Canadian Cancer Clinical Trials Network

The 3CTN Guide to Patient & Public Involvement

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A MESSAGE FROM THE 3CTN SCIENTIFIC DIRECTOR

I am pleased to welcome you to the Canadian Cancer Clinical Trials Network (3CTN). Whether your role is on a 3CTN committee or you are involved in clinical trial site activities, your contributions to the 3CTN initiative are greatly appreciated.

In recent years, there has been increasing support throughout the healthcare research sector to include patients and caregivers in research planning, design and implementation. This movement of inclusiveness in research, often referred to as Patient and Public Involvement (PPI), is particularly relevant for 3CTN activities as patients, their families and caregivers provide a unique and vital perspective in the development, planning and delivery of all clinical trials. As a result, 3CTN is committed to including PPI in all areas of the Network and all Network initiatives.

Through the contributions of 3CTN Patient Representatives, we know that all our activities will be created and delivered in a manner that overcomes barriers to ensure greater access to cancer clinical trials for Canadian cancer patients. For these reasons, we are delighted to have you on board. Together we will work towards building a robust and sustainable future for the Canadian cancer clinical trial enterprise with the aim of benefiting all Canadians with cancer, or those at risk, for years to come.

Sincerely,

Janet Dancey, MD, FRCPC

Scientific Director, Canadian Cancer Clinical Trials Network

A MESSAGE FROM THE 3CTN PATIENT REPRESENTATIVE ADVISORY COMMITTEE

Welcome to the beginning of an exciting journey as we work together to bring the voice of patients and the public to clinical research within 3CTN!

It has been demonstrated that the voice of the patient and the public can be influential in healthcare research and that including Patient Representatives strengthens accountability and transparency in such endeavors. Patient Representatives can help to steer research in directions that answer questions that are important to patients and the public. Patient Representatives can provide input to trial design and communication strategies that will make sense to patients. They often bring value-added personal and professional skills which can be very helpful to the work of a committee or project. Ultimately, Patient Representatives can truly embody the phrase “nothing about us without us”.

3CTN’s leadership strongly believes in the value of patient and public involvement (PPI) and is committed to ensuring that PPI is embedded in every aspect of the 3CTN framework, both at the Coordinating Centre level and at Network sites across the country. The Patient Representative Advisory Committee’s role is to assist the 3CTN leadership to incorporate PPI in this important initiative.

This 3CTN PPI Guide can be viewed as the “road map” to success for PPI in 3CTN. Not only is it written for the benefit of new and existing Patient Representatives, but it can also be a resource for the scientific, research, and healthcare staff involved in 3CTN. We hope this guide is a one-stop PPI resource for all 3CTN stakeholders. This guide is one tool that will help move us along the path we are travelling. We hope it will provide the basic knowledge and processes that will assist you in your journey within the 3CTN initiative.

We look forward to working together to strengthen the voice of the patient and public in 3CTN!

Acknowledgments: The authours would like to acknowledge the NCIC Clinical Trials Group for their support and appendix contributions during the compilation of this guide.

3CTN PPI GUIDE

Table of Contents

Chapter 1

Introduction

This section covers some background information about cancer clinical trials, the history of 3CTN and the purpose of PPI.

When one hears the phrase ‘cancer research’, it may conjure up a vision of scientists in white lab coats presiding over beakers of colored concoctions, or pouring over large datasets in the hopes a new discovery will surface from all those seemingly random data points. However, while it is true that many new cancer treatments begin in the laboratory, that “Eureka!” moment which signifies a new discovery is only the first step in the ‘bench to bedside’ journey. How does that new discovery or new treatment idea progress from just a concept to a real treatment in the clinic with potential to have a tangible impact on the lives of patients?

The answer is – A CLINICAL TRIAL

Clinical trials are the stage in the overall treatment development pipeline where a new therapy, treatment or other health-related intervention can be brought into the clinic to treat cancer patients while closely monitoring those patients and collecting data to assess the effects of that novel therapy. Therefore, clinical trials are an integral step in the ‘bench to bedside’ journey as they allow clinicians and researchers to assess that new intervention and make sure it is safe for patients and that it represents an improvement in patient outcomes.

Cancer clinical trials are usually conducted in cancer treatment centres and may be focused on investigating a wide variety of different treatment types. For example, a trial may be investigating new drugs, new surgical or radiation techniques, or even designed to test a combination of all these treatment types. Moreover, cancer clinical trials will have one main supporter, called a trial “sponsor” that is responsible to ensure that data collection and general trial conduct are done correctly and in accordance with the laws and regulations that govern clinical trials.

"Academically sponsored" clinical trials are a distinct subset of all cancer clinical trials sponsored by an institution, such as a research hospital, or a cooperative group of clinicians. Academic trials attempt to answer research questions not for commercial ends which is the primary focus of the for-profit pharmaceutical or biomedical companies, but to advance new innovations in medicine. The results are vital for the transfer of knowledge into clinical practice and public health policies. Cancer clinical trials are discussed in detail in Chapter 2.

The Canadian Cancer Clinical Trials Network

Historically, Canada has been viewed as a leader in the global cancer research community, particularly in the area of academic clinical trials. However, in 2011 the Canadian Cancer Research Alliance (CCRA) issued a report on the status of clinical trials in Canada which showed that Canada's academic cancer clinical trials were under threat of declining in favour of those sponsored by drug companies. With concerns that they may disappear altogether from the Canadian research landscape, the CCRA's report called on the Canadian cancer research community to take action in order to help sustain and rebuild Canada's position. A specific recommendation in the report was to establish a pan-Canadian network that could support the conduct of academic clinical trials by investing in sustainable infrastructure at clinical trial centres across Canada. It was from this concept that 3CTN began in 2014 with the establishment of governance and operating components required to run the Network.

VISION

Canadians will have access to the best available cancer treatments through successful execution of academic cancer clinical trials

MISSION

To ensure access to, and efficient execution of academic cancer clinical trials Across the Network

3CTN is designed to revitalize the academic clinical trial community by focusing its efforts in four key areas:

3CTN's Objectives

1. Improve patient access and recruitment to 3CTN Portfolio of trials

2. Enhance PPI across all sites by providing incentives and assistance to sites for the development and implementation of PPI strategies

3. Improve trial performance by focusing on improving trial initiation timelines, recruitment projections and quality initiatives

4. Optimize 3CTN trial Portfolio to create opportunities for new trials and demonstrate its impact

The Value of the Patient and Public Voice in Research

In recent years there has been increasing support throughout all areas of the health research sector to include the patient or caregiver perspective in designing research studies and setting the research agenda. The inclusion of the "patient's voice" when planning and conducting research, often referred to as patient and public involvement (PPI), has the capacity to reshape how health research is conducted.

Patient & Public Involvement (PPI) *is ensuring that the ideas, concerns, and wishes of the 'public' are incorporated in the design, conduct and implementation of research projects. This is usually accomplished by the inclusion of "Patient Representatives" on committees or other types of working groups.*

This movement to include PPI in research planning and execution has been shown to have a positive impact on all stages of research, from initial design and execution, to analysis of information, through to dissemination of research results[1]. Regarding clinical trials specifically, involving PPI in research design and execution is thought to increase patient recruitment by ensuring, 1) the language used in information sheets or other materials is more appealing or easier to understand, 2) patients contribute insight into the realities of living with the health problem in question, 3) patients are more willing to participate in research that they know has involved other patients, as the principle of patient involvement is in itself appealing[2].

PPI and 3CTN

Early in the development of 3CTN, the Patient Representative Advisory Committee was struck to leverage PPI's potential positive impacts, as PPI was felt to be integral to 3CTN's success. Among the recommendations from the Patient Representative Advisory Committee was to embed PPI in every aspect of 3CTN via the addition of 3CTN Patient Representatives. This would help ensure that 3CTN addressed any barriers for patients or caregivers as well as assisting with clinical trial advocacy across the Network. With PPI embedded in its work, 3CTN can help increase patient awareness of clinical trials and also increase patient and public input into clinical trial development and implementation.

3CTN Patient Representative *– a member of the public that may be a cancer survivor or care-giver to a cancer patient, that is not otherwise affiliated with 3CTN, and may not have a professional background in clinical trials.*

Not only is 3CTN committed to having the patient voice represented at the governance level, but 3CTN is also committed to ensuring that 3CTN Network sites start to introduce PPI into site-level activities. Site-level PPI will be essential to translating PPI into meaningful collaboration and increased trial recruitment. A detailed schematic of how PPI fits into the overall 3CTN structure can be found in Chapter 4.

The creation of 3CTN marks the first step in the journey to rebuilding and revitalizing the Canadian cancer clinical trial landscape. 3CTN is the first of its kind for cancer researchers in Canada and 3CTN Patient Representatives will play a vital role in 3CTN's success. The success of 3CTN will ensure that Canada has a robust and sustainable cancer treatment innovation strategy and will ensure patients will have access to cutting-edge clinical trials.

The Purpose of the 3CTN PPI Guide

This guide will serve as a guide and 'road map' for all individuals that are a part of the 3CTN initiative. It can be viewed as a training resource for any new 3CTN members, both Patient and non-Patient Representatives alike. It can also serves as guide to 3CTN site level staff to ensure that the research staff are informed of the best practices to include PPI at the site, and that Patient Representatives at the site level have the resources they require to contribute in a meaningful way to the 3CTN initiative. The remaining chapters and the "Appendix & PPI Tools" section are full of information and tools that can assist all interested 3CTN stakeholders with the infusion of PPI in all Network activities. Furthermore, if there is a particular area where you would like more information, a "Links & Further Reading" section can be found at the end of each chapter.

PPI IN ACTION!

Throughout this guide look for PPI IN ACTION boxes which contain anecdotes of PPI successes throughout healthcare research.

With this road map, all 3CTN stakeholders can help build the necessary and meaningful PPI backbone into 3CTN and ensure that scientists, researchers, clinicians and the public are all pulling together for a robust and sustainable cancer clinical trials future in Canada.

Links & Further Reading

Canadian Cancer Research Alliance:

http://www.ccra-acrc.ca/

The 3CTN Patient Representative Advisory Committee:

https://3ctn.ca/for-patients/pr-community/

Chapter References

1) Brett, J. et al., Mapping the impact of the patient and public involvement on health and social care research: a systematic review. Health Expectations. 2012.

2) Ennis, L. & Wykes, T. Impact of patient involvement in mental health research: longitudinal study. British Journal of Psychiatry, 2013.

Chapter 2

The World of Cancer Clinical Trials

This section explains some basic cancer clinical trials concepts and terms as well as the 3CTN Portfolio.

As explained in the Introduction, clinical trials are just one step in the overall "treatment development pipeline" for new cancer treatments. This section covers the basics you will need to understand cancer clinical trials in Canada, and some specific information about the 'menu' of cancer clinical trials offered by 3CTN ("The 3CTN Portfolio"). After reading this section, you may wish to find out more about clinical trials, so a number of helpful websites are listed at the end.

Types of Trials

While the term 'clinical trial' may be intuitively associated with testing new drugs, a cancer clinical trial may not be focused on new drugs or a new combination of well-established drugs. In the "cancer treatment toolkit" there are three classic treatment disciplines – Chemotherapy, Radiation Therapy and Surgery. There are also new and emerging treatment disciplines like Immunotherapy, Targeted Molecular Therapies and even Behaviour Modification Therapies (for example, impacts of an exercise regimen).

Surgical trials *could investigate if a new surgical technique is a better way to control intra-operative bleeding when removing a tumour.*

Radiation trials *could be designed to test if a new way to deliver a patient's radiation dose causes fewer side effects.*

Combination trials *could be designed to include combinations of drugs, and/or radiation and/or surgery.*

Non-Traditional trials *could be designed to test non-medical interventions, such as the addition of an exercise regime to see if side effects are improved during chemotherapy.*

The idea that a cancer clinical trial could be focused on a wide range of treatments/therapies/interventions is an important concept to bear in mind while reading this guide. For ease of reference the term "intervention" will be used in this guide to refer to any type treatment related entity.

*"**Intervention**" could mean a range of different treatments or therapies, including drugs, radiation, surgery, behaviour modification, and immunotherapy.*

Clinical Trial Phases

For the most part, cancer clinical trials are conducted in discrete stages or "Phases". Each phase has a distinct role in the overall development process to ensure a new medication, treatment, therapy or other type of intervention is safe and it is effective. The purpose of each phase and some examples of trial objectives in each are noted below:

Phase I

- **Number of Patients:** ~10 - 50
- **Main Objective(s):** is the new intervention safe and not cause the patient harm?

Generally speaking, Phase I trials are conducted with a small number of patients, over a short period of time and are primarily concerned with assessing if a new intervention is safe. For a new drug, a Phase I trial is the first time a human has ever taken the medication in question, as prior to Phase I, animal studies are conducted to evaluate preliminary safety, mode of action, ADME – Absorption, Distribution, Metabolism, Elimination - for a promising new cancer drug.

Phase II

- **Number of Patients**: up to ~100
- **Main Objective(s):** is the new intervention safe AND does it work?

Phase II trials are the next stage of development, conducted with a slightly larger patient population. These trials are interested in monitoring the safety of patients while testing the new treatment, but usually these trials are done over a slightly longer timeframe than Phase I trials and will also monitor the patients to see if the treatments/intervention worked well.

Phase III

- **Number of Patients:** 100s to 1000s
- **Main Objective(s):** is the intervention better than what is already used ("Standard of Care"); is it safe in a larger patient population?

Phase III trials require the largest patient population and are primarily designed to ensure the treatment is effective. Phase III trials are sometimes referred to as 'registration trials' as these trials will generate the large datasets, and subsequent data analysis, that will be presented to Health Canada to show that the treatment in question can be approved for doctors to prescribe.

The Trial Sponsor

Regardless of the type of intervention being investigated, all clinical trials have one main 'supporter' that is interested in that study's specific research question. This 'supporter', which is called a trial Sponsor, is usually involved in all components of setting up and running the trial. This will include devising the trial's main objective, designing the study, as well as the development and writing of study documents like the study protocol. Further to trial development, a trial Sponsor will 1) provide the financial support required to run the trial and, 2) be legally obligated to ensure the trial is conducted in accordance with the applicable laws and regulations.

A Trial Sponsor could be a drug company, an academic institution, a single physician or a group of physicians.

This may beg the question: Who can act as a clinical trial Sponsor? The answer to that question often depends on what types of interventions are under investigation. In instances where a trial is testing a new cancer drug, the Sponsor is more likely to be a pharmaceutical company that developed the drug. Most often, a pharmaceutical company is running a trial with a new drug because they are interested in having that new drug approved by Health Canada for purposes of selling that new medication. Therefore, the company will act as the Sponsor due to their vested interest in the drug being approved.

However, consider some of the non-drug clinical trials, like the ones mentioned in the "Some Examples of Clinical Trials" box at the beginning of this Chapter, as these types of trials are just as important when developing new treatments for

cancer patients. But, if the trial is not testing a drug for market approval, there is likely no pharmaceutical company taking on the role of Sponsor and this is where the concept of an 'academically-sponsored' clinical trial comes into the picture. Essentially, an academic entity, like a university, a hospital or a cooperative group of physicians can fill the role of Sponsor for a clinical trial that does not have the financial support of "industry" (i.e., a pharmaceutical company). Academically-sponsored trials are essential for progressing the scientific community's understanding of cancer and answering important cancer research questions which ultimately result in the development of new cancer treatments.

The 3CTN Portfolio of Academically Sponsored Cancer Trials

As noted, the Sponsor of the trial is important for many reasons, including the financial support required to run a trial. Funding a clinical trial is an immensely expensive endeavour and there is sparse funding available for academically-sponsored clinical trials. This is partially why 3CTN exists: to help Cancer Centres to run those clinical trials that will answer important research questions and lead to better cancer treatments.

One of the main tools that 3CTN uses to support academic trials within the Canadian cancer research landscape is the *3CTN Portfolio*. This 'menu' of cancer clinical trials supported by 3CTN is a web-based listing of trials that meet the Portfolio entrance criteria (see box below). This combination of attributes ensures that limited 3CTN resources are used to support the "right" cancer trials that strengthen Canada's cancer trial ecosystem.

3CTN Portfolio Trial is always:

Academically-sponsored

Interventional trials intended for oncology patients

Independently funded (e.g. via an academic grant)

Open at multiple Canadian cancer centres

Peer-reviewed

The trial Portfolio is overseen by the Portfolio Committee (PC) to ensure all trials meet the five Portfolio criteria before they are accepted on to the 3CTN Portfolio. In the early days of 3CTN, the PC spent a lot of time combing the Canadian cancer clinical trial 'landscape' to ensure all the appropriate trials were included on the initial Portfolio listing. The current Portfolio is always in a state of flux, as all across the country new trials are opening or old trials are closing. The 3CTN Coordinating Centre staff and the PC work closely together to monitor and manage the continuous entering and exiting of trials in the Portfolio.

A tool like the 3CTN Portfolio has never existed in the Canadian cancer research landscape. The Portfolio plays an invaluable role in helping 3CTN support the Network centres to identify important clinical trials to offer at their site. The Portfolio is central to advancing the science supported by 3CTN, representing a menu of cutting-edge trials, and eventually treatments, which can be offered to cancer patients across Canada.

Links & Further Reading

The National Cancer Institute:

Basic Clinical Trials Information for Patients/Caregivers:
http://www.cancer.gov/about-cancer/treatment/clinical-trials

What are Clinical Trials? :
http://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials

Dictionary of Cancer Terms:
http://www.cancer.gov/dictionary/

The 3CTN Portfolio:

Main page: https://3ctn.ca/for-researchers/trial-portfolio/

Portfolio Committee: https://3ctn.ca/about/

Search the Portfolio: http://portfolio.3ctn.ca/
Note: Chapter 6 contains information on how to use the Portfolio website.

Chapter 3

3CTN Structure

This section explains the detailed structure of 3CTN so the reader has the required knowledge to understand the relationships to PPI elements discussed in later chapters.

