

MONDAY, SEPTEMBER 21, 2020 | Symposium 1 | 10:00 – 11:30 AM

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

DRUG DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #JA4008220-0000-20-013-H01-P

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.

Relative Dose Intensity: The Neglected Variable in Clinical Trials

Divya Samineni, PhD, Scientist, Genentech Inc

Practical Considerations for the Assessment of Relative Dose Intensity and the Impact on Treatment Outcomes in Oncology Clinical Trials: A Literature Review

Whitney Kirschbrown, PharmD, PhD, Scientist, Genentech Inc

A Novel Methodology to Address the Association Between Relative Dose Intensity & Survival Outcomes

Larry Frank Leon, PhD, Statistician, Celgene Corp

Regulatory Considerations to Determine Drug Tolerability & Lessons Learned from Past Examples

Yaning Wang, PhD, Director, Pharmacometrics, Clinical Pharmacology, US Food & Drug Administration

Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation