CLINICAL TRIALS AND MEDICAL ONCOLOGY TRAINING IN CANADA

PREPAREDNESS FOR CLINICAL TRIALS IN MEDICAL ONCOLOGY SUBSPECIALTY TRAINING IN CANADA – A NATIONAL, BI-LINGUAL, QUESTIONNAIRE

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TITLE: Preparedness for clinical trials in medical oncology subspecialty training in Canada – A national, bi-lingual, questionnaire

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LAY ABSTRACT

Clinical trials are pivotal in the field of medical oncology, leading to the changing diagnostic and treatment landscape in medical oncology. Knowledge of how to participate in clinical trials as an investigator is becoming increasingly important in the field of medical oncology. Early integration of clinical trial experiences can increase early-career physician participation. This study assessed current teaching practices related to clinical trial education in medical oncology subspecialty training programs in Canada. Self-assessments of competence and preparedness to participate in clinical trials after training were low, while self-assessment of willingness to participate was high. In-clinic training trended towards improved self-assessments of competence and preparedness. An approach to medical education that increases in-clinic exposure to clinical trials in the subspecialty curriculum is needed to improve preparedness and competence in clinical trials after medical oncology subspecialty training.

ABSTRACT

Background: There is no standardized approach to clinical trial education for Canadian medical oncology subspecialty training. Canadian medical oncology subspecialty training programs have transitioned to a competency by design (CBD) educational framework. This study aims to determine whether current education practices in medical oncology subspecialty training programs in Canada prepare medical oncology trainees for participating in clinical trials as an investigator.

Methods: A national, online, bi-lingual questionnaire to understand exposure to clinical trials and general research in training, self-perceived competence, preparedness, and willingness to participate in clinical trials was conducted. Participants included medical oncology resident trainees and fellow trainees and new-to-practice physicians who have practiced in medical oncology for less than 5 years. All participants had to complete a medical oncology subspecialty training program in Canada. Data were collected from November 2021 to February 2022. Results are presented using descriptive statistics.

Results: Out of the 41 respondents (response rate: 15%), most were new physicians (41%), from Ontario (61%). 73% did not have formal training on how to participate in clinical trials as an investigator. 65% rated their competence in clinical trials as fair/poor and 74% rated their preparedness for clinical trials as fair/poor after training. 79% were willing to participate as an investigator in clinical trials after training. A correlation analysis revealed structured or in-clinic teaching in clinical trials trended towards improved self-evaluations of competence, preparedness, and willingness to participate in clinical trials ($p > 0.05$). Most respondents (56%) sought additional clinical trial education after training.

Conclusion: Training in clinical trials is highly variable. After training, most trainees do not feel competent or prepared to participate in clinical trials as an investigator, but they have a willingness to pursue clinical trials. Further assessment into how to produce competent medical oncology clinical trial investigators is warranted.

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LIST OF ABBREVIATIONS AND SYMBOLS

CAMO	Canadian Association of Medical Oncologists
CaRMS	Canadian Resident Matching Service
CBD	Competency by design
CBME	Competency-based medical education
CCTG	Canadian Cancer Trials Group
CMAJ	Canadian Medical Association Journal
FITER	Final In-Training Evaluation Report
HiREB	Hamilton Integrated Research Ethics Board
RCPSC	Royal College of Physicians and Surgeons of Canada
ρ	Spearman rho
3CTN	Canadian Cancer Clinical Trials Network

DECLARATION OF ACADEMIC ACHIEVEMENT

I, Michela Febbraro, declare this thesis to be my own work. I am the sole author of this document. No part of this work has been published or submitted for publication or a higher degree at another institution.

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My supervisor, Dr. Gregory Pond, and the members of my supervisory committee, Dr. Rosalyn Juergens and Dr. Ghazaleh Kazemi, have provided guidance and support at all stages of this project. I completed all of the research work.

INTRODUCTION

Clinical trials represent the final step in the evaluation of the efficacy and safety of new therapeutic approaches in medicine. The National Institute of Health (NIH) defines a clinical trial as a research study in which one or more human participants are prospectively assigned to one or more interventions to evaluate the interventional effects on health-related biomedical or behavioural outcomes (NIH 2017). As it relates to drug development, the goal of clinical trials is to improve clinically meaningful outcomes for patients (Unger et al. 2016).

Clinical trials have improved the standards in optimal cancer treatment. The result of a clinical trial has the potential to shape the care for patients. Through the development of innovative treatments and expansion of diagnostic techniques, cancer clinical trials have become instrumental to patient care (Li and Bergan 2020; Jacobs et al. 2014; Grunfeld et al. 2002). Progress in understanding cancer biology through clinical trials and cancer research has led to treatments moving away from chemotherapeutic agents and towards novel therapeutic strategies such as immunotherapy, monoclonal antibody therapy and targeted therapies (Verweij et al. 2019; Janiaud, Serghiou and Ioannidis 2019). Patients given the opportunity to participate in clinical trials obtain access to treatments that may not be available to them otherwise with the potential for more effective outcomes and less toxicity as compared to the current standard of care (ASCO 2003; Bell and Balneaves 2015).

Over the last ten years, more than half of all cancer clinical trials have involved novel therapeutic strategies with a median improvement in overall survival for all cancer types combined of 3.4 months (Paggio et al. 2021). After a clinical trial result is made public and the therapeutic option available for patients, these results allow clinicians to determine the best available treatment for their patients given their diagnosis and clinical picture (Rahman et al. 2011).

Access to clinical trials in medical oncology

It is globally estimated that 3-8% of patients with a diagnosis of cancer enroll in clinical trials (ACS 2018; Unger et al. 2019; Donnelly et al. 2017). In Canada, clinical trial participation varies by province or territory with reported rates of adult cancer patient participation ranging from less than one percent in Newfoundland and Prince Edward Island to 5.8% in Alberta and Ontario (CPAC 2018). To improve clinical trial participation, the Canadian Cancer Trials Group (CCTG) and the Canadian Cancer Clinical Trials Network (3CTN) have created a mandate to improve equity and access to clinical trials in Canada. Any patient diagnosed with cancer can be given the opportunity to participate in clinical trials as a standard of care (3CTN 2022; CCTG 2022).

A clinical trial system that enrolls patients at higher rates while continuing to produce treatment advances and concurrent survival improvements is required (Unger et al. 2016). Several studies have examined reasons for poor clinical trial recruitment in the adult cancer population which have been largely divided into patient factors, physician factors, and protocol-related factors (Bell and Balneaves 2015; Unger et al. 2019). Focusing on physician factors as a barrier to clinical trials, studies cite administrative barriers, financial barriers, and time barriers to be predominant (Bell and Balneaves 2015; Unger et al. 2019). However, prior clinical trial experience over time and involvement in clinical trials during training also affect access (Mannel et al. 2003; Briel et al. 2021). Physicians play a key role in providing clinical trial opportunities to patients, as they often are the gatekeepers to care; providing patients with information about the available treatment options including clinical trials and creating a trusting environment by which the patient feels comfortable and agreeable to take part in patient-centred research (Bell and Balneaves 2015).

Patients with cancer who enroll in clinical trials often hear of the opportunity from their physicians with provider recommendations being a leading factor in clinical trial enrollment (ACS 2018). Over half of patients approached to participate in a clinical trial by their providers agree to enrol (Unger et al. 2019; Unger et al. 2020; ACS 2018).

Given that the clinical trial experience of the oncologist is correlated with increased clinical trial recruitment and patient participation, it has been suggested that oncologists should receive education in the fundamentals of clinical trial design and clinical trial involvement earlier in their careers or during training. Evidence suggests senior oncologists are more likely to be principal investigators in clinical trials, have more experience and exposure to clinical trials, and therefore are more likely to recruit to clinical trials than junior oncologists (Mannel et al. 2003; Briel et al. 2021). Given these findings, it is hypothesized that earlier exposure to clinical trials in training can decrease some of the physician barriers related to clinical trial access (Chen 2003; Rahman et al. 2011). Training in clinical trials and research should be considered an essential component of the physician training curriculum with the integration of a needs-based program to help care providers become patient-oriented clinician-researchers (Rahman et al. 2011; ASCO 2003).

Medical oncology residency training in Canada

Medical oncology is a subspecialty in medicine that consistently sees rapid changes and evolution in the understanding disease biology, molecular therapeutics, and biomedical testing (Falzone, Salomone and Libra 2018). The rapid development of new drugs and therapeutic strategies within the field of medical oncology makes training within this discipline uniquely challenging. To continuously evolve within the field after certification, medical oncologists need to learn valuable skills in their subspecialty training program. Historically, to become a medical oncologist in Canada a trainee must complete a Royal College of Physicians and Surgeons of Canada (RCPSC) accredited medical oncology time-based training program and successfully pass the medical oncology specialty examination (**Figure 1**). Despite this rigorous process, both trainees and program directors had reservations about competence upon graduation (Mann et al. 2020). The achievement of competence was assumed at the end of the training, ultimately granting trainees the necessary qualifications for independent practice (Arora et al. 2020). The issue was that time-based medical oncology subspecialty curriculums

succeeded in evaluating a trainee's knowledge but failed to evaluate or address a trainee's competence and performance (Arora et al. 2020).

In 2018, Canadian medical oncology subspecialty programs with guidance from the RCPSC switched to a competence-by-design (CBD) training framework in which trainees progress through pre-specified stages of training demonstrating knowledge, performance, and competence before progressing to the next stage (**Figure 1**) (Hsu et al. 2021). Through a series of workshops, members of a medical oncology national committee developed subspecialty-specific milestones ultimately creating the medical oncology subspecialty training program that is taught in the competency-based medical education curriculum (CBME) today (Hsu et al. 2021). Current requirements to be a medical oncologist in Canada include successful completion of an RCPSC accredited medical oncology CBD training program, and successfully passing the medical oncology specialty examination.

