

## Canadian Cancer Clinical Trials Network Portfolio Eligibility Criteria and Guidelines

### 1. Introduction

The Canadian Cancer Clinical Trials Network (3CTN) will support a portfolio of academic clinical trials reflecting the priorities of clinicians, researchers, patients, ministries of health and funders. Scientific oversight will be provided by the Portfolio Committee (PC) and operational management by the 3CTN Coordinating Centre.

### 2. Purpose

This document will outline the trial portfolio eligibility criteria and the process for identifying and maintaining portfolio trials.

### 3. Trial Eligibility

To be eligible for inclusion into the portfolio, a study must be an oncology clinical trial and is:

- Academic sponsored;
- Open to multiple network centres;
- Funded independently of 3CTN;
- Peer reviewed by external reviewers.

**Automatically Eligible:** A study will be automatically included into the portfolio if the above criteria apply. Eligibility will be reviewed by the Portfolio Coordinator, the Portfolio Secretariat, Scientific Director and by the PC twice annually.

**Potentially Eligible:** If trial eligibility is uncertain, for example, if the trial appears to meet the objectives or is of benefit to 3CTN and does not meet the above criteria, the study will undergo portfolio eligibility review by the PC.

See Appendix A for definitions.

### 4. Trial Ineligibility:

A trial will be excluded from the portfolio if the study does not meet the above criteria and/or is:

- An audit;
- A needs assessment study;
- A quality improvement and other local service evaluations;
- A routine banking of biological samples or data except where this activity is integral to a self-contained research project designed to test a clear hypothesis.

### 5. Process for Portfolio Status

Once a study has met the portfolio eligibility criteria listed above, interested applicants must submit a completed portfolio application form to be considered for portfolio status. To reduce potential delays, it is recommended a study is submitted for portfolio status at the time of research ethics submission.

The application form will be reviewed by the 3CTN Coordinating Centre for completion. The Manager, Operations and Secretariat for the portfolio will review the application to determine initial trial eligibility. If the study is automatically eligible, it will be added to the portfolio database. If eligibility is uncertain, the study will undergo portfolio eligibility review by the PC members. After a study has been added to the portfolio, all 3CTN sites will be notified and the study will be eligible for 3CTN support until it exits the portfolio.

## **6. Communication of the Network Trial Portfolio**

Trials will be listed in the 3CTN trial database and assessable from the 3CTN website [www.3ctn.ca](http://www.3ctn.ca). Updates to the portfolio will be communicated electronically to all members of the Network.

## **7. Scientific Oversight of the Portfolio**

The PC is responsible for the scientific oversight of the portfolio and reports to the 3CTN Scientific Director and the Steering Committee. PC members will meet at least twice annually to: a) review the portfolio for scientific merit, priority and performance; b) review/approve the trials that were automatically added since their last meeting; c) review the balance of portfolio trials to ensure a wide range of trials of interest/relevance to Canadians and the Canadian health care system.

The committee may highlight important initiatives such as those in rare cancers, young adults, cancer survivors, personalized medicine that may lead to inclusion of trial into the portfolio.

## **Exit Criteria/Change of Portfolio Status**

It is important to direct limited resources to supporting priority trials and to ensure these trials are done efficiently. All trials that exit the portfolio will continue to be tracked for portfolio impact. Studies that meet the following criteria will exit the portfolio:

- Closed to recruitment;
- Deemed not eligible by PC.

## **8. Portfolio Metrics**

For the duration a study has portfolio status, the applicant and all sites receiving 3CTN support must submit trial and portfolio related metrics. The metrics collected on the portfolio are defined in Appendix B.

## **9. Assessment of Initial Portfolio Trials (Phase I)**

An initial assessment of all Canadian academic trials listed on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and [www.canadiancancerclinicaltrials.ca](http://www.canadiancancerclinicaltrials.ca) was completed.

## Appendix A: Definitions

### Academic Sponsored Clinical Trial

As per the Canadian Cancer Research Alliance, "Academic trials are defined as those developed by and coordinated by academic investigators such as trials that are "sponsored" by academic organizations like universities or cooperative clinical trial groups. Trials that are supported by grants from peer-reviewed agencies, charitable funding or by contracts from the pharmaceutical industry may also be included if their conduct, analysis and publication lies in the hands of academic investigators."

### Canadian Academic Sponsor

A trial that is sponsored by a Canadian academic group, for example NCIC Clinical Trials Group, Ontario Clinical Oncology Group etc.

### Clinical Trial (WHO)

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.

### Clinical Trial Application (CTA) (Health Canada)

Clinical Trial Application are required for human clinical trials using drugs not authorized for sale in Canada, including clinical trials in Phases I through III of drug development and comparative bioavailability studies; as well as trials involving marketed drugs, where the proposed use of the drug is outside the parameters of the NOC or DIN , e.g., one or more of the following is different:

- a. Indication(s) and clinical use;
- b. Target patient populations(s);
- c. Route(s) of administration; or
- d. Dosage regimen(s).

### Closed Studies (Health Canada)

Notwithstanding a suspension, cancellation or study closure of a clinical trial in Canada, in its entirety, a study is considered to be completed after the last subject globally completes the "end of study" visit as defined in the protocol. The "end of study visit" is the final visit for study-related tests and procedures, including the capture of any final potential study-related adverse events.

### Collaborator (ClinicalTrials.gov)

A collaborator is an organization other than the sponsor that provides support for a clinical study. This may include funding, design, implementation, data analysis, or reporting.

### Date of Commencement of a Clinical Trial (Health Canada)

For the purpose of the Clinical Trial Site Information Form, this is defined as the date when the clinical trial site will be ready to enroll patients in the clinical trial.

