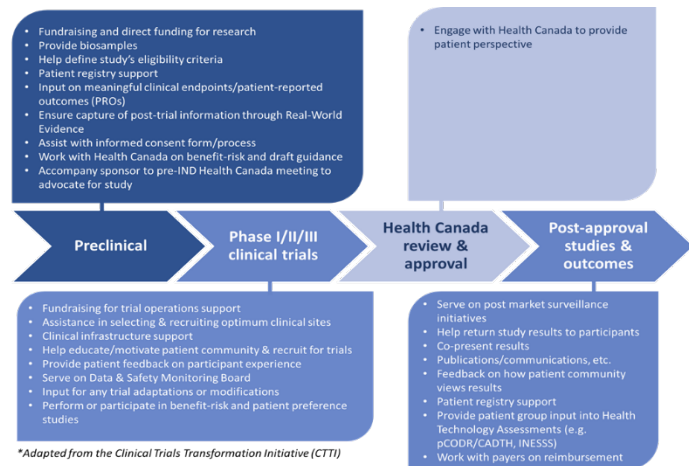


A Canadian Framework for Integrating the Patient Voice Into the Cancer Clinical Trials Continuum

In June 2017 as an outcome of a meeting led by Colorectal Cancer Canada (CCC), a scientific advisory committee including patients, oncologists, clinical trial (CT) networks, and researchers, came to a consensus to Canadianize the Clinical Trials Transformation Initiative (CTTI), with the aim to integrate patient and patient group voices into the cancer clinical trial continuum.

CTTI demonstrated success in the US¹ and had to be adapted to reflect the Canadian research, public payer environment, and the role of patient groups. Endorsed in November 2018, the C-CTTI model shows two main differences from the American pathway model:

1- the effects of global decision-making and 2- the systems of regulatory and funding approvals.²



Leading to the Development of a Charter to Engage Patient and Patient Groups into the Clinical Trial Continuum

Tenet 1	• Making Pt Centricity a Norm in CTs
Tenet 2	• Supporting Education, Training & Development of PG Members
Tenet 3	• Collaborating with PGs as Equal & Independent partners
Tenet 4	• Adhering to Transparency & Accountability
Tenet 5	• Maximizing the Potential to Collect and Utilize RWE/RWD Captured in all CTs

Charter's Tenets

In November 2018, to guide the implementation of patient centricity and engagement in cancer CTs and to operationalize the C-CTTI model, the development of a charter was identified by cancer CT stakeholders.

Led by CCC and a working group (WG) including key CT stakeholders, the *Canadian Cancer Trial Stakeholder Charter* (the Charter) was developed through a series of WG group sessions and stakeholders feedback integration.

Finalized in August 2020, as a tangible framework for cancer CT stakeholders to commit to and to gauge their organizations' patient centricity, the Charter includes five tenets, aiming to make CTs accessible to all patients, improve the design and implementation of CTs to benefit patients, expand recruitment and retention of patients in CTs, and further advance cancer research and treatment.³

Moving forward - Charter Adoption, Implementation, Sustainment and Evaluation (AISE)

As a proposed approach for the Charter adoption, implementation, sustainment and evaluation (AISE), representatives from the broader Stakeholder community are to be recruited to collaboratively:

- Identify and address key opportunities and barriers to Charter AISE
- Secure resources (financial, time, material, etc.) and commitment necessary to develop the framework/infrastructure necessary to support Charter AISE
- Set-up a long-term stewardship/governance and advocate for Charter integration into CT guidelines/standard operating practices

1 Patrick-Lake B. Patient engagement in clinical trials: The Clinical Trials Transformation Initiative's leadership from theory to practical implementation. *Clinical Trials* 2018; **15**: 19-22.

2 Batist G, Michaud S, Richards D *et al.* Developing a model of a patient-group pathway to accessing cancer clinical trials in Canada. *Current Oncology* 2018; **25**: e597-e609.

3 Michaud S, Needham J, Sundquist S *et al.* Patient and Patient Group Engagement in Cancer Clinical Trials: A Stakeholder Charter. *Current Oncology* 2021; **28** (accepted).