

## NEW INVESTIGATOR CLINICAL TRIALS COURSE

August 21-23, 2024

Donald Gordon Hotel and Conference Centre

Queen's University

Kingston, Ontario

### COURSE PROGRAM

Day 1	Wednesday, August 21	Room/Faculty
7:00 am	Registration Opens	Donald Gordon Court
8:00 am	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	Integrating EDIIA into Cancer Clinical Trials	Conference Room A Anna Johnson
8:30 – 10:30 am	Plenary Session 1: Early Clinical Trials of Therapeutics: Phase I and II <ul style="list-style-type: none"> <li>Prerequisites for Therapeutic Studies in Humans</li> <li>Phase I Trials</li> <li>Phase II Trials</li> </ul>	Conference Room A Anna Spreafico Anna Spreafico 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"> <li>Key Elements of a Successful Phase III Trial</li> <li>Statistics for Clinical Trials: Basics of Phase III Trial Design</li> </ul>	Conference Room A Chris O’Callaghan Wei Tu
12:00 – 1:00 pm	Lunch	Donald Gordon Dining Room
1:00 – 1:45 pm	Workshop 1: Sample Size Determination, Methodology, Analysis and Philosophy	Conference Room A Chris O’Callaghan
	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 Jessica Sleeth/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
	Workshop 5: Pre-Operative Surgical Trials in Drug Development	Boardroom Tricia Cottrell/ Pierre-Olivier Gaudreau
	Workshop 6: Platform Trials/Response Adaptive Trials: Overview of Design Elements	Conference Room C Laura Pearce
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: Patient Centric Clinical Trials: An Overview of the CCTG Strategic and Scientific Agenda	Conference Room A Janet Dancey
6:30 pm	Participant & Faculty Dinner + Cash Bar	Donald Gordon Patio

Day 2	Thursday, August 22	Room/Faculty
7:00 am	Registration Opens	Donald Gordon Court
8:00 – 10:00 am	<b>Plenary Session 3: Molecular Biomarkers in Clinical Trials</b> • Liquid Biopsies in Clinical Trials • Clinical Interpretation of Genomic Variants	<b>Conference Room A</b> Scott Bratman Peter Sabatini
10:00 – 10:15 am	Break (refreshments and snacks)	Donald Gordon Court
10:15 – 12:00 pm	<b>Plenary Session 4: Patient and Health Service Outcomes in Phase III Trials</b> • Patient-Reported Outcomes • Economic Evaluation	<b>Conference Room A</b> Joe Pater Annette Hay
12:00 – 1:00 pm	Lunch	Donald Gordon Dining Room
1:00 – 1:45 pm	<b>Workshop 7:</b> Phase II Designs – Options and Practical Considerations	<b>Conference Room C</b> Wendy Parulekar/Wei Tu
	<b>Workshop 8:</b> When is a Biomarker Ready for Use in a Clinical Trial	<b>Conference Room A</b> Scott Bratman/Tricia Cottrell
	<b>Workshop 9:</b> Interim Analyses: Practical Considerations	<b>Boardroom</b> Greg Pond
1:45 – 2:00 pm	Break (refreshments and snacks)	Donald Gordon Court
2:00 – 2:45 pm	<b>Workshop 10:</b> Platform Trials/Response Adaptive Trials: Overview of Design Elements	<b>Boardroom</b> Laura Pearce
	<b>Workshop 11:</b> Data Science in Clinical Trials: Fundamentals of Data Elements and Integration	<b>Conference Room C</b> Wei Tu/Lam Pho
	<b>Workshop 12:</b> When is a Biomarker Ready for Use in a Clinical Trial	<b>Conference Room A</b> Scott Bratman/Tricia Cottrell
2:45 – 3:00 pm	Break (refreshments and snacks)	Donald Gordon Court
3:00 – 3:45 pm	<b>Workshop 13:</b> Data Science in Clinical Trials: Fundamentals of Data Elements and Integration	<b>Conference Room C</b> Wei Tu/Lam Pho
	<b>Workshop 14:</b> Interim Analyses: Practical Considerations	<b>Conference Room A</b> Greg Pond
4:00 – 5:30 pm	<b>Office Hours:</b> 30 minutes one-on-one with a faculty member <b>Sign-up sheets are posted outside of Conference Room A</b>	<b>Various Rooms</b> See sign-up sheets
Evening	Dinner at your own leisure	
Day 3	Friday, August 23	Room/Faculty
7:30 am	Registration Opens	Donald Gordon Court
8:30 – 9:00 am	<b>CCTG Overview: Opportunities for Engagement for Investigators</b>	<b>Conference Room A</b> Wendy Parulekar/Kathy Han
9:00 – 9:30 am	<b>Technological Advances in Clinical Trial Conduct: CCTG Perspective</b>	<b>Conference Room A</b> Lam Pho
9:30 – 10:00 am	<b>Data Sharing Opportunities for Investigators</b>	<b>Conference Room A</b> Annette Hay
10:00 – 10:15 am	Break (refreshments and snacks)	Donald Gordon Court
10:15 – 10:45 am	<b>Patient Engagement</b>	<b>Conference Room A</b> Yvonne Murray
10:45 – 11:45 pm	<b>New Investigator Collaborations and Interactions from an Industry Perspective</b>	<b>Conference Room A</b> Marie-Christine Phan, Pfizer Rudy Rizkalla, AstraZeneca Valerie Chartrand, Merck
11:45 – 12:00 pm	<b>Closing Remarks</b>	<b>Conference Room A</b> Wendy Parulekar