Objective & Background

Objective
To develop a prototype, internet-based tool for researchers to develop and disseminate plain language clinical trial result summaries (PLS).

Background
Plain language is a method of writing that is concise, avoids jargon, and considers the audience’s comprehension. PLS use these concepts to translate complex clinical information into a more understandable and accessible format.

Currently, more industry sponsors are developing and publishing PLS for participants and the public. However, creating and publishing a plain language summary requires dedicated teams, time, and resources. Consequently, trials lacking these may not be delivering clinical trial results to participants in a comprehensible manner.

Methods

1 | Conduct literature reviews and surveys among clinical research professionals (CRPs), and analysis of current industry PLS

2 | Identify the most practical features to be included in the tool from existing literature

3 | Use HTML, CSS, and JavaScript to create a platform

Results

In the prototype, several web pages were created. Each was created and informed by current PLS development practices, such as writing in a conversational tone for participants.

- Survey administered to CRPs showed that 85.4% would consider using the platform (n=82)
- The landing, about, and frequently asked questions web pages inform the viewer of the purpose of the initiative and resources detailing plain language.
- The “For Researchers” page allows researchers to write PLS, with interactive prompts and resources to help guide their writing.
- The “For Participants” page allows participants to view the PLS, provide feedback, and complete a comprehension check to determine how well they understood it.

Conclusions

This research indicated that the creation, dissemination, and review of PLS could be achieved via an online platform, compared to the standard template commonly used within industry PLS. An online platform could offer several benefits over templates for the PLS development process. These benefits include:

- A streamlined collaboration between researchers and participants, where feedback and information can be exchanged on the same platform.
- Writer and participant interaction is the most crucial and necessary part of the development process.
- Plain language best practices and guidelines can facilitate the writing process in real time.
- If there are any missing features or information, the web platform can be edited accordingly.