

CRACK IT Solutions Guide for Participants



Contents

1.	В	ackground	3
2.	С	RACK IT Solutions	3
3.	С	RACK IT Solutions Overview	4
4.	Е	ligibility Rules	5
	4.1	Eligibility of Solution providers	5
	4.2	Eligibility of collaborators	5
	4.3	Eligibility for CRACK IT Solutions funding	5
	4.4	Independence	6
5.	Т	echnology partnering	6
	5.1	Submitting the Solution	6
	5	5.1.1 Guidance on completing "Submit your Solution" form	6
	5.2	CRACK IT Treatment	8
	5.3	Identification of collaborators	8
6.	С	RACK IT Solutions funding	9
	6.1	Application	9
	6.2	Review	.10
	6.3	Agreements and awards	.10
7.	Т	erms and Conditions	.11
	7.1	Recipients of funding	.11
	7.2	Collaborators	.11
	7.3	Intellectual Property	.11
8.	Р	roject Management	.12
	8.1	Project Reports	.12
9.	Р	ublication and Dissemination	.12
10). G	ilossary	.14

1. Background

CRACK IT is an open innovation programme from the NC3Rs which supports the development of marketable products and improved business processes with 3Rs benefits.

The pharmaceutical, chemical and consumer products industries are increasingly seeking solutions from the academic and SME sectors for major challenges to their business. Often these challenges relate to the use of animals, for example the problem of predicting clinical efficacy and safety from nonclinical studies. We have responded to this with CRACK IT Challenges and CRACK IT Solutions which link big business, academia and the SME sector.

CRACK IT has two schemes:

- CRACK IT Challenges is a challenge-led, funding competition. Challenges are
 developed by Sponsors from industry, academia and the charitable sector in
 collaboration with the NC3Rs and put forward to all industries and academia for
 solving. Successful applicants receive funding from the NC3Rs, external funders
 and/or Sponsors along with in-kind support from the Sponsors (for example;
 data, compounds, equipment).
- CRACK IT Solutions is a partnering hub for academics and SMEs to showcase their own ideas and technologies with 3Rs potential to the wider scientific community. Funding from the NC3Rs is available for further development, commercialisation and/or adoption.

This document provides a comprehensive guide to CRACK IT Solutions participants whether they are from academia, SMEs or industry.

2. CRACK IT Solutions

Eligible Solutions are technologies or approaches that have the potential to address business or scientific needs and advance the 3Rs, but which require further development or validation to realise this potential.

CRACK IT Solutions is a technology partnering hub which provides:

- A route for academics and SMEs to showcase their Solutions to the wider scientific community enabling them to find new partners to adopt, validate and/or further develop their research
- A gateway for industry and others to horizon scan for new approaches that have strategic, scientific and business relevance and also, impact on the use of animals

CRACK IT Solutions includes a seed funding scheme to support partnerships in the development and/or validation of Solutions submitted from EU-based companies/ organisations.

 CRACK IT Solutions is run and funded by the NC3Rs. All awards made under the CRACK IT Solutions scheme constitute de minimis aid.

3. CRACK IT Solutions Overview

Technology partnering Submitting the Solution

Solutions are submitted through the CRACK IT website and are reviewed and edited by the CRACK IT team in discussion with the Solution provider. Final approval for showcasing Solutions is provided by the CRACK IT Advisory Panel

CRACK IT treatment

The Solution is published on the CRACK IT website and receives the 'CRACK IT treatment' to showcase as widely as possible.

Identification of collaborators

Potential collaborators contact the Solution provider through the CRACK IT website.

Research conducted independently of CRACK IT Solutions funding

The Solution provider and collaborator(s) work together to further develop and/or validate the Solution without applying for CRACK IT Solutions funding.

CRACK IT Solutions funding application

The Solution provider and collaborator(s) submit an application describing their research and development/validation plans to access the Solutions funding.

Review

Applications are assessed by a virtual panel of experts and the CRACK IT Team at one of four annual assessment meetings, with the decision to award approved by the NC3Rs Chief Executive.

Awards

Awards of up to £50k incl. VAT and 12 months duration are available. Awarded projects must start within six months.

4. Eligibility Rules

4.1 Eligibility of Solution providers

A Solution provider is the individual submitting the Solution on behalf of their company/ organisation.

