

PERFUSE Clinical Research Course 2020 / 2021

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	Date	Time	Topic	Presenter
Week 1	Wednesday, October 7 th	11:00 am EST	<u>Introduction to Clinical Trials and Study Design</u> <ul style="list-style-type: none"> • Randomization • Outcomes 	C. Michael Gibson
Week 2	Tuesday, October 13 th	11:00 am EST	<u>Description of Trial Phases - I</u> <ul style="list-style-type: none"> • Early Phase Trials (Phase 0 and Phase I) 	C. Michael Gibson
Week 3	Tuesday, October 20 th	11:00 am EST	<u>Description of Trial Phases - II</u> <ul style="list-style-type: none"> • Phase II, III and IV Trials 	C. Michael Gibson
Week 4	Tuesday, October 27 th	11:00 am EST	<u>Description of Trial Phases – III</u> <ul style="list-style-type: none"> • Phase III Efficacy and Safety Trials 	C. Michael Gibson
Week 5	Tuesday, November 3 rd	11:00 am EST	<u>Study Design - I</u> <ul style="list-style-type: none"> • Phase I Designs <ul style="list-style-type: none"> ○ Dose-finding designs 	Gerald Chi
Week 6	Tuesday, November 17 th	11:00 am EST	<u>Study Design - II</u> <ul style="list-style-type: none"> • Phase II Designs <ul style="list-style-type: none"> ○ Pilot studies ○ Single arm 	Serge Korjian

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			○ Historical control designs	
Week of November 24th – Thanksgiving Break				
Week 7	Tuesday, December 8 th	11:00 am EST	<u>Study Design - III</u> <ul style="list-style-type: none"> ● Phase III Designs <ul style="list-style-type: none"> ○ Factorial designs ○ Crossover Designs ○ Multicenter Studies 	Arzu Kalayci
Week 8	Tuesday, December 15 th	11:00 am EST	<u>Developing a Study Protocol - I</u> <ul style="list-style-type: none"> ● Introduction, Background, Objectives ● Eligibility, Design 	Clara Fitzgerald
Week of December 22nd & December 29th - Christmas Break				
Week 9	Tuesday, January 5 th	11:00 am EST	<u>Developing a Study Protocol - II</u> <ul style="list-style-type: none"> ● Randomization ● Intervention Details 	Arzu Kalayci

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Week 10	Tuesday, January 12 th	11:00 am EST	<u>Developing a Study Protocol - III</u> <ul style="list-style-type: none">● Assessments and Data collection● Case Report Forms	Gerald Chi
Week 11	Tuesday, January 19 th	11:00 am EST	<u>Developing a Study Protocol - IV</u> <ul style="list-style-type: none">● Amendments● Violations● Introduction to observational studies and Cohort studies	Clara Fitzgerald
Week 12	Tuesday, January 26 th	11:00 am EST	<u>Designing and Conducting Observational Studies – II</u> <ul style="list-style-type: none">● Cross-sectional Studies	Gerald Chi
Week 13	Tuesday, February 2 nd	11:00 am EST	<u>Designing and Conducting Observational Studies – III</u> <ul style="list-style-type: none">● Case-control Studies	Arzu Kalayci
Week 14	Tuesday, February 9 th	11:00 am EST	<u>Statistical Perspective - I</u> <ul style="list-style-type: none">● Descriptive Statistics for Exploring Data	Professor Doros

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Week 15	Tuesday, February 16th	11:00 am EST	<u>Statistical Perspective - II</u> Power and Sample Size	Gerald Chi
Week 16	Tuesday, February 23 rd	11:00 am EST	<u>Statistical Perspective - III</u> Measures of Association (RR, OR)	Gerald Chi
Week 17	Tuesday, March 2 nd	11:00 am EST	<u>Statistical Perspective - IV</u> <ul style="list-style-type: none"> Overview of Regression Models 	Arzu Kalayci
Week 18	Tuesday, March 9 th	11:00 am EST	<u>Ethics of Clinical Trials - I</u> <ul style="list-style-type: none"> Responsible Conduct of Research What is misconduct? Rules of Science 	Clara Fitzgerald
Week 19	Tuesday, March 16 th	11:00 am EST	<u>Ethics of Clinical Trials - II</u> <ul style="list-style-type: none"> Informed Consent Equipoise 	Sonia Ammu
Week 20	Tuesday, March 23rd	11:00 am EST	<u>Running a Clinical Trial - I</u> <u>Study Set-up</u> <ul style="list-style-type: none"> Regulatory Review <ul style="list-style-type: none"> Institutional review board (IRB) 	Maria Ok

