# Online Teaching Opportunity - HMX Pro: Clinical Drug Development

HMX is looking for members of the research and clinical communities at Harvard Medical School and the affiliated hospitals who are interested in gaining experience in online education to join our moderator team. This is a fully remote opportunity with flexible hours and competitive compensation, beginning in April 2023.

HMX offers fully online courses intended for students interested in health care careers as well as professionals working in life science and health care related careers. More information about our courses can be found here: <a href="https://onlinelearning.hms.harvard.edu/hmx/courses/">https://onlinelearning.hms.harvard.edu/hmx/courses/</a>.

We are currently staffing a course on **Clinical Drug Development** that is part of our HMX Pro Pharmacology series. We are looking for researchers and clinicians to support our students' learning by answering questions about the course content in the discussion forums. Applicants should be able to demonstrate teaching experience, as well as in-depth knowledge in this topic area, including relevant research or clinical experience. **We welcome applications from postdoctoral and clinical fellows.** 

Successful candidates will be part of a team of moderators with diverse areas of scientific and clinical expertise, who moderate HMX courses in genetics, pharmacology, immunology, biochemistry, and physiology. The workload for each moderator will vary but generally will be around 5 hours per week, which can be done remotely at flexible hours. Responsibilities for each course will be shared across at least two moderators, providing additional flexibility for busy schedules.

These courses run quarterly (January, April, June, and September), with the upcoming session beginning in April 2023. We prefer applicants interested in remaining with the team for multiple course sessions. For longer-term team members, there may be additional opportunities to provide feedback on and develop course content, or to participate in other collaborations with HMX.

To apply, please email YeaRim Oh (yearim\_oh@hms.harvard.edu) with your current CV and a cover letter describing your interest in moderating the Clinical Drug Development course. **There are a limited number of spots and applicants will be reviewed on a rolling basis.** 

## HMX Pro - Clinical Drug Development

## Course description

Clinical drug development has evolved dramatically over time and the field continues to advance today. The methodology of clinical trials has evolved with new techniques being introduced, the design and statistical aspects have become more sophisticated in parallel with the increased use of technology and the introduction of new drug modalities. The rigor and discipline of this process means that people can trust that the medicines they take are likely to be safe and effective and that beneficial treatments can make their way through the process in a safe and timely manner.

Learning about the process of clinical drug development has important implications for anyone working in health care and related sectors. This advanced course offers a unique way for professionals to learn from leading Harvard Medical School faculty about how drugs are developed clinically and about the advances happening in this field that are ultimately helping to improve the treatment and prevention of disease.

## **Course Topics**

Lesson 1: Overview of Clinical Drug Development

- Introduction to Clinical Drug Development
- The Promise of Clinical Drug Development

#### Lesson 2: Epidemiologic Considerations

- Establishing a Causal Pathway
- Chance and Bias
- Confounding and Effect Modification
- Basic Epidemiologic Considerations
- Surrogate Endpoints
- Clinical Linkage: PCSK9 Inhibitors

#### Lesson 3: Clinical Trials

- Fundamentals of Randomized Trial Design
- Anatomy of a Randomized Trial
- Types of Clinical Trials
- Data Presentation
- Data Interpretation
- Real World Data Interpretation
- Clinical Linkage: Systems Biology

#### Lesson 4: Oversight and Review

• Ethical Issues in Clinical Trials

- Informed Consent and Institutional Review Board
- Data and Safety Monitoring Board
- Regulatory Review
- Process of Drug Review
- Non-neutral Comparators
- Reporting on Clinical Trial Results

### Lesson 5: Wrap-up

• The Future of Clinical Drug Development