HARVARD T.H. CHAN
SCHOOL OF PUBLIC HEALTH
Executive and Continuing Professional Education

PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH

International Distance-Learning Clinical Research Training Program

February – November 2016

Course Director — Felipe Fregni, MD, PhD, MPH, MEd
Associate Professor, Harvard Medical School

This collaborative, interactive distance-learning program in Clinical Research is offered to participants from Boston and throughout the world. The course is designed both for individuals who wish to gain basic and advanced training in clinical trials before moving into the field, and for those who have experience in this area and aim to expand their role in designing, managing, analyzing, and reporting the findings of clinical trials.

Description

Clinical research is vital for advancement in medicine, yet in most medical specialties, and in many countries, its tools are used inappropriately, resulting in invalid results. Furthermore, many clinicians cannot critically evaluate research findings. The purpose of our course is to offer a highly interactive learning environment for clinical research training internationally and to create a global network of clinical researchers to foster future collaboration in clinical research.

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

Course Format

This course blends live and online interaction, via the web and in site centers. Participants have to attend weekly 3-hour interactive videoconference sessions, which are broadcast live from Boston to centers around the world. In addition, we offer four live workshops (three in Boston and one in Brazil) in which participants can deepen their knowledge and interact with Harvard faculty face to face. Participants may enroll either as part of a site center or individually, if they do not have access to a site center. Our program consists of 25 weekly lectures taught by distinguished faculty from Harvard T.H. Chan School of Public Health, Harvard Medical School, and Tufts University. This course uses the case method to enhance learning. We have developed cases for each lecture, which participants are expected to read and discuss. Each lecture is supplemented by mandatory participation in online discussions and a poll addressing the week's topic. Participants are required to complete weekly assignments that emphasize statistical exercises and to work on a group project using an online, interactive Wiki tool. Podcasts and recordings of the lectures are posted weekly. At the end of the course, a 5-day immersion workshop is offered to review and integrate the key concepts learned in this course.

Learning Outcomes

During the course, participants will develop skills in two main domains: design and conduct of clinical research, and interpretation and critical understanding of published research. At the end of the course, we expect participants will be able to formulate an appropriate research question, choose an optimal clinical trial design based on ethical principles, accurately interpret results from statistical analyses, collect data appropriately, use the basic functions of a statistical software package, choose appropriate basic statistical tests, run simple statistical analyses, grasp the basic principles of article publication and the reviewing process, and use key tools and concepts to write effective articles. We also expect this course will have a critical impact on the careers of those not aiming to become clinical scientists. At the end of this course, we expect these participants will be able to critically read research papers, understanding the main sources of bias and confounding, as well the clinical impact of different research findings.

Target Audience

Applicants come from all over the world and usually have a graduate degree or a health care professional degree (MD, MPH, biostatistics, epidemiology, nursing, physical and speech therapy, or dentistry).

Technical Requirements

All participants must have a computer with an excellent internet connection, webcam, and micro-phone. Site centers must be equipped with videoconference technology and have technicians available.

INTERNATIONAL SITES AND CONTACTS

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* Individuals from other locations can still enroll and take the course.

9-Month Main Course Component

(via live site center or live webcast)

Module One

Basics of Clinical Research

Tutorial Lecture, 25 February 2016 – Course Staff and PPCR Course Director - Felipe Fregni

Lecture 1 - 17 March 2016: Steve Freedman
Introduction to Clinical Trials

Lecture 2 – 24 March 2016: Jonathan S. Williams
Selection of the Questions

Lecture 3 – 31 March 2016: Michele Hacker
Study Population

Online Discussion: Ethical and Regulatory Issues

Lecture 4 - 7 April 2016: David Wypij
Basic Study Design

Lecture 5 – 14 April 2016: Joseph Massaro
Study Blinding

Lecture 6 – 21 April 2016: David Wypij
The Randomization Process

Lecture 7 - 28 April 2016: Lotfi Merabet
Recruitment of Study Participants & Participant Adherance

Module Two

Basic Statistics

Lecture 8 - 5 May 2016: Roger Davis
Statistics - Basics

Lecture 9 – 12 May 2016: Farzad Noubary
Statistical Tests I (t-test and ANOVA)

Lecture 10 - 19 May 2016: Farzad Noubary
Statistical Tests II (Kruskal_wallis, Mann-Whitney and Wilcoxon)

Lecture 11 - 26 May 2016: Felipe Fregni
Statistical Tests III (Pearson and Spearman Correlation, Chi-square and Fisher exact tests)

