THE FUTURE OF DATA AI

Guidelines for Using AI in
Data Interoperability for Clinical Trials

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Guidelines for Using AI in Data Interoperability for Clinical Trials

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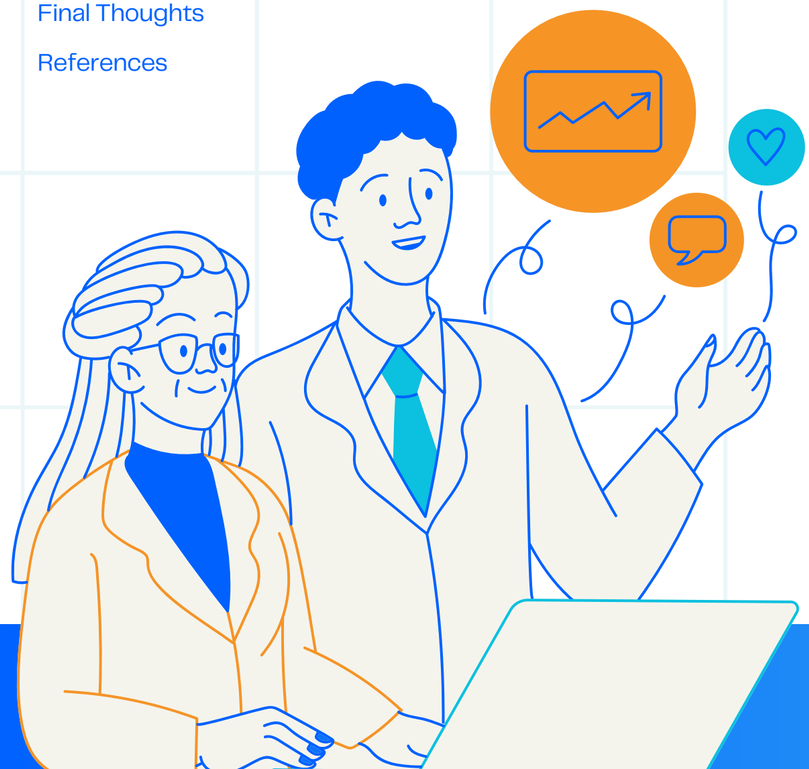


INTRODUCTION

How AI & Data Tools Are Changing Trials

Clinical trials are hard. They take time, money, and a lot of effort. Over the years, I've seen how AI and tools like data management software can help. They don't just make things faster. They fix real problems with clinical data and help trials run smoother.

This book shares ideas about how AI and data analytics are making trials better. It shows how tools like clinical trial management systems and data analytics platforms can make a difference. The message is simple: AI is powerful, but people still play a big role.

Each chapter gives tips and examples you can use. You'll learn how clinical research data management and data analysis can save time and improve results. My goal is to spark ideas and show new ways to tackle challenges in clinical trials. I hope you find something useful to apply in your own efforts.

Can We Trust AI in Clinical Trials?

Clinical trials are essential for medical progress, but they're slow and complex. They produce a huge amount of data from many different clinical data management sources—EDC, CTMS, eCOA.

Making sense of it all takes time. AI can speed up the data processing and uncover insights faster. But speed isn't everything. Trust in AI remains a challenge. In clinical trials, accuracy isn't optional—it's critical.

The Problem: Can We Rely on AI?

AI can make mistakes. It sometimes generates results that are inaccurate or speculative, called "hallucinations." In clinical trials, such errors can have severe consequences. A single bad insight could ruin a study. A call to address AI "Hallucinations" paper published in *Cureus* (Hatem et al.) highlights the criticality of the problem and suggests strategies to mitigate the risk.

At Adaptive Clinical, we take this seriously. We use proven patterns and validated data to guide AI decisions as part of clinical data management. We track every result back to its source. We also incorporate human oversight (HITL) to review and refine the AI's findings. These strategies help AI wrappers for clinical databases produce reliable results that can be trusted. They align with recommendations from research on creating trustworthy large language models in healthcare AI (Ahmad et al.). With the right safeguards, AI doesn't guess. It knows when to stop and deliver valid conclusions.

