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TOPICAL FEATURE

On to the Next Level: ClinicalTrials.gov Goes (More Fully) Plain!

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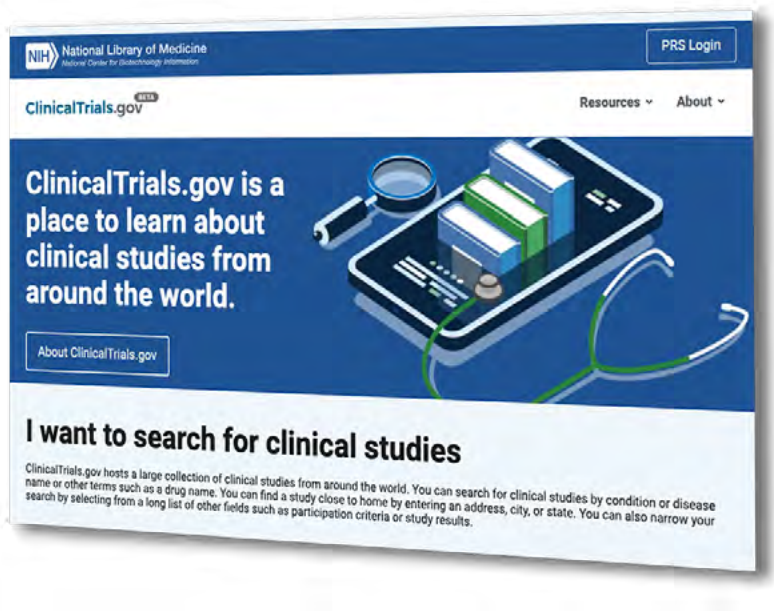
It's a rather tacit revolution that happened on September 26, 2022, in the "What's new" section of the https://clinicaltrials.gov website. A short announcement states that "*A Plain Language Checklist for Lay Brief Summaries (PDF) is added to the Support Materials under Data Element Definitions, Templates, and Checklists. The checklist identifies plain language best practices to help investigators write brief summaries that can be easily understood by the general public.*"



This unemotional announcement is a tremendous move toward more understandable entries in ClinicalTrials.gov (CT.gov)—that is, a move returning to CT.gov's original intentions. The purpose of CT.gov was to make information on clinical trials available to the public, initially to "individuals with serious or life-threatening diseases or conditions, to other members of the public, to health care providers, and to researchers."[1] Hosted by the National Library of Medicine, CT.gov was to be a "consumer-friendly" database that provides easy access to information about clinical trials for patients and their families and members of the public.[2] In 2007, by the US Food and Drug Administration Amendment Act (FDAAA), the mandatory registration of clinical trials was complemented with the requirement to make full trial results available.[3]

However, over the years, CT.gov moved further and further away from its initial intentions and became a website for pharma companies' transparency experts, competitive intelligence analysts, investors, and clinical trial aficionados. This development was a consequence of the technical operationalization of the transparency regulations without having the end user in mind. Responding to the growing disconnect between intention and status, CT.gov has in 2019 initiated a modernization effort with the objective to "deliver an improved user experience."

To foster the overarching objective of transparency of clinical trial research activities, more and more information is to be provided by sponsors and investigators about their clinical trials. The information itself is—however—not presented in a way that "normal people" can readily understand. The disconnect between intention and current practice is particularly obvious for 2 data fields that are of great importance to patients: the Brief Title, a short title describing the trial, and the Brief Summary, a short summary that is meant to provide a general, high-level overview of the trial.

As per CT.gov guidance,[4,5] the text that sponsors are to enter in these data fields needs to be in lay language; that is, it needs to be understandable for the public. Despite CT.gov's intentions, sponsors have not lived up to this.[6,7] To the contrary, Brief Titles are often full of abbreviations and specialist language that renders them incomprehensible for most members of the public. This also applies to the Brief Summaries, which should provide a short, high-level summary of the clinical trial detailing its goal and the intended indication. From a patient view, this is particularly unhelpful as the CT.gov website returns a list of study titles as a response to a search request (eg, trials in a disease area). Thus, the interested user is provided with a list of study titles that mean little to them because they often lack the special-

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ist knowledge to fully understand them. Furthermore, if the user then clicks on a title, they are shown the Brief Summary, which should ideally provide key information about a trial in understandable language. However, the user is often provided with a paragraph of clinical trial gobbledegook and insider technical slang written for the fellow specialist.

Prior to the September announcement, CT.gov had supplied very little guidance on the content of Brief Summaries; therefore, the new guidance amounts to a major improvement. By explicitly providing a plain language checklist, CT.gov reemphasizes the requirement that these key data fields need to be understandable to patients and the public. Should all go well and sponsors do implement the new guidance, key entries of CT.gov will become a lot more accessible for the public—a true revolutionary development, as the database gains a lot more usability for everybody.

For people familiar with plain language writing, the checklist provided is unspectacular and summarizes the most important points of writing in plain language. Although CT.gov addresses the checklist to study managers and investigators, the task of developing useful study titles and understandable study descriptions is better handled by professional writers even better by professional writers with expertise in plain language writing.[8] As anybody who wants to have a go will quickly find out, it is a challenge to provide good study titles and even more so to provide a good, useful study description. It is an even greater challenge doing this in a systematic way across different disease areas in the context of a larger company or research institution. Few study managers would identify patient-focussed writing as one of their core competencies. Hence, the new focus of CT.gov on plain language writing opens a new realm of activity for professional medical writers, particularly those with plain language writing expertise.

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