# Introduction to Clinical Research Training - Dubai. (March-September 2020)

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## Abstract

It is well known that there is a great need for research training programs in the scientific community of the MENA region. The increasing number of clinical trials conducted in the region mandates that all involved personnel undergo the necessary training to work on increasingly complex studies, ensuring adequate quality in clinical trials and adherence to international guidelines. The Introduction to Clinical Research Training program ICRT conducted in Dubai by Harvard Medical School is considered one of the leading clinical research training programs in the region with great benefits and adjustable limitations.

Keywords: Dubai, education, Harvard, Middle East, research, trials

#### INTRODUCTION

The interest in conducting clinical trials in MENA is expected to continue rising in the future. On the one hand, MENA offers a large market, more patients, a variety of diseases, and higher site productivity at lower costs. On the other hand, several MENA countries are steadily developing their clinical trials regulations and infrastructure to attract more clinical studies

There is a general paucity in medical research productivity in the Arab countries. It has been estimated that the Arab world produces 189 publications per 1 million of population, which is almost a quarter of the value for other world countries.<sup>[1]</sup> The growing interest in pharmaceutical business in the MENA region has not been accompanied by a comparable

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increase in participation in clinical trials.<sup>[2]</sup> One of the plausible reasons is the lack of proper research infrastructure and training.<sup>[3]</sup> Research methodology training has recently been incorporated in regional medical and nursing schools in undergraduate level, while other senior staff may have acquired research training as part of their postgraduate academic degree requirements. This leaves a large proportion of practicing professionals to their personal interest to pursue training in that domain. The doctors' attitudes and challenges to undertaking

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323

research particularly in clinical practice have been highlighted by our group in a recent survey from the MENA region.<sup>[4]</sup>

Currently, many pharmaceutical companies, universities and other Clinical Research Organizations and health authorities organize series of lectures and workshops on various aspects of clinical research to in-house employees or interested stakeholders; however, very few offer structured training programs to interested health care providers and scholars.

Perhaps in the MENA region only 2 nondegree certification programs are available. The Scholars in Health Research Program summer certificate is a 7-week long program, delivered by Clinical Research Institute of the American University of Beirut, that covers fundamental skills in the essential disciplines to conduct research, namely epidemiology, biostatistics, research ethics, library sciences/informatics, and involves hands-on training in the analysis and reporting of large health related datasets in Non-Communicable Diseases.<sup>[5]</sup> The second well-established program is the Introduction to Clinical Research Training (ICRT) - Dubai program offered by Harvard Medical School.<sup>[6]</sup>

Recently, Harvard Medical School in collaboration with Ministry of Health of Egypt has announced a new 6-month online program titled Clinical Scholars Research Training (CSRT) primarily targeting clinicians and health-care educators practicing Egypt.<sup>[7]</sup>

## **CONFERENCE HIGHLIGHTS**

## The course and its objectives

ICRT program, developed by Harvard Medical School and conducted in Dubai, provides learners with the foundations in designing, conducting, and implementing clinical research studies. It progresses from developing research questions and testing hypotheses to interpreting and communicating research results to writing organized manuscripts and delivering engaging presentations. The program's skills-based, peer-to-peer blended-learning approach covers topics during the intensive six-month curriculum including epidemiology, biostatistics, STATA programming, and study design, as well as ethical issues, scientific communication, clinical trials, and research leadership concepts. The overarching goal of the Clinical Research Foundations program is to equip the next generation of researchers with the essential skills to become independent clinical research investigators and to assume leadership and mentorship positions throughout their academic careers. The specific educational objectives of the course are provided in Table 1.

## Learning model

The learning in based on two models; The Blended Learning model and Team-based Learning model. The blended-learning approach combines the traditional face-to-face teaching methods of workshops and recorded online lectures supported by interactive webinars, to form an integrated instructional approach. All recorded lectures and webinars are made accessible throughout the course and 6 months after the completion of the program enhancing opportunities for knowledge retention. The team-based learning is essential since collaboration is a critical ingredient in scientific discovery promoting team approaches to solving research problems. Here, students will learn how to work in teams and develop networks. Students are divided into globally diverse groups to collaborate with each other on assignments during the live workshops and in between. As the program in 2020 took place during the COVID 19 pandemic, the second workshop was conducted virtually in contrast to the first one which was delivered in person just before the lockdown early March.

