Building a Platform for Developing, Disseminating, and Gathering Feedback on Plain Language Summaries for Clinical Trial Participants

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Objective & Background

The objective of this project was to develop a prototype internet-based tool that can aid researchers, particularly those conducting investigator-initiated trials, in composing plain language clinical trial result summaries as well as to collect and analyze participant feedback and comprehension.

- Regulation EU 536/2014 has served as an impetus for the clinical trial industry to begin developing and disseminating plain language summaries (PLS) for participants.
- Plain language is a method of writing that is clear, concise, well-organized, avoids jargon, and targets the audience’s literacy level.
- Current PLS development within the industry requires dedicated teams, funding, time, and resources. Investigators lacking these need a streamlined alternative so that more trials develop and disseminate PLS.

Methodology

1. Conduct literature reviews, surveys among clinical research professionals, and analysis of industry development of plain language summaries.
2. From research, determine most practical features and layout.
3. Use HTML, CSS, and JavaScript to build prototype platform.

Implications

- Smaller, investigator-initiated trials without adequate funding, time, resources, etc. can still more effectively develop and disseminate PLS for participants.
- Industry sponsors can also incorporate this platform within their own PLS development workflow. However, the platform would need more work development for such upscaling.
- For investigators not yet engaged in PLS development and dissemination, the platform could eliminate many of the disincentives discouraging them to develop PLS.

Conclusions

- The features necessary for a streamlined approach to PLS development can be implemented within an online platform.
- Transitioning from the industry standard of templates to an online PLS development and dissemination platform offers several benefits:
  1. Ability to collect researcher and participant feedback during PLS development.
  2. Inclusion of the necessary resources for writing PLS, such as best practices and guidelines.
  3. Ability to implement new features and edit the layout based on user feedback.

Future Research

- Pilot platform within clinical trial to ascertain usability and areas for improvement.
- Focus on back-end development for better user security and functionality by conducting focus groups with stakeholders.
- Perform updated research on industry best practices and how they can be incorporated into the platform.