Plain language summaries of clinical trial results: What is their role, and should patients and AI be involved?

Lisa Chamberlain James
Trilogy Writing & Consulting Ltd., Cambridge, England

doi: 10.56012/yayy4394

Correspondence to:
Lisa Chamberlain James
Lisa@trilogywriting.com

Abstract

Plain language summaries (PLSs) of clinical trial results are vital tools in the clinical development process for enhancing transparency and encouraging and facilitating patient engagement. The production of a PLS is now mandated in the EU for all interventional clinical trials by the European Medicines Agency under Regulation EU 536/2014 and became compulsory with the opening of the Clinical Trial Information System portal in January 2022. PLSs are intended to be accessible, comprehensible documents conveying complex trial findings to diverse audiences. This article explores the significance of PLSs, the importance of patient input in their production, and the role and concerns surrounding the use of artificial intelligence in generating them.

Introduction

Clinical trials are the cornerstone of evidence-based medicine. They are pivotal in advancing medical knowledge and shaping healthcare practices, and they rely on the participation of patients and healthy volunteers. Clinical trial participants and the general public should, and increasingly demand to, be informed about the results of clinical trials. This is crucial for them to be able to share and be involved in their healthcare decision making. However, traditional formats for reporting trial results, such as scientific manuscripts and regulatory documents, are often full of technical jargon and complex statistical analyses, which are extremely difficult for non-expert audiences to understand and interpret. To address these challenges, and as part of their transparency and inclusivity initiatives to promote patient engagement in clinical development, the European Medicines Agency (EMA) has mandated the production of plain language summaries (PLSs) of clinical trial results for all interventional trials in the EU.[1] Recently, two key legislations have pushed for plain language clinical trial lay summaries to be made available to the public – either via clinicaltrials.gov in the US or as part of the EMA's Lay Summary of Clinical Trial Results, which became mandatory with the opening of the Clinical Trial Information System (CTIS) in the EU.[2–4]

Complementing these efforts, some journal publishers are making available plain language summaries (PLSs) of journal articles to the general public.[5–8] Some industry sponsors of clinical trials have been doing this for some time, and others are starting similar initiatives,[9–11] with commitments to making these accessible to the public for all clinical trials.[12] Many national public health bodies, research hospitals, patient organisations, and non-profit bodies are now developing and making additional plain language materials such as videos, information brochures, or infographics freely available via their websites and social media channels.[13–15]

