This collaborative and interactive distance-learning program in Clinical Research is offered to participants from Boston and throughout the world. The course is designed 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 broaden their role in the design, management, analysis, and reporting of clinical trials. Participants can earn up to 72 (or 145.5 with all of the available optional workshops) AMA PRA Category 1 Credits™.
Description
Clinical research is critically important for advancements in medicine; however its implementation is still immature in most of the medical specialties. 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 the basics of clinical research (including: how to formulate a research question, select study population, randomization and blinding methods), statistical methods (data distribution and classification, statistical tests, sample size and power calculation, survival analysis, missing data, and meta-analysis), data collection, monitoring and reporting (including training in manuscript writing), and study designs (non-inferiority and adaptive designs and observational and randomized clinical trials).

Course Format
This course has a blended format with live (via web or in a site center) and online interaction. Participants have to attend weekly 3-hour interactive videoconference sessions. In addition we offer five live workshops (four in Boston and one abroad) in which participants can deepen their knowledge and meet face to face with Harvard University Faculty). Videoconference sessions are broadcast live from Harvard to 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 distinguished faculty from Harvard Medical School and Harvard School of Public Health. This course uses the case method to enhance learning. Cases were developed for each lecture and participants are expected to discuss these cases. Additionally, each weekly lecture is supplemented by mandatory participation in online discussions and an online poll addressing the week’s topic. Participants are required to complete weekly assignments that emphasize statistical exercises and to work in 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 intensive workshop is offered to practice the concepts learned in this course.

Learning Objectives
At the end of the course, participants will be able to design clinical trials in an effective manner, collect data appropriately, use the basic functions of a statistical software package, choose appropriate basic statistical tests, run statistical analysis, critically read and understand a research paper, develop clinical research based on integrity principles, design a basic survey, discuss the basics of article publication and the reviewing process, and describe more complex clinical trial designs.

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 excellent internet connection, webcam, and microphone. Site centers must be equipped with videoconference technology and have technicians available.

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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, 26 February 2015 – Course Staff and PPCR Course Director - Felipe Fregni
 Lecture 1 - 19 March 2015: Steve Freedman
Introduction to Clinical Trials
 Lecture 2 – 26 March 2015: Jonathan S. Williams
Selection of the Questions
 Lecture 3 – 02 April 2015: Michele Hacker
Study Population
 Online discussion: Ethical and regulatory issues
 Lecture 4 - 09 April 2015: David Wypij
Basic Study Design
 Lecture 5 – 16 April 2015: Joseph Massaro
Study Blinding
 Lecture 6 – 23 April 2015: Priscilla Driscoll-Shempp
Recruitment of Study Participants & Lotfi Merabet
Participant Adherence
 Lecture 7 - 30 April 2015: David Wypij
The Randomization process

Module Two
Statistics
 Lecture 8 - 14 May 2015: Roger Davis
Statistics - Basics
 Lecture 9 – 21 May 2015: Farzad Noubary
Statistical Tests I
 Lecture 10 - 28 May 2015: Farzad Noubary
Statistical Tests II
 Lecture 11 - 04 June 2015: Jessica Paulus
Sample Size
 Lecture 12 - 11 June 2015: Roger Davis
Survival Analysis
 Lecture 13 – 18 June 2015: Felipe Fregni
Other Issues in Statistics I
 Lecture 14 – 25 June 2015: Felipe Fregni
Other Issues in Statistics II

Module Three
Practical Aspects of Clinical Research
 Lecture 15 –  02 July 2015: Mark Barnes
Integrity in Research & Suzanne George
Phase III and Multicenter Trials
 Lecture 16 – 13 August 2015: Alan Zaslavsky
Design and Analysis of Surveys
 Lecture 17 - 20 August 2015: John Ferguson
Assessing risk and adverse effects in clinical research
 Lecture 18 - 27 August 2015: Karen Lodigiani & Jennifer Meneses
The Business of Clinical Research – Negotiating contracts & Donald Halstead
Manuscript Writing
 Lecture 19 – 03 September 2015: Caren Solomon
Manuscript submission

Module Four
Study Designs
 Lecture 20 – 10 September 2015: Scott Evans
Non-inferiority designs
 Lecture 21 - 17 September 2015: Richard Kuntz
Other Designs
 Lecture 22 – 24 September 2015: Clarissa Valim
Observational Studies
 Lecture 23 – 01 October 2015: Robert Yeh
Confounders in observational studies: using the method of propensity score
 Lecture 24 – 08 October 2015: Shelley Tavorogor & Felipe Fregni
Special Panel: RCT vs. Observational Designs – how to choose?

