Patient Group Pathway Model
to Accessing Cancer Clinical Trials in Canada
What problems are we trying to solve?

1. Too few cancer patients are enrolled in clinical trials.
   - In 2014, <7% of adult cancer patients in Canada were enrolled in a clinical trial, compared to <5% in the United States and 12% in the United Kingdom $^{1}$
   - 85% of clinical trials fail to retain enough patients to continue, 80% fail to finish on time, and half of sites enroll one or no patients $^{2}$
   - 40% of pharmaceutical clinical trial budgets are spent on recruitment and 30% of patients drop out of a study $^{3}$

2. Canada lacks a framework to integrate the patient voice into the cancer clinical trials process.

What problems are we trying to solve?

• Patients and caregivers can add unique and significant perspectives to the evaluation of new treatments. (e.g., PROs)

• Integration of patient input is inconsistent across the clinical trials continuum in Canada. (HTA is leading)
What outcomes do we expect to see?

Benefits of Integrating Patient Groups

Cancer Patients
- Faster access to innovative treatments
- Greater understanding of new cancer therapies
- Improved standard of care

Clinical Trial Sponsors and Investigators
- Improved cancer research and development strategies
- Shorter development timelines
- Lower costs
- Higher approval rates for new treatments
- Better understanding of unmet needs & real-world outcomes

HTA /Funders/Payers
- Increased confidence in assessments

Canada
- More cancer research opportunities
- Lower costs of treatment

All Stakeholders
- Improved relationships among stakeholder groups
CCC Leading the Initiative

- **National non-profit organization dedicated to Awareness, Education, Support & Advocacy to patients, caregivers and the general public.**
  - Extensive networks with patient groups in Canada and internationally
  - Long history of outreach to the general public
  - Strong relationships with research community, HTA bodies, Health Canada, Cancer Centers

- **Supported by a Scientific Advisory Committee**
  - Oncologists, clinical trials networks, clinical researchers, patient groups

- **Kicked off with a consensus meeting, June 2017**
  - 65 attendees: patient groups (40%), academic research organizations (34%), clinical trial sponsors (23%) and health policy organizations (3%)
  - Output: Consensus Agreement that the CTTI model could be adapted for Canada
  - Working Group: Adapted framework for Canada, December 2017
What has been done so far?

Selected Model of Patient Group Integration in Cancer Clinical Trials

Clinical Trials Transformation Initiative (CTTI)

• Set of recommendations for each stakeholder group + suite of tools
• Implemented in 2007; multiple publications
• Demonstrated positive financial benefit to research sponsors

Model “Canadianized” to reflect key differences in U.S.

i. Globalized Research, ii. Public Payer Environments

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Patient Group Engagement In Canadian Clinical Trials System

- Fundraising and direct funding for research
- Provide biosamples
- Help define study’s eligibility criteria
- Patient registry support
- Input on meaningful clinical endpoints/ patient-reported outcomes (PROs)
- Ensure capture of post-trial information through Real World Evidence
- Assist with informed consent form/process
- Work with Health Canada on benefit-risk and draft guidance
- Accompany sponsor to pre-IND Health Canada meeting to advocate for study

Preclinical

- Fundraising for trial operations support
- Assistance in selecting & recruiting optimum clinical sites
- Clinical infrastructure support
- Help educate/motivate patient community & recruit for trials
- Provide patient feedback on participant experience
- Serve on Data & Safety Monitoring Board
- Input for any trial adaptations or modifications
- Perform or participate in benefit-risk and patient preference studies

Phase I/II/III clinical trials

- Engage with Health Canada to provide patient perspective

Health Canada review & approval

- Serve on postmarket surveillance initiatives
- Help return study results to participants
- Co-present results
- Publications/communications, etc.
- Feedback on how patient community views results
- Patient registry support
- Provide patient group input into Health Technology Assessments (e.g., pCODR/ CADTH, INESSS, CDIAC)
- Work with payers on reimbursement

Post-approval studies & outcomes

* Adapted from the Clinical Trials Transformation Initiative (CTTI)
Canadian Cancer Clinical Trials “ecosystem”

**Research Sponsors**
- Canadian Institutes for Health Research (CIHR)
- Canadian Cancer Society Research Institute (CCSRI)
- The Canadian Centre for Applied Research in Cancer Control (CC-ARCC)
- Industry (pharmaceutical, biotech, devices)
- Patient groups
- Private foundations

**Clinical Research Performers**
- Centres of Excellence
- Universities, hospitals, cancer centres
- Clinical research organizations (CROs)

**Regulator**
- Health Canada

**Payers**
- Health Technology Assessment bodies (pCODR/ CADTH, INESSS, CDIAC, pCPA)
- Provincial, territorial, federal drug programs
- Private payers

**Clinical Research Networks**
- Canadian Cancer Trials Group
- Network of Networks (N2)
- Canadian Clinical Trials Coordinating Centre
- Canadian Cancer Clinical Trials Network (3CTN)
- Strategy for Patient-Oriented Research (SPOR) Support Units
- Consortium de recherche en oncologie clinique du Québec (Q-CROC)
- CATALIS
- Exactis
- Clinical Trials Ontario
- BC Clinical Research Infrastructure Network

**Global Clinical Research Networks**
- Cooperative oncology groups
- Corporate headquarters
1. Finalize and adopt the “Patient Group Pathway Model to Accessing Cancer Clinical Trials in Canada”.

2. Develop a “Charter” document encouraging organizations to integrate patient groups into their cancer clinical trials processes.

3. Establish a Training Program to provide patient groups with the knowledge and skills to participate as equals.
How You Can Help

1. **Provide your input** into the “Patient Group Pathway Model to Accessing Cancer Clinical Trials in Canada”

2. **Help us develop the “Charter” and spearhead its adoption** in your organization

3. **Provide us with your thoughts** on the content and delivery of the patient group training program

4. **Spread the word** through your networks
PREVENTABLE, TREATABLE, BEATABLE!

Barry D. Stein
barrys@colorectalcancercanada.com
colorectalcancercanada.com