Paper LI05

Trustworthy and responsible AI in health care and life sciences from a leadership perspective

Mark Lambrecht, SAS, Tervuren, Belgium
Josefin Rosén, SAS, Stockholm, Sweden

ABSTRACT

The adoption of AI is booming. AI is revolutionising human life and opening up a whole new world of innovation - from helping doctors diagnose medical conditions earlier to enabling researchers to develop new drugs to treat them and enabling more effective conservation of endangered species and habitats. As AI becomes more prevalent, it will affect almost every aspect of society, from our professional to our personal lives. AI also carries significant risks if it is developed, implemented and managed without intentionality and discipline. For example, AI systems trained on biased data can learn historical patterns of discrimination against women, people of colour or vulnerable populations. If biases in AI systems are not identified and mitigated before implementation and use, those implemented systems can adopt social biases and cause unintended consequences on a large scale.

INTRODUCTION

Artificial intelligence (AI) is rapidly transforming healthcare and life sciences. Multimodal AI is generating results in drug discovery and in the clinical sciences and these results will rapidly be considered in decision-making factors as biomarkers or dependent variables during clinical trial submissions. As noted by the European Medicines Agency (EMA), the potential of AI is becoming increasingly important in drug development. Rapid advances in this field require careful consideration of benefits and risks. The EMA stresses the importance of ensuring patient safety and the integrity of clinical trials when using AI in drug development.

One of the main concerns is the avoidance of bias in AI applications. Bias in AI systems can lead to inaccurate results and potentially harm patients. Therefore, it is crucial to ensure transparency, trust and security in AI systems.

The rapid evolution of technology presents both opportunities and challenges to healthcare. The integration of AI in drug development is particularly transformative, promising significant benefits while also raising important ethical and safety concerns.. As AI continues to spread across various areas of society, its impact will increasingly touch multiple aspects of our lives. It is crucial to address potential risks associated with AI, particularly biases in training data, to ensure AI's responsible and ethical development and application.

THE BUSINESS IMPERATIVE FOR TRUSTWORTHY AI

The increasing power, speed, and affordability of AI are raising concerns among executives about potential unintended consequences. The lack of standardization in AI algorithms has led to instances of bias, including cases where AI powered tools have objectifiedwomen's bodies. Despite the approval of over 1000 medical AI devices by the U.S. Food and Drug Administration (FDA), their adoption in clinical practice remains limited. This highlights the need for more randomized clinical trials to confirm their safety and effectiveness. By 2026, organizations that prioritize AI transparency, trust, and security are expected to see a 50% increase in AI model adoption, business outcomes, and user acceptance. Building trustworthy AI requires ethical development, safety measures, and a commitment to aligning technology with societal values and ethical considerations.

THE NEED FOR TRUSTWORTHY AI

Responsible and trustworthy AI involves the ethical, transparent and fair application of AI technologies, ensuring that they benefit all patients while minimising risk and bias. This requires a principle-driven approach that focuses on:

- **Human centricity**: AI systems should promote human well-being, agency and equality.
- **Inclusiveness**: AI systems should be accessible to all and take into account different perspectives and experiences.
- **Accountability**: Adverse impacts of AI systems should be proactively identified and mitigated.
- **Transparency**: The operation of AI systems should be openly explained, including potential risks and how decisions are made.
- **Robustness**: AI systems should operate reliably and securely, with mechanisms to assess and manage potential risks throughout a system's lifecycle.
- **Privacy and security**: The privacy of data subjects should be respected.

APPLICATIONS OF AI IN CLINICAL TRIALS

AI can be applied at all stages of the drug life cycle, especially in clinical trials. Some specific applications include:

- Treatment and dose allocation in early-stage studies.
- Transformation and analysis of data, ensuring that algorithms, models and data pipelines comply with ethical and scientific standards.
- Precision medicine, using AI to individualise treatment based on disease characteristics, patient genotype and clinical parameters.
- Mitigation of risks associated with overfitting and data leakage in late-stage studies.

SAS AI GOVERNANCE MODEL

The SAS AI Governance model supports the development and deployment of trustworthy AI, encompassing various aspects including:

- Oversight: AI Governance, Strategy, and Enforcement
- Operations: SOPs with Supporting Infrastructure
- Compliance: Performance and Risk Management
- Culture: Ethically Systemic Norms and Practices

The framework supports critical components of AI governance, including:

- Data Management: Ensuring data quality, appropriate metadata, data preparation, and a data asset catalog.
- Detection: Identifying bias and assessing fairness.
- Mitigation: Mitigating and preventing bias, and generating synthetic data for remediation.
- Explanation: Providing natural language explanations, explainable ML, counterfactual explanations, surrogate model interpretation, and causal inference.
- Privacy & Security: Protecting privacy, ensuring model security, preserving autonomy, and managing consent and control.
- Model Ops: Utilizing model cards, decisioning, lifecycle management, metric monitoring, model robustness, and model oversight.

REGULATORY CONTEXT

The EMA recognises the potential of AI to improve drug development, but also stresses the need for regulation to mitigate risks. The agency has prepared a draft guideline defining the scientific principles relevant to the use of AI in the drug life cycle.

The draft guideline emphasises that Good Clinical Practice (GCP) should be applied to all uses of AI in clinical trials. Moreover, applicants for marketing authorisations should ensure that all AI models and algorithms are fit for purpose and comply with regulatory standards.

The focus is on:

- Patient safety and integrity of clinical study results.
- Promoting AI trustworthiness and mitigating bias
- Defining scientific principles for regulators when AI is used in drug development.

The EMA's draft reflection paper outlines specific requirements for AI/ML usage in clinical trials, emphasizing Good Clinical Practice (GCP) principles and the need for robust statistical analysis plans. The guidance covers aspects such as:

- Treatment assignment and dosing in early-phase trials.
- Individualized treatment in precision medicine.
- Regulatory oversight when AI/ML applications influence posology.

CONCLUSION

As AI continues to transform healthcare, it is imperative for leaders in the field to embrace a principle-driven approach that ensures the development and deployment of trustworthy and responsible AI. By addressing the potential risks and ethical implications, we can harness the power of AI to improve patient outcomes and advance the life sciences industry while safeguarding human well-being and societal values.

The SAS AI Governance framework offers a comprehensive approach to managing AI risks and promoting trustworthy AI practices. Similarly, regulatory initiatives in Europe, such as the EMA's guidelines and the Draft Artificial Intelligence Act, provide a framework for responsible AI development and utilization in the healthcare sector. Collaboration among stakeholders, including regulators, technology developers, researchers, and patients, is essential to navigate the evolving landscape of AI in healthcare and life sciences effectively.

REFERENCES

- Adams et al. Artificial Intelligence in Health, Health Care, and Biomedical Science: An AI Code of Conduct Principles and Commitments Discussion Draft. 2024, National Academy of Medicine, https://nam.edu/artificial-intelligence-in-health-health-care-and-biomedical-science-an-ai-code-of-conduct-principles-and-commitments-discussion-draft/
- Rosner S and Hodosi M. Responsible Use of AI in Healthcare: Work in Progress, DIA 2024 “Responsible AI Solution Room” Summary Report.
- O’Donnell, P Harnessing AI in European Clinical Trials: Regulation in Progress https://www.appliedclinicaltrialsonline.com/view/harnessing-ai-in-european-clinical-trials-regulation-in-progress
- SAS accelerates responsible innovation efforts with new collaborations and a focus on trustworthy AI, press release, May 09 2023, https://www.sas.com/en_be/news/press-releases/2023/may/responsible-innovation-reahl.html
- How SAS drives technology innovation ethically & responsibly, https://www.sas.com/en_us/company-information/innovation/responsible-innovation.html
- Wu, K et al. 2023, 1(1), NEJM AI, Characterizing the clinical adoption of Medical AI Devices through U.S. Insurance Claims, DOI: 10.1056/AIoa2300030

ACKNOWLEDGMENTS

Thank you to the SAS Data Ethics Practice for their advice, support and source materials.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Author Name: Mark Lambrecht
Company: SAS
Address: Hertenbergstraat 6, 3060 Tervuren, Belgium
Work Phone: +32 2 766 07 00
Email: mark.lambrecht@sas.com
Website: https://www.sas.com/en_us/industry/life-sciences.html

Brand and product names are trademarks of their respective companies.