Strategies & Considerations for the Assessment of Relative Dose Intensity in Oncology Drug Development

**DRUG DEVELOPMENT TRACK**

*Offers both CME & CPE Credit*

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ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

**CHAIR:**

Divya Samineni, PhD, Scientist, Genentech Inc

**TARGET AUDIENCE:**

This Symposium will be useful for clinical pharmacologists, biostatisticians, oncologists and drug safety scientists.

**GOALS & OBJECTIVES:**

Following the completion of this activity, the learner will be able to:

1. Describe the relevance of relative dose intensity (RDI) and the clinical/regulatory implications for an inadequate evaluation of RDI on treatment outcomes and regulatory approvals;
2. List the strategic/practical constraints, heterogeneity and inherent biases associated with the current clinical assessment techniques for estimation of RDI during the course of treatment;
3. Adopt novel methodologies and strategic recommendations to evaluate patient-specific RDI values and the impact of individual delays and/or dose reductions reported throughout treatment on treatment outcomes and dosing recommendations;
4. Verbalize the regulatory perspectives on the assessment of drug tolerability and the impact on aligning with regulatory needs to guide review decisions.