Questions and Answers from the CRACK IT Challenge 42 T-ALERT launch webinar

1. **Are solid or liquid tumours the cancer target for CAR-T cells? Is there a preferred cancer indication applicants should focus on?**

The key focus of the Challenge is the ability to detect transformation of T cells and the ability to distinguish between transformed and 'normal' T cells. Both tumour types are therefore in scope. CAR-Ts developed for non-oncology indications are also in scope (e.g. regulatory CAR-T cells).

2. **Is it possible to obtain clinical trial data before submission of a Phase 1 application?**

Sponsors will not be providing in-kind support such as data before awards are made. There are clinical data sets that are publicly available that can be used if required.

3. **Is it a condition of funding that the assay developed be made available either for free or commercially?**

The CRACK IT Challenges competition is designed to support the development of 3Rs technologies and approaches into new marketable products or services that are made widely available to the bioscience sector to use. The application must include a plan for commercialisation and dissemination of the Challenge product.

4. **If an academic is the lead applicant for Phase 1 then how would this shift over to a commercial entity for Phase 2?**

The lead applicant for Phase 2 is expected to be a commercial entity as it provides confidence to the assessment Panel that there is a commitment to commercialise the Challenge product.

If the lead for Phase 2 is an academic institution, the application must include robust plans to commercialise the results into a product or service, for example, this could be through a spin out company or by including a commercial partner in the application.

5. **Could you provide further details on what it means to work with the Sponsors?**

Challenge Sponsors define the Challenges in collaboration with the NC3Rs to set out the business case and 3Rs benefits, with a view to using the product developed. Sponsors provide in-kind contributions to support Challenge delivery. Collaboration with the Sponsors is key to delivery of the Challenge to develop a product

which meets the end-user needs. During Phase 1 it is strongly encouraged that awardees interact with the Sponsors to discuss the science and the project, your planned Phase 2 approach, as well as how you will make use of the Sponsor in-kind contributions. During Phase 2 the Sponsors work closely with the successful applicant through regular milestone meetings and provide in-kind contributions to support development of the Challenge product.

If you would like to be introduced to the Sponsors to discuss your proposed approach before the submission deadline, please contact the CRACK IT team at crackitenquiries@nc3rs.org.uk.

6. **Is animal work allowed to provide proof-of-concept data to show that transformation *in vitro* is actually transformation *in vivo*?**

Historical animal data may be available for this comparison and this should be considered fully before planning *in vivo* studies. Any animal work requested must be fully justified with robust experiment plans, and should comply with the principles set out in Responsibility in the use of animals in bioscience research. Further guidance can be found in section 3.3 of the Two Phase Challenges Guide for participants.

7. **Who is providing the funding for this Challenge?**

The NC3Rs is providing the funding for this Challenge.