Quebec
Cancer Coalition

Report on the Re-opening of Oncology Clinical Trials During the COVID-19 Pandemic

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VIRTUAL THINK TANK MEETING OF JUNE 12, 2020

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Table of contents

Introduction:

The Quebec Cancer Coalition was created in 2001 to give a strong voice to people affected by cancer. It is a group of more than 60 non-profit organizations representing all cancer types and all regions of Quebec, which aims to improve the health care system in Quebec for the benefit of those affected by cancer. It is a patient advocacy organization which defends the rights and interests of patients, survivors, and caregivers. For nearly 20 years, its members have shared their vision for a healthier Quebec, centred on people affected by cancer.

Ever-vigilant over the issues that matter most to patients, the Coalition conducted an initial survey on the impacts of measures to counter the COVID-19 pandemic in early April 2020[1]. It highlighted the consequences of the pandemic on the physical and mental health of oncology patients. The postponement of surgeries, imaging and diagnostic tests, screening programs, and the closure of oncology clinical trials have created a significant increase in anxiety among patients and their families. Patient organizations and clinical professionals alike were concerned about the impact on the continuity of care during this pandemic. Since May, many of these services have resumed, but the status of clinical trials remains uncertain.

When emergency measures were taken to counter the pandemic, and because of the humanitarian disaster experienced in other countries such as Italy, Quebec wanted to protect its health care system as much as possible. It reduced its activities to a minimum, to maintain only what was considered urgent and essential. Clinical research activities, except for studies directly related to COVID-19, were suspended as of March 13, 2020.

The Quebec Cancer Coalition, aware of patients' concerns expressed by its members, wanted to better understand why and for how long clinical trials would be closed and how soon they could resume. The Coalition was particularly concerned about people in the advanced stages of disease. For them, research protocols may be the only hope for survival or for improving their quality of life. When surveying patients and the Coalition's member organizations in clinical research, the expectation was that it could take up to six months. For patients and their loved ones, six months can represent a lifetime. These delays are therefore unacceptable for them, their families, caregivers, and researchers who all felt very anxious and powerless about this situation.

Therefore, we decided to organize a Think Tank session with concerned stakeholders to identify the challenges and find solutions to reopen oncology clinical trials in Quebec as soon as possible. We consulted several of our member organizations in oncology clinical research, patient associations, patient-partners and research professionals in order to better understand the potential obstacles and opportunities. We also invited representatives from the Ministry of Health and Social Services (MSSS) to join the discussion, and their participation was greatly appreciated by all participants, especially by patient-partners.

[1] Survey Summary Report: "Impact of the COVID-19 Pandemic measures on Cancer Patients in Quebec" Pomey, M.P.; Villalba, E.; Taguemout, M.; Ikene, D.L.; Côté, M.A.; Wilhelmy, C. April 14, 2020.

The Think Tank took place on June 12 via the Zoom web platform. A complete list of participants can be found in the annex. A total of 28 people participated, including four patient-partners, four patient associations and five member organizations in clinical oncology research. Nine public research centres were represented.

Context and Evolution of Clinical Trial Guidelines

The three main reasons cited for closing oncology clinical trials were:

1. **Reassignment of research staff** in hospitals to counter the COVID-19 pandemic.

2. **Protection of patients at risk** :
    a. **Lack of Personal Protective Equipment (PPE) for research personnel**: the majority of PPE is destined for essential hospital activities.
    b. **Challenges related to physical distancing and additional hygiene measures**: some establishments did not allow or were not yet prepared to respect these constraints.

3. **Reduced visits to hospitals by non-essential persons**: Sponsor oversight of clinical trials is no longer possible in person, as visits and travel within and between hospitals and regions are restricted by public health measures.

