

AI-Powered Trial Performance Copilot to Improve Speed and Efficiency of Clinical Trials



Mohit Sehgal, PhD
Practice Head- Cell, Gene &
Other Advanced Therapies,
Hexaware Technologies



Venkata Sureshbabu Bondu
Life Sciences & Healthcare Solutions,
Hexaware Technologies



Abstract

AI-powered trial performance co-pilot to accelerate clinical trials

Clinical trials generate vast amounts of complex data, presenting challenges for clinical study teams in efficiently analyzing and extracting meaningful insights. AI-powered Trial Performance Copilot offers an effective solution to this issue. It can rapidly analyze vast quantities of structured and unstructured data, serving as a powerful study team companion, which can generate insights and suggest effective interventions to improve clinical trial outcomes. It supports operational decision-making during clinical development by providing a single source of insights to speed up clinical trials. It empowers study teams in three important ways: conversational AI capabilities to provide tailored, context-aware, real-time actionable insights; smart alerts that enable proactive, early interventions; and automatic drafting of communications to enhance coordination and collaboration with cross-functional team members. This presentation discusses how this co-pilot helps study teams make faster go/no-go decisions and accelerate the delivery of life-saving treatments to patients.



About me

- **PhD in Cell & Molecular Biology**
Drexel University
- **Postdoctoral Research**
Drexel University College of Medicine
The Wistar Institute
- **Senior Research Scientist**
Cell & Gene Therapy Division, Intas Pharmaceuticals
- **Technology Solutions for Life Sciences & Healthcare**
Cognizant
Hexaware Technologies

Research Areas

- **Immunology**
- **Cancer Biology**
- **Infectious Diseases**
- **Cell & Gene Therapy**
- **Virology**



Agenda

1 AI in clinical trials

2 Clinical Trial Performance Copilot

3 AI Governance & Best Practices for Responsible AI

4 Conclusion

5 Q & A



Increasing complexity of clinical trials

Trial Design Complexity

- Complex Innovative Trial Designs such as Adaptive Protocols, Master Protocols
- Increase in Procedures
- Increase in Endpoints

Data Complexity

- Variety
- Volume
- Velocity

Operational Complexity

- Managing Global Studies
- Decentralized Clinical Trials

Clinical Trial + Real World Data

EDC	Labs	IRTs
CTMS	MDR	eConsent
eSource	eCOA	Imaging
Genomics	EHRs/EMRs	Claims
ePRO	Wearables	Social Media
Pharmacy	Registries	Health Surveys



“AI in Clinical Trials” Market is growing rapidly

PRECEDENCE
RESEARCH

AI IN CLINICAL TRIALS MARKET SIZE 2023 TO 2033 (USD BILLION)



Source: <https://www.precedenceresearch.com/ai-in-clinical-trials-market>

Key use cases of AI in clinical trials

- Clinical trial design and optimization
- Clinical Trial Performance Copilot
- Trial site selection and activation
- Patient selection
- Synthetic data generation
- Data analysis and interpretation
- Adverse event monitoring
- Patient-reported outcome (PRO) collection
- Regulatory submissions
- Code Generation for stats programming
- Automation of CSRs & other submission docs
- Real-time monitoring and decision support



Clinical Trial Performance Copilot

AI-powered study companion and conversational agent to enhance trial management

Key features

✓ **Data analysis and insights**

Analyze clinical and operational data from multiple sources to identify potential issues, trends, and areas for improvement within a clinical trial

✓ **Predictive modeling**

Based on historical data, predict potential challenges and proactively suggest mitigation strategies

✓ **Automated alerts and notifications**

Generate timely alerts when key metrics deviate from target ranges

✓ **Decision support**

Provide actionable recommendations regarding site selection, patient recruitment strategies, and other critical decision points

✓ **Facilitate Communication**

Generate concise reports, draft emails, and summarize complex data for better collaboration among team members and stakeholders

