The Intelligence Shift:
AI Driven Clinical Trial

NOV-2025

Agenda

- ❑ New Age of Clinical Development
- ❑ From Protocol to Practice: Roadblocks in Clinical Development
- ❑ The Intelligence Shift
- ❑ Artificial Intelligence (AI) as the core
- ❑ AI-Driven Outcomes Revolutionizing Clinical Development
- ❑ Imminent Transformation Highlights

New Age of Clinical Development

Ever-Growing Data Imperative - Device data, real world data, omics data, **synthetic data,** structured/ unstructured data

Therapeutically minded AI, NLP & Cognitive Computing Improve Science & Health Outcomes

Modern Trial Designs Adaptive, Basket, Umbrella etc. bringing flexibility & efficiency, improving success rates and being more patient focused

In Silico Trials, Digital Twins simulate real world trials to **reduce, refine and replace trials**

Real world evidence Enables more efficient and patient-centric trial design and driving Insights before, during and after the trials

Clinical Data science Clinical Data Science driven Mindset, Insight , Strategies etc.

Risk Based Clinical rial -Risk-based approaches (**RBQM, RBDM**), integrated review etc.

Digital Data Pipeline Leveraging USDM framework for automating data flow & ensuring secure, seamless, reliable flow between integrated systems

AI and data-driven innovation powering faster, smarter, patient-centric clinical trials

From Protocol to Practice: Roadblocks in Clinical Development

Roadblocks

Operational Delays

- Manual processes and reviews
- Reactive decision-making
- Monitoring inefficiencies
- Siloed business function agreements
- Patient and site burden

Fragmented Data

- Disconnected systems
- Lack of data interoperability
- Inconsistent Standards
- Lack of holistic Real time insight
- Multimodal data
- Limited Audit trail review

Regulatory Burden

- Complex and Time-Consuming Documentation
- Evolving regulatory expectations
- Changing guidelines and framework
- Developing standards

Inefficient use of new Technology

- Lack of digitalization
- Multimodal OMICS
- Limited use of Technology for Patient, Country, Site selection

The Intelligence Shift

Clinical Data Science

Clinical Data Scientists bridge domain expertise with data science, generating insights and predictive models. They enable predictive trial design, optimize dosing strategies, and improve endpoint selection.

Digital Twins and The Silico Trials

Digital twins and in silico trials leverage clinical trial data, EHRs, omics, and biomarkers to create virtual patient models and simulate disease-drug interactions.

Synthetic Control Arms

Minimize patient recruitment burden and ethical concerns by simulating trial outcomes using historical patient data from sources like EHR, Clinical Registries etc. to speed up development and reduce cost

AI/GenAI/ Agentic AI

Transforming clinical development by automating processes, predicting outcomes, and optimizing data integrity.

Wearables & Smart Execution

Wearables and remote monitoring reduce site visits, improve adherence, and enable continuous data capture. Real-time alerts and monitoring helps detect safety signals and protocol deviations.

Data Eco- Systems

Harmonizes/unified/ Integrated multi-source data, EHR, omics, imaging, for consolidated review , predictive real time insights

Driving Predictable Outcomes Through Quality by Design

Artificial Intelligence (AI) as the core

- **Optimizes protocol design and amendments**
  Analyze historical protocols to build efficient protocol design, reducing amendments
- **Improves patient recruitment and retention**
  ML models to match eligible patients using EHR and RWD
- **Automated Data Processing**
  AI tools automate data cleaning and transformation, saving significant time and effort in workflows.
- **Enhanced Statistical Modeling**
  Machine learning identifies hidden patterns and relationships beyond traditional statistical methods.

- **Enhances decision-making with predictive insights**
  AI to forecasts dropout risk based on historical patterns
- **Enables Real-time monitoring and risk detection**
  AI to flag safety events from wearable, lab data, trial data etc.
- **Accelerates Trial Execution**
  Auto study build using Standards Library, Intelligent Data Query (IDQ) management , NLP to auto-classifies verbatim terms to MedDRA codes

Data Quality by Design | **Real-time/Risk based trial execution** | **Predictive analytics** | **Efficient Operations** | **Improved Regulatory Compliance**

From design to delivery, AI powers intelligent clinical trial execution

AI-Driven Outcomes Revolutionizing Clinical Development

Patient Dropout Prediction

- Predict dropout risk using adherence data
- Personalized outreach and virtual care for better retention

