

BIOS5005 Clinical Trials

(1.5 credits)

Course Coordinator: Prof Marc Chong

Course Description

The objective of this course is to provide students with a theoretical and practical knowledge of the issues involved in the design, conduct, analysis and interpretation of randomized clinical trials. We will discuss the basic principle of randomization and its importance, proper randomization and blinding procedures, choice of control arm, the importance of clear definition of endpoints, methods to calculate sample size, other statistical considerations and ethical issues in clinical trials. Attention will be given to the problems of conducting clinical trials in both single center and multi-center, and covers trials initiated by industry as well as trials in academic setting. Students will be trained to develop skills to properly design clinical trial, critically analyze and carry out research and to communicate effectively.

Learning Outcomes/Objectives

1. Understand the advantages and disadvantages of various designs in clinical research.
2. Understand the concepts of randomization in controlled clinical trials.
3. Develop a protocol for a clinical trial to address the research questions.
4. Have a general knowledge of the statistical issues commonly encountered in clinical trials.
5. Be aware of the ethical issues in clinical trials.
6. Have an appreciation of the Good Clinical Practice (GCP) requirements in the operation of clinical trials.
7. Learn some basic elements of data management and quality assurance in multi-center clinical trial set up.

Course Schedule

| Session | Date | Time | Venue |
|---------|--------------------|----------------|---|
| 1 | Oct 3, 2016 (Mon) | 6:30 – 9:30 pm | School of Public Health Prince of Wales of Hospital Shatin, N.T., Hong Kong |
| 2 | Oct 17, 2016 (Mon) | 6:30 – 9:30 pm | |
| 3 | Oct 24, 2016 (Mon) | 6:30 – 9:30 pm | |
| 4 | Oct 31, 2016 (Mon) | 6:30 – 9:30 pm | |
| 5 | Nov 7, 2016 (Mon) | 6:30 – 9:30 pm | |
| 6 | Nov 14, 2016 (Mon) | 6:30 – 9:30 pm | |
| 7 | Nov 21, 2016 (Mon) | 6:00 – 9:30 pm | |

Fee

Application Fee: \$100

Course Fee: \$8,800