



Automating the Digital Data Flow with a Standards Foundation

Venu Mallarapu

VP, Global Strategy & Operations
eClinical Solutions

vmallarapu@eclinicalsol.com

Meet the Speaker



Venu Mallarapu

Title : VP, Global Strategy & Operations

Organization : eClinical Solutions

Venu Mallarapu is a digital innovation leader with over two decades of experience in business and IT advisory, strategic consulting, relationship, and delivery management. As eClinical Solutions' Vice President of Global Strategy and Operations, he is responsible for strategic development to meet global demand for the company's platform and service offerings. He is driving adoption, market expansion and innovation of the illuminate® Clinical Data Cloud and eClinical Clinical Data Services. Venu is a subject matter expert in Clinical, Regulatory, Quality and Safety & Pharmacovigilance functions, and has delivered Strategy & Transformation Advisory Consulting to top global Life Sciences clients. He has spoken at various Life Sciences and Tech industry events and is a recognized thought leader in R&D.



Key challenges with current clinical trial process and systems

Modern, Digital clinical trials are generating a deluge of data and putting a strain on data pipelines

- 1 Average lag of 4 months between protocol completion and study start
- 2 Data conversion and standardization adds additional cycle time impacting the time to market
- 3 Challenges with traceability of data across the systems
- 4 Difficulty in re-use of data
- 5 Document based environment