### Enrollment (clinicaltrials.gov)

The number of participants in a clinical study. The "estimated enrollment" is the number of participants that the researchers need for the study.

### Ethics (WHO)

Ethics is concerned with moral principles, values and standards of conduct. The field of health and health care raises numerous ethical concerns, related to, for example, health care delivery, professional integrity, data handling, use of human subjects in research, and the application of new techniques, such as gene manipulation.

**Industry sponsored trial**

A trial that is sponsored by the pharmaceutical industry.

**Funded independently of 3CTN**

The study has external funding from other funding agencies.

**Interventional Study/Clinical Trial** (clinicaltrials.gov)

A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

**Intervention** (clinicaltrials.gov)

A process or action that is the focus of a clinical study. This can include giving participants drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches such as surveys, education, and interviews.

**Medical Devices** (WHO)

A medical device is an instrument, apparatus, or machine used to diagnose, treat, monitor, or alleviate disease or injury. It is also used to prevent disease and compensate for injury. Medical devices cover an extremely wide range of products including: syringes, stethoscopes, hip implants, ECG recorders, X-ray equipment, spectacles and dental equipment. In general, a medical device is any product used specifically for health care purposes which is neither a medicine nor a biological product.

**Multi Provincial**

A trial that is open to recruitment in more than one province in Canada is referred to as a multi provincial trial.

**Observational Study** (clinicaltrials.gov)

A clinical study in which participants identified as belonging to study groups are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to specific interventions (as in an interventional study).

**Open Studies** (clinicaltrials.gov)

Trials that are currently recruiting participants, will be recruiting participants in the future, or involve drugs that are available for expanded access. Recruitment statuses for open studies appear in green text in ClinicalTrials.gov search results and study records. These are: Recruiting; Not yet recruiting; Available for expanded access.

**Open to Multiple Network Centres**

A trial that is open to recruitment in more than one participating Canadian centre.

**Peer Reviewed by External Reviewers**

Studies will be considered peer-reviewed if:

- They are supported by an agency (CIHR, CBCRF, etc) that uses a peer-review process to allocate funding or;
- They are trials undertaken by a cooperative clinical trials group (NCIC CTG, OCOG, etc) or;
- \*Neither 1 or 2, they have been approved by two experts external to the project and the institution(s) supporting it.

*\*Must contact the 3CTN Coordinating Centre ([info@3ctn.ca](mailto:info@3ctn.ca)) for more information before locating external experts.*

### **Phase III Clinical Trial** (Health Canada)

Controlled or uncontrolled trials conducted after preliminary evidence suggesting efficacy of the drug has been demonstrated. These are intended to gather the additional and confirmatory information about the clinical efficacy and safety under the proposed conditions of use for the drug.

### **Research Ethics Board (REB) Approval** (Health Canada)

REBs have an important role in the oversight of the conduct of clinical trials. Sponsors are required by regulations to obtain REB approval for each clinical trial site prior to commencing the trial at that site.

### **Recruitment** (UK CRN website)

Recruitment is the enrolment of an individual person (a participant), that meets the specific inclusion criteria, into a research study. Each study participant who has both provided informed consent to join a study and is taking part in the study (i.e. participants who count towards the sample size of the study as set out in the study protocol), should be recorded as a participant in the Portfolio Database

### **Recruitment Status** (clinicaltrials.gov)

Indicates the current stage of a clinical study and whether it is or will be open for enrollment.

- **Recruiting:** The study is currently recruiting participant
- **Not yet recruiting:** The study has not started recruiting participants
- **Active, not recruiting:** The study is ongoing (that is, participants are receiving an intervention or being examined), but potential participants are not currently being recruited or enrolled
- **Enrolling by invitation:** A study that selects its participants from a population, or group of people, decided on in advance by the researchers. These studies are not open to everyone who meets the eligibility criteria, but only to people in that particular population, who are specifically invited to participate.

### **Sponsor** (Health Canada)

An individual, corporate body, institution or organization that conducts a clinical trial as per Division 5. The sponsor must comply with its obligations as set out in the *Regulations* (including C.05.010-C.05.015) in adhering to good clinical practices for the proper use of the drugs, drug labeling requirements, record keeping, submission of information, reporting of ADRs, and trial discontinuation reporting requirements.

### **Sponsor-investigator** (FDA, 21 CFR)

An individual who both conceives, initiates, designs and conducts a clinical trial and under whose immediate direction the study drug is administered.

**Study Open to Recruitment**

Studies that are currently recruiting participants

**Appendix B: Metrics**

Metrics to be submitted by the trial sponsor and/or participating site:

<b>Data Collected</b>	<b>3CTN Objective</b>
Patient recruitment per trial	Increase patient recruitment
Patient recruitment per site per trial	Increase patient recruitment
Date of trial open to recruitment	Increase operational efficiency
Date of first patient recruited	Increase operational efficiency

Metrics to be collected by 3CTN for internal performance measurement:

<b>Data Collected</b>	<b>3CTN Objective</b>
Number of trials ongoing	Increase number of trials
Number of trials opened	Increase number of trials
Number of trials closed	Increase number of trials
Date of application form submission	Internal efficiency
Date of trial added to portfolio	Internal efficiency
Date trial exited portfolio	Internal efficiency

Information submitted at time of application:

<b>Data Collected</b>	<b>3CTN Objective</b>
Phase of study	Supporting trials that will benefit Canadians
Disease site	Supporting trials that will benefit Canadians
Intervention type	Supporting trials that will benefit Canadians

### Document Revision History

<b>Version</b>	<b>Date</b>	<b>Description</b>
1.0	11/19/2014	New document