APPLIED CLINICAL RESEARCH CERTIFICATION IN AESTHETIC, PHARMACEUTICAL AND REGENERATIVE MEDICINE – *Observational Clinical Study*

Guidebook

In collaboration with

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COURSE BACKGROUND

Conducting clinical medical research is always a challenge, especially in the field of aesthetic, pharmaceutical, and regenerative medicine. This emerging medical field is lacking guidance, training, and reference hence limit the ability to withhold the sanctity of Evidence-Based Medicine (EBM). According to the USMARI centre taxonomy of clinical research, clinical research of this field can be categorised into an experimental (interventional) clinical trial or observational (non-interventional) clinical study.

Experimental (interventional) clinical study (trial) is define as any study performed on human with the purpose of studying or demonstrating the clinical or pharmacological effects of drugs, to establish side effects, or to investigate absorption, distribution, metabolism or elimination, to provide clear evidence of the efficacy or safety of the drug. It also includes studies on medical devices and studies in which surgical, physical, or psychotherapeutic procedures are examined. It compares treatment procedures within a patient population, which should exhibit as few as possible internal differences, apart from the treatment. Experimental (interventional) clinical study (trial) is subject to a variety of legal and ethical requirements, including registering to the responsible authorities and obtained approval from the ethics committee. The clinical trial must be performed following the binding rules of Good Clinical Practice (GCP). Often follow randomisation, including the control group (even though not all the studies). The selection of the control group must be not only ethically defensible, but also be suitable for answering the most critical questions in the study. Ethical consideration is essential such as the patient should sign a declaration of consent (informed consent). It is more robust and sophisticated with appropriate measurement, well-described method, and design, blinding, and uses inferential statistical analysis to ensure fewer biases and error. International recommendations for the reporting of randomized clinical studies can be found in the CONSORT statement (Consolidated Standards of Reporting Trials). Examples of experimental studies (interventional) are Randomised Controlled Trial, Non-Randomised Controlled Trial.

Observational (non-interventional) study, on the other hand, is defined as a study in the context of which knowledge from the treatment of persons with drugs in accordance with the instructions for the use specified in their registration is analysed. The diagnosis, treatment, and monitoring are not performed according to a previously specified study protocol, but exclusively according to medical practice. It also includes studies on medical devices and studies in which surgical, physical, or psychotherapeutic procedures are examined. Similarly to clinical studies, non-interventional therapy studies include a comparison between therapies. The treatment is exclusively according to the physician's discretion, and sometimes the patient wishes. It often does not require approval from the ethics committee. However, ethical consideration and patient signed consent form (informed consent) is essential. Relatively simple and more applicable to clinic set-up as compare to experimental (interventional) trial (Non-randomised, control group seldom required). Observational (non-interventional) study reporting guidelines are unspecified; however, when possible, PROCESS (case series reporting in surgery) and CARE (Case

report) guidelines are recommended. USMARI centre shall suggest its guidelines for reporting observational (non-interventional) clinical research in aesthetic, pharmaceutical, and regenerative medicine. Examples of observational studies (non-interventional) are Before and after study, Controlled before and after study, Spatial cohort studies, Parallel cohort studies, Case-control studies, Cross-sectional studies, and Case series.

COURSE OBJECTIVES

This course aims to guide the student towards achieving competence and proficiency in the theory and practice of observational (non-interventional) clinical study in Aesthetic, Pharmaceutical, Regenerative Medicine. This fundamental objective can be realised through helping these students to develop the subject of their research, encourage the formation of higher level of trained intellectual ability, critical analysis, rigour, and independence of thought, foster individual judgment, and skill in the application of research theory and methods, and develop skills required in writing research proposals and apply the knowledge to conduct a proper well-designed observational (non-interventional) clinical study in aesthetic, pharmaceutical, and regenerative medicine together with proper reporting write up on their own.

