



Best Practice Recommendations for Communicating Results with Clinical Trial Participants

March 2020



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CLINICAL TRIALS BC

Introduction

In 2018, [Clinical Trials BC](#) completed the Canadian Clinical Research Participation Survey, a national project that asked participants about their experiences taking part in clinical trials. The survey showed that many participants were left with unanswered questions both during and at the end of the research study. One participant explained: “I would have liked to have the study follow up to me directly about my results and the results of the over all study.” Another responded: “My experience was incredibly disappointing; I never received the study results.”

This is problematic for three main reasons. First, it leaves participants feeling unsatisfied with their experiences in research, which results in attrition and less willingness to participate in research in the future. Second, the [Canadian Tri-Council Policy Statement\(1\)](#) clearly states that informing participants of the research results is as important as disseminating results to the research community.

Finally, the [Canadian Institutes of Health Research](#) acknowledges that the impact of research on the health care system is directly related to effectively communicating research findings back to knowledge users, including members of the public that may be affected by those findings. Researchers have a growing responsibility to “close the loop” by communicating learnings to their population, and a failure to do so may reduce the effectiveness, impact, and acceptability of their research in a real-world setting.

To help solve this problem, Clinical Trials BC, through the BC Academic Health Science Network, formed a provincial working group in 2019 comprised of previous clinical trial participants, researchers, ethics administrators, and decision makers to learn from each other and make suggestions for future clinical trials. This document summarizes the topics we explored within the group and the communication practices we recommend for improving the experiences of participants taking part in clinical trials.

Canadians regard clinical trials positively with overall perceptions that they provide societal and personal benefits (2). Participants value knowing how their efforts help the success of the research, and how the finished research will in turn help other people in their community.

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“My experience was incredibly disappointing; I never received the study results.”

-Study participants

Many participants also have specific questions about their participation as an individual, that they feel are never fully answered. Some common questions that came up within the working group were:

- “Which study arm was I in?”
- “Based on the tests, am I better or worse?”
- “What’s next?”
- “What was learned?”

Answering these questions can be difficult for research staff. We acknowledge there are limitations to what information may be provided to participants in a research study, and that the recommendations provided may not work in every research situation. However, we believe that by applying these suggestions where possible, we can improve the experience of participants taking part in clinical trials, which may also lead to longer retention in a study and willingness to participate in other research in the future.

Recommendation 1: plan to manage expectations about what information participants will be provided from the very beginning

The outcome of a study is just a part of the picture for participants that have taken part. Participants have questions throughout the study, and at the end. Clear, up front discussions will help participants understand which of their questions will be answered throughout, or at the end of the study, and why some questions might not be answered.

For example, participants may want researchers to explain what their test results mean for them. In this case, be sure to talk to participants in advance about what you will be able to tell them, and what you will not, and why. The consent visit is an excellent time to have this conversation by asking participants what they would like to know about their participation and what they hope to get out of the experience.

It is often a long time after a patient takes part in a study that the outcome is known or published. Let participants know how long they may have to wait to have their questions answered, or to find out how the study ended. The end date of a study may not be known but it is still best for participants have a general idea of how long it *could* be.

N2 offers a variety of [educational toolkits](#) that may help you and your staff communicate with and inform participants, including templates that may be downloaded and branded for your study. Providing participants with links to [ItStartsWithMe.ca](#), and N2’s [Participant Bill of Rights](#) is also an effective way to provide them with a trusted source for the answers to their questions about research and clinical trials.

Having this conversation with participants will also allow you to let them know *how* you will give them updates about the study in the future, for example through email, snail mail, or by telephone. Verbal updates at study visits are also an effective and simple way to provide information like how the enrollment is going, if the study is closing soon or if there will be an open-label phase coming. It is also a great opportunity to ask if the participant has any new questions or concerns. If possible, allow participants to choose how they would like to receive updates during and after their participation.

The Clinical Research Ethics Board at the University of British Columbia provides [consent templates](#) that include space for participants to indicate if they would like to receive a copy of research papers in the future, and how they would like to receive it.

Example actions:

- Ask participants about their expectations and talk to them about what questions may not be answered and why, continue this conversation with participants throughout the study
- Use available resources such as those available through the N2 resources page.
- Provide a post-card or brochure that shows the process and timeline of a clinical trial in an accessible way. Templates can be found [here](#), under the “Clinical Trials Education and Awareness” tab
- Provide links to more information when applicable such as a laboratory website, principal investigator’s bio, and external resources like ItStartsWithMe.ca
- Consider having key resources printed for participants that may not have access to the web

Recommendation 2: support study staff with information and resources for communicating with participants

It may be hard for staff to know how to answer participants’ questions, and what information is okay to share with them. Consider how you can best support your team in responding to participants’ through role-playing, training and resources, and conversations. While each patient may have his or her own questions and concerns, we recommend creating a list of FAQs with responses to common questions asked by participants. This activity can be included as a part of study planning and the document can be updated throughout the study as staff become more familiar with the types of questions asked by participants. Asking participants about their experience when they leave the study will also provide staff with valuable information that they can use when working with future participants and planning future studies.

Example actions:

- Plan for staff to address questions by including these conversations as steps in the study protocol
- Talk to staff about what kinds of questions participants might ask and what information they can and cannot provide
- Create a guide for staff with sample responses to common questions. Always ask the study sponsor what they can do to help support participant education and awareness.
- If the project is sponsored, ask what they can do for patient education, awareness and additional resource material. They may agree to develop and provide something to you for this purpose.