CBME has four overarching themes: a focus on outcomes, an emphasis on abilities, a de-emphasis ofon time-based training, and the promotion of learner-centeredness (Frank et al. 2010). Through a focus on outcomes, there is a delineation between knowledge and skills and the trainee can view the definitions of all essential domains of competence to be acquired. Through an emphasis on abilities, elements within the curriculum build on one another with an additional focus on observable skills. By de-emphasizing time-based training, trainees can progress faster or slower in each curricular component depending on their needs. Finally, through the promotion of learner-centeredness, trainees take responsibility for their progression and development with the use of a transparent pathway from milestone to milestone as they make their way towards achieving competence within a domain.

Clinical trials training in the medical oncology CBME curriculum

Despite the use of CBME as the training model in medical oncology subspecialty programs in Canada, there is no standardized formal training in clinical trials and there

is minimal requirement to demonstrate competency related to clinical trials (Berman et al. 2014; Safa and Jazieh 2006; Todd, Gitlin and Burns 2004). Studies before CBME demonstrated the need for establishing a clinical trial curriculum with a clear approach to obtaining the critical skills required to participate in clinical trials (Safa and Jazieh 2006; Todd, Gitlin and Burns 2004).

Within the current Canadian CBME curriculum, only two competencies specifically address clinical trial experience (RCPSC 2018). The first competency assesses communication; requiring the trainee to identify appropriate available clinical trials and engage patients in enrolment in clinical trials (competency 2.4.1.1). The second competency assesses scholarly activity by requiring the trainee to demonstrate awareness of available clinical trials (competency 4.3.1). When compared to the medical oncology curriculum in place before the launch of CBD in July 2018, these clinical trial competencies align with the final in-training evaluation report (FITER). There is no available medical oncology literature assessing whether these core competencies adequately prepare trainees to be involved in clinical trials once beginning practice.

STUDY PURPOSE

Clinical trials play a pivotal role in the understanding of cancer and how to best improve upon current therapeutic strategies. The root cause creating barriers to access to clinical trials is multifactorial and attributed in part to physician factors, including lack of clinical trial during physician's training. Given that CBME in medical oncology is in its infancy in Canada with an opportunity to evaluate and improve on current standards in medical education, the purpose of this study was to evaluate whether current education practices in medical oncology subspecialty clinical trials training adequately prepare medical oncology trainees for participating in clinical trials as an investigator.

METHODS

Study Design

A novel web-based bilingual (English and French) questionnaire was designed and administered to evaluate clinical trial education in medical oncology subspecialty training programs in Canada and assess whether this training prepares medical oncology trainees to participate in clinical trials. A trainee was defined as a student who is completing their core medical oncology subspecialty training (also known as a resident). As per the National Cancer Institute, the investigator of a clinical trial was defined as the physician responsible for the conduct of a clinical trial at a trial site (NIH 2022). All participants had to have completed or be currently completing a medical oncology subspecialty training in Canada and be a medical oncology subspecialty trainee (resident), a medical oncology fellow, or a medical oncology staff who has been practicing for five years or less. A medical oncology fellow was defined as a physician who has completed their medical oncology subspecialty training and chosen to pursue additional training in medical oncology. Radiation oncologists and surgical oncologists, including residents and fellows, were excluded from participating in the questionnaire. Individuals who completed or are currently completing their medical oncology subspecialty training program outside of Canada were also excluded. Hematologic oncologists, including residents and fellows, were excluded unless they were enrolled in a province whereby subspecialty training combines both medical oncology and hematologic oncology specialties within one training program (i.e. Quebec and British Columbia). The discipline of medical oncology was specifically chosen for this study given the rapid increase in the number of clinical trials available to patients within this discipline. Although hematologic malignancies have also seen a rise in clinical trials, the subspecialty training program also requires specialization in benign hematology which is less specific for this study. Ethics approval was obtained through the Hamilton Integrated Research Ethics Board (HiREB).

Questionnaire Development

The Canadian Medical Association Journal (CMAJ) guide for the design and conduct of self-administered surveys of clinicians was used to develop the questionnaire (Burns et al. 2008). Questionnaire development included four phases: item generation, item reduction, formatting, and testing.

Item Generation

Items were generated through a combination of literature review and the modified-Delphi technique involving experts and potential respondents. *[Keeney, Wiley, 2019]* All potential items (ideas, and constructs) that could be included in the questionnaire were identified by the research team. Item generation was continued until new items could not be identified further. The final list consisted of 100 items generated. Items were then evaluated to determine important domains (categories or themes) that emerged. Items were subsequently grouped into domains. Five domains were identified and agreed upon by the research team after the item generation phase:

Domain 1: Exposure to clinical trials and general research
Domain 2: Self-perceived clinical trial competence
Domain 3: Self-perceived preparedness to participate in clinical trials as an investigator
Domain 4: Willingness to participate in clinical trials as an investigator
Domain 5: Perceived role of the trainee to seek clinical trials experiences during training

Domains were determined upon consensus strategy. Given that the themes identified within the generated items were readily identified with complete research group consensus, factor analysis was not conducted to determine domains.

Item Reduction

To address the research question with 25 or fewer items within the 5 domains identified (Fox 1994), the list of items was reduced through a focus group consisting of four

researchers. These individuals included medical oncologists and research specialists who had completed their training in Canada and were involved in the CBME curriculum. None of the researchers were eligible to participate in the questionnaire. In addition, some individuals had post-graduate training in medical education. Items were identified for inclusion or exclusion using a binary response system (keep or remove), ultimately concluding with group consensus. In instances of uncertainty, items were selected to be kept with revisions as per group consensus. After item reduction, the questionnaire consisted of 17 items pertaining to the research question with the addition of 8 demographic items.

Formatting

Following item reduction, questions were formatted to focus on a single concept. Questions were aimed to be fewer than 20 words and easy to understand and interpret, be non-judgmental and unbiased (Stone 1993). Questions, particularly demographic questions, were phrased in a socially sensitive manner. In addition, the questionnaire aimed at avoiding abbreviations and added definitions of complex terminology to decrease ambiguity (Henry and Zivick 1986).

Closed-ended response formats including binary and ordinal measurements (validated Likert scales) were used. Nominal responses were used for demographic and screening items. The 'other' response option allowed for elaboration in specified sections of the demographic items generated.

Testing

Validity testing was conducted to ensure that the content of the questionnaire provides appropriate measures as it relates to the study purpose. The method for content validation was adapted from the ABC of content validation and content validity index calculation guide (Yusoff and MALAYSIA 2019). A total of six content experts were approached to provide content validation. Four content experts were identified based on

being practicing oncologists with exposure to clinical trials and the medical oncology CBD curriculum. These content experts were from a mix of community and academic cancer centers in Ontario. The final two content experts were chosen given their expertise in questionnaire design and development. None of the content experts were eligible to participate in the questionnaire. Content validation was conducted via a non-face-to-face approach with each expert emailed to participate and, upon agreement, asked to complete the assessment within two weeks. Experts were emailed three days before the two-week deadline as a reminder. No remuneration was provided. The experts assessed the face validity and the content validity of the questionnaire. *[APPENDIX A – Content Validation]* Experts rated the degree of relevance of each item on a 4-point ordinal scale (1 = the item is not relevant to the measured domain; 2 = the item is somewhat relevant to the measured domain; 3 = the item is quite relevant to the measured domain; 4 = the item is highly relevant to the measured domain). This four-point scale was converted to a dichotomous scale (score 0 = relevance scale of 1 or 2; score 1 = relevance scale of 3 or 4). Item content validity index (I-CVI) was calculated for each item, and any item that scored below 0.83 was removed. *[APPENDIX B – Content Validation Data]* The score of 0.83 was used given the literature demonstrating it as an acceptable cut-off score of CVI for six experts (Yusoff and MALAYSIA 2019). The resulting questionnaire had a face validity of 0.83 which satisfies the content validity requirement for a survey (Yusoff and MALAYSIA 2019).

Pre-testing was conducted to minimize the chance of misinterpretation using a semi-structured interaction. Residents currently completing a radiation oncology training program at McMaster University in Hamilton, Ontario, Canada were asked to examine the questionnaire with regards to flow, irrelevant or poorly worded question stems and responses. Feedback was offered in real-time. Radiation oncology residents were chosen given that they work closely with medical oncology programs, often completing rotations in medical oncology, are exposed to the CBD curriculum format within Canadian residency programs and are familiar with the use of clinical trials in the field of oncology. Given the small sample size and concerns regarding response rates, this group of trainees was determined to be an appropriate group for pre-testing without

approaching individuals who were eligible for participation in the survey. This group of trainees was not required to complete the questionnaire, and reliability testing was not completed as the plan to consider test-retest reliability in the future may be conducted. The final questionnaire consisted of 16 items pertaining to the research question with the addition of 8 demographic items. *[APPENDIX C – English Questionnaire]* The final instrument was translated to French by a Francophone medical oncologist. *[APPENDIX E – French Questionnaire]* An electronic version of the final survey was created on LimeSurvey for distribution.

Questionnaire Administration

A call to participate in the study was sent via bilingual email to the medical oncology program directors, program administrators and fellowship coordinators at all Canadian institutions that had a medical oncology subspecialty training program. The email identified the purpose of the questionnaire, the period the questionnaire would be open and asked the questionnaire to be forwarded to all residents and fellows currently in the program or who had graduated from the medical oncology subspecialty training program within the last 5 years. In addition, the Canadian Association of Medical Oncology, a national specialty society in Canada, emailed the questionnaire to its entire membership. The survey was open for 3 months with reminder emails administered at the mid-way point as well as two weeks before the survey closed. Responses were collected anonymously between November 2021 and February 2022. Participants were not compensated for participation.

