

NEW INVESTIGATOR CLINICAL TRIALS COURSE August 3-5, 2022

Donald Gordon Hotel and Conference Centre Queen's University Kingston, Ontario

COURSE PROGRAM

| Day 1 | Wednesday, August 3 | Room/Faculty |
|------------------|--|--|
| 8:00 | Welcome | Conference Room A Wendy Parulekar |
| 8:00 – 8:10 am | Canadian Cancer Trials Group – "Who Are We and Where Are We Going?" | Conference Room A Janet Dancey |
| 8:10 – 8:30 am | Patient Engagement in the Lifecycle of Clinical Trial | Conference Room A Judy Needham |
| 8:30 – 10:30 am | Plenary Session 1: Early Clinical Trials of Therapeutics: Phase I and II Prerequisites for Therapeutic Studies in Humans Phase I Trials Phase II Trials | Conference Room A Rosalyn Juergens Rosalyn Juergens Wendy Parulekar |
| 10:30 – 10:45 am | Break (refreshments and snacks) | Donald Gordon Court |
| 10:45 – 12:00 pm | Plenary Session 2: Comparative Efficacy Studies of Therapeutics: Phase III Key Elements of a Successful Phase III Trial Statistics for Clinical Trials: Basics of Phase III Trial Design | Conference Room A Chris O'Callaghan Greg Pond |
| 12:00 – 1:00 pm | Lunch | Donald Gordon Dining Room |
| 1:00 - 1:45 | Workshop 1 : Sample Size Determination, Methodology, Analysis and Philosophy | Conference Room A Chris O'Callaghan/ Greg Pond |
| | Workshop 2: Phase II Designs – Options and Practical Considerations | Conference Room C Wendy Parulekar/Wei Tu |
| | Workshop 3 : Clinical Trials Regulations & Guidelines and Quality in Clinical Trials: How to Remain in Compliance | Boardroom Clive Hansen/Michelle Savoie |
| 1:45 – 2:00 pm | Break (refreshments and snacks) | Donald Gordon Court |
| 2:00 – 2:45 pm | Workshop 4: Sample Size Determination, Methodology, Analysis and Philosophy | Conference Room A Chris O'Callaghan/ Greg Pond |
| | Workshop 5: Pre-Operative Surgical Trials in Drug Development | Boardroom Wendy Parulekar/Tricia Cottrell |
| | Workshop 6: Platform Trials/Response Adaptive Trials: Overview of Design Elements | Conference Room C Janet Dancey |
| 2:45 – 3:00 pm | Break (refreshments and snacks) | Donald Gordon Court |
| 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: Integral Biomarkers in Clinical Trial Design and Conduct: The Experience of CCTG IND 234 | Conference Room A Alexander Wyatt |
| 6:30 pm | Participant Dinner + Cash Bar | Donald Gordon Patio |

| Day 2 | Thursday, August 4 | Room/Faculty |
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| 8:00 – 10:00 am | Plenary Session 3: Molecular Biomarkers in Clinical Trials Liquid Biopsies in Clinical Trials Clinical Interpretation of Genomic Variants | Conference Room A Alexander Wyatt Harriet Feilotter |
| 10:00 – 10:15 am | Break (refreshments and snacks) | Donald Gordon Court |
| 10:15 – 12:00 pm | Plenary Session 4: Patient and Health Service Outcomes in Phase III Trials Patient-Reported Outcomes Economic Evaluation | Conference Room A Michael Brundage Annette Hay |
| 12:00 – 1:00 pm | Lunch | Donald Gordon Dining Room |
| 1:00 – 1:45 pm | Workshop 7: Phase II Designs – Options and Practical Considerations | Conference Room C Wendy Parulekar/Wei Tu |
| | Workshop 8: When is a Biomarker Ready for Use in a Clinical Trial | Boardroom Harriet Feilotter/Tricia Cottrell |
| | Workshop 9: Interim Analyses: Practical Considerations | Conference Room A Chris O'Callaghan/Greg Pond |
| 1:45 – 2:00 pm | Break (refreshments and snacks) | Donald Gordon Court |
| | Workshop 10: Platform Trials/Response Adaptive Trials: Overview of Design Elements | John Deutsch Janet Dancey |
| 2:00 – 2:45 pm | Workshop 11: Data Science in Clinical Trials: Fundamentals of Data Elements and Integration | Conference Room C Wei Tu/Lam Pho |
| | Workshop 12: When is a Biomarker Ready for Use in a Clinical Trial | Boardroom Harriet Feilotter/Tricia Cottrell |
| 2:45 – 3:00 pm | Break (refreshments and snacks) | Donald Gordon Court |
| 3:00 – 3:45 pm | Workshop 13: Data Science in Clinical Trials: Fundamentals of Data Elements and Integration | Conference Room C Wei Tu/Lam Pho |
| | Workshop 14: Interim Analyses: Practical Considerations | Conference Room A Chris O'Callaghan/Greg Pond |
| 4:00 – 5:30 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 5 | Room/Faculty |
| 8:30 – 9:00 am | CCTG Overview: Opportunities for Engagement for Investigators | Conference Room A Janet Dancey |
| 9:00 – 9:30 am | Technological Advances in Clinical Trial Conduct: CCTG Perspective | Conference Room A Lam Pho |
| 9:30 – 9:45 am | Break (refreshments and snacks) | Donald Gordon Court |
| 9:45 – 10:15 am | Data Sharing Opportunities for Investigators | Conference Room A Annette Hay |
| 10:15 – 11:15 pm | New Investigator Collaborations and Interactions from an Industry Perspective | Conference Room A Zeshan Farooqui, Merck Marie-Christine Phan, Pfizer |
| 11:15 – 12:00 pm | Closing Remarks | Conference Room A Wendy Parulekar |