Canadian Cancer Clinical Trials Stakeholder Charter

Reasonable access to cancer clinical trials ("Clinical Trials") must be the standard of care for all Canadian patients regardless of their age, their location, or their income. Cancer patient groups ("Patient Groups") can help inform cancer patients and caregivers ("Patients) about Clinical Trials and assist in the recruitment, retention, and support of Patients in Clinical Trials. They may also assist in the collection of data both during and following Clinical Trials to better inform health technology assessment bodies of the effectiveness of cancer treatments and their side effects when making drug reimbursement recommendations.

On November 6-7, 2018 in Montreal, Colorectal Cancer Canada (CCC) held its second Patient Group Pathway Model to Accessing Cancer Clinical Trials conference, where participants agreed that the Canadian Cancer Clinical Trials Stakeholder Charter ("Charter") would facilitate the acceptance of Patient Group representatives participating as equal partners in Clinical Trials. They articulated the need for a charter outlining a shared vision, using common language, and providing a framework that Stakeholders could commit to and utilize as a guide to gauge their organizations' patient centricity in Clinical Trials.

The meeting participants envisioned that Patient Groups would be equal partners in Clinical Trials and that they would be fully integrated throughout the Clinical Trial Continuum from the conception through translation. Patient Groups' input would be solicited, valued and acted upon, and their contribution would be supported through education, respectful communication, appropriate feedback, and timely access to information and data. It was further envisioned that the Charter would set out Stakeholders' goals, describe their integration along the clinical research continuum, and demonstrate their expected value.

GUIDING PRINCIPLES

Five guiding principles were established by meeting participants of the November 2018 conference for the development of the Charter. They are as follows:

- Patient centricity
- Commitment to education and training
- Collaboration as equal & independent partners in research
- Transparency & accountability
- High standards in data collection transparency and accountability

THE CHARTER WORKING GROUP

During summer of 2019, the Charter Working Group ("Working Group"), led by CCC, was established, with the goal of facilitating collaboration between Patient Groups and cancer clinical research Stakeholders. The Working Group has incorporated the input provided at the 2018 and 2019 Patient Group Pathway Model to Accessing Cancer Clinical Trials and Real World Evidence conference attendees as well as Patient Groups and trial sponsors in the broader cancer community in Canada into the final edition of the Charter.

We wish to thank all members of the Working Group past and present for their valued contribution to this project.

Vatche Bartekian (Vantage Biotrials), Sabrina Hanna (the cancer collaborative), Sharareh Hosseinzadeh (Novartis), Isabelle Jodoin (Novartis), Dominique Johnson (McPeak-Sirois Group), Stéphanie Michaud (BioCanRx), Judy Needham (Canadian Cancer Trials Group), Stephen Sundquist (Canadian Cancer Trials Network), Patricia Steele (CCC), Sarita Benchimol (CCC) and Barry Stein (CCC). The meetings were facilitated by Anne Marie Weight (Elements Strategy) with the assistance of Elle Doherty (CCC). Previous members of the Working Group of 2019 included Dawn Richards (Clinical Trials Ontario), Emanuela De Franco (Novartis) and Karen Arts (3CTN).

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PREAMBLE

Patients and Patient Groups have increasingly provided unique perspectives to all phases of Clinical Trial research and development, and there is significant evidence demonstrating that Patient Group involvement in this process can positively influence trial outcomes.

Adopters of the Charter believe that Stakeholders must all strive for excellence when conducting cancer research and development as well as direct their efforts toward the development of treatments that provide clinically meaningful results with improved quality of life and Patient outcomes.

The Working Group, in consultation with the broader cancer community, propose the following Five Tenets for Stakeholder Participation in Clinical Trials and cancer research and development. The purpose of these principles is to help guide the relationships among all Stakeholders, make Clinical Trials accessible to all Patients, improve the design and implementation of Clinical Trials, improve recruitment and retention of Patients in Clinical Trials, and further advance cancer research and treatment.

The Five Tenets of the Charter include the commitment to:

1. Making patient centricity a norm in Clinical Trials.
2. Supporting education, training & development of Patient Group members for effective participation in the design & implementation of Clinical Trial protocols on behalf of Patients.
3. Collaborating with Patient Groups as equal & independent partners to optimize the success of Clinical Trials.
4. Adhering to transparency & accountability throughout the Clinical Trial Continuum.
5. Maximizing the potential to collect and utilize RWE/RWD captured in all Clinical Trials.

Tenet

1

Adopters of the Charter commit to:

Making patient centricity a norm in Clinical Trials

What this means:

Using our best efforts to understand and integrate the Patient perspective throughout the Clinical Trial Continuum by considering their experiences and needs. Patient input will be considered throughout the entire Clinical Trial Continuum.

