2025 Global Harmonization Center Clinical Trials Webinar

Trends in Clinical Trials & Updates on ICH Guidelines

Trends in AI and Disruptive Technology in Clinical Development

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Agenda

01 Trends in Clinical Development

02 Trends in AI

03 How is AI currently being used in clinical development

04 What’s coming next?

05 Implementation challenges

06 Key takeaways

01 Trends in Clinical Development

Getting the right treatments to the right patients faster

Cost pressure

Up to **$2.5bn** to develop new medicines[1]

Acceleration

8-12 years development timelines[2]

Patient-centricity

Voice of the patient, decentralisation, DEI etc

The complex landscape of modern clinical development

Data complexity

60% more complex, more data & sources[3]

RBQM

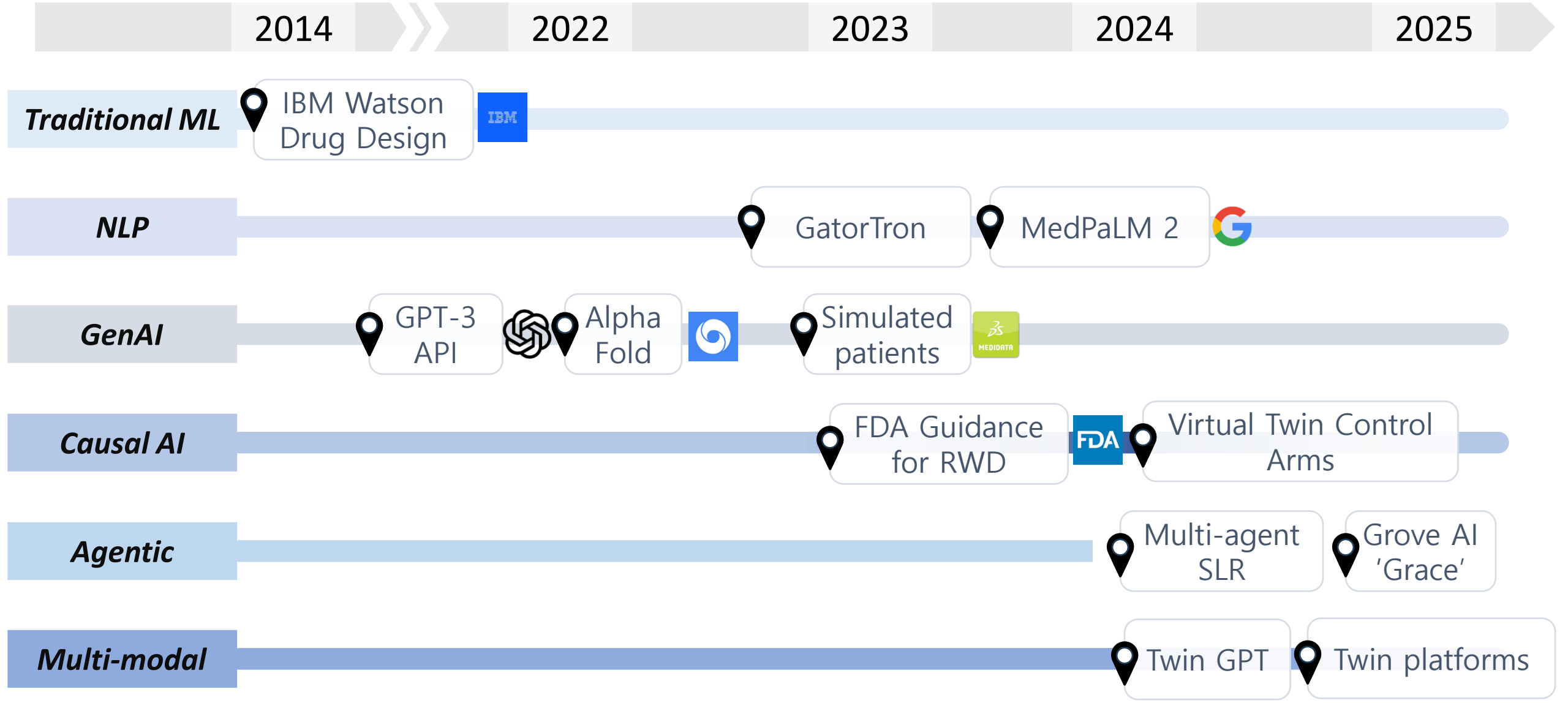
ICH E6 R3 – monitoring, review, cleaning etc

