

Session Name:

Prerequisites for Therapeutic Studies

Educational Objectives:

At the end of the lecture the participant should be able to:

1. Have an understanding of the global drug development process
2. Understand the importance of considering preclinical data for protocol design
3. Understand the preclinical evaluation of novel therapeutics for efficacy, toxicology, and biomarker development
4. Understand the regulatory requirements required to support phase I studies

Summary:

The process of developing a new drug for cancer can take a decade, cost \$1 billion and end in failure. The preclinical assessment of a new therapeutic is a critical consideration in successful clinical trial design and conduct. Key issues around understanding of the target, the drug, preclinical efficacy, toxicology, and biomarker assay development will be reviewed.