Consequently, we will:

- Ensure that studies are designed to realize outcomes that are relevant to Patients and includes their preferences and trade-offs, achieve clinically meaningful results and enhance Patient quality of life and health outcomes, while minimizing the burden of disease and treatment on Patients.
- Increase access to Clinical Trials by reducing barriers and ensuring that eligibility criteria are fair and appropriate.
- Simplify the informed consent document to provide transparent, comprehensible Clinical Trial information in a language that is relevant for Patients.
- Engage Patients in two-way communication throughout the Clinical Trial Continuum, solicit and incorporate their feedback, and provide access to mechanisms such as digital and mobile health technologies where possible.
- Connect Patients to internal and external support programs and other resources through convenient and user-friendly channels.
- Provide Patients with uninterrupted access to effective Clinical Trial therapies.

Tenet

2

Adopters of the Charter commit to:

Supporting education, training & development of Patient Group members for effective participation in the design & implementation of Clinical Trial Protocols on behalf of Patients

What this means:

Engaging Patient Groups as equal partners, consistent with all other Stakeholders, throughout the Clinical Trial Continuum and therefore recognizing their expertise, input, and experience are unique and valued.

Consequently, we will:

- Engage with Patients and Patient Groups early on as well as on an ongoing basis to work together effectively throughout the Clinical Trial Continuum.
- Support training of Patient Groups and evaluation initiatives while working collaboratively with them, encouraging their input and active participation in the development, implementation and reporting of Clinical Trials.
- Support Patient Groups' ability to record patient values and preferences both during and post Clinical Trials.
- Support training of other research Stakeholders including the Sponsor representatives, to ensure best practices are met in their engagement with Patient Groups.
- Evaluate and share the impact of our engagement with Patient Groups.

Tenet

3

Adopters of the Charter commit to:

Collaborating with Patient Groups as equal & independent partners to optimize the success of Clinical Trials

What this means:

Striving to change the culture of Clinical Trials to ensure that Patient Groups are recognized as equal, independent partners to optimize the success of the trial.

Consequently, we will:

- Build strong partnerships with Patient Groups and all Stakeholders by agreeing on joint expectations, responsibilities, and the commitment to promote co-operation.
- Include Patient insight in the development of the consent process and Patient-Facing Materials.
- Facilitate the connection between trial participants and Patient Groups.
- Promote awareness and education of Clinical Trials among Patient Groups, while integrating their involvement in the design and implementation of Clinical Trials.
- Work with Patient Groups to integrate Patient needs from the conception of Clinical Trials, to expedite and facilitate access to Clinical Trial information, Patient-Facing Materials and Clinical Trial consent.
- Act with integrity and respect the independence of Patient Groups.

Tenet

4

Adopters of the Charter commit to:

Adhering to transparency & accountability throughout the Clinical Trial Continuum

What this means:

Building mutually transparent and open communication with Patient Groups on behalf of Patients as part of the Clinical Trial Continuum and maintaining high levels of accountability.

Consequently, we will:

- Bolster trust through open dialogue and interaction with Patient Groups and seeking their input throughout to ensure Clinical Trial Lifecycle and following the Clinical Trial, as required.
- Work collaboratively with Patient Groups to better understand and address Patient unmet needs, preferences and trade-offs, the burden of current treatments and disease.
- Share information with Patient Groups and Patients in a neutral, uninfluencing and objective manner, where data is presented clearly and accurately as well as in a balanced and fair context, to allow Patient Groups to form their own independent opinion and interpretation.
- Hold ourselves to highest levels of accountability by ensuring that the independence of all Stakeholders involved is maintained and by implementing clear conflict of interest and disclosure guidelines.
- Develop trust and confidence in the methods used.
- Transparently share the aggregate results of Clinical Trials with Patients and Patient Groups, regardless of the trial outcome, in a timely, efficient and comprehensible manner.
- Transparently share the individual results with the Patient and/or Patient guardian in the case of a pediatric study, regardless of the outcome, in a timely, efficient and comprehensible manner.

Tenet

5

Adopters of the Charter commit to:

Maximizing the potential to collect and utilize RWE/RWD captured in all Clinical Trials

What this means:

RWE/RWD will be considered in all Clinical Trials to optimize the quality of evidence, minimize risk of bias and build upon public and Stakeholder trust in research credibility and reliability.