Outcomes and Data Analysis

Descriptive statistics were used to summarize respondent characteristics and item responses. The self-assessed competence, preparedness, and willingness to participate in clinical trials were defined as co-primary outcomes. The dichotomization of outcomes was performed (poor/fair versus good/very good/excellent), as well as the dichotomization of selected research questions, for statistical power considerations.

Associations between selected research questions and outcomes, as well as outcomes with each other, were assessed via Fisher's exact tests and descriptively using 2x2 association tables. These associations were determined a priori given the co-primary endpoints of the study being self-assessed competence, preparedness, and willingness to participate in clinical trials. Associations between outcomes were further evaluated using Spearman correlation coefficients based on response ranks. All tests were two-sided and statistical significance was defined as $\alpha = 0.05$. Analyses were conducted using SAS software.

RESULTS

Invitations to participate in the questionnaire were sent to 360 CAMO members (all members that were medical oncologists regardless of years in practice, and medical oncology residents and fellows due to the inability to target specific participants for inclusion) as well as 31 program directors, fellowship directors, and program assistants of medical oncology programs in Canada. Not all medical oncologists are required to register with CAMO. There is no accurate documentation of the number of graduating medical oncologists Canadian subspecialty programs produce yearly. Using the Canadian Resident Matching Service (CaRMS) data *[https://www.carms.ca/]* and information received by CAMO, it is estimated that the total sample size for this questionnaire is 270 individuals. Not all CAMO members were eligible for the study, leading to the discrepancy between sample size and CAMO membership. Responses were received from 41 participants (15% response rate) representing all regions of Canada with two participants not completing the full questionnaire (**Table 1 – Characteristics of respondents**). Responses were evenly distributed between trainees (residents and fellows) and new to practice physicians. Most respondents were training or practicing in Ontario (61%) and, of physician respondents, most were practicing in an academic center (61%). Approximately 40% of respondents had a graduate-level degree.

Exposure to Clinical Trials and General Research

Thirty-nine (95%) respondents noted that teaching regarding critically appraising clinical trials occurred in medical oncology subspecialty training, with 30 (73%) indicated that teaching occurred in small group learning sessions, including case-based or problem-based teaching and journal clubs (**Table 2 – Exposure to clinical trials and general research**). This teaching was found to be adequate by 16 (39%) respondents. Similarly, 37 (90%) respondents deemed that teaching regarding clinical trials research methods occurred in medical oncology subspecialty training, with 24 (59%) noting that teaching occurred in small group learning sessions, including case-based or problem-based teaching and journal clubs. This teaching was found to be adequate by 13 (31%) respondents. The majority of respondents (n = 23, 56%) did not receive teaching on participating in clinical trials. Regardless of teaching method (including no teaching), 28 (68%) respondents reported training to be inadequate or very inadequate. Of those participants, 20 (71%) reported no teaching about participating in clinical trials. Participation in clinical trials as a medical oncology subspecialty resident predominantly included assessing a patient actively enrolled in a clinical trial (n = 31, 75%), while the majority of respondents indicated they had no involvement in clinical trial development or design (n = 27, 66%).

Self-Perceived Assessments of Competence, Preparedness and Willingness to Participate in Clinical Trials

Nineteen (65%) respondents rated their level of competence to participate in clinical trials as an investigator as poor to fair upon completion of their medical oncology subspecialty training (**Table 3** – Self-perceived assessments). Most respondents felt competent in tasks not directly associated with a clinical trial, such as searching for clinical trials (n = 24, 78%), referring a patient for a clinical trial (n = 28, 90%), or discussing clinical trials as a potential therapeutic option (n = 29, 94%). A minority of respondents felt competent in tasks requiring a more active role in clinical trials.

Similarly, 29 (74.4%) respondents rated their level of preparedness to participate in clinical trials as an investigator as poor to fair upon completion of their medical oncology subspecialty training. Respondents felt prepared to participate in tasks not directly associated with a clinical trial compared to tasks requiring a more active role in clinical trials. Conversely, 37 (95%) respondents rated their willingness to participate in clinical trials as an investigator as good to excellent upon completing their medical oncology subspecialty training. Across all clinical trial tasks, most respondents noted that they were willing to perform such tasks.

Clinical Trials Education and Training

Twenty-nine (74%) respondents felt it very or extremely important to have a structured clinical trials curriculum in medical oncology subspecialty training. There was high agreement (n = 33, 85%) that it is the role of the medical oncology subspecialty training program to ensure adequate clinical trials education and that training programs should prepare their trainees to participate in clinical trials as an investigator (n = 32, 82%). Just under half of the respondents (n = 18, 46%) felt the role of the trainee was to seek experiences in clinical trials offered during training. Respondents felt that the responsibility for preparation to participate in clinical trials was not that of the trainee (n = 20, 51%).

Exploratory Analysis

In the exploratory analysis to examine associations of competency with clinical trials training (**Table 4** – Associations of competence), any teaching on how to participate in clinical trials was associated with a non-statistically significant improvement in competence (58% vs 21%, p = 0.056). In-clinic teaching resulted in a non-statistically significant improvement in self-assessment of competence (57% vs 29%, p = 0.21). Having a graduate-level degree was not associated with competence to participate in clinical trials (31% vs 38%, p = 1.00).

Associations between preparedness and clinical trials are presented in **Table** 5. It was observed that any teaching on how to participate in clinical trials was associated with a non-statistically significant improvement in preparedness (44% vs 13%, p = 0.060). In-clinic teaching resulted in a non-statistically significant improvement in self-assessment of preparedness (50% vs 17%, p = 0.087).

When assessing willingness to participate in clinical trials (**Table 6** – Associations of willingness), any teaching on how to participate in clinical trials was associated with nearly no effect on willingness to participate in clinical trials (88% vs 74%, p = 0.43). In-clinic teaching did not affect willingness to participate in clinical trials (80% vs 79%, p = 1.00). Teaching regarding critically appraising a clinical trial (78% vs 100%, p = 1.00) as well as teaching regarding clinical trial research methods (81% vs 68%, p = 0.51) did not affect self-assessment of willingness to participate in clinical trials.

There was a strong relationship between the level of competence and level of preparedness for clinical trials (Spearman $\rho = 0.71$, $p < 0.001$) and a moderate relationship between the level of competence and willingness to participate in clinical trials (Spearman $\rho = 0.38$, $p = 0.12$). There was a moderate relationship between the level of preparedness and willingness to participate in clinical trials (Spearman $\rho = 0.48$, $p = 0.024$).

DISCUSSION

This is the first study in Canada to assess competencies in any residency training program since the establishment of CBME. It is also the first study in Canada assessing clinical trial education practices in any medical discipline as well as in Canadian medical oncology subspecialty programs. This study found that current clinical trial education practices revolve around teaching critical appraisal and research methods with minimal teaching regarding how to participate in clinical trials as an investigator. Most of the teaching occurred in small group sessions with little in-clinic training. Overall,

respondents did not feel competent or prepared to participate in clinical trials as investigators after their training, but many were willing to participate.

The rapid development of new drugs and therapeutic strategies in medical oncology has created an increase in the number of clinical trials available to patients. Despite the opportunity, only a minority of patients diagnosed with cancer participate in clinical trials (Rahman et al. 2011). Access to clinical trials is complex and there is a need for greater participation in clinical trials by physicians. To decrease physician-related barriers, medical oncology subspecialty trainees should receive education and training in the fundamentals of clinical trial design with a curriculum focused on how to participate in clinical trials as an investigator (Rahman et al. 2011; Chen 2003). This study found that current practices in clinical trials education in Canadian medical oncology subspecialty programs, do not translate into competency or preparedness. An approach to clinical trial education that enhances the role integration of the subspecialty trainees to clinical trials clinical research should be considered (Rahman et al. 2011). Previous and prospective participation in clinical research is positively associated with current participation in clinical research (Sumi, Murayama and Yokode 2009). A program that can be designed to encourage trainees to engage in clinical research while integrating an active role in clinical practice can help improve research knowledge thereby increasing preparedness and competence.

A graduate-level degree was documented by 40% of respondents. It is thought that higher-level degrees in research can facilitate physicians to develop translational research in parallel to clinical careers (Rahman et al. 2011; Salto-Tellez, Oh and Lee 2007). In this study, having a graduate-level degree was not associated with competence to participate in clinical trials suggesting that the skills acquired may not translate to clinical trial expertise. Alternatively, this may be because these individuals are more acutely aware of the pressures and skills required to be the investigator of a clinical trial. However, it is noted that the respondents were not required to specify the graduate-level degree received. The graduate-level degree obtained may, therefore, not be related to clinical trials.

This study demonstrated that most respondents are willing to participate in clinical trials upon completion of medical oncology subspecialty training. A strong relationship between the level of competence and level of preparedness for clinical trials was identified, with a moderate relationship between the level of preparedness and willingness to participate in clinical trials. In addition, many respondents were willing to pursue additional clinical trial educational experiences after their medical oncology subspecialty training to better prepare themselves to participate in clinical trials. Factors that motivate and facilitate research rely on both intrinsic and extrinsic factors which are dynamic in nature and depend on the individual circumstances. Although this study did not assess how often physicians participated in clinical trials upon embarking on a medical oncology practice, this study demonstrates that physician willingness to participate in clinical trials can supersede preparedness and competence as physicians continue to explore additional education options and training outside of their subspecialty degree to improve clinical trials experience and expertise. Ultimately, physicians eager to participate in clinical research will do so if a supportive environment is present (Sumi, Murayama and Yokode 2009; Albers 2004; Ellis et al. 1999; D'Arrietta et al. 2022).

