COURSE SPECIFICATION

(Clinical Translation and Trials in Practice Translation)

Faculty of Medicine– Mansoura University

(A) Administrative information

(1) Programme offering the course:	Postgraduate PhD degree of Regenerative Medicine/ RMD
(2) Department offering the programme:	Inter-departmental (Faculty of Medicine)
(3) Department responsible for teaching the course:	Clinical Pathology Department
(4) Part of the programme:	Second part (Semester III)-Elective
(5) Date of approval by Faculty council	9/8/2016
(6) Date of last approval of programme specification by Faculty council	9/8/2016
(7) Course title:	Clinical Translation and Trials in Practice
(8) Course code:	RMD630PS1
(9) Total credit hours:	2 Theoretical + 1.5 Laboratory/Practical + 0.5 field work

(B) Professional information

(1) Course Aims:

The broad aims of the course are as follows:

This course provide students with knowledge about the basics of regulatory requirements for clinical research in humans. They will have gained an overview of the Good Clinical Practice (GCP)-the international quality standard for clinical trials.

Egyptian regulations on advanced cellular therapeutics and local regulations of cell-based therapeutics will be introduced including the requirements of Good Manufacturing Practice (GMP) and genetic manipulation of cells within clinical trials. Students will be familiar with the basics of planning and executing phase I-III trials with an experimental therapy.

They will have an overview of the required infrastructure, preclinical data and bioinformatics required to design an investigator-initiated study. They also know the Declaration of Helsinki and patients' rights policies.

Students will be introduced into the essential documents of clinical protocols, e.g. investigator´s brochure, patient information and informed consent. An own trial synopsis will be developed and discussed. Exercises for completing a case report form as the first step in a data management due to GCP will be performed. In addition, students will join clinician researchers, documentation assistants and study nurses during their practical work including patient and data management.

Students will have a basic understanding of regulatory requirements and preclinical studies including toxicological testing, metabolism and pharmacology which have to be fulfilled before starting a clinical trial. They are also familiar with the tasks and obligations of sponsor and an investigator according to GCP.

(2) Intended Learning Outcomes (ILOs):

A- Knowledge and Understanding:

On successful completion of the programme, the candidate will be able to:

A7: Mention principles of stem cells research and technology.

B- Intellectual skills:

On successful completion of the programme, the candidate will be able to:

B1: Analyze and solve problems related to molecular biology and genetics.

B2: Identify the ethical implications of the work in the field of regenerative medicine.

B3: Execute and report a research project in order to develop skills necessary for independent research.

B4: Apply theoretical concepts to the study of the molecular biology and genetics and evaluate the relationships between theory and practice.

C- Professional/practical skills:

On successful completion of the programme, the candidate will be able to:

C3: Isolate, characterize, culture and transdifferentiate stem cells.

D- Communication & Transferable skills:

On successful completion of the programme, the candidate will be able to:

D1: Communicate effectively using a variety of formats.

D2: Use effectively a range of information sources.

D3: Organize and present intellectual argument commensurate with the level of award.

D4: Work effectively both alone (e.g. on assignments or during the project) and as part of a team (e.g. in group work, during group discussions and workshops).

D5: Demonstrate key skills in the retrieval, preparation, analysis and interpretation of information from different sources.

D6: Acquire continued self-managed professional development.

D7: Apply the principle of reflective practice.

(3) Course content:

Subjects	Lectures	Clinical	Laboratory	Field	Total Hours
Clinical Translation and Trials in Practice / RMD630PS1		**15W**			
1- Phases of a trial-1 2- Phases of a trial-2 3- Pharmacovigilance 4- Lost in translation? 5- In vitro studies 6- In vivo studies 7- In silico studies 8- Role of foundations in regenerative medicine 9- Biomedical research commercialization 10- Clinical trials – fundamentals 11- Bench to bedside- adoption of new therapies 12- Evolution from evidence based medicine to knowledge translation 13- Biomarkers and assays 14- ISSCR guidelines for translation 15- Translational Medicine	2		1.5	0.5	**4 hours**

(4) Teaching methods:

4.1: Lectures

4.2: Practical lab work

(5) Assessment methods:

5.1: Exam Description

The final exam is composed of:

Two written exams (100 marks) 2 hours (Short Essay questions 1 hours 80 marks + MCQ 1 hour 20 marks)

Other logbook activities (Practical part of the course and scientific activities) are assessed by supervisor of the activity without marks

5.2: Marks

Course/ code	Marks					
	Written Exam			Practical Exam	Oral Exam	Total
	Short Essay questions	MCQ	total			
Clinical Translation and trials in practice/ RMD630PS1	**80**	**20**	**100**	--	--	**100**

(6) References of the course:

Text books: Principles of Translational Science in Medicine; from Bench to Bedside.

(7) Facilities and resources mandatory for course completion:

Lecture halls and data show and MERC labs

Course coordinator: Dr. Mohamed Salama

Programme Director: Prof.Mohamed Sobh

Date: