

Thoughts Around Strengthening Meaningful Engagement with Indigenous Participants

Below, we outline several concrete steps we have implemented in our pragmatic trials training program. We do not present these as a definitive model, but rather as practical starting points for teams seeking to strengthen respectful engagement with Indigenous participants:

How We Show Up as a Trial Team

Trial leaders should provide clarity and confidence in the conduct of the study, as this helps build trust. Throughout this program, we have been keen to encourage teams to remain open, humble, and willing to learn. This includes listening carefully to concerns and being prepared to adjust course if aspects of the trial are inappropriate or potentially harmful.

Effective leadership in this context requires balancing confidence in running the trial with humility in how the team listens and responds.

Cultural Safety and Competency Training

Trial teams are encouraged to engage in cultural safety and competency training, such as learning about OCAP® principles, participating in San'yas Indigenous Cultural Safety training, and taking part in experiential learning activities like the Kairos Blanket Exercise. While these trainings are not complete solutions, they help establish a shared foundation and foster understanding of both historical and ongoing contexts that shape Indigenous peoples' experiences with health research.

Including Indigenous Voices on the Trial Team

Where possible, trial teams are encouraged to include Indigenous members in meaningful roles. In our work, First Nations patients have served as patient partners and have helped guide aspects of the trial. Some participating sites now have Indigenous health teams, and we've been reaching out to ask for advice, invite collaboration, and listen to concerns.

Reviewing and Adapting Patient-Facing Materials

For consent forms and patient information sheets, we have been keen on asking Indigenous partners to review them. Key questions that we addressed to them included: Is the language respectful? Could anything be confusing, misinterpreted, or potentially triggering?

For some trials, we've translated written materials into Indigenous languages like Ojibway-Cree, Mohawk, and Ojibway, and we've made audio or spoken versions available on the trial website. We encourage trial leaders to take similar steps as they design and run clinical trials.

Ethics and Governance

For multi-site trials, teams typically seek provincial approval for pan-provincial ethics review, and new national processes are also emerging. When a participating site serves a substantial number of Indigenous patients and has its own local research ethics board or Indigenous governance process, we make a point of submitting there as well. This ensures input from people with Indigenous expertise and strengthens the ethical oversight of the trial.

Reflecting on the Collection and Reporting of Identity Data

Collecting information on race, ethnicity, and Indigenous identity presents important considerations. Without this data, trials cannot demonstrate that Indigenous participants were included, which can feel like a missed opportunity.

At the same time, teams must respect OCAP® principles: ownership, control, access, and possession of data involving Indigenous people, and be mindful of risks such as stigmatization. For example, reporting that a high proportion of participants with a particular condition are Indigenous requires careful consideration of how the information is presented and interpreted. It is also important to balance the rights of Indigenous governance structures to steward data with the rights of individual participants to participate in trials and to self-identify in their own ways.

Throughout our work, we have reflected on these issues and continue to navigate the challenges of finding the right approach.

Sharing Results in Accessible Ways

When a trial concludes, it is important to share findings beyond academic publications. We prepare plain-language summaries and other patient-facing materials, and where possible, translate them into multiple languages. These steps help ensure that results are communicated more broadly and in ways that are accessible to participants and communities.