Building Trust in AI

Growing public skepticism toward vaccines and medical science overall shows how fast doubt can grow. AI can help rebuild that trust. It provides clear, traceable answers and reduces human errors. It can also make trials faster without cutting corners. However, it's important for AI to enhance clinical data management systems to recognize their limitations. Research in PLOS Digital Health (Templin et al.) underscores the importance of embedding transparency and accountability into AI to increase trust in healthcare settings.

The Path Forward

AI works best when it's paired with human expertise. It's not just about speed—it's about confidence. At Adaptive Clinical, we build AI systems that are transparent and accurate. We're here to help trials run faster, smarter, and more reliably. Trust is earned, and we're committed to earning it.

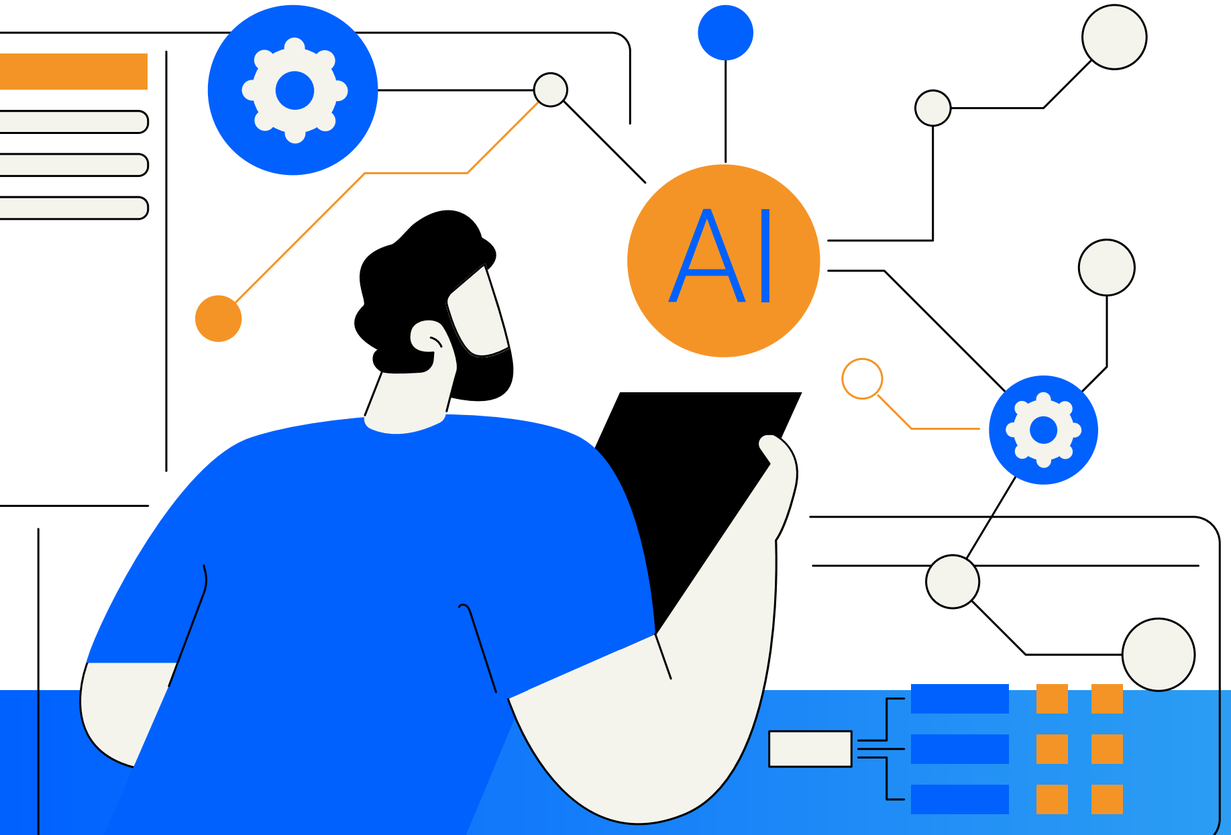
> **"WHEN IT COMES TO USING AI IN CLINICAL TRIALS, ACCURACY ISN'T OPTIONAL – IT'S CRITICAL."**

Embracing AI: Revolutionizing Clinical Trials

The life sciences industry is at a crucial point. Traditional healthcare models are giving way to digitized, personalized, and data-focused methodologies. Here, incorporation of cutting-edge technologies like artificial intelligence (AI) and generative AI onto data management software is becoming increasingly prominent. In this transformative era, the potential of these technologies to reshape clinical trials is remarkable. (Esteva et al.)

