

From Digital Data to Decision Intelligence



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Infrastructure and Algorithms Powering Automation in Risk-Based Monitoring and Data Review



An industry perspective

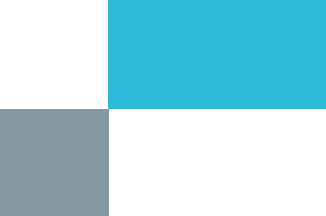
Creating a digital value chain to accelerate clinical research across patients, sites and sponsors

Technology is an imperative to revolutionize and industrialize science



Reference: <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/ten-battlegrounds-for-digital-and-analytics-in-life-sciences>





Enabling modern, digital and data-driven clinical trials

Foundations to power 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



Exploring data review and monitoring concepts for modern clinical trials

Developing integrated automation & AI tools to transform data review, centralized and risk-based monitoring



RISK-BASED MONITORING

Exploring AI technology that enhances risk evaluations through intelligent use of KRIs and measure the likelihood of site performance in the future



AUTOMATED DATA REVIEW

Help data reviewers and managers automate recommendations, evaluate outliers and errors, flag risk in real-time that may affect data quality and integrity

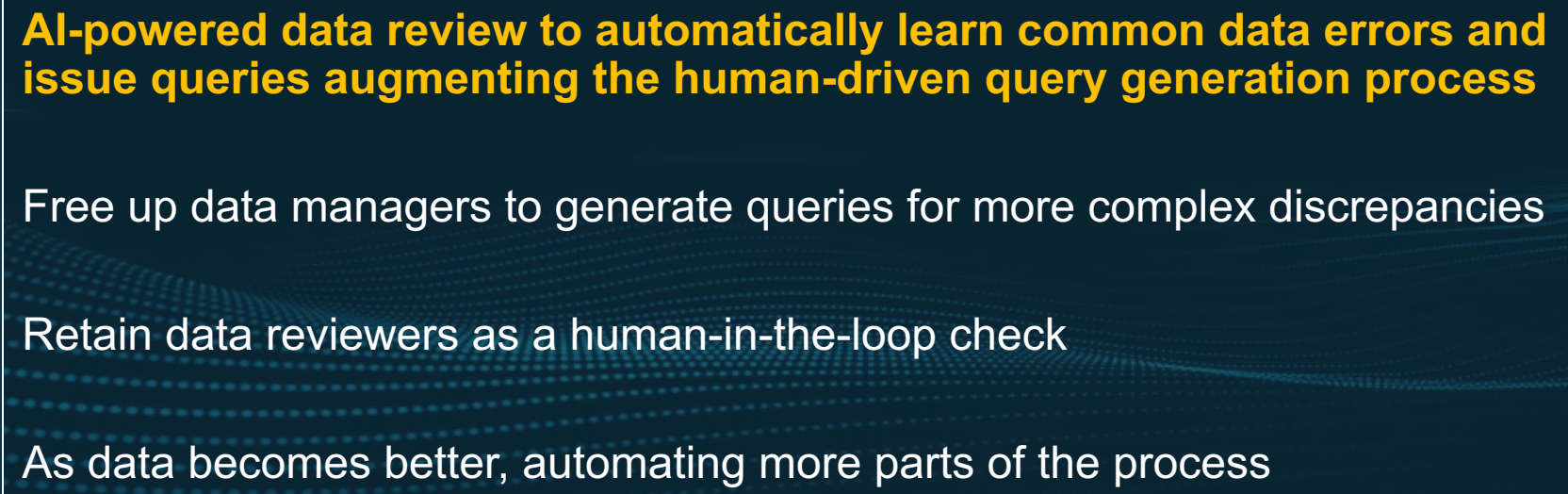


PATIENT CLUSTERING

Cluster and view subjects using AI-powered tools to identify subgroups based on correlated clinical attributes for enhanced insights