Lecture 12 - 2 June 2016: Roger Davis
Survival Analysis

Module Three

Applied Statistics

Lecture 13 – 16 June 2016: Jess Paulus
Sample Size Calculation

Lecture 14 – 23 June 2016: Felipe Fregni
Missing Data & Covariate Adjustment

Lecture 15 - 30 June 2016: Felipe Fregni
Meta-analysis & Subgroup Analysis

Lecture 16 - 7 July 2016: Felipe Fregni
Introduction to Regression Modeling: Adjusted analysis and predictors

5-Week Statistical Study Period

Module Four

Practical Aspects of Clinical Research

Lecture 17 - 18 August 2016: Lotfi Merabet
Safety, clinical and surrogate outcomes

Lecture 18 - 25 August 2016: Mark Barnes
Integrity in Research
&
Suzanne George
Phase III and Multicenter Trials

Lecture 19 – 1 September 2016: Caren Solomon
Manuscript Submission
&
Donald Halstead
Manuscript Writing

Module Five

Study Design

Lecture 20 - 8 September 2016: Scott Evans
Non-inferiority Designs

Lecture 21 – 15 September 2016: Richard Kuntz
Medical Devices Study Designs

Lecture 22 – 22 September 2016: Felipe Fregni
N-of-1 Designs & Adaptive Designs

Lecture 23 – 29 September 2016: Clarissa Valim
Observational Studies

Lecture 24 – 6 October 2016: Roberty Yeh
Confounders in Observational Studies: Using the method of propensity score

Lecture 25 – 13 October 2016:
Shelley Tworoger & Felipe Fregni
Special Panel: RCT vs. Observational Designs - how to choose?

FACULTY:

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Application and Course Admission

Registration is limited. Please submit the following documents online at **www.ppcr.org/registration**: Curriculum Vitae, letter of intent stating the reason for participating in the course, and letter of recommendation. **Applications are due by January 31, 2016**. Late applications will be considered on a case-by-case basis.

Course Dates

9-Month Distance Learning Main Course Component	February - November, 2016
5-Day Immersion Course	October 25 - 29, 2016
Optional Statistical Workshop	July 18 - 19, 2016
Optional Study Coordinator Workshop	July 20 - 21, 2016
Optional Manuscript Writing Workshop	July 21 - 22, 2016

Course Tuition Fees

All registration prices include a 1-year Small Stata 14 (GradPlans™) license. Shipping is included. Main component includes 5-Day Immersion Course.

Main Component + Three Workshops + 5-Day Immersion Course	$5,250.00
Main Component - Site Center or Group	$2,500.00
Main Component - Remote/Web-Based Access	$4,000.00
Main Course Component - Graduate Student	$2,500.00
Each Workshop for PPCR Participants	$750.00
Each Workshop for Non-PPCR Participants	$1,500.00
5-Day Immersion Course for PPCR Participants	$500.00
5-Day Immersion Course for Non-PPCR Participants	$1,500.00

Tuition Refund Policy:
All requests for refunds must be made in writing according to the terms below. There will be no exceptions to these terms.

Main Course Component Refunds: Cancellations on or before January 7, 2016 will be issued a refund less a $150 administrative fee per person. Cancellations received between January 8, 2016 and February 4, 2016 will be issued a refund of 50%. After February 4, 2016, no refund will be issued.

Workshop Refunds: Cancellations on or before May 31, 2016 will be issued a refund less a $150 administrative fee per person. Cancellations received between June 1, 2016 and June 27, 2016 will be issued a refund of 50%. After June 27, 2016, no refund will be issued.

5-Day Immersion Course Refunds: Cancellations on or before September 6, 2016 will be issued a refund less a $150 administrative fee per person. Cancellations received between September 7, 2016 and October 4, 2016 will be issued a refund of 50%. After October 4, 2016, no refund will be issued.

5-DAY IMMERSION COURSE

The 5-Day Immersion Course is the capstone to the PPCR course. It is a highly interactive program hosted by Harvard and other Boston-area professors who will intensively review, discuss, and bring together all the important information presented throughout the year, and give students practical experience in clinical trial design and analysis. Another important aspect of this live course is that students will meet with the faculty to review their group projects. Students will also participate in an intensive Manuscript Writing workshop with Prof. Donald Halstead of Harvard T.H. Chan School of Public Health. This 5-Day Immersion Course is an important component to PPCR, and all students are encouraged to enroll.

