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.

Adherence to Good Clinical Practice (GCP) in the production of scientific research that informs medical practice ensures both the protection of study participants and the credibility of the data obtained. One key tool for achieving high-quality clinical research is the implementation of robust quality assurance and control as integral parts of the quality management system.

The integrity and reliability of clinical trial data depend on the development of sound practices. Fundamental prerequisites such as integrity, safety, and efficacy of research results are essential, not only for prospective studies but also for systematic reviews with meta-analyses. These reviews are often placed at the pinnacle of the evidence hierarchy, from which clinical behaviors are derived and supported by such evidence. The responsibility of the investigator, as outlined in ICH GCP R3, along with quality assurance, is often overlooked—not just by the stakeholders or regulatory authorities but also by those who communicate the results, including international journals. These journals, often divided by impact factor rankings and open-source models, are subject to minimal oversight regarding the rigor of evaluations and the potential conflicts of interest, whether explicit or implicit, among referees.

Let's briefly articulate some of the biases present in the evaluation and publication of these works:

- Repetitive studies that add no innovation or development value, not even providing confirmatory value;

- Papers with an excessive number of authors, even when not conducting multicentric studies;

- Papers with an excessive number of authors who serve as reviewers for the same journals in which their co-authors publish;

- Papers where both authors and reviewers belong to the same special interest group within a scientific society;

- Papers where both authors and reviewers are affiliated with the same privately-owned healthcare system;

- Authors who produce more than 5-7 papers per year;

- Papers whose authors are unfamiliar with the detailed content;

- Meta-analyses that include studies with evident risk of biases, which are sometimes included to substantiate a particular viewpoint as evidence.

It is essential to establish inspections by major regulatory agencies on the publications, scrutinizing their number, authorship, and potential conflicts of interest among reviewers—not solely based on self-declarations (e.g., working for the same proprietary group or being part of the same special interest group within a scientific society exposes one to conflicts). Currently, some publications suffer from poor quality control, both at the preliminary stages and after they become part of the scientific literature that influences clinical guidelines and practices.

This lack of rigorous quality control can lead to the inflation of false H-indices, elevating individuals or references to supposed scientific excellence that is devoid of substantive content. Many CVs boast of astronomical H-indices (with over 30 publications per year), yet produce no results that significantly impact the medical practice of their discipline. Conversely, some works, despite being part of less prominent CVs, have become and continue to be cornerstones in the clinical practice of their fields.

Therefore, we advocate for improved quality control measures, with a more rigorous ex-ante evaluation of the study's expected impact on clinical practice and an ex-post review before dissemination. This should ensure that the expected outcomes align with the achieved results and that the methodology used is rigorously applied, addressing all the aforementioned biases. Failure to do so risks exposing scientific advancements to populist, anti-scientific criticisms due to a lack of credibility.