



# Design and Analysis of Clinical Trials



(EPHD321)

## **Coordinator/Instructor Details:**

Name : Ziyad Mahfoud, Ph.D.

Email : zrm2001@Qatar-med.cornell.edu

Skype name: **ziyad.mahfoud**

**Other instructors:** Ghada El-Hajj Fuleihan, MD, MPH.      email: gf01@aub.edu.lb

## **Course Information:**

Credits : 2

Class Time : Fridays (2 hours) 3:30 pm- 5:30 and Saturdays (4 hours) 9:00 am – 1:00 pm according to schedule given in this syllabus.

Place : Van Dyck room 201 and possibly the Computer Lab

## **Course Description:**

A course that focuses on issues in the design and analysis of randomized controlled clinical trials: Phases patient selection, recruitment, masking and randomization, endpoint definition, different designs and corresponding statistical analysis.

## **Course Objectives:**

1. To understand basic principles of clinical trial design including bias, randomization, blocking, masking, ...etc
2. To be familiar with statistical concepts that will be used in the analysis and interpretations of trial outcomes
3. To demonstrate the knowledge of methods used in the analysis of specific designs like factorial designs, cross over designs...etc

## **Course structure**

In addition to PowerPoint presentations in class, supportive reading material will be made available online when needed. Some of those reading materials will be accompanied with homework to be submitted on a specific date. All lectures, reading materials and exercises will be posted on moodle.

**Tentative Grading:**

Your grade will be based on the following

| <b><u>Activity</u></b> | <b><u>percentage</u></b> | <b><u>Objectives</u></b> |
|------------------------|--------------------------|--------------------------|
| Home Works             | 20%                      | 1,2                      |
| Midterm                | 35%                      | 1,3                      |
| Final                  | 45%                      | 1,2,3                    |

**Academic Integrity/Dishonesty:**

Cheating and plagiarism will not be tolerated. Review the Student Code of Conduct in your handbook and familiarize yourself with definitions and penalties. If you're in doubt about what constitutes plagiarism, ask your instructor because it is *your* responsibility to know. The American University of Beirut has a strict anti-cheating policy. Penalties include failing marks on the assignment in question, suspension or expulsion from University and a permanent mention of the disciplinary action in the student's records.

**COPYRIGHT NOTICE:**

Students are allowed to make one single copy of the course material for personal use during the semester. Copies of course material for third parties are forbidden. Students will be responsible for any misuse of material of this course.

**Accessible Education: Disability Services & Learning Support:**

'AUB strives to make learning experiences accessible for all. If you anticipate or experience academic barriers due to a disability (such as ADHD, learning difficulties, mental health conditions, chronic or temporary medical conditions), please do not hesitate to inform me. In order to ensure that you receive the support you need and to facilitate a smooth accommodations process, you must register with the Accessible Education Office (AEO) as soon as possible: [accessibility@aub.edu.lb](mailto:accessibility@aub.edu.lb); +961-1-350000, x3246; West Hall, 314'.

## Tentative Schedule

| <b>Day</b>      | <b>Date</b>  | <b>Lecture</b>  | <b>Instructor</b>                       |
|-----------------|--|---|---|
| Friday          | 15-Sept-2017<br>(Location: IRB Conference room, Gefinor Bldg, Bloc B, 5 <sup>th</sup> floor) | Introduction to Clinical Trials<br><br>Phase 1 Clinical Trials            | Dr. El Hajj Fuleihan<br><br>Dr. Mahfoud |
| Saturday        | 16-Sept-2017   | Phase 2/phase 3 Clinical Trials   | Dr. Mahfoud                             |
| Friday          | 6-Oct-2017   | Phase 3 Clinical trials randomization, power and sample size              | Dr. Mahfoud                             |
| Saturday        | 7-Oct-2017   | Phase 3 Clinical trials analysis issues and practice                      | Dr. Mahfoud                             |
| Friday          | 20-Oct-2017  | Factorial Designs   | Dr. Mahfoud                             |
| <b>Saturday</b> | <b>21-Oct-2017</b>   | <b>Midterm Exam</b><br>Cross over designs                                 | Dr. Mahfoud                             |
| Friday          | 3-Nov-2017   | Non-inferiority trials<br>Adaptive designs                                | Dr. Mahfoud                             |
| Saturday        | 4-Nov-2017   | Clustered randomized trials<br>Interim analysis issues in clinical trials | Dr. Mahfoud                             |
| Friday          | 17-Nov-2017<br>(Location: IRB Conference room, Gefinor Bldg, Bloc B, 5 <sup>th</sup> floor)  | Practical issues in clinical trials<br>(lesson learned from experience)   | Dr El-Hajj Fuleihan                     |
|                 | <b>TBA</b>   | <b>Final Exam</b>   |   |