



## NCIC Clinical Trials Group

Presents

### **NEW INVESTIGATOR CLINICAL TRIALS COURSE**

September 29-October 2, 2009

Donald Gordon Centre

Queen's University

Kingston, Ontario

#### **Day 1 Tuesday September 29, 2009**

4:30 pm.	Opening Remarks and Welcome Reception	<b>Coach House Pub</b> W. Parulekar
5:30 pm	Keynote Speaker: Clinical Research in Academic Medicine	<b>Conference Room B</b> R. Meyer
6:15 pm	Sign up for Workshops and Office Hours	<b>Coach House Pub</b>
8:00 – 10:00 pm	Faculty Meeting/Dinner	

#### **Day 2 Wednesday September 30, 2009**

7:00 – 9:00 am	Breakfast at Donald Gordon Centre	
9:00 – 10:30 am	<b>Plenary Session 1: Phases of Clinical Development of Therapeutics: Phase I and II</b> <ul style="list-style-type: none"><li>• Prerequisites for Therapeutic Studies Including Biomarkers</li><li>• Phase I Trials</li><li>• Phase II Trials</li></ul>	<b>Conference room B</b> K. Chi L. Siu E. Eisenhower
10:30 – 10:45 am	Break	
10:45 – 12:00 pm	<b>Plenary Session 2: Phases of Clinical Development of Therapeutics: Phase III</b> <ul style="list-style-type: none"><li>• Phase III Trials: Key Elements of a Successful Phase III Trial</li><li>• Statistics for Clinical Trials Part I: Basics of Phase III Trial Design</li></ul>	<b>Conference Room B</b> N. Leighl B. Chen
12:00 – 1:00 pm	Lunch	
1:00 – 1:45 pm	<b>Plenary Session 3: Phases of Clinical Development of Therapeutics: Phase III</b> <ul style="list-style-type: none"><li>• Statistics for Clinical Trials Part II: Interim Trial Analysis, Comparisons and Analysis of Correlative Studies</li></ul>	<b>Conference Room B</b> C. O'Callaghan
1:45 – 2:00 pm	Break	

*Day 2 continued....*

2:00 – 2:45 pm	<b>Workshop 1: Sample Size Determination- Methodology and Philosophy</b>	<b>Conference Room B</b> C. O'Callaghan
	<b>Workshop 2: Phase II Design</b>	<b>John Deutsch Room</b> K. Chi
	<b>Workshop 3: Correlative Studies in Clinical Trials</b>	<b>Boardroom</b> J. Dancey
2:45 – 3:00 pm	Break	
3:00 – 3:45 pm	<b>Workshop 4: Clinical Trials Infrastructure in Centres</b>	<b>Conference Room B</b> L. Siu
	<b>Workshop 5: Effective Presentations of Study Results</b>	<b>John Deutsch Room</b> C. Booth
	<b>Workshop 6: Secondary Analyses and Mining of Clinical Trial Databases</b>	<b>Boardroom</b> W. Parulekar
4:00 – 6:00 pm	Office Hours: 30 minutes one-on-one with a faculty member	
7:00 pm	Dinner (Fort Henry)	

**Day 3 Thursday October 1, 2009**

7:00 – 8:00 am	Breakfast at Donald Gordon Centre	
8:00 – 10:00 am	<b>Plenary session 4: Special Topics in Clinical Trials</b> <ul style="list-style-type: none"><li>• QOL</li><li>• Economic evaluation</li><li>• Biomarkers and laboratory aspects of correlative biology in clinical trials</li></ul>	<b>Conference Room B</b> J. Ringash N. Leighl J. Squire
10:00 – 10:15 am	Break	
10:15 – 12:00 pm	<b>Plenary session 5: Practical Elements of Trial Development: Examples from the NCIC CTG Casebook</b> <ul style="list-style-type: none"><li>• Oversight of safety</li><li>• International and Canadian standards</li><li>• Contracts: negotiation and key elements</li></ul>	<b>Conference room B</b>  E. Eisenhauer M. Walker B. Vandersluis
12:00 – 1:00 pm	Lunch	
1:00 – 1:45 pm	<b>Workshop 7: QOL Analysis</b>	<b>Conference room B</b> J. Ringash
	<b>Workshop 8: Phase II Design (repeat)</b>	<b>John Deutsch</b> K. Chi
	<b>Workshop 9: Correlative Studies in Clinical Trials (repeat)</b>	<b>Coach House Pub</b> J. Dancey
1:45 – 2:00 pm	Break	

**Day 3 continued...**

2:00 – 2:45 pm	<b>Workshop 10: Practical Aspects of Tumour Banking</b>	<b>Conference Room B</b> L. Shepherd
	<b>Workshop 11: Secondary Analyses and Mining of Clinical Trial Databases (repeat)</b>	<b>John Deutsch</b> W. Parulekar
	<b>Workshop 12: Effective Presentations of Study Results (repeat)</b>	<b>Coach House Pub</b> C. Booth
3:00 – 4:00 pm	<b>Plenary session 6: Data Collection, Database and Analysis: Privacy, Security, Accuracy, Validity</b> <ul style="list-style-type: none"><li>• Compilation of the trial database: CRFs and data checking</li><li>• Database analysis and interpretation</li></ul>	<b>Conference Room B</b>  W. Parulekar B. Chen
4:00 – 6:00 pm	Office Hours: 30 minutes one-on-one with a faculty member	
7:00 pm	Dinner (at your own leisure)	

**Day 4 Friday October 2, 2009**

7:00 – 9:00 am	Breakfast at the Donald Gordon Centre	
9:00 – 10:00 pm	<b>NCIC CTG Overview: Structure and Opportunities for Investigators</b>	<b>Conference Room B</b> R. Meyer
10:00 – 11:00 pm	<b>NCIC CTG Collaborations: Academic, Regulatory and Industry</b>	<b>Conference Room B</b> R. Meyer, J. Iglesias
11:00 – 12:00 pm	<b>Panel Discussion: Mentorship in Academic Medicine</b>	<b>Conference Room B</b> P. Bradbury T. Baetz
12:00 pm	Adjourn	