PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH

INTERNATIONAL DISTANCE-LEARNING CLINICAL RESEARCH TRAINING PROGRAM

MARCH 24 – DECEMBER 3, 2022

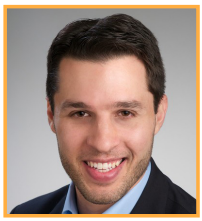
Program Director — Felipe Fregni, MD, PhD, MPH, MEd
Professor of Epidemiology, Harvard T.H. Chan School of Public Health
Professor of Physical Medicine & Rehabilitation, Harvard Medical School

This collaborative, interactive distance-learning program in Clinical Research attracts participants from across the globe, from the U.S. to Brazil to Germany to Japan. The program 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.

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

PPCR since 2008

PROGRAM DIRECTOR



About Felipe Fregni, MD, PhD, MPH, MEd

Prof. Fregni is a Professor of Epidemiology at Harvard T.H. Chan School of Public Health and Professor of Physical Medicine & Rehabilitation, Harvard Medical School. He leads Spaulding Neuromodulation Center, a large clinical research laboratory funded by major NIH grants that are currently investigating techniques to guide and measure neuroplasticity in brain injury. He has been at the forefront of advancing neurorehabilitation science to treat conditions such as stroke, Parkinson's disease and chronic pain. He holds a MD and PhD from University of Sao Paulo, Brazil and three master's degrees from Harvard University. He has more than 440 peer-reviewed publications and has been leading the international training program Principles and Practice of Clinical Research since its foundation in 2007. Dr. Fregni has also been awarded the United States Presidential Early Career Award for Scientists and Engineers.

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 Principles and Practice of Clinical Research (PPCR) 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. PPCR 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). PPCR has been a leading global program in clinical research methods that has trained more than 3,400 participants over the last 14 years.

FORMAT

This program blends live and online interaction via the web and on-site centers. Participants attend weekly three-hour interactive videoconference sessions, which are broadcast live from Boston to centers around the world. Participants may enroll either as part of a site center or individually, if they do not have access to a site center. PPCR consists of 24 weekly lectures taught by distinguished faculty from Harvard T.H. Chan School of Public Health, Harvard Medical School, and Tufts University, amongst other renowned institutions. This program 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. In addition, we offer two live workshops in Boston where participants can deepen their knowledge and interact with Harvard faculty and other subject matter experts. At the end of the program, participants can attend the 5-Day Immersion Course in Brazil to review and integrate the key concepts learned throughout the program.

LEARNING OUTCOMES

During the program, participants will develop skills in two main domains: design and conduct of clinical research, and interpretation and critical understanding of published research. Participants will learn 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. At the end of this program, participants will be able to critically read research papers, understanding the main sources of bias and confounding, as well as 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). The program is designed to have a critical impact on both clinical scientists and other health care professionals alike.

EIGHT-MONTH DISTANCE LEARNING MAIN PROGRAM

MODULE 1	Introduction to Clinical Trials, Selection of the Questions, Study Population, Basic Study Design, Integrity in Research, The Randomization Process, Study Blinding.
MODULE 2	Basics of Statistics, Statistical Tests I, II and III, Sample Size Calculation. You will perform statistical analysis in Stata software.
MODULE 3	Survival Analysis, Missing Data and Covariate Adjustment, Meta-analysis and Subgroup Analysis, Introduction to Regression Modeling.
MODULE 4	Safety, Clinical, and Surrogate Outcomes, Recruitment of Study Participants and Participant Adherence, Clinical Research in the Context of Individualized Medicine (N-of-1 Designs), The Business of Clinical Research, Effective Communication in Clinical Research.
MODULE 5	Non-inferiority Designs, Adaptive Designs, Interim Analysis, Phase III and Multicenter Trials, Observational Studies, Confounders in Observational Studies, Using the Method of Propensity Score, RCT vs. Observational Designs – How to Choose.