Tuesday, October 25, 2016
Introduction and Group Project Preparation

02:00pm – 03:00pm	Registration
03:00pm – 03:15pm	Introduction – Felipe Fregni
03:15pm – 04:00pm	Bias – Lotfi Merabet
04:00pm – 04:45pm	Case Discussion on Pragmatic Trials – Felipe Fregni
04:45pm – 07:00pm	Small Group Discussions

Wednesday, October 26, 2016
Group Project – Design, Regulatory and Management Issues

08:00am – 08:45am	Lecture – Special Topic I – Jess Paulus
08:45am – 12:00pm	Small Group Discussions
12:00pm – 04:00pm	Break
02:00pm – 04:00pm	Individual Office Hours with Speakers (optional)
04:00pm – 05:00pm	Small Group Discussions
05:00pm – 08:00pm	Manuscript Writing Workshop – Part I – Donald Halstead

Thursday, October 27, 2016
Group Project Workshop – Statistical Review

08:00am – 08:45am	Lecture – Special Topic II – Roger Davis
08:45am – 12:00pm	Small Group Discussions
12:00pm – 04:00pm	Break
12:00pm – 04:00pm	Special Statistical Office Hours with Prof. Farzad (slots of 30min): data analysis, data interpretation and other statistical questions
02:00pm – 04:00pm	Individual Office Hours with Speakers (optional)
03:00pm – 04:00pm	Meeting for 2015 participants interested in being PPCR 2016 TAs
04:00pm – 05:00pm	Clarissa Valim: Statistical analysis with large datasets
05:00pm – 08:00pm	Manuscript Writing Workshop - Part II - Donald Halstead

Friday, October 28, 2016
Manuscript Writing and Submission

08:00am – 08:45am	Lecture – Special Topic III – Jess Paulus
08:45am – 12:00pm	Small Group Discussions
12:00pm – 04:00pm	Break
02:00pm – 04:00pm	Individual Office Hours with Speakers (optional)
03:00pm – 04:00pm	Real Life Statistics II – Clarissa Valim and Faculty Facilitators (optional – Alumni and current participants)
04:00pm – 05:00pm	Group Project Presentation to Faculty – small groups with Faculty – final presentation and preliminary grading for bonus points
05:00pm – 08:00pm	Manuscript Writing Workshop – Part III – Donald Halstead
08:00pm – 09:00pm	Break
09:00pm – 11:00pm	Celebration and Awards with dinner

Saturday, October 29, 2016
Manuscript Submission and Post-Submission

08:00am – 10:30am	Final Group Project Presentations – Final Grading
10:30am – 11:00am	Award - Best group project for two projects (all participants of the two best projects will be awarded a special certificate)
11:00am – 11:45am	Practical Exercise and Wrap-up - Felipe Fregni
11:45am – 12:00pm	Closing Remarks - Faculty Members

FACULTY

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Harvard T.H. Chan School of Public Health
Leslie Kalish, ScD
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Donald Halstead
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Lotfi Merabet OD, PhD, MPH
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Farzad Noubary, PhD
Tufts Medical Center
Jessica Paulus, ScD
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Tufts University
Clarissa Valim, ScD, MD
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2-DAY STATISTICAL WORKSHOP, BOSTON

This workshop provides additional statistical training for PPCR participants who want to acquire more advanced methods. Participants will not only review and expand their statistical knowledge but will be able to apply their skills to their own research. During the workshop, participants will learn how to work with data sets, fit a model, conduct statistical tests in STATA, and read and interpret the STATA output. After the workshop, participants will be familiar with the challenges, limitations, and issues of analyzing data and interpreting the results, which will help them to better read the scientific literature, review manuscripts, and write their own manuscripts and grants.

Monday, July 18, 2016

Modeling Continuous Data (Faculty: David Wypij, Felipe Fregni)	
07:00am – 08:00am	Registration
08:00am – 08:15am	Welcome!
Correlation and Causality	
08:15am – 09:00am	The Basics of Correlation and Causality
09:00am – 09:45am	Statistical Tests
09:45am – 10:00am	Break
10:00am – 12:00pm	Practical Applications
12:00pm – 01:00pm	Lunch
Linear Regression	
01:00pm – 01:45pm	Assumptions for Regression
01:45pm – 02:30pm	Transformations to Achieve Linearity
02:30pm – 2:45pm	Break
02:45pm – 3:30pm	Confounding and Correlation
03:30pm – 4:15pm	Simple Linear Regression
04:15pm – 5:00pm	Multiple Linear Regression