Solutions can be submitted by researchers from academic institutions or SMEs from anywhere in the world.

4.2 Eligibility of collaborators

Collaborators are individuals or companies/organisations interested in collaborating with the Solution provider. It is expected that collaborators will provide some level of in-kind contribution to support the development/validation of the Solution.

Collaborators can be individuals or companies from the academic or SME sectors or from large industry and based anywhere in the world.

If collaborators are required to carry out contributory work then there is no restriction on where this is conducted. For practical reasons and for ease of project management, the UK/ EU is preferred, but a case should be made for work outside the EU if this is critical to the success of the project.

4.3 Eligibility for CRACK IT Solutions funding

Only Solutions from EU-based researchers, organisations or companies are eligible to apply for funding through the CRACK IT Solutions scheme.

The work funded by the NC3Rs should be carried out in the EU.

Applicants may already hold a grant or contract from the NC3Rs and other funding bodies for research related to the topic for which new funds are being sought and should provide details of all relevant research funding, including that from industry in their application.

Collaborators are encouraged to provide some level of in-kind contribution to support the development/ validation of the Solution.

Under European Commission Regulation 1407/2013 (*De Minimis* Regulation), CRACK IT Solutions awards constitute *de minimis* aid. There is a ceiling of €200,000 for all *de minimis* aid provided to any one organisation over a three (3) year fiscal period (i.e. current April to March and previous two financial years). Any *de minimis* aid awarded under CRACK IT Solutions will be relevant if applicants wish to apply, or have applied, for any other *de minimis* funding.

Further information on State Aid can be found in the State Aid Manual.

Collaborators from outside of the EU are not eligible to receive funding.

4.4 Independence

A typical project will consist of: one Solution provider (as defined in section 4.1) and one or more collaborators (as defined in section 4.2).

5. Technology partnering

5.1 Submitting the Solution

Solution providers must register with the CRACK IT website.

Solutions are submitted by completing the "Submit your Solution form".

5.1.1 Guidance on completing "Submit your Solution" form

The information below shows what should be included under each heading – try to be concise and specific in your wording.

Only the information marked '*' is mandatory. However, including the additional information may increase the likelihood of finding a suitable partner and may be requested during review by the NC3Rs. When you submit your form, you will receive an email acknowledging your submission and the CRACK IT team will be alerted to your Solution.

*Proposed title of Solution

Please keep this short and be creative to try to catch the attention of any potential partners.

*Contact details

Please include your name, your company/ institution name and your work email address and organisation websites. Your email address will be used to set up alerts from the CRACK IT website to inform you when you have had an expression of interest in your Solution. Your details will not be passed on to third parties by the NC3Rs.

Executive summary (100 words)

Please summarize the key messages that you would want a potential partner to know about your idea, technology or product. If they only read one paragraph, this will be it. Therefore, it should contain enough information to enable potential partners to identify whether the Solution is relevant to their needs and convince them to read further.

Scientific Problem (350 words)

Describe the current challenges faced in your research area and the science behind the Solution you are suggesting to potential partners. This should include the current technologies and approaches in your research area, and competing research where appropriate.

Technology Solution (350 words)

Describe your Solution and how it addresses the scientific problem. Explain how your Solution overcomes the limitations of the previously described current technologies

available, and the applications your Solution may be used for. Where appropriate, include the potential of translating the technology or idea to other research areas and/or sectors.

Need for collaboration (200 words)

Describe why partnership is required and how your Solution would benefit from working in collaboration. It is very important to describe the expertise that you are seeking in a partner and the kind of contributions you may need e.g. access to compounds, data, advice, funding. Include details about what you can offer the collaborators in return, e.g. early access to the technology.

Information on Intellectual Property (if relevant) (50 words)

Please describe existing intellectual property (IP), likely future IP and anticipated approach to ownership of IP. If there are no IP issues, please state this.

3Rs impact assessment (200 words)

A description of the potential impact this work will have on the 3Rs and how this has been arrived at should be provided. This should include, where appropriate, an estimation of the reduction in animal use in your laboratory/establishment/discipline and/or objective indicators of how animal welfare has improved. For further information and examples of how to write effectively about the 3Rs, please visit our website.

References

Please add key references (here and throughout the text) in Harvard style to support your arguments above.

