WITH STANDARDS – UNLOCK THE POWER OF DATA

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2022
US
INTERCHANGE
26-27 OCTOBER | AUSTIN

State of the CDISC Union

David A. Evans
President and CEO, CDISC

Meet the Speaker

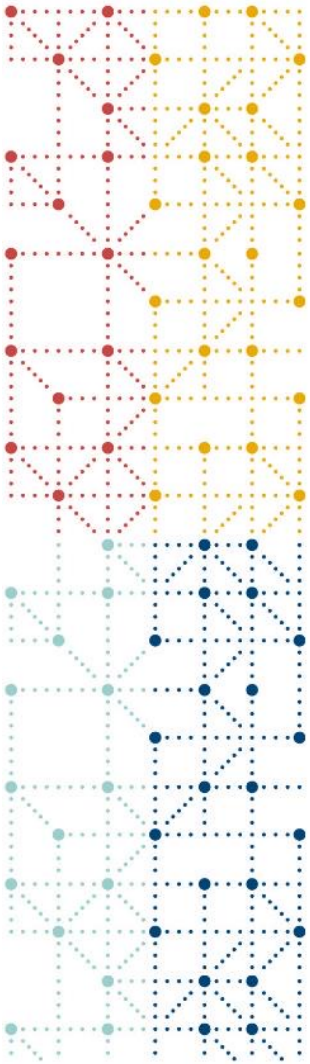
Dave Evans

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 – 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
- Healthy, on Budget Financials
- 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

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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.

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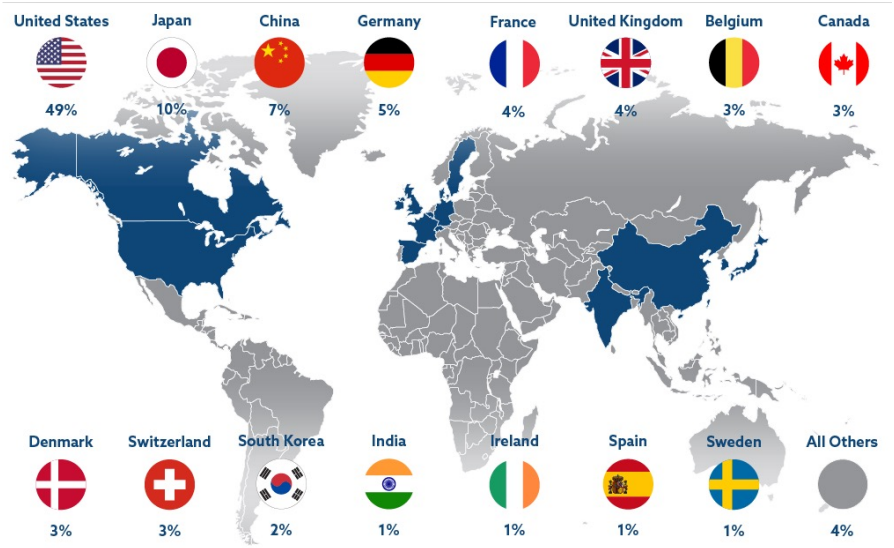
CDISC – a look into this year

- 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

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 Membership

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?

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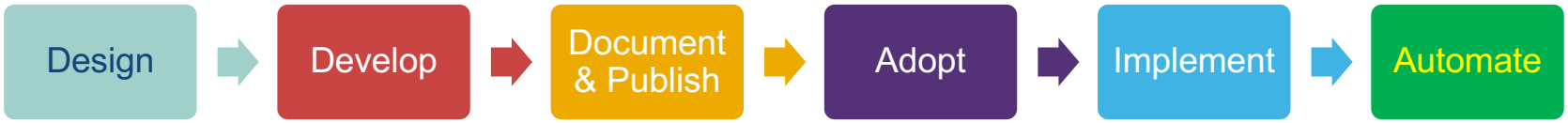
CDISC Data Standards Lifecycle



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*

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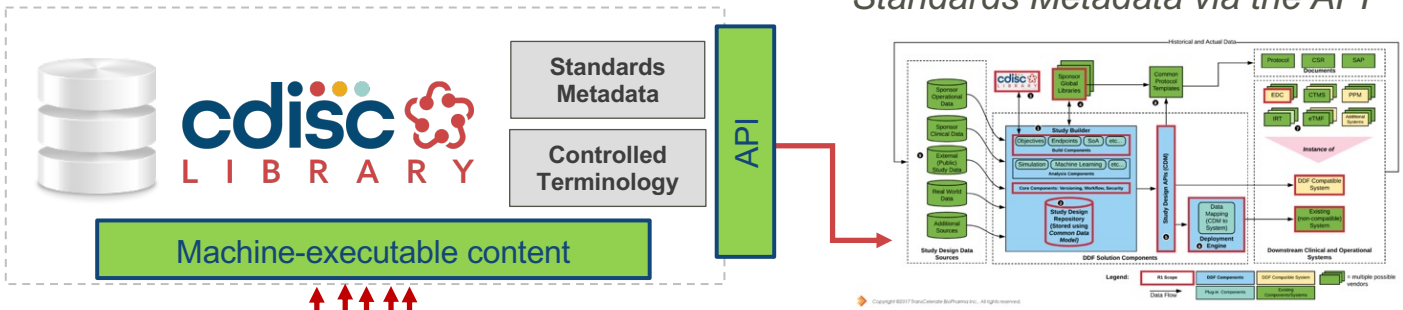
CDISC Library Provides the Foundation