Protocol Deviation Forecasting

- Detect non-compliance via site analytics
- Assigns risk scores to sites and patients enabling proactive interventions

Site Underperformance Detection

- Identify lagging sites via KPIs & velocity
- Suggest staffing and training adjustments using live performance data

Intelligent Data Query

- Identification of patterns from historical data
- Smart detection and raising of query using AI

Intelligent Database Design

- Auto-build study using standards/protocols
- AI driven validation rules/edit checks from CRF

Amendment Impact Prediction

- Analyze amendments from past historical data TA/molecule
- Embed learnings in new study to reduce mid-study changes

Risk-Based Data Review

- Prioritize data via RBQM algorithms
- Flag anomalies in clinical data for early intervention

Synthetic Control Arm Creation

- Build virtual arms using trial + RWD
- Accelerate timelines, reduce recruitment burden

Endpoint Optimization Analytics

- Improve statistical power
- Enhance endpoint selection via predictive modeling

Smart prediction and proactive optimization — AI drives end-to-end clinical transformation

How advance visualization supporting AI-Driven Clinical Trial

Protocol Deviation Metrics

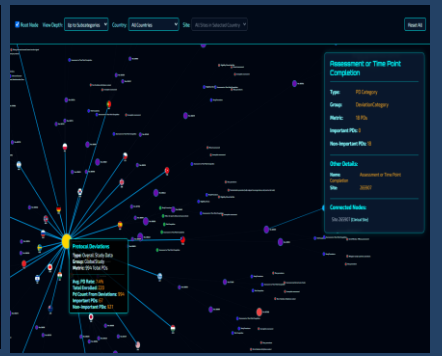
- **Country-Level Density**: Heatmaps showing deviation hotspots.
- **Drill-Down**: Country → Site → Category → Form → Field.
- **Trend Monitoring**: Review outlier deviation spikes over time.
- **Root Cause**: Correlate deviations with protocol sections or delays.

DESCRIPTIVE:

Protocol Deviation (PD) Analytics

PREDICTIVE:

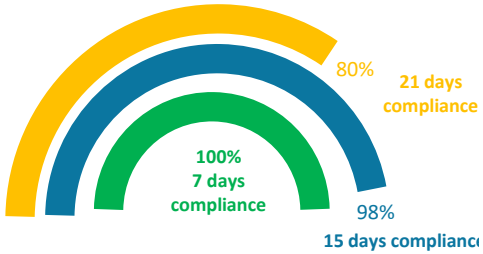
Protocol Deviation Causality



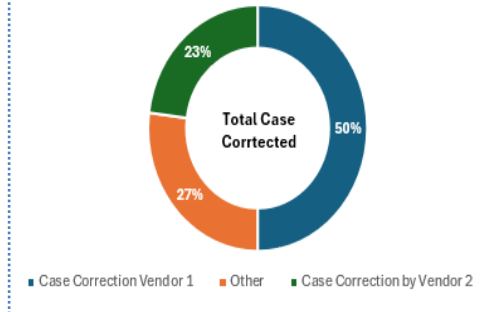
Site-Level Insights

- **Form/Field Tracking**: Monitor update frequency and types.
- **Rate Change Analysis**: Spot sudden surges in data entry or corrections.
- **Audit Trail Visualization**: Detect edit patterns for compliance and fraud.
- **Role-Based Density**: Identify frequent editors and workload risks.

Compliance Metrics



Data Correction Metrics



Imminent Transformation Highlights

The intelligence shift promises personalized medicine, faster access to life-saving treatments, and improved patient outcomes

Quantitative Highlights

~40 %	~30 %	~35 %
Faster Patient Enrolment	Cost Saving of CT	Timeline reduction in CT

by accelerating patient recruitment, increate enrolment success rate, automating data analysis , real time monitoring, risk based approaches & automating manual process…

Qualitative Highlights

- **Better Data Quality & Insights:** AI-driven analytics provide deeper insights and higher data integrity
- **Enhanced Patient Experience & satisfaction:** Patient-centric designs improve satisfaction and adherence, leading to more robust data

Experience Transformation

Trial Cost Reduction	Enhance Patient Outcomes	Clinical Trial Efficiency Gain	Faster Time to Market

Thank you