Canadian Remote Access Framework for Clinical Trials (CRAFT)

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1. Executive Summary

Clinical trials are the essential step to prove that treatments and other health interventions are safe and effective. For many patients, a clinical trial can offer alternative or otherwise unavailable options, including access to innovative drug therapies, diagnostic or imaging technologies, surgical procedures or supportive care interventions that have the potential to lead to improved outcomes in survival and/or quality of life. In addition to bringing new therapies to patients, clinical trial activity has been demonstrated to improve the performance of health systems [1]. Moreover, financial investments in clinical trials have a positive impact on the economy as measured by GDP [2].

Access to trials is limited for many Canadians. The distance to the nearest cancer centre currently precludes at least 10 million Canadians from participating in trials [3, 4]. Travel time and associated costs for rural and remote populations are prohibitive.

There are strong arguments for addressing this challenge.

- *Ethical principles require addressing disparity in access*. Consistent with the core principle of *accessibility* outlined in the Canada Health Act, improved trials access aligns with the ethical principles of promoting welfare, justice and respect for persons [5].
- *It will result in better science.* With broader geographic participation and a more representative trial cohorts, results will be more readily generalizable and show greater concordance with what might be expected in the real world. It will also be easier to evaluate treatments for more rare cancers and molecular subtypes to realize the potential of precision medicine.
- *It will contribute to better outcomes.* Facilitating remote access to trials holds not only expands treatment options and potential benefit for individual patients, but faster overall accrual expected for the study would generate results sooner, contributing to more rapid availability of research findings and adoption by the healthcare system.
- *It will improve productivity and global competitiveness.* While Canada distinguishes itself in terms of both productivity and the quality of its clinical research compared to other countries, trial sponsors also prioritize rapid accrual, reliable projections and performance [6]. Innovation that leverages technology to bring more patients into trials, more quickly, can offset relatively low population densities that are the reality in most areas of the country and bring participation rates more in line with international benchmarks.
- *The time is right.* New regionalized models of care and advances in digital technology, like telehealth and virtual consults, have created an opportunity to address the problem of remote access to clinical trials in Canada.

The Canadian Cancer Clinical Trials Network (3CTN) is a national organization focused on strengthening and supporting clinical trials performance. Recognizing the challenges, opportunities and benefits described above, 3CTN formed a multi-stakeholder Steering Committee to create a Canadian Remote Access Framework for Clinical Trials (Appendix A). The Steering Committee provided oversight of the framework development process including articulating the recommendations in this document.

Key steps in developing the Framework included:

- A structured literature review
- An analysis of two case studies selected or detailed analysis
- Key informant interviews

- A multi-stakeholder workshop and validation of its findings

A draft framework was developed at a structured, solution-focused workshop. The framework was based on leading practices from the literature, case studies and interviews and discussion from workshop participants. The workshop participants unanimously endorsed moving forward with the proposed Framework recommendations and develop plans for implementation.

The Framework is structured as a series of formal recommendations focused on:

- Infrastructure development and system support (includes training and required tools)
- Costs and funding requirements
- Patient privacy
- Considerations for trial planning and conduct
- Regulatory requirements to accommodate and support remote access trials
- Ethics Review
- Indemnity and insurance issues
- Engagement, communications and advocacy

The Framework was developed in the context of oncology with a view to being useful and adaptable in other therapeutic areas.

An implementation roadmap is structured around:

- Pilot and formally evaluate proof of concept clinical trials in the Canadian setting;
- Incorporate "lessons learned" into scaling activities i.e. additional regions, trial designs, trial site configurations, disease types; and,
- Establish health policy, research and professional practice norms to recognize remote trial conduct as a standard practice in Canada.

Implementation of the Framework recommendations activities are now underway.

2. Introduction & Background

The ethical principles guiding the conduct of research support improving access to clinical trials for people who live in remote and rural areas. The principles of respect for persons and equity, including the just distribution of resources and of risk and benefit, requires that people, regardless of where they live, should have the opportunity to participate in clinical trials [7].

Participation in clinical trials is low in Canada. For cancer trials, the reported rates of trial participants to new incident cancer cases are 4.7% overall and as low as 1% in some Canadian provinces as compared to 14% in the UK [8, 9]. It is likely that these differences are linked to the issue of access, at least in part. In Canada, over 30% of the population reside outside of large/medium population areas where regional cancer centres may be located [10]. Trial recruitment and retention is challenging for these patients. Study protocols may have eligibility criteria that limit distance from the participating centres. Healthcare providers and patients cite the ability for attending study visits that take place at the cancer centre as a primary factor for considering trial participation [11]. Making trials more available in community-based centres would broaden the treatment options for individuals in rural and underserved regions where the physical and financial burden of trial participation is greater. Given low patient accrual is a leading reason cited for premature trial closure, the scale of unrealized accrual potential in Canada is enormous [4].

Creating recruitment opportunities for all patients, regardless of their place of residence creates a favourable and fairly balanced distribution of potential risk and benefit. Individuals and the people they represent that are excluded from clinical trials cannot benefit directly from research interventions and generalizability of findings may be reduced. Conversely, when the study populations more accurately represent the cross-section of Canadians, there is a potential to increase reliability and generalizability of findings and overall benefits arising from the research. The Canadian Partnership Against Cancer in its Canadian Strategy for Cancer Control called for a focused pan-Canadian effort to identify and systematically address inequities in the cancer system to ensure everyone has a chance to achieve the best possible outcomes [12].

The time is right to consider new approaches to delivery trial opportunities to patients in remote and rural areas. The widespread use of telemedicine/telehealth services in all provinces has created the mechanism for more equitable access. Using a hub and spoke model of telemedicine healthcare delivery at 63 geographic sites throughout the interior and northern British Columbia, thoracic surgical cancer patients living remotely saved an average travel distance of 766 km. With over 15,000 patient encounters between 2003-2015, more than 11.5 million km of travel was deferred [11]. In Ontario, telemedicine helped patients avoid more than 270 million km travel for >890,000 consultations in 2017/18 alone [13].