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

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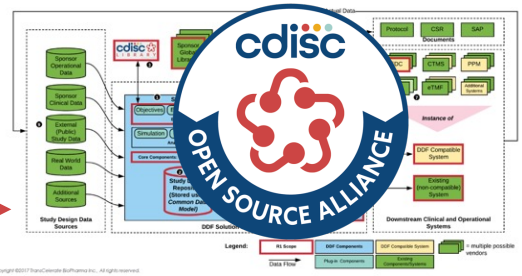
CDISC Standards

Informative Content

CDISC Library Provides the Foundation

Session 2 – CDISC Looking Ahead

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

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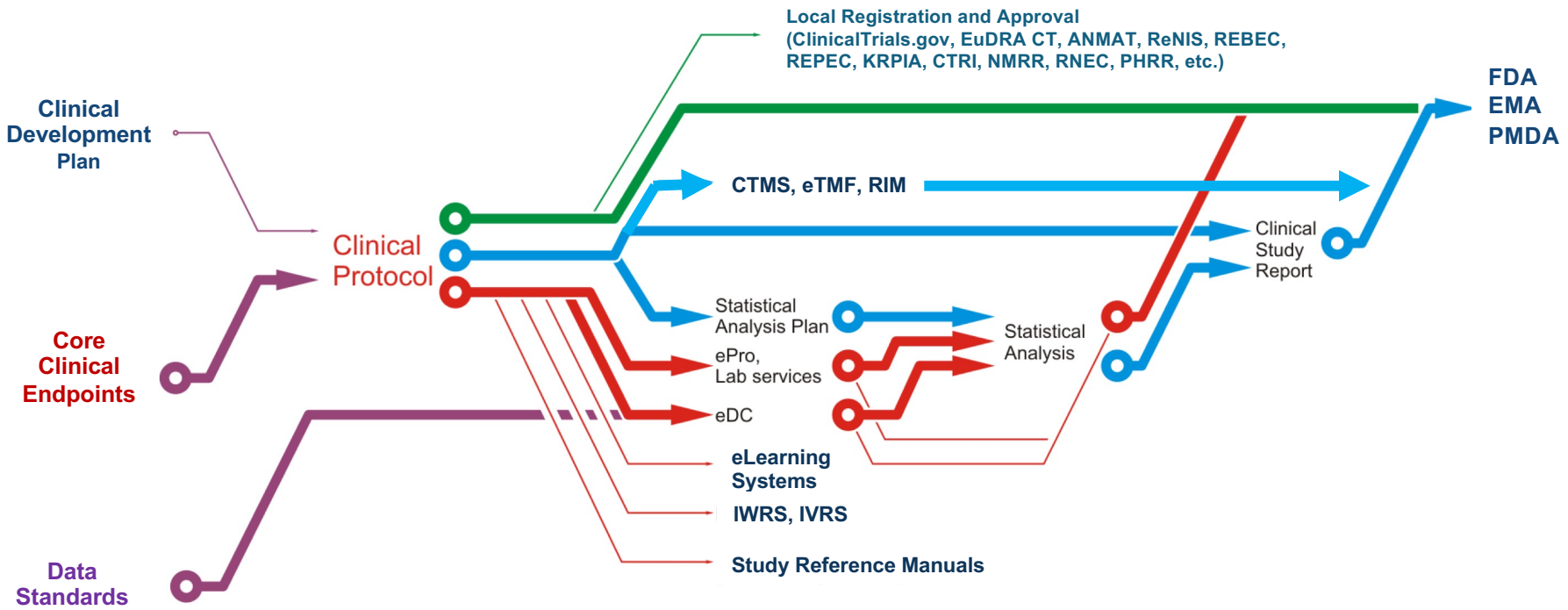
CDISC Standards

