Lack of transparency for Investigators in clinical trials: A bibliometric analysis of literature

INTRODUCTION

Transparency is a term that is associated with openness and relates to both a relationship attribute and the environmental state of a process. It is the foundation for trust in stakeholder interactions.[1] Clinical trials, during the COVID-19 pandemic, provided an opportunity to be not only inclusive for the scientific community at large[2] but also necessitated more openness and confidence in technical and social spheres.[3] This phenomenon warrants assessing transparency in clinical trials more closely, specifically with the two key participants – investigators and patients.

Patients seek a heightened reliance on the investigator's competence, skills, and goodwill[4] as they possess a lack of knowledge and mistrust toward investigational drugs.[5] Therefore, investigator–patient relationship is critical in clinical trials. Ambiguity in the extent of information accessible to the investigator and subsequently to patients undermines trust in this relationship and creates an unfavorable environment[4] for the efficient conduct of clinical trials, resulting in additional challenges for investigators in achieving the objectives of clinical trials.[5]

Research shows that investigators' involvement and participation in clinical trials are discouraged by a lack of information.[6] Increased accountability and openness lead to higher levels of trust, which in turn results in higher levels of participation.[1] Therefore, enhancing and boosting transparency is essential to ensure that investigators are well-informed and supportive of executing clinical trials with confidence and conviction.

METHODOLOGY

Data mining was performed using the Scopus database in November 2023, aimed at identifying original research articles that included author keywords such as transparency, clinical trial, and physician published between 2012 and 2023. Bibliographic details such as author, title, publication type, language, year, address of the contributors, country of publication, and source were also collected.

RESULTS

A search of documents in Scopus between 2012 and 2023 (November 2023) related to clinical trial transparency for investigators resulted in 648 publications in Scopus, which constitutes 91% of the total publications in this field. Most of the articles were published in English (97.6%) and in the area of medicine (57.6%), and authors from the USA led the table (57%), followed by the United Kingdom (13.14%) and Canada (10.36).

With 20 publications, the *Journal of Clinical Oncology* accounted for 3.09% of the total published documents, followed by *PloS ONE* (2.63%) and *British Medical Journal* ONE (2.16%). Charlotte R Blease, of Harvard Medical School, USA, is the most productive author (six articles) for works in this field.

Co-occurrence analysis performed using VOSviewer shows transparency having strong links with ethics, conflict of interest, public health, trust, and registries; clinical trials are also closely associated with these factors. Transparency and trust did not have any co-occurrence with the clinical trial and investigator.

DISCUSSION AND CONCLUSION

With so many clinical trials conducted annually, no significant contribution comes from India in this field. There is a need to concentrate on and actively collaborate with studies on clinical trial transparency. The primary focus of published articles for clinical trial transparency at the moment is on the publication of trial results and registration on public registries. Little research was found on the transparency of investigators in a clinical trial. Consequently, it is critical to look into the field, comprehend its needs and ramifications from many angles, and offer recommendations for improving this.

The COVID-19 pandemic brought clinical trials closer to the general public, which has further heightened the demand for transparency. The results are not conclusive as they include bibliographic analysis with data only from the Scopus database. Therefore, studies in the future should consider developing models and scales to assess

transparency for investigators and its impact on improving clinical trial conduct.

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Conflicts of interest

There are no conflicts of interest.

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