



NCIC Clinical Trials Group

NEW INVESTIGATOR CLINICAL TRIALS COURSE

August 21-23, 2013
Donald Gordon Centre
Queen's University
Kingston, Ontario

Day 1	Wednesday, August 21	Room/Faculty
9:00 – 10:30 am	Plenary Session 1: Early Clinical Trials of Therapeutics: Phase I and II <ul style="list-style-type: none"> Prerequisites for Therapeutic Studies In Humans Phase I Trials Phase II Trials 	Conference Room A Scott Laurie Phil Bedard Penny Bradbury
10:30 – 10:45 am	Break	
10:45 – 12:00 pm	Plenary Session 2: Comparative Efficacy Studies of Therapeutics: Phase III <ul style="list-style-type: none"> The NCIC CTG CO.17, CO.20 & CO.23 Colon Cancer Studies: Examples of Successful Phase III Trials Statistics for Clinical Trials: Basics of Phase III Trial Design 	Conference Room A Chris O'Callaghan Bingshu Chen
12:00 – 1:00 pm	Lunch (Donald Gordon Dining Room)	
1:00 – 1:45 pm	Workshop 1: Sample Size Determination, Methodology, Analysis and Philosophy Workshop 2: Phase II Design	Conference Room Chris O'Callaghan Conference Room C Penny Bradbury / Dongsheng Tu
1:45 – 2:00 pm	Break	
2:00 – 2:45 pm	Workshop 3: Clinical Trials Infrastructure in Centres Workshop 4: Practical Elements of Trial Development: Regulatory Standards and Contracts Required Elements Checklist Roles and Responsibilities	Conference Room A Susan Dent Conference Room C Alison Urton / Wendy Parulekar
3:00 – 5:00 pm	Office Hours: 30 minutes one-on-one with a faculty member Sign-up sheets are posted outside of Conference Room A	Various Rooms See sign-up sheets
5:30 – 6:30 pm	Keynote Address: Tips for Success in Translational Research	Conference Room A Fei-Fei Liu
6:30 pm	Participant Dinner/Cash Bar	Patio (weather permitting)

Day 2 Thursday, August 22

8:00 – 10:00 am	Plenary Session 3: Correlative Studies in Phase III Trials: Biomarkers <ul style="list-style-type: none">• Design elements of clinical trials involving biomarkers• Laboratory aspects of biomarker studies	Conference Room A Gary Clark Fei-Fei Liu
10:00 – 10:15 am	Break	
10:15 – 12:00 pm	Plenary Session 4: Correlative Science Studies in Phase III Trials <ul style="list-style-type: none">• QOL• Economic Evaluation	Conference Room A Harriet Richardson Natasha Leighl
12:00 – 1:00 pm	Lunch (Donald Gordon Dining Room)	
1:00 – 1:45 pm	Workshop 5: QOL Analysis	Conference Room A Harriet Richardson / Mike Brundage
	Workshop 6: Economic Evaluation	Conference Room C Natasha Leighl
1:45 – 2:00 pm	Break	
2:00 – 2:45 pm	Workshop 7: Statistical Analysis of Biomarker Data	Conference Room A Gary Clark
	Workshop 8: Practical Aspects of Tumour Banking	Conference Room C Lois Shepherd
3:00 – 5:00 pm	Office Hours: 30 minutes one-on-one with a faculty member Sign-up sheets are posted outside of Conference Room A	Various Rooms See sign-up sheets
Evening	Dinner (at your own leisure)	

Day 3 Friday, August 23

8:00 – 9:00 am	NCIC CTG Overview: Structure and Opportunities for Investigators	Conference Room A Wendy Parulekar / Annette Hay
9:00 – 10:00 am	New Investigator Collaborations and Interactions: Regulatory and Industry	Conference Room A Candice Hilder / Steve Atiyeh
10:00 am	Hand in Evaluation Form and receive CME Accreditation Certificate	Registration Desk
	Adjourn	

To obtain CME Accreditation Certificate

This event is an Accredited Group Learning Activity (Section 1) as defined by the Maintenance of Certification Program of The Royal College of Physicians and Surgeons of Canada, approved by Queen's University (Maximum number of hours = 13.5)

Credits for Others: This is an accredited group learning activity which provides up to 13.5 hours of Continuing Education.

To obtain a certificate: You will be provided with an Evaluation Form to fill out during the Course and hand in at the end of the Course at the registration desk. We will provide your certificate to you then.

