INTRODUCTION/BACKGROUND

- Patients avoid participating in cancer clinical trials (CTs) due to perceived or real barriers, leading to suboptimal enrollment and retention rates in CTs.
- Patient preferences and values are increasingly at the core of value-based decision-making in all phases of the CT continuum, drug development and reimbursement including at Health Canada, CADTH* and INESSS**.
- The Clinical Trials Transformation Initiative (CTTI) developed in the United States (U.S.) by Duke University and the Food and Drug Administration (FDA) to improve the quality and efficiency of CTs.
- The Canadian CTTI (CTTI) Pathway Model (Pathway Model), was adapted to the Canadian environment to encourage participation of patient groups (PGs) in all phases of the CT continuum. The major roles of PGs in CTs are summarized in Figure 1.
- With the adoption of the Pathway Model, PGs engagement in CTs can help capture real-world data (RWD) and develop real-world evidence (RWE).
- PGs input, patient preferences and values enrich CTs and health technology assessment. HTA at all phases of the CT and HTA continuums. Adoption of the Charter throughout the continuum will aid the advancement of CTs.
- *Canadian Agency for Drugs and Technologies in Health
- **Institut national d'excellence en santé et services sociaux

OBJECTIVES

- Improve patient participation and retention rates in CTs
- Improve and facilitate PG engagement in the CT continuum
- Improve patient and PG input into HTA

METHODS

Building a collaborative relationship to better engage Patients and PGs, Trial Sponsors, and other Stakeholders by defining roles and expectations using a common language.

To maximize the potential of Patients and PGs to participate as equal partners in the CT continuum.

TIMELINE

- June 2017: First multi-stakeholder conference
- November 2018: Final Health Canada stakeholder conference
- December 2018: Public consultation document released (v. 1.0)
- October 2019: Final Health Canada review & approval
- October 2020: Draft path model finalization

DISCUSSION

- Precision medicines involve smaller patient populations eligible for CTs, making phase III trials nearly impossible.
- RWD gathered post-CT, upon conditional approval, would allow for determination of drug effectiveness in a broader population, increase certainty, and permit faster access to therapies for patients.
- RWD can also extend, augment, and/or enrich CTs, and support patient-centered care.
- PG participation in CTs and post-CTs in the collection of patient RWD can enrich input to HTA bodies and provide a better understanding of patient values and preferences, drug effectiveness and side effects.

NEXT STEPS

- Next steps in the implementation and adoption of the CTTI Pathway Model & Charter.
  - Communication plan for the Pathway Model and Charter.
  - Adoption of the Charter by key stakeholders.
  - Development of PG and stakeholder CT training programs.
  - Developing WG methodologies to technology frameworks to aid PGs in tracking and reporting on patient preferences.

- Increasing PG participation in all phases of the CTTI Pathway Model. Demonstrate the value of the CTTI Pathway Model and Charter by utilization of PGs in CTs.
- Develop Key Performance indicators
- Publication of ongoing development of the Pathway Model and Charter.

*Adapted from the Clinical Trials Transformation Initiative (CTTI)

Patient Group Pathway Model to Accessing Cancer Clinical Trials (Pathway Model) & The Canadian Cancer Clinical Trials Stakeholder Charter (Charter)

Colorectal Cancer Canada | June 29, 2020

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