



Rethinking Automation in the AI Era

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Disclaimer

This presentation reflects the views of the author and not necessarily presents the views or policies of MMS Holdings.

No AI expert.

Role within leadership to identify gaps in our processes and ways to improve on time/efficiency.

Responsibility to execute process improvements, as well as inspiring and encouraging others to bring ideas forward.



Agenda

- Setting the scene
- Ultimate goal
- Reasons for AI/Automation
- Picking the right tool for the job
- Use cases
- Security/Privacy concerns
- Current questions
- Conclusions

Setting the scene

AI dominates conversations in clinical data transformation

What is the role of AI (artificial) vs AI (automation)?

In some cases, are we mislabeling automation as artificial intelligence?

Stakeholders and board members looking for innovation, driving digital transformation in clinical operations.

External industry pressures to increase urgency to adopt AI, amplifying internal pressure.

Focus: Complementing human expertise, not replacing it

Drawing on practical applications from a CRO perspective, we'll look at how automation has been used to streamline data flows and reduce manual rework, ultimately contributing to more efficient delivery.

Ultimate goal

To accelerate, optimize, and de-risk the drug development process while maintaining regulatory compliance and scientific integrity and guaranteeing quality first time.



Automating repetitive programming tasks (e.g., SDTM/ADaM dataset generation, TLFs, data cleaning) to reduce time and human error.

Faster analysis cycles → getting results to statisticians, clinicians, and regulators quicker.

Ensuring reusable/forward thinking code, to enable further analysis without reprogramming.

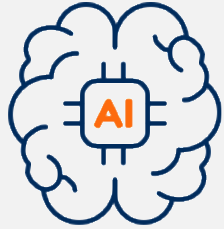
- Detecting anomalies, protocol deviations, or data inconsistencies much earlier.
 - Maintaining independence across production and validation programming.
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Smarter decisions- AI powered predictive analytics to identify early signals of efficacy or safety.



Organizations should focus on enhancing quality, efficiency, and reducing submission time over terminology.

Reasons for AI/Automation



Choosing between automation and artificial intelligence (AI) could depend on the nature of the task, the complexity of the data, and the need for regulatory compliance.



Repetitive, rule-based tasks:

These include standard data mapping, 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).



Adaptive analytics and prediction:

AI models can learn from data, suggest mappings, detect errors, and support decision-making.



In domains like medical writing, AI can accelerate report generation, flag inconsistencies, and assist with validation, but always requires human oversight to ensure context and accuracy.

Picking the right tool for the job

Automation

Patient data driven tasks:

SDTM automation
ADaM automation
TFL automation

Repetitive tasks:

Reruns
Refreshes
Interim analysis

AI

Code generation
Code reviews
Consistency between PROD & QC

Creation of TFL shells from SAP

Medical writing...

Use cases:

Medical Writing: Hybrid Authoring

Hybrid Medical Writing Approach

Integration of AI and automation with expert oversight enhances medical document generation without compromising quality.

Applications in Document Types

AI assists Plain Language Summaries, Informed Consent Forms, and patient narratives while automation aids data extraction and formatting.

Benefits and Governance

Shortened development time, improved accuracy, reduced review burden, with governance by an AI steering committee ensuring compliance.

Scalability and Case Studies

Approach starts with simpler documents and scales up; case studies show time savings up to 180 business days.



Use cases:

Statistical Programming: SDTM Workbench

Automation in SDTM Mapping

Approximately 80% of SDTM mapping is automated using rule-based engines, reducing manual effort and ensuring consistency.

AI Assistance for Complex Tasks

The remaining 20% of complex mappings receive AI assistance to suggest data placements and help onboard new programmers.

Quality Control and Compliance

Expert review and double programming ensure output quality, while the AI Steering Committee monitors compliance with standards.



