

The Intelligence Shift: AI Driven Clinical Trial

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Disclaimer

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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 trial
-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

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



Technology

- Legacy systems not scalable
- Lack of end-to-end digitalization
- Inadequate real-time analytics tools

The Intelligence Shift

Clinical Data Science



Clinical Data Scientists bridge domain expertise with data science, generating insights and predictive models.

Digital Twins and The Silico Trials



Digital twins and in silico trials to create virtual patient models and simulate disease-drug interactions.

Synthetic Control Arms



Simulating trial outcomes using historical patient data from sources like EHR, Clinical Registries etc. to speed up development

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.

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



Patient Recruitment

Mine vast amounts of data from clinical trial databases, registries, EHR, EMR to match participants with investigation treatments



Patient Stratification

Predict the probability of a serious AE, Based on **predicted risk** for these SAE, stratified patients into different groups and monitored accordingly



Dose Regimen Optimization

AI can predict how a drug behaves in the body, estimate how different doses will affect patients, and through QSP models forecast the dose-response curve even before a clinical trial begins.



Patient Adherence

Smartphone alerts, ePRO reminders, medication e-tracking, and digital biomarkers enable remote monitoring of patient adherence.



Endpoint Assessment

Detect clusters of signs and symptoms to identify a potential safety signal, as well as help detect cases with safety issues in real time



Patient Retention

AI-driven real-time insights from chatbots and DHTs help predict dropouts and AEs for better retention

Agentic AI the Game Changer

The Future of Study Setup: One Click. Zero Complexity

- Study docs, specs, test scripts can be generated in minutes
- UAT Testing no longer happens at the end,
- API-driven workflows promote standardization, reduce manual intervention, and create a traceable, integrated build lifecycle

Potential Benefit :

50-60% reduction in study-startup timelines with consistent, audit-ready documentation



Query Management powered by Agentic AI

- Manual data review is a legacy system
- Agentic AI does the heavy lifting: detecting issues, grading risks, and recommending actions long before a human ever gets involved

Potential Benefit :

40-50% reduction in data-cleaning timelines with consistent, audit-ready, real-time data oversight



Reimagining the SAP: From Months to Minutes.

- AI refines hypotheses, identifies evidence-based endpoints, and generates first-draft SAPs instantly
- Predictive models estimate recruitment, sample size, and effect size
- Better traceability and metadata consistency

Potential Benefit :

35-45% faster from protocol to CSR. Enables concurrent programming and accelerates study start-up.



Talk to data

- Just ask, and insights appear, No need of dashboards, no complexity
- A culture shift from data-consuming to data-driven
- Works as personal data analyst available 24/7

Potential Benefit :

Insights that once took hours now take seconds



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



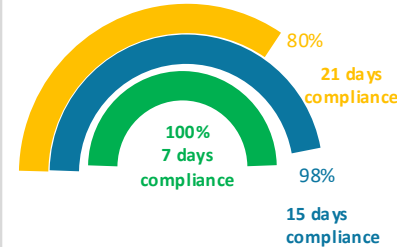
PREDICTIVE: Protocol Deviation Causality



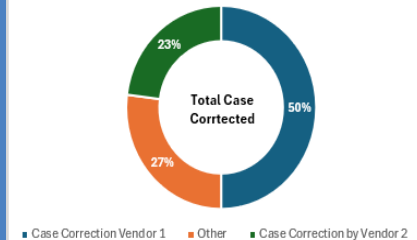
Site-Level Insights

- **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



The intelligence shift promises personalized medicine, faster access to life-saving treatments, and enhanced health impact

Quantitative Highlights

~40 %

Protocol to Go Live

~30 %

Manual efforts
reduction

~50 %

LPLV to DBL

by accelerating Protocol to Go live, real time analytics, 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

