
HMX Short Course - Biomarkers: Discovery, Validation, and Clinical Implementation

Learn how biomarkers are transformed from concept to clinical setting.

Biomarkers are used daily by medical professionals to diagnose patients, monitor conditions, make treatment decisions, and evaluate disease risk. They are used at every step of drug discovery and development: from assay development to patient stratification in the clinic. Biomarkers are an integral part of research and medicine, but many health conditions lack specific biomarkers that would be helpful for patient care. Unlike clinical drug development, the process for biomarkers is generally not well understood and articulated by the scientific community, and lacks clearly defined phases.

In this HMX short course, you will learn from Harvard Medical School faculty about the biomarker discovery and development pipeline. You will gain a practical framework for how to approach this process and see the real-world impact of having the validated biomarkers with clinical utility.

Participants will

- Map the entire biomarker discovery and development pipeline, from initial signal identification to clinical deployment
 - Apply understanding of analytical and clinical validation and clinical utility concepts to assess the requirements that a biomarker needs to meet to receive a regulatory approval
 - Explore the factors that determine whether a well-validated test achieves clinical adoption
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Topics Covered Include

- Why Biomarkers Fail: The Stakeholder Problem
- Designing the Biomarker Before You Discover It
- Discovery Strategies: Finding Signal in Biology
- Deep Dive: Omics Modalities
- Deep Dive: Analyzing Signals From Data
- From Candidates to Assays
- In Focus: Assessing the Performance of Diagnostic Tests
- Clinical Validation and Utility
- Regulatory Navigation, Clinical Deployment, and Lifecycle Management
- Interactive: Building a Better TB Test
- Clinical Linkage - Discovery of Asthma Biomarkers

HMX Short Courses feature targeted lessons on the latest medical science information and advancements to keep learners up to date.