

Peer Review

Review of: "Integrity of Clinical RCTs: Safeguarding Trust, Evidence, and Patient Welfare"

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The manuscript is well-written and offers a comprehensive conceptual framework for understanding clinical trial integrity. Overall, it is a worthwhile contribution; however, a few minor improvements could further strengthen the manuscript:

1. Breaking a few paragraphs into shorter units would improve readability without changing the content.
2. The section on artificial intelligence is currently too brief given its growing role in clinical research. A more comprehensive discussion of AI's potential contributions to clinical trial integrity would strengthen the manuscript. In addition, important limitations and challenges, including hallucinations, bias, validation requirements, transparency, and human oversight and accountability, should be addressed.
3. Given the breadth of topics covered, the manuscript would benefit from a substantially expanded reference list. The current list appears limited relative to the scope of the review and does not fully reflect the extensive literature on clinical trial integrity, estimands, trial conduct, data quality, transparency, reporting, and research integrity. Additional references would strengthen the scholarly foundation of the article and better position it as a review paper.

Declarations

Potential competing interests: No potential competing interests to declare.