

Webinar hosted by the American College of Toxicology (ACT):

Early Toxicology Studies – From Design to Dose Selection: What You Need to Know

11:00 AM ET, Wednesday, July 24, 2019

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The purpose of this webinar is to provide early career professionals with a general understanding of the design of Acute/Dose Range Finding (DRF) studies and identification/selection of a high dose level. Primary objectives of an Acute/DRF study are to 1) establish a dose response, 2) provide data for subsequent studies, and 3) establish initial toxicity data including a maximum tolerated dose. Initial dose selection may be based on literature, efficacy data, or pharmacokinetics/toxicology of related compounds. Nevertheless, as Acute/DRF studies are often the first toxicology studies examining doses above pharmacologic levels, dose setting and justification can be challenging. The challenges can be greater when the candidate is suspected to have severe toxic effects; although an absence of clear toxicity presents its own challenges. Rodent studies are often the starting point, but for certain drug classes, such as biologics, rodents can be of limited, or no relevance, and non-rodent species are the most relevant animal model. As outlined in ICH M3(R2), the high dose level may be characterized using a maximum tolerated dose (MTD), however, “limiting doses” including those that achieve large exposure multiples, saturation of exposure, or use the maximum feasible dose (MFD), may also be used to justify a high dose. The presenters will provide examples of study designs for Acute/DRF studies as well as how to rationalize a high dose for these early toxicology studies.