



Harvard Medical School

Department of Continuing Education

Offered By

Department of Physical Medicine and Rehabilitation - Spaulding Rehabilitation Hospital

PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH

International Distance-Learning Clinical Research Training Program

Course Director: **Felipe Fregni, MD, PhD, MPH**
ASSOCIATE PROFESSOR, HARVARD MEDICAL SCHOOL

February – November 2012
Courtyard Marriott – Cambridge, MA

What You Can Expect

The collaborative distance-learning program in Clinical Trials is offered to participants from Boston and throughout the world. This 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. Participants can earn up to 72 credits (or 118 with the optional 4-day workshop and optional 2-day Statistical workshop in São Paulo, Brazil) *AMA PRA Category 1 credit(s)*[™].



Please contact: info@clinicalresearchlearning.org for more information

www.clinicalresearchlearning.org

Principles and Practice of Clinical Research

DESCRIPTION:

Despite the critical importance of clinical research for advancements in medicine, it is still immature in most of the medical specialties and in addition, many clinicians cannot evaluate research evidence critically. The purpose of our course 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.

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).

LEARNING FORMAT:

This course is a distance-learning course; however, participants have to attend weekly 3-hour interactive videoconference sessions. Videoconference sessions are broadcast live from Harvard to different centers across the world. Participants may enroll as part of a site center, or individually if a site center is not accessible to them. Our program consists of 24 lectures taught by faculty from Harvard Medical School, Harvard School of Public Health and Boston University. Additionally, each weekly lecture includes a required online discussion forum and an online poll addressing the topic. Participants are required to complete weekly homework assignments, including some statistical exercises. Participants are required to work in a group project using the online interactive Wiki tool. Podcasts and recordings of the lectures are posted weekly. At the end of the course, there will be an optional 4-day intensive workshop to practice the concepts learned in this course in Sao Paulo, Brazil.

LEARNING OBJECTIVES: At the end of the course, participants will be able to design clinical trials in an effective manner, collect data properly, use the basic functions of a statistical software, choose appropriate basic statistical tests, critically read and understand a research paper, understand basics of article publication and review and more.

TARGET AUDIENCE: Applicants usually have a graduate degree or a health care professional degree (MD, MPH, biostatistics, epidemiology, nursing, physical and speech therapy, or dentistry) and they come from several countries since participants can take this course in their hometown.

Course Site: Courtyard Marriott Cambridge, 777 Memorial Drive, Cambridge, MA 02139. Telephone: 617-492-7777

TECHNICAL REQUIREMENTS: All participants must have a computer with excellent Internet connection, webcam, and microphone. Sites must have videoconference technology and technicians.

COURSE DATES AND TUITION FEES: Distance Learning: February through November 2012

Optional 4-Day Workshop in São Paulo, Brazil: October 25-28, 2012

Optional 2-Day Statistical Workshop in São Paulo, Brazil: October 23-24, 2012

6-month distance learning (or live learning in Boston) and 4-day optional course in Brazil - \$6,500

6-month distance learning (or live learning in Boston) only - \$5,000

6-month distance learning (or live learning in Boston) only for Residents and Fellows - \$2,500

Additional 2-day statistical workshop - \$1,500

Optional course textbook and STATA software - \$500

APPLICATION AND COURSE ADMISSION: Registration is limited. Please submit the following documents online: curriculum vitae and letter stating the reason to participate in the course. Application is due by January 31, 2012.

Contact us at info@clinicalresearchlearning.org for late application consideration.

INTERNATIONAL SITES AND CONTACTS:

USP – São Paulo, Brazil: *Dr. Wu Tu Hsing* – wu@fmusp.org.br

ISPRM – International site: *Dr. Marta Imamura* – martaimf@gmail.com

FCMMG – Belo Horizonte, Brazil: *Dr. Mariana Lopes* – mazalua@yahoo.com

Universidad de Cuenca – Cuenca, Ecuador: *Dr. Arturo Carpio* – Arturo.carpio@ucuenca.edu.ec

Coimbra University Hospital – Coimbra, Portugal: *Dr. Monteiro* – pedromonte@gmail.com

Instituto Etica – Salvador, Bahia: *Dr. Juleilda Nunes* – curso.pesquisa@yahoo.com.br

UFRGS – Porto Alegre, Brazil: *Dr. Wolnei Caumo* – caumo@cpovo.net

PUCE – Quito, Ecuador: *Dr. Edison Chaves* – dr.edisonchaves@hotmail.com

USMP – Lima, Peru: *Dr. Tamara Jorquera* tjorquera@usmp.edu.pe

FCV – Salvador, Colombia: *Dr. Ronald Garcia* – ronaldgarcia@fcv.org

** Individuals from other locations can still enroll and take the course using Adobe Connect*

ACCREDITATION: The Harvard Medical School is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Harvard Medical School designates this live activity for a maximum of 118 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity. Course Only: A maximum of 72 *AMA PRA Category 1 Credits™*. Optional 4-day workshop in Brazil: A maximum of 31.25 *AMA PRA Category 1 Credits™*. Optional 2-day Statistical workshop: A maximum of 14.75 *AMA PRA Category 1 Credits™*. This course is designed to meet the following ACGME competencies: Medical Knowledge, Practice-based Learning and Improvement, and Professionalism.

