BACKGROUND AND OBJECTIVE

Basic results posted in tabular form and with limited fields for entry in the Clinical Trials.gov template can introduce risk in interpretation of results.

Moreover, journals not inclined to follow International Committee of Medical Journal Editors (ICMJE) criteria may consider this a violation of the ‘Ingerling Rule’.

Thus, there exists a need to at least submit clinical trial results for publication in peer-reviewed journals before results are released to Clinical Trials.gov so as to generate sufficient interest and allow for proper interpretation of the findings.

We piloted an approach to determine the feasibility of submitting a primary publication to a peer-reviewed journal before results are released to the ClinicalTrials.gov Web site.

RESULTS

A Publications Steering Committee Meeting was organized immediately after database lock (DBL).

All authors contributed to this discussion. The overall time to complete a final draft for submission was within 0–7 months after LPLV.

Conclusions: Our case study indicated that manuscript submission can be completed at least 5 months before posting of results to the registry.

ABSTRACT

BACKGROUND AND OBJECTIVE

Implementation of the US Food and Drug Administration Amendments Act (FDAAA) in 2007 resulted in new requirements regarding the need to submit a manuscript before posting of results to the registry, the date usually being the first anniversary of last patient last visit (LPLV). We piloted an approach to determine the feasibility of expediting submission timelines.

Research Design and Methods: Raw data were made available within 4–8 weeks of database lock and shared with authors (internal and external) at an off-site steering committee meeting. Stakeholders, clinical trial coordination, publication planner, and medical writer were additional attendees. The focus of this meeting included an in-depth review and interpretation of the data, and discussion of the need for additional statistical analysis. Another component of this meeting was to discuss the contents of the primary manuscript, including the Introduction and Discussion sections, and journal selection. All authors contributed to this discussion.

Results: Differences of opinion among authors on interpretation of the data were reached during the meeting. Based on the verbal discussion and subsequent agreement on the contents of the manuscript, the draft was developed within 3–5 months after the steering committee meeting. All authors reviewed, provided additional input, and approved the final version that was submitted. The overall time to complete a final draft for submission was within 0–7 months after LPLV.

Conclusion: Our case study indicated that manuscript submission can be completed at least 5 months before posting of results to the registry.

INTRODUCTION

The Food and Drug Administration Amendments Act (FDAAA), a US federal law enacted in 2007, mandates registration and results reporting for certain clinical trials of drugs, biological products, and devices, regardless of funding source, at ClinicalTrials.gov, an online registry and results database operated by the National Library of Medicine of the National Institutes of Health.

Section 801 of the FDAAA (FDAAA-801) launched in September 2008, expanded the scope of mandatory clinical trial registration to include reporting of “basic results” at the ClinicalTrials.gov Web site (https://ClinicalTrials.gov).

In general, the law requires study sponsors or designated principal investigators (i.e., “responsible parties” in FDAAA-801) to report summary results information usually in a tabular form for the interventional trials of drugs, biological products, and devices within 1 year of completing data collection (the date usually being the first anniversary of last patient last visit [LPLV]) for the prespecified primary outcome, regardless of sponsor or funding source.

REFERENCES


Presented at the 7th Annual Meeting of the International Society for Medical Publication Professionals (ISMPP), April 4–6, 2011, Arlington, VA.