In 2012, the Canadian Senate Committee on Clinical trials identified the need for infrastructure improvements. The goal of which was to increase Canada's global competitiveness in the clinical trial sector and ultimately to improve access to innovative medicine for Canadians [14]. Teletrials can enhance Canada's potential for patient accrual in the eyes of research sponsors. Maximizing recruitment by extending opportunities to a broader segment of the population can favorably impact study feasibility decisions, particularly in the case of rare diseases where the potential number of patients in a research site's catchment area may be very low. Establishing less burdensome means for remote participation will help promote recruitment, retention and access to treatment interventions for those who are otherwise unable to travel.

Recognizing the challenges, opportunities and benefits described above, a multi-stakeholder Steering Committee convened to create a Canadian Framework for Remote Access to Clinical Trials. The committee reviewed current models for remote access to determine suitability for Canada's health care system and clinical research environment. This paper summarizes the result of these deliberations and proposes a framework applicable for conducting trials across all regions of Canada that draws from comprehensive and structured, multi-stakeholder review of existing teletrials programs and services.

3. Framework Development

The process for developing the framework is illustrated in Figure 1. A Steering Committee of stakeholders with expertise and knowledge of Canada's clinical trial environment was convened by 3CTN (refer to Appendix A for a list of Steering Committee members and committee terms of reference). The committee was charged to review existing models for remote access to trials; assess Canadian health system readiness; identify needs and enabling mechanisms; and to develop recommendations that would serve as a framework for a Canadian approach.

Published literature was searched using MESH terms "clinical trials" and "health services accessibility" of Medline and Embase databases to identify existing models that enabled rural and remote patients to

participate in trials closer to their homes. Both publications and references were reviewed for relevance. Stakeholder interviews, including trial sponsors, ethics board members, regulators, health services providers, patients and clinical trial researchers were conducted to identify relevant initiatives, case studies and existing resources to help plan, assess feasibility and support trial conduct for geographically remote patients.

Results from the publications and interviews informed the focus of a structured workshop held at the 2019 Canadian Cancer Research Conference (see Appendix B). Workshop participants included trial sponsors, experts in telemedicine delivery, clinical trial agreements, regulatory affairs, research ethics and privacy, clinical research professionals and patients from cancer centres and satellite sites as well as representatives from Health Canada. Interactive sessions were designed to obtain opinion on framework options put forward by the project Steering Committee, advice on implementation including highlighting where clarification within current regulatory guidelines would be necessary to foster adoption.

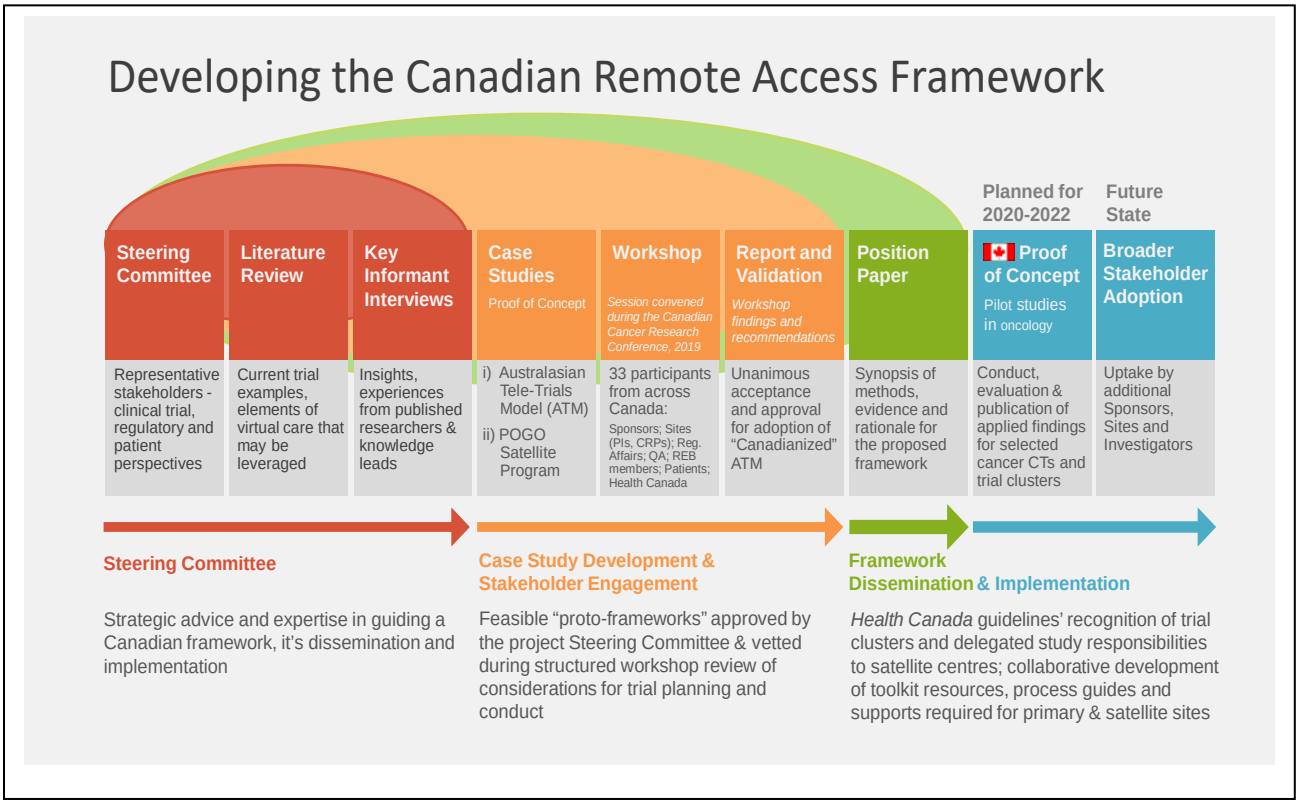

Figure 1. Project overview and framework development process

Highlights from the Literature Review

Multiple publications include recommendations that call for trial sponsors and researchers to explore the use of technologies and other tools to reduce the time and travel burdens associated with clinical trial participation [15, 16]. Although the review found limited examples of decentralized trial conduct in the Canadian population [17, 18], it did reveal existing mechanisms for delivering standard of care cancer treatment at local community healthcare centres via telemedicine programs. All provincial healthcare systems support telemedicine use for remote clinical services [11, 19]. For example, Alberta's Community Cancer Network enables coordinated care and treatment amongst tertiary, associate and community cancer centres. The potential for leveraging routine use of technologies for

remote healthcare for clinical research activities was widely noted. A number of publications summarized methods and results of processes for teleconsent, remote patient monitoring, data capture and reporting of safety and other trial endpoints and patient reported outcomes [15, 20-23]. A few models of central coordination of trials with some activities conducted at satellite centres were identified and summarized below.