Key words

Please select up to ten relevant key words for your Solution that can be used for search purposes.

Images

Please provide a representative and eye-catching image to accompany your solution. This should be high resolution and should be attached to the email containing this form. Please include a short legend to describe the image.

Logo

Please provide a high-resolution organisation logo. This should be attached to the email containing this form.

Additional Information

Please include any relevant references or other information that may be useful, either in the box below or as an attachment to the email containing this form.

Terms and Conditions:

The NC3Rs reserves the right to review each submission for scientific quality, relevance and 3Rs benefit and also not to publish on the website unless these are clear. An internal review will be carried out to ensure these criteria are met. The NC3Rs will not publish any solution without your previous written consent.

There is no deadline for submitting potential Solutions to CRACK IT.

Once submitted, the Solutions are reviewed and edited by the CRACK IT team in discussion with the Solution provider to highlight the aspects of interest to industry and the 3Rs benefits.

5.2 CRACK IT Treatment

Once the final text has been agreed the Solution receives the CRACK IT Treatment to showcase it as widely as possible and maximise the likelihood of identifying potential new users and collaborators. This includes:

- Promotion through the CRACK IT website and the CRACK IT and NC3Rs newsletters, LinkedIn groups and Twitter account.
- Sharing through a variety of networks and associations (e.g. One Nucleus, PraxisAuril, Association of the British Pharmaceutical Industry (ABPI), learned societies, specific LinkedIn special interest groups, etc.).
- Direct 1:1 partnering with contacts in companies developed through NC3Rs activities.
- Identification, in collaboration with the Solution provider and through literature/internet searches, of relevant individuals/companies to send the Solution to.

Solution providers are also given an electronic flyer summarising their Solution and its 3Rs benefits which they can use to engage potential collaborators.

5.3 Identification of collaborators

Potential collaborators must register with <u>CRACK IT</u> before they can express their interest in a Solution through the CRACK IT website.

The CRACK IT team and the Solution provider will be notified of new responses to the Solution and will contact the Solution provider directly.

Once a collaborator(s) has been identified, the Solution provider and collaborator(s) embark on a collaboration to further develop and/or validate the Solution either with, or independently of, CRACK IT Solutions funding from the NC3Rs – see section 6.

6. CRACK IT Solutions funding

6.1 **Application**

The CRACK IT Solutions funding competition is run by the NC3Rs.

CRACK IT Solutions funding can only be used to support Solutions submitted from EU-based organisations/ companies.

Once a collaborator(s) has been identified, the Solution provider, together with the collaborator(s) can apply for funding using the application form and <u>guidance notes</u>. When completing the application form you will be asked to describe:

- Detailed research plans for the development/ validation of the Solution;
- Public-facing abstract;
- 3Rs impact;
- The need for collaboration;
- Collaborator in-kind contributions;
- Impact of the Solution on business/ scientific needs;
- Budget (up to £50k including VAT) and a breakdown of costs;
- Track record of the team;
- Project management plans.

Collaborators are encouraged to provide in-kind contributions or co-funding in addition to expertise and advice. Please provide a letter of support from your collaborator(s) detailing how this project will impact on their research/ business.

Please list any cash or in-kind contributions that the collaborator(s), or other public/private bodies, will provide to support the development/validation work.

The application must be submitted by the Solution provider as the lead applicant.

Applications must be made within twelve months of the Solution going live on the CRACK IT website and decisions will be made at quarterly assessment meetings – visit our website for quarterly application deadlines.

Applicants must cost their award and enter a total including VAT/ EU RC as appropriate.

It is the responsibility of the lead applicant to determine whether VAT/ EU RC should be paid; if VAT/ EU RC should be paid, the total amount including VAT/ EU RC should not exceed the £50k available.

Where more than one partnership has been identified with distinct projects, separate applications will need to be submitted for funding. The total budget available for any Solution would be £50k (inclusive of VAT) regardless of the number of applications submitted.

Additional funding from external sources: Please provide details of additional funding from external sources that will support this project.

De minimis aid: Please advise of any other *de minimis* aid which your commercial entity, and any entity linked to it, has received during the last three (3) fiscal years (April – March). Please include any additional funding described in the 'Additional funding from external sources' table above which is subject to *de minimis* aid rules. Note that *de minimis* aid includes not only the grant but also assistance such as free or subsidised consultancy services, marketing advice etc. If you are in any doubt about whether previous assistance received falls under *de minimis*' assistance, please include it.