Clinical trials - the cornerstone of pharmaceutical and healthcare - innovation, have long grappled with challenges such as data management, data interoperability, privacy, and operational efficiency. However, the emergence of AI and generative AI heralds an optimistic path forward. Harnessed effectively, these technologies could redefine the entire scope of clinical trials by enhancing data interpretation and data analysis, bridging data gaps, and driving efficient operations. (HealthIT.gov: Interoperability, 2023) The future of clinical trials is upon us - it's adaptive, automated, private, and driven by AI. (Reddy et al.)

The emergence of AI stands in stark contrast to the prevailing trend in clinical trials and the broader Life Sciences industry, which often focuses on incremental improvements. An apt illustration of this contrast can be found in a recent newsletter, where the innovative usage of generative AI in EHR systems was set alongside the advantages of transitioning from physical to cloud-based fax technology for enhanced compliance. (Fax, really?) In the same issue, another article compares ChatGPT and other personal assistants with evidence-based answers to public health questions. Both articles highlight a great opportunity for the industry to fundamentally rethink and update current practices, improve communications and, ultimately, patient outcomes. The clinical data management technology is available, and it's time for industry to harness it to its fullest potential. (EHR Intelligence, June 20, 2023)



In summary, the integration of AI and generative AI in clinical trials harbors immense potential for the future of healthcare. It offers solutions to long-standing challenges in clinical trials, ranging from data interoperability to data analytics to privacy concerns. Equipping the industry with the necessary technology and tools to leverage the power of AI while safeguarding data privacy and ensuring operational efficiency is critical as clinical trials seek new automation and self-service tools. The future of clinical trials is upon us - it's adaptive, automated, private, and driven by AI. (Reddy et al.)

Conquering Bias with Precision Focus - Harnessing Specialized Expertise in AI

In the realm of artificial intelligence, "bias" often carries a stigma, yet a shift in perspective can transform it into a valuable asset. When bias is recast as focused expertise, it becomes a powerful tool, especially within the framework of private AI utilizing proprietary data.

The Power of Specialized Data

Private AI augmented clinical data management software systems, equipped with high-quality, proprietary data, cultivate a depth of knowledge in niche domains. Adaptive Clinical's work serves as a prime example, where our experience in integrating data flows from biometrical devices to EDC, analyzing EMR systems, and managing CTMS feeds, has created a wealth of focused patterns. Such patterns, amassed through numerous projects, represent a concentrated form of knowledge that's been shown to improve AI's effectiveness in specific domains (Murff et al.).

Bias as Focus

This repository of experience can be considered a form of "good bias". It's not a prejudice or a blind spot but a cultivated expertise. The AI models, "biased" by these specific patterns, are not constrained but empowered to perform more effectively in their specialized roles (Rajkomar et al.). It's akin to a seasoned doctor whose years of focused practice enables a sharper diagnosis.

Focused AI for Future Success

For companies like Adaptive Clinical, this focused expertise becomes a strategic asset. It guides our AI models to navigate complex projects with an informed understanding that generic models simply can't match. This demonstrates how a nuanced form of "bias" can be reframed as an invaluable focus, improving the efficiency and success in specialized fields. (Beam & Kohane)

Conclusion

The distinction between bias and focus is a matter of context and application. Under the right conditions, what is often perceived as bias can be an asset, providing AI systems with a level of expertise that's unmatched by generic models. Embracing this strategic focus could be the key to unlocking new horizons for AI's application in specialized industries.

