Halloran

A ProductLifeGroup Company

Life science *insight*, life-changing *impact*

Thank you for joining us!

It was a pleasure to have you attend our webinar

AI in Clinical Development – a Global Primer on Regulatory Expectations

Watch the Recording

KEY TAKEAWAYS

Audience Poll Responses

1. **How are you currently using AI in clinical trials?**
   a. Actively using: 4%
   b. Planning to implement: 22%
   c. Exploring: 52%
   d. No plans currently: 22%
2. **What is your biggest challenge in implementing AI in clinical trials?**
   a. Regulatory uncertainty: 57%
   b. Lack of internal/external expertise, availably systems, budget: 36%
   c. Culture: 0%
   d. Other: 7%

Key Use Cases

- Patient recruitment and site selection
- Clinical trial protocol optimization
- Risk-based monitoring
- Document automation and data cleaning

Regulatory Perspectives

- While AI-driven innovation is exciting, and global health authorities are increasingly acknowledging AI's potential, they are proceeding with measured caution, particularly in the clinical settings where patient safety, data integrity, and reproducibility are non-negotiable.
- FDA: The FDA emphasizes risk-based oversight, transparency, and lifecycle management to ensure AI tools are fit for regulatory decision-making through a combination of Good Machine Learning Practice (GMLP) principles and a Draft Guidance, Regulatory Decision Making for Drug and Biological Products, that outlines a seven step framework for assessing AI model credibility based on Context of Use.
- EMA: AI Act provides a legally binding framework categorizing AI systems by risks, and setting clear obligations for high-risk applications including those used in clinical trials. The complimentary EU Reflection Paper outlines strategic governance principles for responsible AI use.
- WHO: Focused on ethics, governance, equity, and transparency.
- All Agencies require transparency re: how the AI model is developed, how it was trained/tuned, data usage, bias controls, and how the model's performance will be monitored throughout the lifecycle.

SPEAKERS

- Sheila Gwizdak, Vice President, Strategic Consulting Solutions, Halloran
- Jessica Fowler, Associate Principal Consultant, Halloran
- Caitlin Schuler, Consultant, Halloran
- Kanchana Iyer, Senior Consultant, Halloran

ABOUT HALLORAN

Halloran Consulting Group is a life science consulting firm providing strategic development, regulatory, quality, clinical, and organizational support to industry leaders in the pharmaceutical, biotechnology, and medical device sectors. Our consultants are subject matter experts with technical and strategic expertise, who deliver a tailored approach to each engagement, successfully propelling our clients to their next inflection point.

Operationalizing Compliance – a Key Challenge

- It's one thing to understand the guidance in theory but operationalizing it across global programs is where the real challenges begin.
- One of the biggest challenges is demonstrating model credibility, especially in GxP-regulated environments. Ultimately, the model needs to be sufficiently credible for its intended use in regulatory decision-making.

Global Risk Planning

- When you're designing a global trial with AI-enabled systems, you're navigating a fragmented and evolving regulatory landscape, which demands proactive risk management. Sponsors should ask: What are the potential risks? How will those risks be detected and mitigated? How may we explain our model's credibility during early engagements with Health Authorities?

Looking for support to assess your AI readiness or build a roadmap for compliant implementation? Let's connect today.