On March 17, 2020, following the work of the *COVID-19 Clinical Subcommittee – Oncology*[2], a letter was sent to the CEOs of public health and social services institutions by Deputy Minister Yvan Gendron, giving certain guidelines regarding clinical trials[3]:

> *- Cease research activities in adult oncology, except for treatments that have already started and for patients for whom there is no other therapeutic alternative or for whom a clinical benefit has been assessed by the physician.*
>
> *- Physicians and other professionals (e.g. nurses) who devote a significant part of their practice to research activities could be released to support clinical activities.*

Since these guidelines leave room for interpretation, they have not been applied in the same manner across the health care network. The majority of centres took this memo to mean that, except for patients already on research protocols, all other clinical activities were suspended until further notice. Only clinical trials on

[2] COVID-19 Clinical Subcommittee - Oncology. https://www.msss.gouv.qc.ca/professionnels/covid-19/directives-cliniques-aux-professionnels-et-au-reseau/

[3] Internal memo from the Ministry of Health and Social Services. N/Réf. : 20-MS-00496-30

COVID-19 were prioritized. How many patients who would have been referred to clinical trials saw their health deteriorate seriously without access to this last treatment option? Unfortunately, we do not even have access to this data, despite many tragic anecdotes from patients and caregivers.

On **June 5, 2020**, a second letter was sent to the CEOs of public health and social services institutions, this time by Deputy Minister Pierre Lafleur[4]. This letter was clearer about the possibility of a "gradual resumption of research activities".

> *The decision to resume suspended research activities and to start new research projects on themes other than that of COVID-19 must be taken by each institution, in consultation with the directorate responsible for research and the institution's steering committee. Decisions regarding the resumption, if any, and its scope, must be consistent with the local control situation of COVID-19.*

This guideline was developed in collaboration with the *COVID-19 Clinical Subcommittee – Oncology*,and allowed flexibility for each institution to organize itself according to its specific situation.

Discussion with participants during the Think Tank session:

All research centres discussed their level of activity in clinical research. The majority had ceased all recruitment and new protocol initiation activities but continued to treat patients already enrolled in studies. Only 1 in 9 centres continued to accept new patients during the pandemic, having interpreted the March 17 directive differently and preserving access to research protocols for patients for whom there is a clinical benefit. All have seen a significant decrease in the volume of clinical studies, with the majority continuing only research protocols for patients already enrolled. The majority of centres with a large volume of COVID-19 cases were affected by a lack of staff and resources. Most clinical trials were suspended by facility directors, but also in some cases by sponsors.

Are the reasons given for the temporary closure of clinical trials still relevant?

1. **Reassignment of research staff elsewhere in hospitals to counter COVID-19**

   According to participants, very few research staff have been reassigned elsewhere, except for a few at the beginning of the pandemic. However, some resources (e.g., research space) may have been reallocated to deal with new challenges related to managing the COVID-19 pandemic.

2. **Protection of vulnerable patients:**

[4] Internal memo from the Ministry of Health and Social Services. N/Réf. : 20-CP-00283

a. **Lack of Personal Protective Equipment (PPE) for research personnel**

According to several research centres, the issue of adequate and sufficient PPE was certainly a real one until very recently. However, since research activities were often considered to be of lower priority, the distribution of PPE to researchers was sometimes inadequate.

b. **Challenges related to social distancing and additional hygiene measures**

Lack of space was cited by many as a barrier to the ability of some centres to adequately reopen their research centres.

Note that Deputy Minister Lafleur's letter of June 5 confirms that *"current public health measures remain applicable at all times in the research context in order to limit the transmission of the virus and to protect research participants, their entourage and research personnel. In addition, the institution's own rules on infection prevention and control, including wearing personal protective equipment, should apply to research personnel and academic researchers when research is conducted in the institution".*

3. **Reduced visits to hospitals by non-essential persons**

Surveillance of clinical studies is no longer possible in person, as visits and travel within hospitals and between regions are restricted by public health measures. This is by far the most persistent issue and remains a real obstacle for the research centres consulted. Remote monitoring is possible for some institutions with greater computer resources, but most of the smaller centres are not necessarily able to offer this option within a short period of time.

Patient Testimonials, Caregivers, and the Perspective of Patient Associations

Four patient-partners, including a caregiver, testified about their experience with clinical studies and its restricted access during the COVID-19 pandemic period. Despite the March 17, 2020 directive to keep the clinical trials open to those for whom there is a clinical benefit, patients were told that not only were the studies closed in several centres in the Greater Montreal area, but that they would not be reopened for six months. For patients in the advanced stages of the disease and their loved ones, time is more important than ever, and this delay is unacceptable. A patient also testified that for rare cancer patients, clinical trials are often their best hope. Their closure contributes to a perception of abandonment and feeds despair. Other patients cite the great confusion perceived by people affected by cancer in relation to the ever-changing directives of public health, the MSSS, institutions and research centres. Some oncologists continue to refer to clinical studies, without knowing whether or not they remain open, causing great distress for patients.