Use cases:

Video Data Review: Streamlining Long-Form Review

AI-Driven Data Analysis

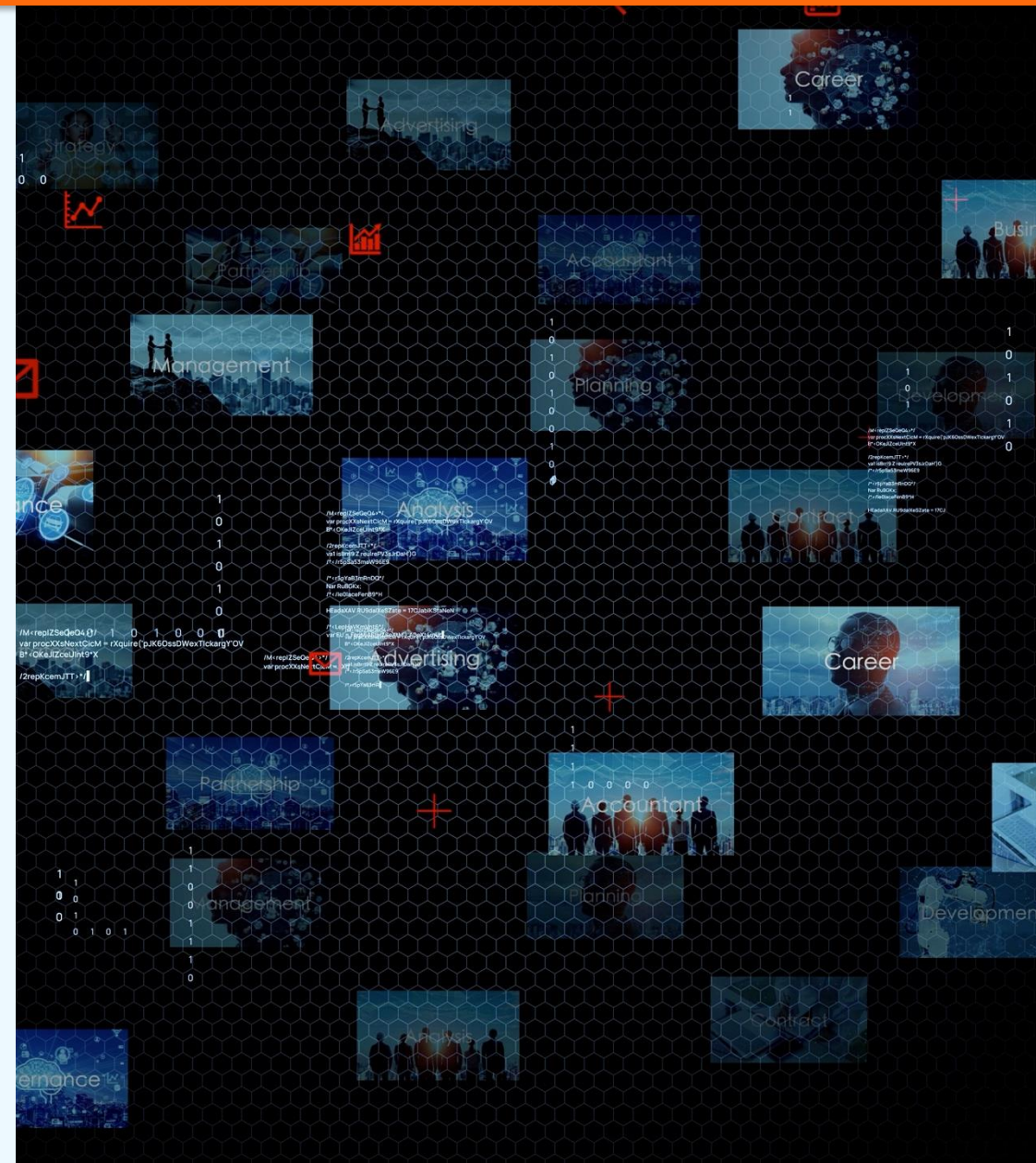
AI identifies patterns and extracts key insights from long-form video and audio data efficiently.