The Introduction touched on the history of how 3CTN was created and the four key areas in which 3CTN aims to improve Canada's capacity and efficiency to conduct practice-changing cancer clinical trials. In this section, the governance and operational structure of 3CTN and the Network are described in detail.

The 3CTN Coordinating Centre

3CTN is a Network of cancer centres that are running academically-sponsored cancer clinical trials and at the pinnacle of this Network is the 3CTN Coordinating Centre (CC). The 3CTN CC is the communication and information hub for all aspects of the Network and the CC staff are responsible for running the various committees and working groups that are vital to 3CTN's governance and day-to-day operations.

Network Structure

The basic structure of 3CTN can be seen in the schematic on the next page.

Network Cancer Centres (NCCs) are large cancer treatment centres with the capability to recruit patients to a broad range of Portfolio trials and will work with smaller referring cancer centres within their region to ensure broader patient access to trials. Patients are actively seen or enrolled in clinical trials at NCCs.

Network Affiliated Cancer Centres (NACCs) are smaller cancer treatment centres with ability to directly recruit to a smaller number of Portfolio trials and have the ability to refer patients to NCCs if the appropriate trial is not open at the NACC level. Patients are also actively seen or enrolled in clinical trials at NACCs.

A “Local-Regional Node” refers to the combination of each NCC + linked NACCs.

A Listing of all Canadian cancer centres involved in 3CTN can be found on the www.3ctn.ca website.

Advisory Committees

3CTN has three advisory bodies that assist with overall strategies to improve the academic clinical trial environment in Canada as well as advise on sustainability of 3CTN. Below is a brief description of the function of each of the external advisory committees:

Scientific Advisory Board: Provides recommendations for strategic priorities for trials and activities; Reviews and evaluates 3CTN at 18 and 36 months; Advises on policies and trends in health care, science and technology.

Funders Oversight Committee: Advises 3CTN on approaches to engage government and other sources/opportunities for funding; Advocates to raise Network profile across stakeholder groups.

Patient Representative Advisory Committee: Identifies the role of the Patient Representative; Advises 3CTN in accomplishing meaningful patient representation; Liaises with community groups who have an interest in advancing PPI in cancer clinical trials (see Appendix 2: The 3CTN Patient Representative Advisory Committee Terms of Reference).

Governance Committees

It is important that 3CTN’s governance be representative of its stakeholders, be responsive to their interests and priorities, be transparent in any decision-making processes, and ensure the Network operates effectively. In light of this, 3CTN is governed by the Management Committee, of which there is a subset Executive Committee for certain matters. The functions of both Committees are described below:

Management Committee: Provides oversight of processes for implementing 3CTN scientific and operational objectives; Ensures 3CTN deliverables are achieved; Promotes 3CTN collaboration and support amongst external stakeholders; Reviews finances, milestones and deliverables; Approves the Network’s annual budget;

Executive Committee: A subset of the Management Committee that acts on its behalf for urgent matters and may be designated to provide final recommendations if Management Committee consensus is not achieved.

Operational Committees

Apart from the guidance provided by the external advisory and governance committees, 3CTN requires support from operational committees, which help with day-to-day operational aspects of the 3CTN initiative. The functions of these groups are described below:

Portfolio Committee: Reviews portfolio for scientific merit, priority, performance, strategic balance.

Performance Strategy Team: Evaluates Network performance, identifies problems and proposes initiatives or tools increase site efficiency; seeks improvement of site staff through education, training and mentoring, and methods.

Chapter 4

The Role of 3CTN Patient Representatives

This section covers information on the role of 3CTN Patient Representatives and how these individuals fit in the 3CTN structure.

The role of the Patient Representative in 3CTN is to work with the 3CTN team of scientists, researchers, health professionals and administrators to achieve the vision and mission of the organization to strengthen Canada' s academically sponsored cancer clinical trial capacity, and thereby improve outcome for patients.

PPI Supports 3CTN's Goals and Objectives

As described in the Introduction, 3CTN has set specific goals and objectives to carry out its mandate and there are a number of ways these objectives are reflected in the PPI arena (box below). Achieving these goals will improve access to clinical trials for cancer patients across the country, provide answers about the effectiveness of new interventions more quickly, and ensure the funds raised for cancer research are used effectively. These are all important issues for cancer patients, their families and the public.

Increase the number of adults and children enrolling in academic clinical trials

Increase the number of centres offering academic clinical trials across the country

Improve the efficiency and effectiveness of the management of clinical trials to complete trials in a timely manner

Streamline processes such as training of trial personnel, ethics review and specimen collection and storage nationally

Demonstrate the positive impacts of this work on the Canadian health system

PPI Opportunities Throughout the Network

Patient Representatives at 3CTN can contribute in a variety of ways: as patient partners at their local Cancer Centre's clinical trial unit, through participation in Network governance and advisory committees as well as project working groups.

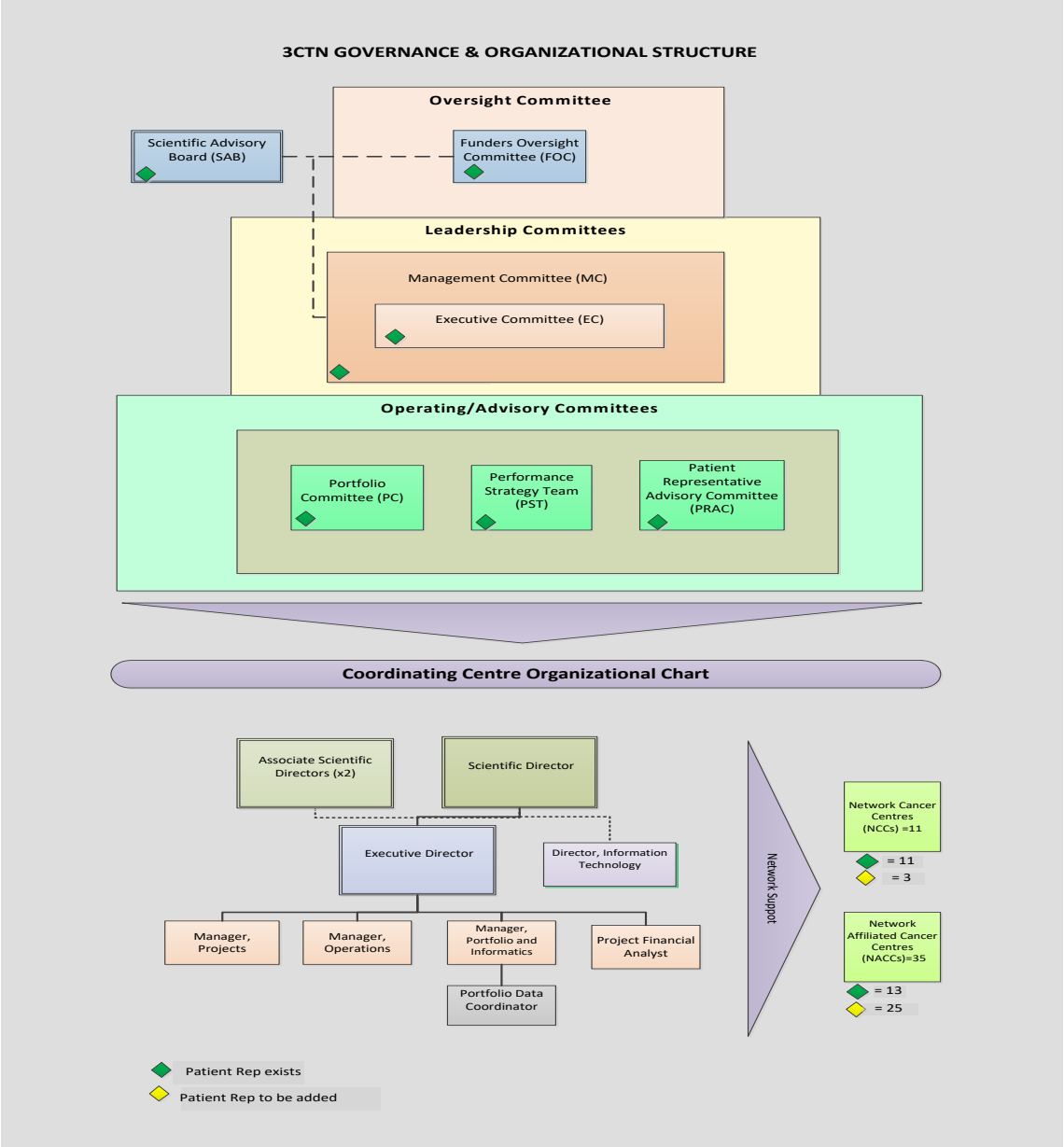

Figure 1 Schematic diagram showing the infusion of PPI throughout 3CTN.

3CTN is committed to ensuring that PPI will be embedded at each level of the Network.

The nature of PPI involvement in each Network centre varies and depends both on the specific needs of the centre as well as on the skills, experience and interests of the Patient Representative. Some centres may already have aspects of PPI, such as a Patient and Family Advisory Committee, and/or other mechanisms for working with patients, families, caregivers, advocates and interested members of the public interested in contributing to research activities. Conversely, other centres are just beginning to develop their local PPI programs and have little or no previous experience working with patient partners as part of their clinical trials programs; the inclusion of PPI in such cases can represent a significant shift in work culture and processes. As with all cultural change, leadership is required from the centre administration and supports available to develop the integration of Patient Representatives.

