Sharing Plain Language Summaries of Clinical Research Results with Participants at Princess Margaret Cancer Centre

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① Background

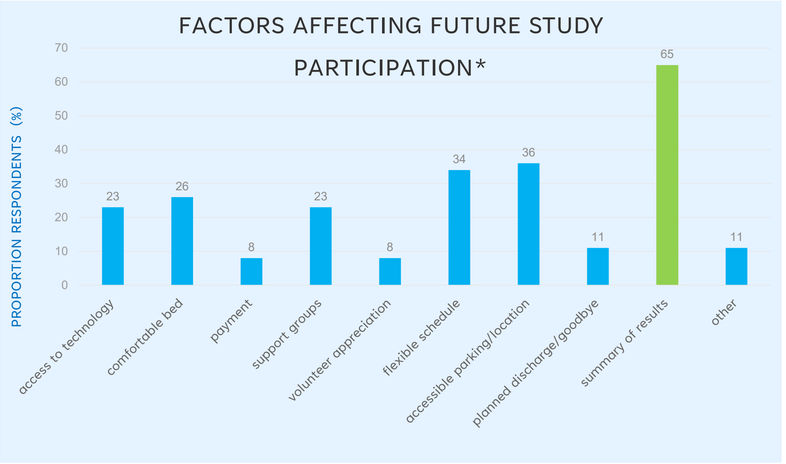
Greater transparency has been called for in communicating information related to clinical research to both participants and the public.

A recent survey of over 14,000 people in the United States demonstrated that 88 percent of respondents felt that "scientists should be sharing their results in easy-to-understand language".[1]

Multiple 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.[2]

Sharing results with the participants who contribute to the research helps promote inclusivity and transparency by making scientific information more accessible.

At Princess Margaret (PM), feedback received from a survey of over 500 clinical trial participants indicated that the top factor influencing their decision to participate in future studies is obtaining the overall research results.



*Princess Margaret participants were asked to select from a list of factors, those which they deemed important when considering future study participation

② Objectives

The project was conceived with the goal of developing 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, meaningful information can be provided to study participants and the public by facilitating knowledge translation and supporting patient-centered care.

This initiative was developed with the intention of increasing patient engagement, promoting transparency, and acknowledging the value of participants' contributions to clinical research and the advancement of medical knowledge.

③ Methods

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

The initiative will provide a service to support clinical researchers and staff, who wish to improve participants' experiences, although may lack the expertise or capacity to address the return of research results in lay language. .

④ Outcome

A pilot study was completed, involving three academic clinical trials, to assess the feasibility of developing PLSs. Investigators, study team members, and sponsors representatives expressed support for the engagement of participants and translation of research results into accessible formats.

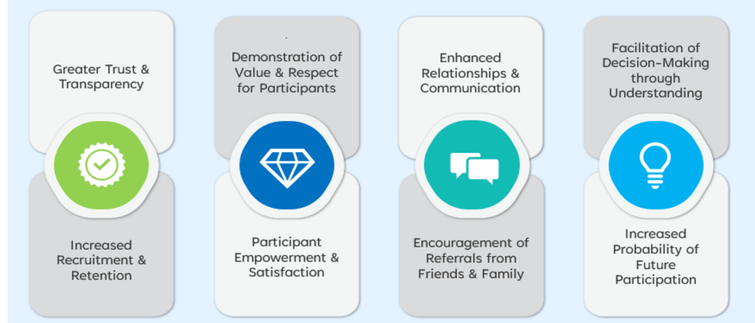
Following the success of the pilot, a standard process to operationalize requests for the development of PLSs was created. Resources were designed to support this initiative, including general information for users, an application form, a process summary and guidance documents (including a "frequently-asked-questions" sheet). Development of a standard operating procedure is currently underway.

⑤ Lessons Learned & 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 in order to reduce administrative burden and turn-around times. In support of promoting patient and public engagement and fostering transparency, we also plan to create a public-facing website to share the PLSs of our clinical research results with the broader community.

BENEFITS OF SHARING PLAIN LANGUAGE SUMMARIES OF RESEARCH RESULTS WITH PARTICIPANTS[3-6]



⑥ References

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