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 commentary addresses the quality of clinical studies. Despite the presence of guidelines, this remains an area with notable deficiencies, making this article highly valuable in that context.

In clinical studies, sample size, transparency, and reproducibility are as crucial as the ethical dimension of the research. In addition, in 2012, some medical journal editors submitted an appeal to other medical journal editors, highlighting areas of deficiency in the field of diagnostics. This appeal was published simultaneously in multiple journals, making it relevant to emphasize this issue in the commentary (Rifai N, et al. An appeal to medical journal editors: the need for a full description of laboratory methods and specimen handling in clinical study reports. Statement by the Consortium of Laboratory Medicine Journal Editors. Ann Clin Biochem 2012;49:105-7. doi: 10.1258/acb.2011.201201).

The following requirements are briefly outlined in that publication:

1. "For commercial diagnostic tests, authors must include the specific name and generation of the assay, the manufacturer, and the instrument used for analyses.
2. Authors must report the performance characteristics, such as the imprecision of the assay in the investigators' laboratories, the assay's reportable range, and any reference (normal) range used in the study.
3. Authors must clearly indicate the types of specimens analyzed and the storage conditions for these specimens."

Therefore, these areas of deficiency should be considered in all clinical trials.