Recommendation 3: share study outcomes in accessible ways and provide choices when possible

Some participants may be interested in reading the scientific articles that come from the study. Asking participants if they would like a copy of future articles is an excellent practice. Many participants, however, may find these articles challenging to understand. Participants might feel like a piece is missing when scientific articles do not show what the outcome of the study means for their community.

We recommend offering participants the choice to receive a copy of scientific articles, as well as a general summary meant specifically for them. The general summary should share what the research team learned, and address questions participants may have, such as what's next for a drug, and how their participation helped other people. A good practice is to always consider your study population, and summarize research findings in a way that could be understood at a 6th grade reading level. If your study has a sponsor, ask if they will help. Some research institutes will also draft a lay summary for your team, and organizations like the [Centre for Information and Study on Clinical Research Participants \(CISCRP\)](#) also offers this service. A town hall-style meeting or presentation may also help communicate the outcome of your study. Inviting participants may provide an additional opportunity for them to provide feedback.

Think about whether your team has access to other tools that can be used to share study progress and outcomes with participants. For example, summaries, flowcharts, and diagrams made for research posters may be adapted for a patient audience. When sharing statistics or numbers, be sure to include an explanation of what they mean and consider providing links to extra resources when possible. Also consider the possibility of posting updates online, such as on a social media page or a laboratory or institutional website.

Giving participants the option of checking for updates online allows them to have more control in their clinical trial experience. Even simple updates that show the study has not finished yet, or that researchers are analyzing data, will give participants peace of mind and let them know they have not been forgotten.

Finally, if you have persons with lived experience or community partners on your research team, ask them for assistance with building this strategy and creating these materials. They should not be overlooked as an excellent resource to consult about effective methods of engagement, appropriate language, and the needs and wants of their peers.

Example actions:

- Build a knowledge translation strategy into your research plan that includes your population
- Consider budgeting upfront for how you will share the outcome of the study or turning this task into a student project. If industry sponsored, they may have resources available to help support you
- Create a sharable summary of the study that can be understood at a 6th grade reading level. Avoid jargon and keep it simple.
- Adapt material from conference posters to share with participants (e.g., abstracts, diagrams, flowcharts)
- Give participants options for how they would like to get information about the study:
 - Scientific article vs. general summary
 - Email vs. regular mail
 - Updates on websites or social media

Recommendation 4: say thank you

Finally, always remember to say ‘thank you’ to the participants taking part in your study, both throughout their participation and when the study is complete. Consider giving ‘thank you’ cards to participants in person at the end of their participation, or via mail at the end of the study, or both. A personal touch such as a handwritten note, having the card addressed to the patient by name, or having study staff sign the card will all go a long way in helping the patient feel appreciated, important, and connected to the study.

Acknowledging participants’ contributions plays a large role in their overall experience taking part in a study. Letting participants know how their participation supports both the study and their community will also help grow their interest in research and taking part in research.

Example actions:

- Verbally thank participants as they take part in the study
- Provide a personalized thank you card
- Plan a time for the Primary Investigator to personally thank each patient
- Formal letter from the Primary Investigator

Closing

The recommendations set forth by our group of previous research participants, researchers, ethics administrators, and decision makers was founded on the feedback from clinical trial participants and their identified areas for improvement of the clinical trial participation experience. With some additional planning, research teams can:

- manage expectations that participants have concerning what information they can expect to receive throughout the trial;
- support study staff with tools and guidance to better communicate with participants;
- share study outcomes in a way that is clear and is meaningful for participants; and
- help participants feel valued as partners in their journey through clinical trial participation.

Our hope is that by applying these suggestions where possible, we can improve the experience of participants taking part in clinical trials, which may not only improve their experience, but also lead to longer retention in a study and willingness to participate in other research in the future.

Clinical Trials BC Provincial Working Group, BC Academic Health Science Network

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Resources and links

1. [TCPS 2 \(2018\) – Chapter 4: Fairness and Equity in Research Participation](#)
2. Willison, D. J., Richards, D. P., Orth, A., Harris, H., & Marlin, S. (2019). [Survey of Awareness and Perceptions of Canadians on the Benefits and Risks of Clinical Trials](#). Therapeutic Innovation & Regulatory Science, 53(5), 669–677. <https://doi.org/10.1177/2168479018805433>
3. [Blog post/Summary "Taking a look at NASEM's report titled, "Returning Individual Research Re..."](#) Full report can be found here: National Academies of Science, Medicine, and Engineering (NASEM) released a report titled, ["Returning Individual Research Results to Participants: Guidance for a New Research Paradigm."](#)
4. [How a simple 'thank you' could improve clinical trials](#) - Everyone would benefit if researchers did more to make participants feel part of a study
5. [CISCRP Trial Results Summary Services](#)
6. [White Paper on Best Practices for Returning Study Results to Participants](#) co-authored by the Center for Information and Study of Clinical Research Participation (CISCRP) to learn about the current best practices for the content and preparation of plain language summaries, and the current guidance for how sponsors should work with Institutional Review Boards (IRBs) which have oversight of the clinical trials for which the summaries are provided.
7. Taylor Jeremy. [Reporting research findings to participants is an ethical imperative](#) BMJ 2019; 367: l6324
8. Raza MZ, Bruhn H, Gillies K. Dissemination of trial results to participants in phase III pragmatic clinical trials: an audit of trial investigators intentions. BMJ Open 2020;10: e035730. doi: 10.1136/bmjopen-2019-035730

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