There was high agreement amongst respondents that medical oncology subspecialty programs in Canada do not provide adequate clinical trial education. Trainees felt it is the role of the subspecialty program to ensure adequate clinical trial education and that training programs should prepare their trainees to participate in clinical trials as an investigator. A medical oncology curriculum that educates subspecialty trainees in the fundamentals of clinical trial design and process, with a review of implications of clinical trials research for the physician-patient relationship and guidance through practical experience in training can build upon the willingness of trainees to participate in clinical trials and improve competence and preparedness of the subspecialty trainees. The competence and preparedness gained in training can be reinforced through continuing education thereafter (Chen 2003; D'Arrietta et al. 2022). Even if a trainee is not willing to participate in clinical trials or finds themselves in a practice that does not have access to

clinical trials, it is still important to ensure patients understand the role of clinical research and the therapeutic strategies available to them. Physicians unwilling to participate in clinical trials can help their patients understand the salient differences between clinical trial research, clinical practice, and the therapeutic options available (Chen 2003). This knowledge and understanding can be encouraged in a training curriculum that supports clinical trial education.

LIMITATIONS

Although this was the first questionnaire assessing clinical trial education in medical oncology subspecialty programs there are a few limitations to note. The estimated response rate of 15% was lower than anticipated. The study made several attempts to optimize response rates in the study design. This study was endorsed through CAMO, multiple emails were sent to program directors and fellowship directors throughout the country and the questionnaire was developed in both English and French to increase equity. The use of incentives was not entertained for this project but may have been a missed opportunity to increase the response rate. In addition, direct outreach through travel and conferences was limited due to the coronavirus pandemic. Despite the low response rate, this study did demonstrate the current landscape for clinical trial education practices in Canada with representation from across the country. Many of the respondents were from Ontario and Quebec, provinces that have the largest proportion of medical oncology programs in Canada.

Questionnaire-based studies are more likely to appeal to potential respondents who are interested or engaged in the topic of the questionnaire. This introduces selection bias. Selection bias can be seen in this study given that the majority of respondents were willing to participate in clinical trials. It's uncertain whether this directly reflects the larger population of medical oncologists in Canada or if there was a population was missed. One way to assess this further would be to re-do the questionnaire with more individuals (both those willing to participate and those unwilling to participate in clinical trials).

This questionnaire covered a subset of the relevant factors that can affect medical oncology clinical trials competency. There was no attempt for open-ended questions as the study was not designed to include qualitative analysis. In addition, self-assessment questions can under-or over-estimate true competence or preparedness. However, self-assessment can be a predictor of future action, especially for learners. Learners who have low self-assessments for a particular task or skill will take more time to enact that skill when independent (Barron, Khosa and Jones-Bitton 2017).

Lastly, this study does not go beyond the level of the trainee. It does not assess clinical trial education in medical oncology subspecialty programs from the view of educators or program directors. It did not assess productivity following graduation from a subspecialty program asking fellows and physicians how often they participate in clinical trials or their roles in clinical trials in practice. The goal of this study was to obtain baseline information regarding clinical trial education in Canada as it relates to medical oncology. The plan is that this questionnaire can be modified to be used for other groups of learners or upon reassessment in the future. This plan will also take into consideration the need for reliability testing which can be done longitudinally, over time, as individuals are re-tested with this questionnaire and additional groups of learners are asked to participate in this questionnaire in the future.

FUTURE NEEDS

The longitudinal goal of this project will be to change current CBME competencies addressing clinical trials in medical oncology subspecialty training such that they reflect the requirements to create competent clinical trial clinicians. Medical oncology subspecialty trainees in Canada are willing to participate in clinical trials but lack competence and preparedness at the end of subspecialty training. This finding is key when there is data to suggest that physicians' positive attitudes toward clinical trials can positively affect patient enrollment (Jacobs et al. 2014). The attitude physicians hold toward the value of research can be intrinsically motivating while simultaneously leading to decreasing barriers to access (D'Arrietta et al. 2022).

Standalone teaching in evidence-based medicine has demonstrated improvements in learner knowledge but does not lead to improvements in skills, attitude, or behaviours. A curriculum that marries evidence-based medicine with experiential learning techniques can simultaneously improve knowledge while also increasing skill acquisition and learner attitude towards a topic as well as future behaviour as it relates to performing a skill (Coomarasamy and Khan 2004). As such, a medical oncology subspecialty curriculum focusing on teaching around knowledge-based competencies such as clinical trial design and health research methods, clinical placements with clinical trials teams for practical workplace-based experiences and education for mentors around supporting placements with improved assessments of competencies is recommended. The training curriculum in medical oncology needs to reflect acquiring knowledge to critically appraise and understand trials in the field of evidence-based medicine while simultaneously acquiring the range of skills and experience needed to participate in clinical trials as an investigator. This curriculum can also be tailored to meet the trainee's needs. Not all trainees will require the same teaching in evidence-based medical education or require the same experiential learning focus depending on the trainee's goals and objectives for the rotation and future endeavours. By making the curriculum able to be tailored to learners' skill sets, the tenets of CBME will be at the forefront of the curriculum. Meaningful clinical trial training can enhance trainees' enthusiasm and confidence for research while improving competence and preparedness for graduation (Stehlik et al. 2020; Smith 2005; Leahy and Sheps 2008).

Expansion of this questionnaire and subsequent clinical trials curriculum to other oncologic specialty training programs (such as hematology-oncology and radiation oncology) or other specialties, in general, can also occur.

CONCLUSION

Clinical trials are a foundational component of the field of medical oncology. Medical oncology subspecialty trainees are willing to participate in clinical trials but are not

competent or prepared to participate as investigators after training. Medical oncology subspecialty programs need to effectively prepare trainees to become competent clinical trial investigators at the end of training by increasing the current CBME requirements for clinical trial education with a focus on clinical placements and in-clinic experiences.

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TABLES AND FIGURES:

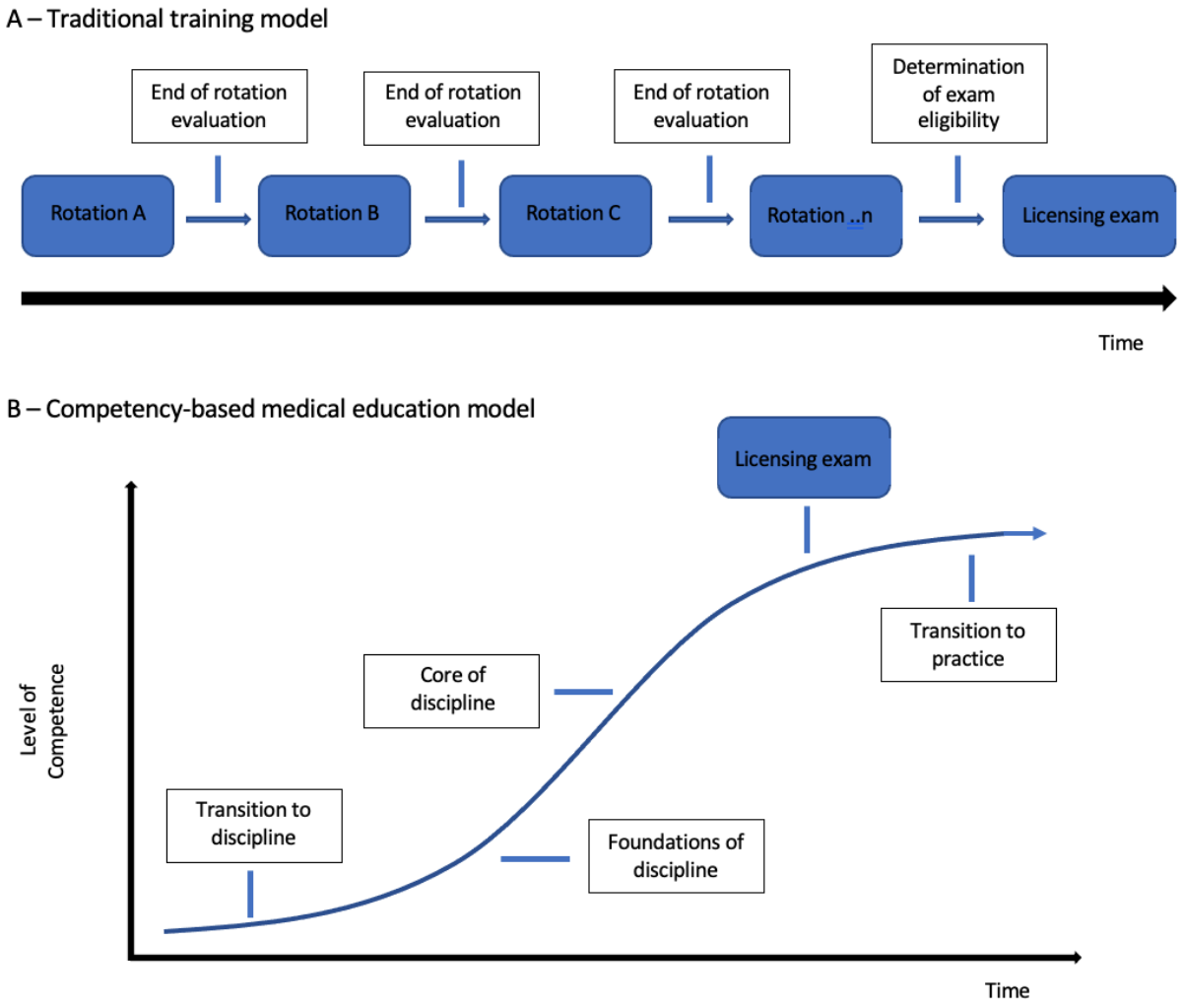

Figure 1: Comparison of the traditional training model (A) to the competency-based medical education (CBME) model (B). In the traditional training model, a time-based approach occurred whereby trainees rotated through different rotations receiving evaluations determining successful completion within the subspecialty program. In the CBME model, trainees progress through four stages of learning: (1) transition to discipline whereby trainees concentrate on orientation to their medical specialty; (2) foundations of discipline whereby trainees focus on predetermined foundational skillsets; (3) core of discipline whereby trainees concentrate on predetermined competencies required within their medical specialty; and (4) transition to practice whereby trainees demonstrate the ability to practice autonomously.