Four patient associations also shared what they hear from their patients. Patients report a great deal of concern about the impact of the pandemic on the continuity of their care, but also fear of contracting COVID-19. Many

patients do not show up for appointments or clinical trials because they fear they are not sufficiently protected. Raising awareness, for example, through a call that explains the safety, hygiene and distancing safeguards in place to protect patients and healthcare staff, could reassure patients and increase the participation rate in clinical studies when they reopen. Patient organizations could also play a role in educating oncology patients in this regard. Several research networks are currently on pause across the country and around the world, with only a few exceptions. Quebec could serve as a model with a detailed pandemic clinical trial plan. It is also suggested to use centres outside the hot zones with satellite centres outside the hospital, or even favour centres in regions less affected by the pandemic (while helping patients financially for travel). Other resources external to the hospital (e.g. community clinics (CLSCs), home-care, Patient Support Programs) could be used to minimize hospital visits and thus reduce travel and inherent risk to patients, whether it be for blood tests, vital signs or other diagnostic tests. Telemedicine is also very well received by patients and should be used for the same reasons whenever possible.

Current Context & Identified Challenges

Several patient and research centre representatives mentioned that clinical trials fall under the authority of three ministries[5], which can sometimes lead to confusion about the authority or which guidelines to prioritize. In addition, there is a consensus that the pandemic has exacerbated existing problems related to the pressing need to modernize clinical trials in Quebec. With the renewal of the Quebec Life Sciences Strategy[6], the government aims to make Quebec a welcoming and innovative place for clinical research. Other organizations, such as Catalis, Oncopole, Q-CROC and the Quebec Cancer Coalition, share the objective of creating a climate that is favourable to clinical research and thus promoting access to cutting-edge treatments for all Quebecers. There is therefore an opportunity to learn from this health crisis, to modernize and propel clinical trials in Quebec with all key stakeholders.

Several research centres continued their research protocols with oncology patients already enrolled, but the majority suspended recruitment and the opening of new studies. Some studies were suspended by study sponsors, while others had to be temporarily paused due to lack of resources. Hospital centres that were designated for hospitalizations related to COVID-19 were particularly affected in their activities, including research.

In addition to the initial reasons cited in the context leading to the closure of clinical trials, other challenges were identified by participants and created bottlenecks that are blocking the reopening of oncology research activities in Quebec:

[5] Ministry of Economy and Innovation; Ministry of Health and Social Services; Ministry of Education and Higher Education

[6] Quebec Life Sciences Strategy 2017-2027.
https://www.quebec.ca/en/government/ministere/economie/publications/2017-2027-quebec-life-sciences-strategy/

a) Competition between clinical research and the institution for limited resources - personnel, space, equipment, drugs.
b) Lack of procedures and infrastructure necessary to promote remote monitoring.
c) Lack of flexibility from sponsors: the guarantees required were not always realistic in the current context. For example, adapting the protocol by minimizing hospital visits by patients and clinical staff.
d) New trials were put on hold without a resumption date - not all sponsors adapted to the new reality.
e) Uncertainty about the safety of collecting samples (especially live tissue) for bio-banking in the context of COVID-19.
f) Data access issues - the Quebec Cancer Registry still does not provide researchers with rapid access to reliable and up-to-date data, and documents relevant to clinical trial follow-up are not computerized.

Proposed Solutions

In order to be able to reopen oncology clinical trials throughout the Quebec health network, we must find win-win solutions for all stakeholders through innovation and collaboration. Several participants contributed to identifying and sharing their best practices, innovative solutions, existing or potential, that will facilitate the success of clinical research in Québec.

Challenges related to limited resources (human and material)

- Reassignment of research staff elsewhere in hospitals to address COVID-19.
- Competition between clinical research and the institution for limited resources - staff, space, equipment, drugs.
- Lack of information on the availability of other research centres.

Best Practice: The **Maisonneuve Rosemont Hospital Research Centre (CRHMR)** uses **adapted shifts** to **better distribute material** (e.g., space) **and human** (e.g., nurses) **resources** between the hospital and the research centers and to **facilitate social distancing**.

Catalis Québec proposed the creation of a "**provincial resource pool**" to address the issue of limited research resources.

