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Editorial

Cancer Biomarkers: An Emerging Means of Detecting, Diagnosing and Treating Cancer

The potential of molecular markers to significantly improve early detection of localized cancers provides an unprecedented opportunity to understand the biology, improve diagnosis, enhance treatment, and reduce mortality. Research in the past 30 years has deepened our insights into nearly all biological processes, particularly with the complete sequencing of the human genome in 2000. Yet, translating these discoveries into daily medical practice has been elusive.

The challenge is to identify biomarkers that provide an earlier indication of disease with a more reliable and precise predictive ability than current methods. The past decade has witnessed a remarkable progress in biological science in which researchers can study thousands of different molecules in a single experiment. These so-called high-throughput studies allow a multitude of genes or proteins to be analyzed simultaneously. Genes, the functional and physical unit of heredity passed from parent to offspring, are pieces of DNA, with most genes containing the information for making a specific protein. Proteins are molecules made up of amino acids that are needed for the body to function properly and form the basis of body structures such as skin or hair, and of substances such as enzymes, cytokines, and antibodies.

A number of technologies emanating from gene- and protein-based approaches are being applied to discover and evaluate biomarkers. Although these approaches do not yet remove the "needle-in-a-haystack" quality of discovering novel biomarkers, they do provide the capability to inventory components within the "haystack" at an unprecedented rate. In fact, such capabilities already have exponentially expanded knowledge of the different types of proteins within serum, and opened the way for novel technologies for diagnosing cancers to emerge. Molecular strategies involving imaging, proteomic and genomic analysis of tumors and other specimens may ultimately identify small and early lesions that to date have been inaccessible in conventional clinical practice.

The time for applying biomarkers to screening populations at risk, providing target-based therapy, and establishing a personalized treatment for cancer has never been better. Advances in technologies such as genomics, proteomics, bioinformatics, and nanotechnology have grown exponentially. Integrating these technologies will facilitate the discovery of biomarkers. The challenges in relying on biomarkers as surrogate endpoints will not only require proof of their high sensitivity and specificity, but also significant confidence in their predictive value. To this end, prospective studies will rely on access to clinical specimens and collaboration between academia, government, and industry.

The future of biomarkers in clinical application requires close interactions between the public and private sectors: the government, the pharmaceutical and biotechnology industries, and academia. Numerous challenges lie ahead in leveraging and sharing these constituencies' unique research resources. While industry can provide reagents and technology, academic centers and medical schools can provide access to biological specimens that will be required to test and validate biomarkers in their ability to distinguish between normal and cancer cells. The most unique research resource is access to a clinical center's primary tissue, body fluids repository, and associated clinical data generated through well established cohorts, clinical trials and other large clinical studies. These tissues and fluids are precious to the biomarker scientist since these hold the outcome of the assays they seek to prove clinical significance retrospectively.

While the potential of biomarkers in detection, diagnosis and treatment of cancer is enormous, many chal-

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lenges remain. The potential benefit of biomarkers will require proof of their sensitivity, specificity, and predictive value. The application of cancer biomarkers as reliable predictors of outcome requires evaluations of their therapeutic value. If the reliance on surrogates does not lead to clinical benefits, then the outcome may not only lead to the adoption of useless therapies, but also harmful treatments. Only a carefully designed prospective testing in patients at risk of cancer will establish the critical threshold for the early detection of cancer. The use of biomarkers as surrogate endpoints should only be supported when the biomarkers have biological plausibility, success in clinical trials, and the risk-benefit outweighs public health considerations.

For 2005 we are pleased to announce our new journal *Cancer Biomarkers*, a new, separate section of *Disease Markers* of which the first issue is expected to appear this Spring. The journal will publish contemporary articles on biomarkers related to detection, diagnosis and treatment of cancer. Since so many disciplines will be involved in furthering research on cancer biomarkers, this journal is a beginning in bridging the gap between our understanding of cancer biology and clinical needs for detection, diagnosis, prevention and treatment of cancer. We hope that use of biomarkers will help us meet the eventual goal: reduction of cancer mortality and morbidity. In the spirit of assisting researchers on biomarkers to be able to share their findings, and disseminate timely information , we are delighted to launch this journal.

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Editor-in-Chief