

The Decentralized Trials Data Problem: Foundations for the Future of Clinical Trials

Raj Indupuri
CEO, eClinical Solutions

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With the rise of Decentralized Trials (DCT)

Overcoming the increasing complexities of data management and driving impact with patient-centric technology solutions

DATA

Increasing data sources, new clinical endpoints, novel data types, real-time and centralized data collection

TECHNOLOGY

Require modern infrastructure, platform-centric approach, but fit-for-purpose and interoperable applications

PROCESS

Proactive planning, risk and mitigation strategies, specialized tools and unified and automated workflows

PEOPLE

Need to upskill data managers to expand analytical and clinical skills, understanding and use of DCT data and alternative data capture designs



TO ENABLE BETTER OUTCOMES

FOR PATIENTS

Increase patient access to trials, education and less burden
Increase patient education and retention
Improve safety and efficacy

FOR SPONSORS & SITES

Improve data accuracy and standardization
Increase speed and better outcomes
Unified workflows and seamless experience
Better communication and collaboration between all parties

Enabling digital and data-driven clinical trials

Powering the modern clinical trial value chain requires modern technology and infrastructure, data and analytics

MODERN CLINICAL TRIALS DATA LIFECYCLE

Technology infrastructure for data collection from wearables, validated instruments, genomics, sensors, etc.

Data pipeline and modern technology infrastructure, data intelligence and automation

Enabling data-driven decision-making through data mining, modeling, analytics and data science

INTELLIGENT DECISIONS, REDUCING CYCLE TIMES, FASTER TIME TO VALUE



Modernizing clinical data management

Keeping up with the complexities of modern trials and the revolutionary science and technology breakthroughs



DCT Foundations

Enabling decentralized trials with strategic innovations built on the core technology foundations and infrastructure

INNOVATIONS

EXPERIENCES

Simple, intuitive and personalized experiences

ARTIFICIAL INTELLIGENCE

Pervasive AI and embedded insights

DATA FABRIC

Data usable anywhere, by anyone, regardless of where data lives

FOUNDATIONS

INTEROPERABLE SYSTEMS

CLOUD ARCHITECTURE

DATA STRATEGY AND STANDARDS

PLATFORM-CENTRICITY

AUTOMATION AND CONNECTIVITY

METADATA MANAGEMENT



AI for modern data management

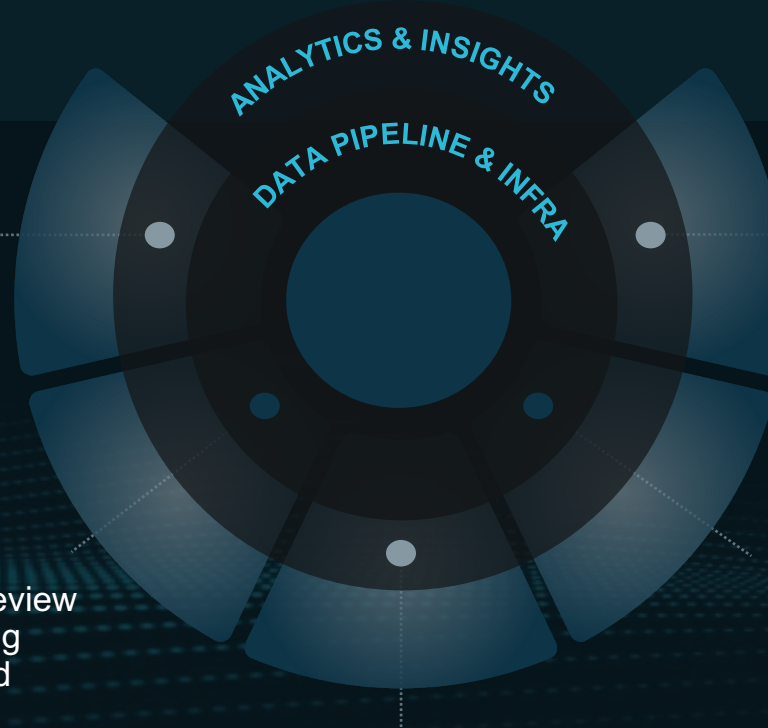
To enhance data management and data review capabilities, automate and deliver new insights

ANOMALY DETECTION

Evaluate anomalies, data errors, and trends across multiple data sources to improve data integrity

AUTOMATED DATA REVIEW

AI-enabled query automation for review actions, error evaluation and raising queries to improve data quality and integrity



SUBJECT ANOMALY DETECTION

Leveraging statistics to detect subject-level anomalies to quickly identify potential patient safety issues

