

Completing the Circle: Lay Summary of Protocol Results for Study Participants

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1. Background

The success of clinical trials includes developing strong, valued partnerships with participants and their families through the life cycle of a study. Our Patient Family Advisory Council (PFAC) which embodies our community of patients and families identified the inability to communicate study results to participants as an important gap in this relationship. We developed and implemented a project to provide a lay summary of study results to patients and families through the St. Jude web portal.

2. Goals

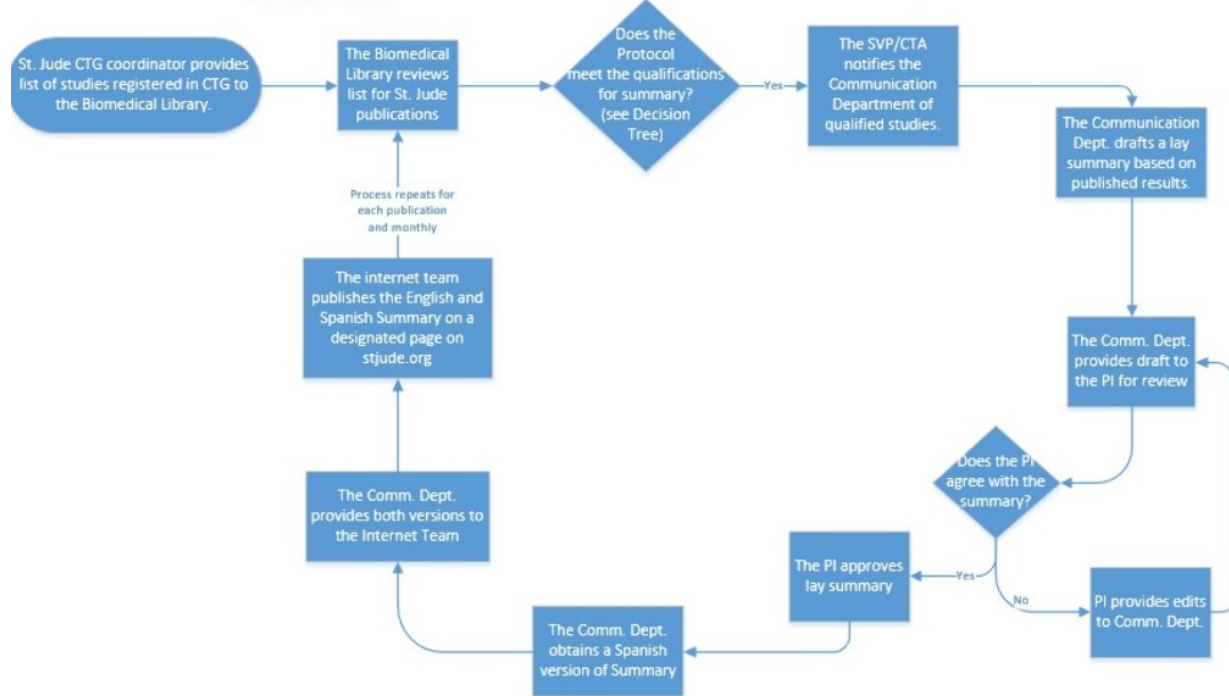
Our goal was to define a process that would result in a web-based solution working with multiple stakeholders that included the Communications Department, the Patient Experience Office, the Biomedical Library, the St. Jude *clinicaltrials.gov* coordinator, the Internet Team and investigators. The initial scope was limited to St. Jude–initiated clinical trials that have published peer-reviewed results and have an NCT number. The aim was to provide lay summaries of study results that were consistent in format and content, written in lay language and that outlined the study's key findings. We sought the input of the PFAC in assessing the relevance of the content structure and how well it would communicate information that was understandable and aligned with their needs. To address the ethnic diversity of our patient population, we also aimed to have the lay summaries posted in English and Spanish.

3. Solutions and Methods

We defined a structured content for each summary, which included the following domains: why the study was done, when it was done, what the study consisted of, what we learned from it, what the next research steps were as a results of that study, how the study's findings affected the patient, whom should be contacted for more information, and where the results were published. We defined a stepwise process, including a decision tree of which studies would qualify for lay summaries and the stakeholder handoffs. See Figure 1.

Lay Summary for Protocol Results for Participants

PROCEDURE



4. Outcomes

The project was completed in 5 months. Currently, 18 lay summaries in both English and Spanish are available through the St. Jude website. We developed a communication strategy that included input from the Patient Family Advisory Council to bring awareness of this initiative and to alert parents about the availability of study results.

5. Lessons Learned

Working with the Internet Team, we plan to provide greater awareness and optimization of content by employing additional tools to provide a search-engine function based on study title/mnemonic, notification when there is a new posting, and monitoring metrics of impact (survey, website use, etc.).