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Rethinking Automation in the AI Era

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ABSTRACT

While artificial intelligence continues to shape conversations around clinical data transformation, many teams risk overlooking the immediate opportunity of expanded use of automation intelligence across the end-to-end data lifecycle. The integration of process automation, rule-based logic, and domain expertise enhances decision-making and improves consistency- complementing, not replacing human input. This session explores how thoughtfully embedded automation intelligence – used alongside targeted AI- realizes tangible value across use cases from statistical programming to pharmacovigilance. Drawing on practical applications from a CRO environment, we'll look at how automation has been used to streamline data flows and reduce manual rework, ultimately contributing to more efficient delivery. The aim is to share not just outcomes but also pose questions and spark discussion as we look ahead to a future of integrated AI and intelligent automation.

INTRODUCTION

In clinical trials today, artificial intelligence seems to be both everywhere and nowhere all at once. Conferences are packed with AI panels, vendors promise intelligent automation, and sponsors ask how AI will accelerate database lock or regulatory submission. Yet, when it comes to real, practical implementation, many teams are still figuring out what AI can do, what it should do, and what actually counts as AI.

This paper sets out to discuss and clarify the roles of automation and AI in clinical data workflows. Automation intelligence which is rooted in rule-based logic and repeatable processes tremains the most suitable solution for many routine, high-volume tasks, ensuring quality, speed, and regulatory compliance. AI, meanwhile, is typically best applied to complex pattern recognition, adaptive analytics, and tasks where human expertise can be augmented rather than replaced.

We will share practical examples from programming, medical writing, and video analytics, with the goal of provoking discussion about how integrated intelligent systems can solve current challenges while preparing teams for future opportunities. By balancing innovation with responsibility, and keeping human expertise at the center, we can realize the full potential of both automation and AI in clinical research.

AUTOMATION OR AI?

In clinical research, choosing between automation and artificial intelligence (AI) depends on the nature of the task, the complexity of the data, and the need for regulatory compliance.

Automation is usually most suitable for:

Repetitive, rule-based tasks: These include standard data mapping, routine report generation, and quality control checks. Automation excels at tasks that require consistency, speed, and traceability, such as programming SDTM and ADaM datasets or generating standard tables, figures, and listings (TFLs).
Processes requiring auditability: Automation ensures that every step is documented and reproducible, which is essential for regulatory submissions and inspections.
High-volume, low-variability workflows: When the process is well-defined and the data structure is stable, automation delivers efficiency without sacrificing quality.

AI is currently most suitable for:

Complex pattern recognition: AI can identify anomalies, trends, or outliers in large, unstructured datasets, such as video/audio data in decentralized trials or sentiment analysis in patient-reported outcomes.
Adaptive analytics and prediction: AI models can learn from data, suggest mappings, detect errors, and support decision-making in areas where rules alone are insufficient.
Augmenting human expertise: In disciplines like medical writing, AI can accelerate report generation, flag inconsistencies, and assist with validation, but always requires human oversight to ensure context and accuracy.

Blurring the Line:

In practice, the distinction between automation and AI is not always clear. Many tools marketed as "AI" are, in fact, advanced automation, involving streamlining processes without learning or decision-making capabilities. The most effective clinical workflows will combine automation for efficiency and AI for insight but always keeping human expertise at the center.

USE CASES

Selecting the right approach, whether automation or artificial intelligence, depends on the specific challenges faced in clinical research. Automation excels in tasks that are repetitive, rule-based, and require high consistency and traceability, making it indispensable for standard data processing and regulatory workflows. AI, on the other hand, is most valuable where data complexity, variability, or the need for adaptive analysis exceeds what rule-based systems can handle.

The following use cases have been highlighted to illustrate this distinction and demonstrating how automation and AI are applied to solve real problems in programming, medical writing, video analytics, and data management. By examining these scenarios, we will highlight not only the efficiencies gained, but also the importance of expert oversight and the need to balance innovation with regulatory and operational requirements.

VIDEO & AUDIO DATA ANALYTICS

With the rise of decentralized trials and patient-reported outcomes, long-form video and audio data have become more common. AI-enhanced analytics can streamline the review of these media by extracting transcripts, keywords, and sentiment, allowing reviewers to quickly identify areas of interest. Visualization tools, such as heatmaps layered onto video timelines, help experts focus their attention where it counts, improving efficiency without sacrificing interpretability.

