



Principles and Practice of Clinical Research

Clinical Trials Course - 2010



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: 1 recent photo 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@fmusp.org.br

– Deadline for registration: February 15th, 2010.

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

– Computer connected to Internet will be necessary for all classes.

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:

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

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

• **Course General Instructions** –
Felipe Fregni, MD, PhD, MMSc, MPH

Module 1: BASICS OF CLINICAL RESEARCH

Lecture 1 – 18 March
Lecture 2 – 25 March
Lecture 3 – 01 April
Lecture 4 – 08 April
Lecture 5 – 15 April
Lecture 6 – 22 April
Lecture 7 – 29 April

• **Introduction to Clinical Trials** – Steve Freedman, MD, PhD
• **Selection of the Questions** – Felipe Fregni, MD, PhD, MMSc, MPH
• **Study Population** – Michele Hacker, ScD
• **Basic Study Design** – David Wypij, PhD
• **Study Blinding** – Joseph Massaro, PhD
• **The Randomization Process** – David Wypij, PhD
• **Recruitment of Study Participants** – Paul R. Conlin, MD

Module 2: STATISTICS

Lecture 8 – 06 May
Lecture 9 – 13 May
Lecture 10 – 20 May
Lecture 11 – 27 May
Lecture 12 – 10 June
Lecture 13 – 17 June

• **Statistics - Basics** – Roger Davis, ScD
• **Clinician Perspective (Case study)** – Munir Boodhwani, MD, MMSc
• **Sample Size** – Jessica Paulus, ScD
• **Using Statistics for the Study Design and Hypothesis Testing - a Clinician Perspective** – Munir Boodhwani, MD, MMSc
• **Statistical Tests** – Felipe Fregni, MD, PhD, MMSc, MPH
• **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
Lecture 15 – 01 July
Lecture 16 – 19 August
Lecture 17 – 26 August
Lecture 18 – 02 September
Lecture 19 – 09 September

• **Integrity in Research** – Gretchen Brodnicki
(Dean for Faculty Research and Integrity, Harvard Medical School)
• **The future of Clinical Data in Clinical Research** –
Frank Newby, COO, CDISC
• **The business of Clinical Research - Negotiating Contracts** –
Dennis J. LaCroix, JD
• **Assessing Risk and Adverse Effects in Clinical Research** –
John Ferguson, MD
• **Design and Analysis of Surveys** – Alan Zaslavsky, PhD
• **Manuscript submission** – Caren Solomon, MD
(Deputy editor – New England Journal of Medicine)

Module 4: STUDY DESIGNS

Lecture 20 – 16 September
Lecture 21 – 23 September
Lecture 22 – 30 September
Lecture 23 – 07 October
Lecture 24 – 14 October

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

Support