Informative Content

The Clinical Trial Information Flow



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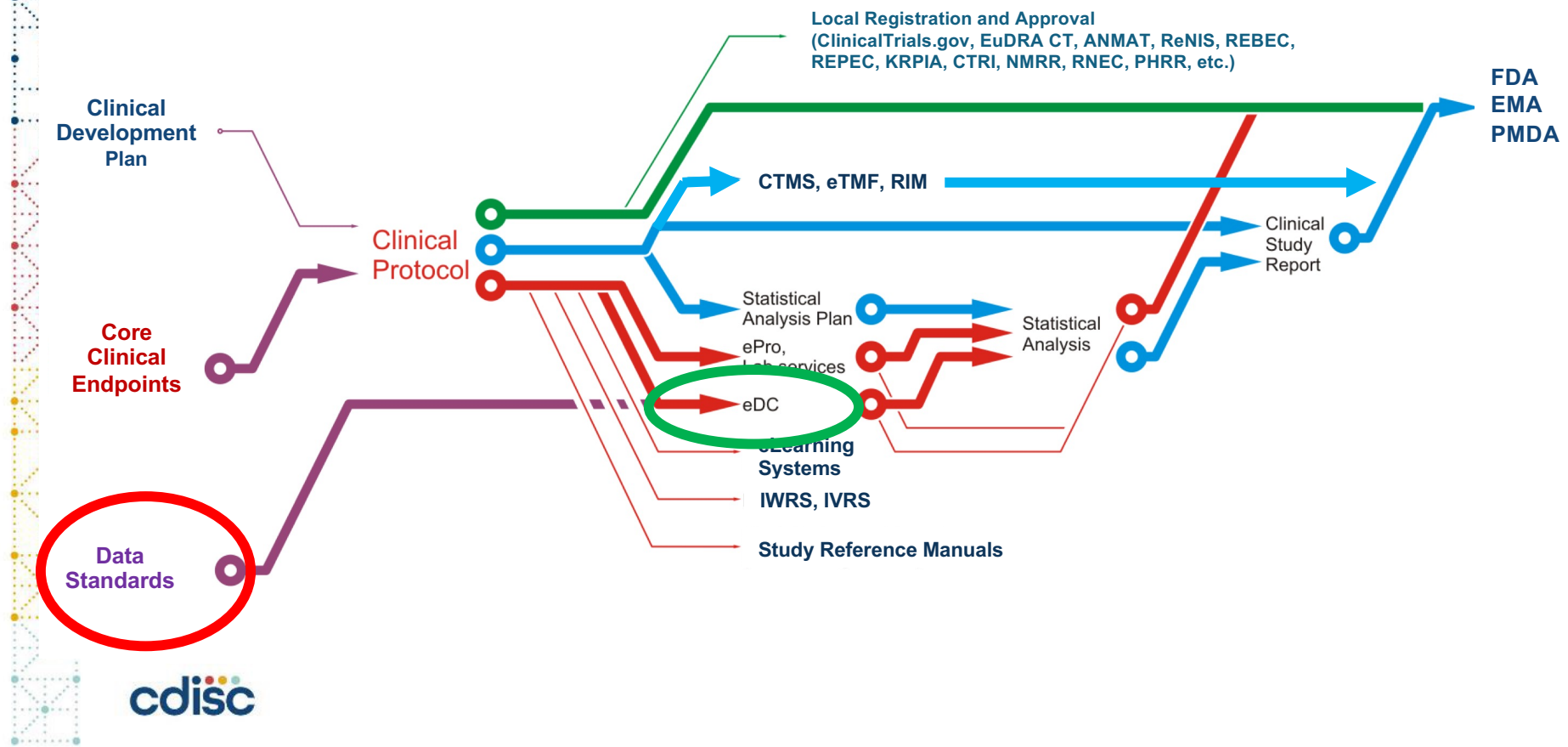

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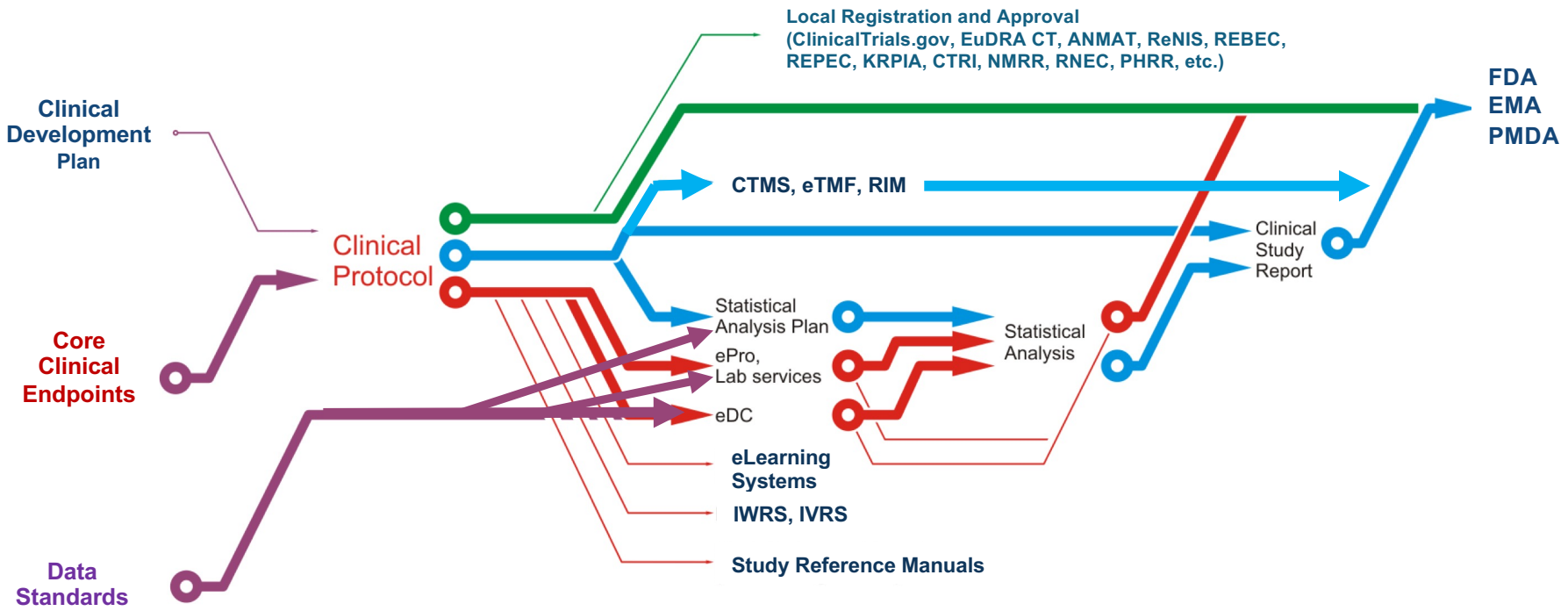

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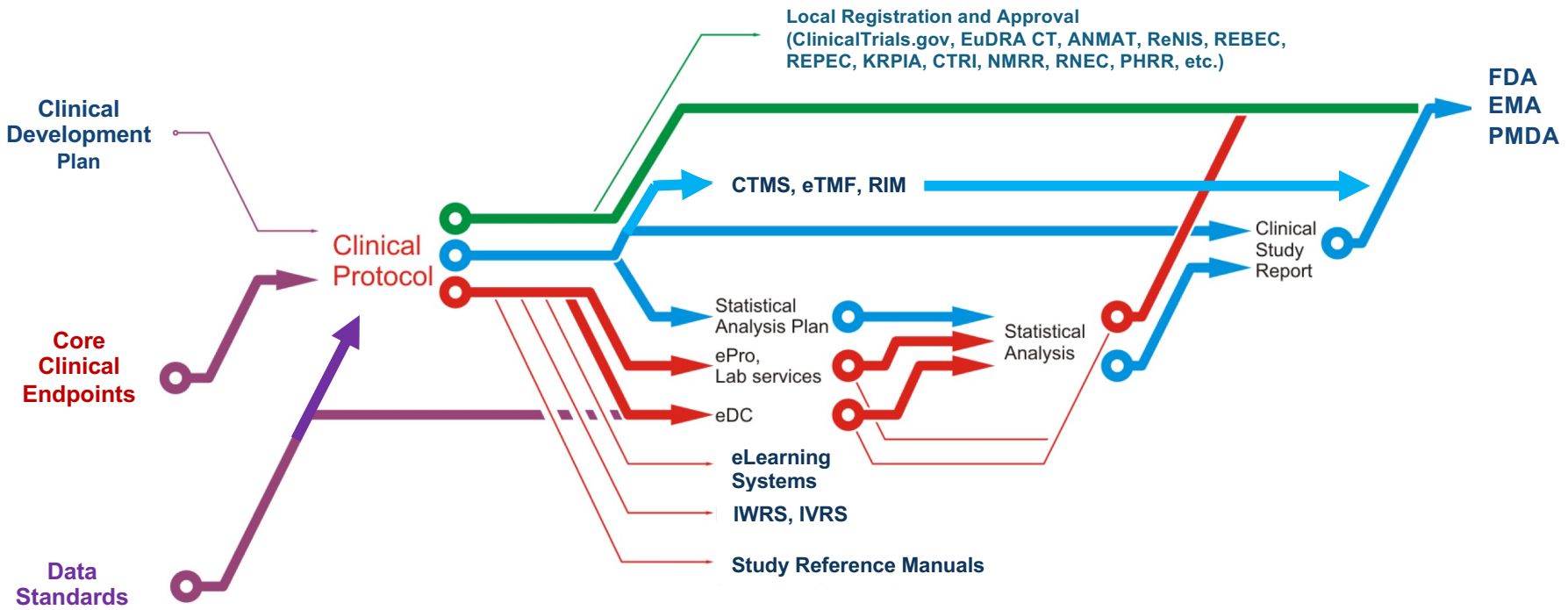

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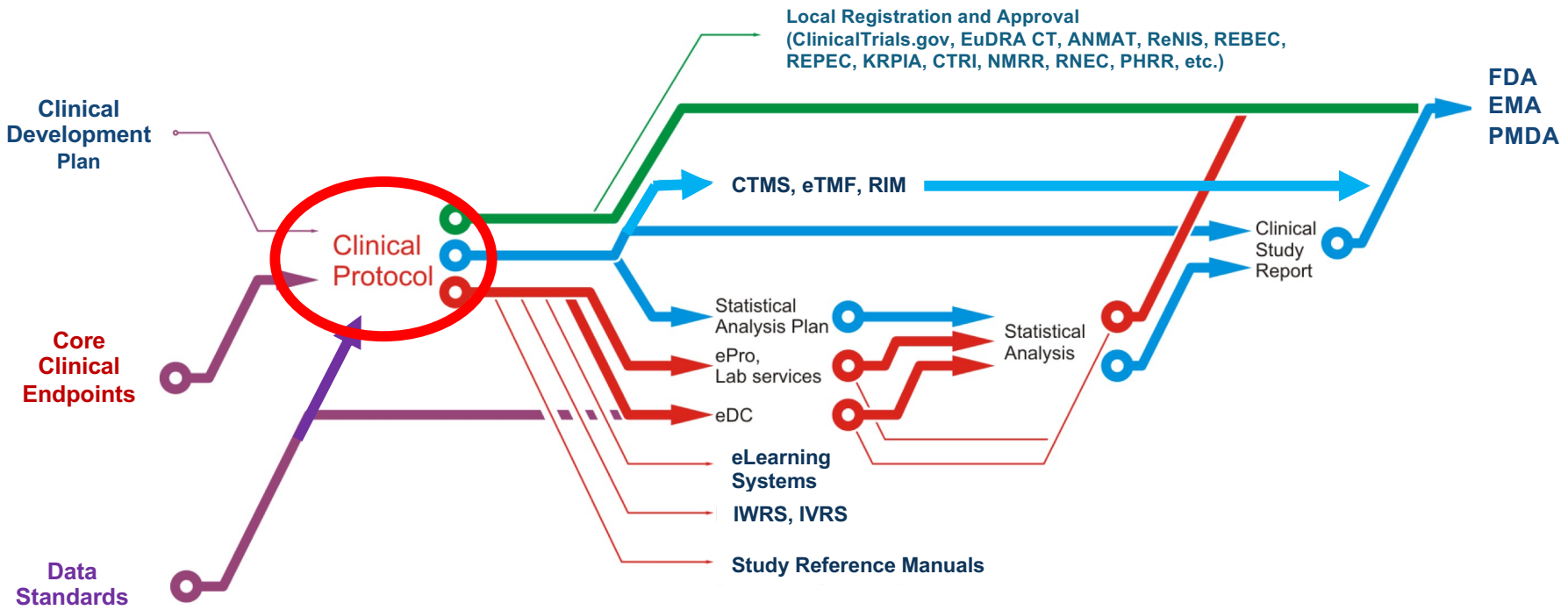

