Canadian Cancer Trials Group

“How to Get Engaged”

2019 New Investigators Clinical Trial Course

Janet Dancey, MD, FRCPC
Director, Canadian Cancer Trials Group
Session Name: How to Get Engaged.

Educational Objectives:

To review:

1. How to become a CCTG investigator and committee member
2. Opportunities for investigators
3. How to engage with the CCTG
Canadian Member Centres

• All centres in Canada providing medical care to cancer patients are eligible to become a member centre

• Membership package is assessed and Participating Centre Agreement is executed:
  • Established oncology or malignant hematology practice and a commitment to participation and enrollment
  • Adequate resources and Standard Operating Procedures, including compliance with applicable regulations and guidelines
  • Established system for ethical review and pharmacy, laboratory, and imaging facilities
  • Designated leaders that will serve in institutional specific roles

• Continued membership requires trial activation, accrual, and compliance with audit and monitoring
Canadian Member Centre Roles

- **Centre Representatives**: Investigators who lead coordination of all CCTG trials activated at their centre and who are the main liaison between the centre and the OSC

- **Contact Clinical Research Associates (CCRA)**: Senior CRA responsible for overseeing and reporting centre activities with respect to CCTG trials

- **Ethics Representative (EREP)**: Institutional contact for issues relating to REB review of consents, protocols, and amendments; Main contact with OSC to ensure dissemination of new policies and procedures that apply across trials

- **Contact Pharmacist**: Responsible for oversight of processes related to the receiving, handling, dispensing, and accountability of IMP
CCTG Centre Representative

• Centre Representative assumes overall responsibility for liaising with CCTG.

• Duties include:
  • Function as overall ‘principal investigator’.
  • Communication to and from the CCTG.
  • Supervise the establishment of a mechanism for distributing per case funding.
  • Appoint, in conjunction with central office, committee and subcommittee members.
  • Participate in the nomination of investigators/CRAs for the participant’s meeting.
  • Receive and, if necessary, respond to the periodic assessments of centre performance.
  • Supervise the implementation of corrective measures.
How to Become a CCTG Investigator

• Qualified, practicing at a current CCTG member site, undergone training, provided documentation.

• Credentialing Requirements
  • Register with CCTG as an investigator and annually renew registration.
    • CCTG Investigator Registration Form
    • Current curriculum vitae (CV).

• Additional credentialing requirements for participation as an investigator on CCTG clinical trials.
  • Completion of GCP training program
  • Completion of training in the Protection of Human Research Participants
  • Annual completion of NCI CTEP Investigator Registration; required for all investigators participating on trials sponsored by NCI CTEP
  • Completion of Health Canada Qualified Investigator Undertaking Form; only required for QIs participating on trials under a Clinical Trials Application (CTA) in Canada
Investigator Training

https://www.ctg.queensu.ca/public/toolbox

Training

NIH Ethics Training - Protecting Human Research Participants: NIH Office of Extramural Research

GCP - Good Clinical Practice

Division 5 part C

Site Training Utility - Protocol specific training

Canadian Cancer Trials Group Supplementary Training Module
Committees

Scientific Committees
- Disease Sites
- IND Program
- Endpoints

Oversight Committees
- Clinical Trials
- Data Safety Monitoring
- Strategic Executive Advisory

Support Committees
- CRA
- Pharmacy
- Auditing Monitoring
- Lay/Patient
- Centre Representative
- RTQA

1. Brain*
2. Breast
3. GI
4. GU
5. Gyne
6. Hematology
7. H&N*
8. Lung
9. Melanoma*
10. Sarcoma*
11. Symptom Control

1. Quality of Life
2. Economic Analysis
3. Correlative Biology/Banking

*Rare cancer initiative

> 80 member sites and 2,100 Investigators

Operations and Statistics Centre at Queen’s (100 Staff & 12 Faculty)
Scientific Committee Structure

• Chair/co-chair – National/internationally recognized in the field.

• Executive – Established investigators with required expertise, demonstrated ability and commitment to lead, develop, participate in trials.

