MASTER OF MEDICAL SCIENCES IN CLINICAL INVESTIGATION

High-impact clinical research training using a modern pedagogic approach.

For curriculum, schedule, and admissions information:
HMS.HARVARD.EDU/MMSCI
SENIOR ASSOCIATE DEAN’S MESSAGE

The Harvard Medical School Master of Medical Sciences in Clinical Investigation (MMSCI) is a two-year degree program specifically targeted to attract future world leaders in patient-oriented research. The provision of outstanding training in clinical research methodology is essential for the future success and development of biomedical sciences and related fields. The MMSCI curriculum embodies this goal, incorporating training in core subjects, such as epidemiology and biostatistics, with an innovative skills-based approach to modern pedagogy.

The primary mission of the MMSCI program, in keeping with the mission of HMS, is to play a key role in the training and development of the best and brightest students from all corners of the globe. The matriculation of students with an MMSCI degree from HMS represents a key milestone for each individual student and the beginning of exciting and productive careers as physician-scientists, clinical scholars and biomedical researchers.

I encourage you to participate in this innovative and interactive program.

Ajay K. Singh, MBBS, FRCP (UK), MBA
Senior Associate Dean
Global and Continuing Education
Harvard Medical School
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Dr. Singh, Senior Associate Dean for Global and Continuing Education, is a member of the renal division in the Department of Medicine at Brigham and Women's Hospital and an Associate Professor of Medicine at HMS. He completed his undergraduate and medical training at University College London School of Medicine in England and his clinical and research renal fellowship at Tufts-New England Medical Center. He has written more than 200 publications and edited 11 books in nephrology and internal medicine. He has earned international recognition for his work in medical education, leading several global clinical trials in nephrology, including the CHOIR study and the ASCEND phase 3 program. His research has been published in the New England Journal of Medicine, Circulation, JASN, Kidney International and Science Translational Medicine. Dr. Singh is a Fellow of the Royal College of Physicians in London, and received his MBA from Boston University.

Dr. Mc Causland is a nephrologist at Brigham and Women’s Hospital and Assistant Professor of Medicine at HMS. Dr. Mc Causland received his medical degree from University College Dublin, Ireland and completed higher specialist training in nephrology and medicine before joining the Renal Division at Brigham and Women's Hospital. Dr. Mc Causland’s major research interest relates to the cardiovascular consequences associated with hemodialysis. He is the Principal Investigator of two ongoing randomized controlled trials related to the dialysate prescription and its effect on hemodynamic stability. He has received funding from the National Institutes of Health, the American Heart Association and the National Kidney Foundation. Dr. Mc Causland received his Master of Medical Sciences degree in clinical investigation from Harvard Medical School.
CORE FACULTY

JULIE BURING, ScD
Professor of Medicine
Harvard Medical School
Professor of Epidemiology
Harvard T. H. Chan School of Public Health
Senior Epidemiologist
Brigham and Women's Hospital

E. FRANCIS COOK, SM, SD
Professor of Epidemiology
Harvard Medical School
Professor of Epidemiology
Harvard T.H. Chan School of Public Health

RANJAY GULATI, BA, BS, SM, PhD
Jaime and Josefina Chua Tiampo Professor of Business Administration
Unit Head, Organizational Behavior Chair
Advanced Management Program
Harvard Business School

BRIAN HEALY, PhD
Director Clinical Research Methodology
Global and Continuing Education
Harvard Medical School

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PEARL O'ROURKE, MD
Associate Professor
Harvard Medical School
Director, Human Research Affairs
Partners Health Care System, Inc.

MARC A. PFIEFFER, MD, PhD
Victor J. Dzau Professor of Medicine
Harvard Medical School
Senior Physician
Brigham and Women's Hospital

PRIYA SINGHAL, MD
Global Head, Senior Vice President
Safety and Benefit Risk Management
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CAREN G. SOLOMON, MD, MPH
Associate Professor of Medicine
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Deputy Editor
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SCOTT SOLOMON, MD
Edward D Frohlich Distinguished Chair
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ROBERT TRUOG, MD
Professor of Medical Ethics
Anaesthesiology & Pediatrics
Director of the Center for Bioethics
Harvard Medical School

SUSHRUT WAIKAR, MD, MPH
Associate Professor of Medicine
Harvard Medical School
Constantine L. Hampers Distinguished
Chair & Director of Translational Research
Renal Division
Brigham and Women's Hospital
ABOUT THE PROGRAM

The Harvard Medical School Master of Medical Sciences in Clinical Investigation (MMSCI) degree provides world-class training in the methods and conduct of clinical discovery for future leaders in patient-oriented research. This two-year program, which requires students to reside in Boston for its duration, combines innovative forms of pedagogy from leading Harvard faculty with an individual mentored research experience. This program is designed for post-graduate clinician-scientists working in clinical research at the fellowship and junior faculty level (or equivalent). Candidates holding an MD, MBBS or a comparable academic degree, are eligible to apply.