Benefits of driving automation through Digital Data Flows

Facilitate consistency of data

Minimize bottlenecks between processes and systems

Minimize manual work, data re-entry, and data inconsistencies

Improve efficiencies by achieving seamless information flow across systems

Spark innovation that will drive interoperability and automation

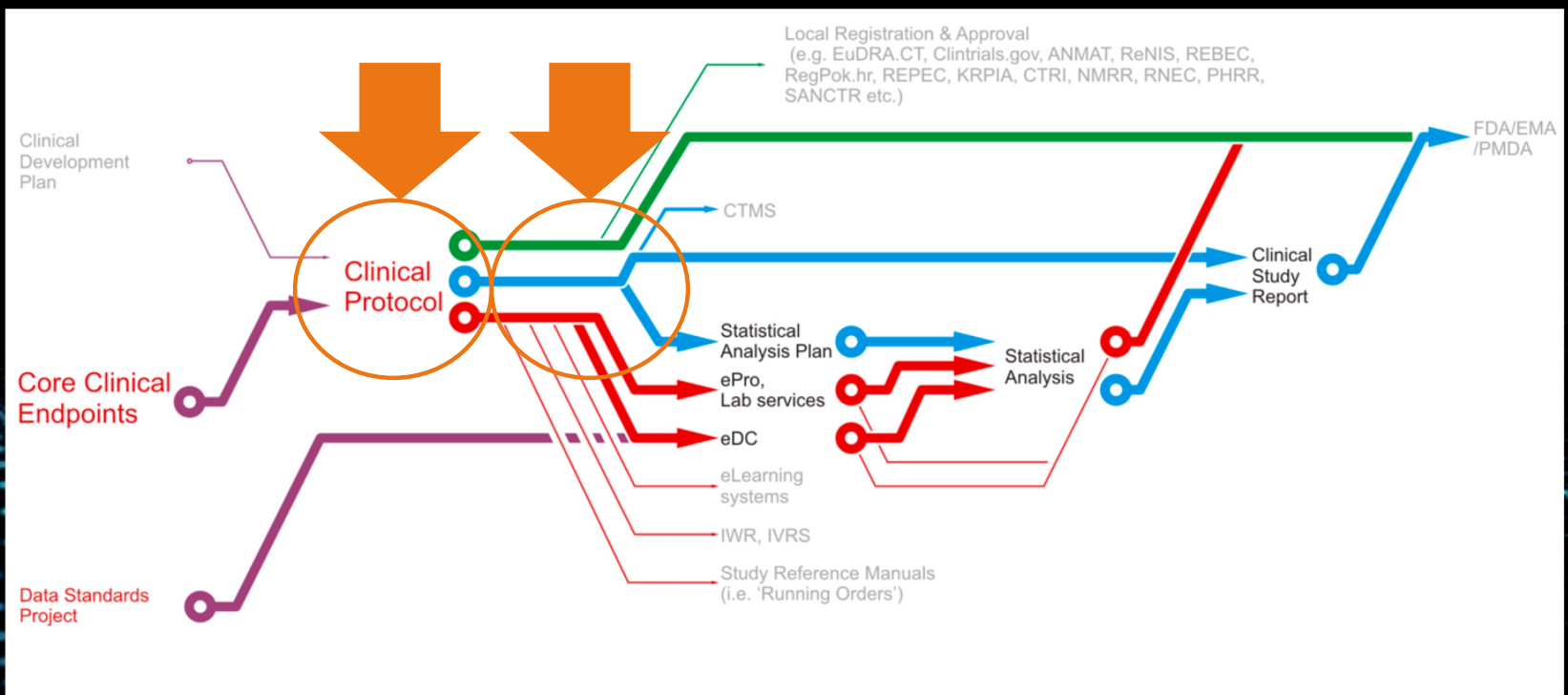