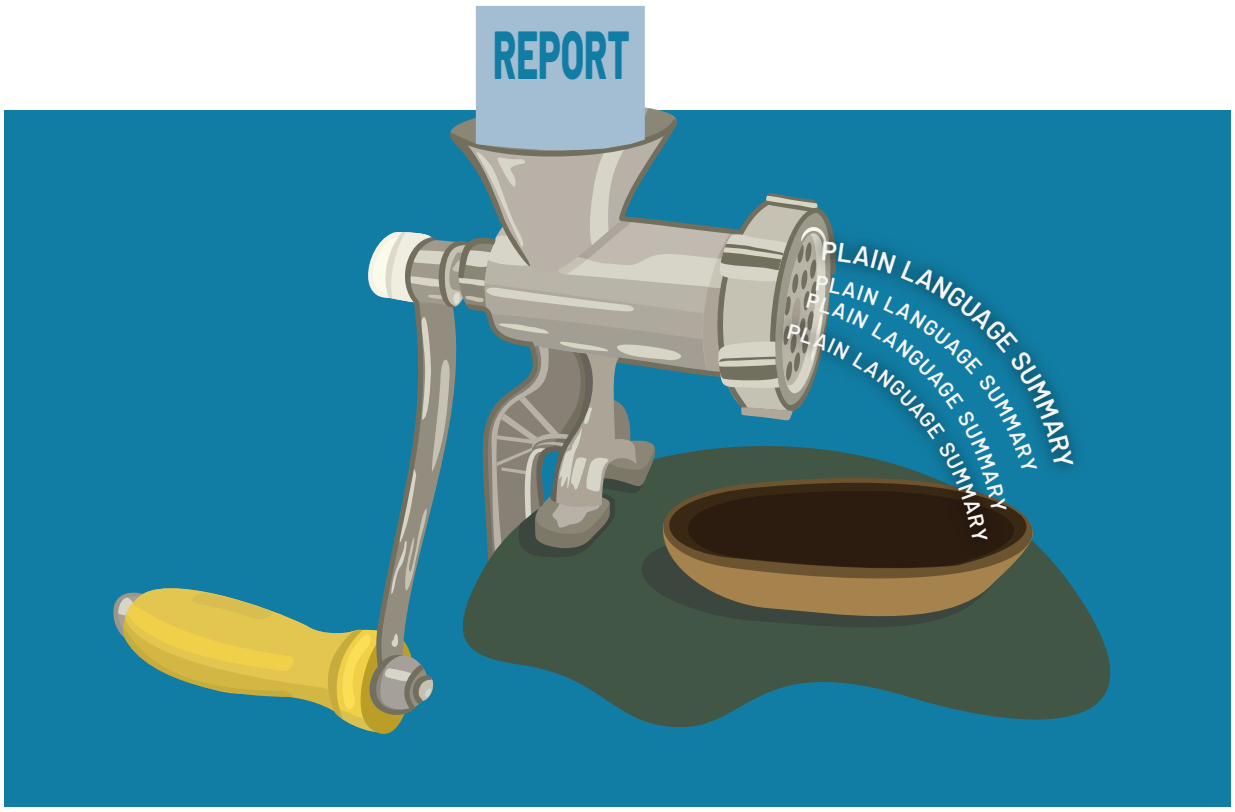
The aim of the PLS is to translate complex clinical information into clear, concise, and understandable documents aimed at the general public (non-expert audiences).

The aim of the PLS is to translate complex clinical information into clear, concise, and understandable documents aimed at the general public (non-expert audiences). This article explores the significance of PLSs, the importance of patient input in their production, the current use of artificial intelligence (AI) in generating them, and their role in enhancing transparency and patient engagement in the clinical development process.

Significance of plain language summaries

Clinical trial results are usually discussed and disseminated through scientific journals, regulatory documents, and conference presentations, which are all primarily targeted at healthcare professionals, the pharmaceutical industry, and researchers.[15] However, these formats use complex technical terminology and statistical analyses that are challenging for non-experts, such as patients and the general public, to understand. This knowledge gap not only hinders informed decision-making but limits patient engagement in healthcare decisions and the clinical development process.[16] PLSs serve as a bridge between the technical language of clinical research and the everyday language of patients and the general public. By distilling complex trial findings into plain language, PLSs help people make informed decisions about their healthcare and participate more actively in shared decision-making processes.[17] Moreover, PLSs play a crucial role in promoting transparency and accountability in clinical research by disseminating trial results in a format that is accessible and comprehensible to diverse audiences, which fosters trust between the general public and the pharmaceutical industry.[18] PLSs serve as a valuable resource for patients, caregivers, and patient advocacy groups seeking information about specific medical interventions or health conditions.[18]

Research has demonstrated the positive impact of personalised patient materials on patient understanding, satisfaction, and trust in the healthcare system. For example, a study by Bhattad et al. (2022) found that patients who received personalised patient education materials, in addition to verbal education by their doctors, had improved patient care via shared decision making and by improving patient satisfaction.[19]



Regulatory mandates for plain language summaries

The EMA requires the submission of a PLS for all interventional clinical trials conducted in the EU as part of EU Regulation 536/2014.[1] This regulatory mandate underscores the critical role of PLSs in promoting transparency and patient-centricity in the clinical development landscape.[20] By ensuring that trial results are communicated in a format that is accessible and comprehensible to diverse audiences, regulatory authorities empower patients to make informed decisions about their healthcare and encourage greater participation in clinical research.[18,21,22] However, despite the progressive movement towards clinical trial transparency, easily accessible PLSs on clinical trials are currently scarce.[23] It is hoped that this will change as the demand from, and awareness of, patients and the general public increases.