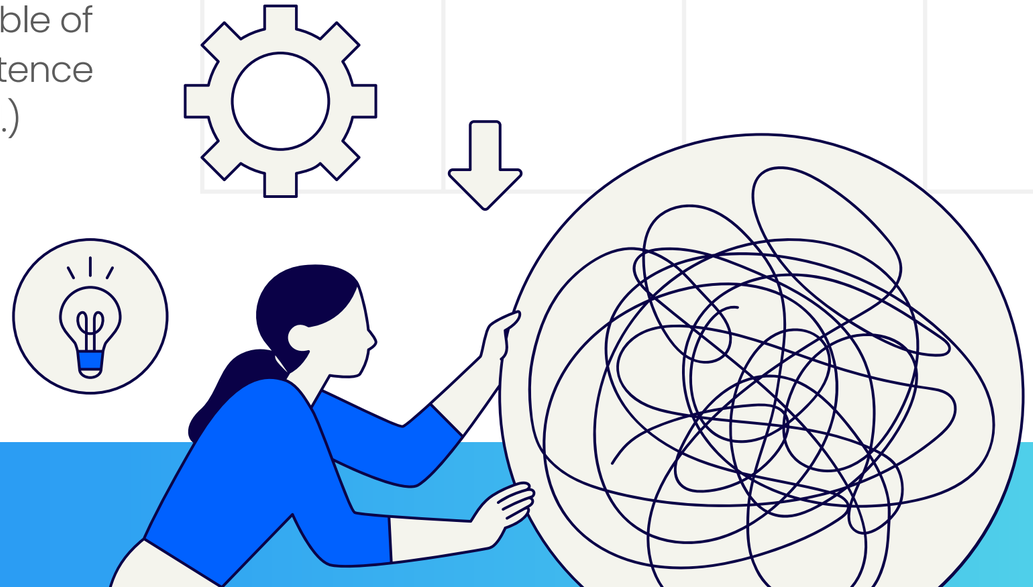
Integrating AI and Human Insights: Enhancing Clinical Trials with HITL AI

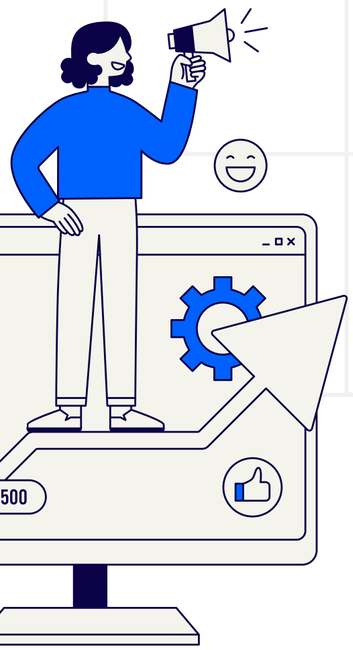
Healthcare professionals, clinical trials data scientists, and tech enthusiasts are exploring how Artificial Intelligence (AI) and Human-in-the-Loop (HITL) bring about significant improvements in clinical trials, by enhancing efficiency, accuracy, and prioritizing patient needs. AI and HITL as complementary technologies are pivotal in shaping the future of clinical data management and therefore medical research. The mechanics behind this transformation are essential for the future of healthcare, illustrated by insights from key research.

AI's Diagnostic Precision

AI's ability to diagnose diseases like skin cancer with accuracy comparable to human experts marks a significant advancement in medical diagnostics. The work of Esteva et al. illustrates how AI using CNNs (Deep Convolutional Neural Networks) and "achieves performance on par with all tested experts (...) demonstrating an artificial intelligence capable of classifying skin cancer with a level of competence comparable to dermatologists." (Esteva et al.)

This progress is a testament to the synergy between AI's analytical capabilities and human oversight. Esteva et al.'s work exemplifies the potential of AI in enhancing diagnostic processes when complemented by human expertise.





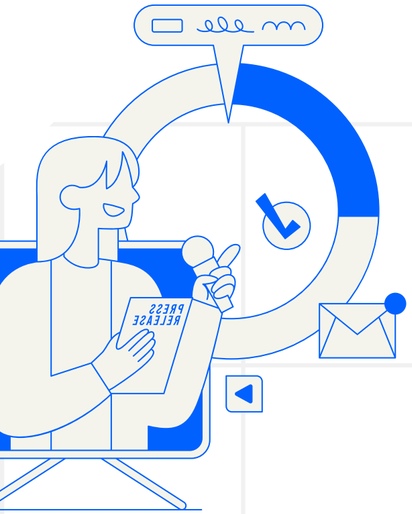
Navigating AI Bias with Human Guidance

Addressing bias in AI systems, especially in healthcare, is a multifaceted challenge. It requires not just identifying biases but actively working to mitigate them. (Holstein et al.) It emphasizes the necessity of human oversight in AI development, ensuring that AI systems are guided by ethical principles and inclusivity. At the same time Holstein et al.'s research highlights the need for "explicitly considering biases that may be present in the humans embedded in the various stages of the ML development pipeline, such as crowd workers who annotate training data or user-study participants tasked with surfacing undesirable biases in ML system.

Moreover, "Conquering Bias with Precision Focus," explores how perceived biases can be reframed as specialized expertise, enriching AI's development, and applications. This perspective underlines the synergy between AI insights and human expertise, reinforcing the significance of human input in refining AI tools.

> **"WITH THE RIGHT SAFEGUARDS, AI DOESN'T GUESS. IT KNOWS WHEN TO STOP AND DELIVER VALID CONCLUSIONS."**

Enhancing Decision-Making in Clinical Trials with Human-AI Collaboration



In clinical settings, decisions often involve complex judgments that benefit significantly from the nuanced understanding of healthcare professionals. AI systems, designed with an understanding of human intuition's role, can provide valuable support by offering data-driven insights that complement human judgment. The integration of human intuition and AI predictions marks a significant advancement in refining clinical trial methodologies.

Chen et al.'s study delves into the dynamics of this relationship, revealing pathways through which human decision-makers can effectively integrate their intuition with AI-generated data: “Our findings provide fundamental knowledge about the human-AI decision-making process that could support a generalizable understanding of when and what explanations can help decision-making, and point to user needs for AI decision-support systems that better accommodate human decision intuition, are more compatible with human intuition, and support a more critical understanding of AI.” (Chen et al.)

Streamlining Data Management

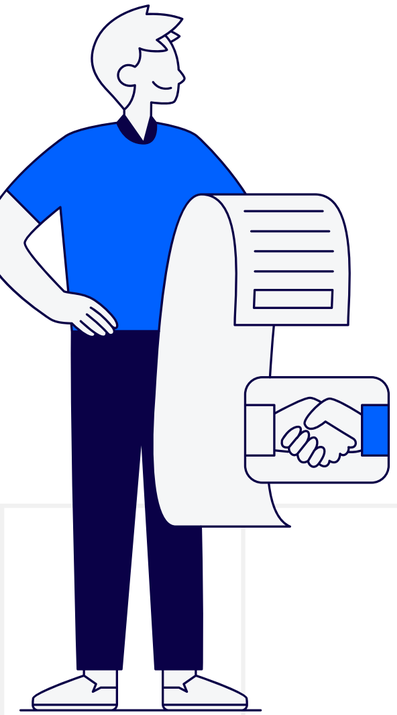
AI and HITL are transforming the management of data in clinical trials, making the data exchange and interoperability between systems more efficient, precise, and automated. This shift highlights the beneficial impact of blending AI with human insights on clinical research data management. “AI can automate many tasks in SDTM transformation, such as data cleaning, mapping, and transformation. This can free up human resources for more complex tasks like data analysis and interpretation. AI can also help improve accuracy by identifying and correcting errors. However, human oversight is critical to ensure data is converted accurately and by regulatory requirements.” (Thukral & Bhardwaj)

Conclusion

Integrating AI with human insights — or more aptly, human expert insights — signals a transformative impact on clinical trials and healthcare outcomes. It's clear that AI could bring to light insights and analytics previously obscured, while human expertise remains invaluable, blending nuanced understanding with AI's analytical prowess. This fusion promises a future where clinical trials are not just faster and more efficient but also deeply aligned with patient-centric values, driving forward healthcare innovation. This takes data analysis and moves it data science.

Bridging Clinical Trials with AI: The Effectiveness of Adaptive Tooling and Data Architecture

In the realm of clinical trials, data is the compass guiding us to the desired outcomes of life science research. The emergence of innovative data architectures highlights the central importance of seamless data management, interoperability, and real-time data exchange. At Adaptive Clinical Systems, we navigate the landscape with a suite of robust tools, facilitating the construction of a data ecosystem conducive to agile, precise, and compliant clinical trials.