Recommendation 1: Create a "provincial resource pool" for clinical research in Quebec. Provide for the use of adapted shifts to allow better use of available resources and space. Coordinate the use of resources with other departments in the institution. Facilitate referrals between institutions.

Procurement Challenges

- Lack of personal protective equipment (PPE) for research personnel
- Risk of drug shortages

Recommendation 2: Improve strategies for forecasting supply needs (e.g., PPE, respirators, drugs) for clinical research, especially in anticipation of a second wave of the pandemic.

Challenges related to the adaptation of physical spaces and hygiene measures

- Lack of clarity on additional safety, hygiene and distancing measures to be implemented in a clinical research context.

Recommendation 3: Publish (via the Quebec Institute for public health - INSPQ), hygiene and distancing standards specific to clinical research.

Challenges related to minimizing non-essential hospital visits

- In-person monitoring of trials by sponsors is no longer recommended.
- Lack of procedures and infrastructure to support remote monitoring visits.
- Patients must make a non-essential visit to the research centre to sign the consent form.

Best Practices: The **CHU de Québec - Université Laval** has **implemented a protocol for remote monitoring visits**[7] using a consent and confidentiality form between the parties, access to data via secure and time-limited VPN, and very stringent measures to ensure data protection and smooth validation of research data for the sponsor.

[7]INTERNAL MEMO CHU DE QUÉBEC - UNIVERSITÉ LAVAL. " Instructions de travail : Procédure à respecter lors d'une visite de surveillance à distance". Stéphane Bolduc, Clinical Research Assistant Director, June 12, 2020.

The Jewish General Hospital has a **dedicated room in a cold zone of the hospital for surveillance visits**. In addition, they have established a new protocol - approved by their ethics committee - **for verbal consent of patients in clinical studies**[8] in order to avoid a non-essential visit to the hospital. Researchers at McGill University have also published an article that "examines how written consent could be expanded to allow the use of consent given in electronic form[9].

At the **CHUS Research Centre in Sherbrooke (CRCHUS)**, Dr. François Lamontagne and Dr. William Fraser are world experts in clinical trials who have developed several practices to promote **remote surveillance in the context of a pandemic** (e.g. Ebola and COVID-19) in collaboration with the WHO. The MSSS could benefit from their expertise to deploy a plan based on world best practices in remote surveillance for all of Quebec.

A discussion among participants to consider the possibility of using dedicated rooms outside the hospital, but in the same CISSS/CIUSSS (for example, in a CLSC). This was welcomed as a potential solution, if other options were not available.

Even in a normal context, without a pandemic, we should modernize clinical research in Quebec and promote remote surveillance as much as possible. This would benefit research centres outside the major urban centres and thus the accessibility of research in regions. In addition, far too much money is being spent on this aspect without any added value, which could eventually reduce the industry's investment in research and development, and therefore drug prices. On the other hand, in a regular context, on-site monitoring should still be maintained for:

- the initiation visit
- sites that have been identified as problematic during remote monitoring
- sites that have too many queries or protocol deviations/violations

Recommendation 4: Put in place the infrastructure and processes to enable remote monitoring by clinical research sponsors. Build on the CHUQ model, and the expertise at the CRCHUS. If this is not immediately possible, find a dedicated room in a cold zone of the hospital or CISSS/CIUSSS.

[8] Based on an electronic consent document from the University of British Columbia (UBC) and the "Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 (2018)". https://ethics.gc.ca/fra/policy-politique_tcps2-eptc2_2018.html and FDA « Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers » https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers

[9] Kirby, E., Zawati, M. N. H., & Knoppers, B. M. (2012). Electronic consent to health research in Canada. *Can. B. Rev.*, 91, 417. https://heinonline.org/HOL/LandingPage?handle=hein.journals/canbarev91&div=17&id=&page=

Recommendation 5: Put in place the infrastructure and processes to enable electronic patient consent. Work with institutional Research Ethics Boards (REBs), patient-partners and study sponsors to accelerate the adoption of electronic consent.