• Members – Investigators with interest/expertise, committed to participate in committee activities, appointed by their centre representative.

https://www.ctg.queensu.ca/private/terms-reference
How to Become a Committee Member

• Disease site committees
  • Talk to your CCTG centre representative

• Endpoint committees
  • Talk to the committee chairs/senior investigator

• Support committees
  • Discipline/role specific committees for Centre Representatives, CRA, pharmacy, patients, RTQA

• Oversight committees
  • Recommendations are solicited from current leadership/members and confirmed by the Director

https://www.ctg.queensu.ca/public/disease-site-ind-committees
https://www.ctg.queensu.ca/public/standing-committees
https://www.ctg.queensu.ca/private/terms-reference (ToR and committee contacts)
How to Become a Study Chair

Have an idea
Discuss it with the committee leadership to refine and get buy-in
Submit a proposal to the clinical trial committee for review (or IND executive)

Review assessed by:
1. Priority of the study question
2. Background and rationale
3. Trial methodology
4. Relevant correlative questions
5. Feasibility
6. Site committee-specific strategic priorities

Approval leads to protocol development and activation steps
New Investigator Education

- Annual Spring Meeting of Participants
- Fellowships
- Biennial New Investigator Clinical Trials Course
- Clinical Trials Practicum
- Clinical Trial Participation
- Secondary Analyses
NEW INVESTIGATOR CLINICAL TRIALS COURSE
KINGSTON 2019
Fellowships

Also, studentships and sabbatical opportunities

https://www.ctg.queensu.ca/public/fellowships
CCTG New Investigators Clinical Trial Practicum

• Purpose: to deliver a training program that includes practical trial experience at cancer sites throughout Canada over a one-year period.

• Cancer Investigator Certificate as proof of their expertise.
  • A 12-month curriculum
    • Attendance at young investigators workshop at the Spring Meeting.
    • Observer-ships at CCTG disease site committee meetings and CCTG oversight committees;
    • Teaching and mentorship on practical aspects clinical trial conduct in Kingston at OSC, at site and on Audit/Monitoring visit(s).
    • Direct clinical trial mentorship at the Site with involvement in a CCTG clinical trial.
    • Participation in the CCTG New Investigator Alumni.

• CCTG sends a call for applicants early in the Calendar year.
  • Eligible applicants will be within the first two years of their first faculty position (fellows transitioning into faculty at that site will be eligible).
  • The site must be participating in, or agree to activate, one of the active CCTG led clinical trials.
  • The local Principal Investigator of the trial must agree to be an active mentor
  • The centre representative must confirm site support for the applicant.

• Completion: Cancer Trials Investigator Certificate at the next annual scientific meeting
## New Investigator Practicum 2018-2019

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Sonia Cerquozzi</th>
<th>Adrian Sacher</th>
<th>Osama Souied</th>
<th>Derek Tsang</th>
<th>Josee-Lynn Ethier</th>
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<tbody>
<tr>
<td>Mentor</td>
<td>Carolyn Owen</td>
<td>Penny Bradbury</td>
<td>Haji Chalchal</td>
<td>Warren Mason</td>
<td>Jim Biagi</td>
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<tr>
<td>Centre Rep</td>
<td>Patricia Tang</td>
<td>Penny Bradbury</td>
<td>Haji Chalchal</td>
<td>Penny Bradbury</td>
<td>Aamer Mahmud</td>
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<tr>
<td>Institution</td>
<td>Tom Baker, Calgary</td>
<td>UHN/PM, Toronto</td>
<td>Allan Blair, Regina</td>
<td>UHN/PM, Toronto</td>
<td>CCSEO, Kingston</td>
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<tr>
<td>Committee</td>
<td>Heme</td>
<td>Lung</td>
<td>GI</td>
<td>Brain</td>
<td>Gyne</td>
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Funding provided by: Gill Radcliffe Foundation, EMD Serono Canada

## New Investigator Practicum 2019-2020 Class

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Ali Hosni Abdalaty</th>
<th>Ayesha Bashir</th>
<th>Jacques Raphael</th>
<th>Aly Khan Lalani</th>
<th>Thai-Hoa Tran</th>
<th>Terry Ng</th>
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<td>Jolie Ringash</td>
<td>Haji Chalchal</td>
<td>Stephen Welch</td>
<td>Rosalyn Juergens</td>
<td>Julie Bergeron</td>
<td>John Hilton</td>
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<td>Centre Rep</td>
<td>Penny Bradbury</td>
<td>Haji Chalchal</td>
<td>Scott Ernst</td>
<td>Rosalyn Juergens</td>
<td>Yvan Samson/Lucas Sideris</td>
<td>Rachel Goodwin</td>
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<tr>
<td>Centre</td>
<td>UHN/PMCC, Toronto</td>
<td>Allan Blair, Regina</td>
<td>London</td>
<td>Juravinski, Hamilton</td>
<td>Ste-Justine, Montreal</td>
<td>Ottawa</td>
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<td>Committee</td>
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<td>Head and Neck</td>
<td>Lung</td>
<td>GU</td>
<td>Hematology</td>
<td>Breast</td>
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Funding provided by: Gilead Sciences, EMD Serono Canada
Recognition Awards

