

BME215e Clinical Trials

Level: 2

Credit Units: 5 Credit Units

Language: ENGLISH

Presentation Pattern: EVERY JULY

E-Learning: BLENDED - Learning is done MAINLY online using interactive study materials in Canvas. Students receive guidance and support from online instructors via discussion forums and emails. This is supplemented with SOME face-to-face sessions. If the course has an exam component, this will be administered on-campus.

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

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:

| Continuous Assessment Component | Weightage (%) |
|---------------------------------|---------------|
| QUIZ | 12 |
| TUTOR-MARKED ASSIGNMENT | 12 |
| PRE-CLASS QUIZ | 2 |
| PRE-CLASS QUIZ | 2 |
| PRE-CLASS QUIZ | 2 |
| Sub-Total | 30 |

| Examinable Component | Weightage (%) |
|----------------------|---------------|
| Written Exam | 70 |

| | |
|------------------|-----------|
| Sub-Total | 70 |
|------------------|-----------|

Weightage Total **100**