Introduction to the Modern Data Architecture Landscape

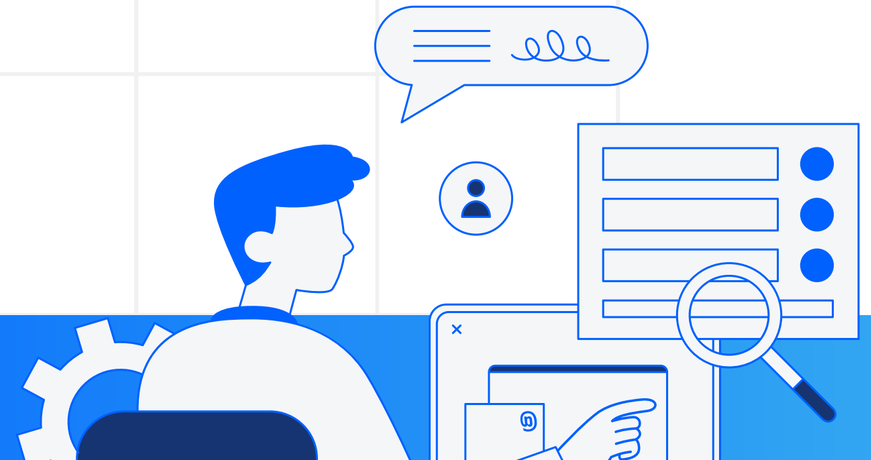
The transition from Data Lakes and Data Warehouses to the comprehensive approach of Data Lakehouse architecture has been crucial, especially for the Life Sciences domain. This transformation facilitates a structured yet flexible data management framework, fostering a seamless flow of data across various stages of clinical trials (Datanami, 2022; Datanami, 2023).

Secure Data Sharing through Adaptive Tooling

Adaptive's eClinical Bus and connectors have been instrumental in promoting secure data sharing, paralleling the capabilities of AWS RDS. By enabling real-time data exchange, these tools significantly enhance collaborative efforts and streamline operations across clinical trials. (AWS, 2023).

Upholding Data Quality for Precise Insights

Our automated AI-driven data mappers are akin to Snowflake's Streams and Tasks, emphasizing the importance of high-quality real time data at the source. Ensuring the accuracy and consistency of data is paramount for deriving precise insights that drive informed decisions in clinical trials (Snowflake, 2023).



Robust Data Management for Consistent Access and Integrity

Our tools not only offer interoperability with widely acknowledged generic data management platforms, but also provide the adaptability to integrate with specific clinical trial data systems like Veeva, Medidata and Medrio, managing data from healthcare device manufacturers like Massimo, Medisante, etc. This unique blend of generic and specific data management capabilities sets us apart, ensuring data integrity, consistency, and accessibility.

Data Security and Compliance as Cornerstones of Patient Trust in Clinical Trials

Our end-to-end encryption protocols, along with practices similar to Dynamic Data Masking and secure views, form a robust foundation for safeguarding patient confidentiality and ensuring compliance. Incorporating privacy-preserving AI techniques further solidifies our commitment to data security, fostering a trustworthy environment for all stakeholders. Moreover, our focus extends to ensuring stringent compliance with regulatory standards like PCI-DSS, HIPAA/HITECH, FedRAMP, GDPR, FIPS 140-2, and NIST 800-171 through our adaptive tooling. Our proactive approach significantly mitigates risks and fosters a compliant data management ecosystem, exemplified by our AI that learns from project data without compromising client confidentiality (Microsoft Azure, 2023).

Conclusion

Adaptive Clinical Systems, with its eClinical Bus, connectors, and automated AI-driven data mappers, stands at the forefront of navigating the data landscape effectively. Our industry-leading solutions are not merely a response to the evolving data architecture landscape but a leap forward, ensuring that the domain of clinical trials is well-prepared to embrace the future.

Final Thoughts: 6 Simple Steps to get started with AI

We've talked about how AI can improve clinical trials. Now it's time to think about how to use it effectively. Here are a few points to keep in mind:

1. **Maintain Trust**
   Use reliable tools like clinical database software. Use clean, verified and validated data. Always double-check results to ensure accuracy and traceability.

2. **Work With AI**
   Think of AI as a partner, not a control layer. People still need to make the big decisions based on data analysis.

3. **Use the Right Tools**
   Platforms like Adaptive eClinical Bus make clinical data management and integration easy. They save time and reduce errors.

4. **Focus on Patients**
   Use AI to find patients, track their progress, and improve care. Keep patient-focused data science as your goal.

5. **Stay Flexible**
   Technology evolves fast. Be ready to try new business analytics tools or adapt your clinical trial management system as needed.

6. **Teach Your Team:**
   Help your team understand the value of AI and data management software. Show them how it can help and where to be careful.

AI and tools like data analytics platforms can make trials faster and more accurate. But there is no magic - they still need planning and smart use. When you combine them with people's skills, you can improve trials and help patients.

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