Benefits

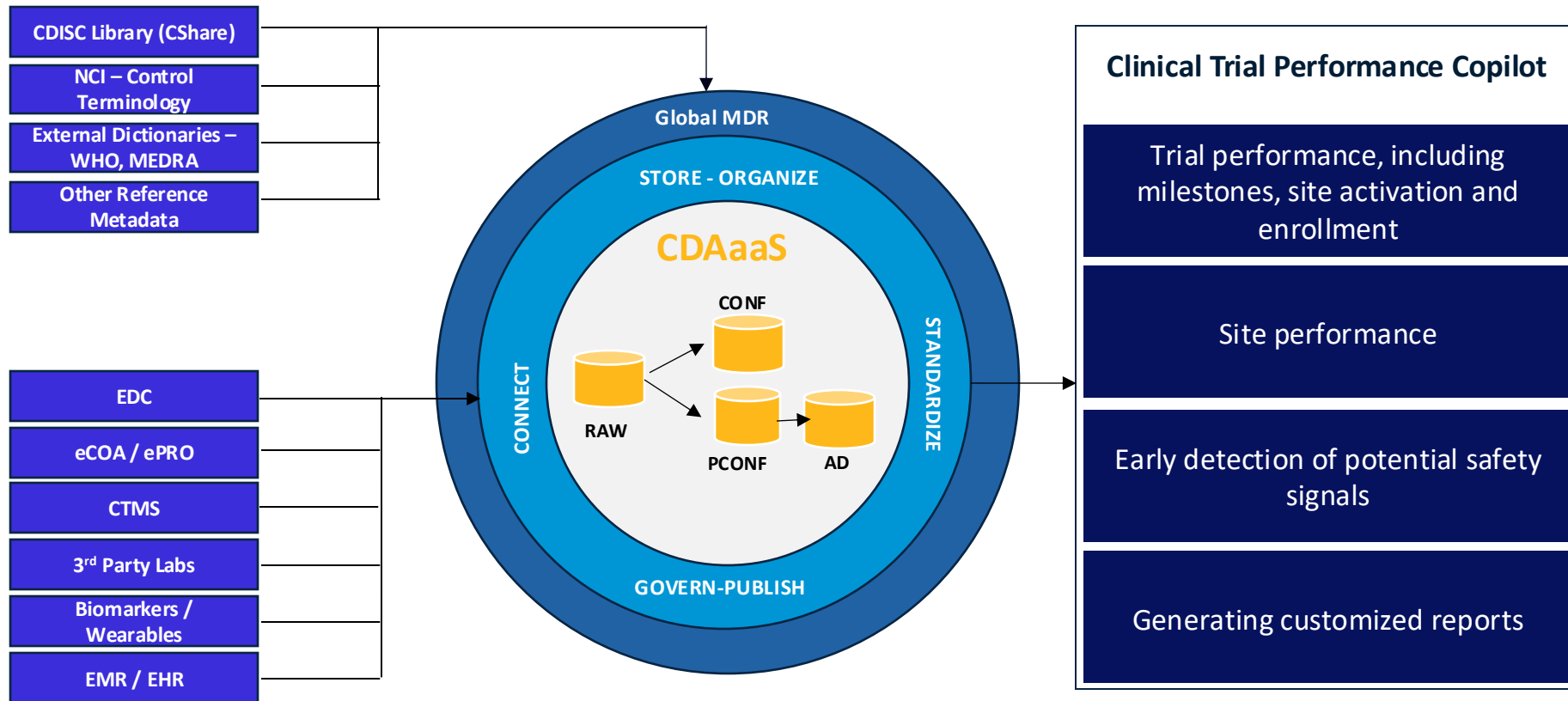
✓ **Faster trial completion**

✓ **Cost efficiency**

✓ **Higher success rate**



Unified Data Platform to collect, manage and analyze data from multiple sources





Let's look at a specific scenario

Clinical Trial Manager

Why is my trial behind plan?

Copilot

Your enrollment forecast is 20 days delayed because screening is behind plan, with two sites turning dormant last month

Clinical Trial Manager

Which sites are dormant and why?

Copilot

Site A and Site B became dormant, with no screenings in past 2 months, due to PI turnover

Copilot

Here is an email I drafted that can be sent to the new PIs at Site A and Site B



AI Governance

Set of guidelines, principles, frameworks, policies, and best practices that:

- Maximize the benefits of AI while minimizing potential risks
- Ensure that AI systems are built, deployed, and used in a way that aligns with business, legal, and ethical requirements