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Application and Course Admission

Registration is limited. Please submit the following documents online at www.ppcr.hms.harvard.edu/registration: Curriculum Vitae, letter of intent stating the reason to participate in the course and letter of recommendation. Application is due by December 31, 2014. Late application will be considered on a case-by-case basis.

Course Dates

<table>
<thead>
<tr>
<th>Course Component</th>
<th>Dates</th>
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</thead>
<tbody>
<tr>
<td>9-Month Distance Learning Main Course Component</td>
<td>February - November, 2015</td>
</tr>
<tr>
<td>Optional 5-Day Workshop</td>
<td>October 20 - 24, 2015</td>
</tr>
<tr>
<td>Clinical Research Fellow Practice Workshop</td>
<td>February - December, 2015</td>
</tr>
<tr>
<td>Optional 2-Day Study Coordinator Workshop</td>
<td>July 13 - 14, 2015</td>
</tr>
<tr>
<td>Optional 2-Day Statistical Workshop</td>
<td>July 16 - 17, 2015</td>
</tr>
<tr>
<td>Optional Introductory Workshop and Evidence-Based Medicine</td>
<td>March 9 - 10, 2015</td>
</tr>
</tbody>
</table>

Course Tuition Fees

All registration prices include a 1-year Small Stata 13 (GradPlans™) license. Shipping is included.

<table>
<thead>
<tr>
<th>Course Component</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Component + Three Workshops</td>
<td>$10,000.00</td>
</tr>
<tr>
<td>Main Component + Two Workshops</td>
<td>$9,500.00</td>
</tr>
<tr>
<td>Main Component + One Workshops</td>
<td>$8,500.00</td>
</tr>
<tr>
<td>Main Course Component</td>
<td>$7,500.00</td>
</tr>
<tr>
<td>Residents &amp; Fellows Main Component</td>
<td>$3,750.00</td>
</tr>
<tr>
<td>Main Course Component Group For A Site Center</td>
<td>$3,500.00</td>
</tr>
<tr>
<td>Clinical Research Fellow Practice Workshop</td>
<td>$1,750.00</td>
</tr>
<tr>
<td>2-Day Statistical Workshop (with three-week online component)</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>2-Day Study Coordinator Workshop (with three-week online component)</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>Independent 5-Day Workshop</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>Introductory Workshop and Evidence-Based Medicine</td>
<td>$1,500.00</td>
</tr>
</tbody>
</table>
5-DAY WORKSHOP

The optional 5-day live intensive course will host Harvard and other Boston professors who will review and discuss material presented throughout the year in a detailed and intensive fashion. One important part of the 5-day live course is that students will review their group projects with the Harvard faculty. Also, students will have a practical Manuscript Writing workshop with Prof. Donald Halstead from Harvard School of Public Health. This 5-day live course is an important component and is intended to give students hands on experience in clinical trials design and analysis.

Tuesday, October 20, 2015
Introduction and Group Project Preparation
04:30pm – 05:00pm Registration
05:00pm – 05:15pm Introduction – Felipe Fregni
05:15pm – 06:00pm Bias – Lotfi Merabet
06:00pm – 06:45pm Case Discussion on Pragmatic Trials – Felipe Fregni
06:45pm – 08:00pm Small Group Discussions

Wednesday, October 21, 2015
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 – 06:00pm Break
03:00pm – 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 22, 2015
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
02:00pm – 04:00pm Individual Office Hours with Speakers (optional)
04:00pm – 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 23, 2015
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 – 07:00pm Manuscript Writing Workshop – part III – Donald Halstead
07:00pm – 11:00pm Celebration and Awards with dinner