4. Case Studies

Two successful models of remote trial access were identified through the literature review and key informant interviews: the Clinical Oncology Society of Australia (COSA) Australasian Teletrial Model (COSA ATM) and the Pediatric Oncology Group of Ontario (POGO) Satellite Program [24, 25]. Both models leverage telemedicine technologies and health care collaborations to enable participation of remote and rural patients in trial research. These programs not only provide templates for structures and processes to conduct trials with remote patient participation but also show the feasibility, efficiency and effectiveness in trial site organization and operation. Experiences drawn from each model provide learning opportunities for adapting and scaling the approaches to a range of trials/activities and trial site capabilities in Canada.

COSA Australasian Tele-trial Model

Australia has historically experienced lower rates of clinical trial enrollment than would be expected from international recommendations and benchmarks. For rural, regional and rare cancer patients, rates of enrollment are even lower. The main rural and regional barriers to the availability of trials closer to home are travel-related costs and inconvenience. Pre-existing regulatory and governance processes had not been able to adequate address these problems [26, 27].

To address the challenge, the COSA ATM was developed in collaboration with stakeholders to improve access to clinical trials. The model was endorsed by both professional organizations such as COSA and governments which provided funding for development and implementation of the model and pilot studies. The tele-trial model is conceptually straightforward: patient recruitment, retention and national trial capacity are enhanced by decentralizing the processes of a clinical trial. With agreement from the trial sponsor, a primary site holds overall responsibility for supervision and coordination of trial-related matters for the “trial cluster” in collaboration with local satellite site(s) (see Figure 2). Depending on capabilities and clinical research experience, defined trial procedures may be delegated to satellite site clinical personnel and conducted during in-person patient visits or via telemedicine.

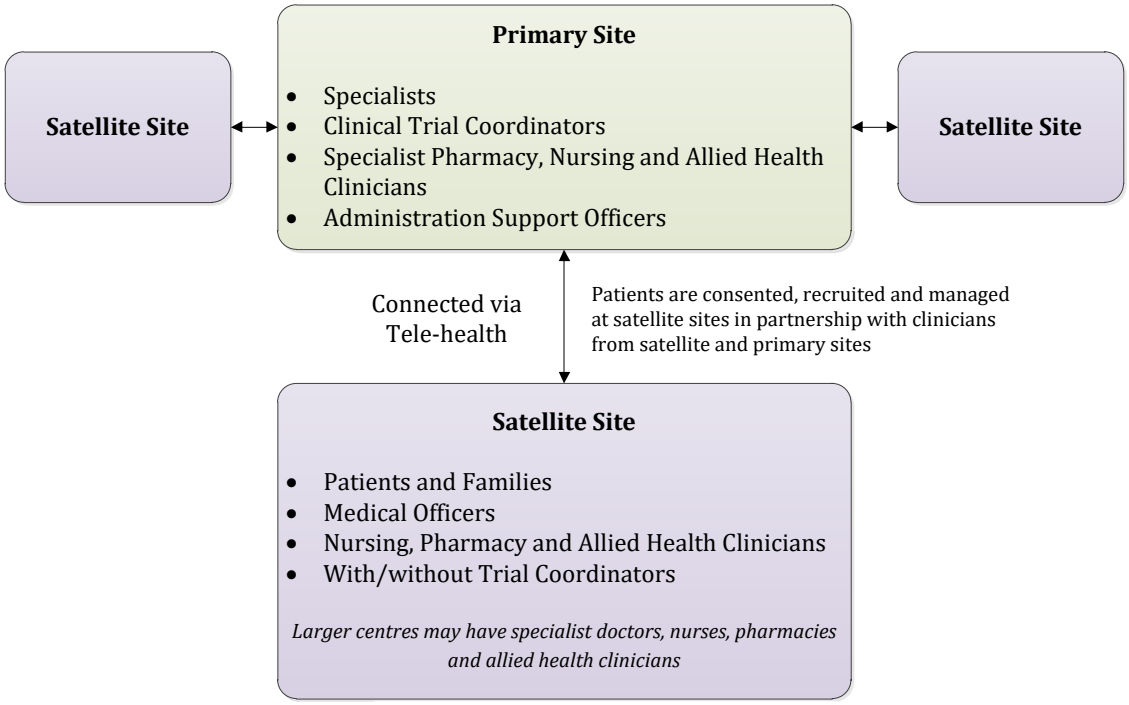

Figure 2. A trial cluster from the Australasian tele-trial model. Adapted from Clinical Oncology Society of Australia, Australasian Tele-Trial Model: A National Guide for Implementation. 2016.

Central to the COSA ATM model is the concept of a "cluster" in which there is an explicit delegation of roles and accountability between primary (i.e. cancer centre) and satellite sites (i.e. remote health care centre). The COSA ATM provides tools defining roles and responsibilities, ensuring competencies and overseeing and managing delegated investigator responsibilities for protocol conduct between the primary trial sites located at tertiary cancer centres and satellite sites. The model is sufficiently flexible for different site configurations and range of satellite site capabilities [26, 27].

Successful pilot studies of the COSA ATM model include industry, cooperative group and investigator-sponsored trials of different designs and interventions. A formal evaluation of a randomized Phase III trial (Monarch E) conducted using the model found that [28]:

- The data produced was acceptable for commercially sponsored research destined for marketing applications and regulators;
- The teletrials model enabled rural and remote patients to access clinical trials closer to home;
- Teletrials was an efficient way of increasing clinical trials capability and training of regional sites in Good Clinical Practice (GCP);
- There was broad national support for the implementation of a uniform teletrials model.

The model was adopted by Australian states and recently the Federal Government of Australia announced an investment of $100 million over the next five years to provide stimulus funding for innovative proposals with potential for scaling and national application [29].