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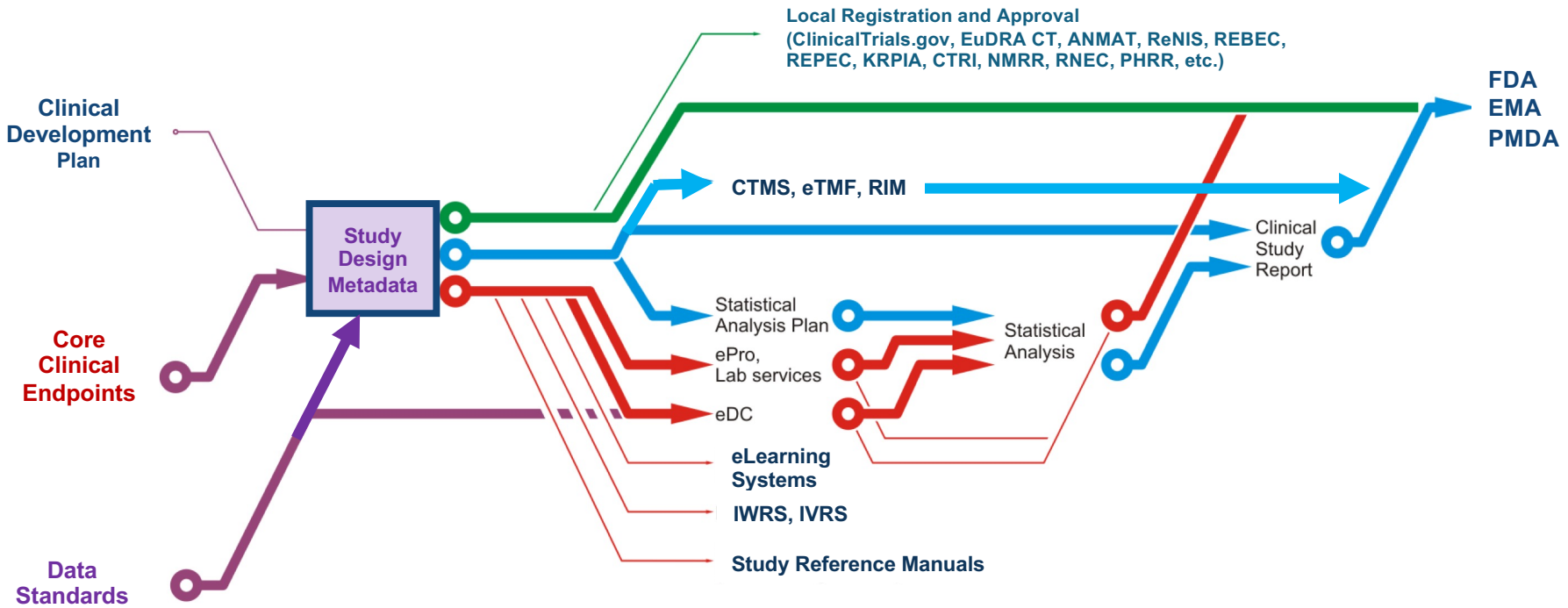