The importance of patient input in PLS production

Numerous studies have highlighted the benefits of incorporating patient input into the development of healthcare materials. This has even been echoed in the advice given by regulatory agencies and government bodies.[24] Furthermore, a systematic review by Davis et al. (2007) underscored the positive impact of patient engagement on healthcare communication and decision-making processes.[25]

These findings underscore the importance of integrating patient perspectives into the production of PLSs to enhance their effectiveness and utility for patients and caregivers. Incorporating patient input into the production of PLSs is essential for ensuring relevance and usability and for making sure that these summaries effectively address the informational needs and preferences of diverse patient populations.[26,27] Patients bring unique perspectives and insights that can enrich the content and readability of PLSs, making them more relatable and user-friendly. Engaging patients in the development process can help identify key concepts, terminology, and formatting preferences that resonate with the intended audience.[28]

Moreover, involving patients in reviewing and validating PLSs can enhance their accuracy, relevance, and overall impact on patient decision-making.[29] By prioritising patient input, stakeholders can foster a culture of patient-centred communication and help patients make informed choices about their healthcare.[28]

The current use of artificial intelligence in generating PLSs

By automating tedious tasks such as literature review, data extraction, and summarisation, AI tools enable researchers and medical writers to focus on higher-level tasks such as content curation and quality assurance.[30–32]

In terms of PLS production, advances in AI technology have revolutionised the generation of PLSs, offering innovative solutions to streamline the production process and enhance efficiency by automating labour-intensive tasks. AI-powered natural language processing algorithms can analyse and synthesise complex trial data into clear, concise summaries tailored to specific audience needs.[33]

AI-powered natural language processing algorithms can analyse and synthesise complex trial data into clear, concise summaries tailored to specific audience needs.

Recent studies have explored the use of AI-driven approaches to generate PLSs for clinical research. McMinn et al. (2023) demonstrated the feasibility of using AI to produce PLSs for clinical trials, highlighting the potential for AI to

accelerate the production of summaries.[34] However, while AI holds promise for enhancing the efficiency and scalability of PLS production, human oversight remains critical to ensure accuracy, relevance, and adherence to regulatory requirements.[33,34]

Conclusion

PLSs play a pivotal role in enhancing transparency and promoting patient engagement in the clinical development process. Regulatory mandates underscore the importance of accessible communication of trial results to allow patients to make informed decisions about their healthcare. By incorporating patient input into the production of PLSs, these summaries can effectively meet the informational needs and preferences of diverse patient populations. Moreover, advances in AI offer innovative solutions to streamline the generation of PLSs, although human oversight remains critical. Moving forward, continued collaboration among stakeholders, including patients, researchers, regulators, and the pharmaceutical industry, will be essential to optimise the utility and impact of PLSs in fostering a culture of transparency, accountability, and patient-centred communication in clinical research.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