Program Schedule 2012

6-month distance learning (or live learning in Boston): Course Schedule

Module One – Basics of Clinical Research:
Tutorial Lecture - 23 February, 2012:
Course Staff and Course Director
Opening Remarks

Lecture 1 - 15 March 2012: Steve Freedman
Introduction to Clinical Trials

Lecture 2 - 22 March 2012: Felipe Fregni
Selection of the Questions

Lecture 3 - 29 March 2012: Michele Hacker
Study Population

Lecture 4 - 05 April 2012: David Wypij
Basic Study Design

Online discussion: Ethical and regulatory issues

Lecture 5 - 12 April 2012: Joseph Massaro
Study Blinding

Lecture 6 - 26 April 2012: David Wypij
The Randomization Process

Lecture 7 - 03 May 2012:
Paul Conlin
Recruitment of Study Participants
Lotfi Merabet
Participant Adherence

Module Two - Statistics:

Lecture 8, 10 May 2012 - Roger Davis
Statistics - Basics

Clinician Statistical Corner - Munir Boodhwani
Data classification and Sample Size Calculation in clinical research

Lecture 9 - 17 May 2012: Jessica Paulus
Sample Size

Lecture 10 - 24 May 2012: Felipe Fregni
Statistical Tests I

Lecture 11 - 31 May 2012: Felipe Fregni
Statistical Tests II

Lecture 12 - 07 June 2012: Roger Davis
Survival Analysis

Lecture 13 - 14 June 2012: Felipe Fregni
Other Issues in Statistics I

Lecture 14 - 21 June 2012: Felipe Fregni
Other Issues in Statistics II

Module Three – Practical Aspects of Clinical Research:

Lecture 15 - 28 June 2012: Gretchen Brodnicki
Integrity in Research

Lecture 16 – 16 August 2012: Dennis LaCroix
The Business of Clinical Research
Vera Novak
Being a Clinical and Translational Scientist

Lecture 17 - 23 August 2012: Alan Zaslavsky
Design and Analysis of Surveys

Lecture 18 - 30 August 2012: John Ferguson
Assessing risk and adverse effects in clinical research
Suzanne George
Phase III and Multicenter Trials

Lecture 19 - 06 September 2012: Caren Solomon
Manuscript submission

Module Four – Study Design:
Online discussion: International/global research

Lecture 20 - 13 September 2012: Scott Evans
Non-inferiority designs

Lecture 21 - 20 September 2012:

Clarissa Valim
Observational Studies

Lecture 22 - 27 September 2012: Laura Mauri
Confounders in observational studies: using the method of propensity score

Lecture 23 - 04 October 2012: Richard Kuntz
Other Designs

Lecture 24 - 11 October 2012: Merit Cudkowicz
Experimental Design - Randomized Clinical Trials

Final Exam will be scheduled in November after the 4-Day Live intensive course.

FACULTY:

Felipe Fregni, MD, PhD, MPH
(Harvard Medical School)

Munir Boodhwani, MD, MMSc (University of Ottawa)

Gretchen Brodnicki, JD
(Harvard Medical School)

Paul Conlin, MD
(Harvard Medical School)

Merit Cudkowicz, MD
(Harvard Medical School)

Roger Davis, ScD
(Harvard School of Public Health)

Jessica Elder, ScD
(Harvard School of Public Health)

Scott Evans, PhD
(Harvard School of Public Health)

John Ferguson, MD
(Novartis Vaccines and Diagnostics)

Steve Freedman, MD, PhD
(Harvard Medical School)

Suzanne George, MD
(Harvard Medical School)

Michele Hacker, ScD
(Harvard School of Public Health)

Donald Halstead
(Harvard School of Public Health)

Christine Jesser, PhD
(Harvard School of Public Health)

Richard Kuntz, MD
(Harvard Medical School)

Dennis LaCroix, JD
(Genzyme)

Joseph Massaro, PhD
(Boston University School of Public Health)

Laura Mauri, MSc
(Harvard Medical School)

Lotfi Merabet, OD, PhD
(Harvard Medical School)

Vera Novak, MD, PhD
(Harvard Medical School)

Jessica Paulus, ScD
(Tufts University School of Medicine)

Lauren Dewey Platt, PhD
(Harvard Medical School)

Caren Solomon, MD
(Harvard Medical School)

Clarissa Valim, ScD, MD
(Harvard School of Public Health)

David Wypij, PhD
(Harvard School of Public Health)

Alan Zaslavsky, PhD
(Harvard Medical School)