CDISC – TransCelerate Partnership to drive automation using standards

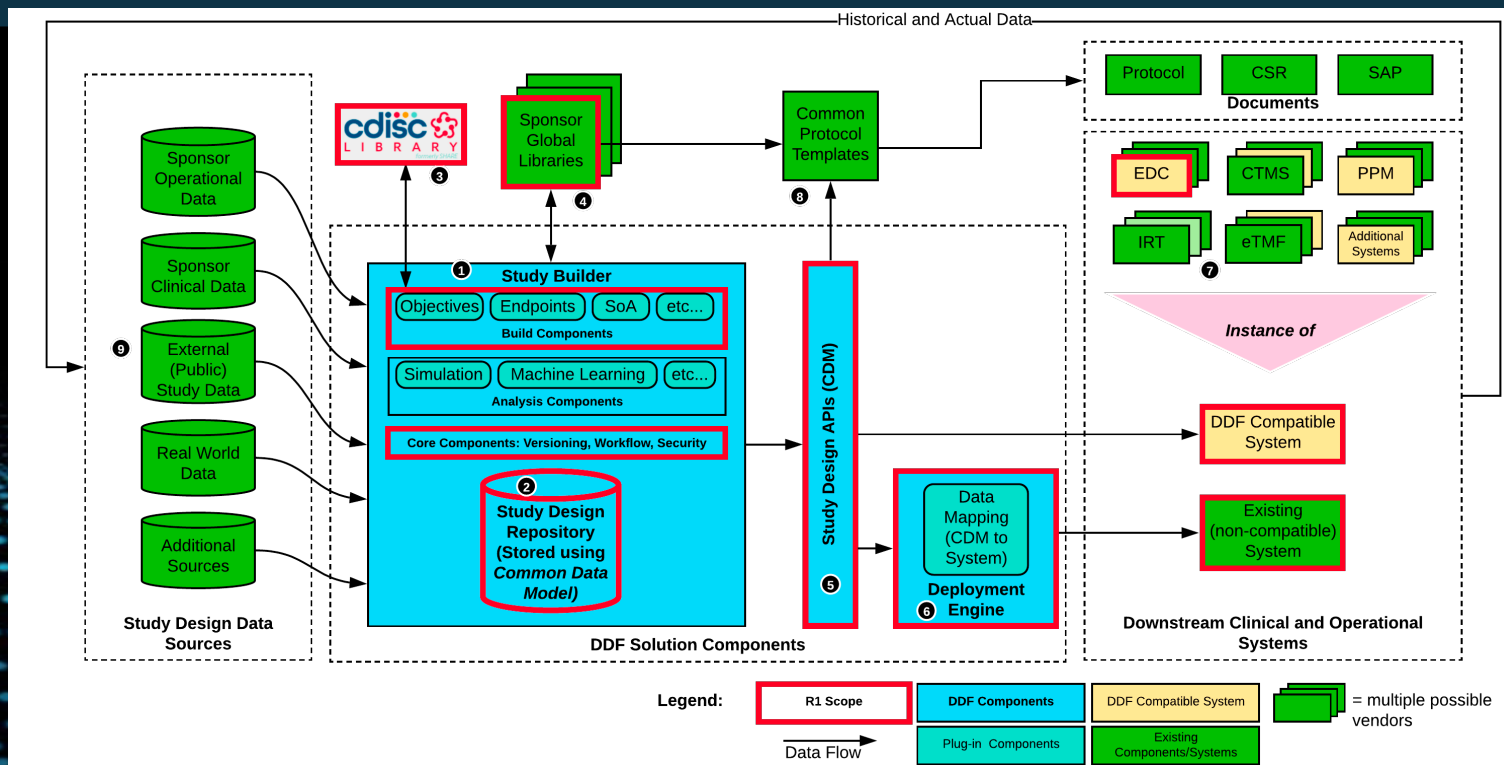
- Standard **Machine-executable content** for Useability
- Standard **Technology Interfaces for Integration** for Accessibility
- Standard **Verification and Conformance Rules for Integrity**
- Standard **Trial Design Specifications** for Total Automation of the Digital Data Flow



