



Principles and Practice of Clinical Research

Clinical Trials Course - 2010



Department of Neurology
Department of Continuing Education
Department of Physical Medicine & Rehabilitation
Harvard Medical School

Offered by Department of Continuing Education, Harvard Medical School
Organization: Department of Continuing Education, Harvard Medical School
Departments of Neurology and Physical Medicine & Rehabilitation, Harvard Medical School
Felipe Fregni, MD, PhD, MPH; Lauren Dewey-Platt, PhD (Boston, EUA)
Wu Tu Hsing, MD, PhD; Rui Imamura, MD, PhD; Marta Imamura, MD, PhD (Brazil)

Start: March 11st 2010

TARGET: Academics for the health care system, researchers, health care legislators, professionals from pharmaceutical companies.

COURSE OBJECTIVES: Provide theoretical understanding of the design, conduction, analysis and interpretation of randomized controlled trials of health interventions. Develop skills to scrutinize information, critically analyze and carry out research, and to communicate effectively. Other clinical research courses are offered in Boston by the Clinical Effectiveness Program From Harvard School of Public Health www.hms.harvard.edu/gradprograms/scsp/ [45 days (Summer course - HSPH: US\$ 15,000; 2-year course: US\$60,000 (estimative)); Department of Health Policy, Management and Evaluation at University of Toronto <http://www.hpme.utoronto.ca/> (one year: CND\$14,252.82 to 18,452.82 for international applicants).

LEARNING METHODS: This course is an interactive collaborative CME accredited course (Continuing Medical Education of American Medical Association) that uses different tools of learning, such as two-way video conference system with Harvard professors, interactive online forum of discussion, podcasts, chat with course staff and interactive statistical training. Check our website: www.clinicalresearchcourse.org

DURATION: 7 months (March 18th to October 24th 2010)

FACULTY MEMBERS: Harvard Medical School, Harvard School of Public Health

SCHEDULE: (the course will be in English, without translation)

- **Weekly lectures by teleconference:**
Every Thursday 5:00pm to 8:00pm
Brasilia time zone (GMT-3:00)
U.S. Eastern time 4:00pm to 7pm.
From March to October/2010
- **Live 4-day intensive course (optional):**
October 28th-31st, 2010
Thursday to Sunday 8am to 6pm
Classes will be given at - São Paulo, Brazil

FEES: Registration fee: US\$ 3,500.00
Monthly fee: US\$ 500.00
(7 months: March to October/2010)

ELIGIBILITY: Health care with doctoral degree or director of a health care service or previous experience with clinical research.

APPLICATION AND ADMISSION: Attendance is limited.

Please, submit the following documents soon: 2 recent photos ID, professional license, PhD diploma, a letter from a chief or director of a health service. Submit curriculum vitae and a letter stating the reasons for participating in the course for approval by e-mail to clinicaltrials@fmsp.org.br

– **Deadline for registration: February 15th, 2010.**

Notification of admission will be mailed before the course start date.

In order to receive a certification letter at the end of the course, the student must accomplish:

- (1) Attendance in at least 5 (out of 6) lectures of each module (total of at least 20 lectures);
- (2) Score of 80% or more in the final examination.

INFORMATION:

E-mail: clinicaltrials@fmsp.org.br
www.clinicalresearchcourse.org
Fone: 55 11 3061-7495 – Natalia Duarte

Live connection with Harvard will be given at:
Instituto de Câncer do Estado de São Paulo
Av. Dr. Arnaldo, 251 - 6º andar, auditório grande
São Paulo - S.P. - Brazil

Course Program

Tutorial – 11 March
Lecture – Felipe Fregni, MD, PhD, MMSc, MPH

Module 1: BASICS OF CLINICAL RESEARCH

- Lecture 1 – 18 March • **Introduction to Clinical Trials** – Steve Freedman, MD, PhD
- Lecture 2 – 25 March • **Selection of the Questions** – Felipe Fregni, MD, PhD, MMSc, MPH
- Lecture 3 – 01 April • **Study Population** – Michele Hacker, ScD
- Lecture 4 – 08 April • **Basic Study Design** – David Wypij, PhD
- Lecture 5 – 15 April • **Study Blinding** – Joseph Massaro, PhD
- Lecture 6 – 22 April • **The Randomization Process** – David Wypij, PhD
- Lecture 7 – 29 April • **Recruitment of Study Participants** – Paul R. Conlin, MD

Module 2: STATISTICS

- Lecture 8 – 06 May • **Statistics - Basics** – Roger Davis, ScD
- Lecture 9 – 13 May • **Clinician Perspective (Case study)** – Munir Boodhwani, MD, MMSc
- Lecture 10 – 20 May • **Sample Size** – Jessica Paulus, ScD
- Lecture 11 – 27 May • **Using Statistics for the Study Design and Hypothesis Testing - a Clinician Perspective** – Munir Boodhwani, MD, MMSc
- Lecture 12 – 10 June • **Statistical Tests** – Felipe Fregni, MD, PhD, MMSc, MPH
- Lecture 13 – 17 June • **Survival Analysis** – Roger Davis, ScD
- **Other Issues in Statistics I** – Felipe Fregni, MD, PhD, MMSc, MPH
- **Other Issues in Statistics II** – Felipe Fregni, MD, PhD, MMSc, MPH

Module 3: PRACTICAL ASPECTS OF CLINICAL RESEARCH

- Lecture 14 – 24 June • **Integrity in Research** – Gretchen Brodnicki (Dean for Faculty Research and Integrity, Harvard Medical School)
- Lecture 15 – 01 July • **The future of Clinical Data in Clinical Research** – Frank Newby, COO, CDISC
- Lecture 16 – 19 August • **The business of Clinical Research - Negotiating Contracts** – Dennis J. LaCroix, JD
- Lecture 17 – 26 August • **Assessing Risk and Adverse Effects in Clinical Research** – John Ferguson, MD
- Lecture 18 – 02 September • **Design and Analysis of Surveys** – Alan Zaslavsky, PhD
- Lecture 19 – 09 September • **Manuscript submission** – Caren Solomon, MD (Deputy editor – New England Journal of Medicine)

Module 4: STUDY DESIGNS

- Lecture 20 – 16 September • **Non-inferiority designs** – James Ware, PhD
- Lecture 21 – 23 September • **Observational Studies** – Clarissa Valim, ScD, MD
- Lecture 22 – 30 September • **Confounders in Observational Studies: Using the Method of Propensity Score** – E. Francis Cook, SD
- Lecture 23 – 07 October • **Other designs** – Richard Kuntz, MD
- Lecture 24 – 14 October • **Experimental Design – Randomized Clinical Trials** – Alexa B. Kimball, MD, MPH (Vice Chair, Department of Dermatology, Massachusetts General Hospital; Associate Professor, Harvard Medical School)

Support