Pediatric Oncology Group of Ontario (POGO) Satellite Program

Participation in multi-centered trials is a core component of childhood cancer care. Given the relatively small numbers of children with cancer, it is not feasible for community hospitals centres to independently obtain the expertise, capacity or infrastructure required for engaging in trial activities. Since 1998, POGO's Provincial Pediatric Oncology Satellite Program has enabled the transfer of certain aspects of a child's clinical care including clinical research activities to a community hospital closer to the child's home. The POGO model is a networked, shared-care system based on a partnership between Ontario's five tertiary hospitals and POGO Satellite Centres in community hospitals.

Figure 3. Map of POGO-affiliated tertiary-satellite sites. Reprinted from Childhood Cancer Care Plan: A Roadmap for Ontario, 2018-2023. Toronto: Pediatric Oncology Group of Ontario (POGO);2018. Reprinted with permission.

The POGO model defines the Satellite Practice and is funded by Ontario's Ministry of Health and Long-Term Care (MOHLTC). Tertiary and satellite centres sign letters of agreement (LOA) and receive

funding to implement Satellite Program standards & guidelines, operating requirements and responsibilities. All satellite centres recognize the Ontario Cancer Research Ethics Board (OCREB) as the board of record for all studies that have patients sent "closer-to-home" on protocol. POGO provides central oversight and serves as a coordinator and administrative lead for maintaining satellite program and research agreements, designated satellite investigator (DSI) curriculum vitae & current medical licenses. POGO further supports the streamlined ethics review process and core clinical research training delivery (Tri-Council Policy Statement (TCPS) v2, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Guideline for Good Clinical Practice (ICH-GCP) & Health Canada Food and Drug Regulations, Part C, Division 5). Study-specific training can typically be facilitated and completed by POGO in advance or just-in-time training may be completed by the Principal Investigator as required.

In this model, the scope of responsibilities at the primary site includes:

- Ongoing development of its existing satellite site network and expansion, as necessary;
- Delegated review and inspection of research study processes at satellite sites;
- Facilitating communication and supporting knowledge exchange for satellite sites;
- Centre funding disbursements and expenditure reporting;
- Assuring adherence to provincial standards and guidelines;
- Managing standard operating procedures (SOP) quality and compliance;
- Assessing protocol feasibility and risk management, for example assessing drugs (IV vs oral, phase, capacity to transport, expertise to store/prepare/give), complexity of treatment, access to diagnostic tests and their timelines to ensure tests can be done in the protocol-defined windows, data collection and management;
- Ensuring an appropriate risk-based monitoring program in place, through a combination of central, peer-to-peer onsite monitoring.

The success of this initiative is due to a number of factors. First, POGO's centralized approach for managing regulatory compliance systems and SOPs allows centres to focus on trial patient care and case management and effective multi-stakeholder engagement, oversight and collaboration. Second, stakeholders include trial sponsors and coordinating groups such as C^{17} - the national pediatric oncology network, the Children's Oncology Group (COG), and the US National Cancer Institute (NCI), which endorse the model for conduct of their trials [25, 30].

Findings from the Case Study Models

Proof of Concept

Both the COSA ATM and POGO's Satellite Program provide proof of concept that remote access models can effectively and efficiently provide access to trials for populations that would otherwise be excluded by virtue of geography. US National Cancer Institute Community Cancer Centers Program three year pilot provides further evidence of feasibility and improvement in trial recruitment [31]. Results showed an increase in the number of open trials as well as faster rates of patient accrual by community-based cancer centres when compared to national data.

The models have structural similarities. A primary centre and its Qualified Investigator hold the overall responsibility for trial activities in a hub-and-spoke or 'cluster' collaboration with satellite sites. Trial responsibilities and activities may be delegated to sites based on their interest, personnel and infrastructure to support clinical trials. Both models leverage existing health care system technologies and clinical care pathways. Lastly, both models apply a risk-based approach in:

- Selecting participating centres;
- Establishing the scope of activities performed in those centres;
- Developing supervision and monitoring plans to each locations' qualifications and capacity;
- Using pre-approved agreement templates to expedite trial startup.

While both models show that leveraging health care delivery systems to encompass clinical trial activities is feasible, there are some differences: POGO serves as a central, network support for site/investigator qualification, compliance, quality systems and coordination. The POGO Satellite Program was tested in the Canadian environment, builds on a tradition of integrating trials into pediatric cancer care. The COSA ATM model is applied on a trial by trial basis based on protocol requirements and site capabilities [8]. Similarities between Canada and Australia suggest the COSA ATM approach would be a feasible option for Canada given similarities of rural population distributions, existing national cancer center networks and comparable regulatory and health system funding arrangements.

Leveraging Telemedicine and Building on other Emerging Models of Care in Canada

Leveraging existing and emerging provincial models for remote care delivery is critical to the success of remote trial participation. In Canada, all provincial governments have facilitated implementation and expansion of telemedicine services driven by service uptake, cost savings analyses and high patient and provider satisfaction data. Health data platforms and technology advancements that are compliant with privacy regulations have simultaneously enabled timelier, effective patient assessments and data collection and review between health providers at different health care facilities.

In addition, there are examples in Canada of care services that extend outside of regional and tertiary centres*. Alberta Health Services' Community Cancer Network* is one such model. It is comprised of two tertiary centres, four associate centres and 11 community cancer centres. The network provides treatment, psychosocial & palliative care, prevention and screening services. Community cancer centres must satisfy eligibility criteria for safe and effective chemotherapy treatment and follow-up care. Once the criteria are met, patients are eligible to participate under the Outpatient Cancer Drug Benefit Program.

The North East Regional Community Oncology Clinic Network (COCN) teleoncology program operating out of Sudbury, Ontario serves a population of 600,000 spread over about 300,000 square kilometers. A regional network of fourteen regional satellite clinics offer imaging, chemotherapy and in one case, radiotherapy to 5,000 patient consults annually. In Atlantic Canada, the *Closer to Home* policy covers pediatric care of patients within four provinces seen at the two regional centres located in Halifax, Nova Scotia and St. John's, Newfoundland.