DATA ANONYMIZATION & HARMONIZATION

Preparing large clinical datasets for reuse often requires anonymization and harmonization across multiple sources. AI-powered tools can automate the removal of personally identifiable information and standardize data structures, enabling secure data sharing while maintaining compliance with privacy regulations. Automation ensures consistency and auditability, while AI can adapt to complex data scenarios and evolving requirements.

MEDICAL WRITING

AI-powered authoring tools are increasingly used to accelerate report generation, flag inconsistencies, and assist with validation in clinical research. These solutions automate routine documentation tasks and help identify formatting errors or anomalies in clinical study reports. However, every output is reviewed and contextualized by experienced professionals, maintaining a "human in the loop" philosophy that is essential for regulatory compliance and data integrity. This integrated approach allows teams to efficiently focus effort on the most critical aspects of medical writing, ensuring both quality and traceability. .

SDTM MAPPING

Automation has significantly improved programming workflows, especially in mapping SDTM (Study Data Tabulation Model) and ADaM (Analysis Data Model) datasets. Automated mapping tools can reduce manual programming effort by up to 80%, streamlining data flows and minimizing human error. AI can further augment these well established processes by suggesting mappings, detecting anomalies, and supporting code review. Nevertheless, the core value remains in ensuring quality and traceability through automation.

HUMAN AND MACHINE PARTNERSHIP

While automation and AI offer powerful tools for improving efficiency and insight in clinical research, their true value is realized only when paired with expert human oversight. The “human in the loop” philosophy recognizes that technology should augment, not replace, the judgment and experience of clinical professionals.

In practice, this dynamic means that automated systems and AI models handle routine tasks, flag anomalies, and suggest improvements, but final decisions and interpretations should remain with skilled statisticians, programmers, medical writers, and data managers. Human expertise will continue to be essential for validating outputs, ensuring regulatory compliance, and contextualizing results within the broader goals of each clinical trial.

By combining the strengths of intelligent systems with human knowledge, organizations can focus effort on the most critical aspects of data review and analysis, maintain high standards of quality, and adapt to the challenges posed by increasing data volume, variety and velocity against the backdrop of R&D productivity pressures. This integrated approach not only improves operational efficiency but also builds trust in the use of advanced technologies across the clinical research lifecycle, helping to further adoption.

GOVERNANCE, VALIDATION, AND FUTURE DIRECTIONS

As automation and AI become increasingly embedded into clinical research, it is vital for organizations to ask themselves critical questions about governance, validation, and readiness for future challenges:

How do we govern and validate intelligent systems?

What frameworks and processes are needed to ensure that automation and AI tools are reliable, transparent, and compliant with regulatory standards?

What opportunities do we see for automation intelligence?

Where can automation deliver the greatest value, and how can we identify new areas for its application across the clinical data lifecycle?

Where are the biggest gaps today?

What limitations exist in current technology, processes, or expertise, and how can these be addressed to maximize the benefits of intelligent systems?

How can we prepare teams for this integrated future?

What skills, training, and cultural changes are required to enable teams to work effectively alongside automation and AI?

What should we be doing to innovate responsibly and sustainably?

How can we balance innovation with responsibility, ensuring that patient safety, data integrity, and ethical standards remain at the forefront?

By continually examining these questions, we can make informed decisions that support both operational excellence and regulatory compliance.

CONCLUSION

In clinical research, the key to successful innovation is not simply adopting the latest technology, but selecting the right tool for the problem at hand. Automation excels when tasks are well-defined, repetitive, and require consistency and traceability, making it indispensable for improving efficiency and maintaining quality in routine workflows. Artificial intelligence, meanwhile, brings value where data complexity and variability demand adaptive analysis and pattern recognition, augmenting human expertise in areas such as anomaly detection and advanced analytics.

Ultimately, our focus should remain on solving the core challenges we face, delivering high-quality data, accelerating timelines, and ensuring regulatory compliance. By understanding the strengths and limitations of both automation and AI, and by keeping expert oversight at the center of every process, sponsors and CROs alike can make informed decisions that drive meaningful improvements across the clinical data lifecycle.

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