

Plain Language Summaries of Clinical Trials

Letter to Editor

Lay summaries or plain language summaries are research reports targeting general audience. One of the prime objectives of lay language summaries is to keep the non-scientific population engaged with research. Lay summaries are a valuable tool in the field of medicine and health, and are often written by organizations conducting clinical research to engage their participants. Also, lay summaries help organizations to demonstrate the impact of their research to non-specialist audience (common people). Lay research summaries not only are useful to common people, but they are also helpful to scientific professionals as the data is made available in a simplified language [1].

Lay summaries are used to describe the on-going research to a new participant to be recruited, as the new participant will not only be able to understand the objectives of the clinical trial, but he will enable him to decide whether to participate in the trial or not. Also, recently the European Clinical Trial Regulation (EU No 536/2014) had made it mandatory for funding agencies or clinical trial sponsors to provide results of clinical trials in a summary that is understandable to laypersons. This summary shall be available in an EU-wide public-domain database.

A lay language summary should at least contain (but not limited to) its clinical trial identifier number, sponsor details, objectives, scope and population of the subjects, therapeutic interventions used, frequency of adverse events, results and outcomes of clinical trial outcomes and last but not the least, participant's contribution in the clinical trial. Also, resources for additional information's should be also provided wherever applicable [2].

One of the major issues faced by sponsors of clinical trials is to maintain consistency between the data presented in full clinical study report with the results presented in lay summaries while

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accounting for scientific and statistical jargons (e.g. p values and confidence intervals), so that even a 14 year old class 8 student reading the lay summary could comprehend the results.

To conclude, lay summaries play a critical role in engaging the non-scientific part of the clinical trial setup with rest of the team. However, the inclination of regulatory bodies towards lay summaries had already called up a need to lay detailed guidelines for writing lay summaries.

References

1. Duke M (2012) 'How to Write a Lay Summary'. DCC How-to Guides & checklists.
2. Katharina B, Kamila SS, Thomas MS (2012) New European clinical Trial Regulation: The Requirement for lay summaries and its impact on medical communicators. AMWA Journal 30(2): 1-4.

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