The MMSCI program provides each student with the unique opportunity to perform cutting-edge research in a Harvard-based laboratory, under the direct supervision of a Harvard mentor. Guided by a dedicated thesis committee, each student must complete two first-author manuscripts based on the work from their individual research projects. Our innovative curriculum is specifically designed to deliver the theoretical and practical skills that will complement this mentored research experience.

The central pillars for delivering our fully integrated program consist of three intensive workshops at the beginning, mid-point and end of the two years. Between each workshop, students will continue to acquire core knowledge and skills by way of longitudinal lectures and a longitudinal seminar series. In addition to the traditional learning of biostatistics, epidemiology and study design, our goal is to promote the development of critical thinking skills, writing and presentation skills, and leadership experience.

To complement individual learning and development, the MMSCI program places a core emphasis on practical skills and team-based approaches to clinical research training. Facilitated by continual access to HMS faculty who are leaders in their field, the MMSCI structure is designed to ensure that students are equipped with the necessary tools to launch productive, fulfilling and successful research careers upon graduation.
AFTER COMPLETING THIS PROGRAM, SCHOLARS WILL BE ABLE TO:

1. Construct focused research questions and formulate testable hypotheses
2. Design and implement well-designed clinical research studies
3. Analyze, interpret and present clinical research data

WHO SHOULD APPLY

Applicants must hold an MD, MBBS or an equivalent doctoral degree. We will consider candidates with a PhD degree for admission on a case-by-case basis.

“The MMSCI program is a unique and novel learning experience. It is the perfect combination of learning theoretical concepts as well as their application in real life through a mentored research project with the highest quality faculty. In addition to its high academic profile, this master’s program is enriched by the outstanding faculty that lead it. The faculty display full-time dedication to our needs while encouraging and helping us with our difficulties along the way. The coordination team does a great job organizing every activity and is always ready to help. Finally, my class has given me the opportunity to meet colleagues from all over the world, allowing me to learn from their culture and native practice of medicine, and to become great friends with them.”

- Lourdes Perez-Chada, MD
MMSCI Student, Class of 2018
KEY FEATURES

- A two-year intensive mentored research experience at a Harvard-affiliated laboratory in Boston.
- Fully integrated curriculum designed specifically for MMSCI students.
- Contemporary pedagogical approaches include ‘flipped classroom’ methods, team-based learning and development of critical thinking skills.

LEARNING MODEL

- MENTORED RESEARCH EXPERIENCE: The core feature of the MMSCI program is the mentored research experience in a Harvard-based research group. During the two years of the program, under the guidance of their primary mentor and dedicated thesis committee, each student is required to develop and execute his or her individual research projects. In order to graduate, students must submit and defend a thesis based on their mentored research experience. This should take the form of two original manuscripts in which the student is first-author.

- INTENSIVE WORKSHOPS: The central pillars of the MMSCI program will consist of three intensive workshops at the beginning, mid-point and end of the two years. The didactic sessions will be complemented by journal clubs, office hours, computer laboratory classes, team-based projects and presentations.

- LONGITUDINAL TEACHING: Between each workshop, further exploration of contemporary research topics will occur at weekly interactive sessions. Novel pedagogic approaches for this longitudinal series include the use of 'flipped classroom' methods, where students review and dissect learning material in advance of facilitated discussions.

- LONGITUDINAL SEMINAR SERIES: The seminar series is designed to complement the didactic and longitudinal curriculum by placing the learned theory in the context of real-world examples of successful clinical research projects. In addition, students are invited to present updates on their individual projects, with constructive feedback provided from both faculty and peers.

- INDIVIDUALIZED LEARNING: Opportunities for customized learning include training in scientific communication at the New England Journal of Medicine and receipt of individual feedback on grant and manuscript writing. Under the program and mentor’s guidance there are post-graduate research opportunities at leading biopharmaceutical companies.
The MMSCI program is specifically designed to ensure that each student is fully prepared to attain and surpass our core learning objectives. During this two-year program our desire is to stimulate critical thinking, development of practical skills, networking and learning how to deal with uncertainty in patient-oriented research. To achieve these aims, we have developed an integrated curriculum involving epidemiology, biostatistics, ethics and clinical trials that will address the three key tasks of clinical research: description, prediction and causal inference. Theory will be reinforced and consolidated with case studies and examples, while skills will be developed and refined with practice-oriented tasks.

### CORE CURRICULUM

**CI706**  
*Mentored Research Experience*

During the mentored research experience each student will have the opportunity to take the lead on clinical research projects in their individual areas of interest. Working in a Harvard-based laboratory, under the direct supervision of a primary mentor, each student is required to complete a thesis at the end of the program. This must take the form of two original manuscripts that have been submitted to a peer-reviewed journal in which the student is first-author.

The purpose of this requirement is two-fold: 1) To highlight the importance of publishing quality research in peer-reviewed academic journals; and 2) To promote excellence in the practice of scientific communication. Additional guidance and oversight is provided to each student by a thesis committee, that consists of the student, the primary mentor, one external member (i.e. someone who is not in the student’s primary laboratory and who is not directly involved in the student’s research) and a MMSCI program representative.

**CI701**  
*Clinical Data Science: Design & Analytics I*

This course introduces methods for the generation and analysis of data for clinical research through seamless integration of epidemiology, biostatistics and machine learning. The course is structured in three components that correspond to the three main objectives of clinical research: description, prediction and causal inference. The descriptive component introduces different data types and study designs, summary measures (including frequency and occurrence measures) and statistical inference (hypothesis testing, confidence intervals). The predictive component introduces association measures, regression (linear as well as logistic) and other learning algorithms with applications to screening and clinical classification. The causal component introduces a causal inference (counterfactual) framework via randomized clinical trials, which covers survival analyses, sample size calculation, biases and effect heterogeneity. The course emphasizes critical thinking and practical applications, including assignments based on articles published in medical journals and a case study at the end of each week. All methods are taught along with Stata software to implement them.
CI708
Clinical Data Science: Design and Analytics II
This course extends the topics introduced in Design and Analytics I for each of the three goals of clinical research: description, prediction and causal inference. The description sessions discuss data wrangling, data visualization and unsupervised learning with a focus on clustering. The prediction sessions discuss building and evaluation of predictive models via regression and other learning algorithms. The causal inference sessions discuss advanced design of randomized clinical trials (factorial, non-inferiority, adaptive, crossover, cluster-randomized trials) and evidence synthesis using meta-analysis.

CI722
Clinical Data Science: Comparative Effectiveness Research I
This course introduces causal inference methodology when randomized trials are not feasible. The course focuses on the use of epidemiologic studies, electronic health records and other big data sources for comparative effectiveness and safety research. Key concepts of bias, such as confounding, selection bias and measurement bias are described via causal diagrams. Methods for confounding adjustment, including stratification, outcome regression, propensity scores, matching and standardization are introduced along with an emphasis on formulating well-defined questions in clinical research.

CI732
Clinical Data Science: Comparative Effectiveness Research II
This course extends the topics introduced in Comparative Effectiveness Research I. The course covers efficient epidemiologic designs such as case-control, case-cohort and case-crossover. It also dives into advanced methods for confounding adjustment (inverse probability weighting, parametric g-formula) for the comparison of sustained treatment strategies and instrumental variable estimation. The course also covers techniques for the secondary analysis of randomized clinical trials in the presence of deviations from protocol.
CI712

Drug Development and Safety
This course will include topics such as: How are Drugs Discovered and Developed, Case Study of the Pre-clinical Stages of Drug Development, Moving a Compound through the Drug Development Process, Good Manufacturing Practices--a Global Perspective, and Overview of Diagnostic Device Development.

CI740

Leadership and Management
This course examines different aspects of working with, managing and leading a team. Lectures will discuss the skills and techniques that are needed to manage a talented group of people effectively, pilot successful collaborations within and outside a group, navigate the complexities of the institution and manage the inevitable conflicts that arise in a high-stakes environment.

