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Automating the Digital Data Flow with a Standards Foundation

Presented by: Jason Konn, Solutions Consultant, eClinicalSolutions



Meet the Speaker

Jason Konn

Title: Solutions Consultant

Organization: eClinicalSolutions

As a Solution Consultant, Jason works with Sponsor organizations to understand their challenges and come up with creative solutions leveraging the illuminate platform. Jason has lead design & development for several products ranging from a Data Management Workbench, Data Integrations, Clinical Operations Platform, Clinical Analytics, and Risk Based Quality Management. Jason has been in the clinical trials industry for over 15 years and his prior experience includes, global central laboratory, eCOA design, process improvement, and building an automated workforce.



Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*



Agenda

1. Current Key Challenges
2. Benefits of Driving Automation
3. Addressing Study Start Up Challenges
4. Addressing Data Pipeline Challenges



Current Key Challenges



Key challenges with current clinical trial data flow 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



Benefits of driving automation through Digital Data Flows

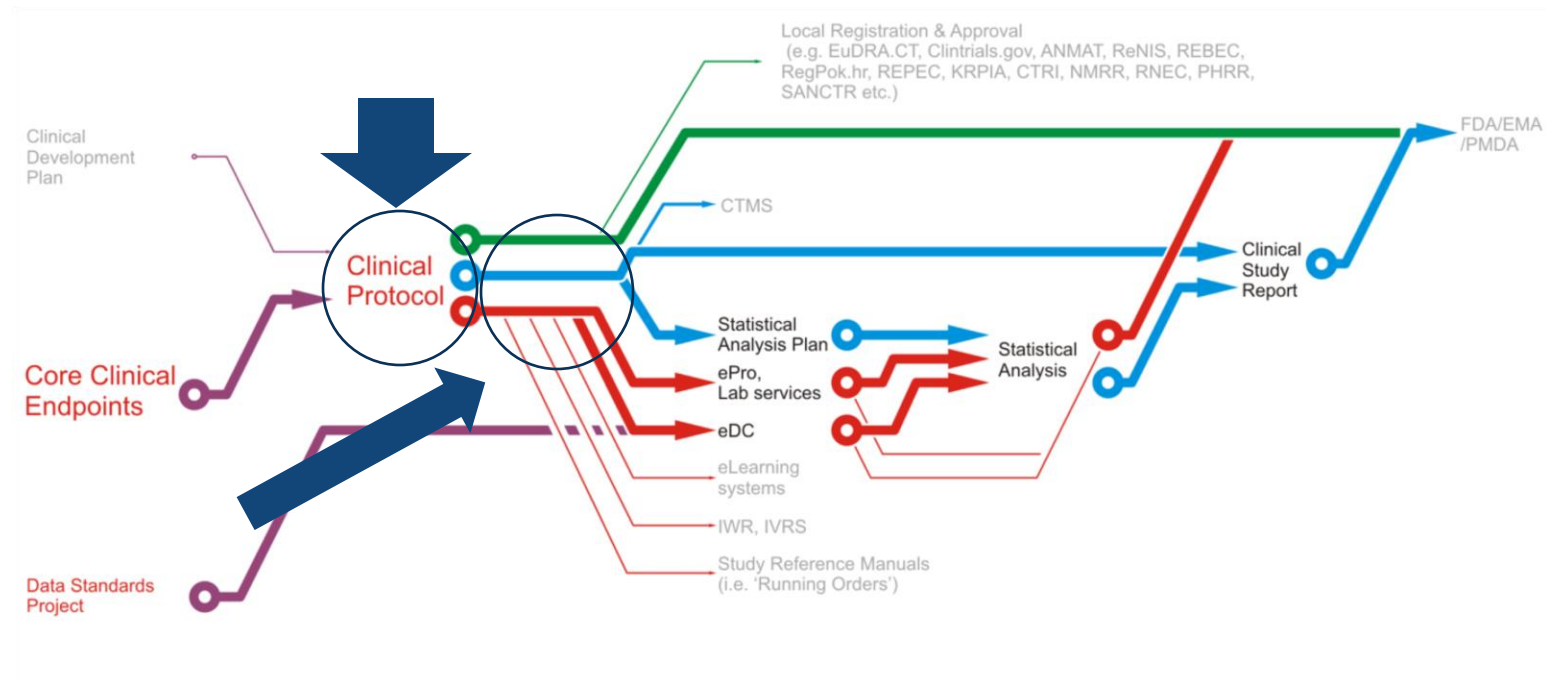
- Facilitate consistency of data
- Minimize bottlenecks between processes and systems
- Minimize manual work, data re-entry, and data inconsistencies
- Improve efficiencies by achieving seamless information flow across systems
- Spark innovation that will drive interoperability and automation



