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
Coach House Pub

5:30 pm  Keynote Speaker: Clinical Research in Academic Medicine
Confrence Room B

6:15 pm  Sign up for Workshops and Office Hours
Coach House Pub

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  Plenary Session 1: Phases of Clinical Development of Therapeutics: Phase I and II
Conference room B

- Prerequisites for Therapeutic Studies Including Biomarkers
  K. Chi
- Phase I Trials
  L. Siu
- Phase II Trials
  E. Eisenhauer

10:30 – 10:45 am  Break

10:45 – 12:00 pm  Plenary Session 2: Phases of Clinical Development of Therapeutics: Phase III
Conference Room B

- Phase III Trials: Key Elements of a Successful Phase III Trial
  N. Leighl
- Statistics for Clinical Trials Part I: Basics of Phase III Trial Design
  B. Chen

12:00 – 1:00 pm  Lunch

1:00 – 1:45 pm  Plenary Session 3: Phases of Clinical Development of Therapeutics: Phase III
Conference Room B

- Statistics for Clinical Trials Part II: Interim Trial Analysis, Comparisons and Analysis of Correlative Studies
  C. O’Callaghan

1:45 – 2:00 pm  Break
Day 2 continued…

2:00 – 2:45 pm  Workshop 1: Sample Size Determination- Methodology and Philosophy
                   Conference Room B  C. O’Callaghan
                   Workshop 2: Phase II Design
                   John Deutsch Room  K. Chi
                   Workshop 3: Correlative Studies in Clinical Trials
                   Boardroom  J. Dancey

2:45 – 3:00 pm  Break

3:00 – 3:45 pm  Workshop 4: Clinical Trials Infrastructure in Centres
                   Conference Room B  L. Siu
                   Workshop 5: Effective Presentations of Study Results
                   John Deutsch Room  C. Booth
                   Workshop 6: Secondary Analyses and Mining of Clinical Trial Databases
                   Boardroom  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  Plenary session 4: Special Topics in Clinical Trials
                   Conference Room B  J. Ringash
                   • QOL
                   • Economic evaluation
                   • Biomarkers and laboratory aspects of correlative biology in clinical trials  N. Leighl
                   J. Squire

10:00 – 10:15 am  Break

10:15 – 12:00 pm  Plenary session 5: Practical Elements of Trial Development: Examples from the NCIC CTG Casebook
                   Conference Room B  E. Eisenhauer
                   • Oversight of safety
                   • International and Canadian standards
                   • Contracts: negotiation and key elements  M. Walker
                   B. Vandersluis

12:00 – 1:00 pm  Lunch

1:00 – 1:45 pm  Workshop 7: QOL Analysis
                   Conference room B  J. Ringash
                   Workshop 8: Phase II Design (repeat)
                   John Deutsch  K. Chi
                   Workshop 9: Correlative Studies in Clinical Trials (repeat)
                   Coach House Pub  J. Dancey

1:45 – 2:00 pm  Break
### Day 3 continued…

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<th>Time</th>
<th>Event</th>
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<th>Presenter(s)</th>
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<tr>
<td>2:00 – 2:45 pm</td>
<td>Workshop 10: Practical Aspects of Tumour Banking</td>
<td>Conference Room B</td>
<td>L. Shepherd</td>
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<td>Workshop 11: Secondary Analyses and Mining of Clinical Trial Databases (repeat)</td>
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<td>John Deutsch</td>
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<td></td>
<td>Workshop 12: Effective Presentations of Study Results (repeat)</td>
<td>Coach House Pub</td>
<td>W. Parulekar</td>
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<td>3:00 – 4:00 pm</td>
<td>Plenary session 6: Data Collection, Database and Analysis:</td>
<td>Conference Room B</td>
<td>W. Parulekar</td>
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<td>Privacy, Security, Accuracy, Validity</td>
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<td>B. Chen</td>
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<td>• Compilation of the trial database: CRFs and data checking</td>
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<td>• Database analysis and interpretation</td>
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<td>4:00 – 6:00 pm</td>
<td>Office Hours: 30 minutes one-on-one with a faculty member</td>
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<td>7:00 pm</td>
<td>Dinner (at your own leisure)</td>
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### Day 4  Friday October 2, 2009

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