Projects are for a maximum of 12 months in duration and a final report must be submitted at the end of the project.

6.2 Review

Applications are assessed by three members of a virtual Panel of experts and the CRACK IT team with the decision to award approved by the NC3Rs Chief Executive. The Panel is comprised of researchers from academia and industry with expertise across the spectrum of animal and non-animal research, animal welfare and the 3Rs. As NC3Rs Panel Members, they are bound to a code of conduct, including confidentiality. Virtual Panel membership and Declarations of Interest are published on our website. To avoid conflicts of interest, the three virtual Panel Members appointed to assess applications at each quarterly assessment meeting will depend on the content of the applications.

Applications will be assessed using the following criteria:

- Quality of the science;
- Potential 3Rs impact;
- Value for money;
- Likelihood of the wider uptake of the Solution;
- Potential impact of the Solution on business/scientific processes;
- Strength of the team and the collaboration.

The lead applicant will be informed by email of the decision of the assessment meeting approximately two weeks after the meeting. The decision is final.

6.3 Agreements and awards

Awards are made to the lead applicant's organisation which then administers the award including subsequent process requirements such as returning signed documentation.

Awards made are subject to the terms and conditions outlined in the contractor agreement.

It is the responsibility of the Solution provider and collaborator(s) to ensure that a suitable agreement is in place, detailing the arrangements for access to intellectual

property (IP) arising from the project and any other matters that are necessary for the project to go ahead.

Work must start within six months of the confirmation of the award from the NC3Rs. Failure to do so will result in the award being withdrawn.

The NC3Rs will provide the full funding to the lead applicant's organisation at the start of the project.

7. Terms and Conditions

These are set out in the contractor agreement to the successful applicant. Additional terms and conditions can be found in sections 8 and 9.

7.1 Recipients of funding

The recipients of funding must comply with the <u>Guidance on Responsibility in the Use of Animals in Bioscience Research</u>. This guidance must be followed even if the work is conducted outside the UK.

7.2 Collaborators

Collaborators are encouraged to provide some in-kind contribution or co-funding to facilitate the development/validation of the Solution. Although no formal estimation of the value of the in-kind contribution or auditing of the work done is undertaken, the NC3Rs expects collaborators to act in good faith in providing a contribution that adds significant value to the financial contribution of the NC3Rs and is complementary to the research undertaken by the Solution provider.

A list of the in-kind contributions is required for the application. These might include data, data processing, clinical materials, human and animal cells and tissues, access to equipment, complementary in-house experiments, hosting of investigators, specific essential guidance/advice and so on.

If the in-kind contribution involves the use of animals, the research must conform to the standards required by UK legislation and adhere to the <u>Guidance on Responsibility in</u> <u>the Use of Animals in Bioscience Research</u>, even if this work is conducted outside the UK.

7.3 Intellectual Property

IP developed within the project is the property of the lead applicant, as described in the contractor agreement. The recipient of NC3Rs funding should be the IP manager for the project. Further details on IP can be found in the contractor agreement from the NC3Rs to the lead applicant.

Although the NC3Rs is not a joint owner of any IP arising from a project, it is a condition of funding from the NC3Rs that work furthering the 3Rs must be made available to the rest of the bioscience sector. The protection of IP through filing of patents should therefore be pursued without unreasonable delay, and access by third parties to 3Rs benefits must be provided through publication and dissemination, or by appropriate licences, royalty-free or royalty-bearing on fair and reasonable terms.

Collaborators are also not joint owners of any IP arising from a project. Collaborators may benefit from early access to any new technology, through granting of royalty-free licences or through favourable pricing for an agreed period during and beyond the term of the project. Expectations of the collaborators(s) in this respect should be described in an agreement with the Solution provider detailing the arrangements for access to IP arising from the project and any other matters that are necessary for the project to go ahead.

8. Project Management

The NC3Rs requires the establishment of a Project Management Team whose members include the Solution provider and the collaborator(s). The Chair of the Project Management Team should normally be the lead applicant, and acts as the liaison to the NC3Rs. The responsibilities of the Chair are described in the contractor agreement to the lead applicant.

The Project Management Team is responsible for ensuring the project is completed within agreed timeframes.