Existing technology to support telemedicine and remote care can be utilized to conduct some trial specific activities. For example, existing technologies can support centrally-managed teleconsent process at the coordinating site, virtual meetings for training, to assess trial progress and review trial patients, document management, compliance and data quality [9, 11, 23]. Teletrials is a natural extension of telemedicine and holds the potential for clinicians and researchers to bring more trials currently offered at urban cancer centres across the country to patients that may be interested and potentially benefit from participation.

5. Recommendations for Success

Enabling trial clusters

Experiences summarized above support the potential for successful, application and scaling of remote access models for Canada that have smaller local and regional health centres with varied research capacities functioning as satellites of larger centres for trials that otherwise would not be able to be offered locally or even regionally. While the benefits of improving access to trials are clear, the creation of trial clusters would require additional work and resources at participating centres. Primary centres would assume responsibility for training, oversight and coordination for each satellite site. Satellite centre staff would need to follow study protocol requirements. However, development and implementation can be facilitated through development of tools, templates and trial budgets that cover the scope of activities.

For primary centres, it important to anticipate, and make provisions for, an increased workload activities such as:

- Management of delegates and their responsibilities for trial conduct;
- Coordination of remote visits with community care providers and the patient;
- Maintenance of trial records, data and quality.

Trial complexity in terms of the protocol-specified treatment, frequency and types of assessments and duration of follow-up would impact workload and costs. Workshop participants highlighted the need to offset incremental costs by building efficient pathways to identify available trials that match eligible patients and satellite site capabilities, as well as effective communication and collaboration to ensure continuity of care, follow-up, and other aspects of trial conduct.

Although resource availability and structural issues create health system gaps in rural Canada, remote trial participation is within the individual competence of practitioners and health care centres. Healthcare providers practicing in rural and remote sites are regulated health professionals capable of managing patients within their clinical expertise and resources of their medical facility. The extent of trial-specific training required by remote practitioners and staff may depend on the specific activities they performed for the trial, i.e. whether activities fall within the scope of standard of care and routine practice or are research-specific. For example, remote practitioners may assess patient for adverse effects but treatment continuation or dosing changes may remain with the Qualified Investigator at the primary site. Decisions related to patient management and trial conduct would likely require training on clinical research principles and core competencies and orientation to the trial protocol. Satellite staff may need an introduction to clinical research principles, regulations, compliance, roles, and accountabilities as well as protocol-specific training. Developing a working knowledge of clinical trials and trial processes assures compliance and confidence with patient interactions and management during trial visits.

An increase in trial costs related to the creation and activities of the trial cluster may be offset by financial benefits associated with expanded trial activity. Additional costs may be included in the budgets for industry sponsored trials. Increased recruitment may cover costs. Generally, clinical trials activity has been found to have a positive net economic benefit through jobs creation, drug cost savings on drugs covered by trial sponsors [2, 25].

Assuring Patient Privacy

Privacy regulations support remote patient care delivery under proper conditions. These conditions are respected through fully informed consent processes and use of communication platforms that have undergone appropriate privacy impact assessments and security reviews. Expanding communication technologies beyond current telehealth capabilities to more accessible platforms should also be

explored. For example, use of Skype is currently accepted for virtual health appointments by BC Cancer and the Provincial Health Services Authority [32]. Although current interpretation is variable between health care jurisdictions and centres, it should be consistently viewed that clinicians and staff who care for patients on clinical trials fall within definition of "the circle of care" and may access personal information to ensure appropriate patient management and trial conduct. Concerns for welfare, autonomy and respect for persons mean that patients' abilities to make decisions about research are crucial when assessing unnecessary restrictions regarding privacy risks that adversely affect their ability to participate in research.

Addressing indemnity and insurance

Generally, the sponsor will hold clinical trial insurance and the clinical trial agreement with the centre and will include indemnification provisions. In addition, the Canadian Medical Professional Association (CMPA) provides professional liability for physicians. The Association assists with aspects of the research that concern medical care (e.g. delivery of treatment but not breech of Good Clinical Practice). Indemnity and insurance may also be covered though third-party agreements (e.g., Healthcare Insurance Reciprocal of Canada (HIROC)). Satellite site physician and staff coverage in sponsor agreements and/or other mechanisms will be needed during the study planning phase.

Pilot projects

To understand and address the real and perceived operational barriers for trials participation requires creating process guides and resources to enable pilot studies as was done in the Australian case study. Centres leading a trial cluster would benefit from access to a curated set of education and training materials appropriate for satellite staff. Resources that support the implementation of a trial cluster such as site assessment and qualification tools, templates for agreements and budgets that incorporate remote trial activities, and study supervision and monitoring plans would also be valuable. The pilot study evaluation that includes qualitative as well as quantitative measures can be expected to provide lessons around challenges and guide adjustments needed to bring remote trial participation to scale. Successful adoption holds great potential for maximizing Canada's clinical trials capacity, trial conduct and potential benefits.

Based on the above considerations, the following recommendations were developed and approved by the Steering Committee following review of literature, interviews and workshop. The recommendations are grouped to address specific requirements for primary and satellite sites; ensure compliance with ethics, regulatory, legal requirements of trial conduct, as well as suggested training and tools that would support rapid formation and implementation of trial cluster models. The final recommendations address sustaining engagement to continue to enable remote patient participation in trials.

Table 1. Summary of Recommendations

	Framework Element (s)		**Recommendations**
1	Infrastructure and System Development	1.1	Address human resources, equipment and facility requirements at satellite centres.
		1.2	Develop contingency plans to assure patient participation can be supported throughout the course of the clinical trial and long-term follow-up.
		1.3	Use a risk-based approach to identify protocol-specific training needs for satellite personnel that is based on the extent of delegated responsibilities and scope of practice.

