

**Clinical Trials Committee**  
**Terms of Reference**  
**August 2015, Updated August 2016**

## Background

The Canadian Cancer Clinical Trials Group (CCTG) is the only Canadian research facility capable of supporting the development and conduct of the entire range of cancer trials arising from proposals from the academic cancer research community and in collaboration with government and the healthcare industry<sup>1</sup>. The CCTG supports early phase (e.g. phase I-II) studies to large international randomized controlled phase III trials of all treatment modalities across all cancer types. By facilitating the conduct of trials that examine questions developed and driven by clinicians and that take advantage of emerging science and new therapies, the CCTG contributes to observations that are now translated into practice and have improved cancer outcomes. CCTG and the researcher network that uses it provide a mechanism for the independent assessment of new therapies and diagnostic tests, their costs, risks and benefits. The conduct and the results of the research are recognized as being of high quality necessary to change practice and policy around the world.

## CCTG Mission and Vision

The CCTG's Mission is to develop and conduct clinical trials aimed at improving the treatment and prevention of cancer with the ultimate goal of reducing morbidity and mortality from this disease.

The CCTG is also bound by the Mission Statement of the Canadian Cancer Society (CCS): "The Canadian Cancer Society is a national, community-based organization of volunteers whose mission is the eradication of cancer and the enhancement of the quality of life of people living with cancer."

CCTG trials:

- Ask important questions;
- Address questions of importance to the academic, health policy and patient communities;
- Change clinical policy and practice;
- Reduce mortality, unnecessary treatment and costs;
- Reflect the intellectual leadership of CCTG investigators; and,
- Reflect an internationally competitive caliber of science.

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<sup>1</sup> The term "healthcare industry" refers to commercial developers of medicines and devices and is therefore inclusive of the pharmaceutical industry, biotechnology and biopharma companies, as well as medical device and diagnostics companies.

## Purpose of the Clinical Trials Committee

The CCTG Clinical Trials Committee (CTC) is the most senior scientific advisory committee of the CCTG and plays an essential role in helping to shape the overall research agenda of the Group through review and recommendation of proposed trials and other initiatives coming from the CCTG's Disease Site Committees.

## Objectives and Responsibilities

The CTC advises the Director based upon knowledge of the strategic directions of the Group, and its work includes an important role in rating and prioritizing proposed projects and ensuring a balanced portfolio of research across diseases and disciplines in keeping with the CCTG overall mission to develop and conduct clinical trials aimed at improving the treatment and prevention of cancer with the ultimate goal of reducing morbidity and mortality from this disease.

## Committee Chair and Membership

### Chair

- The CCTG Director is the Chair of the Clinical Trials Committee.

### Members

Membership will include the following representation and will include members who are both internal and external to the Group. These include:

- Senior oncologists with radiation, medical, surgical and hematological oncology expertise;
- Representative expertise across cancer types;
- Representative expertise from across Canada;
- Early and mid-career investigators;
- Chair and rotating member of the Lay Representatives Committee;
- Chair of the CRA Executive Committee;
- One representative from the Canadian Cancer Society; and,
- The NCI US Cancer Therapy Evaluation Program liaison to the CCTG

## Duties, Expectations and Terms of Members

Members are appointed by the Director for 3-year terms, renewable. CCTG Senior investigators and Senior Biostatisticians are members of the Clinical Trials Committee.

All CTC members will be expected to:

- Attend, as a high priority, all CTC meetings whether in person or by teleconference, be prepared for and actively engage in reviews and discussions, and score all proposals unless a conflict exists; and,
- Declare any and all potential conflicts of interests as they arise.

### Frequency of Meetings

The CTC will have three meetings annually (minimum) at least one of which will be face-to-face. Additional meetings by teleconference will be at the call of the Chair.

### Quorum

A Quorum is achieved with 50% of external members present.

### Deliberations and Recommendations

For ranking of trial proposals, the CTC will review documents submitted by the Disease Site Committee and each proposal is assigned a primary and secondary reviewer. Following presentation and discussion, proposals are assigned a score by all external CTC members, as well as Senior Investigator members of the CTC who have no conflict on the proposal being discussed based on pre-circulated criteria that include scientific merit, feasibility and impact (see attached). Ranking of proposals will be based on their relative and absolute scores.

### Administrative Support

The Clinical Trials Committee will be supported by the CCTG Group Administrator's Office.

### Remuneration

There is no remuneration or honorarium for members; however, travel/accommodation costs associated with meeting participation will be reimbursed by the Group.