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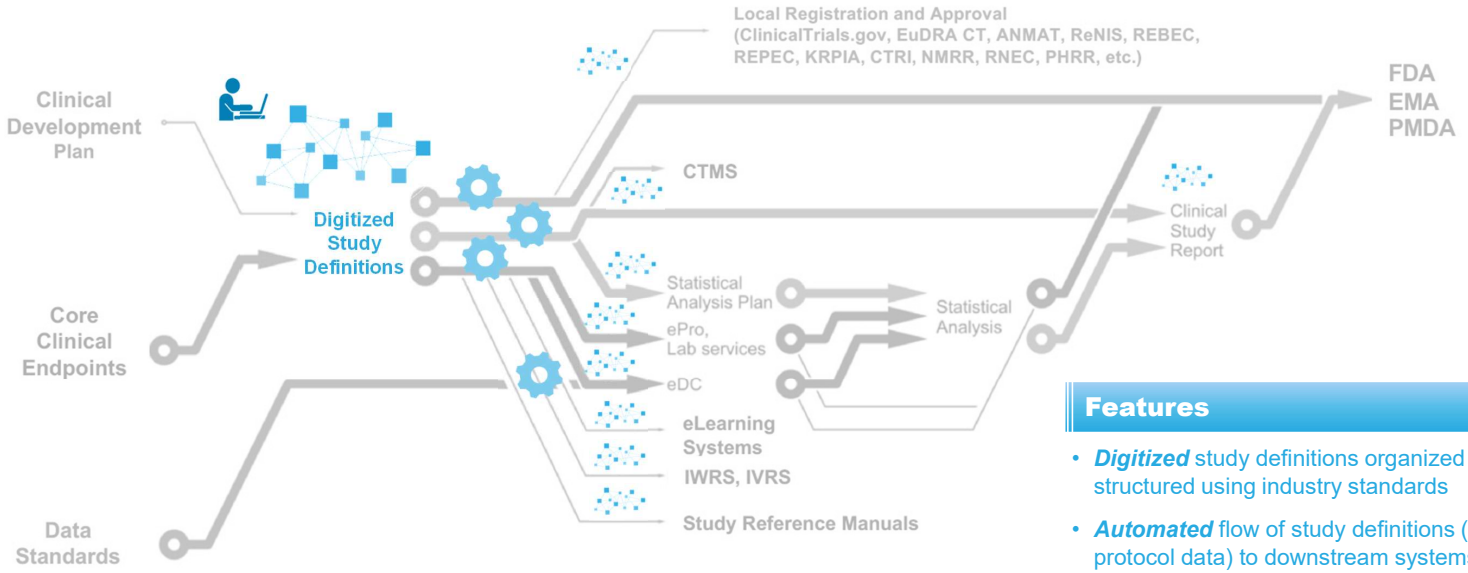
TransCelerate Digital Data Flow (DDF)

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 3 – Digital Data Flow

Session 5 – Trial Design

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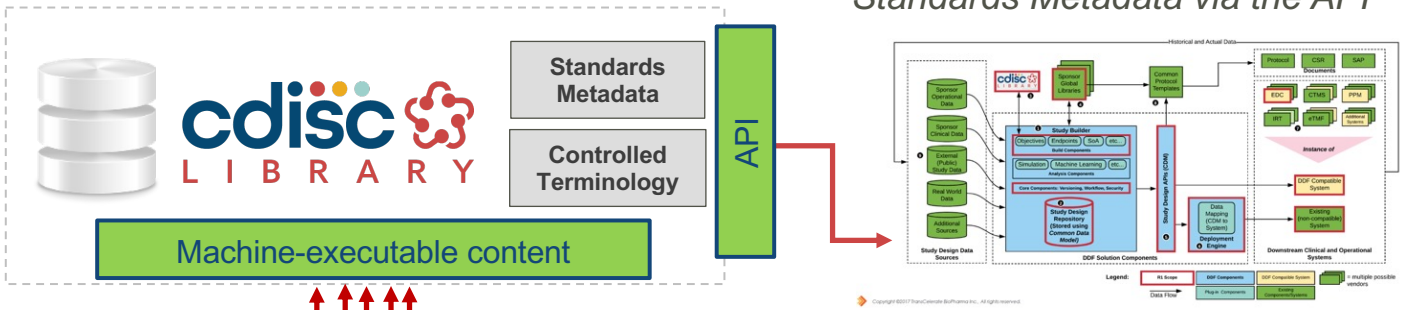

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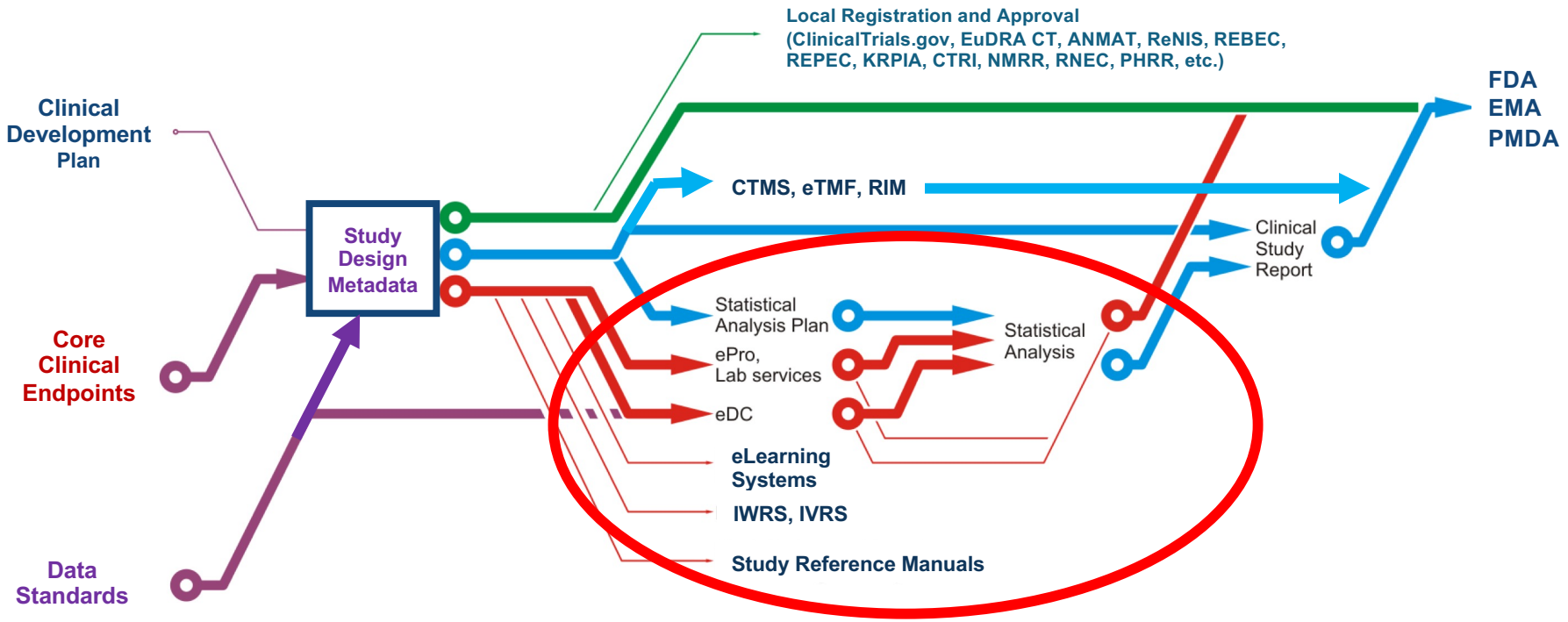
CDISC Standards *Informative Content*