PPI IN ACTION!

Canadian organizations have also demonstrated a strong PPI commitment. The NCIC CTG Lay Representative Committee has effectively provided the patient's perspective in the development and delivery of clinical trials. Further influence has been seen by reversing a company's decision to discontinue trial drug supply, and supporting clinical trial awareness in specific patient populations.

PPI in 3CTN Operations and Committees

Advisory Committees

Advisory Committees

Patient Representative Advisory Committee

Scientific Advisory Board

Funders Oversight Committee

Each of these committees brings expert knowledge at a high level and is critical to the success of 3CTN as it provides a link to the broader Canadian cancer research environment with the aim of maintaining 3CTN's relevance and sustainability. In this context, the role of the Patient Representative is to bring the voice of the patient and public to the committee discussions; however, the knowledge required and the community linkages that will enable a meaningful contribution varies with each committee. Patient Representatives in these committees will need to be knowledgeable, or interested in developing the required knowledge, about the importance of the clinical trial enterprise to the broader goals of the Canadian healthcare system from an advocacy, fundraising and policy perspective. They need to feel comfortable in a board governance-

type environment and have connections to community patient-focused advocacy or fundraising groups and/or experience in government or policy environments.

The Patient Representative Advisory Committee's role is to guide and advise on the Network's strategy and oversee initiatives that will assist in the development of PPI both centrally and within the regional networks, including:

- PPI and patient-facing content the 3CTN website;
- Ongoing orientation and training activities for new members;
- Promoting Network-, Cancer Centre- or PPI initiatives;
- Educating Network stakeholders, including Patient Groups, potential funders and collaborators on the accomplishments and unique benefits of the Network in promoting PPI and patient priorities for clinical trials;

The role of the Patient Representatives within the remaining committees varies depending on the structure and function of each and the experience, skills and knowledge that a given member brings to the table. The success and meaningfulness of Patient Representatives' contributions begins with a culture of mutual respect and is enhanced by ensuring the scope of involvement is clearly understood and alignment with the unique interests and abilities of the Patient Representative.

Governance and Operating Committees

These committees have an operational focus and therefore require a basic understanding of the clinical trial enterprise, 3CTN's strategic plan including specific goals, objectives, deliverables and activities to support them. Patient Representatives on these committees are linked to the Patient Representative Advisory Committee to ensure a connection between high-level operations and PPI development within 3CTN. The Patient Representative on the Management Committee and the Patient Representative Advisory Committee is crucial to resolving operational concerns within 3CTN and to make sure that the PPI initiatives are consistent with the direction and current environment in the organization. Individuals filling this role are best suited if they have experience and interest in operational areas such as budgeting, strategic planning, etc.

Governance & Operating Committees

Management/Executive Committee

Portfolio Committee

Performance Strategy Team

Also, these committees have a strong quality focus supporting activities and innovation that will strengthen overall Network performance and outcomes across Canada. The Patient Representative on these committees should ideally be linked to the work at the local-regional node level, so they can bring an understanding of the experience of patients who are participating in clinical trials and the research questions of importance to them. It is helpful for these Patient Representatives to have lived with, or been exposed to, the cancer treatment process and/or have experience through direct participation in a clinical trial or as a caregiver to a trial patient. Those with experience and comfort in telling their personal stories are helpful to keeping these teams grounded in the patient perspective.

PPI at Network Centres

The structure of the Network and designation of a centre as an NCC or NACC is dependent on many factors, such as population size, geography, previous affiliations, etc. and may differ further in each region of the country. PPI at the Cancer Centre aims to improve patient centeredness and meaningfulness of research activities, promote local trials awareness both within the institution and the local area and benefit the efficiency and effectiveness of the clinical trial enterprise; all of which contribute to 3CTN's success as well.

- **Governance** – Critical for its success, Organizational leadership must be fully committed to the value of PPI and to creating the supports necessary for meaningful patient participation. Inclusion of more than one Patient Representative at the governance level would support the development of a sustainable PPI strategy and is most realistic given expected limits to time and availability.

  The PPI strategy at this level may include input into selection of trials for the site, development of trail processes, strategies for recruitment of patients into clinical trials, promoting clinical trials' awareness at the institution as well as locally/regionally through connections with patient-led community groups and other area stakeholders.

PPI IN ACTION!

The Provincial Clinical Trials Advisory Committee of the BC Cancer Agency has long included PPI positions; their aim is to "provide guidance to leadership on communication and engagement of public, patients, funders, and stakeholders around cancer clinical trials in British Columbia".

- **Trial Prioritization and Trial Development** – Patient Representatives bring a unique perspective to the discussion about which trials should be opened at a particular centre. Their perspective will reflect the importance of the research questions to be studied from the patient perspective, which may, in turn, impact recruitment. From a trial development perspective, Patient Representatives will focus on the potential burden of various trial designs to patients, a factor which may impact the successful accrual of patients to a clinical trial. Inclusion of Patient Representatives in these roles reflect the four general ethical goals of community consultation[1], which are:

    - **Enhanced Protection:** Enhances protection for subjects and communities by identifying risks or hazards that were not previously appreciated and by suggesting or identifying potential protections;

    - **Enhanced Benefits:** Enhances benefits to participants in the study, the population for which the research is designed, or the community in which the study is conducted;

    - **Legitimacy:** Confers ethical/political legitimacy by giving those parties with an interest or stake in the proposed research the opportunity to express their views and concerns at a time when changes can be made to the research protocol;

    - **Shared responsibility:** Consulted communities may bear some degree of moral responsibility for the research project and may take on some responsibilities for conducting the study.

- **Patient Access and Recruitment** – Lack of access to clinical trials is a common concern expressed by patients and 3CTN has the potential to improve access

through greater cooperation among centres within each region. Patient Representatives bring this issue to the forefront and can work with committee/team members to find solutions.

PPI IN ACTION!

In conjunction with two of their patients, the London Health Sciences Centre clinical trials unit operated an information booth where new and current cancer patients could stop, chat and ask questions about ovarian cancer and clinical trials.

- **Communications** - Patient Representatives bring a patient and public perspective to the language used in communication materials (e.g., consent forms), and to the best means of bringing messages about clinical trials to patients and the public. Ennis and Wykes (2013) note that "the language used in information sheets is more appealing or easier to understand for patients because of vetting by other patients". They also state that "patients are more willing to participate in research that they know has involved other patients, as the principle of patient involvement is in itself appealing". 3CTN Patient Representatives are well positioned to liaise with patient and public led community groups in the region to capitalize on already established communication vehicles, such as existing newsletters or social media.

PPI IN ACTION!

"Before Network of Networks (N2) created a website to promote clinical trials within the general public, we knew we wanted to involve patients and caregivers. Our Lay Representatives provided perspectives from different disease-types, demographics, as well as all areas of the country. Through the design and content development of the website as well as the processes to brainstorm and select the tagline and domain name, the direction, input and feedback from the Lay Representatives was critical as they provided feedback that we otherwise would not have captured. Now that we have collaborated with the very stakeholders we are aiming to help with the website, we have created something more meaningful with more potential to help people than if we had not included PPI". ***Dawn Richards, Project Manager, N2***

- **Fundraising** – Patient Representatives involved in the important work of the 3CTN are well positioned to speak to community groups about the goals of increased access to clinical trials for patients and improved efficiency and quality of trials. These messages are important to a wide variety of groups including disease specific organizations, health advocacy groups and potential fundraisers.

Links & Further Reading

Network of Networks (N2):

Main website: http://n2canada.ca/

Clinical Trial Awareness website: http://itstartswithme.ca

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Chapter 5

Maximizing PPI Impact

This section covers pragmatic tips for the Patient Representatives as well as non-patient 3CTN Stakeholders to support meaningful PPI contributions and enhance the impact of Patient Representatives within 3CTN.

Although PPI is a relatively novel addition to healthcare research initiatives in Canada, there are many publications to help guide PPI inclusion to ensure a meaningful collaboration. As discussed, the inclusion of PPI in 3CTN is not only vitally important to the success of the Network, but also ensures that a robust and sustainable cancer research enterprise is maintained in Canada. The contributions of 3CTN Patient Representatives will inform may important decisions throughout the Network and this section endeavors to describe some of the "best practices" for 3CTN Patient Representatives.

Patient Representatives: How to Enhance Your Experience

The results of a survey published in 2015[1] found almost universal agreement from both Patient Representatives and non-Patient Representatives that there is value in having Patient Representatives on health research committees[1]. Further to this, the Canadian Institute for Health Research (CIHR) Strategy for Patient-Oriented Research (SPOR) points out that patients benefit as a Patient Representative, showing increased confidence, mastery of new skills, access to information they can understand and use and a feeling of accomplishment.

