



Cancer Genomics: Chapter 7. Biomarker Discovery and Development through Genomics

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Many hope that the promise that “omics” science holds for medicine will be realized through the development of better biomarkers for patient management. However, the development of omic technologies magnifies the issues and challenges of performing high quality biomarker studies. The complexity of these technologies and of the resulting high-dimensional data require rigorous technical, statistical, bioinformatics, laboratory, and clinical procedures to develop, evaluate and validate these tests. A number of considerations are key to the design and successful execution of genomic biomarker studies. These include the assessment of (1) the complexity and heterogeneity of cancer samples, (2) the quality and quantity of tumor specimens, (3) the potential bias inherent in the assays, (4) the availability of appropriate controls or standards, (5) technical validation of assays and bioinformatics analysis, and (6) the validity of the final interpretation of results. In this chapter, we review these key considerations required to design and conduct biomarker studies that will yield results that can confidently inform future clinical research and clinical practice.

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