- Elizabeth Eisenhauer Early Drug Development Young Investigator Award
- Ralph Meyer Phase III Program Young Investigator Award
- Frances Shepherd Travel Award
Strategic Plan 2016-2021 Enabling Strategies

- Engaging patients as partners
- Network revitalization
- Modernizing trial capabilities & platforms
- Strengthening portfolio management
- Communications
- Sustainable funding
# CCTG Investigator Engagement

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<thead>
<tr>
<th></th>
<th>Website member access</th>
<th>Scientific meeting</th>
<th>Secondary analyses</th>
<th>Trial Chair/Cttees</th>
<th>Scientific Cttees Member</th>
<th>Scientific Cttees Exec</th>
<th>Oversight Cttees</th>
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<tr>
<td>Trainees</td>
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<td>Non-funded Invitation</td>
<td>Y</td>
<td>-</td>
<td>Observer</td>
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<td>Young Inv</td>
<td>Y</td>
<td>Funded Invitation</td>
<td>Y</td>
<td>New Curriculum</td>
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<tr>
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<td>Y</td>
<td>Y</td>
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<tr>
<td>Senior Inv</td>
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<td>Funded Invitation</td>
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<td>Y</td>
<td>Y</td>
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Strategic Planning Cycle for 2021-2026 Plan

1. External CCTG Reviews (multiple)
   - CCSRI 2016, CFI 2016, NCTN 2018, CFI MidTerm 2019 (next)

2. Internal CCTG Review of progress against current Strategic Plan and Grants
   - 3Q2019

3. Environmental Scanning and Stakeholder Interviews
   - 4Q2019

4. OSC Retreat and Portfolio Discussions
   - 1Q2020

5. Strategic Planning Retreats with Network Leadership
   - Feb 2020 & April 2020

6. Plan Development
   - 3Q2020

7. Plan Presentation & Dissemination
   - 4Q2020

8. Final Strategic Plan
   - 4Q2020

Open to new YI initiatives and activities.
Send your investigator engagement ideas!
Why to Engage with CCTG-Top Ten Reasons

1. A critical mission – to find the best treatment for cancer patients
2. Trials that improve outcomes
3. Results that change practice
4. A national mandate
5. A global reach
6. Constant flow of new trial ideas
7. Massive network to realize new trial ideas
8. Unparalleled operational expertise & support
9. Strong chance of trial approval
10. 39 years of experience and success
Opportunities for Investigators

• Trials
  ✓ Propose – a trial idea
  ✓ Participate – in the trial
  ✓ Publish – trial results

Change practice!

• Committees
  ✓ Disease Site & Oversight Committees
  ✓ Supporting Committees (e.g. Audit and Monitoring, Clinical Research Associates, Pharmacist Network)

• Data Sharing
  ✓ Submit a proposal via Scientific Committees or OSC Senior Investigators to access data
  ✓ Check out the data sharing and access policy is here: https://www.ctg.queensu.ca/public/policies

• Correlative Science
  ✓ Submit a proposal via Scientific Committees to access tissue
    ✓ Check out correlative science policy and inventory https://www.ctg.queensu.ca/public/cctg-tissue-bank-correlative-science

• Meetings of Mutual Interest
  ✓ Young Investigators Course (bi-annual Kingston), Spring Meeting (annual Toronto), workshops

• Access Expertise
  ✓ Trial methodology, biostatistics, regulatory, ethics, data management, IT, grant preparation and submission support
How to Be Engaged

• Communicate your interest
  • Within centre: to centre reps and current committee members
  • To CCTG senior investigators and Scientific committee chairs
  • Participate in meetings
    • Let any special skills/expertise be known
    • Bring your ideas forward

• Volunteer to be committee member
  • Speak to your CCTG Centre Representative
  • Consider an operations committee e.g. Audit / Monitoring

• Be active in your centre
  • Participate in trials
  • Respond to surveys of interest
Summary

• Education is fundamental to our activity
• Investigator engagement is key to our success
• We have multiple opportunities for New Investigators and interested in hearing about how to do better
• Know your centre representative and committee leadership.
• Make yourself known through participation and contribution
Thank you!