# Protecting the rights of clinical trial patients through disclosure: The significance of plain language

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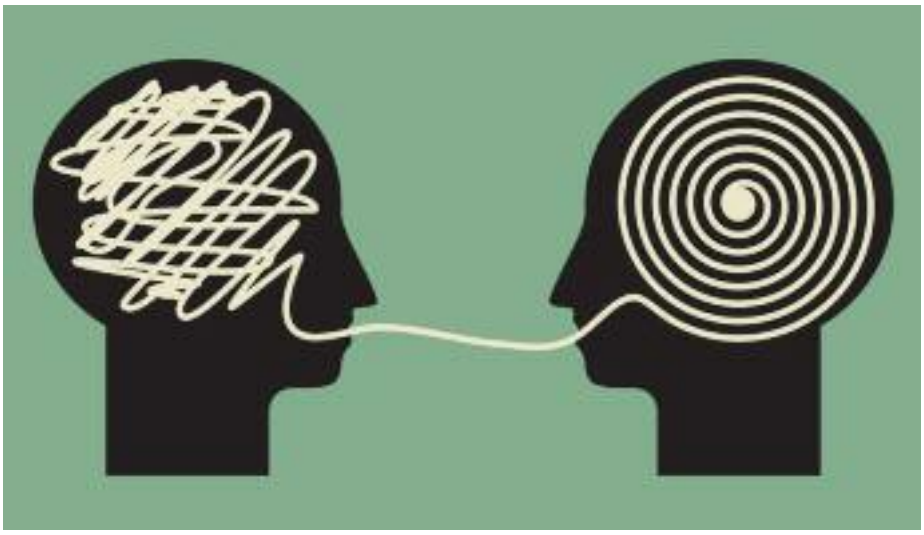
## Abstract
Taking a step back to understand the history of clinical trial regulation triggers a broader perspective on the work we do or the work we will do. As regulatory medical writers, our role is often limited to the more technical submission-level component of either a trial design or a trial outcome. With the advent of plain language summaries (also known as patient lay summaries), we have a unique opportunity to inform the clinical trial patient population directly, and in turn the wider public audience.



Medical writers come from diverse backgrounds with varying professional roles, frequently serving as subject matter experts in a particular niche of the field. Writing skills and technical understanding are developed and broadened over many years. Looking back on the early days of my own medical writing career, some scientific aspects of medical writing were intimidating. Whilst working for an early phase unit, I attended presentations on introductory statistics and pharmacokinetics that were given to a cross-functional group in lay terms (i.e., *plain language*). This plain language explanation of complex topics made a lasting impression and the newly acquired knowledge instilled confidence during my early career. Consider that the use of plain language is vital when communicating with an audience of unknown and varied backgrounds because it facilitates understanding and aids retention.

Clinical trial volunteers certainly qualify as an audience of unknown and varied backgrounds whose need for clarity may be heightened by their clinical condition. In the US, readability studies suggest that consumer comprehension is compromised when content exceeds a seventh-grade reading level, which is the average American reading level as identified by the United States Department of Health and Human Services.[1] As potential authors of clinical trial plain language summaries, it is important to achieve an understanding of health literacy and its impact on readability by region as this is a known variable across the trial volunteer audience.

In the June 2018 issue of *Medical Writing*, we read invaluable information about the writing process for clinical trial disclosure documents, including the bookmark-worthy "Writing lay summaries: What medical writers need to know".[2] Here, the intent is to further explore the topic of plain language in the context of clinical trial patients' rights, sponsor responsibilities, and the medical writer's role in delivering transparency.

## Where it all began
The FDA was founded as a scientific institution in 1848, and the US Congress passed the Pure Food and Drugs Act in 1906. Thereafter, legislation gradually required greater accountability for marketing food and drugs; this in turn increased the need for testing drugs in clinical trials.[3] The EMA was founded in 1995 as a partner of the European Commission and regulatory authorities within individual countries. Both the FDA and the EMA, often in partnership with patient advocacy organisations, have been influential in advancing the concept of clinical trial disclosure.

The history of clinical trial participation and patient protection is a fascinating and a troubling one, often triggered by significant national and global tragedies, or human abuses.[4,5] By the early twentieth century, clinical trials had come under increasing government regulation as authorities recognised a need to better control emerging medical therapies.[3] To date, several milestones have led us to where we are today, beginning with the Universal Declaration of Human Rights after World War II through to the 1996 International Conference on Harmonisation (ICH) Good Clinical Practice guidelines (Table 1).

Health literacy has been defined as "the degree to which an individual has the capacity to obtain, communicate, process, and understand basic health information and services to make

appropriate health decisions".[7] Globally, when health literacy is low, a patient's ability to make appropriate informed health decisions is diminished. The use of clear terms and language that the lay person can fully understand is vital with nearly half of US adults having difficulty accessing, understanding and utilising health information.[7]

The use of plain language has been advocated across several decades and disciplines. Toward the end of the twentieth century and start of the twenty-first century, tangible outcomes of this advocacy started to emerge. In 1977, the *New York Times* published an article, "The Plain Language Movement is Gaining", which reported that attempts to simplify legal language dated as far back as the third US president, Thomas Jefferson.[8] At that time and with the growth of consumerism, an accelerated movement for plain language had gained momentum resulting, for example, in a New York state law that required clear and understandable language in contracts such as apartment leases and loan agreements. However, the article also warned that the path to simplification is hazardous as the standard of simplicity had not been defined. At the time, critics of plain language believed that complex ideas could not always be expressed in language that is simple.[8] Although critics of plain language exist today, they are more outnumbered than ever before.