The Clinical Trial Information Flow



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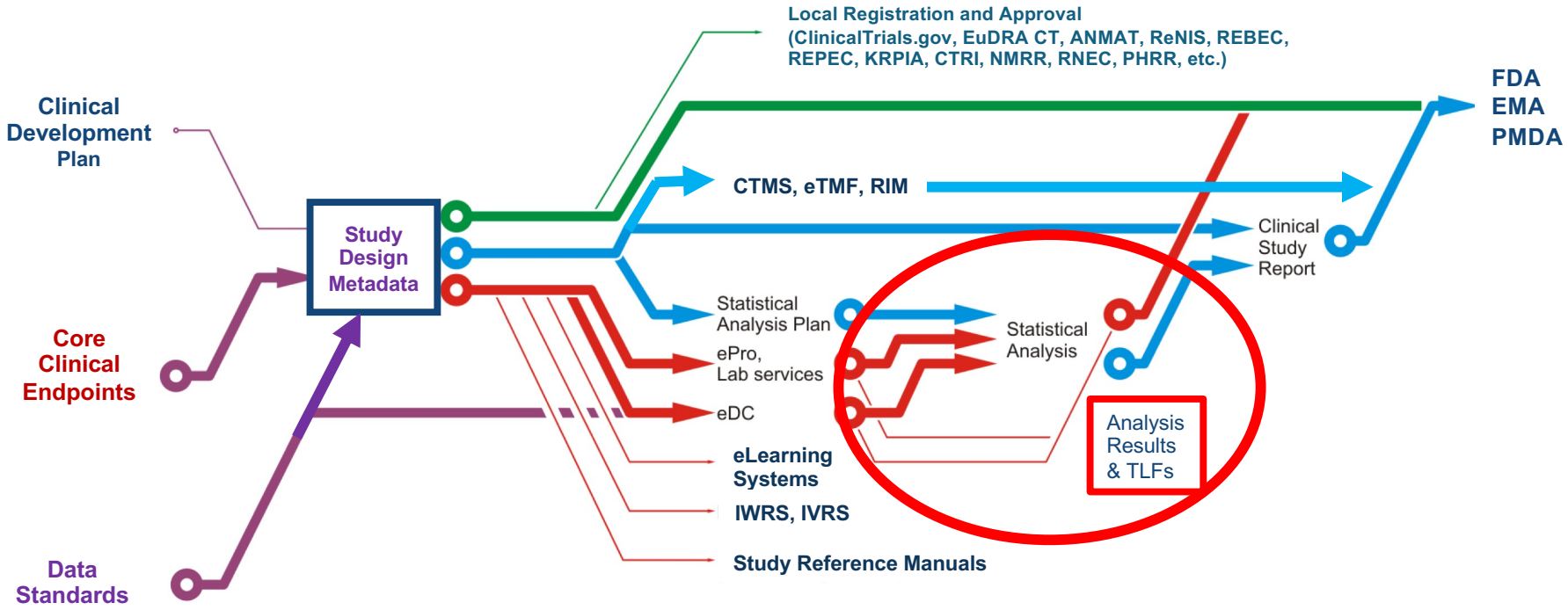
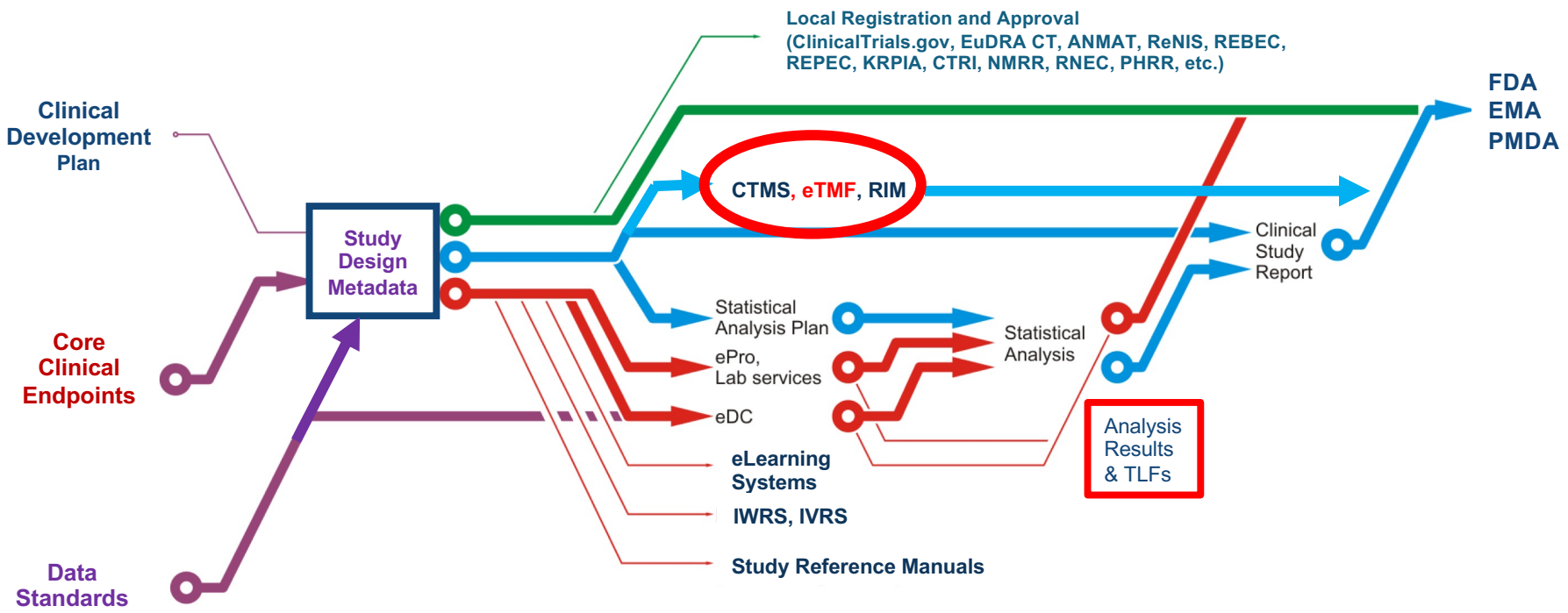


Session 5C – Analysis Results Standards

The Clinical Trial Information Flow



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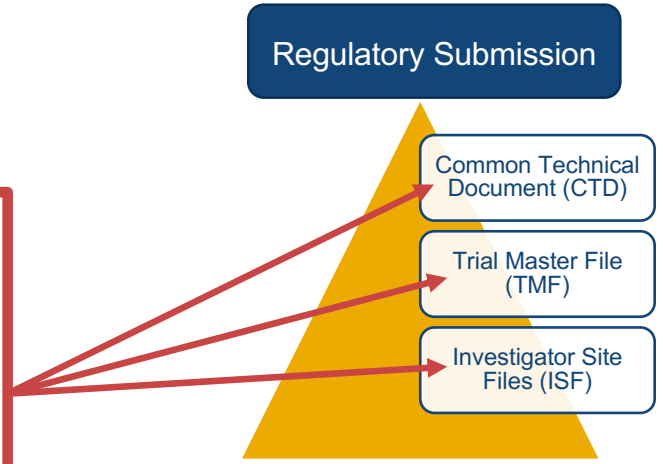
What is a Trial Master File?

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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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)

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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

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The Future as a Standard!

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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

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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.

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TRIAL MASTER FILE TMF powered by cdisc REFERENCE MODEL

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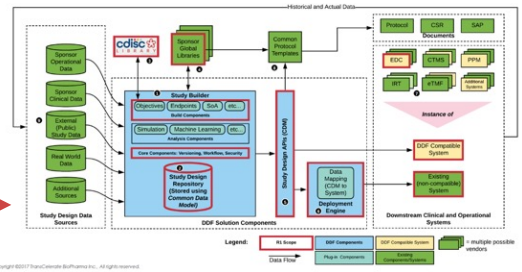

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CDISC Standards

Informative Content

TRIAL MASTER FILE TMF powered by cdisc REFERENCE MODEL

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We welcome the TMF RM Community to the CDISC Consortium of Clinical Research Standards & The CDISC TMF Reference Model

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Session 7 – TMF Plan

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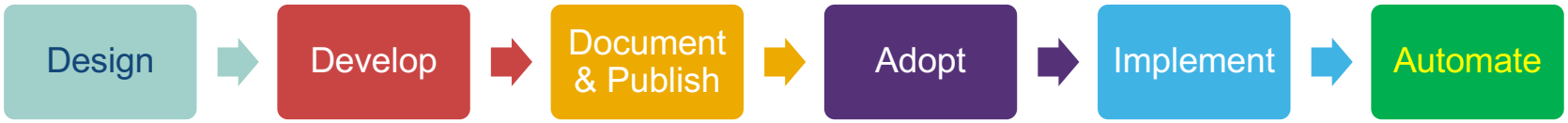
CDISC Data Standards Lifecycle



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