

NEW INVESTIGATOR CLINICAL TRIALS COURSE

August 3-5, 2022

Donald Gordon Hotel and Conference Centre

Kingston, Ontario

Draft Program

See list of potential workshops at end of program

| Day 1 | Wednesday, August 3 | Room/Faculty |
|------------------|---|---|
| 8:00 – 8:10 am | Canadian Cancer Trials Group – “Who Are We and Where Are We Going?” | Janet Dancey |
| 8:10 – 8:30 am | Data Sharing Opportunities for Investigators | Annette Hay |
| 8:30 – 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 | 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 <ul style="list-style-type: none"> Key Elements of a Successful Phase III Trial Statistics for Clinical Trials: Basics of Phase III Trial Design | Chris O’Callaghan Greg Pond |
| 12:00 – 1:00 pm | Lunch | Donald Gordon Dining Room |
| 1:00 – 1:45 pm | Workshop 1: | TBD |
| | Workshop 2: | TBD |
| | Workshop 3: | TBD |
| 1:45 – 2:00 pm | Break (refreshments and snacks) | Donald Gordon Court |
| 2:00 – 2:45 pm | Workshop 4: | TBD |
| | Workshop 5: | TBD |
| | Workshop 6: | TBD |
| 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: <i>Personalized Medicine: The Promise of ctDNA</i> | Alexander Wyatt |
| 6:30 pm | Participant Dinner + Cash Bar | (Weather permitting) |
| Day 2 | Thursday, August 4 | Room/Faculty |
| 8:00 – 10:00 am | Plenary Session 3: Molecular Biomarkers in Clinical Trials <ul style="list-style-type: none"> Liquid Biopsies in Clinical Trials Clinical Interpretation of Genomic Variants | Alexander Wyatt Harriet Feilotter |

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| 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 <ul style="list-style-type: none"> • Patient-Reported Outcomes • Economic Evaluation | TBD |
| 12:00 – 1:00 pm | Lunch | Donald Gordon Dining Room |
| 1:00 – 1:45 pm | Workshop 7: | TBD |
| | Workshop 8: | TBD |
| | Workshop 9: | TBD |
| 1:45 – 2:00 pm | Break (refreshments and snacks) | Donald Gordon Court |
| 2:00 – 2:45 pm | Workshop 10: | TBD |
| | Workshop 11: | TBD |
| | Workshop 12: | TBD |
| 2:45 – 3:00 pm | Break (refreshments and snacks) | Donald Gordon Court |
| 3:00 – 3:45 pm | Workshop 13: | TBD |
| | Workshop 14: | TBD |
| 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 | Janet Dancey |
| 9:00 – 9:30 am | Technological Advances in Clinical Trial Conduct | Lam Pho |
| 9:30 – 9:45 am | Break (refreshments and snacks) | Donald Gordon Court |
| 9:45 – 10:15 am | Drug approval access in Canada: CADTH perspective | TBD |
| 10:15 – 11:15 pm | New Investigator Collaborations and Interactions from an Industry Perspective | Conference Room Industry Panel |
| 11:15 - 1200 | Closing Remarks | Wendy Parulekar |

Workshops confirmed:

- **WK 1-Sample Size Determination, Methodology, Analysis and Philosophy**
- **Wk 2-Phase II Designs – Options and Practical Considerations**
- **WK 3-Clinical Trials Regulations & Guidelines and Quality in Clinical Trials: How to Remain in Compliance!**
- **Engagement of Patient Representatives as Partners in the Life Cycle of a Trial**

Workshops are being ranked by participants:

- **Platform Trials/Response Adaptive Trials: Overview of Design Elements**
- **Pre-Operative Surgical Trials in Drug Development**
- **When is a Biomarker Ready for Use in a Clinical Trial?**
- **Data Science in Clinical Trials - Fundamentals of Data Elements and Integration**
- **Interim analyses: Practical Considerations**