While the value of the Patient Representative is widely recognized, the 2015 survey[1] also pointed out some pervasive issues that can hinder a Patient Representative's ability to provide meaningful contributions and feelings of being useful. The survey identified the following issues:

- Time commitment and heavy workload;

- Uncomfortable/nervous speaking at meetings/perceived lack of opportunity to speak at meetings;
- Lack of role clarity;
- Lack of scientific knowledge/training.

An earlier publication[2] identified additional PPI constraints, including:

- member fatigue due to lengthy tenure;
- overly large committees;
- perceived pressure from the presence of expert members.

To ensure meaningful PPI contributions, it is therefore important that 3CTN Patient Representatives and other team members are aware of these issues and provide the appropriate support to minimize them. With this in mind, 3CTN strives to support Patient Representatives to contribute in a way that is meaningful and satisfying. This requires commitment and action from both the Patient Representatives and the non-Patient Representatives within the 3CTN framework.

Patient and non-Patient Representatives must have a shared understanding and acceptance of the values underpinning PPI. The Institute for Patient and Family Centered Care (IPFCC) suggests that a commitment to the following values be clearly articulated:

- Collaboration;
- Dignity and Respect;
- Sharing Information;
- Participation.

These values should be included as the guiding principles in governance documents and in the Terms of Reference for any committees that include Patient Representatives. The IPFCC includes a checklist on their website which may be helpful to review (see the Links & Further Reading section).

Participating as a Patient Representative in research committees can be a daunting experience for even the most seasoned volunteer. The following suggestions are offered to make the role more satisfying and meaningful:

1. Patient Representatives should make an informed decision to accept the role on a committee or project. This includes reading

the position description and any other materials provided about the work of the committee, seeking information if required, discussing expectations with the Chair, and participating in a meeting of the committee before making a final decision.

2. Patient Representatives should learn as much as possible about the subject matter and realize there may be a learning curve or the development of the role will take time.

3. Patient Representatives should take advantage of opportunities for networking with other 3CTN Patient Representatives locally, regionally or nationally, when possible, to share experiences and learn from others.

4. Patient Representatives will benefit from reading this guide, materials on the 3CTN website and materials provided by the local Patient Representative support staff. Although overwhelming at first, this information provides background and context for meaningful involvement.

5. Patient Representatives should ask questions to get specific information and to demonstrate interest as Non-Patient Representative committee members will sometimes worry about offending Patient Representatives or making them feel uncomfortable and a Patient Representative can allay these concerns by approaching individual committee members to gain further understanding of their perspectives. Often, questions can be

PPI IN ACTION!

Mary Manojlovich has been a Lay Representative with a Disease Site Committee (DSC) at the NCIC Clinical Trial Group for many years. The Study Coordinator for the DSC meets with Mary before each meeting to review all the new trials and updates her on any developments on existing trials. She monitors activities happening with the DSC and provides the PPI perspective to the chair when appropriate.

posed before or after meetings or during the breaks if responses are not required immediately.

6. Patient Representatives can request to have an assigned mentor to answer their questions and provide guidance on their participation (see box on previous page).

Interactions with Patient Representatives

The non-patient membership on 3CTN committees and working groups will benefit from the information covered in this section. Participants with scientific expertise, specialists (e.g., bioethicists, lawyers) and other research professionals will typically have a solid conceptual understanding of the subject area(s) that the committee is charged with addressing (e.g., clinical trial design).

The role of the Patient Representative in a committee must similarly serve a useful and meaningful purpose. The role should be constructed with the same amount of importance as the non-Patient Representative roles on the committee. If there is any perception that the role of the Patient Representative is nothing but an act of "public relations"[2], this will result in the devaluing of the role and PPI will be unsuccessful. Similar to all roles on the committee, if the Patient Representatives feel that their voice is heard and valued, they will be more engaged and will develop a strong sense of commitment to the group. As the inclusion of Patient Representatives needs to be a carefully constructed process, the following sections outline a step-wise progression of the required activities.

Creating the Patient Representative Job Description

Once the decision has been made to realize PPI within a committee, one of the first steps is to create the job description for the role. This document is an excellent starting point to help crystallize the understanding of the Patient Representative as it applies to a particular committee. The job description for the Patient Representative is a valuable tool for both the committee and the potential candidates.

Ideally, the Chair of the committee will discuss this with the committee and develop a job description or a clear statement of the role, qualifications and interest that would assist the Patient Representative to contribute. It is valuable to have the Patient Representative job description reviewed by the members of the committee

so they can provide feedback. This feedback will help develop an understanding and acceptance of the role of the Patient Representative.

A well written job description is one that is clear, to the point and not overly complicated (Appendix 3: Example Job Descriptions).

A Job Description Includes:

- *The job/position title;*
- *Committee information, including any associated or umbrella organizations;*
- *The reporting structure with information about who the position reports to;*
- *A brief summary of the position;*
- *A list of responsibilities and estimated workload of the role;*
- *A list of essential qualifications;*
- *A list of "nice to have" qualifications;*
- *Any qualities that might disqualify a person from the role;*
- *Contact information of the person doing the recruiting and/or hiring.*

According to Tri-Council Policy Statement 2[3], the Patient Representative should not be affiliated with the committee/institution, should ideally have experience being enrolled on a clinical trial (or responsible for a family member who has been enrolled on a clinical trial – like their child), and they should not be engaged in research as their primary employment.

Patient Representative Recruitment Strategies

A key component to ensuring a successful experience of PPI for the committee members as well as the Patient Representative is to match the requirements of the committee or project with the interests and background of the Patient Representative. This information should be included in any recruitment advertisements for the position

PPI IN ACTION!

The NCIC Clinical Trials Group (CTG), a national collaborative cooperative clinical trial group, recently implemented a successful recruitment strategy to bring on 16 new Patient Representatives.

and posted in as many appropriate venues as possible, such as the websites of appropriate cancer agencies, patient-focused community agencies, the press and social media (Appendix 4: Example Job Advertisement).

The following are a number of suggestions on how to advertise for the Patient Representative role to find interested candidates:

1. **Website:** Post the job description/job advertisement and any other job related information on the committee or organization's website.
2. **Social Media:** Post information about the position on Facebook, Twitter, email lists and other social media avenues to generate interest about the role.
3. **Word of Mouth**: Ask committee members to put forward names of individuals they think might be interested and approach patient advocacy based organizations to ask for recommendations.

It may be valuable to only task one or two people on the committee to approach potential candidates. This will provide consistent messaging to the candidates about the role and the work of the committee.

People who are former patients and research participants may be interested in participating as Patient Representatives. If there is a Patient and Family Advisory Committee in the region, they will likely have experience of recruiting for members in their region and may be of assistance. Interested applicants should be interviewed for the volunteer role so the committee and the applicant can both make a determination about the interest and ability to participate.

PPI IN ACTION!

I had an immensely positive experience when I was recruited as a Lay Representative for Gastrointestinal Disease Site Committee at NCIC CTG. My involvement with this committee has been an exciting learning curve and easily managed using the support and tools provided by NCIC CTG. In addition to learning about oncology clinical trials, I have met an incredible group of like-minded individuals whose collective wisdom I admire. I am proud to be associated with this professional, hard-working, dedicated group.

Marie-Térèse Little, Lay Representative, NCIC CTG

Introducing the Candidate to the Role of the Patient Representative

When a Patient Representative candidate is found, it is possible to introduce them to the committee and the role in a number of different ways. The following are some suggestions:

1. The first meeting with the candidate could be a simple phone conversation with a member of the committee to provide a brief introduction about the group and the role of the Patient Representative. This telephone meeting could be an initial gauge of interest by both parties.
2. A follow-up meeting could take place in-person or over the telephone. This meeting would be a more formal interview and should take place with the Chair of the committee and any other interested members (Appendix 5: Potential Interview Questions).
3. Allow the candidate to attend a meeting as an observer so he or she is able to gain first-hand experience on what happens in a meeting and how the committee functions.

Realizing the Role of the Patient Representative

When the ideal candidate is found, he or she must formally be offered the role of the Patient Representative. If the candidate accepts the offer, the next stage of work begins to provide training and orientation to the individual taking on this new and important opportunity.

Educating the Patient Representative

There are many different ways to help provide the Patient Representative with the necessary training and development to be an effective member of the team. It is recommended that some level of training take place before the Patient Representative attends the first meeting. However, education and development needs to continue as the Patient Representative becomes more entrenched and comfortable in his or her role[4]. It is possible that some Patient Representatives may need more education than others and this should be assessed during the interview process to better understand the needs of the new member.

The 3CTN PPI Education Toolkit:

The 3CTN PPI Guide

3CTN website & PPI webpage

Regular webinars hosted by the 3CTN CC

The following are examples of areas of training that could be provided to the Patient Representative. This is not an exhaustive list and should be customized based on the needs of the committee. Training could be provided in person, by video/teleconference, and tasks could be assigned to the Patient Representative to complete on his or her own time. It is very important that training of some kind is provided to the Patient Representative.

