A Comprehensive Online Platform for Plain Language Summary Development

Objective & Background

Objective: Develop a prototype, internet-based tool for researchers to develop and disseminate Plain Language Clinical Trial Result Summaries (PLS).

Background

- Regulation EU 536/2014 has incited the industry to begin developing and disseminating plain language summaries (PLS) for CT 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 industry requires dedicated teams, funding, time, and resources, which may not be possible for investigator-initiated trials (IIT).

Methods

1. Conduct literature reviews, surveys among clinical research professionals, and analysis of industry development of PLS.
2. From research, determine most practical features and layout. Criteria used to determine most practical features was:
   - Features to assist researchers in writing in plain language
   - Features necessary to develop the PLS
   - Features to assist participants with PLS review and feedback
3. Use HTML, CSS, and JavaScript to build prototype platform.

Results

Within the prototype, the following webpages & features were able to be developed:

- Landing, About, and Frequently Asked Questions webpages, which housed resources like plain language best practices
- An interactive webpage for researchers to create a PLS with prompts and relevant resources and examples.
- An interactive webpage for participants to view and provide feedback on a PLS.

Conclusions

Necessary features for a streamlined approach to PLS development can be implemented within an online platform, rather than traditional templates. An online platform can:

- Collect researcher and participant feedback during PLS development.
- Include resources such as best practices and guidelines.
- Implement new features and edit the webpage layout based on user feedback.
- Allow IITs to more readily develop and disseminate PLS to participants.