

DIA 2013 49th Annual Meeting "Advancing Therapeutic Innovation and Regulatory Science" June 23 – 27, 2013 Boston Convention and Exhibition Center Boston, MA

Session 130- Translational Aspects from Preclinical Animal Toxicology Studies to Early Human Health Risk Assessment: Needs and Limitations

Bringing therapeutic agents into the clinic entails some degree of risk, both for patients, and for developers which invest in clinical trials. The decision to proceed into the early clinical phase, as well as the design of trials, is based on a given therapeutic's mechanism of action, class effects and in *vivo* animal toxicology testing. In *Translational Aspects from Preclinical Animal Toxicology Studies to Early Human Health Risk Assessment: Needs and Limitations (Session 130)*, three presenters discussed various aspects of preclinical animal toxicology studies.

Celine Adessi, PhD detailed the difficult decision making process facing therapeutic developers when confronted with a non-measureable toxicity in preclinical models. Her emphasis was on vasculitis, which according to Dr. Adessi, "has weak evidence for translation from animal to human and vice versa." She argues that poor translation of this toxicity requires additional factors and information be considered before a "no go" decision is made on a therapeutic.

Andrea Greiter-Wilke, DVM, PhD explored the technology and methodology for assessing blood pressure change in preclinical models. She highlighted the need for blood pressure and heart rate measurements that avoid the restraining of animals. Finally, Dinah Duarte, PharmD, MSc gave an overview of the use of juvenile animals as preclinical models for pediatric drug development, focusing on the decision making process for initiation of these types of preclinical studies. In all, the speakers deftly addressed some of the limitations of preclinical toxicology, while also asserting their importance in translational medicine.

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