

PERFUSE Clinical Research Course 2020 / 2021

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

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

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

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

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			<ul style="list-style-type: none"> <li>○ Independent ethics committee (IEC)</li> </ul>	
<b>Week 21</b>	To be confirmed- Tuesday, March 30 <sup>th</sup>	11:00 am EST	<p><b><u>Running a Clinical Trial - II</u></b></p> <ul style="list-style-type: none"> <li>● Study Team</li> <li>● Budget and Contract</li> </ul>	Maria Ok
<b>Week 22</b>	To be confirmed- Tuesday, April 6 <sup>th</sup>	11:00 am EST	<p><b><u>Running a Clinical Trial - III</u></b> <b><u>Study Conduct</u></b></p> <ul style="list-style-type: none"> <li>● Good Clinical Practice (GCP)</li> <li>● Delegation of Authority</li> <li>● The Informed Consent Process</li> </ul>	Danielle Feingold
<b>Week 23</b>	To be confirmed- Tuesday, April 13 <sup>th</sup>	11:00 am EST	<p><b><u>Missing Data</u></b></p> <ul style="list-style-type: none"> <li>● Missing Data and the Impact on Clinical Trials</li> </ul>	C. Michael Gibson
<b>Week 24</b>	To be confirmed- Tuesday, April 22 <sup>nd</sup>	11:00 am EST	<ul style="list-style-type: none"> <li>● <b><u>The Role of Academic Research Organizations in Clinical Research</u></b></li> <li>● <b><u>Sponsor</u></b></li> </ul>	Don Cutlip

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<b>Week 25</b>	To be confirmed- Tuesday, April 27 <sup>th</sup>	11:00 am EST	<p><b><u>Data Review Committee - I</u></b></p> <ul style="list-style-type: none"> <li>● Assessing and Reporting Adverse Events</li> </ul>	TBD
<b>Week 26</b>	To be confirmed- Tuesday, May 4 <sup>th</sup>	11:00 am EST	<p><b><u>Data Review Committee - II</u></b> Clinical Events Committees</p>	David Weiss
<b>Week 27</b>	To be confirmed- Tuesday, May 11 <sup>th</sup>	11:00 am EST	<p><b><u>Data Review Committee - III</u></b> Data and Safety Monitoring Board</p>	Sam Ciaranca
<b>Week 28</b>	To be confirmed- Tuesday, May 18 <sup>th</sup>	11:00 am EST	<ul style="list-style-type: none"> <li>● <b><u>Data Sharing</u></b></li> <li>● <b><u>Open Source</u></b></li> <li>● <b><u>CT.gov Reporting</u></b></li> </ul>	C. Michael Gibson
<b>Week 29</b>	To be confirmed- Tuesday, May 25 <sup>th</sup>	11:00 am EST	<p><b><u>Roles and Responsibilities of the Clinical Research Team</u></b></p> <ul style="list-style-type: none"> <li>● Principal Investigator</li> <li>● Sub-investigator</li> </ul>	Serge Korjian

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<b>Week 30</b>	To be confirmed- Tuesday, June 1 <sup>st</sup>	11:00 am EST	<b><u>Reporting and Interpreting of Results - I</u></b> <ul style="list-style-type: none"><li>● Authorship</li><li>● Disclosure of Conflict of Interest</li></ul>	Arzu Kalayci
<b>Week 31</b>	To be confirmed- Tuesday, June 8 <sup>th</sup>	11:00 am EST	<b><u>Reporting and Interpreting of Results - II</u></b> <ul style="list-style-type: none"><li>● Presentation of Data</li></ul>	Clara Fitzgerald
<b>Week 32</b>	To be confirmed- Tuesday, June 15 <sup>th</sup>	11:00 am EST	<b><u>Reporting and Interpreting of Results - III</u></b> <ul style="list-style-type: none"><li>● Interpretation</li></ul>	Gerald Chi
<b>Week 33</b>	To be confirmed- Tuesday, June 22 <sup>nd</sup>	11:00 am EST	<b><u>Reporting and Interpreting of Results - IV</u></b> <ul style="list-style-type: none"><li>● Publication Bias</li></ul>	Arzu Kalayci
<b>Week 34</b>	To be confirmed- Tuesday, June 29 <sup>th</sup>	11:00 am EST	<b><u>Journal Club Session - I</u></b> <b><u>Critical Appraisal of Clinical Research</u></b> <ul style="list-style-type: none"><li>● What is the research question?</li><li>● What is the study type (design)?</li><li>● Selection issues</li></ul>	Gerald Chi

<b>Week 35</b>	To be confirmed- Tuesday, July 6 <sup>th</sup>	11:00 am EST	<b><u>Journal Club Session - II</u></b> <b><u>Critical Appraisal of Clinical Research</u></b> <ul style="list-style-type: none"><li>● What are the outcome factors and how are they measured?</li><li>● What are the study factors and how are they measured?</li><li>● What is the statistical method used in the study?</li></ul>	Clara Fitzgerald
<b>Week 36</b>	To be confirmed- Tuesday July 13	11:00 am EST	<b><u>Journal Club Session - III</u></b> <b><u>Critical Appraisal of Clinical Research</u></b> <ul style="list-style-type: none"><li>● Interpretation of statistical results</li><li>● What conclusions did the authors reach about the research question?</li><li>● Are ethical issues considered?</li></ul>	Arzu Kalayci
<b>Week 37</b>	To be confirmed- Tuesday, July 20 <sup>th</sup>	11:00 am EST	<b><u>Future Direction</u></b> <ul style="list-style-type: none"><li>● Artificial Intelligence in Clinical Trials</li><li>● Apple Heart Study</li></ul>	C. Michael Gibson