References

1. EUR-Lex: access to European law. Document 32014R0536. 2022 [cited 2024 May 21]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536
2. European Commission. Clinical trials–Regulation EU No 536/2014 2023 [cited 2023 August 7]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0536
3. Center for Drug Evaluation and Research; Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health. Draft FDA guidance on provision of plain language summaries. 2017 [cited 2023 August 7]. Available from: https://downloads.regulations.gov/FDA-2017-D-5478-0001/attachment_1.pdf
4. European Medicines Agency. Clinical trials information system. 2022 [cited 2023 October 9]. Available from: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system.
5. New England Journal of Medicine. Search results: research summaries. 2023 [cited 2023 August 7]. Available from: https://www.nejm.org/search?q=%22Research+Summary%22&startPage=1&objectType=nejm-media&isFiltered=true&sortBy=pubdate-descending
6. Taylor & Francis Online. Articles with a plain language summary (PLS). 2023 [cited 2023 August 7]. Available from: https://www.tandfonline.com/topic/article-features/plain-language-summary?_ga=2.39289636.664843318.1691384765-60020648.1684563006&_gl=1.
7. Future Science Group. Making the most of your article – Plain language summaries. 2023 [cited 2023 August 7]. Available from: https://thepublicationplan.com/2021/01/29/future-science-group-publishing-plain-language-summary-of-publications-as-standalone-journal-articles/
8. Sage Publications. Plain language summaries. 2023 [cited 2023 August 7]. Available from: https://us.sagepub.com/en-us/nam/plain-language-summaries
9. Pfizer. Plain language summary for the manuscript: time to response for clinical and patient-reported outcomes in patients with psoriatic arthritis treated with tofacitinib, adalimumab, or placebo. 2022 [cited 2023 August 7]. Available from: https://pfizer.figshare.com/articles/journal_contribution/Plain_language_summary_for_the_manuscript_Time_to_response_for_clinical_and_patient-reported_outcomes_in_patients_with_psoriatic_arthritis_treated_with_tofacitinib_adalimumab_or_placebo/19817614?file=35225041
10. Kudos. COVID-19: plain language research summaries from Kudos. 2023 [cited 2023 August 7]. Available from: https://www.growkudos.com/projects/covid-19
11. Centre for Open Science. Search results: plain language summary; 2023 [cited 2023 August 7]. Available from: https://osf.io/search/?q=plain%20language%20summary&page=112.
12. Ipsen. Our pledge: summaries in plain language for all journal publications. 2022 [cited 2023 August 7]. Available from: https://www.ipsen.com/general/our-pledge-summaries-in-plain-language-for-all-journal-publications/