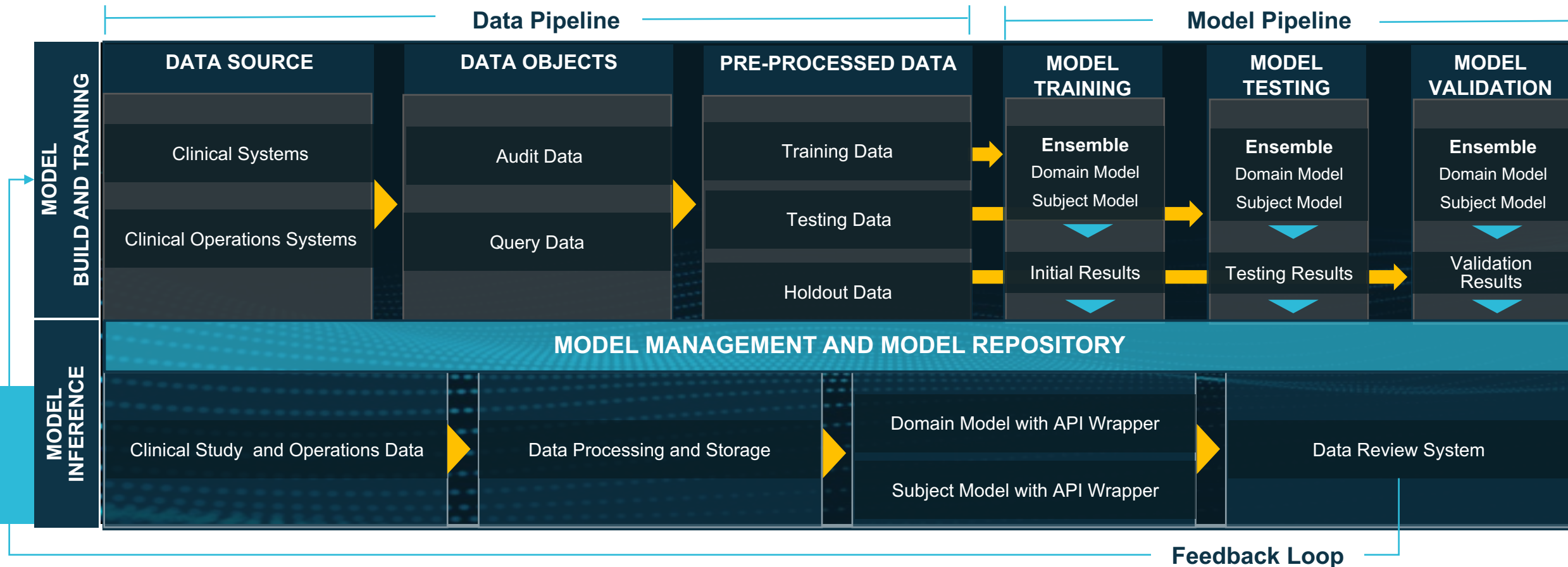
Taking a practical approach to getting there....





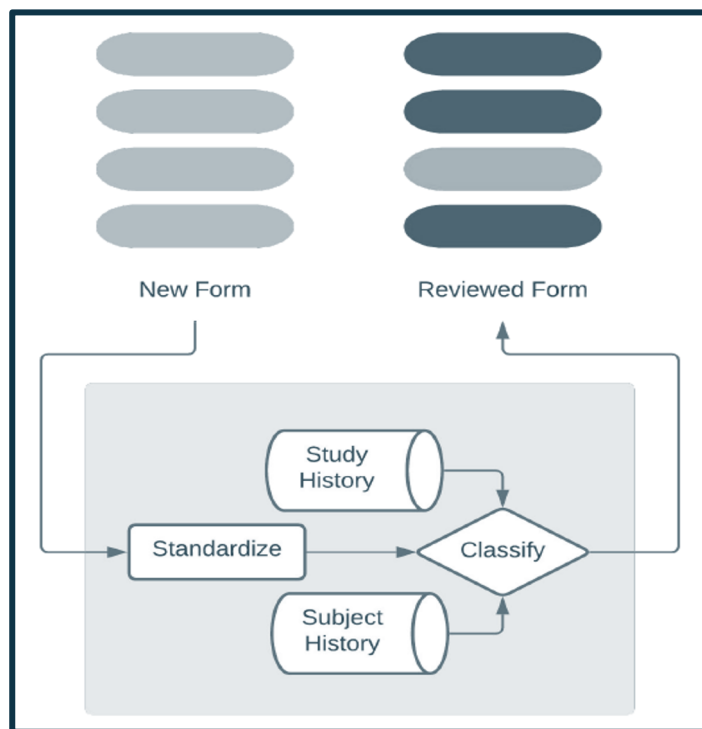
Aggregating and restructuring data intelligently for developing a powerful AI system