The Project Management Team should meet at least quarterly during the award period.

The Project Management Team is expected to escalate to the NC3Rs in a timely manner any problems which they cannot resolve themselves and which may impact on the completion of the project within agreed timeframes and budget.

The NC3Rs reserves the right to attend at least one Project Management Team meeting during the course of the project.

8.1 Project Reports

Award holders should report the outputs and outcomes of the research we have funded on a regular basis within Researchfish. Log-in details are provided by Researchfish Ltd. Outputs and outcomes data should be submitted during and after the lifetime of the award. Data can be inputted at any time and there is an annual compulsory data submission period. The NC3Rs reserves the right not to consider further applications from an award holder where the reporting requirements on previous awards are not observed. Further information on reporting requirements can be found in Table 5.

All awardees are required to submit a final scientific report and a Final Expenditure Statement (FES) within one (1) month of the completion/termination date. The final report should include all information about how the project advanced the 3Rs.

The report and FES templates will be sent to all awardees two (2) weeks before the completion date.

9. Publication and Dissemination

Holders of awards are expected to disseminate their results by publishing in appropriate scientific journals and at relevant conferences. The Research Council UK policy on open access should be adopted.

Publications should have the prior agreement of the Project Management Team and in particular, publication timing must respect the need to protect IP arising from the work.

The NC3Rs support for the project should be acknowledged on all publications and presentations where such support has been significant (i.e. accounts for at least 20% of funding). The NC3Rs should be informed of any publications or other promotional material or events arising from the award.

Studies using animals should be reported in accordance with the <u>ARRIVE</u> guidelines, taking into account the specific editorial policies of the journal concerned.

Solution providers and collaborators are encouraged to place NC3Rs/CRACK IT logos on promotional materials arising from the collaboration by prior agreement with the NC3Rs.**Table 5:** Researchfish Reporting Requirements

Who?	 Compliance with Researchfish reporting is a requirement for every CRACK IT contract issued by the NC3Rs. The lead contractor is ultimately responsible for ensuring his/her Researchfish record is up-to-date.
	 Contractors can, and should, submit information to Researchfish all year round and after the contract has ended for at least three (3) years.
	In line with the Research Councils, the NC3Rs also has an annual collection period.
When?	There is also a requirement to update Researchfish when your contract is coming to an end.
	 Details of all outputs, outcomes and impacts, when available, arising from the contract.
What?	 In particular, complete the sections on Publications and Replacement, Reduction and Refinement.
	 Researchfish is one method by which we monitor progress on contracts. Contractors who do not report into Researchfish when requested to do so, or use the system inappropriately, may become ineligible to apply for additional awards from the NC3Rs (and potentially the Research Councils).
Why?	 Researchfish is not a publicly accessible data repository. However, data held in Researchfish may be used by the NC3Rs to populate our website and for production of publications such as our Annual Report.

10. Glossary

The 3Rs – The replacement (avoiding the use of animals where they would otherwise have been used), refinement (reducing suffering and improving animal welfare where animal use is unavoidable) and reduction (minimising the number of animals required) and of animals in research. For more information visit: www.nc3rs.org.uk/3rs.

CRACK IT – The world's first open innovation platform in the 3Rs linking scientists from universities, the SME sector, and large industry to tackle business challenges with a 3Rs theme. For more information visit: www.crackit.org.uk.

Collaborator – An individual or company/organisation interested in collaborating with the Solution provider. It is expected that collaborators will provide some level of in-kind contribution to support the development/ validation of the Solution.

Lead applicant – The individual submitting the application for funding through CRACK IT Solutions. It is generally accepted that this will be the Solution provider.

NC3Rs – The National Centre for the Replacement, Refinement and Reduction of Animals in Research

is an independent, scientific organisation tasked by Government with supporting the biosciences through the application of the 3Rs. CRACK IT, including CRACK IT Solutions is run by the NC3Rs. For more information visit: www.nc3rs.org.uk.

Project Management Team – The group made up of representatives from the Solution provider and collaborator(s) that will oversee the successful delivery of the project within the specified timeframes.

Solution – A technology or approach that has the potential to address a business or scientific need and advance the 3Rs, but which requires further development or validation to do so.

Solution provider – The individual submitting the Solution on behalf of their company/organisation.