Before the first meeting:

- Overview of the 3CTN vision, mission, structure and function;
- Information on the value and roles of PPI in cancer research;
- The purpose and responsibilities of the committee as a whole;
- The roles and responsibilities of the members of the committee;
- Meeting processes and norms;
- Expectations of involvement, workload, and individual responsibilities;
- Administrative information (e.g., conflict of interest);

- Introduction to commonly used terminology and acronyms;
- Introduction to important scientific concepts (e.g., clinical trial process);
- Additional qualifications (e.g., The Tri-Council Policy Statement 2 Tutorial);

Ongoing Training:

- Ongoing training and support in the form of mentoring from administrative personnel may be helpful, especially for those Patient Representatives who are reluctant to approach their fellow non-Patient Representative members with questions or for those who are reticent to express their opinions during meetings. Establish a mentorship arrangement where a Patient Representative is paired with a non-Patient Representative. The Patient Representative could ask questions of his or her mentor at various points, but specifically before meetings so that he or she feels confident entering the discussion;
- Have a member of the committee connect with the Patient Representative(s) at regular intervals (e.g., quarterly) to proactively address any issues and gather feedback;
- Provide a list of websites, email lists (listservs), and publications that would be valuable for the Patient Representative to read on a regular basis to keep current with particular subjects and concepts that impact the committee.

Training at Specific Points in Time:

- Provide a more detailed examination of important scientific concepts. These could be presented by different members of the committee. This could be done during the regular meeting time, or a different day and time could be required to provide this type of training;
- Inform the Patient Representative about talks and educational sessions that may be provided by other organizations on topics related to the purpose of the committee (e.g., grand rounds meetings at hospitals).

It is important to recognize that Patient Representatives bring their own personal and professional knowledge to the table as well as their experience as a patient or representative of a specific community. They may bring skills that the other

committee or project members may not have, (for example in areas such as marketing, strategic planning, communications) or they may have a background in healthcare or clinical research.

Give the Patient Representatives the tools that they need to understand the committee, their role, the subject matter and workload expectations. This will help them develop a sense of confidence that will in turn result in a richer interaction within the team.

Training for non-Patient Representatives is also a critical component of successful PPI integration. Non-Patient members should be educated about the value and purpose of PPI through the inclusion of Patient Representatives. They need to understand the role and expectations of the Patient Representative on their committee and the values that underpin their involvement.

When a New Patient Representative Joins the Committee

When new Patient Representatives join the committee it is possible that they may feel nervous about their role and assignment. This can especially be the case if this is their first time filling the role of a Patient Representative and if this is their first time as part of a committee that is charged with making highly technical and important decisions, and particularly those that are scientific in nature. The Patient Representative may feel somewhat intimidated by the other technical members in the committee and could feel reticent about speaking up during meetings. Helping the Patient Representative feel welcome in the committee is an important way to lay a foundation of respect and connection within this new relationship.

For the Scientific and Non-Patient Representatives, it is particularly important to formally welcome the Patient Representative to the committee. At the Patient Representative's first meeting, it is important for the Chair, or another member, to introduce the Patient Representative, provide some background on their experience, and information about why they were chosen for the role. If time permits, the Patient Representatives could also say a few words to the committee to provide any other information about oneself.

At meeting breaks, it is recommended that members of the committee introduce themselves to the Patient Representative. It may be valuable for the Chair to encourage and remind the members of the committee to introduce themselves personally to the Patient Representative. Establishing connections and common foundations between members is an excellent way to help engender committee

cohesiveness. Helping to create associations between members will in turn develop an environment of openness and mutual respect.

During the Committee Meeting

A fundamental aspect to a well-functioning and effective team is respect and open communication. This is especially important when a team is composed of a diversity of members who may play very different roles and have very different expectations. The communication that takes place within the committee must be respectful and professional, and with this in place there will be a strong foundation upon which all members will feel confident in their ability to contribute and be active members of the team.

The Patient Representative may be very concerned about asking 'stupid questions'; however, there are times when these questions can play a role in opening doors to other conversations and levels of understanding about a problem that were not previously considered. Or, the Patient Representative could ask questions that others in the committee were thinking but were not comfortable brining to the team. It is important to let the Patient Representative ask questions to further both their understanding and to allow them to open a dialogue that may result in looking at a problem differently. The ability to ask 'stupid questions' is a culture that must be engendered within the committee, especially with the support of the Chair. The members of the team must work to respond to each other's questions with patience, professionalism and understanding.

During the meeting, the Chair could call on the Patient Representative to provide his or her input; however, this should be discussed as part of the orientation to ensure that the Patient Representative is expecting it. Additionally, a report or comment from the Patient Representative could also be included as part of the meeting structure or agenda. For example, if the purpose of the meeting is to review and choose clinical trials for a centre's portfolio a checklist of items for the Patient Representative to consider would be helpful.

It is important to remember that becoming an effective Patient Representative can take time and will evolve over many meetings and interactions. The learning curve can be steep and it is the responsibility of the entire committee to ensure that every member is supported as they develop and settle into their roles.

If You Have Concerns about a Contribution from a Patient Representative

If a member of the committee has a concern about how the Patient Representative is fulfilling his or her role, it is important for that person to discuss the issue directly with the Patient Representative. It is important to speak with the Patient Representative outside of the meeting and in private. Any feedback must be provided in a constructive and respectful way, with a clear pathway to helping the Patient Representative understand how he or she may be able to improve within the role. If the non-Patient Representative is uncomfortable with approaching the Patient Representative, he or she could speak directly with the committee Chair about the concerns.

When a Patient Representative Leaves the Committee

When a member of the team retires from the position, it is important to recognize the contribution and commitment to the committee. This is also important when the Patient Representative leaves a committee. Ensure that the team expresses their appreciation for that person in a meaningful way. It is important to inform the committee of the change to the committee at the start of the Patient Representative's last meeting so that all of the members have the opportunity to say good-bye. It is also kind to have the members of the committee sign a thank you card for the Patient Representative.

Remember that an outgoing Patient Representative may play a role with recruiting and training the next Patient Representative that will join the committee.

Links & Further Reading

Canadian Institute for Health Research (CIHR):
Main page: http://www.cihr-irsc.gc.ca/e/47473.html

Strategy for Patient-Oriented Research (SPOR):
http://www.cihr-irsc.gc.ca/e/41204.html

Institute for Patient- and Family-Centered Care:
Main page: http://www.ipfcc.org/

Checklist for Attitudes about Patient and Families as Advisors:
http://www.ipfcc.org/advance/Checklist_for_Attitudes.pdf

Tri-Council Policy Statement Tutorial:
http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

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Chapter 6

Training and Development

This section covers training resources that are available for 3CTN Patient Representatives.

As shown at the end of each of the previous chapters, there are the "Links & Further Reading" sections to review for more information about any particular topic covered in this guide. This section includes some of the training resources available to excel as a 3CTN Patient Representative.

Good Clinical Practice (GCP) Training

The Good Clinical Practice (GCP) principles are an internationally recognized standard of excellence for conducting clinical trials. In fact, in Canada specifically, these principles have been incorporated into the laws and regulations that govern how all clinical trials are to be conducted. This guide cannot exhaustively cover the GCPs, but it may be beneficial to read more about the GCPs to function effectively inside the 3CTN framework.

Ethics Training

The ethical conduct of clinical trials is an immense topic and it is not the aim of this guide to cover all aspects of ethics training required to function with 3CTN. In a similar manner to the GCPs for clinical trials, there are many ways in which ethical principles have been incorporated in the laws and best practices that govern clinical research/clinical trial personnel. You can read more about any of the following topics to help get a better understand of ethics in clinical research:

- Research Ethics Boards (REB)/Institutional Review Boards (IRB)
- Tri-Council Policy Statement 2
- Declaration of Helsinki
- The Belmont Report

3CTN Training Sessions

The 3CTN Coordinating Centre will host regular webinar sessions for any 3CTN stakeholders interested in learning more about the 3CTN PPI program. These sessions can be attended by new or existing Patient Representatives, Network site staff or any other 3CTN stakeholder. Details of any upcoming sessions can be found on the 3CTN website (https://3ctn.ca/stay-connected/#/?&category=events&page=1&order=desc).

The 3CTN Website

The 3CTN website is a valuable resource that all 3CTN stakeholders use regularly. To help navigate the sections of the website related to PPI and the 3CTN Portfolio, here are some screen shots with annotation about some important links.

Homepage – www.3ctn.ca
The main navigation for the 3CTN website is conducted through six tabs at the top of the home page. For PPI purposes, the “Patient/Public” tab and the “Portfolio” tab will likely be the most commonly used.

PPI Program Homepage – https://3ctn.ca/for-patients/overview/
After clicking on the “Patient/Public” tab, the page below can be seen. This page is the main hub of information about PPI within 3CTN. There are various tools and resources for 3CTN Patient Representatives on this page and a link to the Patient Representative Advisory Committee members is found in the right side menu. The bottom of the page is constantly updated with other links and resources that may be useful for 3CTN stakeholders interested in PPI activities.

Portfolio Homepage – https://3ctn.ca/for-researchers/trial-portfolio/
After clicking on the “Portfolio” tab on the 3CTN Homepage, the main Portfolio page is displayed. This page has a lot of information about what Portfolio trials are and how 3CTN sites can submit an application for a new trial to be considered for Portfolio status. You can browse this page to learn many things about the Portfolio, but to see the ‘live’ Portfolio, click the “Search the 3CTN Portfolio” link.