People + Process + Technology

Ethical/Responsible/Trustworthy AI



Transparency & Explainability



Privacy & Data Governance



Human Oversight



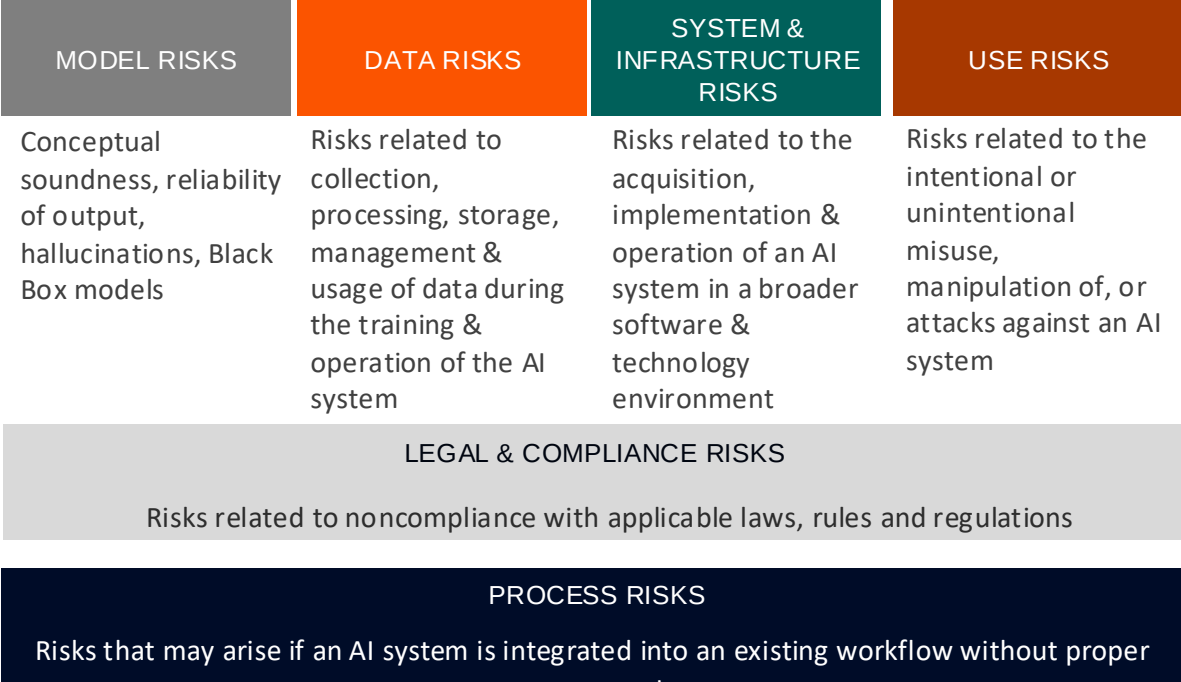
Technical Robustness, Safety,
Accuracy & Reliability



Accountability

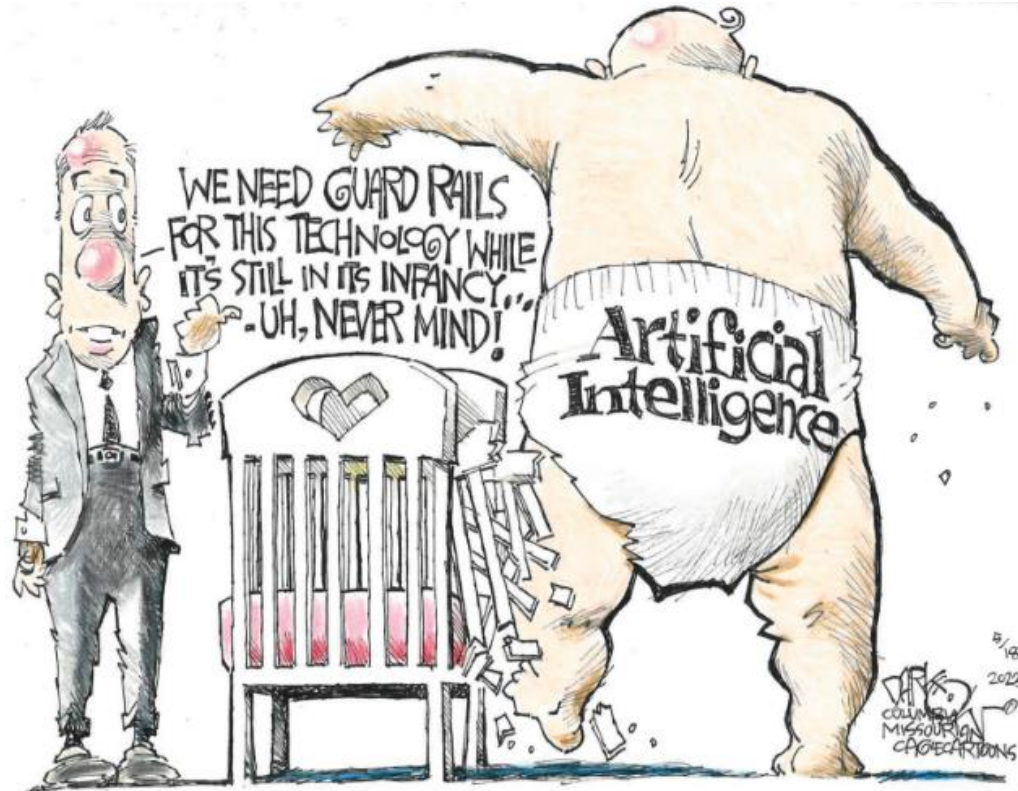


Societal and environmental
well-being



AI/Gen AI is poised to transform clinical trials

However, success requires organizational change, redesigning of processes and guardrails to ensure ethical and responsible use of AI



Thank You!



Mohit Sehgal, PhD
mohits12@hexaware.com



Venkata Sureshababu Bondu
VenkataSureshBabuB@hexaware.com