

# Framework for Intelligent Non-Animal Methods for Safety Assessment

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# 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

3

1

## 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

- 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

### Examples

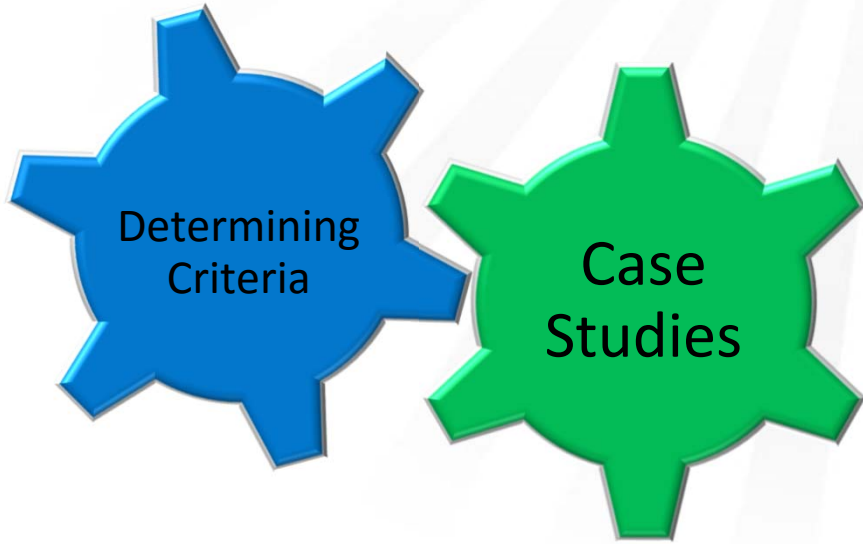
	ER	hERG	IVIVE	...
Endpoint				
Test set size				
Biological verification of fit-for purpose				
Limitations				
Domain of Applicability				
...				

Criteria





# How?



Determining  
Criteria

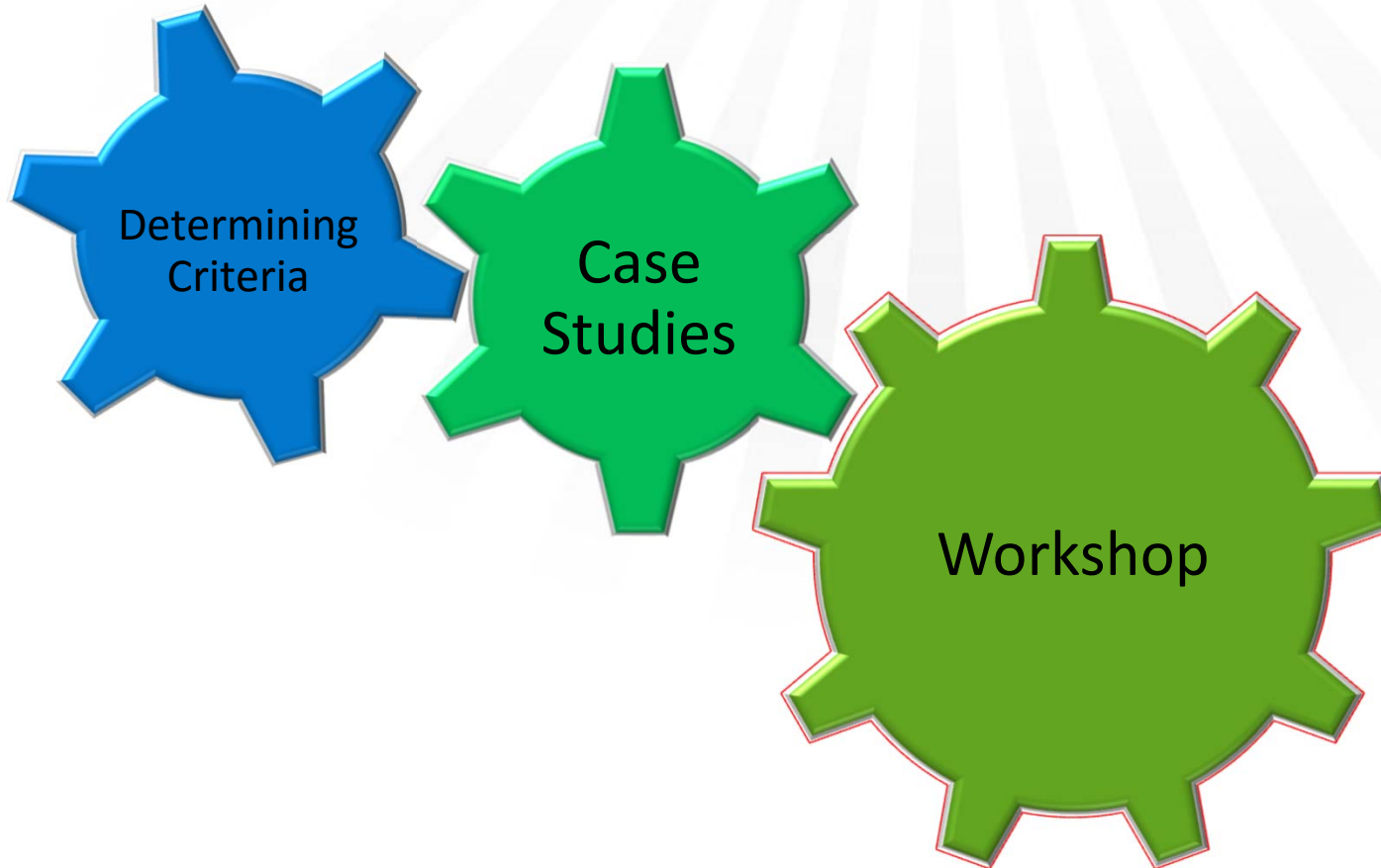
Case  
Studies

# 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?



# 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?



# Summary

**H**armonization – looking across initiatives for consensus in criteria

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

**M**ulti-sector – input across sectors and backgrounds

**A**ceptability – peer engagement to assess the acceptability of the criteria proposed

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