Saturday, October 24, 2015
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
CLINICAL RESEARCH FELLOW PRACTICE, BOSTON

Formerly known as the Latin American Initiative, the course aims to enhance the interest in Clinical and Basic Science research in developing countries by offering the opportunity to learn and practice research skills. The objective is to train future clinician investigators who will become leaders for international collaboration in medical clinical research and medical education. Accepted participants will come to Boston for one year, and be enrolled in the Principles and Practice of Clinical Research (PPCR) main course component. Participants will have to be in a Boston laboratory as a research fellow and develop in parallel a project based on their practical laboratory experience. We will assist with placement in Boston laboratories, but the final decision for acceptance in the Boston laboratories will come from the laboratory directors. However, acceptance for this program will come from PPCR. Participants will also be an integral part of the Practice Workshop organizational team and share their work with health care professionals from different parts of the globe. The participants will work on research projects and, therefore, have the opportunity to become co-authors in future publications.

Meeting 1 - April 2, 2015
7:00pm - 8:30pm Welcome and general instructions, Introduction of program, Main goals and expectations - Prof. Fregni

Meeting 2 - April 23, 2015
7:00pm - 8:30pm 10 minute presentation of research project and review proposal - I - Prof. Fregni

Meeting 3 - May 7, 2015
7:00pm - 8:30pm 10 minute presentation of research project and review proposal – II - Prof. Fregni

Meeting 4 - June 28, 2015
7:00pm - 8:30pm Practical challenges in clinical research - Prof. Ivan Rosas

Meeting 5 - June 25, 2015
7:00pm - 8:30pm Update of projects and mid-course evaluation - Prof. Fregni

Meeting 6 - August 27, 2015
7:00pm - 8:30pm Practical challenges in basic research - Prof. Friehs

Meeting 7 - September 24, 2015
7:00pm - 8:30pm Setting up a laboratory and future career opportunities - Prof. Merabet

Meeting 8 - November 5, 2015
7:00pm - 8:30pm Mentoring in clinical research - Prof. Ivan Rosas

Meeting 9 - February 4, 2016
7:00pm - 8:30pm Final presentation of projects and review papers and final evaluation - Prof. Fregni
STUDY COORDINATOR WORKSHOP, BOSTON

The 2-day live intensive course will host five Harvard professors and directors of clinical research centers at Harvard affiliated hospitals who will teach the theoretical and practical aspects of being a study coordinator in a detailed and intensive fashion and will be critical for PPCR students who want to become or are currently study coordinators and plan for a future career as a study coordinator. Topics will include 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. During the workshop students will conduct practical exercises in study groups and develop a study project.

Monday, July 13, 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>07:00am – 08:00am</td>
<td>Registration</td>
</tr>
<tr>
<td>08:00am – 08:15am</td>
<td>Welcome!</td>
</tr>
<tr>
<td>08:15am – 09:00am</td>
<td>Initiating a Study I: site selection</td>
</tr>
<tr>
<td>09:00am – 09:45am</td>
<td>Initiating a study II: assessing feasibility (recruitment, budget, staffing)</td>
</tr>
<tr>
<td>09:45am – 10:00am</td>
<td>Break</td>
</tr>
<tr>
<td>10:00am – 12:00am</td>
<td>Practical Exercises I: students will be divided in groups and choose sites and negotiate agreements with mock sites</td>
</tr>
<tr>
<td>12:00am – 01:00pm</td>
<td>Lunch</td>
</tr>
<tr>
<td>01:00pm – 01:45pm</td>
<td>Regulatory issues (IRB, HIPAA and FDA)</td>
</tr>
<tr>
<td>01:45pm – 02:30pm</td>
<td>Study first steps I (Informed consent, paperwork, electronic medical records)</td>
</tr>
<tr>
<td>02:30pm – 2:45pm</td>
<td>Break</td>
</tr>
<tr>
<td>02:45pm – 3:30pm</td>
<td>Study first steps II (recruitment strategies)</td>
</tr>
</tbody>
</table>

