

NEW INVESTIGATOR CLINICAL TRIALS COURSE August 21-23, 2024

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

DRAFT COURSE PROGRAM

Day 1	Wednesday, August 21	Room/Faculty <i>Room & Faculty TBD</i>
8:00	Welcome	
8:00 – 8:10 am	Canadian Cancer Trials Group – “Who Are We and Where Are We Going?”	
8:10 – 8:30 am	Patient Engagement in the Lifecycle of Clinical Trial	
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 	
10:30 – 10:45 am	Break (refreshments and snacks)	
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 	
12:00 – 1:00 pm	Lunch	
1:00 – 1:45	Workshop 1: Sample Size Determination, Methodology, Analysis and Philosophy	
	Workshop 2: Phase II Designs – Options and Practical Considerations	
	Workshop 3: Clinical Trials Regulations & Guidelines and Quality in Clinical Trials: How to Remain in Compliance	
1:45 – 2:00 pm	Break (refreshments and snacks)	
2:00 – 2:45 pm	Workshop 4: Sample Size Determination, Methodology, Analysis and Philosophy	
	Workshop 5: Pre-Operative Surgical Trials in Drug Development	
	Workshop 6: Platform Trials/Response Adaptive Trials: Overview of Design Elements	
2:45 – 3:00 pm	Break (refreshments and snacks)	
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	
5:30 – 6:30 pm	Keynote Address: Integral Biomarkers in Clinical Trial Design and Conduct: The Experience of CCTG IND 234	
6:30 pm	Participant Dinner + Cash Bar	

Day 2	Thursday, August 22	Room/Faculty <i>Room & Faculty TBD</i>
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 	
10:00 – 10:15 am	Break (refreshments and snacks)	
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 	
12:00 – 1:00 pm	Lunch	
1:00 – 1:45 pm	Workshop 7: Phase II Designs – Options and Practical Considerations	
	Workshop 8: When is a Biomarker Ready for Use in a Clinical Trial	
	Workshop 9: Interim Analyses: Practical Considerations	
1:45 – 2:00 pm	Break (refreshments and snacks)	
2:00 – 2:45 pm	Workshop 10: Platform Trials/Response Adaptive Trials: Overview of Design Elements	
	Workshop 11: Data Science in Clinical Trials: Fundamentals of Data Elements and Integration	
	Workshop 12: When is a Biomarker Ready for Use in a Clinical Trial	
2:45 – 3:00 pm	Break (refreshments and snacks)	
3:00 – 3:45 pm	Workshop 13: Data Science in Clinical Trials: Fundamentals of Data Elements and Integration	
	Workshop 14: Interim Analyses: Practical Considerations	
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	
Evening	Dinner (at your own leisure)	
Day 3	Friday, August 23	Room/Faculty <i>Room & Faculty TBD</i>
8:30 – 9:00 am	CCTG Overview: Opportunities for Engagement for Investigators	
9:00 – 9:30 am	Technological Advances in Clinical Trial Conduct: CCTG Perspective	
9:30 – 9:45 am	Break (refreshments and snacks)	
9:45 – 10:15 am	Data Sharing Opportunities for Investigators	
10:15 – 11:15 pm	New Investigator Collaborations and Interactions from an Industry Perspective	
11:15 – 12:00 pm	Closing Remarks	