Using historical clinical audit data to predict when data will generate manual queries for data change



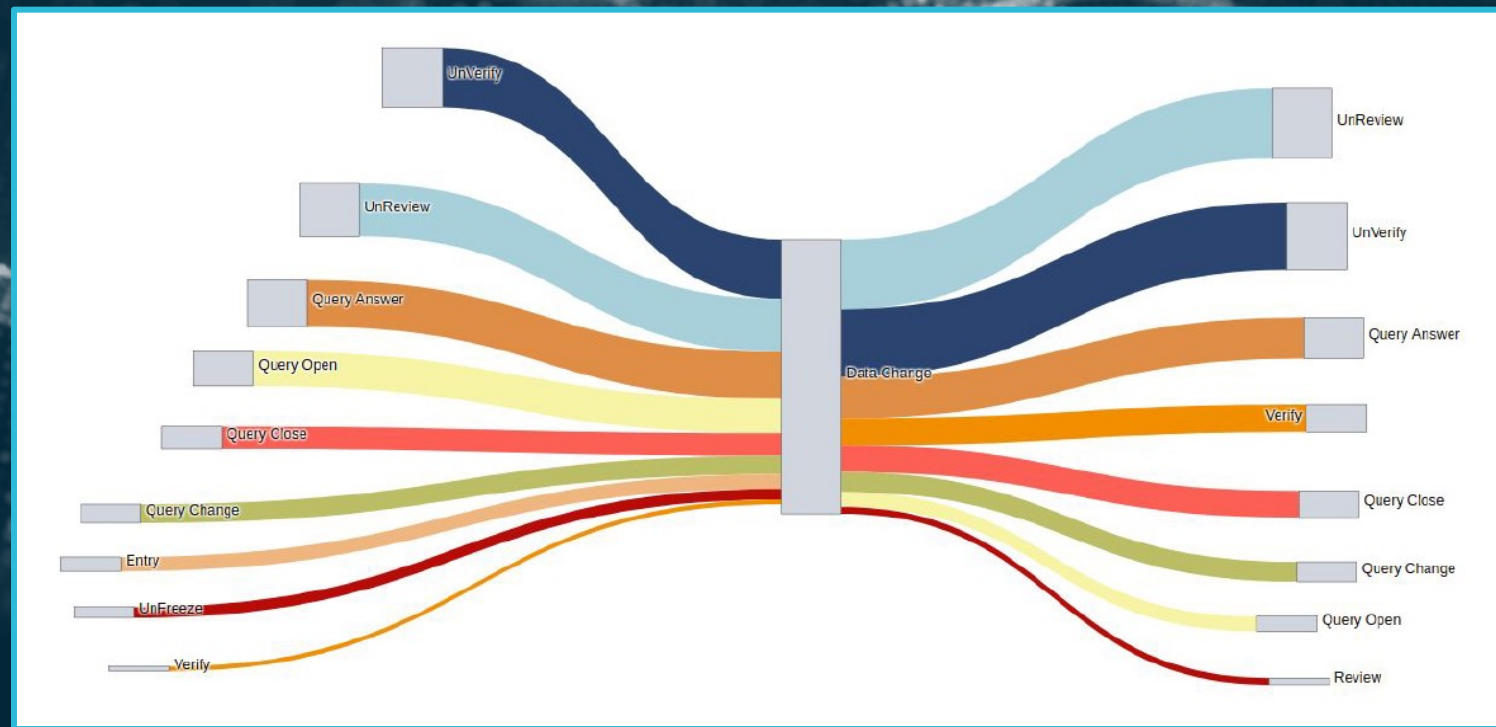
Smart Query Data Review System

AI-driven data review enabling data reviewers to work more efficiently



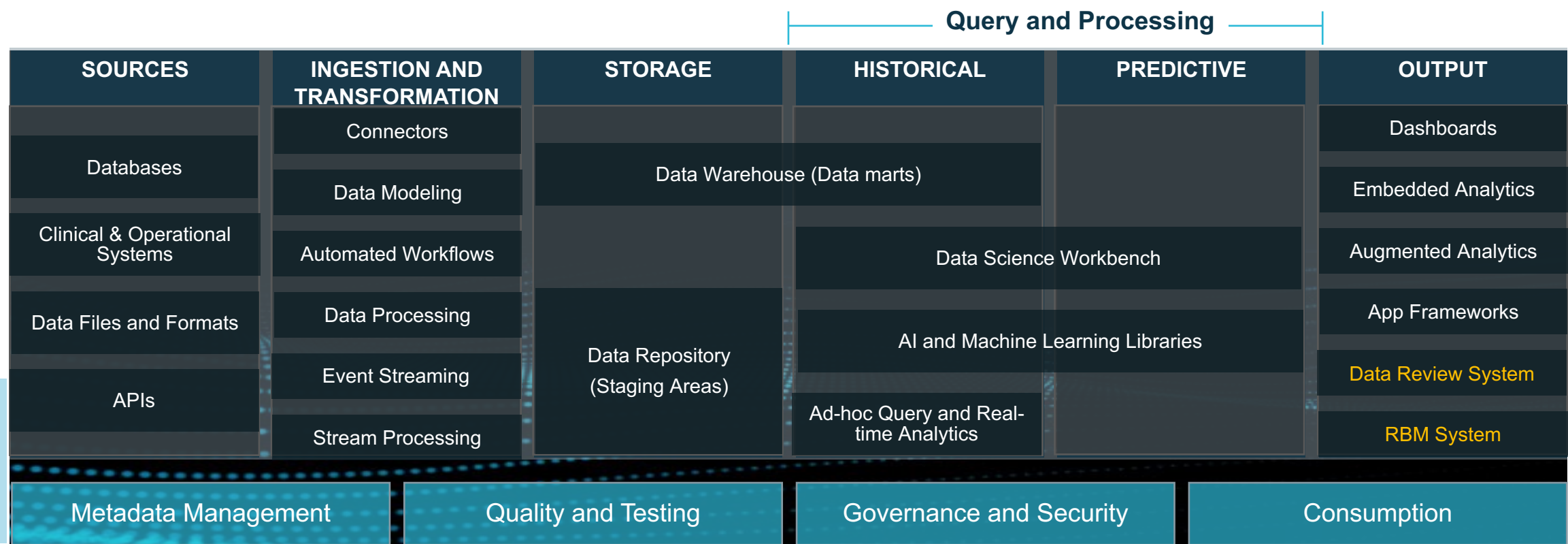
PRODUCTIONIZED SMART QUERY SYSTEM

AI/ML-driven data review system supporting data reviewers
A data review automation system which learns from past queries



Building a technology foundation with a unified architecture for modern data infrastructure

Scalable and flexible technologies for building robust data pipelines and deploying AI/ML models



Reference: <https://a16z.com/2020/10/27/blueprints-for-data-infrastructure-lakehouse-storage-data-is-not-the-new-oil-more/>



Future-proof for emerging and new digitization trends

Solving for advanced data review, centralized and risk-based monitoring systems

Require **modern data infrastructure** to support,

- Manage exorbitant amount of increasingly complex data
- Robust data pipeline from clinical and operations systems
- AI/ML-powered capabilities to transform data into insights for decision intelligence

Transferring and combining the human factor to train models to adapt, learn and improve over time, especially when the data is a small data problem

Thank You