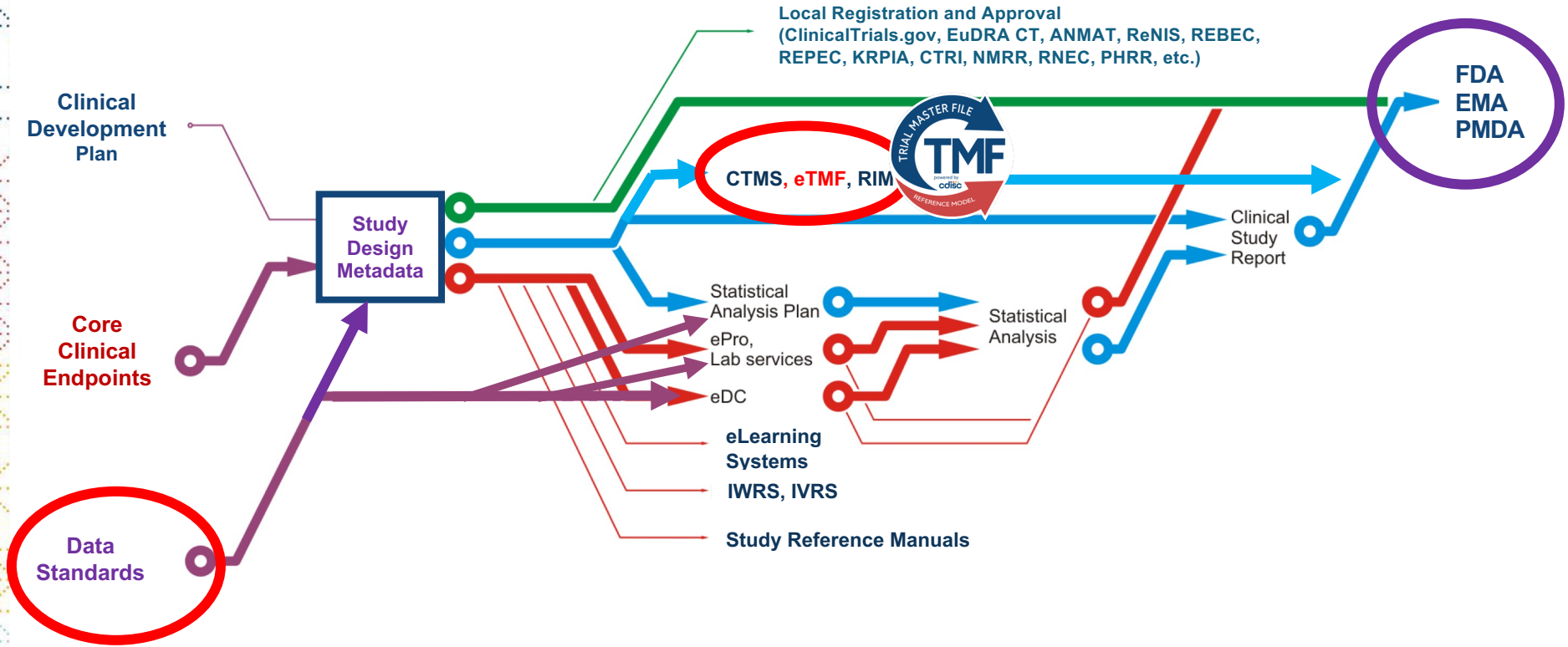

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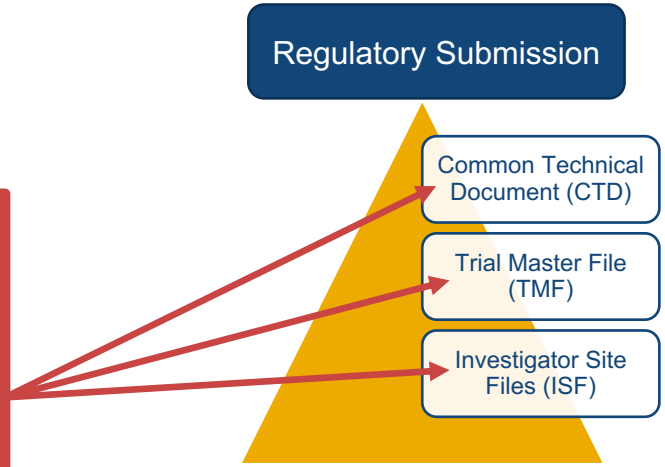
What is a Trial Master File?