Table 1 – Characteristics of respondents		
Characteristics		Responses – n (%)
N		41
Participant status		
	Resident	10 (24.4)
	Fellow	14 (34.2)
	< 5 years in practice	17 (41.5)
Age		
	Mean (standard deviation)	33 (27, 43)
Gender		
	Male	13 (33.3)
	Female	26 (66.7)
Location of medical oncology subspecialty program		
	Atlantic Canada	3 (7.3)
	Quebec	5 (12.2)
	Ontario	25 (61.0)
	Central/Western Canada	8 (19.5)
Practice setting*		
	Academic	11 (64.7)
	Community	4 (23.5)
	Mixed	2 (11.8)
Graduate Level Degree (Masters or PhD)		
	Yes	16 (41.0)
	No	23 (59.0)
Language of Questionnaire		
	English	37 (90.2)
	French	4 (9.3)
*Practice setting was only asked for in-practice physicians (N = 17)		

Table 2 - Exposure to clinical trials and general research		
Question		Responses – n (%)
In your medical oncology subspecialty, how were you taught about critically appraising a clinical trial?		
	There was no teaching	2 (4.9)
	Didactic lecture	19 (46.3)
	Small group learning	30 (73.2)
	Online/web-based modules	1 (2.4)
	Independent learning	23 (56.1)
	Teaching from clinical trials department	0 (0)
	Teaching while in clinic	19 (46.3)
	Formal education through accredited programming	5 (12.2)
	Other	0 (0)
How adequate was the training regarding clinical trial critical appraisal?		
	Very inadequate	1 (2.4)
	Inadequate	8 (19.5)
	Neutral	8 (19.5)
	Adequate	16 (39.0)
	Very adequate	8 (19.5)
In your medical oncology subspecialty training, how were you taught about clinical trials research methods?		
	There was no teaching	4 (9.8)
	Didactic lectures	20 (48.8)
	Small group learning	24 (58.5)
	Online/web-based modules	0 (0)
	Independent learning	16 (39.0)
	Teaching from clinical trials department	1 (2.4)
	Teaching while in clinic	21 (51.2)
	Formal education through accredited programming	4 (9.9)
	Other	2 (4.9)
How adequate was the training regarding clinical trials research methods?		
	Very inadequate	2 (4.9)
	Inadequate	12 (29.3)
	Neutral	10 (24.4)
	Adequate	13 (31.7)
	Very adequate	4 (9.8)
In your medical oncology subspecialty training, how were you taught about participating in clinical trials as an investigator?		
	There was no teaching	23 (56.1)
	Didactic lectures	2 (4.9)
	Small group learning	1 (2.4)

	Online/web-based modules	2 (4.9)
	Independent learning	5 (12.2)
	Teaching from clinical trials department	2 (4.9)
	Teaching while in clinic	11 (26.8)
	Formal education through accredited programming	1 (2.4)
	Other	1 (2.4)
How adequate was the training regarding becoming a clinical trials investigator?		
	Very inadequate	5 (12.2)
	Inadequate	23 (56.1)
	Neutral	8 (19.5)
	Adequate	4 (9.8)
	Very adequate	1 (2.4)
During your medical oncology subspecialty training, did you participate in the following clinical scenarios:		
	Clinical trial protocol review	6 (14.6)
	Clinical trial consent	15 (36.6)
	Clinical trial eligibility assessment	19 (46.3)
	Assessment of a patient actively enrolled in a clinical trial	31 (75.6)
	None of the above	6 (14.6)
During your medical oncology subspecialty training, did you participate in the following:		
	Clinical trial question development	7 (17.1)
	Clinical trial protocol development	7 (17.1)
	Clinical trial research ethics board (REB) application	9 (22.0)
	Clinical trial funding application	3 (7.3)
	None of the above	27 (65.9)

Table 3 – Self-perceived assessments		
Question		Response – n (%)
Upon completion of your medical oncology subspecialty training, how would you rate your level of competence* to participate in clinical trials as an investigator?		
	Poor	10 (32.3)
	Fair	10 (32.3)
	Good	9 (29.0)
	Very good	2 (6.5)
	Excellent	0 (0)
Upon completion of your medical oncology subspecialty training, how would you rate your level of competence* for the following:		Good to Excellent
	Searching for a CT	24 (77.4)
	Referring a patient for a CT	28 (90.3)
	Discussing a CT as a potential therapeutic option with a patient	29 (93.5)
	Consenting a patient for a CT	24 (77.4)
	Participating in a CT as a steering committee member	10 (32.3)
	Participating in a CT as a principal investigator	8 (25.8)
	Participating in a CT as a sub-investigator	18 (58.1)
	Developing a CT protocol	9 (29.0)
	Applying for CT funding	7 (22.6)
Upon completion of your medical oncology subspecialty training, how will/would you rate your level of preparedness to participate in clinical trials as an investigator?		
	Poor	15 (38.5)
	Fair	14 (35.9)
	Good	9 (23.1)
	Very good	1 (2.6)
	Excellent	0 (0)
Upon completion of your medical oncology subspecialty training, how would you rate your level of preparedness for the following:		Poor to Fair vs Good to Excellent
	Searching for a CT	30 (76.9)
	Referring a patient for a CT	31 (79.5)
	Discussing a CT as a potential therapeutic option with a patient	33 (84.6)
	Consenting a patient for a CT	29 (74.4)
	Participating in a CT as a steering committee member	11 (28.2)
	Participating in a CT as a principal investigator	9 (23.1)
	Participating in a CT as a sub-investigator	18 (46.2)

	Developing a CT protocol Applying for CT funding	11 (28.2) 10 (25.6)
Upon completion of your medical oncology subspecialty training, how will/would you rate your willingness to participate in clinical trials as an investigator?		
	Poor Fair Good Very good Excellent	0 (0) 2 (5.1) 7 (17.8) 17 (43.6) 13 (33.3)
Upon completion of your medical oncology subspecialty training, how would you rate your willingness for the following:		Poor to Fair vs Good to Excellent
	Searching for a CT Referring a patient for a CT Discussing a CT as a potential therapeutic option with a patient Consenting a patient for a CT Participating in a CT as a steering committee member Participating in a CT as a principal investigator Participating in a CT as a sub-investigator Developing a CT protocol Applying for CT funding	37 (94.9) 37 (94.9) 38 (97.4) 38 (97.4) 29 (74.4) 27 (69.2) 31 (79.5) 22 (56.4) 22 (56.4)
CT, clinical trial *Questions regarding competence were not asked to residents (N = 10) as it was determined competence could only be appropriately evaluated after having completed medical oncology subspecialty training.		

Table 4 – Associations of competence

Question	Answer*	N	Good to Excellent Competence n (%)	p-value
In your medical oncology subspecialty, how were you taught about participating in a clinical trial?	There was no teaching	19	4 (21.1)	
	Any teaching present	12	7 (58.3)	0.056
	In clinic teaching*	7	4 (57.1)	
	All other teaching**	24	7 (29.2)	0.21
In your medical oncology subspecialty, how were you taught about critically appraising a clinical trial?	There was no teaching	1	0 (0)	
	Any teaching present	30	11 (36.7)	1.00
	In clinic teaching*	7	4 (57.1)	
	All other teaching**	24	7 (29.2)	0.21
In your medical oncology subspecialty, how were you taught about clinical trials research methods?	There was no teaching	3	1 (33.3)	
	Any teaching present	28	10 (35.7)	1.00
	In clinic teaching*	16	7 (43.7)	
	All other teaching**	15	4 (26.7)	0.46
Are you completing or have you completed a graduate level degree?	No	16	6 (37.5)	
	Yes	13	4 (30.7)	1.00
Upon completion of medical oncology subspecialty training, will you/did you feel the need to seek out additional clinical trials training?	No	13	5 (38.5)	
	Yes	16	5 (31.3)	0.71

*Including clinical trials departmental teaching
**Including responses of no teaching

Table 5 – Associations of preparedness				
Question	Answer*	N	Good to Excellent Preparedness n (%)	p-value
In your medical oncology subspecialty, how were you taught about participating in a clinical trial?	There was no teaching	23	3 (13.0)	
	Any teaching present	16	7 (43.8)	0.060
	In clinic teaching*	10	5 (50.0)	
	All other teaching**	29	5 (17.2)	0.087
In your medical oncology subspecialty, how were you taught about critically appraising a clinical trial?	There was no teaching	2	0 (0)	
	Any teaching present	37	10 (27.0)	1.00
	In clinic teaching*	10	5 (50.0)	
	All other teaching**	29	5 (17.2)	0.087
In your medical oncology subspecialty, how were you taught about clinical trials research methods?	There was no teaching	3	0 (0)	
	Any teaching present	36	10 (27.8)	0.56
	In clinic teaching*	20	7 (35.0)	
	All other teaching**	19	3 (15.8)	0.27
Are you completing or have you completed a graduate level degree?	No	23	8 (34.8)	
	Yes	16	2 (12.5)	0.15
Upon completion of medical oncology subspecialty training, will you/did you feel the need to seek out additional clinical trials training?	No	17	4 (23.5)	
	Yes	22	6 (27.3)	1.00
*Including clinical trials departmental teaching **Including responses of no teaching				

Table 6 – Associations of willingness

Question	Answer*	N	Good to Excellent Willingness n (%)	p-value
In your medical oncology subspecialty, how were you taught about participating in a clinical trial?	There was no teaching	23	17 (73.9)	
	Any teaching present	16	14 (87.5)	0.43
	In clinic teaching*	10	8 (80.0)	
	All other teaching**	29	23 (79.3)	1.00
In your medical oncology subspecialty, how were you taught about critically appraising a clinical trial?	There was no teaching	2	2 (100)	
	Any teaching present	37	29 (78.4)	1.00
	In clinic teaching*	10	8 (80.0)	
	All other teaching**	29	23 (79.3)	1.00
In your medical oncology subspecialty, how were you taught about clinical trials research methods?	There was no teaching	3	2 (66.7)	
	Any teaching present	36	29 (80.6)	0.51
	In clinic teaching*	17	17 (85.0)	
	All other teaching**	19	14 (73.7)	0.45
Are you completing or have you completed a graduate level degree?	No	23	19 (82.6)	
	Yes	16	12 (75.0)	0.69
Upon completion of medical oncology subspecialty training, will you/did you feel the need to seek out additional clinical trials training?	No	17	12 (70.6)	
	Yes	22	19 (86.4)	0.23

*Including clinical trials departmental teaching
**Including responses of no teaching

APPENDIX A - Content Validation

DOMAIN 1: EXPOSURE TO CLINICAL TRIALS AND GENERAL RESEARCH

Definition: The purpose of this domain is to determine:

- How subspecialty trainees are taught about clinical trials in their training
- The exposure to clinical trials in training
- Adequacy of education and exposure to clinical trials

Tested Items	Relevance			
	1	2	3	4
1. In your medical oncology subspecialty, how were you taught about ***critically appraising*** a clinical trial? *(note: critical appraisal is the systematic process used to identify the strengths and weaknesses of a research article)*	☐	☐	☐	☐
2. In your medical oncology subspecialty training, how were you taught about ***clinical trial research methods***?	☐	☐	☐	☐
3. In your medical oncology subspecialty training, how were you taught about becoming a ***clinical trials investigator***?	☐	☐	☐	☐
4. During your medical oncology subspecialty training, were you able to participate in the following: *Check all that apply* • Clinical trials protocol review • Clinical trial consent • Clinical trial eligibility assessment • Assessment of a patient actively enrolled in a clinical trial • None of the above	☐	☐	☐	☐
5. During your medical oncology subspecialty training, did you have formal training in the following: *Check all that apply* • Clinical trial question development • Clinical trial protocol development • Clinical trial research ethics board (REB) application • Clinical trial funding application • None of the above	☐	☐	☐	☐
6. As a medical oncology subspecialty trainee, rate your level of understanding of the following clinical trials concepts: • Non-inferiority design • Sponsor • Serious adverse event • Principal investigator (PI) • Sub-investigator	☐	☐	☐	☐

7. In your medical oncology subspecialty training, how adequate was the training regarding of the following: • Clinical trial critical appraisal • Clinical trial research methods • Becoming a clinical trial investigator	☐	☐	☐	☐

Please provide any suggestions or justifications necessary to support judgments of the above items reviewed in Domain 1:

DOMAIN 2: SELF-PERCEIVED CLINICAL TRIAL COMPETENCE

Definition: The purpose of this domain is to evaluate the participant's level of competence as a clinical trials investigator upon completion of medical oncology subspecialty training. Competence is defined as the ability to do something successfully or efficiently and was chosen to align with the Royal College Competence by Design curriculum.

Tested Items	Relevance			
	1	2	3	4
8. Upon completion of medical oncology subspecialty training, how would you rate your ***competence*** to participate in clinical trials as an investigator? *(Note: competence is defined as the ability to do something successfully or efficiently)*	☐	☐	☐	☐
9. Upon completion of your medical oncology subspecialty training, what was your level of competence for the following: • Searching for a clinical trial for a patient • Referring a patient for a clinical trial • Discussing a clinical trial as a potential therapeutic opportunity with a patient • Participating in a clinical trial as a steering committee member • Participating in a clinical trial as a principal investigator (PI) • Participating in a clinical trial as a sub-investigator • Developing a clinical trial protocol • Applying for clinical trial drug funding	☐	☐	☐	☐

Please provide any suggestions or justifications necessary to support judgments of the above items reviewed in Domain 2:

DOMAIN 3: SELF-PERCEIVED CLINICAL TRIAL PREPAREDNESS

Definition: The purpose of this domain is to evaluate the participant's level of preparedness as a clinical trials investigator upon completion of medical oncology subspecialty training. Preparedness is defined as a state of readiness.

Tested Items	Relevance			
	1	2	3	4
10. Upon completion of medical oncology subspecialty training, how would you rate your preparedness to participate in clinical trials as an investigator? *(Note: preparedness is defined as a state of readiness)*	☐	☐	☐	☐
11. Upon completion of your medical oncology subspecialty training, how would you rate your preparedness for the following: • Searching for a clinical trial for a patient • Referring a patient for a clinical trial • Discussing a clinical trial as a potential therapeutic opportunity with a patient • Participating in a clinical trial as a steering committee member • Participating in a clinical trial as a principal investigator (PI) • Participating in a clinical trial as a sub-investigator • Developing a clinical trial protocol • Applying for clinical trial drug funding	☐	☐	☐	☐

Please provide any suggestions or justifications necessary to support judgments of the above items reviewed in Domain 3:

DOMAIN 4: WILLINGNESS TO PARTICIPATE IN CLINICAL TRIALS

Definition: The purpose of this domain is to evaluate how willing a participant is to participate in clinical trials as an investigator upon completion of medical oncology subspecialty training.

Tested Items	Relevance			
	1	2	3	4
12. Upon completion of medical oncology subspecialty training, how would you rate your willingness to participate in clinical trials as an investigator?	☐	☐	☐	☐
13. Upon completion of your medical oncology subspecialty training, how would you rate your willingness for the following: • Searching for a clinical trial for a patient • Referring a patient for a clinical trial • Discussing a clinical trial as a potential therapeutic opportunity with a patient • Participating in a clinical trial as a steering committee member • Participating in a clinical trial as a principal investigator (PI) • Participating in a clinical trial as a sub-investigator • Developing a clinical trial protocol • Applying for clinical trial drug funding	☐	☐	☐	☐
14. Upon completion of medical oncology subspecialty training, did you feel the need to seek out additional clinical trials training?	☐	☐	☐	☐

Please provide any suggestions or justifications necessary to support judgments of the above items reviewed in Domain 4:

DOMAIN 5: PERCEIVED ROLE OF THE TRAINEE TO SEEK CLINICAL TRIALS EXPERIENCES DURING TRAINING

Definition: The purpose of this domain is to explore the trainee and the subspecialty program role in providing clinical trial experiences and education during training.

Tested Items	Relevance			
	1	2	3	4
15. When choosing a medical oncology subspecialty training program, did the quality of the clinical trials training effect your choice of school?	☐	☐	☐	☐
16. How important do you feel a structured clinical trials curriculum is in medical oncology subspecialty training?	☐	☐	☐	☐
17. What is your level of agreement with the following statements:				
a) It is the role of the trainee to seek experiences in clinical trials during training	☐	☐	☐	☐
b) It is the role of the trainee to prepare oneself to participate in clinical trials as an investigator	☐	☐	☐	☐
c) It is the role of the training program to ensure adequate clinical trials education	☐	☐	☐	☐
d) It is the role of the training program to prepare its trainees to participate in clinical trials as an investigator	☐	☐	☐	☐

Please provide any suggestions or justifications necessary to support judgments of the above items reviewed in Domain 5:

APPENDIX B – Content Validation Data

	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Experts in Agree-ment	I-CVI	UA	Mod UA
Item										
Q1	1	1	1	0	1	1	5	0.83	0	0
Q2	1	1	1	1	1	1	6	1	1	1
Q3	1	1	1	1	1	1	6	1	1	1
Q4	1	1	1	1	1	1	6	1	1	1
Q5	1	1	1	1	1	1	6	1	1	1
Q6	1	0	0	1	1	1	4	0.67	0	-
Q7	1	1	1	1	1	1	6	1	1	1
Q8	1	1	1	1	1	1	6	1	1	1
Q9	1	1	1	1	1	1	6	1	1	1
Q10	1	1	0	1	1	1	5	0.83	0	0
Q11	1	1	1	1	1	1	6	1	1	1
Q12	1	1	1	1	1	1	6	1	1	1
Q13	1	1	1	1	1	1	6	1	1	1
Q14	1	1	0	1	1	1	5	0.83	0	0
Q15	0	1	0	1	1	1	4	0.67	0	-
Q16	1	1	1	1	1	1	6	1	1	1
Q17a	1	1	1	1	1	1	6	1	1	1
Q17b	1	1	1	1	1	1	6	1	1	1
Q17c	1	1	1	1	1	1	6	1	1	1
Q17d	1	1	1	1	1	1	6	1	1	1
							S-CVI/Ave	0.94	-	-
							S-CVI/UA	-	0.75	-
							S-CVI/UA	-	-	0.83
Proportion Relevance	0.95	0.95	0.80	0.95	1.00	1.00				
Average proportion of items judged as relevant across the 6 experts							0.94			

Ave, average; I-CVI, item CVI and is calculated by dividing the number of experts in agreement by the total number of experts for each item; S-CVI, scale-CVI; UA, universal agreement; S-CVA/Ave is the average of the I-CVI scores for all items; S-CVI/UA is the proportion of items on the scale that achieved relevance

APPENDIX C – English Questionnaire

Domain 1: Exposure to clinical trials and general research

Q1.1: In your medical oncology subspecialty, how were you taught about ***critically appraising*** a clinical trial?
(Note: a critical appraisal is a systematic process used to identify the strengths and weaknesses of a research article)

Click all that apply

☐ There was no teaching
☐ Didactic lectures during academic days
☐ Small group learning (including case-based sessions and journal clubs)
☐ Online/web-based modules
☐ Independent learning
☐ Teaching through clinical trials department or clinical trials educator
☐ Teaching while in clinic
☐ Formal education through accredited programming (ie CCTG, ASCO, ESMO, etc)
☐ Other: _____