This brings us to the next series of important milestones in the timeline of the ethical protection of patient rights – international regulations for clinical trial registration[9] – which in turn led to clinical data transparency or, more specifically, plain language summaries, also known as patient lay summaries. These regulations will enable clinical trial participants to understand what *will* happen and what *did* happen during a clinical trial in which they participated.

In 1998, Dave Skinner of the Translation Service European Commission published a poem titled *Clarity*. In the poem, he muses that we frequently talk about transparency, yet we proliferate opacity, when what we need is clarity – which he further specifies as "abandoning obscurity / And preferring more simplicity". He advises: "Write English as it ought to be".[10]

## Current patient expectations

The Center for Information and Study on Clinical Research Participation (CISCRP) is a non-profit organisation in the US, committed to educating patients and the general public about the importance of the clinical research process.[11] In a 2017 study on public and patient perceptions, CISCRP found that many patients (74% of 12,427 respondents) were interested in discussing clinical trial participation within an online-peer community. This tells us the significance of patient expectations regarding information accessibility. While 84% of respondents indicated that it was important to be aware of clinical trials being conducted in their community, approximately 40% were not confident that they could find an appropriate clinical study. Survey participants were also asked the following question: "How much do you trust pharmaceutical companies to give full and accurate information about the health risks and benefits of new medicines?" Just over half (53%) responded "some" and approximately 25% responded "not too much".[11]

The EU Clinical Trials Regulation 536/2014 states that trial sponsors should provide a clinical trial results summary in a format understandable by a lay audience. While the US encourages sponsors to provide plain language summaries, this requirement was not included in the Final Rule (FDAAA 801).[9] When the regulatory requirements and recommendations are combined with patient expectations relevant to clinical trials, the critical nature of public disclosure comes into distinct focus.

## Resources to improve transparency

In the field of medical and health research, English translators at the European Commission authored *Fight the Fog* in 1998, a publication that

***Table 1. Important milestones in regulating the ethics of medical research***

| Year | Milestone |
|---|---|
| 1947–1948 | Nuremberg Code 10 principles on the ethical conduct of medical research involving human subjects; first international guidance which resulted from the mistreatment of prisoners in Nazi concentration camps during World War II.[3]<br>Universal Declaration of Human Rights (adopted by the General Assembly of the United Nations) substantiated global concern regarding the involuntary maltreatment of human subjects. |
| 1962 | Kefauver-Harris amendments proposed greater federal oversight to ensure the FDA review claims of efficacy (versus safety alone) before drug approval, monitor pharmaceutical advertising, and ensure that all drugs had readable generic names.[6] |
| 1964 | Helsinki Declaration developed by the World Medical Association as a list of ethical principles that serve as guidance for clinicians and clinical trial human participants, material, or data. |
| 1966 | International Covenant on Civil and Political Rights, a human rights treaty adopted by the United Nations to protect the civil and political rights of individuals.<br>"In particular, no one shall be subjected without his consent to medical or scientific treatment". |
| 1974 | US National Research Act authorised federal agencies to develop regulations for human research. |
| 1979 | Belmont Report released by the US National Commission documented key principles of ethical research and influenced research ethics regulations in the US. |
| 1991 | The Common Rule (45 CFR 46) established regulatory framework applicable to all US federal agencies. |
| 1996 | International Conference on Harmonisation published Good Clinical Practice, which remains the industry standard for the ethical conduct of clinical trials. |

Source: Bhatt A. Evolution of clinical research: a history before and beyond James Lind.[3]

consisted of simple suggestions to "put the reader first".[12] In the US, the Centers for Disease Control (CDC) published the *Plain Language Thesaurus for Health Communications* in 2007[13] and later in 2016 *Everyday Words for Public Health Communication*.[14] The CDC publications provide lists of "frequently used terms in public health materials and their common, everyday alternatives in plain language sentences". These are important and relevant tools designed to encourage the use of easy-to-understand language when communicating complicated health information to the general public.

A quick guide to health literacy, published by the US Department of Health and Human Services,[15] identified the key elements of plain language as:

- Organising information so that the most important points come first
- Breaking complex information into understandable sections
- Using simple language and defining technical terms
- Using the active voice.

The use of plain language is just one of many components to improve health literacy. Several resources are available to improve clinical data transparency via the plain language summary of trial results (Figure 1).

***Figure 1. A word cloud of clinical trial plain language summary resources***


## Time to get on board

As new scientific disciplines and technologies become part of drug development, the regulatory and ethical landscape will continue to evolve.[3] As a globally-connected society, well into the digital age, our expectations have shifted with the advent of accessible and contemporaneous information, particularly in developed countries. Most in the medical writing community are accustomed to scientific writing within the confines of regulatory requirements, and we now have an exceptional opportunity to inform alternative audiences. Armed with the legacy of plain language, and keeping clarity in mind, we may influence perceptions of clinical research and make a difference in the lives of patients and those of the wider population.

## Acknowledgements

The author would like to thank Alison McIntosh, Julia Statham, and Richard Watson for editorial contributions.

## Disclaimers

The views expressed in this article are those of the author and do not necessarily reflect those of EMWA.

## Conflicts of interest

None

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