

An Overview of Oncology Clinical Trials

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Abstract:

The Oncology therapeutic area is a high-growth area within the pharmaceutical industry. It presents unique challenges due to the patient population – which is often very ill with poor prognosis – and available treatment options which can be toxic. It is also an exciting area with many new scientific discoveries, e.g. in molecular biology, which have the potential to lead to ‘personalized’ therapy. In this talk, I’ll present an overview of Oncology clinical trials based on experiences as a statistician in the pharmaceutical industry. Discussion topics will include disease processes, treatment options, clinical development pathways for regulatory approval in the United States (e.g. Phase I/II/III clinical trials), and statistical methods and issues encountered. Typical roles and responsibilities of the statistician within the pharmaceutical industry will also be discussed along with emerging hot topics and suggestions for building skill sets.