Canadian Cancer Clinical Trials Network

Recruitment Best Practices Inventory

Last Updated: March 1, 2016

1. INTRODUCTION

Recruiting patients to cancer clinical trials is a complex process that can require the coordination and expertise of physicians, clinic staff and research staff. However, furthering medical knowledge around cancer prevention, screening and treatment is directly dependent on the information gained by recruiting to, and completing, cancer clinical trials. In this way, fulfilling cancer trial accrual targets is vital to improving the lives of Canadian cancer patients.

The Canadian Cancer Clinical Trials Network (3CTN) is a national initiative with the goal to strengthen the ability of our Network sites to conduct efficient cancer clinical trials. One of 3CTN's key objectives to achieve this goal is to increase patient recruitment to academically-sponsored cancer clinical trials.

This manual has been compiled as a central repository for our Network sites to gain access to as many best practices, tools and templates as possible that will assist with this very important goal. The first section contains general recruitment tools and strategies that can be considered and implemented by sites at any time. The subsequent sections (Before, During and After the trial) can be considered and implemented at specific points in a trial's life cycle. We encourage sites to consider local implementation of as many of these best practices/tools as possible to assist with patient recruitment to cancer clinical trials.

2. GENERAL

These are some recruitment tools and templates that sites may use at any time. AccrualNet and the 3CTN Guide to PPI are intended as site staff resources. The education trials website "ItStartsWithMe.ca" and the Preparatory Education about Clinical Trials are a general trial information resources for patients and families. Sites can help make patients and families aware of this resource to help educate the general public about clinical trials.

Title	Description	Link(s)	Type
AccrualNet	Developed by the National Cancer Institute, a searchable database of strategies, tools, resources to support accrual to clinical trials	https://accrualnet.cancer.gov	Resource
The Center for Information & Study on Clinical Research Participation (CISCRP)	An independent non-profit organization dedicated to educating and informing public and patients about clinical research. The website contains resources for clinical research professionals, patients and the public.	www.ciscrp.org	Resource
It Starts With Me	Clinical trials education website	http://itstartswithme.ca/	Resource
3CTN Guide to Patient and Public Involvement (PPI)	A guide and road map for lay representatives and site level staff to ensure that research staff are informed of PPI best practices	http://3ctn.ca/page/patient-public	Resource
Preparatory Education About Clinical Trials (PRE-ACT)	Educational program to provide general information about clinical trials.	http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/pre-act	Resource

3. BEFORE A TRIAL

This section contains recruitment strategies and tools to consider during trial development or when selecting which trial(s) are suitable to open at your site. Even if a site does not develop the trial internally, consideration of the best/appropriate trials to open at your site based on the patient population at the site is important.

Consider the following activities when developing a trial:

- **Consider national & local stakeholder enthusiasm for the trial**
  - Evaluate the level of scientific interest in the trial from the field in your institution
  - Evaluate the level of commitment from the field in your institution with an eye toward trial feasibility
  - Check for competing trials at your institution and nationally
- **Evaluate the trial for recruitment feasibility**
  - Determine the availability of the study population at your institution and nationally
  - Assess and minimize the study burden on patients
  - Use feasibility studies to test recruitment strategies
- **Choose study sites carefully**
  - Evaluate the recruitment histories of potential sites
  - Determine the available resources of potential sites (e.g., staffing or facilities)
  - Look at the potential sites' competing trials
  - Look at the sites' interest level in the trial—both scientific interest and their thoughts on feasibility
- **Prepare trial-specific materials**
  - Prepare participant-friendly informed consent document
  - Create trial-specific materials for participants
  - Ensure that materials are culturally appropriate

Table 1. List of available tools, resources and templates to use during trial development

Title	Description	Link(s)	Type
Clinical trial listings	Review clinical trial listings for competing trials at your institution and/or nationally	• National: o www.portfolio.3ctn.ca o www.clinicaltrials.gov o www.canadiancancertrials.ca • Provincial: o http://www.geoq.info	Resource
Disease Site Group Clinical Trial Assessment & Approval Form	Disease site groups use this form to assess the clinical trial to ensure local buy-in of PIs. This can also be used to assess if the site already has competing trials open.	http://3ctn.ca/page/recruitment-best-practices-inventory	Template
Clinical trials asset maps	A database to identify clinical research sites and investigators across Canada. Each province/region may have their own database (i.e., Q-CROC mapping tool)	Canadian Clinical Trials Asset Map (CCTAM): www.cctam.ca	Resource
SPIRIT Initiative	International initiative to improve the quality of clinical trial protocols by defining an evidence-based set of items to address in a protocol	www.spirit-statement.org/	Tool