Challenges Related to Study Sponsors (Pharmaceutical Industry)

There was consensus among participants that clinical study sponsors also need to make trade-offs in the pandemic context in order to ensure continued access to clinical trials. The pandemic has simply highlighted some of the gaps in clinical research, and this is a good opportunity to modernize and encourage remote monitoring of clinical trials (which would encourage research in the regions). Better collaboration between sponsors, health institutions and principal investigators is also essential to modernize and make processes more efficient. Sponsors need to think about how to adapt to new contexts and propose solutions to problems. Challenges cited by researchers participating in the brainstorming session included:

a) Lack of flexibility from sponsors: the guarantees required from investigators were not always realistic in the current context (level of risk and predictability affected during a pandemic).
b) Sponsors did not always agree to adapt the protocol, for example by minimizing hospital visits (e.g. home visits).
c) Sponsors need to show openness to modernize and adapt their practices, by agreeing to conduct remote monitoring. It would be advantageous to show greater flexibility - if the company refuses to allow its employees to travel, they should accept the remote monitoring proposed by the institution.
d) New trials were put on hold without a resumption date - not all sponsors have adapted to the new reality. Therefore, sponsors should have a contingency plan for a similar pandemic.

Recommendation 6: Work with clinical trial sponsors to find solutions, adaptations and modernizations that will allow not only for the continuity of clinical trials in the pandemic context, but also for increased clinical research in less urban regions.

Communication Challenges

Although the Ministry of health (MSSS) wishes to give each establishment the latitude to adapt in its own way, the ambiguous directives leave too much room for interpretation. Moreover, the majority of establishments had not reopened their clinical studies by the beginning of June. There is still a great deal of confusion between the directors of the institutions, the assistant directors of clinical research, and the directives coming from the MSSS, the MEI and the Ministry of Education. Some centres are still awaiting directives from the MSSS for the reopening of clinical trials at their centre since the directors of their institution have not yet approved the resumption of recruitment. Clear standards and guidelines that can

be adapted to each individual's situation would promote a more rapid reopening of clinical trials. In addition, there is an important issue of access to data - information to follow up patients in clinical studies is often only available in hard copy, and the Quebec Cancer Registry still does not allow researchers quick access to reliable and up-to-date data. The NAGANO[10] electronic research records platform is not deployed in all centres and its full functionality is not yet accessible. Finally, a lack of information and communication regarding the safety of collecting samples (especially live tissue) for bio-banking in the context of COVID-19 has led to a great deal of uncertainty and a slowdown of activities at the level of specialists in the field, even though the WHO[11] and the CDC[12] have issued clear guidelines in this regard.

Best Practice: The **CHU de Québec - Université Laval** sent an internal memo with a detailed recovery plan for its research centre[13]. The **MUHC** is looking into a procedure for storing live specimens in their biobank.

Recommendation 7: Each important new memo from the MSSS should be associated with a short webinar allowing institutions to ask questions, clarify the meaning and intentions of the directives, and ensure better understanding by all institutions. This will also help the MSSS to better understand the reality of the research centres.

Recommendation 8: Provide a framework for a recovery plan that includes all the elements that research centres need to plan and address in order to safely and successfully reopen for patients and staff. Include clear criteria and benchmarks for reopening clinical trials. Share best practices with more challenging centres.

Recommendation 9: Deploy the NAGANO electronic platform and its harmonized forms in all research institutions, making it possible to centralize the documents relevant to clinical trial follow-up electronically and optimize the process. Support smaller centres in the implementation of technology to ensure greater regional equity and standardization of electronic platforms.

Recommendation 10: Ensure that researchers have direct access to reliable and up-to-date data in the Quebec Cancer Registry.

[10] https://ciusssmcq.ca/a-propos-de-nous/enseignement-et-recherche/guichet-unique-de-la-recherche/nagano/
[11] Laboratory biosafety guidance related to coronavirus disease (COVID-19), May 13, 2020. https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-(covid-19)
[12] Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19), July 18th 2020. https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html
[13] INTERNAL MEMO 15 May 2020. COVID-19 et RECHERCHE CLINIQUE au CRCHUdeQc-UL

Recommendation 11: Establish an identification and screening test process for COVID-19 for stored samples and communicate best practices to all bio-banks in Quebec. INESSS could adapt the WHO and CDC guidelines for samples in the context of COVID-19 to the reality of Quebec.

