



## EDUCATION PROGRAM 2011 -2012



It includes 2 modules:

- Module of academic course (obligatory):
  - 112 hours for the UD of the "Fundamentals in Medical Research"
  - 80 hours for the CRA "Clinical Research Assistant" and CRT "Clinical Research Technician"
- Module consisting in a minimum of 2 weeks of professional training. This training is optional for persons working in research units.

Modules in blue are specific to the UD; modules in black are common to the UD (post-doc) and to the professional certificate of ARC and CRT (Bac +3)

### THE ACADEMIC COURSES

#### MODULE 1: 20, 21, 22 October 2011

##### Biology and New therapeutic approaches

###### Thursday 20

- 16h – 16h30 Introduction (Pr. Roland Asmar)  
16h30 – 17h30 Endocrinology - Diabetes (Dr. Zelia Francis)

###### Friday 21

- 16h – 17h Infectious diseases (Dr. Nadine Yared)  
17h – 18h Urology – Nephrology (Dr. Jose Khabout)  
18h30 – 20h30 Genome and Therapy (Dr. Rana Bazzi)

###### Saturday 22

- 9h – 10h Gastroenterology (Dr. Antoine Abi Rached)  
10h – 11h Pulmonary (Dr. Wajdi Abi Saleh)  
11h15 – 12h15 Oncology (Dr. Fadi Nasr)  
12h15 – 13h15 Neurology – Psychiatry (Dr. Wadih Naja)  
14h15 – 16h15 Cardiology (Pr. Roland Asmar)

#### MODULE 2: 11, 12 November 2011

###### Friday 11

##### Research bases and methodology

- 16h – 18h Safeguarding of persons participating in research studies, Ethics committees, Declaration of Helsinki, regulation; Responsibilities and insurance: manufacturer, investigator, hospital, patient (Me Charles Ghafari)

##### Pharmacology

- 18h30 – 20h30 Pharmacokinetics – Pharmacodynamics (Pr. Atul Pathak)

###### Saturday 12

- 9h – 13h Toxicity – Tolerability  
Basic knowledge on pharmacogenetics (Pr. Atul Pathak)

##### The pharmacist and the clinical trials

- 14h – 20h Pharmaco-vigilance: organization, methods, and imputability  
Role of the hospital pharmacist in clinical trials; Drug management; IVRS (central randomization)  
Traceability of therapeutic units  
(Dr. Marie Thérèse Sawaya)

#### MODULE 3: 2, 3 December 2011

###### Friday 1

- 16h – 20h Workshop: Clinical Research applied to medical devices. From development to post marketing. (Dr. Abdelnour Faraj)

###### Saturday 2

- 9h - 13h Workshop: Clinical Research applied to medical devices. From development to post marketing. (Dr. Abdelnour Faraj)  
14h – 18h Applied genomics: toward personalized medicine (Dr. Rana Bazzi)  
18h15 – 19h15 Hematology – Immunology (Dr. Adlette Inaty)

Fondation – Institut de Recherche Médicale

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## MODULE 4: 13, 14 January 2012

### Friday 13

16h – 20h

Careers in Clinical Research  
Quality Management in Clinical Research

### Saturday 14

9h – 18h

Essentials of a study: protocol, CRF, e-CRF and Data base: creation and follow-up  
Monitoring and follow-up of a study  
Closing, analysis and report of a study  
Operating procedures applied to a study; interface with data management, statistic, pharmacovigilance, logistics of treatment, CROs, ...  
(Dr. Léna Massad)

## MODULE 5: 20, 21 January 2012

### Friday 20

16h – 20h

Applied Research in the evaluation of health care systems: evaluation of needs, selection and implementation of supply (Dr. Walid Ammar)

### Research bases and methodology

### Saturday 21

9h – 18h

Regulatory requirements of national and international agencies and administrative commissions: FDA, EMEA, Good Clinical Practice and Good Research Practice principles, « International Conference on Harmonization » (ICH)  
« CoreLab ». Adjudication; « Data monitoring Committee »; The organization of Research: Budget and Organization; Confidentiality (NDA)  
The various types of medical research: Experimental, biological and molecular research; Clinical and epidemiological research; new research prospects: industrial and non industrial  
(Dr. Luc Feldmann)

## MODULE 6: 9, 10 February 2012

### Drug development – Preclinical and clinical development

### Thursday 1

16h – 20h

Animal experimentation  
Studies in human, the various phases of clinical trials: preclinical phase, phase I

### Friday 2

16h – 20h

Studies in human, the various phases of clinical trials: phases II, III & IV, post-marketing studies, morbidity studies  
The major steps: duration, cost, commercialization, patents and brands

(Dr. Raphael Laoun)

## MODULE 7: 15, 16, 17 March 2012

### Thursday 15

16h – 20h

Risk management and adverse events  
Coding and data reconciliation  
(Dr. Léna Massad)

### Friday 16

16h – 20h

Data analysis: Database constitution; Data management and analyses (Dr. Jirar Topouchian)

### Saturday 17

9h – 13h

Workshop: Role of the CRAs and CRTs (Dr. Jirar Topouchian)

14h – 18h

Workshop: Transcription of data. Verification. Quality Control  
(Dr. Léna Massad)



## MODULE 8: 19, 20, 21 April 2012

Thursday 19: 16h- 20h

Friday 20: 16h – 20h

Saturday 21: 9h -13h

### Statistics et data analysis

Statistical principles for clinical trials

Data analysis and interpretation: primary and secondary endpoints, post-hoc analysis ...

The statistical report

(Dr. Pascale Salameh & Dr. Nadine Yared)

### Organization of a clinical trial: role of the CRAs and CRTs

14h – 18h      Communication: Means and methods (Dr. Souleima Chamat)

## MODULE 9: 10, 11, 12 May 2012

Thursday 10

16h – 20h

Systematic review – theory and practical application

Critical analysis of diagnostic studies

Critical analysis of prognostic studies

Article review

(Dr. Antoine Elias)

### Introduction to bibliographic handling and to medical writing

Friday 11

16h – 20h

The tools of bibliographic research: index medicus, pubmed

Preparation of a reference list

Basic principles and methods in article writing

(Dr. Jean Jacques Mourad)

Saturday 12

9h - 13h

Workshop: Bibliographic handling and to medical writing (Dr. Jean-Jacques Mourad)

## MODULE 10: 1, 2 June 2012

Friday 1

16h – 20h

(Dr. Lilianne Massad)

Saturday 2

9h - 14h

(Dr. Lilianne Massad)

14h – 18h

Workshop: Communication and Publication (Dr. Souleima Chamat)

## MODULE 11: 8, 9 June 2012

Friday 8

16h – 20h

Introduction to fundamental research; Organization, methods and means (Pr. Ziad Mallat)

### Organization of a clinical trial: role of the CRAs and CRTs

Saturday 9

9h – 18h

Contribution to the elaboration of study protocols

Study implementation, pre-investigation visit

Control of the quality and the reliability of the collected study data

Data quality assurance: Quality control and audit; Management and follow-up of the study visits

(Pr. Tabassome Simon & Pr Ziad Mallat)



## **THE PROFESSIONAL TRAINING**

A 2-week min active training session will be organized for all students having successfully achieved written tests; this training is optional for persons already working in research units.

This active training phase will take place in laboratory research units, contract research organizations (CRO), academic hospital centers, or in clinical investigation centers (CIC). Training sessions will be carried out in Lebanon first, then in other countries, depending on the availability of positions and the student's grade at the final exam.

A training agreement will settle and fix the training modalities and relationships between the student, the university and the laboratory where the training will take place.