AI and the Evolving Role of Medical Writers

Based on: Chamberlain James L, Cooper J. AMWA Journal. 2025;40(2):4–6

Background

- Medical writers ensure clarity, consistency, and compliance in regulatory submissions.
- 2021 AMWA survey:
- - 87% of reviewers: poor-quality documents hinder assessments.
- - 77%: delays due to poor writing quality.
- Growing demand + shortage of trained medical writers = AI opportunity.

Purpose of Article

- Explore how AI can:
- - Improve document quality.
- - Support medical writers in regulatory submissions.
- - Be integrated safely while preserving compliance and scientific integrity.

Benefits of AI

- Consistency – check terminology, grammar, formatting.
- Clarity – reduce redundancy, improve conciseness.
- Automation – generate tables, summaries, cross-references.
- Quality Control – flag regulatory inconsistencies.

Challenges & Risks

- Data security: sensitive clinical trial data must be protected.
- Ethics & bias in AI-generated content.
- Risk of misinformation, plagiarism, outdated content.
- AI cannot contextualize or provide strategic insight.

Regulatory Agencies & AI

- Some agencies exploring AI for document review and data analysis.
- Emphasis on transparency and traceability in AI-assisted submissions.
- Writers must stay updated on evolving AI-related regulations.

Convergence of AI & Writers

- AI handles drafting/administrative tasks; humans provide context and strategy.
- Writers focus on:
- - Strategic messaging.
- - Regulatory compliance.
- - Synthesizing complex data into clear narratives.
- New skills: AI literacy, prompt engineering, interdisciplinary collaboration.

Future Directions

- AI adoption is inevitable – a tool, not a replacement.
- Supports efficiency and reduces redundancy.
- Critical thinking, strategy, and regulatory expertise remain irreplaceable.
- Writers must adapt and adopt to thrive.

Critical Appraisal

- Strengths:
- - Timely, relevant topic.
- - Balanced view of opportunities and risks.
- - Practical insights for writers and regulators.

- Limitations:
- - Limited quantitative data beyond 2021 survey.
- - Predictions may quickly be outdated.
- - Limited discussion on training and costs.

Discussion Questions

- 1. How comfortable should regulators be with AI-assisted submissions?
- 2. What training should medical writers prioritize to remain competitive?
- 3. How do we balance efficiency with accuracy and ethics in AI use?
- 4. Could over-reliance on AI weaken core writing skills?