Title	Description	Link(s)	Type
Informed consent templates	To prepare participant-friendly informed consent documents	• www.who.int/rpc/research_ethics/informed_consent/en/ • OCREB templates	Template

Consider the following activities when selecting a trial:

- **Evaluate your institution's trial portfolio and participant population**
  - Confirm that the trial's scientific question is relevant and of interest to your institution
  - Assess where the trial fits within your institution's portfolio of open trials and check for competing trials
  - Verify that there are no conflicts of interest in this trial
  - Ensure that the trial matches your patient population
  - Assess the financial burden the trial will place on participants
  - Determine the level of study burden on participants and their support systems
- **Assess your institution's infrastructure and resources**
  - Obtain feedback on the trial from key staff
  - Assess the financial burden of the trial on your institution
  - Assess the capacity of your institution to conduct the trial
  - Determine if you have adequate staffing levels
- **Ensure stakeholder commitment**
  - Ensure a clinical "champion"
  - Ensure staff buy-in
  - Ensure buy-in from experts/specialists who are needed to implement the trial
  - Confirm buy-in at the institution level
- **Create a clinical trials friendly environment**
  - Integrate the importance of clinical trials into your institution's culture
  - Provide a comfortable physical environment for participants in trials
  - Understand participants' perceptions of being part of a clinical trial
  - Establish an efficient work environment to effectively conduct clinical trials
  - Discuss clinical trial options with every patient
  - Ensure all staff members are trained in conducting clinical trials
  - Ensure staff is aware of your institution's available trials
- **Plan internal processes to conduct the trial**
  - Complete a study start-up checklist
  - Plan trial logistics and scheduling
  - Dedicate staff and budget to recruitment in the beginning
  - Identify "go-to" research staff for the trial
  - Provide trial-specific training to staff
  - Pre-authorize insurance or develop alternate payment options for the trial
  - Implement information technology (IT) processes for the trial
- **Write a comprehensive recruitment and retention plan**
  - Integrate recruitment and retention plans with institutional activities
  - Determine how to screen and identify potential participants
  - Prepare site-specific trial promotional materials for potential participants
  - Address diverse and underserved populations
  - Include plans for community outreach (i.e., Ask Me Campaign, promote ItStartsWithMe.ca)
  - Include plans to work with referring physicians
  - Write a trial-specific Evaluation Plan
  - Set milestones, metrics, goals, back-up plans
  - Determine methods for tracking accrual progress
  - Set accrual performance thresholds (e.g., time from trial opening to first participant enrollment)

Table 2. List of available tools, resources and templates to use when selecting and preparing to open a trial.

Title	Description	Contact/Link(s)	Type
Disease Site Group Clinical Trial Assessment & Approval Form	Disease site groups use this form to assess the clinical trial to ensure local buy-in of PIs. This can also be used to assess if the site already has competing trials open.	http://3ctn.ca/page/recruitment-best-practices-inventory	Template
Clinical Research Impact Assessment Form	An impact assessment form to assess and facilitate communication about potential initiation of new studies	http://3ctn.ca/page/recruitment-best-practices-inventory	Template
SOP: Impact Assessment Procedure	The process for impact assessment associated with a new study	http://3ctn.ca/page/recruitment-best-practices-inventory	Resource
3CTN site efficiency metrics	Review 3CTN site efficiency metrics to establish an efficient work environment to effectively conducts clinical trials	Contact your 3CTN site representative or info@3ctn.ca	Resource
Clinical Trials Management System (CTMS)	Use a CTMS (i.e., EDGE or other institutional CTMS) to set and track accrual and other metrics	For EDGE CTMS, contact info@3ctn.ca	Tool
Initiative to Streamline Clinical Trials (ISCT)	An initiative to develop specific, pragmatic and practical interpretation of current regulations, laws and guidelines to facilitate Canadian clinical trials.	www.n2canada.ca/isct/	Resource
Network of 3CTN Recruitment Specialists	3CTN supports Recruitment Specialists across Canada.	Contact your 3CTN site representative or info@3ctn.ca	Resource
Clinical Trials Flowsheet	A flowsheet outlining available clinical research studies based on disease site and subtypes to review your site's available and competing trials. Flowsheet can also be used to evaluate patients for clinical trials.	http://3ctn.ca/page/recruitment-best-practices-inventory	Template
Resource Utilization letter and Signature Page	Notification letter outlining resources required and tracking of signatures	http://3ctn.ca/page/recruitment-best-practices-inventory	Template
Protocol Review Committee Form	Form to be reviewed by the protocol review committee	http://3ctn.ca/page/recruitment-best-practices-inventory	Template