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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CDISC Library Provides the Foundation

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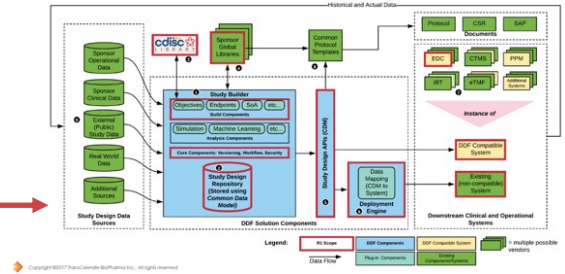

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Standards Metadata

Controlled Terminology

API

Machine-executable content

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CDISC Standards

Informative Content

TRIAL MASTER FILE TMF powered by cdisc REFERENCE MODEL

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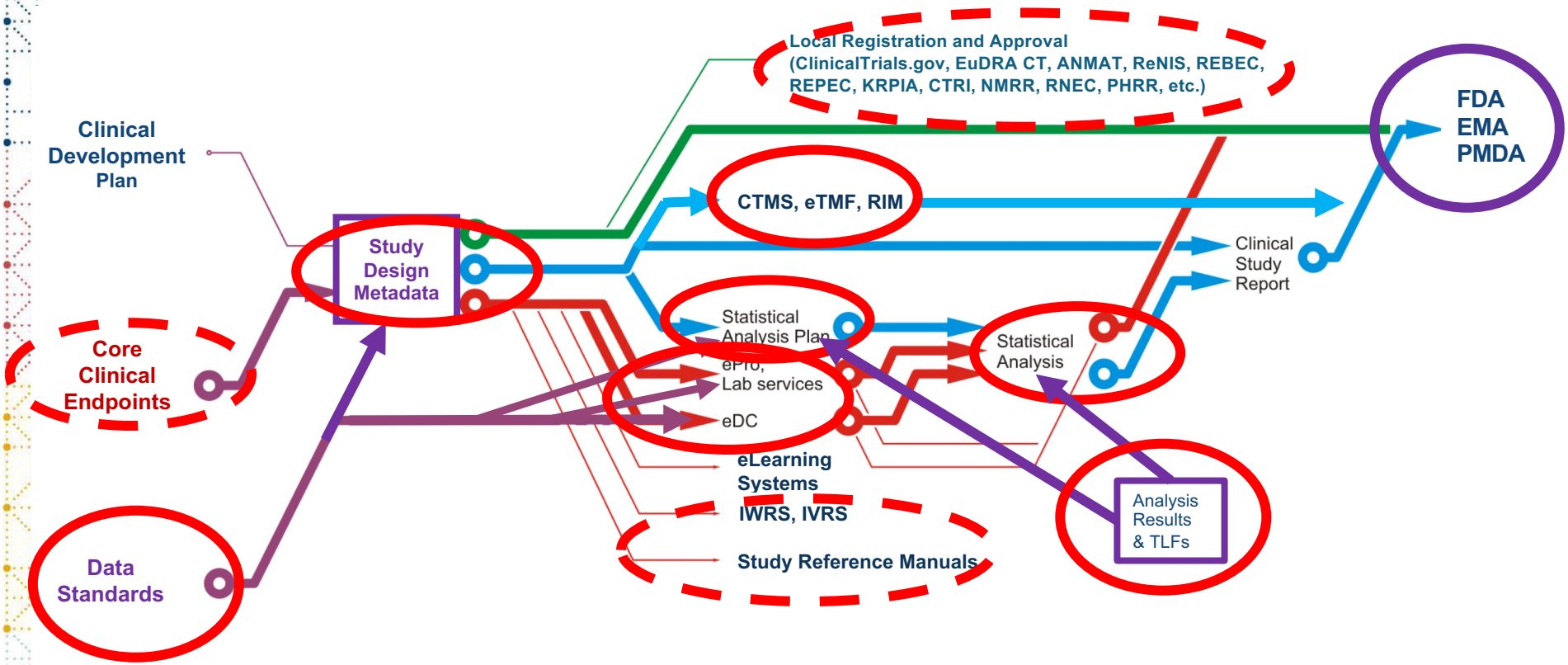
The Clinical Trial Information Flow



