



Harvard Medical School

Department of Continuing Education

PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH

*International Distance-Learning Clinical Research
Training Program*

Course Director: Felipe Fregni, MD, PhD, MPH

ASSISTANT PROFESSOR, HARVARD MEDICAL SCHOOL

February – October 2011

Courtyard Marriott – Cambridge, MA

What You Can Expect

Our collaborative distance-learning Harvard Medical School program in Clinical Trials is offered to participants from Boston and throughout the world. This HMS-CME course is designed for individuals who wish to gain basic advanced training in clinical trials before moving into the field and for those who have experience in this area and aim to broaden their role in the design, management, analysis, and reporting of clinical trials. Earn up to 63 credits (or 94.75 with the optional 4-day workshop in São Paulo, Brazil).



Please contact: info@clinicalresearchlearning.org for more information

www.clinicalresearchlearning.org

General Information

Who Is Right for the Program

The applicants usually have a graduate degree or a health care professional degree (MD, MPH, biostatistics, epidemiology, nursing, physical and speech therapy, and dentistry) and they come from several countries since participants can take this course in their hometown. However, interaction with other students and instructors as well as participation in the course activities is a requirement for a successful completion of this program. Onsite students are required to be present during the videoconference activities.

Some distance learning programs (at Harvard and elsewhere) do allow the option to attend either on-site or virtually.

Investment in the Future

By helping clinical researchers to improve their skills in clinical research in a highly interactive environment with clinical researchers across different countries, this program will promote personal and professional growth and make clinical researchers more effective in their work. We also expect that the interactive environment of our course will promote connections among participants and therefore foster future collaborative multicenter projects.

Program Content

Our program covers from the basics of clinical research (such as: how to formulate a research question, select study population, randomization and blinding methods) to statistical methods (data distribution and classification, statistical tests, sample size calculation, survival analysis, missing data, and meta-analysis); data collection, monitoring and reporting (including training in manuscript writing); and study designs (observational studies, non-inferior and adaptive designs and randomized clinical trials).

Format

This course is a distance-learning course; however, participants have to attend weekly 3-hour interactive videoconference sessions with participants from the same location (for instance, participants from Sao Paulo meet at the University of Sao Paulo for the live connection with Harvard). Videoconference sessions are broadcast from Harvard to different centers across the world (please contact us for the list of participating centers – individual participants are also welcome to participate) and participate in forum discussions. Participants are also required to read articles and complete statistical exercises. At the end of the 6-month course, there will be an optional 4-day intensive workshop to practice the concepts learned in this course in Sao Paulo, Brazil.

Learning Tools

The following learning tools are used in our program:

- Live connection with Harvard (videoconference lectures): our program consists of 24 lectures taught by faculty from Harvard Medical School, Harvard School of Public Health and Boston University. Each weekly lecture includes a 45-minute teaching/lecture module; a 45-minutes live question/answer discussion module in which participants interact directly with faculty teaching this course. In addition, a 30-minute interactive module to discuss the online poll and a case written specifically for this course is conducted by course directors.

- Discussion forum: Each weekly lecture/topic includes a required online discussion forum.

- Online poll: Participants have to participate in weekly polls addressing the topic of the following lecture.

- Homework assignments: Participants are required to resolve statistical problems as part of the statistical training of this course.

- Ask questions: Participants have intensive interaction with faculty and staff via office hours chat and the “ask the professor” section.

- Group project/Wiki: Participants are required to work in a group project in which they have to write a grant application together using the online interactive Wiki tool – same tool used in Wikipedia.

- Podcasts: Podcasts with topics discussed are posted on the website.

- To learn more and see our course program, please go to:

www.clinicalresearchlearning.org

Course Materials and Language

Although this course is broadcast to several countries, the entire course is offered in English only – including participation on the website.

Application and Admission

Registration is limited. Please submit the following documents online: curriculum vitae and a letter stating the reasons to participate in the course. Applications are due by February 15, 2011.

Goals

Our goal is to offer a highly interactive learning environment for clinical research training internationally and also to create a global network of clinical researchers to foster future collaboration in clinical research.

Long-term Vision for Participants

Participants are strongly encouraged to continue their interaction through our Alumni website (www.clinicalresearchalumni.org) created to maintain interaction between participants and discussion of clinical research topics.

Technical Requirements

All participants must have a computer with excellent internet connection, a webcam and microphone. Sites must have videoconference technology and technicians. Please contact us if you would like to propose a new site in your country.

Dates and Fees

Distance Learning: February 11-October 13, 2011

Optional 4-day onsite in Sao Paulo, Brazil: October 27-30, 2011

For more information on course enrollment and fees, please contact info@clinicalresearchlearning.org

Executive and Site Directors:

Felipe Fregni – Fregni.felipe@mgh.harvard.edu - course director

Wu Tu Hsing – wu@fmusp.org.br - site director

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Accreditation

HMS-DCE Course

Harvard Medical School is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Harvard Medical School designates Distance-Learning Only for a maximum of 63 AMA PRA Category 1 Credit(s)[™] and Distance-Learning and Optional 4-day Workshop in Brazil for a maximum of 94.75 AMA PRA Category 1 Credit(s)[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity.