

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

14 and 15 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	<b>Registration</b>
10.30 – 10.40	<b>Welcome and introduction</b> Dr Carl Westmoreland; Unilever (Chair)
10.40 – 10.55	<b>Introduction to NC3Rs</b> Dr Anthony Holmes; NC3Rs
<b>Building confidence in mathematics within multidisciplinary project teams</b>	
10.55 – 11.15	<a href="#"><u>Mathematical modelling to support the development of a new liver bioreactor for <i>in vitro</i> to <i>in vivo</i> extrapolation</u></a> Dr Steve Webb; Liverpool John Moores University
11.15 – 11.35	<a href="#"><u>Building confidence in a model-based approach to skin allergy risk assessment</u></a> Dr Cameron Mackay; Unilever
11.35 – 11.55	<a href="#"><u>Applying mathematical modelling to crop protection development</u></a> Dr Kim Travis; Syngenta
11.55 – 12.15	<b>Speaker panel discussion</b>
12.15 – 13.30	<b>LUNCH</b>
<b>Does model complexity influence confidence – Moderated by Syril Petit (HESI)</b>	
13.30 – 13.35	<b>Introduction to HESI</b> Ms Syril Petit, HESI, USA
13.35 – 13.55	<a href="#"><u>A simple modelling solution for ion-channel related cardiac toxicity</u></a> Dr Hitesh Mistry; University of Manchester

13.55 – 14.15	<a href="#"><u>Mathematical predictions of cardiac toxicity in human: Advances towards the 3Rs in Safety Pharmacology</u></a> Dr Alfonso Bueno; University of Oxford
14.15 – 14.35	<a href="#"><u>Uncertainty and confidence in applying mathematical models and <i>in vitro</i> data in toxicological safety assessments</u></a> Dr John Paul Gosling; University of Leeds
14.35 – 15.00	<b>Speaker panel discussion</b>
15.00 – 15.30	<b>Coffee</b>
15.30 – 16.00	<a href="#"><u>Enhancing acceptance of models</u></a> Dr Bette Meek; University of Ottawa, Canada
<b>Breakout group session 1</b>	
16.00 – 17.20	What are the barriers to wider adoption <ul style="list-style-type: none"> <li>- Facilitated session to explore what the barriers are to acceptance and adoption of modelling for decision making</li> <li>- Themes from this will be used during the breakout group sessions on day 2</li> </ul>
17.20 – 17.50	Feedback session
17.50 – 19.00	<b>Networking reception</b>
~19.00	<b>End of day 1</b>

## Day 2

9.00 – 9.15	<b>Registration</b>
9.15 – 9.25	<b>Introduction to day 2</b> Dr Carl Westmoreland; Unilever (Chair)
9.25 – 10.25	<b>Poster showcase</b> <ul style="list-style-type: none"> <li>- <b>Tao Chen (University of Surrey);</b> <a href="#"><u>A mechanistic <i>in-silico</i> modelling approach to study percutaneous penetration</u></a></li> <li>- <b>Mark Coles (SimOmics Ltd / University of York);</b> <a href="#"><u>Evidencing models in virtual laboratories</u></a> - Development and application of evidencing and argumentation tools in the NC3Rs CRACK-IT Virtual Infectious Disease Laboratory and Virtual Fish Ecotoxicology Laboratory Projects</li> <li>- <b>Manasi Nandi (King's College London);</b> <a href="#"><u>Reconstructing blood pressure waveforms for the earlier detection of sepsis: a maths in medicine case study</u></a></li> <li>- <b>Ros Walley and John Sherington (UCB);</b> <a href="#"><u>Exploring the use of Bayesian statistical models to reduce the number of animals in control groups</u></a></li> </ul>

Plenary session	
10.25 – 11.00	<a href="#">Innovation in clinical trials: current trends and future perspectives</a> Dr Arseniy Lavrov; GlaxoSmithKline
11.00 – 11.20	<b>Coffee</b>
Regulatory perspectives on acceptance of data derived from mathematical modelling	
11.20 – 11.40	<a href="#">Regulatory perspective on data derived through mathematical modelling</a> Dr David Jones; Medicines and Healthcare products Regulatory Agency
11.40 – 12.00	<a href="#">Metabolic modelling, simulated populations, and <i>in silico</i> preclinical trials in type 1 diabetes</a> Dr Enrique Campos-Nanez; University of Virginia, USA
What lessons can be learnt from other industry sectors?	
12.00 – 13.00	<b>How has confidence in mathematical modelling been built in other industries and what can the biosciences learn from these experiences?</b> <ul style="list-style-type: none"> <li>- <a href="#">Energy sector</a> – Jonathan Carter</li> <li>- <a href="#">Aeronautics</a> – Gordon May, Rolls Royce</li> <li>- <a href="#">Small scale microfluidics</a> – Robert Barber, Daresbury Laboratory, STFC</li> <li>- <a href="#">Defence</a> – Paul Westoby, DSTL</li> </ul>
13.00 – 13.20	<b>Speaker panel discussion</b>
13.20 – 14.15	<b>Lunch</b>
Breakout group session 2	
14.15 – 15.30	Developing a framework for expediting the acceptance of data-derived from mathematical modelling for decision making in product development in the biosciences
15.30-16.00	<b>Coffee</b>
16.00 – 16.30	Feedback
16.30 – 16.45	<b>Summary/next steps</b> Anthony Holmes, NC3Rs
16.45	<b>Meeting close</b>