Harvard Medical School’s Master of Medical Sciences in Clinical Investigation (MMSCI) is a two-year degree program specifically targeted to develop future world leaders in patient-oriented and translational research. The provision of outstanding training in clinical and translational research and laboratory methodology is essential for the future success and development of biomedical sciences and related fields. The MMSCI curriculum embodies this goal by incorporating training in core subjects—such as epidemiology and biostatistics; implementation science and clinical trials; and translational methods such as genetics, immunology and systems biology—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 student, as well as the beginning of an exciting and productive career as a physician-scientist, clinical scholar or biomedical researcher.

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

Ajay K. Singh, MBBS, FRCP (UK), MBA
Senior Associate Dean
Postgraduate Medical Education
MMSCI Program Director
Harvard Medical School
Ajay_Singh@hms.harvard.edu
Harvard Medical School's 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 and translational 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. Each student is provided the opportunity to perform cutting-edge research in a Harvard-based laboratory under the direct supervision of a Harvard mentor.

The MMSCI program is designed for postgraduate clinician-scientists working in clinical or translational research at the fellowship and junior faculty level (or equivalent). Candidates holding an MD, MBBS, MBBCh, PhD or comparable academic degree are eligible to apply.

The program format features three intensive workshops across a two-year span. Between each workshop, students will continue to acquire core knowledge and skills by way of longitudinal lectures and a course in Contemporary Topics in Clinical and Translational Investigation. In addition to the traditional learning of biostatistics, epidemiology and translational methods, 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 provides students the choice of a Clinical Investigation (CI) or a Translational Investigation (TI) track, and places a core emphasis on practical skills and team-based approaches in each track's training. Additionally, the CI track offers a choice of comparative research pathway or a clinical trials pathway for individualized learning.

The MMSCI structure is designed to facilitate continual access to multidisciplinary faculty across Harvard schools and research groups who are leaders in their fields and to ensure that students are equipped with the necessary tools to launch productive, fulfilling and successful research careers upon graduation.
Who Should Apply

Applicants to the MMSCI program must have an MD, PhD, MBBCh, MBBS or equivalent degree. We will consider applications from candidates with a master’s degree on a case-by-case basis.

Students accepted into the program must demonstrate, through grades and performance in graduate-level training, the potential to learn effectively in a challenging educational environment.

APPLICATIONS DEADLINES & TUITION INFORMATION

Please visit hms.harvard.edu/msci for more in-depth application and tuition information.

The program begins on September 2, 2020.

“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
**Program Objectives**

AFTER COMPLETING THIS PROGRAM, YOU WILL BE ABLE TO:

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

**Key Features**

• A two-year intensive, mentored research experience at a Harvard-affiliated laboratory in Boston
• Leading clinical and translational research faculty from Harvard Medical School, Harvard T.H. Chan School of Public Health and laboratories from Harvard-affiliated organizations
• Fully integrated curriculum designed specifically for MMSCI students
• Contemporary pedagogical approaches such as “flipped classroom” methods, team-based learning and development of critical thinking skills
• Specialized tracks and pathways for individualized learning

“The MMSCI program is a unique and novel learning experience. It is the perfect combination of learning theoretical concepts and applying them in real life through a mentored research experience with the highest-quality faculty. In addition to its high academic profile, this master's program is enriched by the outstanding faculty who lead it. They 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 of 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
• **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 a primary mentor and dedicated thesis committee, each student is required to develop and execute research projects.

• **INTENSIVE WORKSHOPS:** The central pillars of the MMSCI program will consist of three intensive workshops and didactic sessions that are 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.

• **CONTEMPORARY TOPICS IN CLINICAL INVESTIGATION:** This course is designed to complement the didactic and longitudinal curriculum through team-based database analysis: presenting the data in figures and tables in various formats (poster, short presentation and a research presentation), as well as “state-of-the-art” talks.

• **INDIVIDUALIZED LEARNING:** Opportunities for customized learning, including new tracks both in Clinical Investigation and Translational Investigation, as well as individualized pathways in clinical trials and comparative research.
Program Tracks

Clinical Investigation (CI) Track
This track is co-led by Finnian R. Mc Causland and Ajay K. Singh, who both have extensive experience in observational research and clinical trials. The Clinical Investigation track allows customized learning for students through the pursuit of either a comparative research pathway or a clinical trials pathway. Guided by a dedicated thesis committee, each student must complete two first-author manuscripts (one published and one submitted in a peer review journal) based on the work from their individual research projects. The innovative curriculum is specifically designed to deliver the theoretical and practical skills that will complement a mentored clinical research experience.

