

BME215 Clinical Trials

Level: 2

Credit Units: 5 Credit Units

Language: ENGLISH

Presentation Pattern: EVERY JULY

Synopsis:

In this course, students will be introduced to the basic principles behind the design of clinical research trials to effectively test medical hypotheses. The critical components of a well designed clinical research protocol will be explored. Students will be exposed to the different types of clinical trials used in the industrial, government and academic sectors for pharmaceutical, medical device, or biologic interventions.

Topics:

- Introduction to Clinical Trials
- Clinical Trial Design, Protocol and Planning
- Clinical Trial Regulation
- Clinical Trial Administration and Management
- Biostatistics
- Scientific Writing and Scientific Literature Appraisal

Textbooks:

BME215 Singapore Guideline for Good Clinical Practice, Ministry of Health, Singapore
ISBN-13: RD-0107

BME215 Study Guide Jul15
ISBN-13: SG-1011

Learning Outcome:

- Comment on the different clinical trial types, phases, processes and parties involved
- Examine the roles and responsibilities of the various parties involved in clinical trials
- Illustrate the essential features of clinical trial design, protocol write-up and project planning
- Discuss on the regulatory issues and bodies concerned
- Practice the principles of good clinical practice
- Analyze the clinical data collected using basic statistical tools.

Assessment Strategies - Regular Semester (Evening Class):

Components	Description	Weightage Allocation (%)
Overall Continuous Assessment	PRE-CLASS QUIZ 1	2
	PRE-CLASS QUIZ 2	2
	PRE-CLASS QUIZ 3	2
	QUIZ 1	12
	TUTOR-MARKED ASSIGNMENT 1	12
Overall Examinable Components	Written Exam	70
Total		100

*The information listed is subject to review and change.