Data Privacy and Anonymization

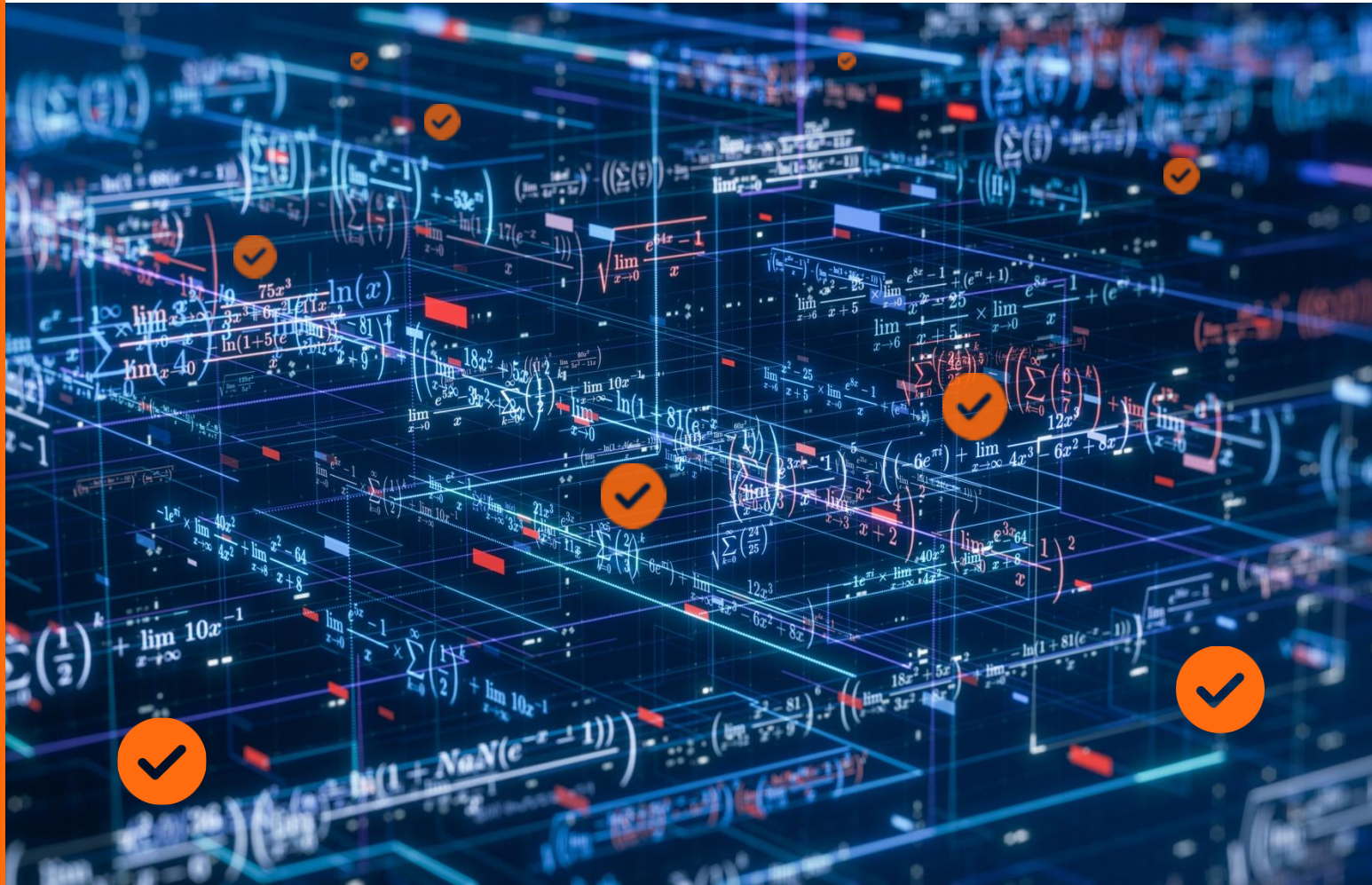
Sensitive content is anonymized to maintain privacy while supporting trial and regulatory compliance.

Operational Efficiency

Automation reduces reviewers' workload, speeding up decision-making for behavioural and patient studies.



