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Peer Review

Review of: "Ensuring Quality in Clinical Research: The Impact of Quality Assurance and Quality Control in the Field of Good Clinical Practice"

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This manuscript presents a comprehensive and timely review of quality assurance (QA) and quality control (QC) practices in clinical research, with specific emphasis on Good Clinical Practice (GCP) compliance. The authors successfully connect historical context, current regulatory standards, and emerging trends, including ICH GCP R3 and remote auditing practices. The paper is well-intentioned and brings attention to a crucial but often overlooked aspect of clinical research — data quality and regulatory preparedness. The effort to highlight deficiencies found during inspections, along with reflections on the evolving role of investigators and QA professionals, is particularly commendable.

The paper would benefit from improved structural organization, enhanced clarity in several sections, and a more consistent narrative voice. The content is rich but can occasionally feel dense or repetitive. With thoughtful revision, this manuscript can become a valuable reference for investigators, quality professionals, and regulatory stakeholders.

Major Comments

Clarity and Organization:

The manuscript covers a wide range of topics, from the origin of ethical standards to contemporary audit findings. However, it would benefit from clearer section transitions and thematic grouping. Consider breaking the longer sections into subsections with headers to aid reader navigation. For example, before discussing inspection findings, use:

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"This section summarizes recent inspection findings from major regulatory bodies to illustrate common compliance issues and underscore areas needing greater attention."

Use of Subheadings:

Introduce subheadings to clearly segment thematic content. For instance, the section titled "Auditors in the evaluation of QC and QA activities" could be divided as follows:

4.1 Role and Responsibilities of Auditors

4.2 Risk-Based and Remote Auditing Practices

4.3 Emerging Tools and Analytics in Auditing The abstract could be more concise and specific. For example, instead of broadly stating the importance of QA/QC, briefly highlight the key themes or findings discussed (e.g., implementation challenges, regulatory trends, inspection findings).

Consistency and Terminology:

Terms such as QA, QC, GCP, ICH GCP R3, and ALCOA-C are used effectively, but they are sometimes introduced without consistent definitions or context. Ensure that each abbreviation is defined at first mention in every major section.

The term "principal investigator" is sometimes used interchangeably with "investigator." Consider aligning with the terminology used in ICH GCP R3 for consistency.

Depth of Analysis:

While the manuscript provides extensive detail on inspection findings, it would be valuable to include a discussion on common root causes of these deficiencies and practical recommendations for prevention.

The discussion around QA tools such as risk-based monitoring and data analytics is promising. More detail on the implementation and effectiveness of these tools (e.g., specific metrics or examples of success) would enrich the narrative. For example - "A 25% reduction in critical data errors was reported in a recent FDA audit following the implementation of RBM approaches."

Regulatory Context:

The authors make an excellent point about the regional limitations in access to regulatory updates in North Macedonia. Consider expanding on how this regulatory gap could impact trial quality and what strategies local institutions can adopt to mitigate this.

The manuscript references ICH GCP R3 but could more clearly distinguish which changes are new compared to R2, and how these might reshape investigator responsibilities in practice.

Minor Comments

Some paragraphs are quite long and would benefit from being split for readability, especially in the "Auditors in the evaluation of the QC and QA activities" and "Inspection findings" sections.

Occasional language and grammatical issues slightly hinder clarity. A language edit would help polish the manuscript (e.g., "more effective in several ways by including remote technologies" could be rewritten for precision).

Figures or visual summaries (e.g., inspection trends, QA responsibilities) would greatly help readers digest complex data.

References are comprehensive and relevant but would benefit from consistent formatting and careful proofreading for citation style.

Conclusion and Recommendation

This manuscript addresses an essential and under-discussed dimension of clinical research—ensuring quality through effective QA and QC. With minor structural refinements, clearer definitions, and enhanced critical synthesis, this paper has the potential to serve as a useful guide for clinical research professionals navigating GCP compliance in both local and global contexts. I recommend minor to moderate revisions to strengthen its clarity, coherence, and applied value.

Declarations

Potential competing interests: No potential competing interests to declare.