## Program overall structure

The interactive workshop curriculum was focused on the hands-on the development of clinical research skills. Key elements of the workshop have included practical exercises in manuscript and research proposal development, critical assessment of the medical literature, and practical training on STATA statistical software using real-life data sets from Framingham Heart Study and the Digitalis Investigation Group Study. In addition, training in mentorship, academic career development, and leadership were covered during the course of the program.

#### Table 1: The Specific, measurable, attainable, relevant, and time educational objectives of the Introduction to clinical research training - Dubai 2020

At the end of the program a participant is expected to

Demonstrate a clear understanding of the core concepts of biostatistics and epidemiology pertaining to clinical research

Develop a research question and formulate a testable hypothesis Apply the design, implementation and presentation of a clinical research study

Synthesize essential statistical analyses using STATA software Evaluate the ethical principles relevant to clinical research

#### Table 2: The five module of the course

M1. Introduction to epidemiology

M2. Ethical issues in clinical research

M3. Introduction to biostatistics

M4. STATA workshop

M5. Clinical trials

#### **Modules and assessment**

The five modules of the course are listed in Table 2. Online lectures covering topics in epidemiology, biostatistics, study design, scientific writing, dissection of scientific papers, management and leadership Interactive webinars designed to expand or review lecture topics. The course material delivered by faculty from schools across Harvard University. Each module is followed by an MCQ-based quiz reinforcing the learning experience. Further assessment was carried out through the completion of two team assignments enriching group collaboration in summarizing and critically appraising a specified original publication from Ethics point of view in the first assignment, and presenting a novel research question using a feasible innovative approach in the second. Individual assessment was done through presenting page 1 of a research proposal including the research question, relevance, background, connecting the hypotheses and aims with the research questions.

#### Limitations

Despite the high standards of the course, few limitations are noteworthy. First, a lot of the emphasis was made on training for conduct of clinical trials. This aspect of research may not be widely needed and even if it is conducted, a lot of the control of the studies would be guided by the sponsors and international bodies. Therefore, more emphasis would have been better made on conducting research in the real world, appraising other designs using various examples of published work from the region. Second, a major limitation is related to the use of the statistical package choice, and spending great deal of time on explaining programing codes rather than interpretation of results, which is far more important for non-statisticians. STATA software, though a robust tool, is rarely used in the MENA region, and use of a more commonly used package such as SPSS would have been a wiser choice.

Many participants have expressed their dissatisfaction with the high cost of the program as many were in their early stages of their medical career. Obviously, the restraint imposed by the current pandemic state has made face to face interaction rather impossible. Otherwise an additional physical workshop dedicated to hands-on training on the statistical package would have been much worthy. Including certification in Good Clinical Practice within the course of 6 months could have added greater value to the program encouraging candidates to take part in ongoing research initiatives. Finally, more emphasis should have been put on writing skills and submissions, choice of journals, responding to reviewers, finalization of manuscripts, and be wary of predatory journals and publishers. Finally, many participants were expecting more training on how to conduct and mange and large databases in multicenter studies, however, this exercise was lacking.

#### **FINAL REMARKS**

The program is one of its kind in the region. In spite of the limitations imposed by the COVID 19 situation, the program has attracted many candidates to actively participate during this difficult period, reflecting the need for research training. As an introductory course to clinical research with flexible online component, ideally suited for busy health care providers with limited experience in medical research, ICRT is highly recommended.

#### Authors' contributions

Both authors have attended the 2020 program, and have contributed equally to the information presented.

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Nil.

### **Conflicts of interest**

There are no conflicts of interest.

#### **Compliance with ethical principles**

Not applicable.

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