	Framework Element (s)		Recommendations
		1.4	Assess what aspects of core clinical trial competency training (ICH GCP E6(2) GCP, Ethical Conduct of Research, TCPS) may be required for remote activities.
		1.5	Establish mentoring relationships with satellite personnel for professional trial competencies development.
		1.6	Provide a decision guide for risk-based assessment with criteria for establishing satellite site suitability for a trial.
		1.7	Provide templates for clinical trial budgets, agreements between the sponsor and primary site in a cluster as well as sub-agreements between the primary site and each satellite.
		1.8	Provide tools (e.g. template checklists) to inform supervision plans and roles and responsibilities for satellite activities.
2	Costs and funding requirements	2.1	Provide financial support for pilot studies and evaluation activities.
		2.2	Provide financial support to primary sites to support initial costs to create infrastructure, systems, training and visits at satellite centres to set up the cluster.
3	Trial planning and conduct	3.1	Design clusters to be robust and flexible to allow the addition of satellite sites throughout the period a trial is open.
		3.2	Leverage pre-existing telemedicine/care delivery practices with satellites, when feasible.
		3.3	Engage clinicians and patients from rural and remote sites in trial design.
		3.4	Consider protocol accommodations for clinical trial conduct at satellite centre.
		3.5	Adopt risk-based criteria to determine remote centres involvement in the trial. Such criteria may include complexity of trial design, product safety profile, or required protocol assessments.
		3.6	Adopt a risk-based criteria to determine activities that can be delegated to a satellite site, required staffing complement, qualifications, equipment and facilities.
4	HC regulatory guidelines and inspections	4.1	Update or interpret the Health Canada Food and Drug Regulations, Part C, Division 5 "Drugs for Clinical Trials Involving Human Subjects" to recognize the required elements of the proposed framework. Specifically, that: i. A clinical trial cluster conforms to the definition of a trial site; and ii. Qualified/Principal Investigator responsibilities may be delegated to satellite clinicians and staff within the scope of each delegate's professional practice.
		4.2	Health Canada reviews and inspections should recognize the trial cluster, delegation of Qualified Investigator responsibilities to satellite sites and assess regulatory compliance so as not to cause undue burden for the primary site or for satellite sites.

	Framework Element (s)		Recommendations
5	Ethics Review	5.1	Recognize the primary site's REB as the REB of record for the cluster so as not to introduce added, unnecessary steps or barriers to the ethics review process for satellite sites.
6	Patient privacy	6.1	Adopt the interpretation of the Personal Information Protection and Electronic Documents Act (PIPEDA) legislation and provincial privacy laws that clinical trial staff and patient participants are within a circle of care to access to personal health information.
7	Trial agreements, Indemnity and insurance	7.1	Trial sponsors should be willing to execute agreements with the primary site and extend terms of coverage for the scope of a primary site's coordination of satellite centres.
8	Engagement, communications and advocacy	8.1	Develop dissemination and knowledge mobilization strategies to generating broader awareness and advocacy among sponsors, researchers, clinicians, patient communities, ethics boards and regulators that can be scaled and sustained over time.
		8.2	Create a strategy for health policy advocacy to recognize and support clinical trials as standard of care.

6. Dissemination, Implementation and Evaluation of the Framework

The proposed framework described in this publication is a work in progress. Additional development of the framework will be pursed through: 1) the engagement of broader range of stakeholder groups for further consultation on the proposed framework to support remote access of patients on clinical trials and 2) the design and implementation of pilot studies to determine feasibility of the cluster model in Canada. The results of these two streams of activities will inform and improve the framework.

Additional due diligence on the framework and its recommendations will be aimed at engaging clinical research, health policy, insurers and advocacy communities to improve the framework. Three areas identified by the Steering Committee that require further refinement are: 1) identifying the most feasible and cost effective options for establishing linkages between centres; 2) identifying options that address professional liability and indemnity with investigators, healthcare providers (or their representatives), insurers and sponsors; 3) consulting with Health Canada to ensure federal regulation and interpretation supports trial conduct at satellite centres.

Developing pilot studies to test the feasibility of remote patient participation in clinical trials is a key step to understanding structural and operational challenges and identifying solutions. Pilots that build upon existing regional networks of shared clinical care and with site personnel that are supportive of improving trial participation could be rapidly developed with high probability of success. Pilot clusters would be extending care delivery to include trial delivery by leveraging site networks' existing regional patterns of care and telemedicine capacity. The cluster could begin by participating in a trial of lower complexity interventions, and good product safety profile such as a trial assessing different standard of care treatments or supportive care measures. A low risk/complexity trial would facilitate creating and implementing the cluster, and developing the processes to ensure trial oversight and conduct (e.g., site contracts, REB, training, delegation of responsibilities). There are a number of existing resources to support training and education (e.g., CITI GCP training courses), trial SOPs, and trial risk assessment tools that can be used to support satellite training and trial conduct.

Pilot studies would include an evaluation plan. The evaluation plan would ideally include a logic model as well as qualitative and quantitative measures. Qualitative measures of success may include experiences, benefits and challenges from the perspectives of all groups (e.g. site personnel, patients), while quantitative measures may focus on the effectiveness of the model on trial participation, data quality and protocol compliance. Opportunities for optimization of remote access approaches can be identified by review of adoption successes from the pilot studies. Longer-term evaluation planning will be necessary to measure impacts that widespread use of remote trial access models have on patient participation and outcomes, as well as changes to clinical trials accrual, efficiencies and costs.

7. Conclusions

The impetus to develop this framework was based on compelling ethical, scientific, and economic reasons that improve access to trials for remote and rural patients that would benefit both individual patients as well as the Canadian health care system. Technology and the evolution of more sophisticated models of cancer care have created an opportunity. Proof of concept has been established that it is possible for eligible and interested patients in rural/remote areas to be offered the option of participating in clinical trials, and the oversight and management of their safety and integrity of trial conduct can be assured throughout the trial. In recent months and coinciding with the completion of this initiative, urgent responses to the COVID-19 pandemic by sponsors, research institutions, patient partners and regulatory authorities have driven a rapid expansion of the scope and scale of virtual trial management. Many of the steps to manage trial patients during the COVID-19 emergency are consistent with the framework recommendations and the experience gained will undoubtedly inform remote access approaches that will become standard in the future. There is now the opportunity to implement the remote access framework and improve it through additional stakeholder assessments, systematic pilot testing and evaluation, as well as policy development that recognizes and enables equitable access to clinical trials as a fundamental component of standard of care delivery within our healthcare system.