4. DURING A TRIAL

This section contains recruitment strategies and tools to consider while a trial is open at your site. While a trial is actively recruiting, it is vital to monitor the recruitment progress to assess if targets will be met. If recruitment is not on track, corrective actions may need to be considered by site staff. This tools in this section will help with these activities.

Consider the following activities while recruiting/communicating with participants:

- **Engage intermediaries to aid accrual:**
  - Assure that plans to reach referring physicians are being executed
  - Assure community outreach plans are being executed
  - Generate advocate buy-in
  - Engage patient navigators
  - Physician referral networks with Specialists (e.g., PIs reaching out to Urologists and ensuring they are aware of open trials)
  - Work with local advocacy groups to share clinical trials patient stories in media
  - Host drop-in education sessions for patients
  - PPI representatives on advisory and/or patient engagement committees
- **Identify potentially eligible participants:**
  - Query your institution's paper or electronic medical record system(s)
  - Follow up with potentially eligible but non-consented individuals
  - Identify and report on participant non-adherence indicators
  - Identify participants:
    - Pre-screen clinic lists
    - Flag charts for clinical trials discussion between physician and patient
  - Physician referral networks with Specialists
  - Ensure decision-making for opening new trials includes a review and/or consideration of patient population so site has an appropriate suite of trials to meet
- **Engage participants in the informed consent process:**
  - Use plain language
  - Use participant-friendly materials
  - Present the trial in a culturally appropriate manner
  - Seek the help of translators when needed
  - Emphasize the key role of the physician presenting the trial
  - Present the trial in a balanced manner—both pros and cons
  - Provide continued support as people consider their decision to participate and continue on the trial
  - Manage communication of screening results and failures
  - Be aware of and monitor regulatory issues such as HIPAA regulations
  - Research Nurse to follow up after consented to schedule time to meet and for questions
  - Screening database used to track those approached and reasons not eligible
  - Translators available to support patients as needed
- **Maintain the morale and interest of staff, participants and their families:**
  - Watch for early signs of non-adherence and provide support to meet needs
  - Keep in touch with participants on trials (e.g., through newsletters or reminders)
  - Offer support groups, participant networking, lists of local and online support resources
  - Conduct satisfaction surveys with trial participants
  - Acknowledge and celebrate successes while supporting any staff who need help
  - Regularly update staff on trial accrual:
    - Investigator incentives
    - Poster/email/whiteboard to highlight weekly recruitment
    - Staff meetings
    - Emails and/or meetings to discuss non or low accruing trials
  - Use project management tools (i.e., kick off meeting, regular status reports, project close out meeting to discuss lessons learned and celebrate successes)
  - Encourage staff to provide feedback about the trial

- Forward 3CTN communications to staff:
  - A feature trial highlighted in the 3CTN monthly newsletter
  - Monthly notification of new portfolio trials

☐ **Update participants regarding study related events and results:**

- Keep contact lists current and note the best way to communicate with individual participants (e.g., through email, newsletter, telephone call)
- Monitor media regularly and have a plan in place to respond to trial-relevant media stories (to participants, to the media, and to stakeholders)
- Have a plan for notifying participants/families, staff, and stakeholders if the trial is put on hold or closes unexpectedly

Table 3. List of available tools, resources and templates to use while recruiting/communicating with participants.

