

Development of a Process to Share Plain Language Summaries of Clinical Research Results With Participants at Princess Margaret Cancer Centre

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1. Background

There has been a call for greater transparency in communicating information related to clinical research to both participants and the public. A recent survey of over 14,000 people in the United States showed that 88 percent of respondents thought that “scientists should be sharing their results in easy-to-understand language.” Various stakeholders, including medical journals, publishers, associations, and agencies, have responded to this appeal by making research outcomes available to lay audiences. For example, the European Union regulations governing clinical trial conduct require sponsors to submit plain language summaries (PLSs) of their trial results.

Sharing clinical research results with participants who contribute to the research helps promote inclusivity and transparency by making scientific information more accessible. At Princess Margaret Cancer Centre (PMCC), feedback received from a survey of over 500 of our clinical trial participants indicated that the top factor influencing their decision to participate in future studies was obtaining the overall research results.

2. Goals

The objective of our project is to develop a means of sharing clinical research results with participants and the public in an accessible and comprehensible format. By sharing results written in plain language, we endeavor to provide meaningful information to our participants and the public by facilitating knowledge translation and supporting patient-centered care. We hope that this initiative will serve to increase patient engagement, promote transparency, and acknowledge the value of participants’ contributions to clinical research and the advancement of medical knowledge.

3. Solutions and Methods

Our project constitutes a new initiative to support PMCC investigators and study teams by developing PLS documents of their research results to share with their participants. The project will address an unmet need, fulfilling participants’ expressed interest in obtaining the results of studies to which they contributed.

Our work will also support clinical researchers and study staff, who wish to improve participants’ experiences, but who may lack the expertise or capacity to address the return of research results in lay language.

4. Outcomes

We completed a pilot study to assess the feasibility of developing PLSs, involving three academic clinical trials. We received positive feedback from investigators, study team members, and sponsors’ representatives, who expressed support for our efforts to engage patients and translate research results into accessible formats. Following the success of the pilot, we proceeded to operationalize our initiative and formalize a process for requesting and developing PLSs. This includes the creation of an application form, process summary, guidance documents, and resources for study teams.

5. Lessons Learned and Future Directions

Piloting our PLS initiative highlighted the importance of developing a standardized process to assist study teams with requesting and obtaining requisite approvals for pls distribution to study participants. we are currently working with our research ethics board to standardize the application submission process for PLSs, to reduce administrative burden and turn-around times. In an effort to promote patient and community engagement and foster transparency, we also plan to create a public-facing website to share the PLSs of our clinical research results.