

The Hottest New Term in Biotech

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The term biomarker has become a buzzword in the pharmaceutical industry. Recent technological advances now enable a discovery-based approach in which thousands of constituents of the body can be measured in an unbiased way to find the few that change in response to a drug or disease state.

What exactly is a biomarker? At the 1999 NIH/FDA conference a biomarker was defined as a characteristic objectively measured and evaluated as an indicator of normal biological processes, pathogenic process or pharmacologic responses to a therapeutic indication.

Leading experts claim the use of biomarkers to indicate drug efficacy and toxicity has the potential to significantly reduce cost and duration of clinical trials. The biotechnology and pharmaceutical industry, along with the FDA, have acknowledged the need for biomarkers in their product tool kit.

Biomarkers have been used in limited circumstances for many years, but only recently has the FDA announced the Critical Path Initiative that highlights biomarker discovery. This initiative was created to help address the industry's pipeline problem of fewer drugs approved at a greater cost. In essence, every drug discovery and development program should be biomarker enabled.

Biomarker technologies applied to the drug development process help determine appropriate dosing of a drug; make more rapid go/no go decisions based on efficacy or safety; and improve understanding about a disease so that patients can be categorized as responders or non-responders, increasing chances of a successful trial. A trial with a biomarker endpoint can also



PPD's proprietary cytometry technology enables us to analyze and profile hundreds of cell populations and cell-surface markers in small volumes of whole blood and other biofluids.

save time and money if it can replace one of two or more pivotal trials that use clinical endpoints. Biomarkers can provide a preview of the clinical effects of a drug and thereby provide a roadmap for more informed decision-making along the path from lead compound to marketed drug.

PPD incorporates proprietary technologies for profiling and analyzing thousands of proteins (proteomics), peptides (peptidomics), low-molecular-weight organic molecules (metabolomics) and immune cell populations (cytometry) in small amounts of blood or other biological material. Integration of this data along with clinical and biological information enables PPD to provide a fingerprint of identified markers based on biological pathways involved in disease or in therapeutic or adverse responses. Read more about PPD's biomarker services on our Web site.

To learn more about our biomarker services, contact your PPD representative, or Howard Schulman, Vice President, Biomarker Discovery Sciences at +650 470 2316, e-mail: Howard.Schulman@menlo.ppd.com

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