Developing a Solution to Current SGBA+ Gaps in Clinical Research

Group 5

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Assignment Acknowledgement

The Turnitin originality score was 22%. Grammarly was also used for grammatical correctness.

Author Contributions

Student Name	Student Number	Contributions
Vanesa Berati	251101092	Conducted a literature review to formulate the solution, attended meetings, wrote a skeleton of the solution and final solution brief, helped edit the final product.
Ikjot Bedi	251159384	Researched the Health Canada Mandate Met with the group to discuss a solution Wrote up how the decided solution follows the 4 Health Canada Responsibilities
Rishika Sharma	251008648	Created Teams Chat, created Google Doc, Researched the extent of geographical barriers, started meetings, wrote up how the purposed solutions addresses the barriers/challenges, edited assignment, formatted assignment
Nour Abdelrahman	251156074	Researched relevant policy levers and incorporated that into our solution. Wrote the policy lever section.

Solution Name: DTP: DCT Training Program

Brief Description of the Solution:

It is evident that there is a need to invest in more robust infrastructure for clinical trials at the community level. Health Canada, in partnership with the Canadian Institute of Health Research (CIHR), proposes a grant to invest in a new training platform intended to provide trial leaders with the knowledge and resources to implement Decentralized Clinical Trial (DCT) procedures within their practice. DCTs encompass a hybridized approach promoting increased participant recruitment and retention, regardless of geographical area, thus, enhancing accessibility and outreach. Through the complementary development of a matching platform, healthcare professionals will be provided infrastructure to search for existing clinical trials to best identify and discuss available trial options with their patients. To ensure that primary healthcare physicians understand how to implement this matching platform, they will be trained as part of the purposed training platform. Therefore, this training platform encompasses two parts: (1) providing trial leaders with training on increasing clinical trial accessibility through the implementation of DCTs, and (2) ensuring that primary healthcare physicians are aware of accessible trials for their patients, through training and establishing the clinical trial matching platform.

CIHR will establish partnerships between providers from large academic health care centres with community providers to facilitate collaboration and drive greater patient enrollment and retention. Follow-up evaluation of the Program will monitor changes in access to clinical trials, community sites' participation in research, demographic data, adverse events, as well as clinician and patient attitudes.

Which policy lever(s) is being used?

Opening targeted grant and contribution programs is important to overcome the low participation rates in clinical trials across Canada, more specifically in rural and remote areas. The funding will allow DCTs to be conducted and increase focus on rural regions where trial access is difficult. Secondly, researchers in these regions need education and training on trial protocols and patient management affiliated with DCTs (Chen & Kummar, 2023). Funding grants by a Health Canada/CIHR collaboration can accelerate knowledge transfer and resource sharing between academic centers and community providers. This will then likely increase trial capacity by enabling more sites to conduct trials, reduce geographic barriers, and improve participant enrollment. Another lever associated with our purpose solution is information and education, as researchers, primarily trial leaders, and investigators, will need knowledge of maintaining, sustaining and implementing DCTs, and hence the training platform. Additionally, primary healthcare clinicians in rural areas will need training on how to use the trial matching service.

Moreover, successful applicants into the training platform will receive a grant to implement their DCTs, hence extending the grants and contributions lever. Information Programs will be important for instructing healthcare researchers. Online training modules, workshops, and certification programs will help researchers acquire knowledge on clinical trial processes to communicate with patients appropriately (Hess et al., 2015). The approach will also boost the confidence of providers and increase the rate of patient referrals, resulting in increased participation rates of patients (Hanley et al., 2023). Altogether, these policy levers will be integrated to provide a robust framework for DCTs, education and training. This will result in a more inclusive and effective clinical research environment within Canada that benefits patients and healthcare systems alike.

Which challenge(s) / barrier(s) will be addressed by the solution?

Patient participation in clinical trials is vital for research and greater participation is essential in advancing novel interventions to improve public health outcomes. However, historically, certain populations have been underrepresented in clinical trials resulting in a need for more generalizability of new interventions. Different groups of individuals are underrepresented in trials for various reasons, including, but not limited to socioeconomic status (SES), race, sex, gender, ethnicity and more. One such factor that significantly impacts trial participation and proper representation is geographical area (Sedhai et al., 2023). According to the Federal Drug Administration (FDA) of the United States, cardiovascular diseases constitute the largest amount of clinical trial participants, however, they are most impacted by a lack of diversity due to the underrepresentation of individuals belonging to low SES, different minority groups, and rural areas (Sedhai et al., 2023). The unavailability of clinical trials in rural geographical areas impedes trial participation and results in the inadequate representation of these populations (Sedhai et al., 2023). Representation is critical in clinical trials, as it allows for the generalizability of an intervention to a wider population and a lack thereof incurs a cost of hundreds of billions of dollars (National Academies of Sciences, Engineering, and Medicine, 2022). Moreover, a lack of diversity in clinical trial participants hinders the ability to examine variation in intervention efficacy. Inaccessible clinical trials increase the gap in health disparities in underrepresented populations (National Academies of Sciences, Engineering, and Medicine, 2022).