AUTOMATED DATA CLASSIFICATION

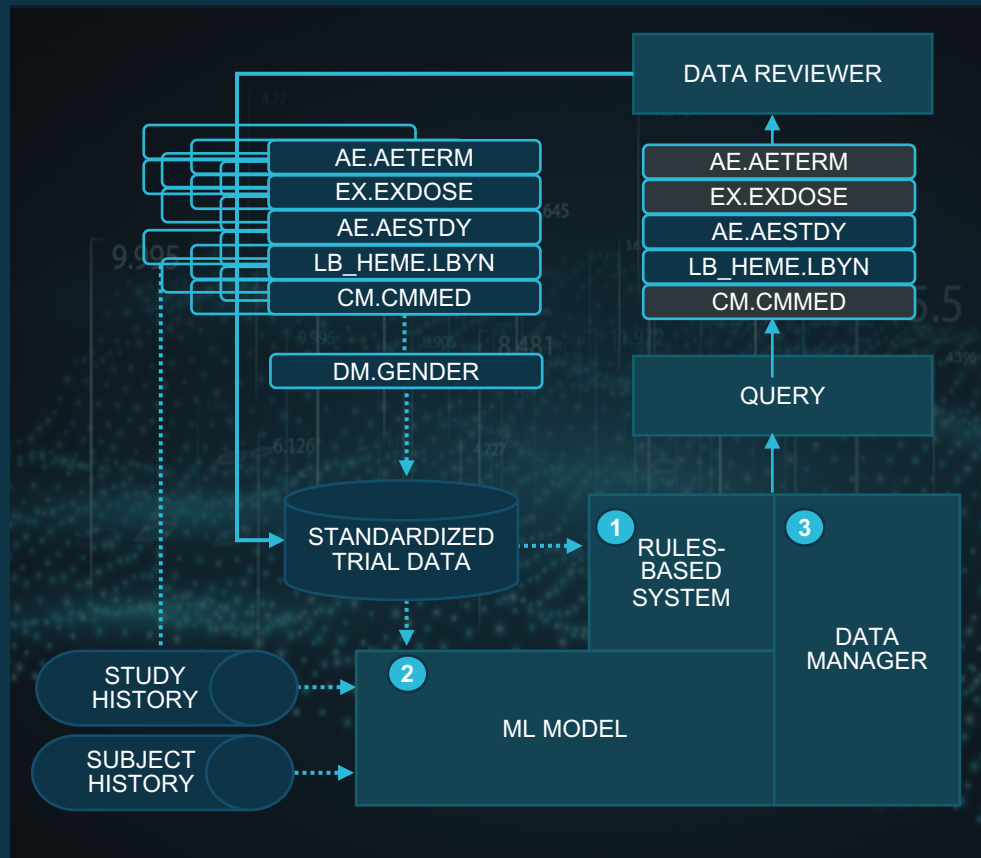
Classify data attributes to support auto configuration, auto mapping and data handling tasks at scale

CENTRAL STATISTICAL MONITORING

Enhance risk evaluations through intelligent use of KRIs and predict site performance

