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# Single Day Event

## Elevating Healthcare Excellence Through Intelligent Standardization

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# Introduction

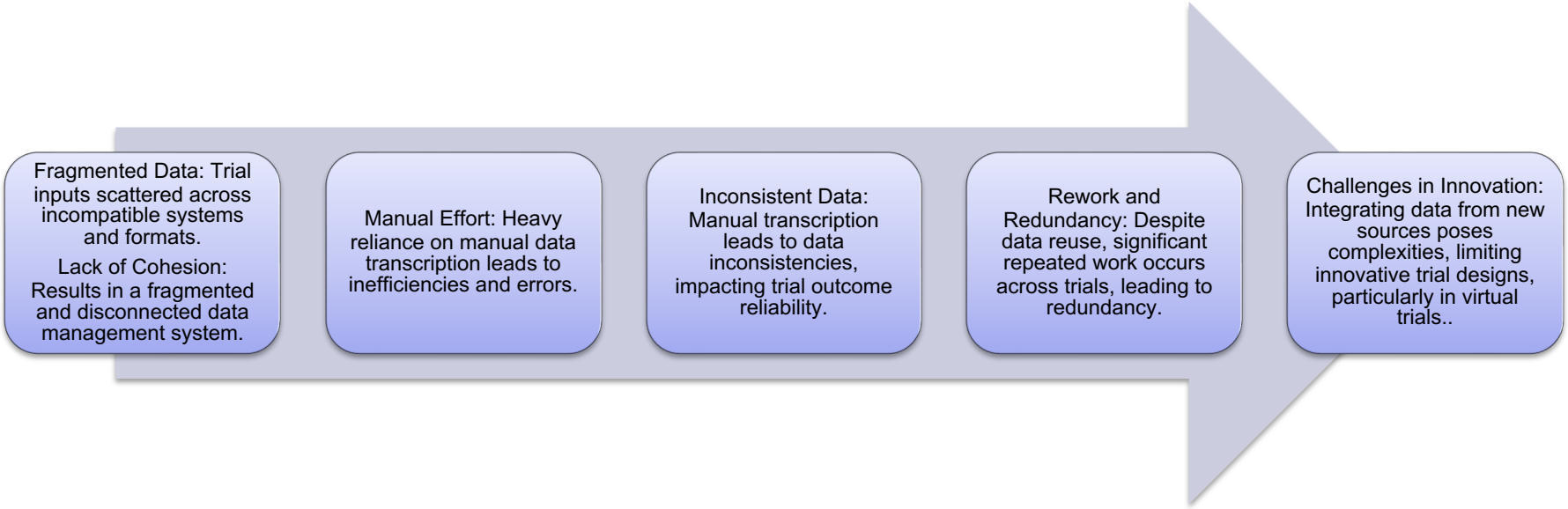
The increasing interest in incorporating AI into clinical trial programming seeks to improve efficiency and decrease human intervention. This presentation introduces an innovative method, the metadata recycling approach, to transform the statistical programming process. The main objective is to reduce reliance on human input for global metadata updates and enable systems to autonomously learn from data.

# Current Landscape

- Extended Timeframe: Bringing new drugs to market takes 10-12 years on average, and clinical trials last 5-7 years.
- Patient Delays: Lengthy processes cause significant delays for patients in need of life-saving treatments.
- Data Flow Challenges: Life sciences companies struggle with fragmented and inefficient data flow.
- Swift Delivery Hindered: Cumbersome processes hinder the quick delivery of drugs to patients.
- Complex Lifecycle: Traditional clinical trial lifecycle involves manual efforts, rework, and inefficiencies.
- Artifact Development: Over 20 artifacts need development and reuse, contributing to increased cycle times

