CRACK IT

Q&A Summary of the Virtual Second Species Challenge Launch webinar.

Any further questions please email crackitenquiries@nc3rs.org.uk

Q: How many toxicological endpoints are expected to be predicted by the model?

The overall aim of the Challenge is to model multiple toxicological endpoints across a series of interconnected organs and/or systems. These toxicological endpoints should ultimately cover all relevant toxicities.

For Phase 1 proof of concept, it is understood that focussing on a single organ or single toxicological endpoint data 'type' would be appropriate.

The paper from Prior *et.al.,* https://doi.org/10.1016/j.yrtph.2020.104624, contains details of target organ toxicities that will provide an initial reference point.

Q: Will the Sponsors be carrying out any of the work required to develop the model?

Sponsors collaborate throughout the Challenge providing the expertise and in-kind contributions outlined in the Challenge brief. In Phase 2 there is the potential for Sponsors to perform, for example, *in vitro* studies to help fill any data gaps identified.

Q: How will data curation be done (for the data supplied by the sponsors)?

All data provided by eTRANSAFE will be in a digitised format.

Sponsor data will be provided across a range of formats, depending on the type of study, when it was done and how it was archived. Where possible, Sponsor data will be provided in digitised format- SEND or other, but there will be a significant amount of data in, for example, pdf and scanned formats that will need extracting and curating by the Challenge winners in Phase 2. Work packages should be allocated to do this work.

Q What are limitations on use, for example commercialisation of the model, from sponsor data

The ultimate aim of the Challenge is to develop a model/ suite of models that is accessible across relevant sectors for and users to access, either commercially or potentially open source. The Sponsor data provided to build and/or test the model, will remain under the ownership of the Sponsors and Sponsors will not be granting third Party access to this IP. Therefore, any model developed, that may contain Sponsor data and/or

IP, must be constructed in such a way so that end user does not have access to the Sponsor data / IP when they are using the model. A Sponsor may decide to permit use and or access to data on a case by case basis but the Challenge should be approached with the protection of Sponsor IP and data in mind.