Joint International Workshop
Challenges for Inhaled Drug Discovery and Development: Induced Alveolar Macrophage Responses

Organized by the Academy of Pharmaceutical Sciences Great Britain (APSGB) & the Health and Environmental Sciences Institute (HESI) Immunotoxicology Technical Committee

30-31 October 2012
The Health and Environmental Sciences Institute (HESI)

- **HESI Mission**
  Engage scientists from academia, government, research institutes, and industry to identify and resolve global health and environmental issues.

- **HESI Vision**
  Creating science-based solutions for a sustainable, healthier world.

- **HESI Philosophy**
  HESI 's scientific programs bring together scientists from around the world from academia, industry, and regulatory agencies and other governmental institutions, to address and reach consensus on scientific questions that have the potential to be resolved through creative application of intellectual and financial resources. This “tripartite” approach forms the core of every HESI scientific endeavor. As a non-profit organization, HESI provides a unique, objective forum for initiating dialogue among scientists with different perspectives and expertise.
HESI: A Resource for Scientific Collaboration and Progress

- HESI is a nonprofit organization with global activity.

- By pooling experience, data, resources, and diverse perspectives, HESI’s scientific collaborations offer benefits that independent research and participation in other groups cannot.

- HESI scientific committees are unique opportunities to contribute combined technical knowledge and innovative perspectives to the scientific community via workshops, peer reviewed publications, etc. as part of all HESI projects.
HESI’s Role – The 5 Pillars

- **Collaborative** – reaching across academia, government, industry, research institutes, nonprofits, across sectors, international, etc.;
- **Interdisciplinary** – bridging across different scientific disciplines;
- **Translational** – supporting the movement of science from early formulation to implementation to help meet public health needs;
- **Structured** – providing staffing and management structure to progress novel collaborative programs and activities;
- **Resource Effective** – pooling in-kind, intellectual, and financial inputs to drive research.
Scientific Endeavors at HESI

- Experimental / Laboratory Programs
- Data Sharing
- Database Development, Population, & Analysis
- Expert Panels
  - Discussion forums of leading experts, white papers, best practices.
- Scientific Outreach: Workshops & Publications
  - Workshop design and execution.
  - Peer-reviewed publications.
- HESI is **not itself** a laboratory facility.
Scientific Portfolio 2012

Translational Biology
- Cardiac safety evaluation
- Biomarkers of renal toxicity
- Developmental and reproductive tox
  - Immunotoxicology

New Technologies
- Imaging for safety evaluation
- Genomics in mechanism-based risk assessment

New Approaches
- Biological significance of DNA adducts
- Adjuvant/vaccine safety and risk of autoimmunity
- Frameworks for Alternative Chemical Assessment and Selection of Safer, Sustainable Alternatives

Environmental Toxicology
- Animal alternative needs in environmental risk assessment
- Methods for a tiered approach to assess bioaccumulation

Assessing Risk
- Risk assessment in the 21st Century (Risk 21)
- Relevance of positive results from in vitro genotoxicity testing
- Protein allergenicity
- Distinguishing adverse from non-adverse/adaptive effects
- Assessing risks from mixtures
- Evaluating causality in epidemiologic studies
The Immunotoxicology Technical Committee

Mission:
• To identify and address scientific issues related to the development and application of immunotoxicology to public health and human health risk assessment

• To promote the understanding and appropriate use of immunotoxicologic data to protect human health

• To contribute substantively to the scientific decision-making processes relative to the development of guidelines and regulations for immunotoxicologic testing at the local, national, and international levels
An inclusive network ....

DRUGS IN THE LUNGS

DDL
BALR
PQRI
CCAMS
RDD
ISAM
AIT
DMDG
Meet
Regular, accessible, low cost, high quality, relevant, interactive

Debate
Scientific, data-rich, current, informed, supportive, inclusive

Act
Co-operative, pre-competitive, data sharing/generating, opinion-leading
Today’s Workshop: Interpretation of macrophage responses to inhaled drugs – A scientific challenge

- Identification and quantification of effects during pre-clinical and clinical drug development
- Distinguishing adverse events from normal / adaptive lung responses

Key Issues:
- Biology of responses
- Measurement and interpretation
- Risk factors
- Assays and their improvement
Workshop Aims

- Enhance understanding of the biology of alveolar macrophage responses
- Explore current practices (a number of case study presentations) in assessment and interpretation of alveolar macrophage responses
- Identify key challenges in development of safe inhaled therapies
- Discuss translation of findings from pre-clinical to clinical settings
- Evaluate new/emerging methodologies for assessing alveolar macrophage responses
- Identify gaps and research needs
- Discuss best practices in assessment of alveolar macrophage effects and paths forward

Outcome:
» The organizing committee will develop a manuscript for publication in the peer-reviewed literature describing the workshop proceedings and outcomes.
For more information contact:

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Please enjoy the meeting!