Description: This course is designed for graduate students in statistics or biostatistics interested in the issues underlying the design of interventional studies. General topics include designs for various types of clinical trials (Phase I, II, III), endpoints and control groups, statistical inference in interventional studies, sample size determination, and design considerations for adaptive designs and interventions. Regulatory and ethical issues will also be covered. Students should have a working knowledge of basic biostatistical principles and familiarity with a statistical programming language (e.g. R, SAS). (0.5 course unit, second half of fall semester)

Prerequisites: Permission of instructor

Required Texts: Readings will be taken from the classic and current literature, including textbooks and journal articles

Supplementary Texts: See next page (optional, students may find helpful for additional reading)

Grading: There will be two homeworks and one final exam. Grading will be based on the homework (40%), the final exam (40%), and class participation (20%).

<table>
<thead>
<tr>
<th>Date</th>
<th>Lecture</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 22</td>
<td>Lecture 1</td>
<td>Introduction to Interventional Studies</td>
</tr>
<tr>
<td>October 24</td>
<td>Lecture 2</td>
<td>Phase I Clinical Trials and Pharmacokinetics</td>
</tr>
<tr>
<td>October 29</td>
<td>Lecture 3</td>
<td>Phase II Clinical Trials</td>
</tr>
<tr>
<td>October 31</td>
<td>Lecture 4</td>
<td>Control Groups and Mechanics of Treatment Assignment</td>
</tr>
<tr>
<td>November 5</td>
<td>Lecture 5</td>
<td>Endpoints in Interventional Studies</td>
</tr>
<tr>
<td>November 7</td>
<td>Lecture 6</td>
<td>Hypothesis Testing and Effect Estimation</td>
</tr>
<tr>
<td>November 12</td>
<td>Lecture 7</td>
<td>Experimental Designs</td>
</tr>
<tr>
<td>November 14</td>
<td>Lecture 8</td>
<td>Sample Size and Power for Measured Outcomes</td>
</tr>
<tr>
<td>November 19</td>
<td>Lecture 9</td>
<td>Monitoring and Group Sequential Designs</td>
</tr>
<tr>
<td>November 21</td>
<td>Lecture 10</td>
<td>Adaptive Designs</td>
</tr>
<tr>
<td>November 26</td>
<td>Lecture 11</td>
<td>SMARTs for Adaptive Interventions</td>
</tr>
<tr>
<td>December 3</td>
<td>Lecture 12</td>
<td>Statistical Analysis Plans and Reproducible Research</td>
</tr>
<tr>
<td>December 5</td>
<td>Lecture 13</td>
<td>Final Exam</td>
</tr>
</tbody>
</table>
Texts Recommended for Further Reading on Clinical Trials

Highly-recommended:


Other Texts on Clinical Trials in General:


Specialized Trial Designs:


Sequential/Adaptive Methods and Monitoring:


Related Topics: