Plain Language Clinical Trial Result Summaries: Are Participants Getting it?

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Summary

Clinical trial perceptions and factors for participation may be influenced by a number of elements, such as whether comprehensible results are returned to participants. Delivering plain language clinical trial result summaries (PLCTRS) to participants may lead to better clinical trial perceptions and recruitment. In this study, the extent to which PLCTRS were available and their quality from the top 30 corporate sponsors of clinical trials by number of trials sponsored was evaluated. To assess usage of plain language within an academic setting, clinical research professionals (CRPs) were surveyed about their usage of plain language within their own research teams and whether they could benefit from plain language templates or standard operating procedures (SOPs). Results indicated variable existence of PLCTRS from corporate sponsors. Over a third of CRPs did not have personnel dedicated to developing and disseminating PLCTRS, and over two-thirds indicated that templates and SOPs would benefit them.

Background

In the past decade, there have been a number of initiatives by regulators, industry, and patient groups to make clinical trials and their results more accessible and easy to understand. This includes the use of plain language clinical trial result summaries (PLCTRS). One of the drivers for global biopharmaceutical companies is EU Clinical Trial Regulation (536/2014).

Methods

Clinical trial records from clinical-trials.gov between 2005-2014 were used to identify the top 30 corporate sponsors of clinical trials during the period. After identifying the top 30 sponsors, a search was conducted online using a public search engine. In the search, the sponsor’s name, plus keywords such as “plain language summary”, “lay language summary”, and “clinical trial result summary”, were used to simulate the search experience of participants or members of the public. Each sponsor was evaluated by criteria such as whether a PLCTRS exists, whether it was translated into the trial site local language, adherence to EU Regulation 536/2014, the flesch-kincaid reading level scores, and flesch-kincaid grade levels. If summaries did not exist, another criteria evaluated whether the sponsor planned on future availability.

Results

Findings indicated that a significant number of corporate sponsors have still not begun disseminating plain language clinical trial result summaries to participants. Out of 30 sponsors, 14 had plain language clinical trial result summaries available. Of the sponsors who had clinical trial result summaries available, all 14 adhered to all EU Regulation 536/2014 strictures. The average flesch-kincaid reading level was 49.4 and grade level was 9.68. For the clinical research professionals survey, to analyze these results relative to real-world industry experience, CRPs – clinical research coordinators, data managers, sponsors, auditors, monitors,

Institutional Review Board reviewers, investigators, and students – were surveyed on whether their clinical research team had dedicated personnel for development and dissemination of PLCTRS and whether guidance through SOPs or a template would aid their team in development and dissemination of PLCTRS. Survey results indicated that more than two-thirds of CRPs do not have, or did not know if their research team had dedicated personnel to develop/distribute PLCTRS. Additionally, more than two-thirds of CRPs indicated their clinical research team would benefit from SOPs or a template PLCTRS development process.

Conclusions, Implications and Future Research

To support patient and participant engagement, corporate sponsors should improve on the development and dissemination of PLCTRS. This may have a positive impact on clinical trial recruitment and attitudes. If corporate sponsors are not fully dedicated to the PLCTRS development process, then investigator-initiated trials may be even less likely to implement them. Developing unified templates and/or SOPs could help both industry and investigator-initiated trials in developing PLCTRS. Future research includes developing templates and SOPs to address lack of PLCTRS. In addition, future research will measure compliance with Regulation EU 536/2014 and timely dissemination of PLCTRS.

References


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