Tuesday, July 14, 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>03:30pm – 5:00pm</td>
<td>Practical exercises II: students will be divided in groups and create recruitment strategies</td>
</tr>
<tr>
<td>05:00pm – 6:00pm</td>
<td>Management and leadership in clinical research</td>
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</tbody>
</table>

Study Activities

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:00am – 08:45am</td>
<td>Study activities I (General tracking procedures, forms and study folders, software programs)</td>
</tr>
<tr>
<td>08:45am – 09:45am</td>
<td>Study activities II (Drug storage, monitoring drugs and monitoring visits)</td>
</tr>
<tr>
<td>09:45am – 10:00am</td>
<td>Break</td>
</tr>
<tr>
<td>10:00am – 10:30am</td>
<td>Study activities III (Improving study adherence)</td>
</tr>
<tr>
<td>10:30am – 12:00pm</td>
<td>Practical exercises II: students will be divided in groups and define strategies to manage trials</td>
</tr>
<tr>
<td>12:00pm – 12:30pm</td>
<td>Lunch</td>
</tr>
<tr>
<td>12:30pm – 03:30pm</td>
<td>Final project presentation and group discussion</td>
</tr>
</tbody>
</table>

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This workshop serves as additional statistical training for participants from PPCR who wish to learn more advanced statistical methods. During the course, STATA (same platform used in PPCR) will be used. Participants will have an opportunity to review and expand their statistical knowledge and will be prepared to practically apply their skills to their own research. During the classes, participants will be asked to work with data sets, how to fit a model, how to conduct statistical tests in STATA and how to 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, to better review manuscripts and to write their own manuscripts and grants.

Thursday, July 16, 2015
07:00am – 08:00am Registration
08:00am – 08:15am Welcome!
08:15am – 09:00am Correlation and Causality
09:00am – 09:45am Statistical Tests
09:45am – 10:00am Break
10:00am – 12:00am Practical Applications
12:00am – 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

Friday, July 17, 2015
07:00am – 08:00am Breakfast
08:00am – 8:45am Categorical Variables
8:45am – 9:45am Construction of Models
9:45am – 10:00am Break
10:00am – 11:00am Special Situations
11:00am – 12:00am Assumptions for Logistic Regression
12:00am – 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
3:15pm – 5:30pm Student Presentation
5:30pm – 6:00pm Final Remarks and Awards
INTRODUCTORY WORKSHOP AND EVIDENCE-BASED MEDICINE, BOSTON

This Workshop is an introduction about the importance of Evidence Based-Medicine. In this workshop participants of PPCR will also get to know each other and discuss the importance of knowing the principles of Evidence Based-Medicine. This will be an important Workshop for the participants taking the PPCR course, especially for those who are taking the course in order to improve their clinical skills.

Monday, March 9, 2015

Study Activities
08:00am – 08:45am Registration
08:45am – 09:45am Goals and expectations of Principles and Practice of Clinical Research
09:45am – 10:00am Students Introduction and brief presentation
10:00am – 10:30am Break
10:30am – 12:00pm Practical Exercises on Importance of EBM
12:00pm – Afternoon Practical Exercises in group and preparation of next day

Tuesday, March 10, 2015

07:00am – 08:00am Breakfast
08:00am – 08:50am History of Scientific Investigation
08:50am – 09:40am Why Evidence-Based Medicine
09:40am – 10:30am Clinician vs. research perspective in Medicine-Based Evidence
Assessing Medical/Research Information

FACULTY
Felipe Fregni, MD, PhD, MPH, MEd
Harvard Medical School
Ben Illigens, MD
Harvard Medical School
Lotif Merabet, OD, PhD, MPH
Harvard Medical School

02:00pm – 02:50pm Keeping up with medical literature
02:50pm – 03:40pm Medical Evidence
03:40pm – 04:30pm Randomized clinical trials, Observational Studies and Case reports – assessing quality of evidence – practical exercise

Assessing Medical/Research Information
Accessing the validity of medical information
Methods of access and databases
Advanced searches
Lunch
Limitation and challenges of searching