Canadian
Cancer Clinical
Trials Network

Enhancing CRAFT Implementation and Advancing Decentralized Clinical Trials in Canada

CRAFT 2.0 Workshop

March 7, 2025

"What We Heard" Report

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Background and Context

On March 7, 2025, the Canadian Cancer Clinical Trials Network (3CTN) hosted a collaborative workshop designed to advance decentralized clinical trials (DCTs) across Canada by enhancing the implementation of the Canadian Remote Access Framework for Clinical Trials (CRAFT). The workshop was designed to accomplish two distinct but interconnected objectives:

1. Provide updates on the current DCT landscape in Canada, including the challenges and opportunities related to CRAFT implementation; and

2. Identify solutions to overcome key barriers in enhancing CRAFT implementation and advancing DCTs in Canada – with a particular focus on (I) interprovincial barriers; (II) regulatory requirements; (III) cost barriers; and (IV) challenges related to professional liability and indemnity.

This report captures the key themes and highlights that emerged from the workshop and reflects the wide range of participants who came together from across the Canadian clinical trials ecosystem – including representatives from C17 Council, the Canadian Partnership Against Cancer, Health Canada, N2 Canada and numerous hospitals across the country.

Key Themes

Three key overarching themes emerged during the workshop:

1. The feasibility and value of DCTs and CRAFT have been clearly demonstrated through the CRAFT Proof-of-Concept (PoC) projects and international case studies.

2. While there is consensus on the feasibility and value of CRAFT, there are remaining barriers that must be addressed to optimize its implementation.

3. CRAFT's long-term success will come by promoting awareness, fostering collaboration, identifying and engaging champions and providing targeted support to lead and satellite sites.

(1) The feasibility and value of CRAFT have been clearly demonstrated through the CRAFT Proof-of-Concept (PoC) projects and international case studies.

Reflecting on the history of CRAFT, the workshop drove home the importance of a flexible approach that can be tailored to meet the specific needs of different regions and different clinical sites. CRAFT's adaptability is evident in the disparate settings selected as original PoC sites in British Columbia, Newfoundland and Northern Ontario. By promoting long-term capacity building for regional and remote clinical sites, CRAFT empowers them to engage in clinical trials in a manner that aligns with their specific expertise, capabilities, and available resources. This foundation not only helps expand the system's ability to deliver trials to more patients over time but also builds stronger ties between smaller sites and larger, more experienced centres. These partnerships create opportunities for collaboration, knowledge sharing and optimized resource utilization across sites, further strengthening the clinical trial ecosystem as a whole.

The initial projects also demonstrated the impact that CRAFT can have on improving access to care for rural and remote populations. By significantly reducing travel time to clinical trial sites, CRAFT helped to ensure more equitable access to clinical trials for patients who would otherwise be excluded. In a country like Canada, where patients sometimes face travel times of over 10 hours to reach the nearest clinical trial site, CRAFT helps reduce the strain on patients' finances, time, energy, health – and helps better connect geographically marginalized communities to clinical trials. As a result, trial outcomes will more accurately and equitably reflect the diverse populations across Canada, ensuring that the data collected can better inform care for all Canadians.

More specifically, CRAFT has proven to enhance access to clinical trials for adolescent and young adult (AYA) patients and patients with rare cancers. By providing a feasible mechanism for patients being treated in adult cancer centres to enrol in clinical trials in pediatric cancer centres, CRAFT ensures a more inclusive approach to trial participation, which is critical for improving treatment options for cancer patients across Canada. Workshop attendees heard that Australia's teletrial model – a DCT model similar to CRAFT – has improved access to clinical trials for patients with rare cancers, even within metropolitan areas, which demonstrates another potential benefit of CRAFT as the framework evolves.

(2) While there is consensus on the feasibility and value of CRAFT, there are remaining barriers that must be addressed to optimize its implementation.

CRAFT can play a key role in the design and delivery of successful DCTs – but all too often, cost and funding barriers hinder or delay their launch. With clinical trials blending elements of care and research, the siloed structure of healthcare can make launching DCTs a challenge, despite the value that CRAFT offers. Additionally, the financial burden of coordinating both primary and satellite sites, combined with the significant initial investments required to implement DCTs (including technology platforms) can create substantial challenges.

Beyond these visible cost barriers lie a range of additional challenges. They also include costs related to human resource issues, such as the lack of capacity in specialized fields like pediatric oncology, where not all sites have the necessary expertise. Additionally, high turnover rates at clinical trial sites exacerbate the issue by creating instability and resulting in a loss of valuable knowledge, adding another layer of cost. While CRAFT offers long-term efficiency benefits, the significant learning curve and required training that must be navigated before those benefits can be fully realized also represent a hidden cost.

In addition to cost barriers, the work required to stay consistent with regulatory guidelines can become an additional complexity. Although international guidelines such as ICH E6(R3) have evolved to become more supportive and enabling of DCTs, there is often a fear among sites that unfavourable interpretation of regulatory guidelines by the Health Canada inspectorate could complicate the implementation of both DCTs and CRAFT.

