Some Aspects of Developmental Oncology in the Genomic Era—New Challenges and Paradigms

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ABSTRACT

Developments in genomics, biotechnology and tumor biology have fundamentally changed the development of therapeutics in oncology. They have led to findings that challenge some of the key assumptions upon which current clinical trial methods are based creating the need for new designs, and new paradigms for clinical trial analysis. For example, the standard phase III clinical trial paradigm of employing broad eligibility criteria and focusing design and analysis on testing the null hypothesis of no overall average effect relegateing no longer has an adequate scientific basis in many oncology settings. It has led to large clinical trials that identified small average treatment effects and resulted in use of drugs that do not benefit most patients to whom they are administered. This problem has become exacerbated with the development of expensive molecularly targeted therapeutics. I will describe some new clinical trials designs using predictive biomarkers that attempt to meet these challenges.

The developments described above also have created great opportunities for basic science discovery using the whole genome tools for profiling tumor tissues. Discovery focused analysis also provides great opportunity for false discovery, however, and I will describe some common errors made in the analysis of high dimensional data.

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