

## NEW INVESTIGATOR CLINICAL TRIALS COURSE

August 28-31, 2007

Donald Gordon Centre

Queen's University

Kingston Ontario

Day 1	Tuesday August 28 2007	
16:30	Opening Remarks and Welcome Reception	<a href="#">Elizabeth Eisenhauer</a>
17:30	Keynote Speaker : Clinical Research in Academic Medicine	<a href="#">Ralph Meyer</a>
20:00	Faculty Meeting/Dinner	
Day 2	Wednesday August 29 2007	
07:00	Breakfast at Donald Gordon Centre	
09:00	<b>Plenary Session 1: Translating Laboratory Observations into the Clinic</b>	
	Prerequisites for therapeutic studies	<a href="#">Lesley Seymour</a>
	Prerequisites for development of biomarker studies and other translational lab studies	<a href="#">Lillian Siu</a>
10:30	Break	
10:45	<b>Plenary Session 2: Phases of Clinical Development of Therapeutics Phase I, II, III</b>	
	Phase I trials	<a href="#">Elizabeth Eisenhauer</a>
	Phase II Trials	<a href="#">Janet Dancey</a>
	Phase III Trials	<a href="#">Mark Levine</a>
12:00	Lunch	
13:00	<b>Workshop 1: Sample Size: Determination, Methodology, Analysis and Philosophy</b>	<a href="#">Mark Levine</a>
	<b>Workshop 2: Phase II Design</b>	<a href="#">Kim Chi</a>
	<b>Workshop 3: Correlative Studies in Early Phase Trials</b>	<a href="#">Ming Tsao</a>
13:45	Break	
14:00	<b>Workshop 4: Statistical Analysis - Stopping Rules</b>	<a href="#">Chris O'Callaghan</a>
	<b>Workshop 5: Clinical Trials Infrastructure in Centres</b>	<a href="#">Kathleen Pritchard</a>
	Workshop 6: Effective Presentations of Study Results	<a href="#">Kim Chi</a>
14:45	Break	
15:00	Plenary Session 3: Special Topics in Trial Design	
	<b>Surrogate efficacy endpoints</b>	<a href="#">Wendy Parulekar</a>
	Quality of life analysis	<a href="#">Michael Brundage</a>
	Economic evaluation	Ana Johnson-Masotti
17:00	Office Hours: 30 minutes one-on-one with a faculty member	
19:00	Dinner (Kingston Dinner Cruise)	
Day 3	Thursday August 30 2007	

07:00	Breakfast at Donald Gordon Centre	
08:00	<b>Plenary session 4: Biomarkers in Clinical Studies</b>	
	Tumour banking	<a href="#">Lois Shepherd</a>
	Hypothesis generating studies/validation studies	<a href="#">Janet Dancey</a>
	Statistical analyses of correlative studies	<a href="#">Chris O'Callaghan</a>
10:00	Break	
10:15	<b>Plenary session 5: Ethical, Legal and Regulatory Aspects of Clinical Trial Conduct</b>	
	Oversight of safety	<a href="#">Lesley Seymour</a>
	International and Canadian standards	<a href="#">Lesley Seymour</a> and Alison Urton
	Contracts: negotiation and key elements	Belinda Vandersluis
12:00	Lunch	
13:00	<b>Workshop 7: QOL Analysis</b>	<a href="#">Michael Brundage</a>
	<b>Workshop 2: Phase II Design</b> (repeat)	<a href="#">Kim Chi</a>
	<b>Workshop 3: Correlative Studies in Early Phase Trials</b> (repeat)	<a href="#">Lillian Siu</a>
13:45	Break	
14:00	<b>Workshop 8: Challenges in Design and Conduct of Prevention Studies</b>	<a href="#">Harriet Richardson</a>
	<b>Workshop 5: Clinical Trials Infrastructure in Centres</b> (repeat)	<a href="#">Kathleen Pritchard</a>
	<b>Workshop 6: Effective Presentations of Study Results</b> (repeat)	<a href="#">Kim Chi</a>
15:00 - 17:00	<b>Plenary session 6: Data Collection, Database and Analysis: Privacy, Security, Accuracy, Validity</b>	
	Data collection	<a href="#">Wendy Parulekar</a>
	Database creation	Lam Pho
	Database analysis and interpretation	<a href="#">Chris O'Callaghan</a>
17:00	Office Hours: 30 minutes one-on-one with a faculty member	
19:00	Dinner (at your own leisure)	
Day 4	Friday August 31 2007	
07:00	Breakfast at Donald Gordon Centre	
09:00	<b>Friday August 31 2007</b>	<a href="#">Ralph Meyer</a> <a href="#">Kathleen Pritchard</a>
10:00	<b>Canadian Cancer Trials Group Collaborations: Academic, Regulatory and Industry</b>	<a href="#">Ralph Meyer</a> <a href="#">Kathleen Pritchard</a>
11:00	<b>Panel Discussion: Mentorship in Academic Medicine</b>	
12:00	Adjourn	