COURSE DESCRIPTION

USMARI Centre offers a five (5) month course leading to the Certificate Of Applied Clinical Research In Aesthetic, Pharmaceutical, And Regenerative Medicine with the main focus on an observational (non-interventional) clinical study. Students enrolling in this course are required to study subjects such as research fundamentals, ethics in research, statistic data analysis & interpretation, clinical intervention research design, methodology, and so on. They are also required to participate in a group activity during classes and after classes group project. These students will learn how to construct and conduct a mock / conformity observational (non-interventional) clinical study during the course. To culminate this course, students will learn to write a comprehensive report according to standard reporting guidelines on Aesthetic, Pharmaceutical, Regenerative Medicine observational (non-interventional) clinical study suggested by USMARI centre. Hopefully, this can equip them with basic knowledge and experience to conduct a clinical study on their own.

Certificate Title	Certificate of Applied Clinical Research in Aesthetic, Pharmaceutical, Regenerative Medicine (Observational Clinical Study)
Duration	5 months
Delivery Mode	Lecture, group discussion, assignment, project
Venue	EMS Training Centre, KL (or other designated venue)
Pre-requisite	NA
Course Codes	UCACR-O/20

COURSE STRUCTURE

The structure of the course is divided into theoretical, practical application of conducting the study and reporting observational (non-interventional) clinical study based on the framework suggested USMARI centre. There are two (2) modules in the course structure.

Module 1: Consist of theoretical knowledge on the fundamentals of clinical research (Overview, Taxonomy of Research design, Literature Review, Ethical issues, Data analysis, References, Appendices, etc.). The delivery mode of this module is by face to face lecture and self-reading (assignment).

Module 2: Entail of practical activities in conducting and reporting the observational (non-interventional) clinical study based on the suggested mock/conformity published clinical papers. Students need to participate in group discussions and perform the observational (non-interventional) clinical study as their final group project.

The course consist of 4 session

Session	**1**	**2**	**3**	**4**
Duration	12 h	10 h	8 weeks	10 h
Activities	Lecture/ Practical/Assignment		Group Project	Practical

OTHER IMPORTANT INFORMATION

1. TIMELINE

1.1. Total session for the course is 4 (four) Sessions within 5 months.
1.2. Each session will be divided into 2 days except session 3, whereby students need to complete the group project within 8 weeks
1.3. The date and time shall be informed by USMARI Centre secretariat at the beginning of the program.
1.4. USMARI Centre secretariat shall notify any change of time, if arises, serving sufficient notice to the students.

2. ATTENDENCE

2.1. Participants need to attend minimum 80% from the total lecture's hours
2.2. Participants shall notify and provide a valid reason to the secretariat if unable to meet the minimum attendance hour's requirement.

3. GROUP PROJECT

3.1. In this course, students are responsible for the timely completion and submission of group project.
3.2. Students need to participate in the classroom discussion during proposal stage and during final report/presentation of the research project.

3.3. They have to write a scientific report including an introduction/rationale, methods/analysis, results, and discussion. The final paper should resemble a scientific journal article in structure, style and format.

3.4. Results presented should include some or all of the following: descriptive statistics (means, standard deviations, frequencies), graphic presentation, reliability and validity, and tests of significance.

4. PROGRAM VENUE

4.1. The venue shall be informed by USMARI Centre secretariat at the beginning of the program

4.2. USMARI Centre secretariat have the full discretion on location of venue for the course.

4.3. USMARI Centre secretariat shall notify any change in the venue, if arises, serving sufficient notice to the Trainees.

5. FEES

5.1. The fee for this course shall be paid before the commencement of the course.

5.2. This fee includes:

- 5.2.1. Lecturer and tutor fee
- 5.2.2. Hands out
- 5.2.3. Lecture hall facilities
- 5.2.4. Food and beverages throughout the course

5.3. The fee is not inclusive of:

- 5.3.1. Accommodation
- 5.3.2. Travelling expenses
- 5.3.3. Reference book

Disclaimer: USMARI will hold the rights to change the programme schedule, the items or guidelines of any part in this guide book without prior notice to the Participants.