“The MMSCI program attracts students from all over the world to learn the theory and develop the practical skills necessary to perform patient-oriented research. You will be immersed in an unparalleled learning environment and stimulated to think and ask questions in new and innovative ways”.

- Julie Buring, ScD
Professor of Medicine
Harvard T. H. Chan School of Public Health
CI700
Ethics in Clinical Research
This course reviews some common challenges in the conduct of patient-oriented research. Lectures examine the history and evolution of ethical codes and regulations; the role and responsibility of physicians as investigators; the preparation of research protocol applications and informed consent documents; and the challenges of conducting research involving children and adolescents.

CI702
Clinical Trials
The course content includes lectures on study design and implementation, including different designs, endpoints, study protocol, study population, recruitment, baseline assessment, randomization, stratification and blinding. Other key issues that are covered include data analysis and sample size and power, treatment regimens and follow-up procedures, and monitoring and interim analysis plans.

CI720
Scientific Communication
This course is designed to develop skills in writing research proposals and manuscripts as well as communicating information effectively in poster and oral presentations. How to write each section of a research proposal, the unwritten rules of earning top scores in grant submissions, as well as how to publish papers in high impact journals are also covered.

CI724
Genetic Epidemiology
The goals of this course are to provide clinical researchers with the skills to: address opportunities to incorporate genetic studies to answer specific research questions; understand basic genotyping techniques; understand the basics of genetic study design and analysis; identify and use publically available databases for genetic research; and understand the principles of ethical conduct of genetic research.

“As a clinical trial physician, the ultimate training need is the integration of medicine, translational sciences and most importantly biostatistics and epidemiology. The clinical investigation program has efficiently integrated all of these components especially the epi and stats aspects while the mentored research experience integrates all other components. This is a unique model that is unparalleled, and I can consider this training as one of the most important journeys in my clinical research career at one of the best medical schools in the world”.

- Girish Naik, MBBS
MMSCI Student, Class of 2018
SPECIAL FEATURES

SCIENTIFIC COMMUNICATION

Publishing in peer-reviewed journals and obtaining independent grant funding are critical for success in clinical research. The MMSCI program places special emphasis on developing skills in writing and the presentation of research data. Opportunities include visits to the New England Journal of Medicine editorial meetings and the opportunity for each student to have their individual writing critiqued by manuscript editors. Innovative pedagogic methods will facilitate the development of presentation skills through self- and peer-review of elevator pitches, oral presentations and sessions on how to give feedback.

INDUSTRY EXPERTISE

The biopharmaceutical industry plays a pivotal role in the advancement of medical knowledge and scientific discovery. Recognizing the need to promote collaborations of physician-scientists with industry, the MMSCI program has developed a selection of post-graduate internships at leading companies in the Boston area. Students wishing to pursue one of these pathways must complete an elective course in translational pharmacology in the second year and complete a separate application and interview process.

These models embody the power of collaboration and development of world-wide networks in the pursuit of research excellence.
APPLICATION INFORMATION

ELIGIBILITY REQUIREMENTS
Applicants for the MMSCI program must have a MD, MBBS or equivalent advanced degree. Enrolled students must reside in Boston during the two-year MMSCI program. We will consider applications from candidates with a PhD degree on a case-by-case basis.

APPLICATION DEADLINES
Applications close on February 1, 2019. Please visit hms.harvard.edu/mmsci for more in-depth application information.

TUITION INFORMATION
Tuition for the AY19 academic year $41,000. Please visit hms.harvard.edu/MMSCI for more information on financial aid.

“This is a career changing program for a researcher at any level. This program allows you to learn from key leaders in medical research that work directly with you and mentor your development. Every real-life component of conducting and publishing research has been implemented into the MMSCI program.”

- Datis Kharrazian, DHSc, DC, MS, FACN
  MMSCI Student, Class of 2018

“The MMSCI is a unique program with an innovative approach that integrates different modules covering a wide range of topics relevant to real-life experiences in clinical research. Being taught by world-renowned leaders, with special emphasis on two key components; teamwork and mentorship, this program represents a state-of-the-art opportunity to learn the theory with a direct hands-on experience. I look forward to the upcoming two years along with my fellow students who I consider a second family.”

- Omar Abu-Qamar, MD
  MMSCI Student, Class of 2018
HARVARD MEDICAL SCHOOL

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