Translational Investigation (TI) Track
This track is co-led by Harvard Medical School faculty Rosalyn Adam and Martina McGrath, who both have extensive experience in bench and translational research. The Translational Investigation track aims to fill an unmet need in providing training for individuals pursuing a career in basic and/or translational research (i.e., in the T0 to T2 spectrum of translational investigation). Incorporating the translational track within the MMSCI program is consistent with the overall goal to train future global leaders in clinical and translational research. Bringing together students and faculty interested in clinical and translational investigation will ensure diversity of experience, skills and ideas, while promoting collaboration across the spectrum of clinical and translational research.
Core Curriculum

INNOVATION WITH INTEGRATION

The MMSCI program is specifically designed to ensure that each student is fully prepared to attain and surpass core learning objectives: to stimulate critical thinking, the development of practical skills, networking and learning how to deal with uncertainty in patient-oriented research. To achieve these aims, there is a foundational first year where students enrolled in both the Clinical Investigation and Translational Investigation tracks learn together. In the second year, students in each track then customize their learning along their interests. Theory is reinforced and consolidated with case studies and laboratory exercises, while skills are developed and refined with practice-oriented tasks.

Clinical and Translational Investigation Thesis Preparation

During the course learners work with their mentors on two thematically linked research projects, which form the basis for two first-author publications, or a body of work. The Clinical & Translational Investigation Thesis Preparation course provides guidance on topics critical to the preparation and presentation of the written and oral forms of the thesis defense. Topics include review of analytic strategies for qualitative and quantitative data, presenting skills for qualitative and quantitative data, writing an academic paper, writing an op-ed (opinion) piece for the popular press and tips for writing and grammar. Weekly writing advising allows students to receive continuous feedback on their thesis composition.

Clinical Data Science: Design and Analytics I

This course introduces methods for the generation and analysis of data for clinical research through the 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 and 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 (counter-factual) 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 each week. All methods are taught along with STATA and R software to implement them.
Leadership and Teamwork
This course will examine the 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.

Ethics and the IRB (Institutional Review Board)
This course will examine the regulatory and ethical oversight of the history and evolution of ethical research codes and regulations. The role and responsibility of physicians as investigators will be discussed, and information about the preparation of research protocol applications and informed consent documents for clinical research will be provided. The course also will review some timely and common challenges in the ethical conduct of patient-oriented research, including recruitment, issues related to vulnerable populations and current topics such as bio banking and the use of social media in research. The curriculum also includes the importance of considering the perspectives of subjects and patients in clinical research. Students will be educated about their regulatory and moral responsibilities to increase transparency within the clinical research environment through lectures on the importance of clinicaltrials.gov and data sharing. The course will include didactic and group work that will emphasize critical thinking and practical application of ethical considerations while developing and implementing patient-oriented research.

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, as well as the basics of genetic study design and analysis; identify and use publicly available databases for genetic research; and understand the principles of ethical conduct in genetic research.

Mentored Research Experience
During the mentored research experience, each student will have the opportunity to take the lead on clinical research projects in their 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.

The purpose of this requirement is twofold: to highlight the importance of publishing quality research in peer-reviewed academic journals and to promote excellence in the practice of scientific communication. Additional guidance and oversight are provided to each student by a thesis committee, which 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 an MMSCI program representative.

“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
## Program Timelines

### COMPARATIVE RESEARCH PATHWAY

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<td><strong>CI708 Design &amp; Analytics II (1.5 Credits)</strong></td>
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### TRANSLATIONAL SCIENCE TRACK

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### CLINICAL TRIALS PATHWAYS

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Clinical Data Science: Design and Analytics II
This course will extend 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 the building and evaluation of predictive models via regression and other learning algorithms. The causal inference sessions discuss the advanced design of randomized clinical trials (factorial, non-inferiority, adaptive, crossover and cluster-randomized clinical trials) and evidence synthesis using meta-analysis.

Clinical Data Science: Comparative Effectiveness Research I
This course will introduce causal inference methodology when randomized clinical 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.

Clinical Data Science: Comparative Effectiveness Research II
This course will extend 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 and 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.

Drug Development, Safety and Translational Pharmacology
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.

Clinical Trials
The goals of this yearlong series, comprising two semester-long courses, are to develop a deep understanding of how clinical trials are conceived, funded, developed (including protocol development and, in the case of industry trials, the industry approval process), conducted and closed out. Key topics will include different trial designs (adaptive, point-of-care, pragmatic designs, etc.), trials in different settings (emergency, pediatrics, cancer, biomarker, device, etc.), statistical monitoring of trials, safety issues, secondary analysis of clinical trial data, committee organization and management, advanced ethics, post-marketing surveillance studies and writing up trials for publication. Practical examples mixed with theory will be emphasized.
Translational Investigation Curriculum

Investigative Models for Translational Research
This course will introduce the range of investigative models within the translational research spectrum, with emphasis on the advantages and disadvantages of each system. Introductory sessions focus on developing well-designed research questions and selecting appropriate analytic methods to interpret results. The course will consider both discovery-based hypothesis-generating as well as hypothesis-driven mechanistic studies, illustrating each with case studies. Participants will learn about the various types of model systems used for translational research, from in vitro and ex vivo approaches to the use of animal models and human biospecimens. Lastly, commonly used bench techniques will be discussed. At the conclusion of this course, participants will have an appreciation for where translational investigation fits within the research spectrum.