Appendix A: Canadian Remote Access Framework for Clinical Trials, Steering Committee & Writing Committee Membership and Terms of Reference

Member	Affiliation(s)	Title(s)
Stephen Sundquist* (Chair)	3CTN	Executive Director
Dr. Gerry Batist	Quebec-Clinical Research Organization in Cancer	Scientific Director
Kathy Brodeur-Robb*	C-17	Executive Director
Dr. Janet Dancey*	3CTN; Canadian Cancer Trials Group	Scientific Director; Executive Director
Kathryn Dyck	CancerCare Manitoba	Clinical Trials Manager
Dr. Bernie Eigl	BC Cancer	Provincial Director – Systemic Therapy Clinical Trials
David K. Lee	Health Canada - HPFB	Chief Regulatory Officer, HC - HPFB
Jacqueline Limoges*	OCREB	Vice Chair
Jim Pankovich	Qu Biologics	Vice President, Clinical Operations
Anna Sadura	Canadian Cancer Trials Group	Manager, Trial Management Group
Patrick Sullivan	Team Finn Foundation; 3CTN; Canadian Cancer Trials Group	Childhood Cancer Research Advocacy; Patient Representative; Research Advisor
Writing Committee Member only		
Dr. Holly Longstaff*	Provincial Health Services Authority	Director, Privacy and Access, PHSA Research and New Initiatives Research & Academic Services

*Writing Committee Member

Terms of Reference

1. Purpose

The Steering Committee ("Steering Committee, SC") will provide expert knowledge and strategic advice in guiding the generation of a position paper outlining recommendations for improving access for cancer patients for whom distance from the nearest cancer center presents a barrier to trial participation. The purpose of the SC is to help inform the project scope, reference elements to be considered and key informants that will be required for a comprehensive review to take place in a planned stakeholder Workshop. The SC will review Workshop outcomes and assist with assessing feasibility and priority-setting for resulting recommendations, follow-up actions required and final report development.

2. Key Responsibilities

The Steering Committee will:

- Review and approve drafted project elements, proposed activities and identify key informants and reference sources to be considered for Workshop development
- Inform long-term strategy for stakeholder engagement through the Canadian clinical trial environment
- Identify and recommend innovative approaches to address anticipated barriers to implementation;
- Identify relevant initiatives, existing resources and/or case examples incorporating elements of remote clinical trial access which may help inform recommendations for a model framework and

long-term implementation strategy that leverages existing infrastructure as much as possible, reflects stakeholder priorities and considers healthcare innovation and technology trends;
- Drafting white paper and summary recommendations for establishing a framework for improved clinical trials access that considers: relative priorities and sequencing, feasibility, enabling requirements and potential barriers

3. Membership & Chair

- Members will have the required knowledge and experience in aspects of clinical trial planning and conduct relevant to this work including – regulatory requirements, ethics, research unit operations, patient involvement, contracts & agreements, community healthcare;
- Committee members will represent the geographical regions of Canada as much as possible;
- There will be 6-8 members, including and at least one member from the 3CTN Executive;
- A Chair will be nominated and approved by the membership to lead planning and conduct of committee meetings and completion of project deliverables.
- Members would be expected to attend planned meetings (see §5.1)
- Members are expected to draw upon personal experience, representative input, references and contacts derived from the knowledge area they represent to inform discussions;
- Members are expected to be prepared for meetings, must foster an open, collaborative climate and contribute constructive input to deliberations that support project objectives.

4. Terms of Appointment

4.1. **Term** – Members will be appointed for the planned scope of the project, from August 2019 to March, 2020. Selection of new members will be based on consultation with 3CTN funders, executive, expert advisors and by fellow Steering Committee members, as may be required.

4.2. **Authority –** Members will function in an advisory capacity and will be called upon to approve the project plan, stakeholder workshop agenda, support the synthesis of workshop outcomes into a comprehensive set of recommendations to be summarized in the summary report/position paper. Final decision on SC recommendations or approval will be determined by majority decision, or as may be required, by the Chair.

4.3. **Withdrawal** – An individual member may withdraw at any time upon written notification to the Secretariat.

4.4. **Removal** – Members will serve on the Steering Committee at the discretion of the 3CTN Executive Director and may be removed or replaced, if required, by written notification.

5. Meetings / Quorum

5.1. **Meetings** All meetings will be scheduled to take place via teleconference/webinar, with timing based on the availability of the majority of participants and will minimally include:

- The Steering Committee will meet in September 2019 for project kick-off as well as additionally as may be required to advise on the overall project scope and support planning for the November 2019 workshop.
- A meeting will take place in the weeks immediately following the Workshop to review outcomes and guide position paper development
- As may be required to resolve any matters stemming from the Steering Committee's collective review of the position paper draft and to approve changes required for the final version.

5.2. **Quorum** – A majority of members shall constitute a quorum. Steering Committee decisions will be captured and reflected for the Workshop and inform summary recommendations in the

position paper.

Members will be expected to demonstrate fairness and a commitment to an in-depth evaluation of all matters under review. Discussions during meetings shall be open, frank and free-flowing. All members will have an equal status during discussions.

6. Compensation

Committee members will be reimbursed for reasonable travel and accommodation expenses required for meetings and workshop attendance in accordance with the 3CTN Travel and Reimbursement policies.

7. Secretariat

Administrative support - preparation and circulation of agendas, background reference materials and minutes - will be provided by the 3CTN Coordinating Center, in consultation with the Executive Director and Steering Committee Chair.