The Portfolio – www.portfolio.3ctn.ca/
This page is the ‘real-time’ view of the active 3CTN Portfolio. You can use this page to view all the Portfolio trials or to search for specific trials. On the ‘Portfolio Homepage’

(previous screen shot) click on the “Portfolio Search Guide” PDF to learn how to use the search functions for the 3CTN Portfolio.

Links & Further Reading

Good Clinical Practices (GCP) Guidelines:

International Conference on Harmonization (ICH): Good Clinical Practice:

http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html

Health Canada – ICH GCP: Guidance for Industry:

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php

Research Ethics:

Declaration of Helsinki:

http://www.wma.net/en/30publications/10policies/b3/17c.pdf

The Belmont Report:

http://videocast.nih.gov/pdf/ohrp_appendix_belmont_report_vol_2.pdf

NIH Training – Protecting Human Research Participants:

https://phrp.nihtraining.com/users/login.php

Appendices & PPI Tools

Appendix 1: 3CTN Patient Representative Advisory Committee Terms of Reference

Background and previous mandate

The 3CTN Patient Representation Working Group was accountable to the 3CTN Steering Committee through the Director, Network Initiatives. The Working Group was responsible for identifying categories of patient representative involvement and support strategies, to enable meaningful for all involved. The recommendations of the Working Group then informed the 3CTN strategic plan. Further, it was determined that the 3CTN Patient Representation Working Group (at the close of their mandate) would transition to the Canadian Cancer Action Network (CCAN) to assume a new mandate. It was also determined that 3CTN and its patient representatives would benefit from a Patient Representative Advisory Committee.

3CTN Patient Representative Advisory Committee mandate

The 3CTN Patient Representative Advisory Committee, working in close collaboration with the 3CTN Secretariat and Executive, made up of a team of 3CTN Patient Representatives, will focus on providing meaningful feedback, insight, expertise and/or support to project deliverables associated with a) Meaningful Patient representation throughout 3CTN; b) In collaboration with the Canadian Cancer Action Network (CCAN), development and validation of a framework and role description for Patient Representatives within 3CTN; c) Further incorporation of Patient Representatives within the clinical research communities, d) Continuing to assist 3CTN with actively soliciting Patient Representative involvement in the development and evaluation of 3CTN activities.

Membership

- Patient Representative Advisory Committee members will demonstrate interest and knowledge of Patient Representative roles and engagement;
- Patient Representatives from respective 3CTN committees and working groups;
- At the discretion of the Committee members, composition may expand based on opportunities to work with interested stakeholders, external patient representatives or healthcare providers;
- There will be at least one member from the Canadian Cancer Clinical Trials Network (3CTN) Coordinating Centre.

Term of Office

The term in office will correspond to the project funding or, from *[start date to end date].*

Primary duties and responsibilities:

- As part of the 3CTN Patient Representative Advisory Committee, members will attend and participate in meetings and participate in reviewing overall 3CTN Patient Representative activities, and milestones and deliverables;
- Advocate for and provide the Patient Representative perspective in the implementation of the 3CTN business plan;
- Advise on involvement of Patient Representatives in the mechanisms to maximise the impact of current 3CTN initiatives;

- Advise and assist 3CTN on a plan of action and mechanism to provide methods, tools and resources to create support materials and processes for Patient Representation;
- Propose recommendations for making the language and content of information and 3CTN communications suitable for the Patient Representative audience.

Qualifications:

- Patient Representatives are members of the public capable of actively participating in discussions relating to the patient journey from diagnosis though to survivorship and end-of-life care;
- Informed of 3CTN and committed to its mission;
- Past committee or board experience an asset;
- The ability to think objectively, regardless of personal experience with cancer.

Skills and requirements:

- Some relevant knowledge or experience of clinical trials, (e.g. as a research participant or a member of an ethics committee or a clinical trials committee) desirable;
- Good communication and interpersonal skills;
- Ability to lend Patient Representative perspective as a contribution to broader 3CTN discussions;
- Comfortable working in a group format;
- Able to foster and contribute to an open, collaborative climate, independent of vested interests;
- Able to draw upon knowledge, contacts and experience to provide informed input into discussions;
- Demonstrate ability to communicate with input from the constituency represented;
- Patient representatives must abide by 3CTN policies.

Remuneration:

Remuneration for travel costs and expenses will be provided according to 3CTN expense policies and guidelines.

Meetings

The Committee will meet quarterly via teleconference and/or webinar to address any items of business that relate to the mandate or, other key emerging issues. Any meetings in-person will be defined by budgetary allowances, as/if permitted. The 3CTN Patient Representative Advisory Committee, by consensus, may elect to defer a meeting during specific times of the year.

Support

The 3CTN Coordinating Centre provides support to the 3CTN Patient Representative Advisory Committee where possible and as required.

Appendix 2: Patient Representatives Orientation Toolkit

The 3CTN Patient Representatives Orientation Toolkit can be used as a starting point to assist with onboarding of Patient Representatives. The toolkit includes Patient Representative Role Description template, Responsibilities Matrix and Onboarding Orientation Checklist: **https://3ctn.ca/for-patients/pr-orientation-package/**

Appendix 3: Sample Job Advertisement Template

NB: *Template is intended as a starting point for outlining the Patient Representative role responsibilities*

Ad Elements

- Title of Patient Representative Position, Name of Organization, Name of Committee/Group
    - Include objectives/goals/mandate of Committee/Group
- Duration of the term on Committee/Group
    - Include anticipated time commitment for the Patient Representative
        - E.g. 1 hour meeting plus 2 hours preparation per month
- Expectations of the role
    - May include types of tasks
- Candidate attributes & skills
    - May included 'required' and 'asset' skills as appropriate
- Contact information and/or method of applying for the role
    - Include application deadline if appropriate

Qualifications: Applicants should have: (***note:*** *to be adapted based on the role*):

- An interest in cancer research, specifically in clinical trials;
- Experience with cancer or caring for someone with cancer;
- Comfort level and interest in participating in research operations and planning meetings and be willing to learn about relevant research and medical concepts;
- Good written and oral communication skills and a comfortable level with constructively expressing informed opinions and sharing learned experiences;
- The ability to commit the time to participate in *meetings and other responsibilities undertaken*
- Electronic communication skills, including basic computer/mobile device skills and access to the internet.

Appendix 4: Sample Interview Questions

Please Note: *The following sample set of questions are suggestive and intended as a starting point.*

Position Title/Committee Name: _____

Applicant's Name: _____ Date: _____

Sample Questions	Interviewer Comments
Background and Qualifications • Can you share with us what inspired you to apply? (Possibly review attributes. • Describe what personal and professional skills you have that would be relevant to the role • What would you say are important qualities for someone in a Patient Representative role?	
Ability to Commit • Probe availability to prepare for and attend each meeting?	
Communications - Ability to Participate • Would you be comfortable in posing questions/perspectives/opinions from a public and patient perspective to members of the Academic, Scientific and Medical community? • Would you be comfortable being called upon by members of this community to express your opinion? • Have you been in a position to do this previously?	
Technical Proficiency • What is your comfort level in accessing any required background/information material independently via the internet? • Ability to work through additional training material, both printed and on-line, etc.? Are you able to commit time needed to do so?	
Candidates Questions *(provide the candidate some time to ask questions)*	
General Closing • discuss next steps in the selection and onboarding process • verify references if applicable	

Appendix 5: Commonly Used Acronyms

Clinical trial or Cancer related terms

A

ABMT	autologous bone marrow transplantation
ADT	androgen deprivation therapy
AE	adverse event
AER	adverse event report
AGC	absolute granulocytes
ALL	acute lymphocytic leukemia
AML	acute myelogenous leukemia
ALND	axillary lymph node dissection
AMPK	adenosine monophosphate kinase (AMPK)
APL	acute promyelocytic leukemia
ASCT	autologous stem cell transplant
ATP	adenosine triphosphate
AYA	adolescent and young adult

B

BCS	breast conserving surgery
BMI	body mass index
BRM	biological response modifiers
BSA	body surface area

C

Ca	cancer / carcinoma
CAEPR	comprehensive adverse event and potential risk
CCRA	contract clinical research associate
CDE	common data elements
CDRT	conventional dose radiation therapy
CEA	cost-effectiveness analysis
CFI	Canadian Foundation for Innovation
CFR	Code of Federal Regulations (US)
CHOP	doxorubicin, vincristine and prednisone
CI	confidence interval
CLL	chronic lymphocytic leukemia
CML	chronic myelogenous leukemia
CNS	central nervous system
COI	conflict of interest
CPA	Cooperative Project Assurance
CPI	centre performance index
CPS	Compendium of Pharmaceuticals & Specialties
CR	complete response
CRA	clinical research associate
CRC	colorectal cancer
CRF	case report form
CRO	clinical research organization
CRT	chemoradiation therapy
CSC	cancer stem cell
CSF	colony stimulating factor

CT	computed tomography
CTA	clinical trials application
CTC	circulating tumour cells
CTCAE	Common Terminology Criteria for Adverse Events
CTEP-AERS	Cancer Therapy Evaluation Program - Adverse Event Reporting System
CUA	cost-utility analysis
CV	curriculum vitae

