This scientific program is committed to:

- Identifying and addressing scientific issues related to the development and application of immunotoxicology to public health and human health risk assessment;
- Promoting the understanding and appropriate use of immunotoxicology data to protect human health; and
- Contributing substantively to the scientific decision-making processes relative to the development of guidelines and regulations for immunotoxicology testing at the local, national, and international levels.

Areas of scientific focus:

- Harmonization of existing immunotoxicology assays and data interpretation
- Developmental and juvenile immunotoxicology best practices
- New predictive immunotoxicology assays and reduction of animal usage
- Predictive tools for immunogenicity, hypersensitivity, and autoimmunity
- Testing strategies and risk assessment
- Application of immunotoxicology for clinical application

Why get involved?

- The Immunotoxicology Technical Committee (ITC) is a unique forum for generating scientific dialogue, fostering research, and developing practical approaches to assessing adverse effects of chemicals and pharmaceutical entities on the immune system and understanding human risk potential.

Key accomplishments:

- Cytokine Release Assays. The Cytokine Release Assay (CRA) working group in collaboration with the National Institute for Biological Standards and Control recently launched a multi-site ring trial to test a repository of positive and negative control capabilities in a CRA. In addition, the group continues to share their data on the \textit{in vitro} to \textit{in vivo} translatability of a CRA in order to build consensus around methodology.
- Developmental Immunotoxicology. The DART and ITC committees have successfully initiated collaboration on a comprehensive review document on the key time points of development of the immune system across several preclinical species and in humans.
- Drug Hypersensitivity Reactions. This working group has been developing a reference document of the available tools and assays for diagnosing and characterizing drug hypersensitivity reactions (DHRs) in both preclinical and clinical settings. Additionally, through a series of webinars, the group has been gathering information for incorporation into the working document as well as for potential use in exploring potential next steps.
- Immunomodulators and Cancer Risk Assessment. The working group recently published a position paper in \textit{Regulatory Toxicology and Pharmacology} based on the October 2014 workshop. The paper highlights the workshop presentations that outlined the current knowledge related to human cancer risk associated with altered immunity and the available
models, tools, and approaches available to conduct weight-of-evidence–based assessments of cancer risk associated with new immunomodulatory therapies. The discussions at the workshop helped to identify knowledge gaps and opportunities for research efforts to improve the conduct of such risk assessments.

- **In Vitro Immunotoxicology Models.** The committee is in the final stages of completing a cross-laboratory study to explore the use of a human lymphocyte activation (HuLA) assay, which evaluates recall responses to influenza virus as an in vitro model to assess immune function. Data are still being generated across the laboratories and analysis is ongoing.

- **Respiratory Sensitization.** The committee organized a workshop in May 2014 in Alexandria, Virginia, which discussed the current state of the science for identification and characterization of respiratory sensitizer hazards and identified the requirements for developing validated standard methods and frameworks. Workshop proceedings highlighting the regulatory and practical needs regarding hazard identification are currently in final preparation.

- **Translational Immunotoxicology.** The committee has been holding a series of webinars on clinically relevant topics throughout 2015-2016. Topics that have been discussed, or are planned for the future, include pediatric investigation plans, latent tuberculosis and testing, and understanding host cell proteins/impurities in biologics.

- **T-Dependent Antigen Response (TDAR): Evaluation of Fit-for-Purpose Keyhole Limpet Hemocyanin (KLH) Attributes.** The committee launched a survey to determine why KLH toxicity was observed after administration. As a follow-up to the survey, the group has proposed a series of studies to better determine the causes and possible best practices moving forward.

The Committee’s focus for May 2016–May 2017:

- Developing next steps and potential projects for the Immunomodulators and Cancer Risk group.
- Launching a new training course on immunotoxicology that ties together the fundamental science and its relevance in drug development.
- Completing the cross-laboratory evaluation of the *in vitro* HuLA assay and identifying the next *in vitro* assay to be evaluated.
- Completing the DHR reference manuscript, identifying knowledge gaps and challenges, and assessing how those could be addressed.
- Completing the CRA-NIBSC Ring Trial to determine the usefulness of standardized controls.
- Conducting regular webinars in the area of clinical immunotoxicology toward increasing dialogue between preclinical toxicologists and clinicians, and identifying gaps and needs between these two communities.
- Publishing the proceedings from the October 2013 CRA workshop and continuing to move forward with the development and validation of reference standards.

2015–2016 Participating organizations

- Amgen Inc.
- Boehringer Ingelheim GmbH
- Bristol-Myers Squibb Company
- Celgene Corporation
- Charles River Laboratories
- Covance
- Eli Lilly and Company
- ExxonMobil Biomedical Sciences, Inc.
- GlaxoSmithKline
- Hoffmann-La Roche Inc.
- Janssen Pharmaceuticals
- MedImmune
- Merck & Co., Inc.
- National Institute for Biological Standards and Control (UK)
- National Institute for Public Health and the Environment (RIVM, The Netherlands)
- National Institute of Environmental Health Sciences
- Novartis Pharma AG
- Pfizer Inc.
- Sanofi
- Syrian Institute for Biological Researches
- Swedish Toxicology Sciences Research Center (Swetox)
- Université Claude Bernard Lyon
- University of Aachen
- University of Manchester
- University of Paris-Sud
- US Environmental Protection Agency
- US Food and Drug Administration

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