PROGRAM DATES AND TUITION

8-MONTH DISTANCE LEARNING MAIN PROGRAM MARCH 24 – DECEMBER 3, 2022 **INCLUDES 5-DAY IMMERSION COURSE** NOVEMBER 15 – 19, 2022	Site Center or Group: $3,000 Remote/Web-Based Access: $4,500 Graduate Student: $3,000
OPTIONAL 3-DAY ADVANCED STATISTICAL WORKSHOP JULY 25 – 27, 2022	For PPCR Participants: $1,500 For Non-PPCR Participants: $2,500
OPTIONAL RESEARCH MANUSCRIPT WRITING WORKSHOP JULY 28 – 29, 2022	For PPCR Participants: $750 For Non-PPCR Participants: $1,500

All registration prices include a 6-Month Stata 15/IC (GradPlans™) license. The fees are for the workshop/course only. Accommodations and transportation are not included. Dates are subject to change.

APPLICATION AND PROGRAM ADMISSION

Registration is limited. Please apply at **www.ppcr.org**. The following documents are required: curriculum vitae, letter of intent stating the reason for participating in the program, letter of recommendation and a professional picture. Applications are due by December 31, 2021. Late applications will be considered on a case-by-case basis.

TECHNICAL REQUIREMENTS

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

ADDITIONAL PPCR WORKSHOPS

3-DAY ADVANCED STATISTICAL WORKSHOP

BOSTON, MA* | JULY 25 – 27, 2022

This workshop provides additional statistical training for PPCR participants who want to acquire more advanced methods especially in how to design and analyze studies using multiple variables (multivariate analysis). Participants will not only review and expand their statistical knowledge but will also 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.

RESEARCH MANUSCRIPT WRITING WORKSHOP

BOSTON, MA* | JULY 28 – 29, 2022

This intensive workshop introduces participants to the essential concepts and structures for preparing and writing research manuscripts. Focusing on a PPCR research manuscript, participants in this collaborative-learning workshop will gain significant new insights into the logical structures and narrative pathways of persuasive arguments that are essential for effective manuscript writing. In addition, after a boot camp writing event, we will present the principles for writing clearly and concisely in English, while utilizing constructive peer review groups for the discussion of participants' draft manuscripts.

5-DAY IMMERSION COURSE

BRAZIL* | NOVEMBER 15 – 19, 2022

The 5-Day Immersion Course is the capstone of the PPCR program. It is a highly interactive course hosted by Harvard and other leading 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. Students will have the opportunity to meet with the faculty to review their group projects and participate in an intensive Manuscript Writing workshop with Prof. Donald Halstead of the Harvard Chan School. All students are encouraged to attend.

(*) Please note that both the July workshops and the 5-day immersion course are subject to change to virtual teaching because of the COVID-19 pandemic. Participants will be notified at least 2 months prior to the start of the programs.

INTERNATIONAL SITES

We have more than 45 sites across the globe that broadcast the PPCR Main Program lectures live each week in the following countries:

> "This course changed my life. I became confident in doing analysis and understanding articles in medical journals. I learned the ethics of analyzing data. All of the faculty were very, very helpful in everything."
>
> Manal Shaker, OB/GYN Resident, Hamad General Hospital, Qatar

THE CORONAVIRUS PANDEMIC AND SITE PARTICIPATION FOR 2022

During this challenging time, our work at Harvard T.H Chan School of Public Health as a research and educational institution has never been more important, and the PPCR Program is committed to guaranteeing the safety of our participants.

Although most of our sites closed in 2021 due to COVID-19, we hope that in 2022 we will see the re-opening of some/all of our sites. All sites will observe the local safety protocols. Therefore, if you register for the site option of $3,000 and your site is closed at the start of the program, you may have to work remotely until your site re-opens – for no additional charge. If and when your site re-opens, you will be expected to attend all class sessions at that site. Those participants who opt for Remote learning ($4,500) may continue to work remotely for the entirety of the program.