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A New Paradigm for Companion Diagnostics in Cancer

Will New Clinical Trial Methods Speed Drug, Biomarker Use?

By Genna Rollins

Rapid advances in both molecular diagnostics and the understanding of cancer biology are transforming the cancer research and drug development enterprise, which experts say will lead to new clinical trial paradigms and testing protocols aimed at better matching patients to studies and therapies. The oncology community largely is viewing these events with enthusiasm and optimism for their potential to bring cancer drugs to market sooner, improve patient outcomes, and to make real the dream of personalized cancer therapy. Such efforts, which depend heavily on validated biomarkers, also are expected to transform the role of clinical laboratorians in oncology diagnostics and treatment.

"We're at a very interesting point. We've now spent the last several decades developing cancer therapeutics, but it's always been evident that even very successful drugs work in only a fraction of patients and all too often for a limited time. The reasons for that have become much clearer with the introduction in the last five-to-10 years of new technologies that allow us to characterize in detail cancer biology," said David Parkinson, MD, a venture partner at New Enterprise Associates, a venture capital firm in Menlo Park, Calif. "We now understand that selection of therapeutic tools ought to match the biological characterization of the patient's tumor at each particular point in the natural history of the patient's disease. This means that if we're going to move toward more efficient cancer therapy we have to have parallel development of biologically targeted therapeutic agents and diagnostics which characterize patients accurately enough for the efficient use of those tools." Parkinson for 5 years led Nodality, a molecular diagnostics start-up, and he co-chairs the cancer steering committee of the Biomarkers Consortium, a public-private biomedical research partnership managed by the Foundation for the National Institutes of Health.

He went on to explain that the old model of single biomarker test results being used to select oncology treatments, monitor the effects of those therapies, and switch therapies as treatment resistance emerges is no longer viable. "It's becoming clear that in order to be able to predict whether or not a cancer agent is going to work in a particular tumor setting is going to require a much more complex series of measurements, and the opportunity is that those measurements taken in whole can much more accurately predict outcomes related to therapeutics."

Cancer: A Chaotic Brew

A substantial body of evidence has dashed forever the notion that cancer is a monolithic disease with a straightforward path to cure. "It now is quite clear that diseases 10 years ago we considered one disease are really a compilation of different tumor types, each with a different driving biology. We now realize that in each tumor type if we just treat with a targeted agent, only a fraction of patients are going to genuinely derive benefit," said Funda Meric-Bernstam, MD, professor of surgical oncology and medical director of the Khalifa Bin Zayed Al Nahyan Institute for Personalized Cancer Therapy at the University of Texas MD Anderson Cancer Center in Houston.

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