



HESI ITC Immunosafety Training Course

Introduction Module

HESI : Human health and Safety Dr. Syril Pettit - HESI	Innate immune cell therapies (e.g. activation, inhibition pathways, therapies, toxicities) Dr. Rashade Haynes - Bristol-Myers Squibb
Safety assessment outside of drug development (e.g. agrichemicals, cosmetics, food additives, etc.) Dr. Vick Johnson - Burleson Research Technologies Lab	Immunopathology: evaluation, assessment, and considerations Dr. Tracey Papenfuss - Charles River Laboratory
Basic principles of toxicology, toxicology of the immune system, relevance to immunosafety Dr. Marc Pallardy - Universite-Paris-Saclay	Assessing adversity in immunosafety (preclinical) Dr. Tracey Papenfuss - Charles River Laboratory
Basic immunology: cells, innate and adaptive immunity Dr. Wendy Jo Freebern - Janssen	Immune-related adverse events (clinical) Dr. Robert Hseia - Genentech
Basic immunology: complement and hypersensitivities Dr. Marc Pallardy - Universite-Paris-Saclay	Animal models and species differences (immune system) Dr. Ashwini Phadnis - Moghe-Bluebird Bio
Immunomodulating therapies (overview) Dr. Marie-Soleil Piche - Charles River Laboratory	Translational biology and immunology: translatability, challenges Dr. Ana Goyos - Janssen
Immuno-oncology Dr. Birgit Fogal - Boehringer-Ingelheim	Diversity of immune responses (impact of age, sex, pregnancy, co-morbidities, etc.) Dr. April Masters - Boehringer- Ingelheim
T cell targeting therapies (e.g. activation, inhibition pathways, therapies, toxicities) Dr. Courtnei Newsome - Bristol-Myers Squibb	Regulatory guidance: Introduction Dr. Dave McMillan - US FDA
B cell targeting therapies (e.g. activation, inhibition pathways, therapies, toxicities) Dr. Marta Fernandez - Janssen	

The field and study of immunosafety is a rapidly evolving area important for the evaluating the relative safety of new drugs, therapies, and environmental agents that affect the immune system and determine risk to human health. There has been an ever-increasing number of such therapies that specifically target the immune system and the ways that various therapies impact and modulate the immune system (whether on-target or off-target) have become increasingly nuanced. Such complex immunomodulatory effects require that scientists become increasingly knowledgeable about the cells, signaling pathways, and overall function of the immune system. This Immuosafety introduction module is design to acquaint audience with foundational aspects in immune safety science by providing "lightning talks" on key concepts, presented by recognized experts in the field.