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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Potential competing interests: No potential competing interests to declare.

In this manuscript, the authors updated information on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guideline and emphasized the importance of investigator compliance with these guidelines to ensure the quality and safety of clinical research. Specifically, the authors pointed out the value of quality assurance activities, including audits of documents and procedures, to ensure the accuracy and validity of research data obtained, and to reduce or eliminate potential findings from sponsor monitoring visits and/or citations by regulatory agency inspections.

The authors concluded that “By incorporating quality into every part of the clinical trial process, organizations can gain significant benefits, ensuring regulatory compliance, enhancing efficiency, and safeguarding patient safety…… Therefore, clinical researchers/investigators are encouraged to implement robust quality assurance and quality control actions to guarantee the accuracy, reliability, and validity of the data collected and analyzed.” (6. Conclusion)

The authors should be commended for recognizing the importance and value of quality assurance activities that include audits, a rather time-consuming and laborious process. However, implementing such a quality assurance program by the investigator in his/her own research is problematic for two reasons:

1. It is a conflict of interest for the auditor, who is an employee of the investigator, to audit his/her own boss’s research activities; and
2. It might not be cost-effective for a research program to afford such a costly quality assurance program.

I would suggest an alternative approach for the authors’ consideration. Institutions conducting research involving human subjects should establish robust quality assurance programs to protect the rights and welfare of human research participants. Depending on the size of the research program, the institution should hire at least one qualified Research Compliance Officer. This research compliance officer should report directly to the institutional official or his/her designee, who are independent of the research office. The research compliance officer will conduct audits of data and documents for integrity and compliance, not only for the investigator’s research programs but also for the quality and performance of the institutional research boards (IRBs) and human research protections programs to ensure the quality of IRB reviews and effectiveness in human research subject protections. (1,2)

Reference:

1. Tsan MF. Assessing the quality and performance of institutional review boards. Scholars' Press. Chisinau, Moldova Europe, 2022.
2. Tsan MF, Puglisi JT. Protecting human subjects participating in research. Am J Transl Res.15(9): 5707-5714, 2023. (www.ajtr.org/ISSN:1943-8141/AJTR0151875)