



## Meeting Sessions and Topic Descriptions

### **Innovation in Immuno-Oncology**

Chair(s): [Wendy Jo Freebern, BMS](#) and [Pia Kasperkovitz, Takeda Pharmaceuticals](#)

The expansive increase in IO therapeutic development has resulted in innovative safety assessment approaches and regulatory packages. In this session, pharmacodynamic and/or immunotoxicologic assessments (such as TDAR and CD8 T-cell activation) will be discussed in the context of pivotal safety study interpretation, and novel study designs addressing specific agency requests for a new IO fusion protein platform will be described. In addition, reproductive toxicology approaches will be discussed that focus on the complexity of enhancing the immune system while maintaining pregnancy. While the breadth of this session is wide, a common theme of innovation in developing IO therapeutics threads throughout the discussions.

### **MABEL**

Chair(s): [Michael Leach, Pfizer](#) and [David Clarke, Lilly](#)

The selection of the dose of a new molecular entity (NME) to be administered to humans for the first time (FIH starting dose) is a critical aspect of drug development. In 2016, IQ convened a Working Group (WG) to evaluate the use of Minimal Anticipated Biological Effect Level (MABEL) in selection of the FIH starting dose. This session will review the output from this WG, beginning with a brief discussion on how the current MABEL thought process came about and a discussion of the 2017 European Medicines Agency's (EMA) guidance on FIH and early clinical trials. The results of a survey the IQ WG conducted in 2017 to determine recent (2012-2017) experience by pharma companies using MABEL approaches, a review of the various current methods for calculating MABEL accompanied by several illustrative case studies, and recommendations of the IQ WG will be presented.

### **Fc Modification**

Chair(s): [Christina de Zafra, Amgen](#)

The Fc portion of a monoclonal antibody is critical for effector functions and contributes to the pharmacokinetics of biotherapeutic drugs. Modifications to the Fc region are often engineered to manage these attributes. Additionally, bispecific mAbs can be made via Fc modifications. This session will include discussion of the rationale for choosing an Fc-modified molecule, impact of Fc modifications on species selection for nonclinical studies, cross-species translatability of findings, and the impact of Fc modifications to the immunogenicity of biotherapeutics.

This session is interested in potential additional speakers from the membership. Please let [Victoria](#) know if you are interested in participating in the session.

## **Specialty Biologics**

Chair(s): [Jenny Marlowe, bluebird bio](#) and [Kathleen Meyer, Sangamo](#)

This session is organized in collaboration with BioSafe's Specialty Biologics Expert Working Group, and will include presentations on the recent regulatory approvals of several novel cell and gene therapies, as well as perspectives on the preclinical development and related regulatory interactions of early-stage gene therapies and gene edited products.

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## **Local Delivery of Biotherapeutics**

Chair(s): [Jessica Lynch, Janssen](#) and [Ronnie Yeager, AbbVie](#)

Targeted (localized) delivery of biotherapeutics has long been viewed as a means to administer novel therapeutics for target engagement at the site of injury/disease, while mitigating potential systemic toxicities. Recent advancements in the field have further enabled discovery and development of targeted delivery for GI, ocular, CNS, and other sites/indications. The goal of this session is to review the strategies, considerations, and challenges in supporting programs utilizing local delivery for clinical development. Topics we hope to explore in this session include the use of devices and/or test material modifications to achieve targeted delivery, and the non-clinical efficacy and safety strategies to advance such modalities into the clinic.

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## **Animal Models**

Chair(s): [Meghan Flaherty, Novartis](#)

How can animal models of disease inform safety assessment? This session will discuss several cases of when pharmacology models were used for more than just evaluating target or mechanistic toxicology questions. The limitation of healthy, young rodent and non-rodent models will be explored in the context of the information obtained from nontraditional models, which may have limited historical control information or confounding features due to the disease. The role of these different models in driving clinical dose setting, clinical monitoring and/or regulatory strategies will be discussed.

This session is interested in potential additional speakers from the membership. Please let [Victoria](#) know if you are interested in participating in the session.