			○ Independent ethics committee (IEC)	
Week 21	Tuesday, March 30 th	11:00 am EST	<u>Running a Clinical Trial part I & II</u> <ul style="list-style-type: none"> ● Regulatory Review <ul style="list-style-type: none"> ○ Institutional review board (IRB) ● Study Team ● Budget and Contract 	Maria Ok
Week 22	Friday, April 9 th	11:00 am EST	<u>Running a Clinical Trial - III</u> <u>Study Conduct</u> <ul style="list-style-type: none"> ● Good Clinical Practice (GCP) ● Delegation of Authority ● The Informed Consent Process 	Danielle Feingold
Week 23	Tuesday, April 13 th	11:00 am EST	<u>Missing Data</u> <ul style="list-style-type: none"> ● Missing Data and the Impact on Clinical Trials 	C. Michael Gibson

Week 24	Thursday, April 22 nd	11:00 am EST	<ul style="list-style-type: none"> • <u>The Role of Academic Research Organizations in Clinical Research</u> • <u>Sponsor</u> 	Don Cutlip
Week 25	To be confirmed- Tuesday, April 27 th	11:00 am EST	<u>Data Review Committee - I</u> <ul style="list-style-type: none"> • Assessing and Reporting Adverse Events 	Serge Korjian
Week 26	To be confirmed- Tuesday, May 4 th	11:00 am EST	<u>Data Review Committee - II</u> Clinical Events Committees	David Weiss
Week 27	To be confirmed- Tuesday, May 11 th	11:00 am EST	<u>Data Review Committee - III</u> Data and Safety Monitoring Board	Sam Ciaranca

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Week 28	To be confirmed- Tuesday, May 18 th	11:00 am EST	<ul style="list-style-type: none"> • <u>Data Sharing</u> • <u>Open Source</u> • <u>CT.gov Reporting</u> 	C. Michael Gibson
Week 29	To be confirmed- Tuesday, May 25 th	11:00 am EST	<u>Roles and Responsibilities of the Clinical Research Team</u> <ul style="list-style-type: none"> • Principal Investigator • Sub-investigator 	TBD
Week 30	To be confirmed- Tuesday, June 1 st	11:00 am EST	<u>Reporting and Interpreting of Results - I</u> <ul style="list-style-type: none"> • Authorship • Disclosure of Conflict of Interest 	Arzu Kalayci
Week 31	To be confirmed- Tuesday, June 8 th	11:00 am EST	<u>Reporting and Interpreting of Results - II</u> <ul style="list-style-type: none"> • Presentation of Data 	Clara Fitzgerald
Week 32	To be confirmed- Tuesday, June 15 th	11:00 am EST	<u>Reporting and Interpreting of Results - III</u> <ul style="list-style-type: none"> • Interpretation 	Gerald Chi
Week 33	To be confirmed- Tuesday, June 22 nd	11:00 am EST	<u>Reporting and Interpreting of Results - IV</u> <ul style="list-style-type: none"> • Publication Bias 	Arzu Kalayci

Week 34	To be confirmed- Tuesday, June 29 th	11:00 am EST	<u>Journal Club Session - I</u> <u>Critical Appraisal of Clinical Research</u> <ul style="list-style-type: none">• What is the research question?• What is the study type (design)?• Selection issues	Gerald Chi
Week 35	To be confirmed- Tuesday, July 6 th	11:00 am EST	<u>Journal Club Session - II</u> <u>Critical Appraisal of Clinical Research</u> <ul style="list-style-type: none">• What are the outcome factors and how are they measured?• What are the study factors and how are they measured?• What is the statistical method used in the study?	Clara Fitzgerald
Week 36	To be confirmed- Tuesday July 13	11:00 am EST	<u>Journal Club Session - III</u> <u>Critical Appraisal of Clinical Research</u> <ul style="list-style-type: none">• Interpretation of statistical results• What conclusions did the authors reach about the research question?• Are ethical issues considered?	Arzu Kalayci

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Week 37	To be confirmed- Tuesday, July 20 th	11:00 am EST	<u>Future Direction</u> <ul style="list-style-type: none">● Artificial Intelligence in Clinical Trials● Apple Heart Study	C. Michael Gibson
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