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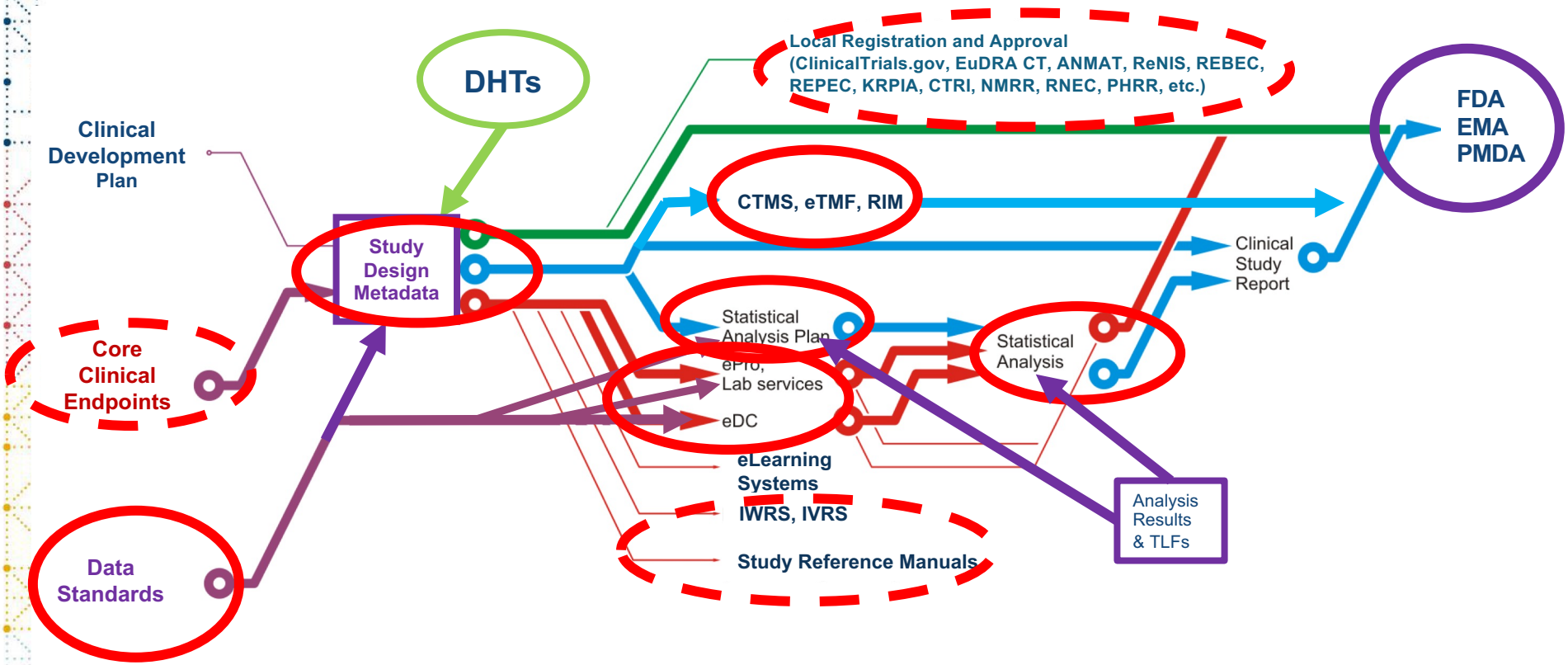