For questions please contact:

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Thank you to the following sponsors for the support provided for the New Investigator Clinical Trials Course

Ontario Institute for Cancer Research (OICR)
Canadian Institutes of Health Research (CIHR)
Canadian Cancer Society Research Institute (CCSRI)

Past New Investigator Clinical Trials Courses

August 9-12, 2011
Donald Gordon Centre
Queen's University
Kingston, Ontario

September 29-October 2, 2009
Donald Gordon Centre
Queen's University
Kingston, Ontario

August 28 to Friday August 31, 2007
Donald Gordon Centre
Queen's University
Kingston, Ontario

New Investigator Clinical Trials Course website <http://www.ctg.queensu.ca/newinv/default.html>

NCIC Clinical Trials Group (NCIC CTG)

The NCIC Clinical Trials Group (NCIC CTG) is a highly respected research group that develops, conducts and analyzes national and international multicentre trials of cancer therapy and supportive care. Its primary mission is to assess the effectiveness of interventions to improve the care of patients who develop cancer. The NCIC Clinical Trials Group is supported by a core grant received from the Canadian Cancer Society Research Institute.

The NCIC Clinical Trials Group is the only adult cooperative oncology group based in Canada that has a national membership and is committed to assessing all modalities of therapy across the spectrum of different types of cancer. NCIC Clinical Trials Group studies span the continuum of phase I testing of novel new agents to the conduct of large phase III (randomized controlled) trials. Over 70 member institutions across Canada, ranging in size from major cancer centres to community hospitals, enroll patients on NCIC Clinical Trials Group studies. Over 1000 physicians, research nurses, data managers and pharmacists participate in the local administration of these trials. Between its inception in 1980 and August, 2013, the NCIC CTG has conducted or is conducting 266 trials within its Phase III Program, which have included 68,974 patients, and 197 phase I or II studies within its Investigational New Drug Program, which have included more than 5,499 patients.

Committees of expert representatives from the participating institutions are responsible for designing and assessing trial proposals for specific disease sites. Separate standing committees have been established to assess special outcomes within the clinical trials such as quality of life, health economics and correlative biologic markers. The unique success of the Group in incorporating quality of life endpoints into its trials has been applauded by researchers on both sides of the Atlantic. In addition, other committees exist to review the conduct of clinical trials, such as a Data Safety Monitoring Committee, quality assurance and audit and monitoring.

In addition to its Canadian-based trials, the NCIC Clinical Trials Group leads and collaborates with other cooperative groups from the United States, Europe and Australia in the conduct of international clinical trials of cancer therapies. The Group regularly joins with these groups to answer treatment questions which can be resolved only by enrolling very large numbers of patients in studies. The NCIC Clinical Trials Group has a special relationship with cooperative groups in the United States through its relationship with the US National Cancer Institute's Cancer Therapy Evaluation Program (CTEP).

A key component of the NCIC Clinical Trials Group is its Investigational New Drug Program. This Program leads trials testing potential new anti-cancer agents obtained in collaboration with the international pharmaceutical industry, small biotechnical companies and CTEP.

The Central Office of the Group, which is responsible for the organization of the trials, for the management and analysis of the data they generate and for satisfying all regulatory requirements, is located at Queen's University, Kingston, Ontario. The staff includes senior faculty members, master's level researchers, computer programmers, and a number of additional administrative and support staff.

NCIC Clinical Trials Group Fellowships

NCIC CTG Thoracic Oncology Clinical Trials Fellowship

The NCIC Clinical Trials Group at Queens University is accepting applications for a Thoracic Oncology Clinical Trials Fellowship. This two-year position is open to motivated individuals who have preferably completed Surgical, Medical or Radiation Oncology training nationally or internationally.

NCIC CTG AstraZeneca Clinical Trials Fellowship

The NCIC Clinical Trials Group is accepting applications for the AstraZeneca Clinical Trials Fellowship. This one year position is open to motivated individuals from the disciplines of Hematology, Surgical, Medical and Radiation Oncology across Canada.

NCIC CTG AstraZeneca Breast Cancer Fellowship

The NCIC Clinical Trials Group is accepting applications for the AstraZeneca Breast Cancer Fellowship. This one year position is open to motivated individuals from the disciplines of Surgical, Medical and Radiation Oncology.

NCIC CTG Drug Development Fellowship

The NCIC Clinical Trials Group is accepting applications for a Two-Year Drug Development Fellowship, supported by AstraZeneca and the CIHR Queens University Transdisciplinary Training Program.

[Queen's University Transdisciplinary Training Program in Cancer Research](#) : information located on website

For additional information on NCIC CTG Fellowships please visit our website at:

<http://www.ctg.queensu.ca/public/fellowship/default.html>