Challenges related to culture

Two major challenges have been raised in relation to the culture change needed not only to get through this pandemic, but also to modernize clinical trials:

- Including patient-partners in clinical research
- Including clinical research in the patient care trajectory

Best Practice: The Centre de **recherche du CHUS (CRCHUS) de Sherbrooke** has set up a **strategic committee of patient-partners**[14] that works together with the centre's management and its Scientific Advisory Board to bring forward priorities identified by patients, and to rethink the best strategic decisions to advance clinical research at its centre and elsewhere. The committee also acts with the various research teams at CRCHUS. They are involved from the development of the research questions, through recruitment strategies and consent forms, to retention and information dissemination strategies. Through this experience, the researchers were able to adapt their process to improve their recruitment and retention of patients as well as the experience of patients in clinical studies.

Although a certain reluctance to this new way of operating may have been perceived at first by researchers, today it is an invaluable practice whose added value is increasingly recognized throughout Quebec and Canada. This model of partnership with patients would be relevant and beneficial in all Quebec research centres.

In addition, most participants also stressed the need to change the predominant culture that places clinical research outside the health system. Because research funding tends to come from the Ministère de l'Économie et de l'Innovation (MEI) or the Ministère de l'Enseignement Supérieur, clinical activities are often given low priority in hospitals. Moreover, from an accounting point of view, research is considered an ancillary activity in the establishments and must be self-financing. Although the Fonds de la recherche en santé du Québec (FRQ-S) finances the indirect costs (infrastructure and administrative support) of some institutions, others do not have access to it. Patients are the ones requesting access to clinical studies because they offer them a promising treatment option and hope, particularly when they have rare or advanced diseases. However, the lack of integration of research into the overall budget of institutions, even

[14] Internal document from the CRCHUS. À quoi ressemble le partenariat patient en recherche au CRCHUS? *(Available on demand to the author)*

though they share certain resources and patients, demonstrates a challenge to be overcome as well as the lack of prioritization in the patient care trajectory.

Clinical research should be an integral part of the service delivery of our health care system. Its integration should be provided for in the design of care and service trajectories. This is a paradigm shift, but it is what patients expect. This is what is expected to bring clinical research in Quebec to modern times.

Recommendation 12: Establish patient-partner committees in clinical research centres in Quebec (CRCHUS model).

Recommendation 13: Foster a culture and paradigm shift in which clinical trials are seen as an integral part of the health care and service trajectory. Include clinical trials in oncology as an important component of the patient care trajectory in the Blueprint for the Quebec Cancer Program. Ensure core funding for the ongoing operations of research centres by the MSSS.

Conclusion

In 2015, the Direction Québécoise de Cancérologie published a report on the evolution of cancer clinical trials in Quebec[15]. This report made specific recommendations to "promote and increase the participation of cancer patients in clinical research in Quebec".

Many of the recommendations of the National Committee on the Evolution of Clinical Research in Cancer echo our own recommendations and priorities, including the following:

- Reinforce the notion that participation in clinical research is an integral part of quality care
- Build sufficient clinical research capacity (resources and training)
- Ensure sufficient funding for the structuring of clinical research, not tied to specific projects
- Increase the efficiency of clinical research in cancer research (achieve economies of scale, reduce duplication)
- Harmoniously integrate clinical research into the Quebec cancer network and its components
- Offer people with cancer easier access to innovative therapies
- Incorporate the development of personalized medicine into the organization of clinical research, including the necessary resources in molecular pathology and bioinformatics

[15] Augmenter la participation à la recherche clinique en cancérologie au Québec - Rapport du Comité national de l'évolution de la recherche clinique en cancérologie. MSSS January 13, 2015. Publication no: 14-902-16W.

This health crisis has forced the world to adapt quickly, to innovate and to think differently. It has accentuated existing problems and provided opportunities to accelerate changes that were slow in coming. The modernization and integration of clinical health research is one such opportunity. By listening to the various research stakeholders and learning about best practices, while having a vision of the desired clinical research environment in Quebec, we were able to arrive at realistic proposals that can be implemented in the short and medium term. We sincerely hope that they will be seriously considered and applied, not as pilot projects or exceptional models, but as innovations to be spread throughout the Quebec clinical network. We will thus have a real "Quebec advantage".