Consequently, we will:

- Consider RWE/RWD in the collection of data in order to render the results more generalizable to achieve greater external validity, better support access, appropriateness of use and affordability of the Therapeutic Interventions being tested in Clinical Trials.
- Communicate (in lay language for good comprehension by Patient Groups and Patients), the research goals, methods, procedures, RWE/RWD collected as well as the findings resulting from the use and analysis of this data.
- Ensure that the RWE/RWD data is complete, reliable, and processed in a consistent manner. Best practices in data collection and analysis should be applied from the initiation of the trial study design and maintained throughout the Clinical Trial Continuum.
- Share RWE/RWD data post Clinical Trial in a timely manner to ensure the greatest impact of Patients/caregivers to help with decision making.

- **Adopters of the Charter:** A person or an organization/institution that chooses to take up, follow or use the Charter for its intended purpose.

- **Clinical Trial:** Any oncology investigation in human subjects intended to determine the clinical pharmacological, pharmacokinetics, and/or other pharmacodynamics effect of an investigational agent, and/or to identify any adverse reactions to an investigational agent to assess the agent's safety and efficacy.

- **Clinical Trial Continuum:** The sequential series of steps involved in the development of clinical trials. These include 1- the Discovery and preclinical stages, the Phase 1-3 trials, the Regulatory review process and the post-approval process.

- **Clinical Trial Lifecycle:** The sequential series of steps involved in the development of clinical trials. These include the discovery and preclinical stages, as well as Phase 0 trials to learn how an agent is processed in the human body and how it may affect the body, Phase I trials seek to find the best dose of a new agent and assess overall safety, Phase II trials aim to further assess the safety as well as determine if the agent works, Phase III trials further investigate product safety, effectiveness of a new agent as compared to the standard of care in larger study populations, Phase IV trials, otherwise known as post-marketing trials, serve to test agents previously approved for use by Health Canada (agents include drugs).

- **Consent Process:** A process in which a healthcare provider educates a Patient about the risks, benefits and alternatives of a given procedure, intervention or treatment. The Patient must be competent to make a voluntary decision about whether to undergo the said procedure or treatment.

- **Patient (Cancer Patient):** A person who is receiving medical treatment for a malignant growth or tumour.

- **Patient Centricity:** The process of designing a service or solution around the Patient. In Clinical Trials it is a trial designed with the Patient at the forefront to improve the overall experience for the Patient by including their concerns and priorities in the design ensuring that the Clinical Trial answers specific unmet needs of the Patient.

- **Patient-Facing Materials:** Documentation associated with each phase of a clinical trial that is written in a language that is tailored to the audience and their cultural area. Titles of studies, terminology and wordings are translated in a patient-friendly manner to ensure maximum transparency and comprehension.

- **Patient Group:** A term encompassing patient advocacy organizations, disease advocacy organizations, voluntary health services, non-profit research foundations and public health organizations for clarity of focus. Our use of the term Patient Group in not meant to refer to individual Patients or individual advocates.

- **Patient Preferences/Perspectives:** Patient Preferences/Perspectives related to therapies and outcomes regarding willingness to accept uncertainty and trade-offs based on potential harm versus benefits. Benefits-risk assessment may also seek to identify subgroups of Patients in a heterogeneous population based on preferences.

- **Protocol (Clinical Trial Protocol):** Every clinical investigation begins with the development of a clinical trial protocol. The protocol is a document that describes how a clinical trial will be conducted (the objective(s), design, methodology, statistical considerations and organization of a clinical trial), and ensures the safety of the trial subjects (participants) and integrity of the data collected (source: Clinical Research Resource Hub).

- **Real World Data (RWD):** Real world data are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources, such as electronic health records and product and disease registries (source: Food and Drug Association (FDA)).

- **Real World Evidence (RWE):** Clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.

- **Researchers:** Individuals engaged in the conduct of scientific research at an academic or pharmaceutical institution.

- **Stakeholders:** Parties with concerns or interests in an organization, endeavor, or initiative. Stakeholders include but are not limited to:
  - Governmental institutions and agencies
  - Medical Researchers
  - Patients/Patient Groups
  - Pharmaceutical/Biotech Companies
  - Regulatory bodies (internal/external)

- **Standard of Care Treatment:** Treatment that is accepted by medical experts as an appropriate treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy (source: National Cancer Institute (NCI)).

- **Standard of Work Practice:** The regulations, guidance and industry standards that make up Standard of Work Practice of good clinical practice are intended to provide assurance that the rights, safety and well-being of Clinical Trial subjects are protected.

- **Study Design:** Study design is a particular framework, or the set of methods and procedures used to collect and analyze data on variables specified in a particular research problem (source: National Institutes of Health (NIH)).

- **Therapeutic Intervention (Oncology):** A clinical effort to improve the well-being of someone who has cancer. Therapeutic interventions in oncology include chemotherapy, immunotherapy, and surgery.

- **Trial Information Data:** The computerized form of results and analysis obtained throughout the Clinical Trial process, including Patient treatment responses and other derived variable.