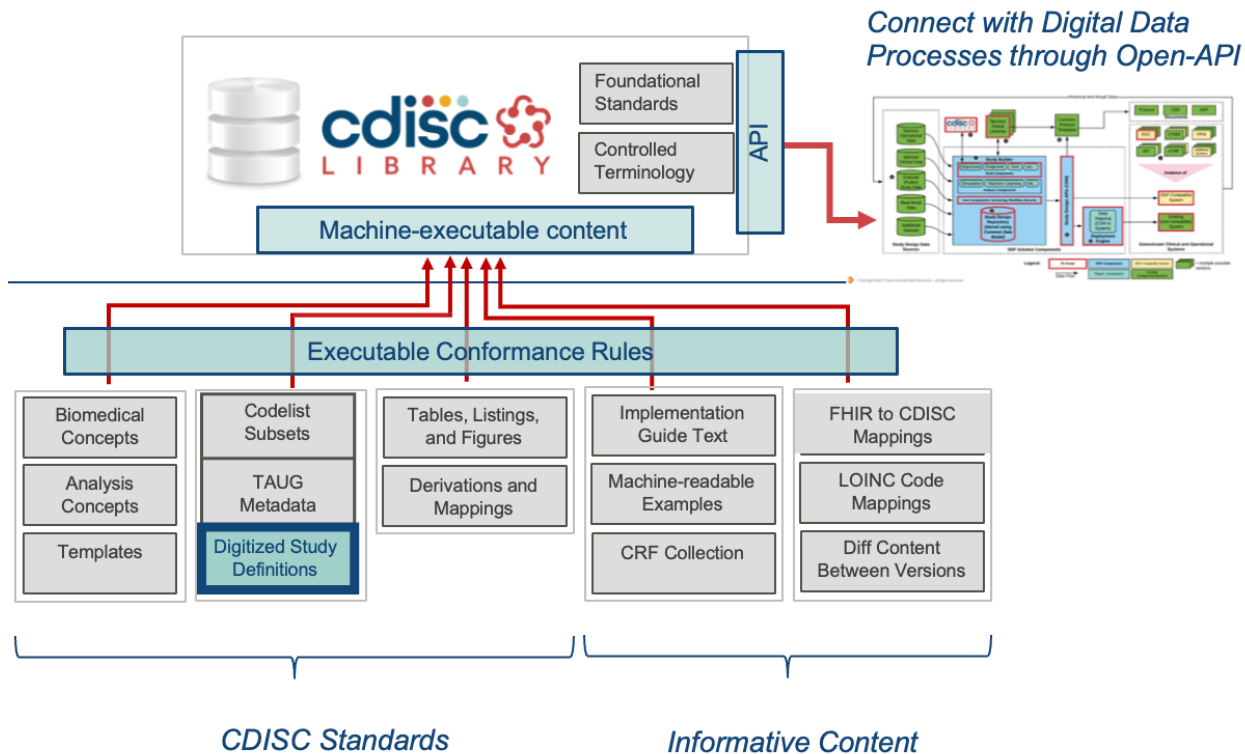
CDISC – TransCelerate Partnership to drive automation using standards

- 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

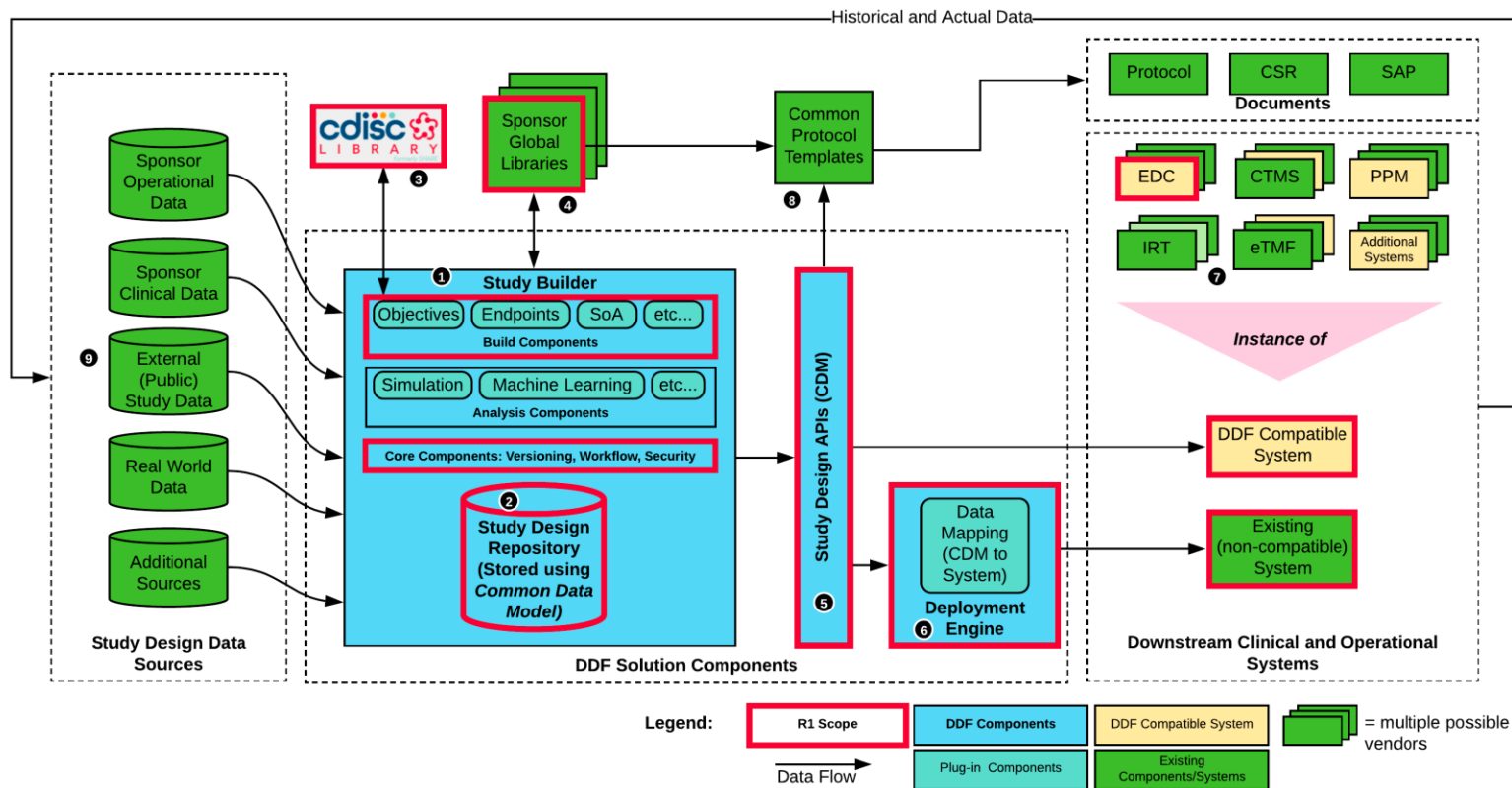
Interventions to move to data-driven Clinical Trial Information Flow



