

# Role of Biomarkers in Clinical Trials

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## Commentary

In drug development and clinical trials, biomarkers may be used to help identify populations for a study, monitor therapeutic response, and identify side effects. The FDA's Center for Drug Evaluation and Research defines the biomarker qualification process for this use. Biomarkers can serve multiple roles. They can be used as a diagnostic tool for the identification of patients with an abnormal condition or as a tool for staging the extent of disease, as an indicator of disease prognosis, or for the prediction and monitoring of response to an intervention.

Routine biomarker tests can confirm the diagnosis. Another important use of biomarkers in clinical medicine is the early detection and diagnosis of chromosome and single-gene disorders. Both cytogenetic and molecular genetic biomarkers have been used to accomplish this. Biomarker is short for biological marker, and is used as an indication that a biological process in the body has happened or is ongoing. While some biomarkers are used to show that the body has been exposed to a chemical, toxin or other environmental impact — most associate biomarkers with medicine.

Blood, urine, and cerebrospinal fluid provide the necessary biological information for the diagnosis. In these conditions, biomarkers are used as an indicator of a biological factor that represents either a subclinical manifestation, stage of the disorder, or a surrogate manifestation of the disease. A biomarker can be any biological indicator that can be measured. For instance, biomarkers can be cellular or molecular (DNA, RNA, protein, metabolites). They are measured from a tissue biopsy or a liquid biopsy.

Let me begin with the definition of a biomarker: a biomarker is a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or biological responses to a therapeutic intervention. ... In this case, glucose is the biomarker. Diagnostic biomarkers are used for the critical determination of whether a patient has a particular medical condition for which treatment may be indicated or whether an individual should be enrolled in a clinical trial studying a particular disease. However, certain universal characteristics are important for any biomarker they should be non-invasive, easily measured, inexpensive, and produce rapid results they should be from readily available sources, such as blood or urine they should have a high sensitivity, allowing early detection.

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