Quality

Documentation, inspection readiness

1 - Pharmaceutical Research and Manufacturers of America, 2024
2 - Tufts Center for the Study of Drug Development
3 – Saama, 2024

02 Trends in AI



03 How AI is currently being used in clinical development

At-scale use of classical AI	*Pilots using classical AI*	*Pilots using next-gen AI*
Risk-based site monitoring	Adaptive protocol optimisation	Causal AI for patient enrolment
Large-scale data analytics	TMF Bots	GenAI document drafting
NLP for medical coding & AE processing	Data-driven site feasibility	Multimodal patient identification

Most AI-powered tools are still in pilot stage – an estimated fewer than 10% of PoCs make it past 3 months

04 What's next?

Deploying the right solutions at scale to tackle the key challenges in Clin Dev

Further scale-up of classical AI

Automation

- Data cleaning & query management
- Real-time data reconciliation
- Extraction, integration & harmonization from multiple sources

Machine Learning

- Enrolment forecasting
- Budgeting & resource allocation
- Predictive patient retention

Getting value from next-Gen AI

GenAI

- Clinical document generation

Causal AI

- Trial simulation & optimisation
- Synthetic control arms

Multimodal AI

- Real-time multi-source data analytics

Agentic AI

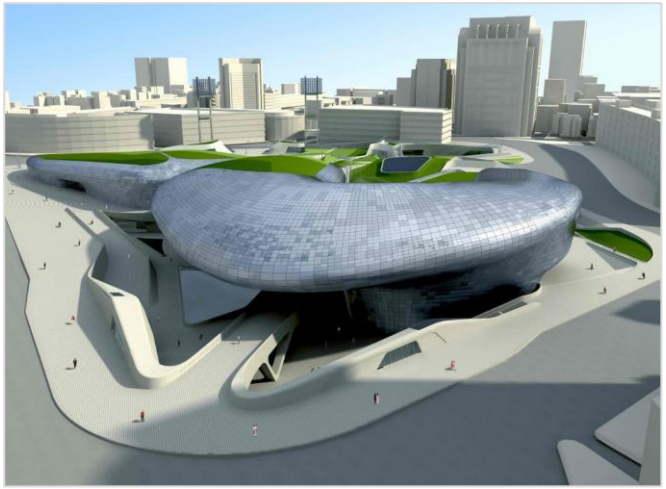
- Continuous data monitoring

04 What's next?

A complete revolution of Clinical Development?

Incremental improvement: adding AI on top of existing technology and processes

Total innovation: agentic-driven, automated clinical development



05 Implementation challenges

What's stopping us?

Business Challenges

Poor collaboration between business, end-users, IT, and development:

- Leadership understanding
- Focus on hype
- Ease of PoC build vs challenge of scale
- End-user input and adoption

Structural Challenges

- Regulatory landscape
- Legal & compliance risk-aversion
- Access to internal data
- Access to emerging tools

06 Key takeaways

1. AI is not currently being deployed at transformative scale in clinical development, but incremental solutions are being increasingly in place

2. We should not over-index on newer AI-powered technologies for situations where more established machine learning and advanced analytics are more appropriate

3. It is important to consider investing in both ‘short-term wins’ as well as longer-term technologies and capabilities

4. The greatest limitations to realising value are collaboration and regulation, not the technologies

Thank You