Systems Biology and Omics Analysis
The goals of this course are to introduce participants to fundamental concepts in systems biology and to provide a basis for experiments that generate large genomic, transcriptomic or proteome datasets. An introduction to gene expression and gene regulation is followed by an exploration of experimental design for the generation of large datasets and their integration using systems biology principles. Mass spectrometry-based proteomics and related technologies are discussed in the context of biomarker discovery and the course concludes with an investigation of the microbiome and its relevance in health and disease.

Cell and Molecular Biology in Medicine
The goal of this course is to provide translational investigators with a broad understanding of the fundamental processes that drive cell function in health and disease. An overview of cell biology is followed by an introduction to specific cell functions that play key roles in disease processes, including inflammation, angiogenesis, wound healing and fibrosis. The innate and adaptive arms of the immune system are covered, with a focus on cutting-edge techniques for immunological investigation. Specific disease entities, including diabetes, cancer, cardiovascular and neurodegenerative diseases, are explored as examples of studies in cellular and molecular medicine. Case studies will be used throughout to illustrate key points, and the course will conclude with a discussion of the therapeutic exploitation of cell biology in the pursuit of precision and personalized medicine.

Translating Innovation into Practice
This course is designed to provide learners with an introduction to the process of translating research innovations into clinical practice. It will examine the design of first in human studies, the process of filing patents, and the regulatory process to bring an innovation to the clinic. Securing funding through industry networks, and how to approach commercializing a discovery are also covered, with case studies throughout.
Dr. Ajay K. Singh, Senior Associate Dean for Postgraduate Medical 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 Harvard Medical School. 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. Dr. Singh has written more than 200 publications and edited 11 books in nephrology and internal medicine. He has earned international recognition for his work in 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. Finnian R. Mc Causland is a nephrologist at Brigham and Women’s Hospital and an Assistant Professor of Medicine at Harvard Medical School. He 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

ROSALYN ADAM, PhD
Director, Urology Research
Associate Professor of Surgery
Harvard Medical School

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

MICHAEL CHO, MD
Assistant Professor of Medicine
Harvard Medical School

MIGUEL HERNAN, MD, MPH, ScM, DrPH
Professor of Epidemiology
Harvard T.H. Chan School of Public Health

SONAL JHATHERI, PhD
Science Program Director
Dana-Farber Cancer Institute

SUSAN Z. KORNETSKEY, MPH
Director of Clinical Research Compliance
Boston Children’s Hospital

SAYEED MALEK, MD
Clinical Director of Transplant Surgery,
Kidney/Pancreas Transplant
Brigham and Women’s Hospital
Assistant Professor of Surgery
Harvard Medical School

MARTINA M. MCGRATH, MBBCh
Medical Director
Live Kidney Donation
Instructor in Medicine
Brigham and Women’s Hospital

PEARL O’ROURKE, MD
Associate Professor
Harvard Medical School
Director, Human Research Affairs
Partners HealthCare System, Inc.

MARCO A. PFEFFER, MD, PhD
Victor J. Dzau Professor of Medicine
Harvard Medical School
Senior Physician
Brigham and Women’s Hospital

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Harvard Medical School
Director, BWH Pulmonary Genetics Center
Channing Division of Network Medicine
and the Division of Pulmonary and Critical Care Medicine
Brigham and Women’s Hospital

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Harvard Medical School

ELLEN SEELY, MD
Professor of Medicine
Harvard Medical School
Director of Clinical Research
Endocrinology
Diabetes and Hypertension Division
Vice Chair, Faculty Development
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Associate Professor of Neurology
Massachusetts General Hospital

PRIYA SINGHAL, MD
Head of Research and Development
Zafgen, Inc.

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Deputy Editor
New England Journal of Medicine
Associate Physician
Brigham and Women’s Hospital
SCOTT SOLOMON, MD
Edward D. Frohlich Distinguished Chair
Professor of Medicine
Harvard Medical School
Director of Noninvasive Cardiology
Senior Physician
Brigham and Women’s Hospital

ROBERT TRUOG, MD
Professor of Medical Ethics,
Anesthesiology & Pediatrics
Director of the Center for Bioethics
Harvard Medical School

DAVID WYPIJ, PhD
Senior Lecturer on Biostatistics
Department of Biostatistics
Associate Professor of Pediatrics
Harvard Medical School
Director of the Statistics and Data
Coordinating Center
Department of Cardiology
Boston Children’s Hospital
Master of Medical Sciences in Clinical Investigation Program

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