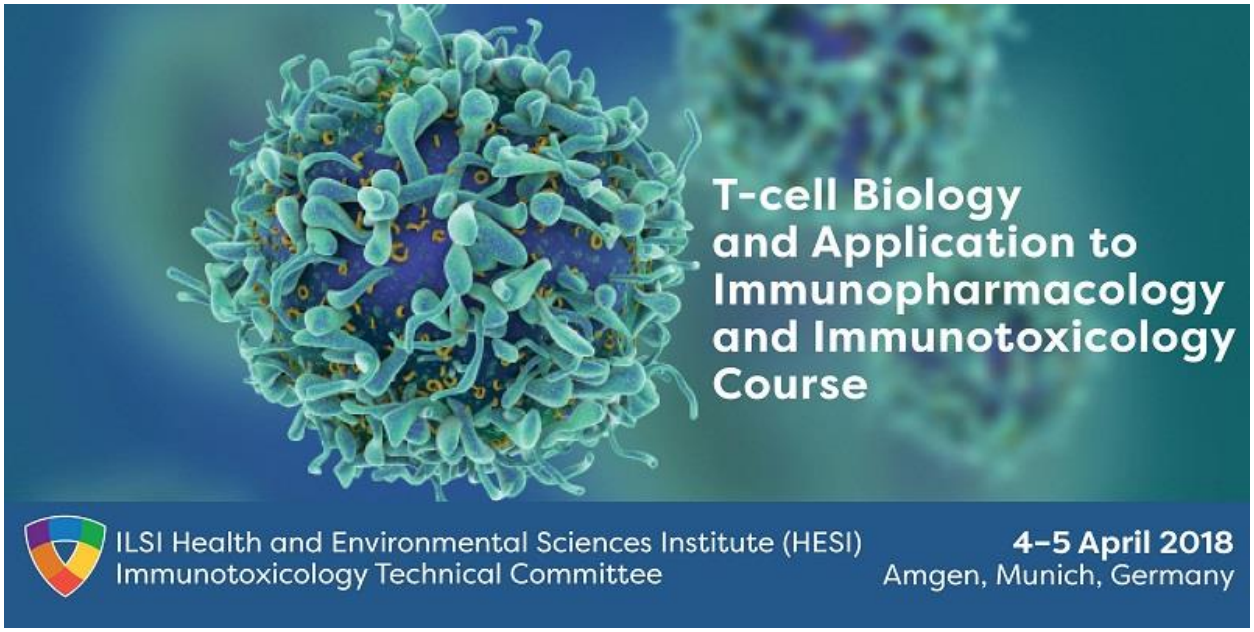

Background / Rationale:
The field of immunotoxicology is a dynamic one in which changing public health concerns, novel biomedical research advances, and innovative technological developments constantly change the landscape and the way in which work is carried out and utilized. As this field requires combined expertise in both immunology and toxicology, the need for continued training and interdisciplinary interactions are critical for those who work within this field. This is essential both for those with an immunology background who seek to apply this expertise to drug development and safety, as well as those who wish to enhance their current drug safety expertise with a deeper understanding of immunology.

Objectives:

- Review the current state of the science to provide an immunological foundation that is pertinent to T cell biology
- Enhance awareness to new discoveries and the potential impact on drug development and safety
- Provide a training mechanism that incorporates the latest science into preexisting drug development methodologies

Output:
Beyond the dialogue that will be generated on the latest science, this training course will provide the opportunity to apply it to a drug development setting through the following means:

- Engagement and discussion with experts in the field will enable participants to see how the science translates to applicability in drug development
- The use of specific case studies will engage and illustrate to participants how they can systematically progress on a sample task

Agenda

Wednesday, April 4th

Continental Breakfast available starting at 8:00 AM

8:30 – 9:00 AM	Welcome and Introduction: Suppression and activation: key issues	*Benno Rattel, Amgen* *Curtis Maier, GSK*

Session 1: **Foundational immunology: Basic T cell immunology + immunopharmacology**
Note: There will be time for Q&A/Discussion after each presenter

9:00 – 10:00 AM	T lymphocytes ontogeny	*Lawrence Kane, University of Pittsburg*
10:00 AM – 10:15 AM	**Break**	
10:15 AM – 11:15 PM	T lymphocytes activation/inhibition pathways	*Lawrence Kane, University of Pittsburg*
11:15 – 12:00 AM	T cell therapies	*Rod Prell, Genentech*
12:00 PM – 1:00 PM	**Lunch**	
Session 2: Non-clinical assessment		
1:00 PM – 2:00PM	Safety profile and preclinical safety assessment of engineered T cells	*Rafael Ponce, Juno Therapeutics*
2:00 PM – 3:00 PM	Safety profile and preclinical safety assessment of CD3-bispecifics	*Benno Rattel, Amgen*
3:00 PM – 3:15 PM	**Break**	
3:15 PM – 4:15 PM	Integrating immunopathology and immunotoxicology data; perspectives from a toxicologic pathologist	*Tracey Papenfuss, MPI Research*
4:15 PM – 5:15 PM	Immune function tests across species: T cells across toxicology species	*Marie-Soleil Piche, Charles River Laboratories*
5:15 PM	**Adjourn for Day 1**	
5:15 PM – 6:15 PM	**Reception**	

Thursday, April 5th Day 2

Continental Breakfast available starting at 8:00 AM

Session 2 (continuation): Non-clinical assessment

8:30 AM – 9:30 AM	Assays for assessing cytokine release syndrome	*Richard Stebbings, Medimmune*
9:30 PM – 10:30 PM	T-cell immunomodulation and cancer risk	*Hervé Lebrec, Amgen*
10:30 AM – 11:00 AM	**Break**	

Session 3: Clinical and Regulatory Considerations
Note: There will be time for Q&A/Discussion after each presenter

11:00 AM – 12:00 PM	Adverse events with immunosuppressive agents – a clinical perspective	*Kiran Nistala, GSK*
12:00 AM – 12:45 PM	**Lunch**	
12:45 PM – 1:45 PM	Diagnosis & Managing Adverse Events with Immune Checkpoint Agents	*Isabella Glitza-Oliva, MD Anderson*
1:45 PM – 2:45PM	Regulatory challenges for immunomodulators	*Gabriele Reichmann, Paul-Ehrlich-Institut*
2:45 PM – 3:00 PM	**Closing Remarks**	
3:00 PM	**Adjournment**	