Compounding cost and regulatory challenges are interprovincial barriers. The processes for obtaining the necessary approvals and resources for patients to participate in clinical trials across provinces and territories (PTs) are often slow, inefficient and managed on a case-by-case basis. This barrier is particularly significant when billing and reimbursement processes vary between PTs. For example, while some hospitals face no significant issues with interprovincial billing, others struggle with determining who should bear the financial responsibility. Interprovincial challenges not only restrict patient access to clinical trials but also create significant logistical hurdles that must be addressed to optimize the implementation of DCTs and CRAFT.

Professional liability and indemnity concerns add another layer of complexity that further impedes DCT and CRAFT implementation. Typically, the principal investigator (PI) of a clinical trial is held accountable for the entire trial process, a

responsibility that becomes even more daunting when the trial is decentralized and involves multiple sites. This is an important barrier that often discourages PIs to take part in DCTs. Additionally, there is currently a lack of communication and collaboration with essential stakeholders, including the Canadian Medical Protective Association (CMPA) and the Healthcare Insurance Reciprocal of Canada (HIROC), both of which are integral to addressing concerns around professional liability.

Ineffective education and a lack of knowledge sharing are additional key challenges hindering the implementation of DCTs and CRAFT in Canada. For smaller, more remote clinical sites, inadequate targeted educational efforts often result in information overload, leading to resistance to participating in DCTs and adopting CRAFT. Additionally, the lack of dedicated platforms for knowledge sharing, coupled with collaboration among key partners being limited to occasional workshops, creates a communication gap that restricts the exchange of best practices and support among participating sites and key partners. Finally, insufficient patient education and involvement hinder patients' ability to access and advocate for DCTs in Canadian health systems, which could be lifesaving and significantly reduce the burden on patients.

(3) CRAFT's long-term success will come by promoting awareness, fostering collaboration, identifying and engaging champions and providing targeted support to lead and satellite sites.

A central focus of the afternoon discussion was to identify solutions to overcome the remaining challenges to CRAFT implementation.

Raising awareness of CRAFT's existence, purpose and applicability through targeted promotion and education is essential to ensuring its successful implementation. One recommendation involves developing targeted informational packages, including slide decks, user testimonials and PoC findings, to effectively pitch the benefits and purpose of CRAFT to potential satellite sites and other stakeholders. Subsequently, conducting a comprehensive environmental scan to identify clinical trials that are particularly suitable for an initial CRAFT implementation will help sites identify and prioritize appropriate opportunities that balance feasibility and risk considerations. Finally, more efforts are needed to educate and involve patient representatives, empowering them to advocate for DCTs and CRAFT by highlighting how these approaches address unmet patient needs within Canadian health systems.

Engagement and collaboration with key partners are important to help them better understand how to integrate CRAFT effectively. Strengthening engagement

with decision-makers, especially at the site level, and experts with specialized knowledge – such as those from CMPA and HIROC – can help more effectively address existing barriers and encourage more seamless and widespread integration of CRAFT. To promote a more comprehensive and collaborative approach to addressing remaining implementation barriers, a multistakeholder working group could be convened to develop a strategic and thoughtful path forward. Such collaboration would also ensure that no critical aspect of the implementation process is overlooked, helping to streamline efforts and build a stronger, unified approach to advancing the uptake of CRAFT across Canada.

Finally, supporting the implementation of CRAFT through site-level training and other capacity-building measures will be critical to its long-term success. This could begin with developing an operational guide/checklist to help guide the implementation of CRAFT. To further support CRAFT implementation, simplifying existing clinical trial training and educational modules is essential. Training modules should only equip site staff with the essential knowledge they need for their specific roles, reducing the risk of information overload and increasing efficiency. Additionally, establishing and integrating a system for continuous feedback, evaluation and knowledge sharing across all CRAFT sites will drive ongoing improvement, ensuring CRAFT evolves to meet the needs of our dynamic healthcare systems and patient populations. Together, these proposed initiatives could optimize the implementation of CRAFT as it evolves over the coming months.

Final Thoughts

The CRAFT 2.0 Workshop was an engaging and productive event shaped by the active participation of diverse stakeholders from across Canada's cancer clinical trials ecosystem. Coupling international case studies with important learnings from CRAFT's first three sites, the workshop laid the foundation for CRAFT's contribution to a new era of DCT excellence across Canada.

Through collaboration and engagement with diverse partners – including patient partners, institutions, regulators, funders and other key partners in Canada's clinical trial ecosystem – 3CTN will further explore the opportunities identified during the workshop and leverage its network of collaborators to maximize the collective impact of CRAFT on the broader world of Canadian DCTs.

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Next Steps for 3CTN

1. Strengthen awareness and engagement
2. Launch a strategic CRAFT 2.0 Implementation Working Group to address remaining challenges
3. Build operational capacity at the site level through education/training/community of practice
4. Identify trials for sites to implement CRAFT model
5. Enhance knowledge sharing and continuous improvement by building a learning network to ensure sustained learning and improvements