Tuesday, July 19, 2016

Modeling Categorical Data (Faculty: Clarissa Valim, Felipe Fregni)	
07:00am – 08:00am	Breakfast
Logistic Regression	
8:00am – 8:45am	Categorical Variables
8:45am – 9:45am	Construction of Models
9:45am – 10:00am	Break
10:00am – 11:00am	Special Situations
Logistic Regression	
11:00am – 12:00pm	Assumptions for Logistic Regression
12:00pm – 1:00pm	Lunch
1:00pm – 2:00pm	Model Building with Logistic Regression
2:00pm – 3:00pm	Model fit and confounding
3:00pm – 3:15pm	Break
Student Presentation	
3:15pm – 4:00pm	Interaction and Quadratic Effects
4:00pm – 5:00pm	Regression Modeling in Practice

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STUDY COORDINATOR WORKSHOP, BOSTON

This live intensive course is critical for PPCR students who are principal investigators and want to conduct and execute their studies successfully, for PPCR students who want to become study coordinators and for current study coordinators who are planning a career in this field. The course will be hosted by five Harvard professors and directors of clinical research centers at Harvard-affiliated hospitals who will offer instruction on the theoretical and practical aspects of being a study coordinator. Topics nclude subject recruitment, budgeting, staffing, regulatory issues (IRB, HIPAA, FDA), reporting of adverse events, informed consent, electronic medical records, study data management (databases, data entry, forms), drug storage and monitoring, study adherence, management and leadership in clinical research. Participants will conduct exercises in study groups during the workshop and develop a study project.

Wednesday, July 20, 2016

07:00am – 08:00am	Registration
08:00am – 08:15am	Welcome!
Initiating a Study	
08:15am – 09:00am	Initiating a Study I: Site selection
09:00am – 09:45am	Initiating a Study II: Assessing feasibility (recruitment, budget, staffing)
09:45am – 10:00am	Break
10:00am – 12:00pm	Practical Exercises I: Students will be divided in groups and choose sites and negotiate agreements with mock sites
12:00pm – 01:00pm	Lunch
First Steps	
01:00pm – 01:45pm	Regulatory Issues (IRB, HIPAA and FDA)
01:45pm – 02:30pm	Study First Steps I (Informed consent, paperwork, electronic medical records)
02:30pm – 2:45pm	Break
02:45pm – 3:30pm	Study First Steps II (recruitment strategies)
03:30pm – 5:00pm	Practical Exercises II: Students will be divided in groups and create paperwork organization for their study and create recruitment strategies
05:00pm – 6:00pm	Management and Leadership in Clinical Research

Thursday, July 21, 2016

Study Activities	
08:00am – 08:45am	Study Activities I (General tracking procedures, forms and study folders, software programs)
08:45am – 09:45am	Study Activities II (Drug storage, monitoring drugs and monitoring visits)
09:45am – 10:00am	Break
10:00am – 10:30am	Study Activities III (Improving study adherence)
10:30am – 12:00pm	Practical Exercises II: Final project presentations and group discussion

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SCIENTIFIC MANUSCRIPT WRITING WORKSHOP, BOSTON

This workshop is an intensive introduction to essential concepts and tools for writing and preparing scientific manuscripts for publication in high-impact, English-language journals. Participants in this collaborative-learning workshop will gain significant new insight into the structures, logical arguments, and narrative pathways embedded in the IMRAD format (Introduction, Methods, Results and Discussion); powerful yet easily applied tools for writing clearly and concisely in English; and new strategies for getting published in top journals. Whenever possible, sections of participants' pre-submitted manuscripts will be incorporated into the course for instruction and constructive peer review.

Thursday, July 21, 2016

02:00pm – 02:45pm	Introductions and review of the workshop's goals, methods, and procedures
02:45pm – 04:15pm	IMRAD manuscript format and scientific argumentation
04:15pm – 04:30pm	Break
04:30pm – 05:30pm	Writing exercises and peer reviews
05:30pm – 06:00pm	Group discussion and preparation for next day

Friday, July 22, 2016

07:00am – 08:00am	Breakfast
08:00am – 10:00am	Principles for writing English clearly and concisely
10:00am – 10:20am	Break
10:20am – 11:10am	Writing exercises and peer reviews
11:10am – 12:10am	Discussion of Exercises
12:10pm – 01:10pm	Lunch
01:10pm – 02:00pm	Publication strategies and dealing with reviewer comments
02:00pm – 03:45pm	Writing exercises and peer reviews
03:45pm – 04:45pm	Final discussion and group feedback

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