Q1.2: In your medical oncology subspecialty training, how were you taught about ***clinical trial research methods***?
Click all that apply

☐ There was no teaching
☐ Didactic lectures during academic days
☐ Small group learning (including case-based sessions and journal clubs)
☐ Online/web-based modules
☐ Independent learning
☐ Teaching through clinical trials department or clinical trials educator
☐ Teaching while in clinic
☐ Formal education through accredited programming (ie CCTG, ASCO, ESMO, etc)
☐ Other: _____

Q1.3: In your medical oncology subspecialty training, how were you taught about participating in clinical trials as an ***investigator***?
(Note: an investigator is the person responsible for the conduct of a clinical trial at a trial site)

Click all that apply

☐ There was no teaching
☐ Didactic lectures during academic days
☐ Small group learning (including case-based sessions and journal clubs)
☐ Online/web-based modules
☐ Independent learning
☐ Teaching through clinical trials department or clinical trials educator
☐ Teaching while in clinic
☐ Formal education through accredited programming (ie CCTG, ASCO, ESMO, etc)
☐ Other: _____

Q1.4: During your medical oncology subspecialty training, did you participate in the following:
Click all that apply

☐ Clinical trials protocol review
☐ Clinical trial consent
☐ Clinical trial eligibility assessment
☐ Assessment of a patient actively enrolled in a clinical trial
☐ None of the above

Q1.5: During your medical oncology subspecialty training, did you participate in the following:
Click all that apply

☐ Clinical trial question development
☐ Clinical trial protocol development
☐ Clinical trial research ethics board (REB) application

☐ Clinical trial funding application
☐ None of the above

Q1.6: In your medical oncology subspecialty training, how adequate was the training regarding the following: *(Note: Adequacy refers to whether the amount of training provided is sufficient to be the investigator of a clinical trial)*						
	Very inadequate	Inadequate	Neutral	Adequate	Very adequate	N/A
Clinical trial critical appraisal	☐	☐	☐	☐	☐	☐
Clinical trial research methods	☐	☐	☐	☐	☐	☐
Becoming a clinical trials investigator	☐	☐	☐	☐	☐	☐

Domain 2: Self-perceived clinical trial competence

The following questions will only be asked of staff and fellows – discussions in our meetings determined that residents may not be able to appropriately assess their competence in this domain.

Q2.1: Upon completion of medical oncology subspecialty training, how would you rate your ***competence*** to participate in clinical trials as an investigator?
(*note: competence is defined as the ability to do something successfully or efficiently)*
(Note: an investigator is the person responsible for the conduct of a clinical trial at a trial site)

☐ Poor
☐ Fair
☐ Good
☐ Very good
☐ Excellent

Q2.2: Upon completion of your medical oncology subspecialty training, how would you rate your ***level of competence*** for the following:

	Poor	Fair	Good	Very good	Excellent
Searching for a clinical trial for a patient	☐	☐	☐	☐	☐
Referring a patient for a clinical trial	☐	☐	☐	☐	☐
Discussing a clinical trial as a potential therapeutic opportunity with a patient	☐	☐	☐	☐	☐
Consenting a patient for a clinical trial	☐	☐	☐	☐	☐
Participating in a clinical trial as a steering committee member	☐	☐	☐	☐	☐
Participating in a clinical trial as a principal investigator (PI)	☐	☐	☐	☐	☐
Participating in a clinical trial as a sub-investigator	☐	☐	☐	☐	☐
Developing a clinical trial protocol	☐	☐	☐	☐	☐
Applying for clinical trial funding	☐	☐	☐	☐	☐

Domain 3: Self-perceived preparedness to participate in clinical trials as an investigator

Q3.1: Upon completion of medical oncology subspecialty training, how will/would you rate your ***preparedness*** to participate in clinical trials as an investigator?
(*Note: preparedness is defined as a state of readiness to take on the role of a clinical trial investigator)*
(Note: an investigator is the person responsible for the conduct of a clinical trial at a trial site)

☐ Poor
☐ Fair
☐ Good
☐ Very good
☐ Excellent

Q3.2: Upon completion of your medical oncology subspecialty training, how will/would you rate your ***preparedness*** for the following:					
	Poor	Fair	Good	Very good	Excellent
Searching for a clinical trial for a patient	☐	☐	☐	☐	☐

Referring a patient for a clinical trial	☐	☐	☐	☐	☐
Discussing a clinical trial as a potential therapeutic opportunity with a patient	☐	☐	☐	☐	☐
Consenting a patient for a clinical trial	☐	☐	☐	☐	☐
Participating in a clinical trial as a steering committee member	☐	☐	☐	☐	☐
Participating in a clinical trial as a principal investigator (PI)	☐	☐	☐	☐	☐
Participating in a clinical trial as a sub-investigator	☐	☐	☐	☐	☐
Developing a clinical trial protocol	☐	☐	☐	☐	☐
Applying for clinical trial funding	☐	☐	☐	☐	☐

Domain 4: Willingness to participate in clinical trials as an investigator

Q4.1: Upon completion of medical oncology subspecialty training, how will/would you rate your ***willingness*** to participate in clinical trials as an investigator:
(Note: an investigator is a person responsible for the conduct of a clinical trial at a trial site)

☐ Poor
☐ Fair
☐ Good
☐ Very good
☐ Excellent

Q4.2: Upon completion of your medical oncology subspecialty training, how will/would you rate your ***willingness*** for the following:					
	Poor	Fair	Good	Very good	Excellent
Searching for a clinical trial for a patient	☐	☐	☐	☐	☐
Referring a patient for a clinical trial	☐	☐	☐	☐	☐

Discussing a clinical trial as a potential therapeutic opportunity with a patient	☐	☐	☐	☐	☐
Consenting a patient for a clinical trial	☐	☐	☐	☐	☐
Participating in a clinical trial as a steering committee member	☐	☐	☐	☐	☐
Participating in a clinical trial as a principal investigator (PI)	☐	☐	☐	☐	☐
Participating in a clinical trial as a sub-investigator	☐	☐	☐	☐	☐
Developing a clinical trial protocol	☐	☐	☐	☐	☐
Applying for clinical trial funding	☐	☐	☐	☐	☐

Domain 5: Perceived role of the trainee to seek clinical trials experiences during training

Q5.1: How important do you feel a structured clinical trials curriculum is in medical oncology subspecialty training?

☐ Not at all important
☐ Low importance
☐ Slightly important
☐ Neutral
☐ Moderately important
☐ Very important
☐ Extremely important

Q5.2: What is your level of agreement with the following statements:							
	Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
It is the role of the trainee to seek experiences in clinical trials during training	☐	☐	☐	☐	☐	☐	☐

It is the role of the trainee to prepare oneself to participate in clinical trials as an investigator	☐	☐	☐	☐	☐	☐	☐
It is the role of the training program to ensure adequate clinical trials education	☐	☐	☐	☐	☐	☐	☐
It is the role of the training program to prepare its trainees to participate in clinical trials as an investigator	☐	☐	☐	☐	☐	☐	☐

Q5.3a: Upon completion of medical oncology subspecialty training, do/did you feel the need to seek out additional clinical trials training?

☐ Yes
☐ No

Q5.3b: If yes, please list the additional clinical trials training received? *Free text option for this answer*

Demographic Information – Screening Questions
To be asked at the beginning of the survey

Q: Did you complete or are you currently completing medical oncology subspecialty training in Canada?

☐ Yes
☐ No

Q: Where did you receive your medical oncology subspecialty training in Canada?
Note only provinces with medical oncology subspecialty training programs are included below

☐ Atlantic Canada (Newfoundland and Labrador, Nova Scotia)
☐ Quebec
☐ Ontario

☐ Central/Western Canada (Manitoba, Alberta, British Columbia)

Q: How long have you been independently practicing in medical oncology in Canada?

☐ I am a resident
☐ I am a fellow
☐ I have been in practice for 5 years or less
☐ I have been in practice for more than 5 years

Q: If you are a medical oncology staff, what is your current practice setting

☐ Academic
☐ Community
☐ Mixed

Demographic Information – Screening Questions
To be asked at the end of the survey

Q: What is your age? *Free text option for this answer*

Q: What is your gender?

☐ Male
☐ Female
☐ Non-binary
☐ Prefer not to disclose

Qa: Are you completing or have you completed a graduate-level degree (Masters or Ph.D.)

☐ Yes
☐ No

Qb: If yes, what degree are you completing or have you completed? *Free text option for this answer*

APPENDIX E – French Questionnaire

Premier Domaine: Enseignement en essais cliniques et recherche générale

Q1.1: Dans votre enseignement de surspécialité en oncologie médicale, comment avez-vous appris à **évaluer de manière critique** un essai clinique?

(Notez bien: l'évaluation critique est la méthode systématique d'identification des forces et des faiblesses d'un article de recherche)

Désigner tout ce qui s'applique

☐ il n'y avait pas d'enseignement
☐ cours didactiques pendant les sessions académiques
☐ apprentissage en petit groupe
☐ modules basés sur Internet
☐ étude indépendante
☐ enseignement avec le département des essais cliniques
☐ enseignement en clinique
☐ enseignement avec un programme accrédité (p.ex. CCTG, ASCO, ESMO, etc.)
☐ Autre: _____

Q1.2: Dans votre enseignement de surspécialité en oncologie médicale, comment avez-vous appris **la méthodologie de recherche** sur les essais cliniques?

Désigner tout ce qui s'applique

☐ il n'y avait pas d'enseignement
☐ cours didactiques pendant les sessions académiques
☐ apprentissage en petit groupe
☐ modules basés sur Internet
☐ étude indépendante

☐ enseignement avec le département des essais cliniques
☐ enseignement en clinique
☐ enseignement avec un programme accrédité (p.ex. CCTG, ASCO, ESMO, etc.)
☐ Autre: _____

Q1.3: Dans votre enseignement de surspécialité en oncologie médicale, comment avez-vous **appris à participer à des essais cliniques** en tant qu'investigateur?

