



Interagency Coordinating Committee on the Validation of Alternative Methods

Presentation Abstracts and Background Materials

SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE TOXICOLOGICAL METHODS

Session 2a: Fostering International Partnerships

Wednesday, September 2, 2020

➤ International Partner Updates

Presenter: **Dr. Anna Lowit, U.S. Environmental Protection Agency Office of Pesticide Programs**

This presentation summarizes key milestones and ongoing activities associated with the international harmonization and implementation of alternative test methods. Updates will be included from partner organizations of the International Cooperation on Alternative Test Methods (ICATM) as well as the Organisation of Economic Cooperation and Development (OECD) Health Effects Test Guidelines program.

Background

- [15 Years Out: Reinventing ICCVAM](#)

➤ FDA, ICH, and the 3Rs

Presenter: **Dr. Paul Brown, U.S. Food and Drug Administration Center for Drug Evaluation and Research**

One way in which the U.S. Food and Drug Administration (FDA) promotes the development of safe and effective drugs is by participating in the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH harmonization efforts help achieve this goal by providing common approaches for the assessment of clinical efficacy and safety, nonclinical evaluations, and drug manufacturing. These efforts are accomplished through Technical Guidelines that are implemented by the regulatory authorities.

Harmonization of recommendations for nonclinical studies means that pharmaceutical companies do not have to conduct different or additional studies to meet requirements for the participating ICH regulatory authorities. In addition, ICH guidances describe a stepwise approach to the conduct of nonclinical studies which avoids conducting unnecessary studies if a drug does not progress to later stages of development. All ICH guidances on nonclinical topics encourage and allow the use of alternative methods when available. Newly finalized guidances continue to contribute to the 3Rs as will future guidances..

Background

- [An FDA/CDER Perspective on Nonclinical Testing Strategies: Classical Toxicology Approaches and New Approach Methodologies \(NAMS\)](#)
- [Guidance for Industry: M3\(R2\) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals](#)
- [International Conference on Harmonization: Recent Reforms as a Driver of Global Regulatory Harmonization and Innovation in Medical Products](#)



Interagency Coordinating Committee on the Validation of Alternative Methods

➤ Non-animal Test Methods for Hazard Classification – Update on UN GHS Activities

Presenter: Dr. Janet Carter, Occupational Safety and Health Administration

This presentation will review the progress in updating health hazards chapters for use of non-animal methods when classifying hazardous chemicals in the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The current work encompasses updates to the skin irritation/corrosion chapter and serious eye damage chapter.

Background:

- [GHS: Revision of Chapter 3.2 to Fully Incorporate Non-animal Test Methods](#)