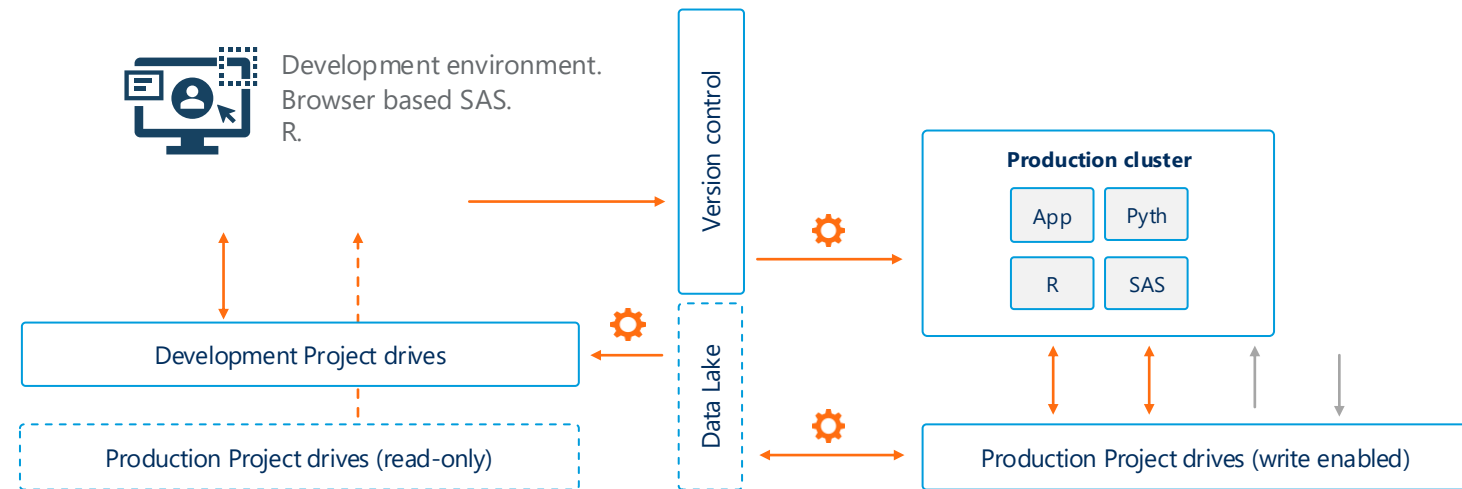
AI as the tireless junior reviewer



- **AI-Assisted Quality Control:**
The Night Shift Reviewer
- Run automated code quality checks while programmers are offline
- Flag potential issues before dual programming and audits
- Email leads each week with prioritized findings (high/medium/low confidence)
- **Value delivered:** Catch audit findings earlier, reduce rework, free senior programmers for complex review
- **The role:** AI as tireless junior reviewer doing initial scanning—humans focus on logic, context, and clinical judgment.

Automation within architecture/computing environment

- Open architecture
- Any development tool
- Automatically run and validate repetitive tasks.
- Readily available updated datasets and TFLs



Use cases:

Security/Privacy Concerns: Local instead of Cloud LLMs



Key Advantages of Local LLMs

- Full Data Control: No external transmission
- Air-Gapped Security: Can run offline, reducing exposure to network-based threats
- Custom Compliance: Easier to align with regulations and internal audit policies
- Tailored Governance: Fine-grained access control, logging, and retention policies
- No Vendor Lock-In: Avoids reliance on third-party cloud providers

Key Challenges of Local LLMs

- High Setup Cost: Requires GPUs, storage, and skilled personnel
- Maintenance Burden: Security patches, model updates, and drift monitoring
- Limited Scale: May struggle with large workloads or real-time demands
- Model Obsolescence: Risk of falling behind state-of-the-art cloud offerings

Use cases:

Security/privacy concerns: Local instead of Cloud LLMs



Dimension	Local LLMs	Cloud LLMs
Data Control	Full local retention	Data sent to external servers
Security Surface	Smaller, self-contained	Broader, includes vendor risks
Compliance	Customizable to organization needs	Depends on vendor certifications
Latency	Low (on-device)	Variable (network-dependent)
Scalability	Limited to local hardware	Virtually unlimited
Cost Structure	High upfront, lower variable cost	Pay-as-you-go, but recurring
Model Freshness	May lag behind	Access to latest models

Human + Machine Partnership

Automation

=

Standardization

+

Scale

Human

=

Judgment

+

Domain Expertise

Together

>

Smarter, Faster, Safer Processes



**SDTM automation
80% mapped based on library**

**Suggest where 20%
should be mapped**

Questions that are current...

- What opportunities do you see for automation intelligence?
 - Where are the biggest gaps today?
 - How can we prepare teams for this integrated future?
 - What should we be doing to protect our industry?
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Conclusion

- There is room for both AI and automation
 - Integrated ecosystems of AI and automation
 - Automation intelligence is here, ready to deliver value now
 - Works best as a complement to AI and human expertise
 - The future: integrated intelligence across the data lifecycle
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- Where should automation stop, and AI begin?
 - How do we govern and validate intelligent systems?





Thank you

Get in touch:

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Learn more on our website:





Any questions?