

PERFUSE Clinical Research Course 2020 / 2021

[Textbook of Clinical Trials](#)

Last Update: 2/2/2021

	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

PERFUSE Clinical Research Course 2020 / 2021

[Textbook of Clinical Trials](#)

Last Update: 2/2/2021

			<ul style="list-style-type: none"> ○ 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

PERFUSE Clinical Research Course 2020 / 2021

[Textbook of Clinical Trials](#)

Last Update: 2/2/2021

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	To be confirmed- 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

PERFUSE Clinical Research Course 2020 / 2021

[Textbook of Clinical Trials](#)

Last Update: 2/2/2021

Week 15	To be confirmed- Tuesday, February 16th	11:00 am EST	<u>Statistical Perspective - II</u> Power and Sample Size	Gerald Chi
Week 16	To be confirmed- Tuesday, February 23 rd	11:00 am EST	<u>Statistical Perspective - III</u> Measures of Association (RR, OR)	Gerald Chi
Week 17	To be confirmed- 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	To be confirmed- 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	To be confirmed- 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	To be confirmed- Tuesday, March 23 rd	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

PERFUSE Clinical Research Course 2020 / 2021

[Textbook of Clinical Trials](#)

Last Update: 2/2/2021

			<ul style="list-style-type: none"> ○ Independent ethics committee (IEC) 	
Week 21	To be confirmed- Tuesday, March 30 th	11:00 am EST	<p><u>Running a Clinical Trial - II</u></p> <ul style="list-style-type: none"> ● Study Team ● Budget and Contract 	TBD
Week 22	To be confirmed- Tuesday, April 6 th	11:00 am EST	<p><u>Running a Clinical Trial - III</u> <u>Study Conduct</u></p> <ul style="list-style-type: none"> ● Good Clinical Practice (GCP) ● Delegation of Authority ● The Informed Consent Process 	Danielle Feingold
Week 23	To be confirmed- Tuesday, April 13 th	11:00 am EST	<p><u>Running a Clinical Trial - IV</u> <u>Study Conduct</u></p> <ul style="list-style-type: none"> ● FDA role as an oversight of the drug development process/ US FDA requirements 	C. Michael Gibson
Week 24	To be confirmed- Tuesday, April 20 th	11:00 am EST	<ul style="list-style-type: none"> ● <u>The Role of Academic Research Organizations in Clinical Research</u> ● <u>Sponsor</u> 	TBD

PERFUSE Clinical Research Course 2020 / 2021

[Textbook of Clinical Trials](#)

Last Update: 2/2/2021

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	TBD
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
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	Serge Korjian

PERFUSE Clinical Research Course 2020 / 2021

[Textbook of Clinical Trials](#)

Last Update: 2/2/2021

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
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