D

DCIS	ductal carcinoma in situ
DCR	disease control rate
DFS	disease free survival
DSC	disease site committee
DOGs	disease-oriented groups

E

EBRT	external beam radiation therapy
ECF	*e*pirubicin, *c*isplatin and 5-*f*lurouracil
EDC	electronic data capture
EGF	epidermal growth factor
EGFR	epidermal growth factor receptor
ER	estrogen receptor

F

FFPE	formalin-fixed, paraffin embedded (tissue)
FFT	fresh frozen tissue
FISH	fluorescence in-situ hybridization
FWA	federalwide assurance

G

GBM	glioblastoma multiforme
GCP	Good Clinical Practice
G-CSF	granulocyte colony stimulating factor
GT	gestational trophoblastic
Gy	amount of radiation used in radiation therapy is measured in gray (Gy)

H

HDC	high dose chemoradiotherapy
HDR	high dose rate
HER	human epidermal growth factor
HGPIN	high grade prostatic intraepithelial neoplasia
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
HPV	human papillomavirus
HR	hazard ratio
HRQOL	health-related quality of life

I

IB	investigational brochure
ICER	incremental cost effectiveness ratio
ICF	informed consent form
IDFS	invasive disease-free survival

IFRT	involved field radiation therapy
IG	intergroup
IGF	insulin-like growth factors
IGRT	image guided external beam radiotherapy
IHC	immunohistochemistry
IMP	investigational medicinal product
IMRT	intensity-modulated radiation therapy
IP	intraperitoneal
IRB	Institutional Review Board
IT	information technology
ITT	intent to treat
IV	intravenous

L

LDR	low dose rate
LRRT	locoregional radiotherapy

M

MRI	magnetic resonance imaging
MTD	maximum tolerated dose

N

NCI CTC	National Cancer Institute (US) Common Toxicity Criteria
NHL	non-Hodgkin's lymphoma
NSCLC	non-small cell lung cancer
NOL	No Objections Letter

O

OR	odds-ratio
ORR	overall response rate
OS	overall survival

P

pCR	pathologic complete response
PET	positron emission tomography
PFS	progression free survival
PgR	progesterone receptor
PLND	pelvic lymph node dissection
PM	product monograph
PRO	patient-reported outcome
PSA	prostate specific antigen
PT	patient

Q

QA	quality assurance
QALY	quality-adjusted life-years
QI	qualified investigator
QLQ	quality of life questionnaire
QoL	quality of life

R

RCT	randomized controlled trial

RDC	remote data capture
RDE	remote data entry
RE	required elements
RECIST	Response Evaluation Criteria in Solid Tumours
RFS	relapse-free survival
RNI	regional node irradiation
RT	radiotherapy
RTQA	radiation therapy quality assurance

S

SAE	serious adverse event
SAP	statistical analysis plan
SAS	Statistical Analysis Systems
SC	study coordinator
SCCHN	squamous cell carcinoma of the head and neck
SD	stable disease
SI	sub-investigator (centre investigator)
SI	senior investigator (NCIC CTG Central office)
SLND	sentinel lymph node biopsy
SNP	single nucleotide polymorphism
SOP	standard operating procedure
SPD	significant protocol deviation

T

TKI	tyrosine kinase inhibitor

U

US	ultrasound

V

VEGF	vascular endothelial growth factor

W

WBI	whole breast irradiation

Intergroup and Other Organizations

ACOSOG	American College of Surgeons Oncology Group
ACOG	American College of Obstetricians and Gynecologists
AGITG	Australasian Gastrointestinal Group
AGO	Arbeitsgemeinschaft Gynaekologische Onkologie
ALLIANCE	Alliance for Clinical Trials in Oncology (amalgamation of previous groups CALGB/NCCTG/ACOSOG
ALTG	Australia Lung Trials Group
ANZGOG	Australia and New Zealand Gynecological Oncology Group
ASTRO	American Society for Therapeutic Radiology and Oncology
BCCA	British Columbia Cancer Agency
BCSC	Breast Cancer Steering Group (US)
BGTD	Biologic and Genetic Therapies Directorate (Health Canada)
BIG	Breast Intergroup
BMS	Bristol Myers Squibb

BOLD	Breast Oncology Local Disease Task Force (US)
CALGB	Cancer and Leukemia Group B
CANO	Canadian Association of Nurses in Oncology
CARO	Canadian Association of Radio-Oncologists
CBCF	Canadian Breast Cancer Foundation
CBCRI	Canadian Breast Cancer Research Initiative
CCRA	Canadian Cancer Research Alliance
CCS	Canadian Cancer Society
CCSRI	Canadian Cancer Society Research Institute
CCCTN	Canadian Collaborating Clinical Trials Network (part of NCTN)
CCCTN	Canadian Cancer Clinical Trials Network (CPAC)
CE	Compliance Executive Committee (NCIC CTG Committee)
CEA	Committee on Economic Analysis (NCIC CTG)
CG	Compliance Group (NCIC CTG)
CODE	Central Office Data Executive (NCIC CTG Committee)
COG	Children's Oncology Group
CCOP	Community Clinical Oncology Program
CIHR	Canadian Institutes of Health Research
CIOMS	Council for International Organizations of Medical Sciences
CIRB	Central Institutional Review Board (CIRB)
COST	Clinical Outcomes of Surgical Therapy Study Group
CPA	Cooperative Project Assurance
CPAC	Canadian Partnership Against Cancer
CRAEX	Clinical Research Associates Executive Committee (NCIC CTG Committee)
CSTB	Correlative Sciences Tumour Biology Committee
CTC	Clinical Trials Committee (NCIC CTG Oversight Committee)
CTEP	Cancer Therapy Evaluation Program (NCI US)
CTMB	Clinical Trials Monitoring Branch (US)
CTG	Clinical Trials Group
CTRNet	Canadian Tumour Repository Network
CTSU	Cancer Trials Support Unit
CUOG	Canadian Urologic Oncology Group
DSMC	Data Safety Monitoring Committee
EACR	European Association for Cancer Research
ECCO	European Conference of Clinical Oncology
ECOG	Eastern Cooperative Oncology Group
ECOG-ACRIN	ECOG/ACRIN group amalgamation
EORTC	European Organization for Research and Treatment of Cancer
ESGO	European Society of Gynecological Oncology
ESMO	European Society of Medical Oncology
ESTRO	European Society for Therapeutic Radiology and Oncology
FDA	Food and Drug Administration (US)
FECS	Federation of European Cancer Societies
GAO	Group Administrator Office (NCIC CTG)
GCF	Gynecologic Cancer Foundation
GCIG	Gynecologic Cancer Intergroup
GEICO	Grupo Espanol de Investigacion en Cancer de Ovario
GINECO	Group d'Investigateurs Nationaux pour l'Etudeded Cancers Ovariens
GOG	Gynecology Oncology Group (US)
HC	Health Canada
HHS	Health and Human Services (US)
HPB	Health Protection Branch of Health Canada
HPFB	Health Products and Food Branch of Health Canada

ICH GCP	International Committee on Harmonization Good Clinical Practice
IGCS	International Gynecologic Cancer Society
INTN	Istituto Nazionale dei Tumori de Napoli
ISOQOL	Internatinoal Society for Quality of Life
JCO	Journal of Clinical Oncology
JGOG	Gynecologic Oncology Group-Japan
MOH	Ministry of Health
MRC	Medical Research Council
NCCTG	North Central Cancer Treatment Group
NCI US	National Cancer Institute of the United States
NCIC CTG	NCIC Clinical Trials Group
NCTN	National Clinical Trials Network
NEJM	New England Journal of Medicine
NIH	National Institutes of Health
NRG	NSABP/RTOG/GOG group amalgamation (pronounced ‘energy’)
NSABP	National Surgical Adjuvant Breast and Bowel Project
NSGO	Nordic Society of Gynecologic Oncology
OCOG	Ontario Clinical Oncology Group
OCREB	Ontario Cancer Research Ethics Board
OHRP	Office for Human Research Protections (US)
OICR	Ontario Institute for Cancer Research
OPEN	Oncology Patient Enrollment Network (US)
OSM	On-Site Monitoring
PMB	Pharmaceutical Management Branch (US)
QOLC	Quality of Life Committee (NCIC CTG)
REB	Research Ethics Board
RECIST	Response Criteria in Solid Tumors
ROQAC	Radiation Oncology Quality Assurance Committee (NCIC CTG)
RTOG	Radiation Therapy Oncology Group
SCT	Society of Clinical Trials
SGO	Society of Gynecologic Oncologists
SoCRA	Society of Clinical Research Associates
SSHRC	Social Sciences and Humanities Research Council
SWOG	Southwest Oncology Group
TMG	Trial Management Group (NCIC CTG)
TPD	Therapeutic Products Directorate
TROG	Trans-Tasman Radiation Oncology Group
TTDR	Tumour Tissue and Data Repository (NCIC CTG)
UICC	International Union Against Cancer
UKCCCR	United Kingdom Co-ordinating Committee on Cancer Research
WHO	World Health Organization