Title	Description	Contact/Link(s)	Type
Ask Me Campaign	A clinical trials awareness campaign to prompt patients and public to ask questions about clinical trials	Contact info@3ctn.ca	Tool
N2 clinical trials brochure	General clinical trials information brochure available in English and French	http://n2canada.ca/news-resources/resources/	Resource
CISCRP Informational Videos	General information videos about clinical research participation	www.ciscrp.org/education-center/informational-videos	Resource
It Starts With Me	Clinical trials education website	http://itstartswithme.ca/	Resource
Permission to Contact program	A patient enrollment strategy whereby patients have provided permission to be contacted about future research opportunities.	Contact Karen.arts@oicr.on.ca	Tool

Consider the following activities while conducting the trial

☐ **Communicate regularly with stakeholders and referring providers:**

- Identify key local stakeholders (local and referring)
- Conduct regular staff meetings to discuss trial accrual
- Regularly communicate the trial's accrual status to key staff/stakeholders and seek feedback
- Discussion and provision of local metrics (including reasons for non-enrolment) of clinical trials at stakeholder meetings:
  - CTU staff
  - Tumour groups
  - Business meetings
- Monthly communication of accrual
- Warning letter to PI for studies with no recruitment at 3 months

☐ **Monitor trial progress and accrual metrics:**

- Monitor recruitment and retention plan activities and adjust when necessary. Include recruitment projections
- Monitor promotion activities and adjust when necessary
- Monitor evaluation goals, objectives, and activities
- Review trial accrual indicators against expected performance
- Regularly assess the trial's costs against its budget
- Monitor screening data for diverse and underserved populations
- Monitor the impact of operations and logistics on trial accrual
- If accrual is problematic, provide timely feedback (reasons) to sponsor, as this may inform future protocol amendment
- Review recruitment progress monthly against projections from recruitment/ retention plan
- Review screening logs monthly and track reasons for non-enrollment

☐ **Implement alternative recruitment strategies when accrual milestones are not achieved:**

- Use data to decide whether to make changes or close the trial

- If changes are made, document expectations and monitor over a specific timeline
- Determine if the state of the science has changed and accrual is unachievable
- Review screening logs for trials with no recruitment at 3 months and assess reasons why patients are not on study
- Discuss recruitment with PI at 3 months if recruitment not meeting recruitment/retention plan milestones

Table 4. List of available tools, resources and templates to use when implementing a trial.

Title	Description	Contact/Link(s)	Type
Performance Dashboard Reports	To track and communicate accruals and other metrics to PIs and site staff.	http://3ctn.ca/page/recruitment-best-practices-inventory	Template
Clinical Trials Management System (CTMS)	Use a CTMS (i.e., EDGE or other institutional CTMS) to set and track accrual and other metrics	For EDGE CTMS, contact info@3ctn.ca	Tool
3CTN quarterly recruitment reports	Use quarterly recruitment reports to regularly communicate recruitment progress to staff	Contact your 3CTN site representative or info@3ctn.ca Network quarterly performance reports: https://3ctn.ca/page/performance-reports	Resource
Clinical Trials Information Sheet	A one page information sheet distributed internally to raise awareness of new trials and stimulate referrals between sites. Note: if an NCC creates trial-specific Information sheets, sharing that sheet with other sites in your node may be helpful.	http://3ctn.ca/page/recruitment-best-practices-inventory	Template
BCCRIN recruitment survey	A survey for patients and public to provide input and advice on their experience with clinical trials, especially those who have declined participation.	www.bccrin.ca/whats-new/bccrin-clinical-research-participant-survey	Resource
Clinical trial listings	Review clinical trial listings at your institution and/or nationally	• National: o www.portfolio.3ctn.ca o www.clinicaltrials.gov o www.canadiancancertrials.ca • Provincial: o http://www.geog.info	Resource

5. AFTER A TRIAL

This section contains tools your site can use after the trial closes. It is equally important to understand why your site had good accrual, as well as if accrual was lower than expected. Either scenario can provide valuable lessons for your trial team or the tools in this section can help with these activities.

Consider the following activities when evaluating the site's recruitment performance:

- **Analyze the trial's accrual data for lessons learned:**
  - Review accrual data and discern lessons learned to improve future trials
  - Determine the trial's value to your institution
  - Analyze data from a terminated trial
  - Use site screening logs
- **Report and share accrual experiences with others:**
  - Prepare and submit a summary of trial-specific accrual findings and lessons learned to key stakeholders
  - Share your experiences with 3CTN
  - Document and submit your experiences and findings to journals and at professional meetings
  - Compare recruitment with other 3CTN sites to determine what strategies are successful

Table 5. List of available tools, resources and templates to use when evaluating accrual and reporting lessons learned.

Title	Description	Contact/Link(s)	Type
Lessons Learned	*Under development:* *A checklist to assist with understanding factors that helped with or was a barrier to recruitment.*		Template