National Centre
for the Replacement
Refinement & Reduction
of Animals in Research

Accelerating the acceptance of mathematical models as evidence in safety and efficacy decision making

14 and15 September 2016

London

Agenda

Objective:

To understand the challenges and opportunities in accelerating acceptance of evidence provided from mathematical models to improve the predictivity of efficacy and safety testing.

Day 1

10.00 – 10.30	**Registration**
10.30 – 10.40	**Welcome and introduction** Dr Carl Westmoreland; Unilever (Chair)
10.40 – 10.55	**Introduction to NC3Rs** Dr Anthony Holmes; NC3Rs
Building confidence in mathematics within multidisciplinary project teams	
10.55 – 11.15	**Mathematical modelling to support the development of a new liver bioreactor for *in vitro* to *in vivo* extrapolation** Dr Steve Webb; Liverpool John Moores University
11.15 – 11.35	**Building confidence in a model-based approach to skin allergy risk assessment** Dr Cameron Mackay; Unilever
11.35 – 11.55	**Applying mathematical modelling to crop protection development** Dr Kim Travis; Syngenta
11.55 – 12.15	**Speaker panel discussion**
12.15 – 13.30	**LUNCH**
Does model complexity influence confidence – Moderated by Syril Petit (HESI)	
13.30 – 13.35	**Introduction to HESI** Dr Syril Petit, HESI, USA
13.35 – 13.55	**A simple modelling solution for ion-channel related cardiac toxicity** Dr Hitesh Mistry; University of Manchester

13.55 – 14.15	**Mathematical predictions of cardiac toxicity in human: Advances towards the 3Rs in Safety Pharmacology** Dr Alfonso Bueno; University of Oxford
14.15 – 14.35	**Uncertainty and confidence in applying mathematical models and *in vitro* data in toxicological safety assessments** Dr John Paul Gosling; University of Leeds
14.35 – 15.00	**Speaker panel discussion**
15.00 – 15.30	**Coffee**
15.30 – 16.00	**Enhancing acceptance of models** Dr Bette Meek; University of Ottawa, Canada
Breakout group session 1	
16.00 – 17.20	What are the barriers to wider adoption - Facilitated session to explore what the barriers are to acceptance and adoption of modelling for decision making - Themes from this will be used during the breakout group sessions on day 2
17.20 – 17.50	Feedback session
17.50 – 19.00	Networking reception
~19.00	End of day 1

Day 2

9.00 – 9.15	**Registration**
9.15 – 9.25	**Introduction to day 2** Dr Carl Westmoreland; Unilever (Chair)
9.25 – 10.25	Poster showcase - *Selected poster abstracts will be invited for oral presentation*
Plenary session	
10.25 – 11.00	**Working in partnership to drive innovation and winning performance in the pharmaceutical industry** Dr Arseniy Lavrov; GlaxoSmithKline
11.00 – 11.20	**Coffee**
Regulatory perspectives on acceptance of data derived from mathematical modelling	
11.20 – 11.40	**Regulatory perspective on data derived through mathematical modelling** Dr David Jones; Medicines and Healthcare products Regulatory Agency

11.40 – 12.00	**Case study - FDA approved UVA/Padova Diabetes Simulator to replace dogs in preclinical testing of insulin treatments** Dr Enrique Campos-Nanez; University of Virginia, USA
What lessons can be learnt from other industry sectors?	
12.00 – 13.00	How has confidence in mathematical modelling been built in other industries and what can the biosciences learn from these experiences? - Energy sector – Jonathan Carter - Aeronautics – Gordon May, Rolls Royce - Small scale microfluidics – Dr Robert Barber, Daresbury Laboratory, STFC - Defence – Dr Paul Westoby, DSTL
13.00 – 13.20	**Speaker panel discussion**
13.20 – 14.15	**Lunch**
Breakout group session 2	
14.15 – 16.00	Developing a framework for expediting the acceptance of data-derived from mathematical modelling for decision making in product development in the biosciences
16.00 – 16.30	Feedback
16.30 – 16.45	**Summary/next steps** Anthony Holmes, NC3Rs
16.45	**Meeting close**