13. Center for Information and Study on Clinical Research Participation, Inc. (CISCRP). Trial results summaries. Boston: CISCRP; 2023 [cited 2023 August 7]. Available from: https://www.ciscrp.org/services/health-communication-services/trial-result-summaries/
14. The Cochrane Collaboration. Updated template and guidance for writing plain language summaries in Cochrane reviews now available. 2023 [cited 2023 August 7]. Available from: https://community.cochrane.org/news/updated-template-and-guidance-writing-plain-language-summaries-cochrane-reviews-now-available
15. Maurer M, Siegel JE, Firminger KB, et al. Lessons learned from developing plain language summaries of research studies. Health Lit Res Pract. 2021;5(2): e155–e161. doi:10.3928/24748307-20210524-01
16. Ghersi D, Clarke M, Berlin J, et al. Reporting the findings of clinical trials: a discussion paper. Bull World Health Organ. 2008. 86(6):492–3. doi:10.2471/BLT.08.053769
17. Weiss BD. Health literacy: A manual for clinicians. American Medical Association. 2007 [cited 2024 May 21]. Available from: http://www.hhvna.com/files/Courses/HealthLiteracy/Health_Literacy_Manual_AMA_Revised.pdf
18. Barnes A, Patrick S. Lay summaries of clinical study results: an overview. Pharmaceut Med. 2019;33:261–8. doi:10.1007/s40290-019-00285-0
19. Bhattad PB, Pacifico L. Empowering patients: promoting patient education and health literacy. Cureus. 2022;14(7):e27336. doi:10.7759/cureus.27336.
20. Center for Information and Study on Clinical Research Participation, Inc. (CISCRP). Perceptions and insights study. Boston: CISCRP; 2017 [cited 2024 May 21]. Available from: https://www.ciscrp.org/services/research-services/perceptions-and-insights-study/
21. Pushparajah DS, Manning E, Michels E, et al. Value of developing plain language summaries of scientific and clinical articles: a survey of patients and physicians. Ther Innov Regul Sci. 2018;52:474–81. doi:10.1177/2168479017738723
22. Riganti P, McKinnon AM. Plain language summaries: enhancing patient-centred care and improving accessibility of health research. BMJ Evid Based Med. 2023;28(5)299–302 doi:10.1136/bmjebm-2022-112200
23. Penlington M, Silverman H, Vasudevan A, et al. Plain language summaries of clinical trial results: a preliminary study to assess availability of easy-to-understand summaries and approaches to improving public engagement. Pharmaceut Med. 2020;34:401–6. doi:10.1007/s40290-020-00359-4
24. Health Research Authority [Internet]. Writing a plain language (lay) summary of your research findings. c2024 [cited 2024 May 21]. Available from: https://www.hra.nhs.uk/planning-and-improving-research/best-practice/writing-plain-language-lay-summary-your-research-findings
25. Davis RE, Jacklin R, Sevdalis N, et al. Patient involvement in patient safety: what factors influence patient participation and engagement? Health Expect. 2007;10(3):259–67. doi:10.1111/j.1369-7625.2007.00450.x
26. Good Lay Summary Practice Guidelines. 2021 [cited 2024 May 5]. Available from: https://health.ec.europa.eu/system/files/2021-10/glsp_en_0.pdf
27. Rosenberg A, Walker J, Griffiths S, et al. Plain language summaries: enabling increased diversity, equity, inclusion and accessibility in scholarly publishing. Learned Publ. 2023 Jan 29 [cited 2024 May 21];36(1):109–118. doi:10.1002/leap.1524
28. Zarshenas S, Mosel J, Chui A, et al. Recommended characteristics and processes for writing lay summaries of healthcare evidence: a co-created scoping review and consultation exercise. Res Involv Engagem. 2023;9:121. doi:10.1186/s40900-023-00531-5
29. Duke M. How to write a lay summary. DCC How-to Guides. Edinburgh: Digital Curation Centre; 2012 [cited 2024 May 21]. Available from: https://www.dcc.ac.uk/guidance/how-guides
30. Virdee N. How AI tech is changing regulatory writing. Certara. 2017 [cited 2019 Aug 5]. Available from: https://www.certara.com/blog/how-ai-tech-is-changing-regulatory-writing/
31. Dezzai. How does AI streamline medical writing workflows? 2023 Dec 28 [cited 2024 May 21]. Available from: https://dezzai.com/en/blog/how-does-ai-streamline-medical-writing/ .
32. Forjanic Klapproth J, Winnier A. Truth be told: where AI and automation can really take us. Medical Writing Special Edition number 2. 2020 [cited 2024 May 21]. Available from: https://trilogywriting.com/document/truth-to-be-told-where-ai-and-automation-can-really-take-us/
33. Norman J, Chamberlain James L. AI for medical writers – friend or foe? Med Writ. 2023;15(3):64–8. doi:10.56012/qovt1204
34. McMinn D, Vinzelberg O, Jenkins M, et al. Artificial intelligence for the development of clinical trial lay summaries: are we ready to replace writers with machines? Poster presented at the 2023 European Meeting of ISMPP, January 24–25, 2023, London, UK.

Author information

Lisa Chamberlain James is a Senior Partner of Trilogy Writing & Consulting, with a special interest in writing for the public, pharmacovigilance, and patient information. Following a PhD and post doc in Pathology at Cambridge, Lisa began her medical writing career in 2000. Since then, she has been involved in EMWA as a member of the Educational Committee, mentor, leader, and assessor of workshops. Lisa holds an EMWA professional development certificate, and is a visiting lecturer for King's College London. She is section editor of the "Medical Communications and Writing for the Public" section of *Medical Writing*, serves on the advisory board for the Pharmaceutical Business Conference Group, and is a Fellow of the Royal Society of Medicine.