Optional 2-Day Statistical Workshop in São Paulo, Brazil: Course Schedule

Tuesday, October 23, 2012

Correlation and Causality

7:00 – 8:00 Registration
8:00 – 8:15 Welcome
8:15 – 9:00 The Basics of Correlation and Causality
9:00 – 9:45 Statistical Tests
9:45 – 10:00 Break
10:00 – 12:00 Practical Applications
12:00 – 1:00 Lunch

Linear Regression

1:00 – 1:45 Assumptions for Regression
1:45 – 2:30 Transformations to Achieve Linearity
2:30 – 2:45 Break
2:45 – 3:30 Confounding and Correlation
3:30 – 4:15 Simple Linear Regression
4:15 – 5:00 Multiple Linear Regression

Wednesday, October 24, 2012

Logistic Regression

8:00 – 8:45 Categorical Variables
8:45 – 9:45 Construction of Models
9:45 – 10:00 Break
10:00 – 11:00 Special Situations

ANOVA

11:00 – 12:00 Assumptions for Using ANOVA
12:00 – 1:00 Lunch
1:00 – 2:00 ANOVA – Single Factor
2:00 – 3:00 ANOVA – Multifactor
3:00 – 3:15 – Break

Other Issues Related to Regression Modeling

3:15 – 4:00 Interaction and Quadratic Effects
4:00 – 5:00 Regression Modeling in Practice

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Program Schedule 2012

Optional 4-Day Workshop in São Paulo, Brazil: Course Schedule

THURSDAY, OCTOBER 25, 2012

7:00 – 8:00 Registration
8:00 – 8:15 Welcome!
8:15 – 9:00 Bias - Lotfi Merabet
9:00 – 9:45 Randomization – Jessica Paulus
9:54 – 10:00 Break
10:00 – 12:00 Small Group Discussion
12:00 – 1:00 Lunch
1:00 – 2:00 Individual Office Hours with Speakers
2:00 – 5:00 Small Group Discussions

FRIDAY, OCTOBER 26, 2012

8:00 – 8:30 Group Exercise
8:30- 9:15 Statistical Review – Roger Davis
9:15 – 10:30 Statistical Review – Clarissa Valim
10:30 – 12:00 Small Group Discussions
12:00 – 1:00 Lunch
1:00 – 2:00 Individual Office Hours with Speakers
2:00 – 4:00 Small Group Discussions
4:00 – 5:00 Group Project Summary
5:00 – 6:00 Optional Session: Journal Club – Lauren Dewey Platt
6:00 – 8:00 Celebration and Awards

SATURDAY, OCTOBER 27, 2012

8:00 – 10:00 Group Project Presentations
10:00 – 11:00 Leadership in Clinical Research – Lauren Dewey Platt
11:00 – 12:00 Case Discussion on Pragmatic Trials – Felipe Fregni
12:00 – 12:30 Guidelines for the Grant Writing Workshop – Donald Halstead
12:30 – 1:30 Lunch
1:20 – 5:00 Manuscript/Grant Writing Workshop – Donald Halstead
5:00 – 6:00 Practical Activity

SUNDAY, OCTOBER 28, 2012

8:00 – 9:00 Working with Investigators: Designing Clinical Research Projects I – Christine Jesser
9:00 – 10:00 Working with Investigators: Designing Clinical Research Projects II – Jessica Elder
10:00 – 12:00 Writing Style: Some Advice to Improve Your Manuscript Before Submission – Donald Halstead
12:00 – 1:00 Lunch
1:00 – 2:30 Practical Exercises: Experience with Manuscript Submission – Felipe Fregni
2:30 – 4:45 Manuscript Review Workshop
4:45 – 5:00 Closing Remarks

The optional 4-day live intensive course will host ten Harvard professors who will review and discuss material presented throughout the year in a detailed and intensive fashion. One important part of the 4-day live course is that students will review their group projects with the Harvard faculty. Also, students will have a 2-day practical Manuscript Writing workshop with Prof. Donald Halstead from Harvard School of Public Health. This 4-day live course is an important component and is intended to give students hands on experience in clinical trials design and analysis.

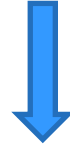
DISCLOSURE POLICY:
Harvard Medical School (HMS) adheres to all ACCME Essential Areas, Standards, and Policies. It is HMS's policy that those who have influenced the content of a CME activity (e.g. planners, faculty, authors, reviewers and others) disclose all relevant financial relationships with commercial entities so that HMS may identify and resolve any conflicts of interest prior to the activity. These disclosures will be provided in the activity materials along with disclosure of any commercial support received for the activity. Additionally, faculty members have been instructed to disclose any limitations of data and unlabeled or investigational uses of products during their presentations.

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Participating International Sites:



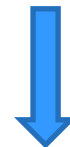
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COURSES



COURSE LIST



PRINCIPAL PRACTICE IN CLINICAL RESEARCH