Supporting Digital Data Flow with Standards

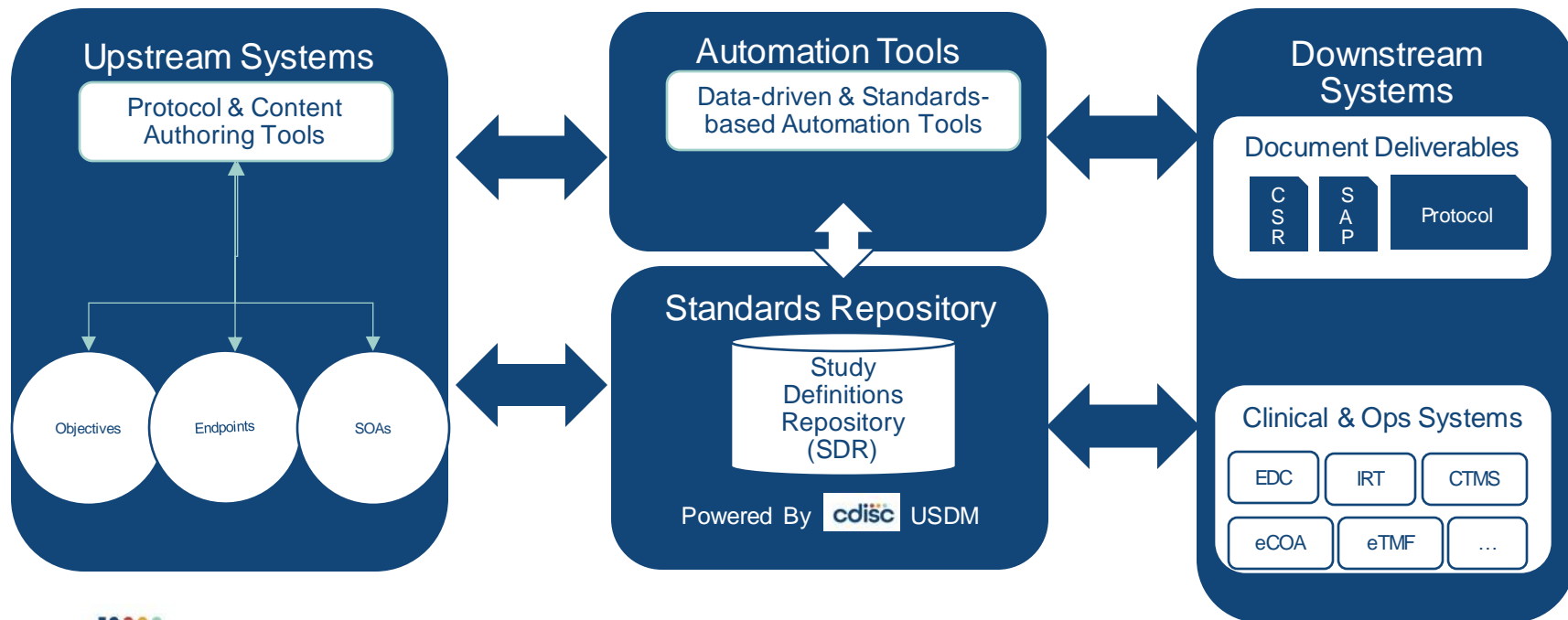


Conceptual System Architecture to realize DDF



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

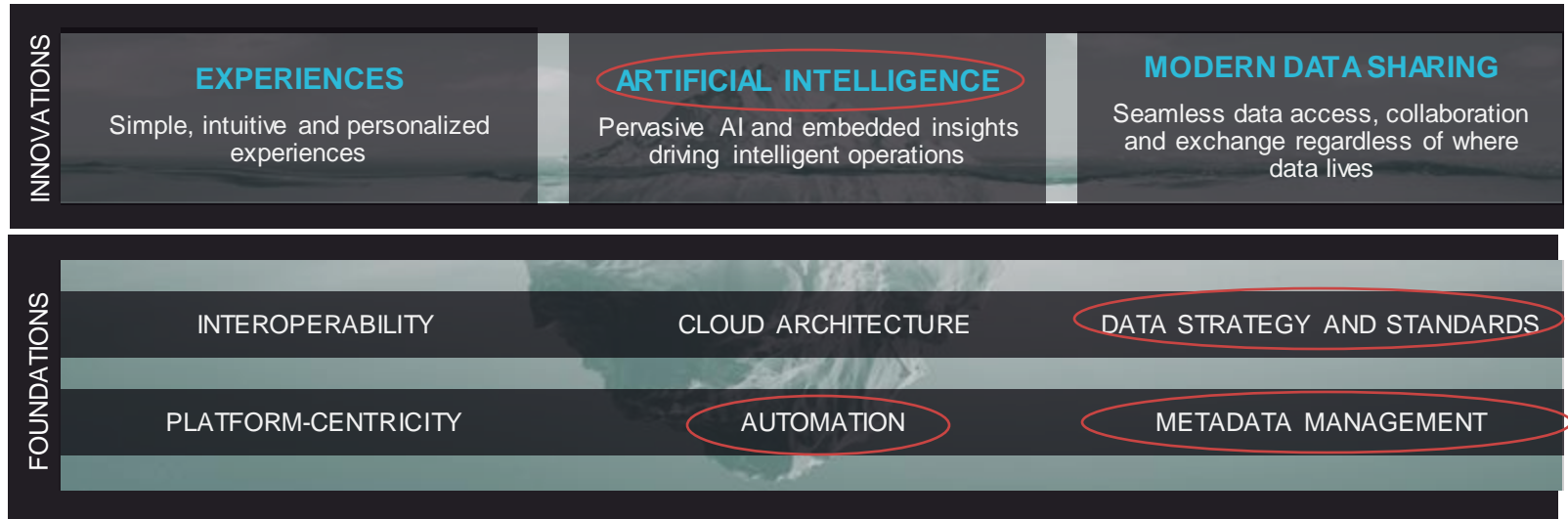
1 Average lag of 4 months between protocol completion and study start



