Workshops

Workshop 1: Species selection in regulatory toxicology

Chairs: Keith Jones, CFMD Ltd., United Kingdom & Sofiene Mhedhbi, Bracco Suisse, Switzerland

Co-chair: Helen Prior, NC3Rs, United Kingdom

In the 2018 MRF species selection was one of the topics, as many of us felt that the minipig is still underused in regulatory safety assessment. And although we heard that regulatory, technical challenges, staff training, facilities, body weight and other aspects are not seen as issues, it was clear that the approaches to considering using minipigs are quite diverse. In the workshop, the view was that more could be done by way of surveys, working groups etc, to get a more consistent approach.

The UK ABPI (Association of the British Pharmaceutical Industry) and NC3Rs (National Centre for the 3Rs) have been conducting a project looking at use of 2 species for regulatory safety assessment and questioning if more opportunities exist for using only 1 species. The industry questionnaire responses only returned 1 example where the minipig had been one of the two species used, and as this seemed very low, it was briefly shared in the workshop in 2018. Further qualitative responses in the questionnaire were not available at the time of the last MRF.

In this year's species selection workshop, we propose to focus on two areas:

1. The NC3Rs project lead, Helen Prior, will join us to share additional information from the questionnaire. Following that, we will discuss what we could do to better establish the minipig as a species in drug development. This might require further survey work, working groups etc. and we will aim at drafting a plan on how to achieve this.

2. Provide an opportunity for asking questions, and getting answers, regarding the choice of the minipig at any stage of safety assessment.

Workshop 2: Designing regulatory toxicology studies

Chairs: Kari Kaaber, Citoxlab, Denmark & Pramila Singh, Citoxlab, France

The purpose of this workshop is to debate and share experience within the field of regulatory toxicology studies using the Minipig as the selected species. Please bring your own examples/questions to the session but examples could be:

- How many animals should we include in each group and why?
- At what age of the animals should we start the studies?
- Sham control groups, when are these beneficial? Are they a requirement from the authorities or a company requirement? And why?
- How do we make sure to include the relevant examinations without stressing the animals? How do we make sure to design the study in a way that we do not compromise one examination by performing another on the same day/time? On the other hand, also make sure that as many examinations are performed in the same study, thereby avoiding using additional number of animals.
- We often hear about small studies where hours or days have been spend training the animals to have a procedure performed. This is not possible in studies with a large number of animals. However, what can be implemented easily? Alternatively, how can we modify a procedure so that it stresses the animals the least.
- Etc., etc.

Workshop 3: Identifying disease model gaps

Chairs: Henrik Duelund Pedersen, Ellegaard Göttingen Minipigs, Denmark & Simone Renner, Ludwig Maximilian University of Munich, Germany

Co-chair: Berit Østergaard Christoffersen, Novo Nordisk, Denmark

In this workshop, we will use the welcoming lecture by Berit Østergaard Christoffersen entitled ”Porcine models of obesity, diabetes and diabetes complications – applications and gaps” as a starting point. The focus will be on identifying the most important model gaps within this area - and discuss how these gaps might be filled by means of creating novel minipig models - leveraging on the fact that several of the speakers on the 2019 MRF program are from centers of excellence regarding creating tailored minipig models by genetic modification.