ANNEX

1- Participants

BioCanRx	Stéphanie Michaud, PhD
Catalis	Danika Laberge (consulted)
Centre de recherche — CISSS Bas-St-Laurent (Rimouski)	Alexandra Dube-Loubert
Centre de recherche — IUCPQ	Brigitte Fortin et Marie-Ève Morneau
Centre de recherche du CHUS (Sherbrooke)	Christian-Alexandre Castellano
CHUM	Dre Rahima Jamal
CHUQ	Éric Vachon
Colorectal Cancer Canada & Patient	Barry Stein
Comité patient-partenaire CRCHUS	Sylvie Breton, Nathalie Ouellet, Louise Gagné
Comité patients, survivants & proches aidants de la Coalition priorité cancer au Québec (CPSPA)	Kelvin Arroyo (caregiver)
CUSM	Dr Jonathan Spicer
Fondation du cancer du sein du Québec	Jida El Hajjar
Groupe McPeak Sirois	Dominique Johnson
Hôpital Maisonneuve Rosemont — Centre de recherche	Dre Luigina Mollica
Innovation Exactis	Suzan McNamarra
Institut d'hémato-oncologie et thérapie cellulaire	Dr Denis-Claude Roy
Jewish General Hospital - Segal Cancer Centre	Dr Gerald Batist
Montréal InVivo	Nathalie Ouimet
MSSS — Direction de la recherche et de la coordination interne (DRCI)	Julie Couture, Nadine Gagnon
MSSS — Programme québécois de cancérologie	Louise Paquet
Myélome Canada	Martine Elias
Oncopole	Maxime Dumais
QCROC	Lucie d'Amours, Marie-Chantale Delisle
Société LMC du Canada	Cheryl-Anne Simoneau (patient)

2- Summary of recommendations

1) Create a "provincial resource pool" for clinical research in Quebec. Provide for the use of adapted shifts to allow for better use of resources and available space. Coordinate the use of resources with other departments in the institution. Facilitate referrals between institutions.
2) Improve strategies for forecasting required supplies (e.g., PPE, respirators, medications) for clinical research, especially in anticipation of a second wave of the pandemic.
3) Publish (via the INSPQ), hygiene and distancing standards specific to clinical research.
4) Put in place the infrastructure and processes to allow remote monitoring by clinical research sponsors. Draw inspiration from the CHUQ model (in the appendix), and from the expertise at the CHUS. If this is not immediately possible, find a dedicated room in a cold zone of the hospital or CISSS/CIUSSS.
5) Put in place the infrastructure and processes to allow electronic patient consent. Work with institutional Research Ethics Boards (REBs), patient-partners and study sponsors to accelerate the adoption of electronic consent.
6) Work with clinical trial sponsors to find solutions, adaptations and upgrades that will allow not only for the continuity of clinical trials in the pandemic context, but also for clinical research in the regions.
7) Each important new memo from the MSSS should be associated with a short webinar allowing institutions to ask questions, clarify the meaning and intentions of the guidelines, and ensure better understanding by all institutions. This will also help the MSSS better understand the reality of the research centres.
8) Provide a framework for a recovery plan that includes all the elements that research centres must plan and address in order to reopen successfully and safely for patients and their staff. Include clear criteria and benchmarks for the reopening of clinical trials. Share best practices with more challenging centres.
9) Deploy the NAGANO [16] electronic platform and its harmonized forms in all research institutions, making it possible to centralize the documents relevant to clinical trial follow-ups electronically and optimize the process. Support smaller centres in the implementation of technology to ensure greater regional equity and standardization of electronic platforms.
10) Ensure that researchers have direct access to reliable and up-to-date data in the Quebec Cancer Registry.
11) Implement an identification and screening test process for COVID-19 for stored samples and communicate best practices to all bio-banks in Quebec. The INESSS could adapt the WHO and CDC guidelines for samples in the context of COVID-19 to the reality of Quebec.
12) Establish patient-partner committees in clinical research centres in Quebec (CRCHUS model).
13) Promote a culture and paradigm shift where clinical trials are considered an integral part of the health care and health services trajectory. Include clinical trials in oncology as an important component of the patient care trajectory in the Master Plan of the Quebec Cancer Program. Ensure core funding for the ongoing operations of research centres by the MSSS.

3- Internal documents referenced and available upon request

1) Procedure for remote monitoring
   (CHU de Québec – Université de - Laval)

2) Consent form for remote monitoring
   (CHU de Québec – Université de - Laval)

3) Guidelines for electronic consent
   (Jewish General Hospital - UBC)

4) Plan to relaunch clinical research activities
   (CHU de Québec – Université de - Laval)

5) Strategic patient-partner committee of the CHUS Research Center
   (Sherbrooke)