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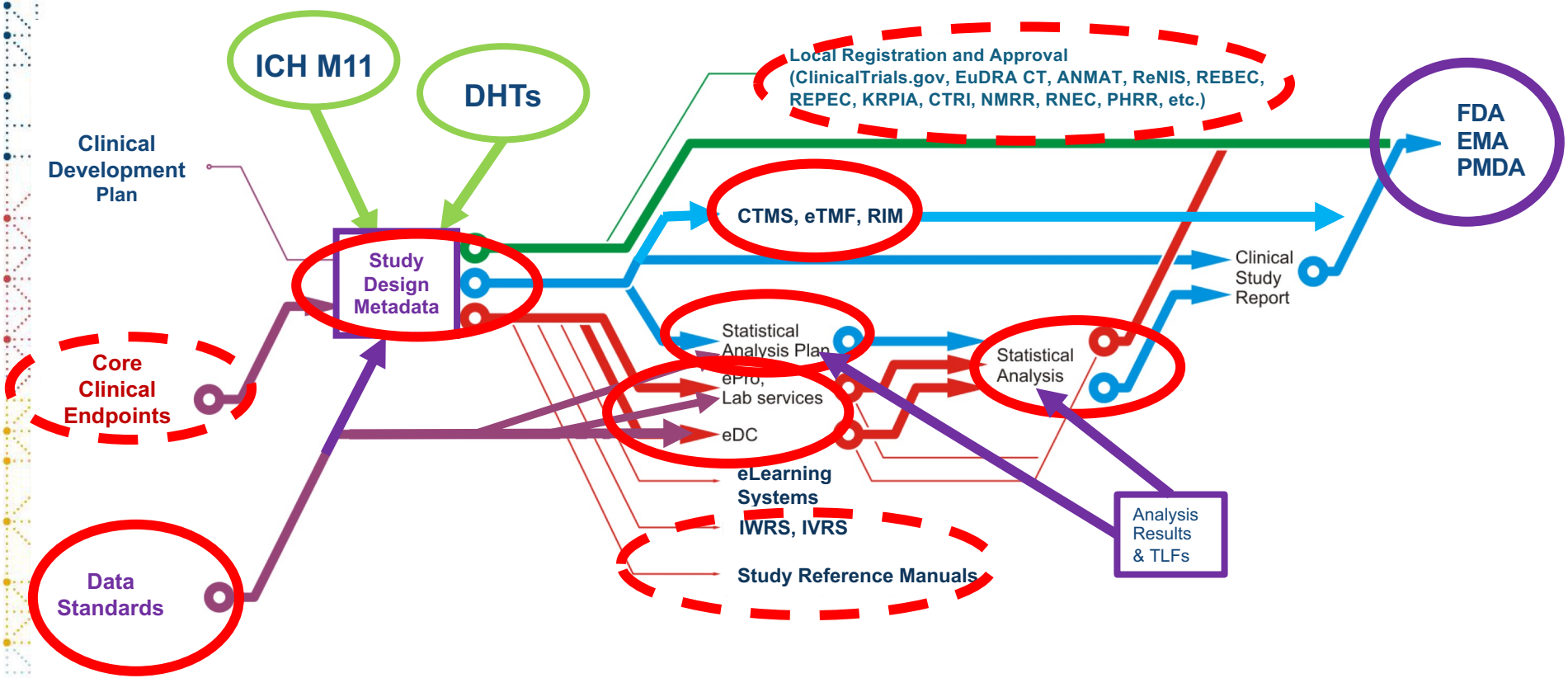

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ICH M11
Clinical Electronic Structured Harmonized Protocol

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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ICH
harmonisation for better health

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 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.

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What is the next stage on the CDISC Journey?

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CDISC Data Standards Lifecycle

Automation requires:

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Thank You CDISC Community!

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

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cdisc CORE OPEN RULES ENGINE

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