
HMX Short Course - Biomarkers in Drug Development: Classification and Applications

Dive into the different FDA categories of biomarkers and discover how they are applied in drug development and patient care.

Despite significant advances in medicine and clinical research, many serious conditions remain undetected until late stages or respond poorly to existing therapies. Physicians and researchers are often left seeking better methods of identifying patients who are at risk, gauging disease activity, or determining the best therapeutic approach. The emergence of biomarkers—measurable indicators of biological processes—offers new ways to address these challenges and move toward truly personalized care.

In this HMX short course, you will learn from industry experts and Harvard Medical School faculty about topics ranging from basic biomarker categories to more advanced concepts, such as regulatory approval pathways and companion diagnostics. You will also see real-world applications of this field in a case study on biomarkers for Alzheimer disease. Understanding the critical role that biomarkers play in diagnosis, therapy selection, and regulatory approval is essential for learners whose work intersects with clinical research, drug development, or patient care.

Participants will

- Learn to identify the major categories of biomarkers, including their characteristics, uses, and limitations.
- Apply their understanding of the context of use of biomarkers to real clinical and research scenarios, including specific clinical applications.
- Calculate and interpret key performance metrics of diagnostic or predictive tests.

Topics Covered Include

- Introduction to Biomarkers
- Diagnostic Biomarkers
- Interactive: Clinical Validation of Diagnostic Tests
- Prognostic and Predictive Biomarkers, part 1
- Prognostic and Predictive Biomarkers, part 2
- In Focus: Clinical Validation of Companion Diagnostics - Assessing Diagnostic Performance
- Monitoring Biomarkers, Part 1
- Monitoring Biomarkers, Part 2
- Biomarker Discovery and Development
- Clinical Linkage: Biomarkers of Alzheimer Disease

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