Our solution aims to address the underrepresentation of rural and remote communities in clinical research by providing grants to fund a training program that aims to implement decentralized trials. Decentralized trials (DCTs) will increase accessibility through clinical trial hybridization. Hybridization offers participants flexible participation, without the stress of frequent, inconvenient travel requirements that would otherwise hinder their participation. Additionally, DCTs relieve the burden of travel expenses for not only participants but also reimbursement costs for the research team. Moreover, through the training platform, we plan to recruit research investigators who will be incentivized by a grant to start a DCT aiming for increased accessibility and a diverse clinical trial participant population. Incentivization promotes willingness and positive attitudes toward change.

Moreover, this training platform will incorporate modules and methods for establishing partnerships with local primary healthcare clinicians, as clinician referrals are essential to clinical trial recruitment (Mohan & Freedman, 2022). We acknowledge it may be outside of the primary healthcare clinician's bandwidth to uphold many partnerships with different trial teams to ensure optimal engagement. Hence, as part of the training program, we invest in a clinical trial matching service. This online tool will promote increased patient recruitment as primary healthcare clinicians, at a community level, will be able to send forward participant referrals at an enhanced pace. This service will not only increase patient recruitment, but it will also allow for primary healthcare clinicians to be involved in the participants' trial journey, which involves quicker adverse event reporting and serve as a bridge for the time delay rooted in participant recruitment number targets. This platform will promote clinical trial accessibility at a community level, thereby increasing participant population diversity and hence representation of currently underrepresented groups.

How does the solution fit within Health Canada's mandate

As per the Health Canada mandate that Canada's healthcare system is preserved, this solution aims to include a larger population of individuals within clinical studies. This improves the system, as incoming research funded by this grant will gather patient enrollment from rural populations, which leads to the analyses of various demographic factors like race, ethnicity,

SES, disability, and more. Clinical trials including these patients are crucial for sustainable and accessible healthcare to all Canadians, not just those in urban populations.

As per the Health Canada mandate that Canadian Health is enhanced, this solution involves research across populations in Canada. This specific mandate focuses on disease outbreaks, drugs, food, chemicals, pesticides, medical devices, and consumer products across Canada. Since our solution involves funding research projects that involve rural populations in clinical trials, the research it funds involves various aspects of healthcare, which include the specific areas of interest that this mandate focuses on.

As per the Health Canada mandate of partnering with other federal departments, agencies, and health organizations, this solution involves a partnership with CIHR, the Canadian Health Research Institute. This mandate specifies that the partnerships should contribute to meeting the needs of all individuals, specifically those at risk. This solution involves populations that are typically underrepresented in clinical studies. Additionally, CIHR is the National Research Institute, and introducing this type of program within the Institute allows for nationwide research involving rural populations to be conducted, not just in heavily populated provinces like Ontario or British Columbia.

As per the Health Canada mandate of communicating with others about health promotion, disease prevention, and safety messaging, this solution involves the education of clinicians in rural settings of various clinical trials and procedures that are available to patients in their local communities. By educating rural physicians, they can educate their patients on the trials available for participation. This is especially important since the local physicians have built rapport and trust with their patients, so the patients are better able to understand and acknowledge information that their healthcare provider is telling them.

References

Chen, J., Lu, Y., & Kummar, S. (2023). Increasing patient participation in oncology clinical trials. *Cancer medicine, 12*(3), 2219–2226. https://doi.org/10.1002/cam4.515

Hanley, D. F., Jr, Bernard, G. R., Wilkins, C. H., Selker, H. P., Dwyer, J. P., Dean, J. M., Benjamin, D. K., Jr, Dunsmore, S. E., Waddy, S. P., Wiley, K. L., Jr, Palm, M. E., Mould, W. A., Ford, D. F., Burr, J. S., Huvane, J., Lane, K., Poole, L., Edwards, T. L., Kennedy, N., Boone, L. R., … Harris, P. A. (2023). Decentralized clinical trials in the trial innovation network: Value, strategies, and lessons learned. *Journal of clinical and translational science, 7*(1), e170. https://doi.org/10.1017/cts.2023.597

Health Canada (2016, March 31). Health Canada's mandate/ https://www.canada.ca/en/health-canada/corporate/mandate.html

Hess, D. W., Reed, V. A., Turco, M. G., Parboosingh, J. T., & Bernstein, H. H. (2015). Enhancing provider engagement in practice improvement: a conceptual framework. *The Journal of continuing education in the health professions*, *35*(1), 71–79. https://doi.org/10.1002/chp.21260

Mohan, S. V., & Freedman, J. (2022). A review of the evolving landscape of inclusive research and improved clinical trial access. *Clinical Pharmacology & Therapeutics, 113*(3), 518-527. https://doi.org/10.1002/cpt.2832

National Academies of Sciences, Engineering, and Medicine, Policy and Global Affairs, Committee on Women in Science, Engineering, and Medicine, & Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical

Trials and Research. (2022). *Improving representation in clinical trials and research: Building research equity for women and underrepresented groups* (K. Bibbins-Domingo & A. Helman, Eds.). National Academies Press. https://www.ncbi.nlm.nih.gov/books/NBK584396/.

Sedhai, Y. R., Patel, N. K., Mihalick, V., Talasaz, A., Thomas, G., Denlinger, B. L., Damonte, J. I., Del Buono, M. G., Federmann, E., Hardin, M., Ibe, I., Harmon, M., Van Tassell, B., & Abbate, A. (2022). Heart failure clinical trial enrollment at a rural satellite hospital. *Contemporary clinical trials*, *115*, 106731. https://doi.org/10.1016/j.cct.2022.106731