Case Study: Applying advanced algorithms for data review

To enable Data Managers and Data Reviewers to work more efficiently

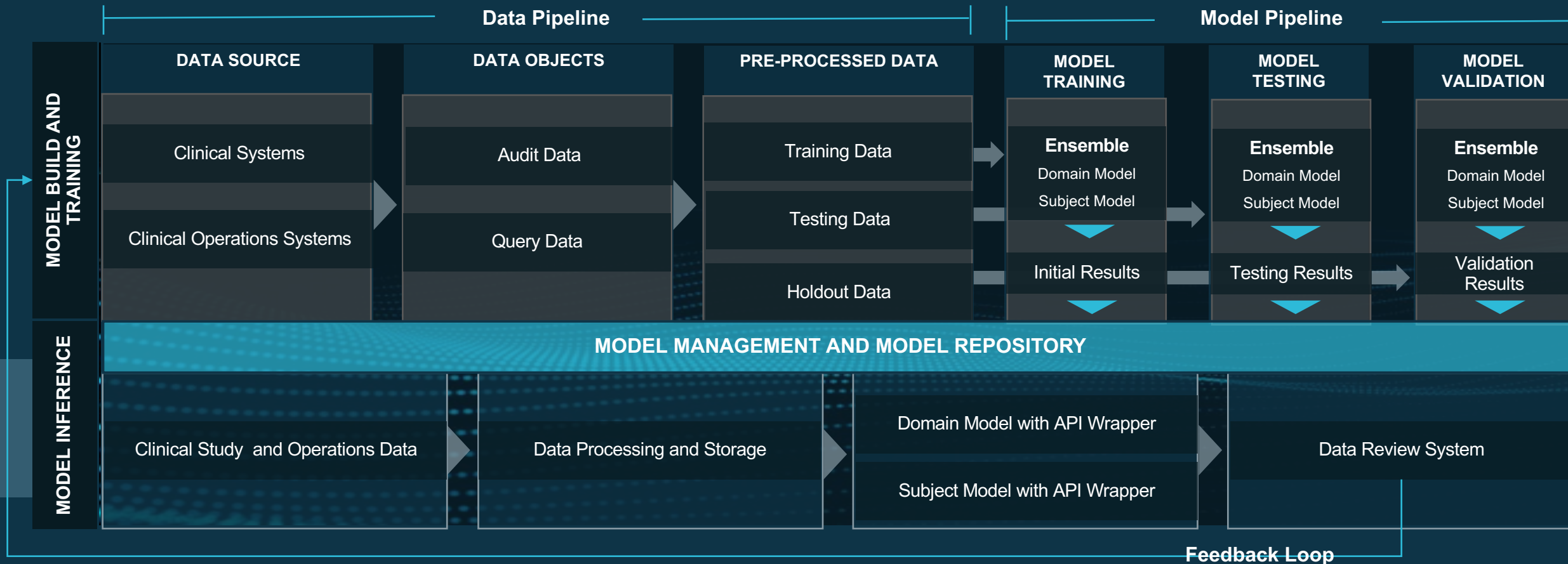


AI-DRIVEN QUERY AND DATA REVIEW SYSTEM

- Identify data discrepancies and data issues faster
- Augmenting human-driven query generation process
- Data managers focus on reviewing more complex discrepancies
- Automatically learn common data errors and issue queries
- Data reviewers retained as a human-in-the-loop check
- As data becomes better, automating more parts of the process

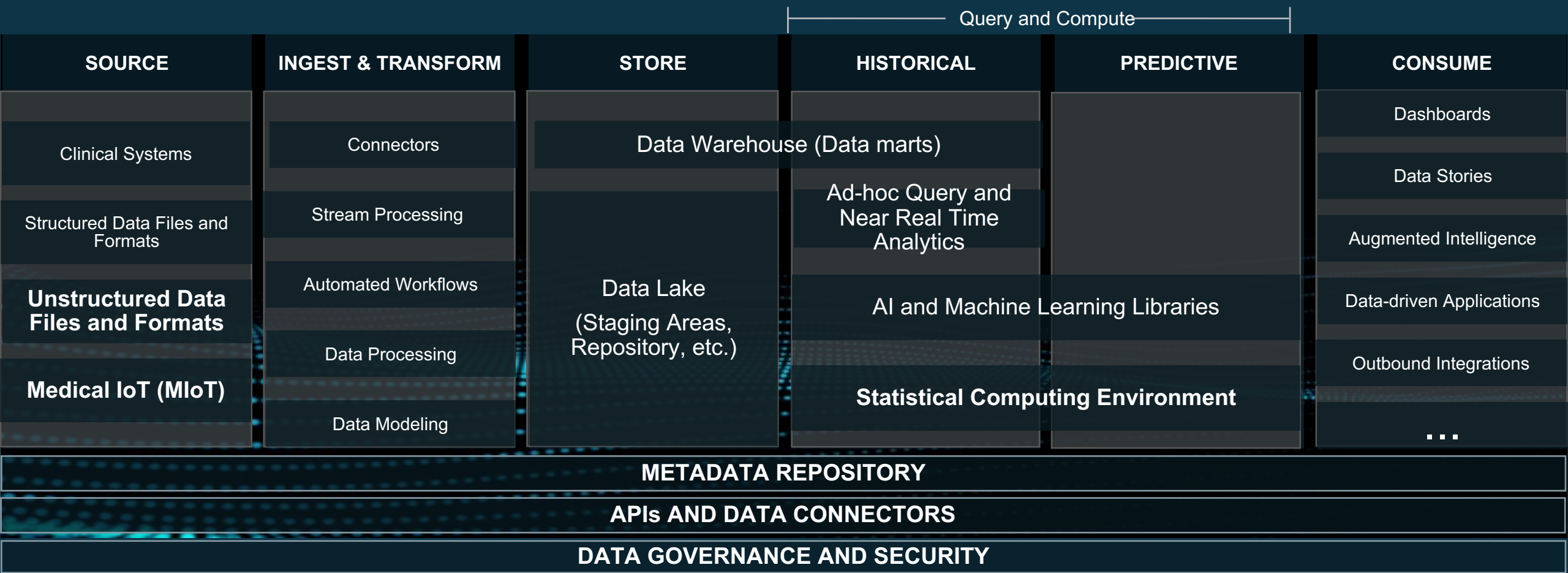
To build a powerful AI system

Requires modern and scalable infrastructure for workloads requiring heavy compute and data storage



Fast evolving blueprint

Unified architecture for modern data infrastructure,
clinical data pipelines and AI



Modernize data infrastructure to future-proof for DCT trials

For centralized data collection and to manage the increasing data sources from new clinical endpoints

Enable several integrated applications for use cases and workflows across the DCT value chain

For seamless user experiences for patients, sponsors and sites with interoperability between clinical systems

Building robust data strategies and data pipelines from clinical and operational data systems

AI/ML-powered capabilities to transform data into insights for actionable intelligence and effective data management



Thank you

Raj Indupuri
CEO, eClinical Solutions
rindupuri@eclinicalsol.com

