Framework for Intelligent Non-Animal Methods for Safety Assessment

Alan Boobis, PhD, Imperial College of London
Overview

• How did we get here?

• Why now?

• What are we doing to address the issue?
How did we get here?

2007/2009 NRC Reports

Global initiatives on non-animal methods – mainly uncoordinated

2014 HESI EI proposal
Determine consensus across initiatives and provide scientific confidence
Why now?

• Determine consensus across initiatives
• Provide scientific confidence
• Guide future development
How are we addressing the issue?

Subgroups
- Performance Characterization
- Model Predictive Performance
- Utilization

Steering Team
- Craig Rowlands – The Dow Company
- Doug Wolf - Syngenta
- Alan Boobis – Imperial College London
- Katie Paul-Friedman – Bayer Crop Science
- Sonja Beken – Federal Agency for Medicines and Health Products
- Suzanne Fitzpatrick – US FDA
- James Freeman - ExxonMobil
- Anna Lowit – US EPA
- Natalie Burden – NC3Rs
- Mark Hurtt – Pfizer
- Beatriz Silva Lima – University of Lisbon
- Norbert Kaminski – Michigan State University
- Daiju Yamazaki – NIHS Japan
- Donna Mendrick – US FDA
- Warren Casey – NIH/NIEHS
How?

Determining Criteria
Determining Criteria

- 3 subgroups with their own set of objectives and questions
  - Performance Characterization
  - Model Predictive Performance
  - Utilization

- Determine set of criteria
  - Extract information from the literature
  - **Determine consensus on minimum criteria required**
## How are we addressing the issue?

### Matrix Development

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How?

Determining Criteria

Case Studies
Case Studies

- Series of case studies developed to “stress-test” framework
  - Currently under development

- Goal to have case studies that carry across the 3 subgroups
  - Are the criteria met, and if not, what is missing?
How?

- Determining Criteria
- Case Studies
- Workshop
Workshop

- Opportunity to receive feedback from outside organizations
  - Invite speakers to provide their viewpoint

- Breakout sessions to disseminate information discussed

- Revise and adjust framework
How?

Determining Criteria

Case Studies

Workshop

Framework for Intelligent Non-Animal Methods for Safety Assessment
Summary

**Harmonization** – looking across initiatives for consensus in criteria

**Umbrella** – creating an umbrella framework, which are consistent, transparent, and generally accepted

**Multi-sector** – input across sectors and backgrounds

**Acceptability** – peer engagement to assess the acceptability of the criteria proposed

**Non-animal methods** – provide a future usefulness in guiding organization-specific guidelines and new non-animal methods