Interventions to move to data-driven Clinical Trial Information Flow

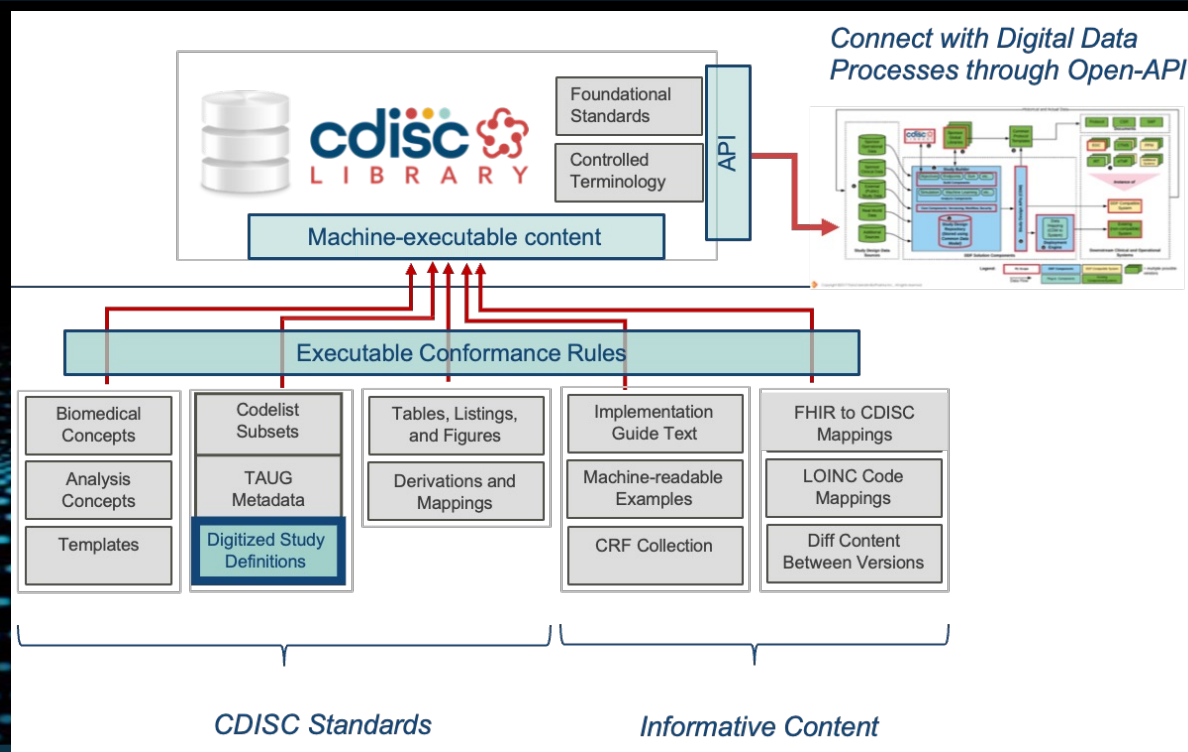


Conceptual System Architecture to realize DDF



Source: CDISC & TransCelerate Biopharma

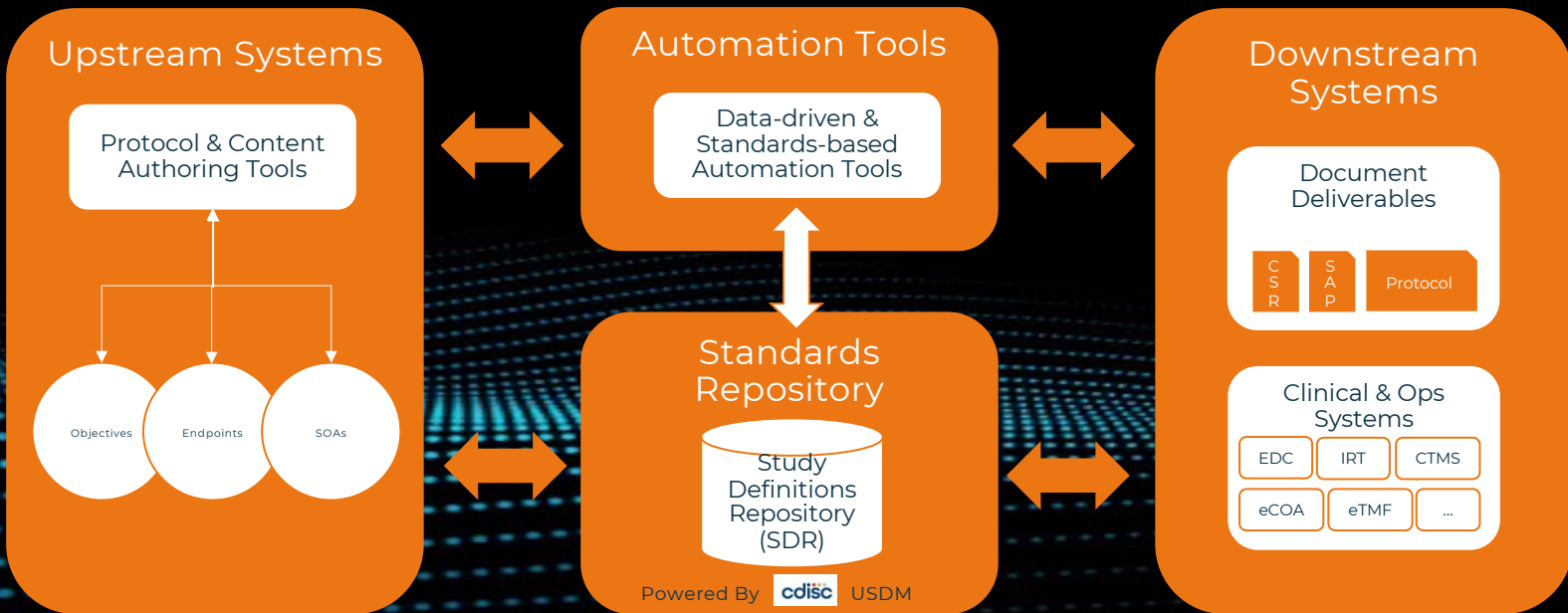
Supporting Digital Data Flow with standards



Source: CDISC & TransCelerate Biopharma

Addressing the Study Startup challenge through digitization of content authoring, SDR & Automation Tools

1



9

Addressing the Data Pipeline challenge using a Unified Data Platform approach (1/2)

- 2
- 3
- 4
- 5

Foundational elements of a platform based approach to automating data pipeline

INNOVATIONS

EXPERIENCES

Simple, intuitive and personalized experiences

ARTIFICIAL INTELLIGENCE

Pervasive AI and embedded insights driving intelligent operations

MODERN DATA SHARING

Seamless data access, collaboration and exchange regardless of where data lives

FOUNDATIONS

INTEROPERABILITY

CLOUD ARCHITECTURE

DATA STRATEGY AND STANDARDS

PLATFORM-CENTRICITY

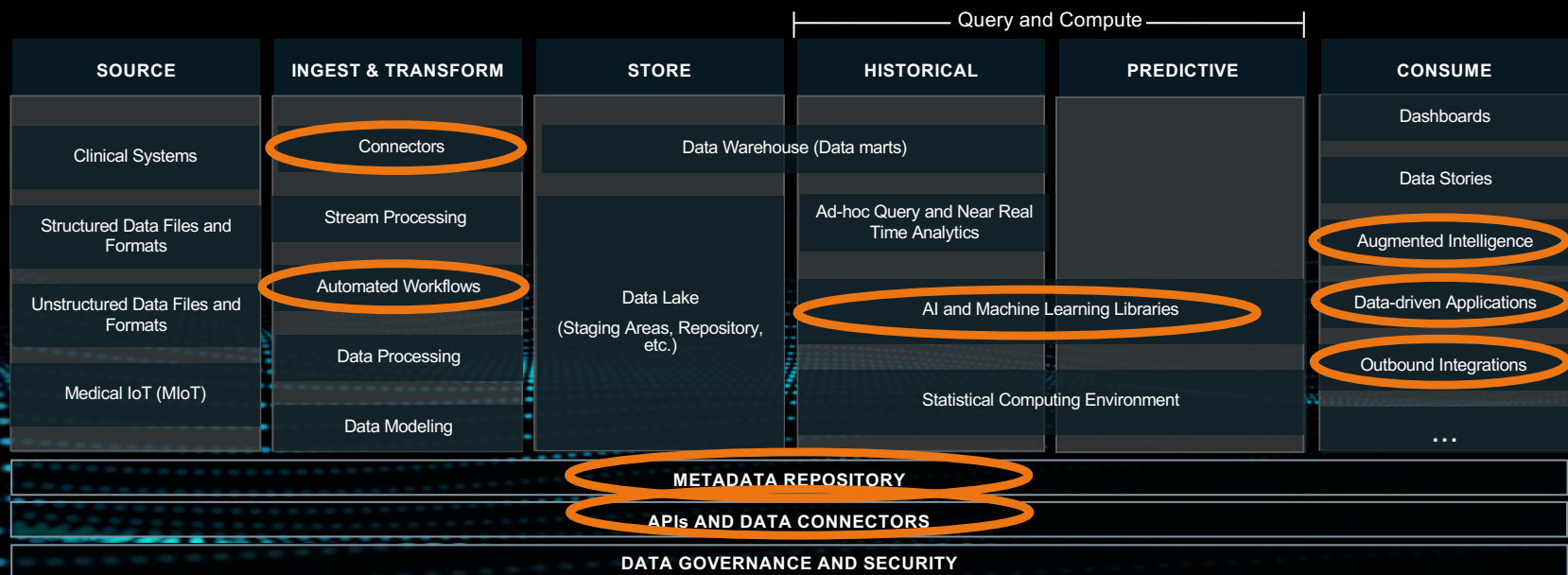
AUTOMATION

METADATA MANAGEMENT

Addressing the Data Pipeline challenge using a Unified Data Platform approach (2/2)

2 3 4 5

Blueprint of a platform based approach to automating data pipeline



Thank You

eclinicalsol.com
877.355.8668 (877-ELLUMN8)
info@eclinicalsol.com

@eClinical_Sol
www.linkedin.com/company/eclinical-solutions/