(Notez bien: Un investigateur est la personne responsable pour la conduite d'un essai clinique à *un site)*

Désigner tout ce qui s'applique

☐ il n'y avait pas d'enseignement
☐ cours didactiques pendant les sessions académiques
☐ apprentissage en petit groupe
☐ modules basés sur Internet
☐ étude indépendante
☐ enseignement avec le département des essais cliniques
☐ enseignement en clinique
☐ enseignement avec un programme accrédité (p.ex. CCTG, ASCO, ESMO, etc.)
☐ Autre: _____

Q1.4: Dans votre enseignement de surspécialité en oncologie médicale, avez-vous **participé** aux activités suivantes:

Choisir tout ce qui s'applique

☐ évaluer un protocole d'essai clinique
☐ consentement à l'essai clinique
☐ évaluation de l'admissibilité d'un patient aux essais cliniques
☐ évaluation d'un patient enrôlé dans un essai clinique
☐ aucune de ces réponses

Q1.5: Dans votre enseignement de surspécialité en oncologie médicale, avez-vous participé aux activités suivantes:

Désigner tout ce qui s'applique

☐ développement de questions pour un essai clinique
☐ développement d'un protocole d'essai clinique
☐ soumission d'une application au comité d'éthique de la recherche sur les essais cliniques
☐ soumission d'une application de financement d'essais cliniques
☐ aucune de ces réponses

Q1.6: Dans votre enseignement de surspécialité en oncologie médicale, dans quelle mesure l'enseignement a-t-elle *été adéquate concernant les éléments suivants:*

(Notez bien: adéquat fait référence à la question de savoir si l'enseignement est suffisant ou non pour devenir un chercheur en essais cliniques)

	Très insuffisant	Insuffisant	Neutre	Suffisant	Très suffisant	N/A
Évaluation des essais cliniques	☐	☐	☐	☐	☐	☐
Méthodes de recherche d'essais cliniques	☐	☐	☐	☐	☐	☐
Devenir chercheur en essais cliniques	☐	☐	☐	☐	☐	☐

Deuxième Domaine: Auto-évaluation des compétence dans les essais cliniques

Q2.1: à la fin de l'enseignement de surspécialité en oncologie médicale, comment évalueriez-vous votre compétence pour participer à des essais cliniques en tant qu'investigateur?

(Notez bien: compétence est définie comme la capacité de faire quelque chose avec succès)
(Notez bien: un investigateur est la personne responsable à la conduite d'un essai clinique à leur centre)

☐ Pauvre
☐ Passable
☐ Bon
☐ Très bien
¨ Excellent

Q2.2: à la fin de l'enseignement de surspécialité en oncologie médicale, comment évalueriez-vous votre niveau de compétence pour les éléments suivants:					
	Pauvre	Passable	Bon	Très bien	Excellent
Trouver un essai clinique pour un patient	☐	☐	☐	☐	☐
Référer un patient pour un essai clinique	☐	☐	☐	☐	☐
Discuter d'une opportunité d'essai clinique avec un patient	☐	☐	☐	☐	☐
Consentir un patient à un essai clinique	☐	☐	☐	☐	☐
Participer en tant que membre du comité directeur d'un essai clinique	☐	☐	☐	☐	☐
Participer à un essai clinique en tant que chercheur principal	☐	☐	☐	☐	☐
Participer à un essai clinique en tant que sous-investigateur	☐	☐	☐	☐	☐
Développer un protocole d'essai clinique	☐	☐	☐	☐	☐
Faire la demande de financement pour un essai clinique	☐	☐	☐	☐	☐

Troisième domaine: auto-évaluation de l'état de préparation à pouvoir participer à des essais cliniques en tant qu'investigateur

Q3.1: à la fin de l'enseignement de surspécialité en oncologie médicale, comment évalueriez-vous votre **état de préparation** à participer à des essais cliniques en tant qu'investigateur?

(Notez bien: préparation est définie comme le fait d'être prêt à assumer le rôle d'investigateur)

(Notez bien: un investigateur est la personne responsable pour la conduite d'un essai clinique à leur centre)

☐ Pauvre
☐ Passable
☐ Bon
☐ Très bien
☐ Excellent

Q3.2: à la fin de l'enseignement de surspécialité en oncologie médicale, comment évalueriez-vous votre état de préparation pour les éléments suivants:					
	Pauvre	Passable	Bon	Très bien	Excellent
Trouver un essai clinique pour un patient	☐	☐	☐	☐	☐
Référer un patient pour un essai clinique	☐	☐	☐	☐	☐
Discuter d'une opportunité d'essai Clinique avec un patient	☐	☐	☐	☐	☐
Consenter un patient à un essai clinique	☐	☐	☐	☐	☐
Participer en tant que membre du comité de pilotage à un essai clinique	☐	☐	☐	☐	☐
Participer à un essai clinique en tant que chercheur principal	☐	☐	☐	☐	☐
Participer à un essai clinique en tant que sous-investigateur	☐	☐	☐	☐	☐
Développer un protocol d'essai clinique	☐	☐	☐	☐	☐
Demander un financement pour un essai clinique	☐	☐	☐	☐	☐

Quatrième domaine: volonté de participer à des essais cliniques en tant qu'investigateur

Q4.1: à la fin de l'enseignement de surspécialité en oncologie médicale, comment évalueriez-vous votre **volonté** à participer à des essais cliniques en tant qu'investigateur?

(Notez bien: un investigateur est la personne responsable pour la conduite d'un essai clinique à leur centre)

☐ Pauvre
☐ Passable
☐ Bon
☐ Très bien
☐ Excellent

Q4.2: à la fin de l'enseignement de surspécialité en oncologie médicale, comment évalueriez-vous votre volonté pour les éléments suivants:					
	Pauvre	Passable	Bon	Très bien	Excellent
Trouver un essai clinique pour un patient	☐	☐	☐	☐	☐
Référer un patient pour un essai clinique	☐	☐	☐	☐	☐
Discuter d'une opportunité d'essai Clinique avec un patient	☐	☐	☐	☐	☐
Consenter un patient à un essai clinique	☐	☐	☐	☐	☐
Participer en tant que membre du comité de pilotage à un essai clinique	☐	☐	☐	☐	☐
Participer à un essai clinique en tant que chercheur principal	☐	☐	☐	☐	☐
Participer à un essai clinique en tant que sous-investigateur	☐	☐	☐	☐	☐
Développer un protocol d'essai clinique	☐	☐	☐	☐	☐
Demander un financement pour un essai clinique	☐	☐	☐	☐	☐

Cinquième domaine: rôle *perçu du stagiaire pour identifier des expériences* en essais cliniques pendant l'enseignement de surspécialité en oncologie médicale

Q5.1: Quelle est l'importance d'un programme éducationnel structuré en essais clinique pendant l'enseignement de surspécialité en oncologie médicale

☐ Pas important du tout
☐ faible importance
☐ peu important
☐ neutre
☐ d'importance modérée
☐ très important
☐ extr*ê*mement important

Q5.2: Quel est votre niveau d'accord avec les affirmations suivantes:							
	Pas du tout d'accord	*Plutôt en d*ésaccord	Quelque peu en *d*ésaccord	Ni d'accord ni en *d*ésaccord	plut*ôt d'accord*	d'accord	Tout à fait d'accord
C'est le rôle *du stagiaire de trouver des expériences* d'essais cliniques pendant l'enseignement de surspécialité en oncologie médicale	☐	☐	☐	☐	☐	☐	☐
C'est le rôle *du stagiaire de se préparer* à participer à des essais cliniques en tant qu'investigateur	☐	☐	☐	☐	☐	☐	☐
C'est le rôle du programme de surspécialité en oncologie médicale d'assurer une formation adéquate sur les essais cliniques	☐	☐	☐	☐	☐	☐	☐
C'est le rôle du programme de surspécialité en oncologie médicale de préparer ses stagiaires à pouvoir participer à des essais cliniques en tant qu'investigateur	☐	☐	☐	☐	☐	☐	☐

Q5.3a: à la fin de vote formation de surspécialité en oncologie médicale, avez-vous ressenti le besoin de rechercher une formation supplémentaire en essais cliniques?

☐ Oui
☐ Non

Q5.3b: si oui, veuillez énumérer la formation supplémentaire re*çue*

Informations démographiques
Demander au début

Q: Avez-vous fini ou *ê*tes-vous en train de finir une formation de surspécialité en oncologie médicale au Canada?

☐ Oui
☐ Non

Q: O*ù a eu lieu votre formation* de surspécialité en oncologie médicale au Canada?

☐ Maritimes (Terre-Neuve-et-Labrador, Nouvelle-Écosse)
☐ Québec
☐ Ontario
☐ Centre et ouest du Canada (Manitoba, Alberta, Colombie britannique)

Q: Depuis combien de temps êtes-vous en pratique indépendante en oncologie médicale?

☐ je suis un résident
☐ je suis un « fellow » (boursier)
☐ je pratique depuis 5 ans ou moins
☐ je pratique depuis plus de 5 ans

Q: si vous pratiquez en oncologie médicale, o*ù* est votre pratique actuelle?

☐ pratique académique
☐ pratique communautaire
☐ pratique mixte

Informations démographiques
Demander a la fin

Q: Quel âge avez-vous?

Q: Quel est votre sexe?

- ☐ Mâle
- ☐ Femelle
- ☐ Non-binaire
- ☐ Préfère ne pas divulguer

Qa: Avez-vous fini ou *ê*tes-vous en train de finir un diplôme d'études supérieures (maitrise ou doctorat)

- ☐ Oui
- ☐ Non

Qb: si oui, veuillez énumérer le(s) diplôme(s) d'études supérieures re*çu(s)*