Appendix B: Project Workshop

Remote Clinical Trial Conduct - Framework Considerations

	Perspectives				
	Sponsor	Sites		Health Canada Food & Drug Regs., Part C, Div. 5 ICH E6(R2)	
		Primary Site	Satellite Site	Interpretation /Guidance	Regulatory Change
General Considerations					
Patient safety, study feasibility, risk-based oversight, data quality					
Pre-Trial Considerations					
Selection of Trials and Satellite Sites					
Study Feasibility Assessment					
Site Accreditation					
Satellite Site Supervision Plan					
Site Visits					
Roles and Responsibilities of Trial Staff					
Pharmacy & Pharmacy facilities					
Pathology & Radiology					
Patient Perspective, Values, Priorities					
SOPs, Study-specific Training					
Technology & Data: platforms/systems/equipment access, validation, support					
Indemnity, Insurance and CTAs					
Research Ethics Board: review & reporting					
Trial Conduct Considerations					
Patient Perspective, Values, Priorities					
Participant Recruitment, Consent, Screening and Enrolment					
Medication handling					
Documentation and Reporting					
Patient Reported Outcomes					

	Perspectives				
	Sponsor	**Sites**		**Health Canada Food & Drug Regs., Part C, Div. 5 ICH E6(R2)**	
		Primary Site	**Satellite Site**	**Interpretation /Guidance**	**Regulatory Change**
Managing reporting AE, SAEs					
Source Documentation and Record Retention					
Monitoring					
Equipment and Facilities					
Financial, Budget					

Appendix C: Summary of Telemedicine Services in Canada

The table summarizes telemedicine services across Canada[19]. Telemedicine is a medical service provided remotely via information and communication technology[33]. Virtual care (VC)/ Telemedicine (TM)/ Telehealth (TH) services are widely available in across Canadian provinces and territories.

Province	Current status	Key providers	Terms of Use/Practice Guidelines
Alberta	• VC is typically deemed appropriate in consultation with a health provider when patients reside far from existing AHS facilities • VC is mainly carried out through videoconference technology, with over 900 videoconferencing sites operating • Primary-care provider use to connect patients to a variety of specialty clinical programs including addiction and mental health, cardiology, pulmonary, pediatric and palliative care • Ongoing efforts to connect rural and remote communities to care through TM	Alberta Health Services (AHS), TM	Prescribing for a patient based on a physical examination conducted by proxy is not acceptable under the current TM standard of practice.
Saskatchewan	• VC includes a broad range of services provided by TM, including clinic, health education and admin. services • TM enables linkage of patients to diverse healthcare teams, including specialized and primary-care providers • TM is deemed appropriate for patients who live in rural or remote areas and have difficulty accessing care • Client navigators, registered nurses, allied health staff provide triage services, link patients to further care, as needed	eHealth Saskatchewan	
Manitoba	• VC encompasses a range of different services designed to overcome barriers of distance, time, and expense • There are no defined eligibility requirements for VC services; appropriate use is determined by providers through consultation with MBTelemedicine including equipment/process training • TM is the most prominently used type of VC platform. Other modes include secure text messages, patient portal communications and remote-home monitoring tools	Services delivered by MBTM: videoconferencing for clinical and nonclinical events, secure text messaging, image sharing, & eConsults	

	• Work is underway to determine how best to enhance the use of VC (e.g. provision of care for hard-to-reach populations, expand counselling services offered for some chronic conditions such as COPD to other chronic conditions)		
Ontario	• VC services delivered through synchronous tools (e.g., videoconference, both scheduled and 'on-demand' emergency services); asynchronous applications (e.g., for consultation between professionals); and remote home-monitoring • Specific eligibility requirements focus on use for patients most likely to benefit from VC. For services associated with formal eligibility criteria, the healthcare provider is responsible for assessing the appropriateness of VC tools for a given scenario • Virtual-care services delivered to patients at home are provided by clinicians in collaboration with the existing primary healthcare team (ie Telehomecare for COPD/CHF). Others allow patients to register for software that allows connection via clinically held, anonymous online link for access to assessment & care support tools & information (i.e. Big White Wall). • Services include: telephone triage (through TM Ontario); on-demand/ emergency videoconferencing services, including Telestroke (hyper-acute phase); virtual ICU; scheduled videoconferencing services in acute care, primary care, community, long-term care and home settings supported by a scheduling solution tailored to TM and an online directory of providers and sites crossing almost all specialties/subspecialties; general eConsult services as well as teledermatology and teleopthalmology • In addition, new models of care delivered through VC include using digital tools to provide wound care, surgical transitions, mental health, CKD, and palliative care	Ontario TM Network	Any health service provider can use VC in their practice, however, if they intend to bill OHIP for TM (videoconferencing) services, they must first register with the Ontario TM Network, who then requests that OHIP enable that physician's TM claims to be paid
Prince Edward Island			No prescribing of narcotics/controlled medications
British Columbia	Both primary care physicians and specialists in British Columbia are able to provide a range of TM services directly to patients and		

	have not been restricted to using specific platforms, networks, or TM facilities.		
Quebec	• Technologies include telephone, email, secure text messaging, videoconference and remote home monitoring • VC is divided into four broad groups: teleconsultation; teleexpertise; telemonitoring; and teleassistance: o Teleconsultations/ teleexpertise/teleassistance – inter-professional, in the absence of a patient; to provide diagnostic or therapeutic advice or support for care delivery o Telemonitoring - remote monitoring by a physician (e.g. home monitoring of chronic conditions • Teleconsultation and TM services are restricted to settings that are private and confidential • Most VC services are provided by specialists or to link specialists through TM networks set up by Rèseaux Universitairs Intégrés de Santé, and include specialties such as cardiology, ophthalmology, women's health and mental health	Rèseaux Universitairs Intégrés de Santé	Physicians providing virtual-care services to residents of Quebec (whether the physician is within or out of province) must hold a permit to practice by the Collèges des Mèdicins du Québec and be enrolled on the Roll of the Order
New Brunswick	• VC includes a broad range of services delivered through technology, including TM services, teletriage, telehomecare and remote patient monitoring, and Navicare/SoinsNavi	Horizon Health Network	Physicians must be licensed with a medical regulatory authority and register on the TM Provider List; for services that yield direct reports to hospitals (i.e., pathology, radiology), and noninsured services, physicians must acquire a special TM license
Newfoundland and Labrador	• TM established over 30 years ago and is expanding to new locations and interested health care providers. Current focus of care is on chronic disease management.		The College does not issue TM licenses. Physicians practicing medicine via TM must be licensed to practice

			medicine in Newfoundland and Labrador and/or in the jurisdiction in which the physician is located.
Nova Scotia	• VC uses audio/video technology to connect patients with Nova Scotia Health Authority and IWK Health Centre health care providers, closer to home.	Nova Scotia Health Authority	Not prescribe opioids or other controlled medications to patients whom they have not examined in person, or with whom they do not have a longitudinal treating relationship

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