Symposium 9

Justification for Species Selection for Pharmaceutical Toxicity Studies (NC3Rs session)

Chairs: Dr C Ross, Covance & Dr F Sewell, NC3Rs

This symposium will consider the justification of species choice for toxicology studies with a focus on pharmaceuticals. Current regulatory guidelines for pharmaceuticals usually require safety data from two species, a rodent (rat or mouse) and a non-rodent (dog, minipig or non-human primate). This session will provide an overview of the results of the NC3Rs/ABPI international initiative reviewing the need for two species in regulatory toxicology studies. It will challenge the opinion that non-human primates are the only species for evaluation of biologics, and will address the practical and scientific considerations for the minipig as a toxicological species. Finally, the session will provide an opportunity for comments and views regarding what does and does not constitute species justification and a reflection of the topics covered in the symposia.

Title	Speaker	Institution
NC3Rs/ABPI review of two species use: can we further exploit ICHS6 opportunities for one species?	Dr H Prior	*NC3Rs*
Are non-human primates (NHP) always the species of choice for development of biologics?	Dr A Wolfreys	*UCB*
Minipig as the Non-Rodent Toxicology Species?	Richard Haworth	*GSK*