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KEY QUESTIONS

When Considering AI in Clinical Trials

Are you a life sciences sponsor or CRO exploring the use of AI for data collection or management in clinical trials? AI can help the industry move faster, increase data accuracy, and reduce costs— but it's human judgment and expertise that turns AI insights into actionable steps.

With human feedback and oversight, AI can produce accurate and reliable results, even in a niche and regulated environment. By keeping a human-in-the-loop, you ensure that AI adapts and thrives.

AI isn't here to replace human expertise—
it's here to super-charge it!

QUESTIONS to understand AI benefits and limitations:

1 What is the underlying model? How was it trained?

Understand the AI's underlying algorithms and development process to support its reliability. A careful approach to methods and training will reduce the risk of incorrect, misleading, or fabricated information.

2 How is data quality ensured before AI processing?

Ask your CRO for information on the EDC's pricing, capabilities, customization options, data validation features, reports, security measures, integration capabilities, and optional services.

3 Are there protocols for identifying and addressing data quality issues?

Verify if protocols exist that address data quality issues to aid quality AI performance and optimal trial outcomes.

4 How does the AI handle missing or incomplete data?

See a live demonstration of the EDC. Understand how the system will address trial-specific needs, user-friendliness, data collection, validation, and reporting.

5 What data sources are being used for AI training and analysis?

Evaluate the breadth and relevance of information available to the AI to foster confidence in its capacity to generate robust insights. Carefully curated data will result in quality AI outputs.

6 What is the interpretability of the AI outputs?

Facilitate better decision-making by making sure study stakeholders can interpret, trust, and communicate outputs.

7 How is the AI system validated? Are there ongoing evaluations?

Clarify how the AI is validated and re-evaluated so it consistently performs as expected under real-world conditions. Be aware of regulatory requirements for Computer Systems Validation.

8 How does the AI adapt to new data?

Understand how the AI adapts new or unexpected data types in dynamic trial conditions.

9 What regulatory considerations are addressed?

Maintain compliance with relevant regulations and guidelines so data is legally acceptable upon submission.

10 What are the potential biases in the AI models?

Identify potential biases that could impact data accuracy, interpretation, and patient outcomes.

11 What is the impact on trial timelines and costs?

Assess the effect of AI on timelines, trial costs, and overall efficiency.

12 How will user training and support be provided?

Know what resources will be available to stakeholders to empower effectively utilizing AI tools.

Connect with Medrio experts to learn more about introducing efficiencies in your trials.

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