



NCIC Clinical Trials Group Presents

NEW INVESTIGATOR CLINICAL TRIALS COURSE

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

Day 1 Tuesday, August 9

4:30 pm	Opening Remarks and Welcome Reception	Coach House Pub Wendy Parulekar
5:30 pm	Keynote Speaker: Clinical Research in the 21 st Century: Evolving Paradigms for Clinical Trials	Conference Room A Janet Dancey
6:15 pm	Sign up for Office Hours	Coach House Pub
8:00 – 10:00 pm	Faculty Meeting Dinner	

Day 2 Wednesday, August 10

7:00 – 9:00 am	Breakfast at Donald Gordon Centre	
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 Kim Chi Lillian Siu Elizabeth Eisenhauer
10:30 am	Break	
10:45 – 12:00 pm	Plenary Session 2: Comparative Efficacy Studies of Therapeutics: Phase III <ul style="list-style-type: none">• Key Elements of a Successful Phase III Trial• Statistics for Clinical Trials Part I: Basics of Phase III Trial Design	Conference Room A Wendy Parulekar 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	Room 8 Chris O'Callaghan
	Workshop 2: Phase II Design	John Deutsch Kim Chi/Bernie Eigl
	Workshop 3: Correlative Studies in Clinical Trials	Boardroom Ming Tsao/ Lois Shepherd
1:45-2:00 pm	Break	

2:00 – 2:45 pm	Workshop 4: Clinical Trials Infrastructure in Centres	Room 8 Bernie Eigl
	Workshop 5: Practical Elements of Trial Development: Regulatory Standards and Contracts	John Deutsch Room Ralph Meyer
	Workshop 6: Secondary Analyses and Mining of Clinical Trial Databases	Boardroom Penny Bradbury/ Dongsheng Tu
3:00 – 5:00 pm	Office Hours: 30 minutes one-on-one with a faculty member	Various Rooms *See sign-up sheets
7:00 pm	Participant Dinner	Merchant Tap House

Day 3 Thursday, August 11

7:00 – 8:00 am	Breakfast at Donald Gordon Centre	
8:00 – 10:00 am	Plenary Session 3: Correlative Studies in Phase III Trials: Biomarkers <ul style="list-style-type: none"> • Design elements of biomarker studies • Laboratory aspects of biomarker studies • Statistical Analyses 	Conference Room A Janet Dancey Ming Tsao Chris O’Callaghan
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 Jolie Ringash Nicole Mittmann
12:00 - 1:00 pm	Lunch (Donald Gordon Dining Room)	
1:00 – 1:45 pm	Workshop 7: QOL Analysis	Room 8 Jolie Ringash
	Workshop 8: Phase II Design (repeat)	John Deutsch Room Kim Chi/Bernie Eigl
	Workshop 9: Practical Aspects of Tumour Banking	Boardroom Lois Shepherd
1:45 – 2:00 pm	Break	
2:00 – 2:45 pm	Workshop 10: Correlative Studies in Clinical Trials (repeat)	Room 8 Ming Tsao/Lois Shepherd
	Workshop 11: Secondary Analyses and Mining of Clinical Trial Databases (repeat)	John Deutsch Room Penny Bradbury/ Dongsheng Tu
	Workshop 12: Practical Elements of Database Creation: Examples from the NCIC CTG casebook	Boardroom Anna Sadura/ Elizabeth Eisenhauer
3:00 – 5:00 pm	Office Hours: 30 minutes one-on-one with a faculty member	Various Rooms *See sign-up sheets
7:00 pm	Dinner (at your own leisure)	

***Office hours sign-up sheets are posted outside of Conference Room A**

Day 4 Friday, August 12

7:00 am	Breakfast at the Donald Gordon Centre	
9:00 – 10:00 am	NCIC CTG Overview: Structure and Opportunities for Investigators	Conference Room A Ralph Meyer
10:00 – 11:00 am	NCIC CTG Collaborations and Interactions: Academic, Regulatory and Industry	Conference Room A Jose Iglesias Norman Viner Jim Biagi
11:00 – 12:00 pm	Panel Discussion: Mentorship in Academic Medicine	Conference Room A Jose Monzon Jim Biagi Wendy Parulekar
12:00 pm	Adjourn (Lunch at your leisure)	

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 19.25)

Credits for Others: This is an accredited group learning activity which provides up to 19.5 hours of Continuing Education.

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

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

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

Past New Investigator Clinical Trials Courses

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 prevention, therapy and supportive care. Its primary mission is to assess the effectiveness of interventions to prevent the development of cancer or improve the care of those patients who do 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 90 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 July, 2011, the NCIC CTG has conducted or is conducting 252 trials within its Phase III Program, which have included 62,987 patients, and 187 phase I or II studies within its Investigational New Drug Program, which have included more than 5,065 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 Translational Research Fellowship

The NCIC Clinical Trials Group is accepting applications for the NCIC CTG Translational Research Fellowship. This position is open to motivated individuals who have completed their oncology or hematology specialty training or PhD in a science discipline from across Canada. The duration of the Fellowship is flexible and may be one or two years in duration.

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

NCIC CTG Fellowship website: <http://www.ctg.queensu.ca/public/fellowship/default.html>