# Current Landscape

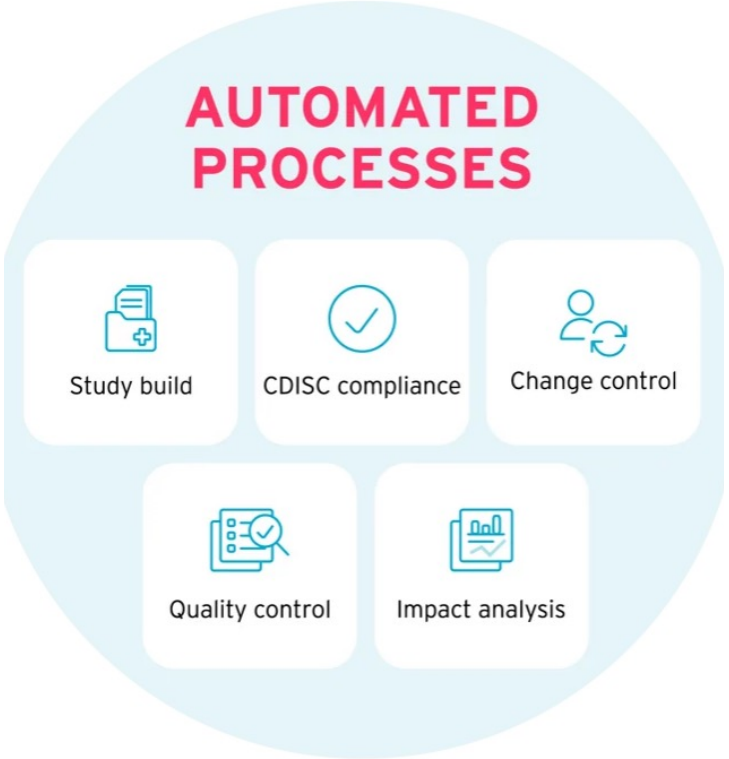
Key limitations of the traditional clinical trials process include:




Addressing these limitations is crucial for streamlining the clinical trial process, reducing cycle times, and ultimately delivering effective treatments to patients in a timelier manner.

# Using AI to power digital data flow

- **Auto Study Build:**
  Studies built automatically from existing standards; new content created only when needed.
- **Auto Compliance:**
  Standardized content ensures CDISC compliance, aiding quick regulatory data review.
- **Auto Change Control:**
  Changes undergo automatic approval and tracking, eliminating manual complexity.
- **Auto Impact Analysis:**
  Identifies upstream/downstream impacts of standard changes automatically.
- **Auto Quality Control:**
  Enforces quality control through a customizable metadata lifecycle.



# Efficiency + speed + savings = Value for you and your patients

### Faster Trial Cycle Times:

Downstream use of data elements, along with automated suggestions based on past studies, reduces repetitive data input and completion times.

Automated data quality checks offer prompt feedback and speed up queries to sites.

User-driven SDTM conversions decrease the need for developer involvement, streamlining communication.

Cloud-based design and application accelerators contribute to faster implementation.

### Greater Trial Efficiency and Data Quality:

Collaborative authoring platform facilitates efficient workflows and approval submissions.

Metadata traceability to standards and digital export to the EDC system eliminate manual configuration, ensuring data quality.

Machine learning automates SDTM configuration and conversion.

Faster data availability for analytics enhances site monitoring and informed decision-making.

Automation of manual processes frees up resources for value-added activities.

### Lower Trial Costs:

Standardized workflows and documentation reduce manual errors, resulting in cost reduction.

Automation capabilities enable the addition of studies at a lower cost by limiting resource requirements.

# Detailing use cases to enable future state vision

## Use Cases

### Protocol builder

Use AI/ML and Biomedical Concepts in conjunction with the Common Protocol Template to enable creation of digitized protocol and traceability of common elements from protocol to CSR

### CRF Builder

Use metadata collected for each visit as defined in the study builder to generate an ODM/ALS import file to automate CRF build in EDC System

### SDTM Conversion

Automate data quality checks and mapping from source clinical/non-clinical data (CRF, EHR, device, Epro, etc.) to SDTM and SEND, and analysis

## Outputs

**Digital Protocol including SoA**

Metadata is passed along to design CRF

**EDC System Design Metadata**

Metadata is passed along to define the SDTM domain, variables, and lookups

**SDTM CDISC Complaint Data & Documentation**

# Detailing use cases to enable future state vision


Integrated mapping environment from source clinical/ non-clinical data (CRF, EHR, device, ePRO etc.) to SDTM

Automated draft generation and collaborative authoring of the Statistical Analysis Plan with metadata traceability to Study Builder details to automate update trigger and review workflows

Integrated mapping environment from SDTM to ADaM and ML routines to select analysis routines to drive automation

Platform solution that automates machine-readable protocol elements linked to standards to create TLFs, enabled by a recommendation engine for standards selection and mappings, as well as a graph database to manage semantic relationships between protocol elements, study definitions, and data standards

# Summary

- Initiating an efficient clinical trial begins by establishing quality metadata. Having standardized and approved metadata enables quicker trial commencement with reduced manual efforts. Early insights can be obtained, facilitating a faster-paced trial progression.
- The implementation of a CMDR, incorporating automated metadata management, offers enduring advantages. As CDISC standards evolve and additional regulations emerge, CMDRs will play a pivotal role in organizing and standardizing data. This accelerates the clinical trial process, simplifying operations for organizations. Standardized and automated clinical metadata allows organizations to concentrate on expediting treatments to market.

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# *Thank you*


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