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

- 2 Data conversion and standardization adds additional cycle time impacting the time to market
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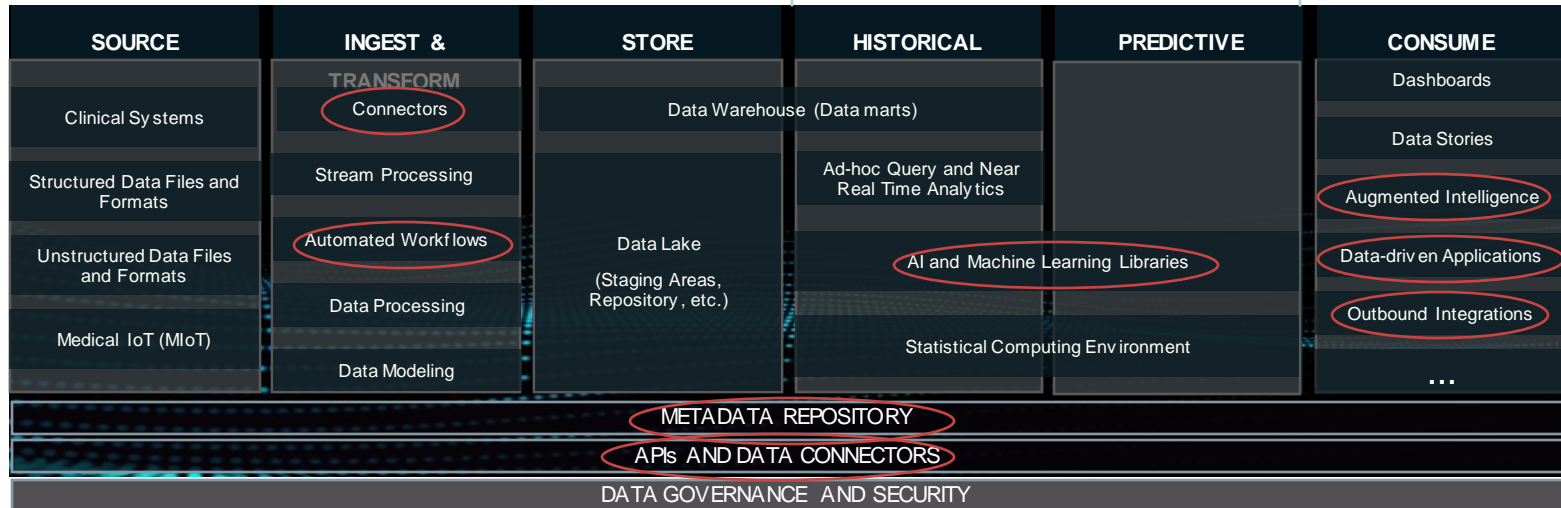
Foundational elements of a platform based approach to automating data pipeline



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

- 2 Data conversion and standardization adds additional cycle time impacting the time to market
- 3 Challenges with traceability of data across the systems
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Blueprint of a platform based approach to automating data pipeline





Conclusion

- Start to think about your organization's strategy towards standards in coordination with DDF
- A data strategy should in part have a strong standards foundation
- Consider how a technology platform can support your data strategy in terms of having that strong standards foundation



Thank You!

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The logo for CDISC, featuring the word "cdisc" in a bold, lowercase, sans-serif font. Above the letters "i", "s", and "c" are three small colored dots: a red dot above the "i", a yellow dot above the "s", and a light blue dot above the "c".