
HMX Pro Pharmacology - Clinical Drug Development

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.

Participants will:

- Learn some of the key epidemiological considerations that need to be taken into account when designing and conducting a clinical trial
- Understand how a clinical trial is designed, carried out, interpreted, and presented
- Learn about the process of drug review and the regulatory steps that are taken to move a drug from clinical drug development to the drug market for use in patients

Topics Covered

Overview of Clinical Drug Development

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

Epidemiologic Considerations

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

Clinical Trials

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

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

Wrap-up

- The Future of Clinical Drug Development

The HMX Pro Series offers a new online learning experience designed to get busy professionals up to speed on the latest advances in medicine. Concepts are taught using whiteboard-style videos and animations and reinforced by interactive elements, true-to life scenarios, and real patient cases to enhance learning.