

Technologies to Tools

Applicant guidance

Contents

Con	Contents1					
1.	. O	/erview	2			
	1.1 C	ompetition objectives	2			
	Table	3				
	1.2 C	3				
	Table	e 2: Modified Technology Readiness Levels (mTRL) and their definitions	4			
	1.3 E	ligibility criteria	5			
2.	. Th	e application process	6			
	2.1 H	low to apply	6			
	2.2 T	he application form	6			
	1.	Application details	6			
	2.	Previous NC3Rs grant details	7			
	3.	Project summary	7			
	4.	Commercial opportunity	7			
	5.	Financial planning	8			
	6.	Team and Expertise	8			
	7.	Project costings	8			
	8.	3Rs impact	9			
	9.	Declaration	9			
	Table 3: Summary of attachments					
3.	. As	sessment procedure	9			
	Table 4: Panel assessment criteria					
	3.1 A	ward starting procedures	10			
4.	. Po	est award information	10			
	4.1	Intellectual property	10			
	4.2	Project management	11			
	4.3	Reporting	11			

1. Overview

The National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) and the Medicines Discovery Catapult (MDC) have established a strategic collaboration to accelerate the translation of NC3Rs grant-funded project outputs into industry consumable products and services, maximising their potential for uptake and 3Rs impacts.

Applicants will have the opportunity to apply for up to £50k (inclusive of VAT, where applicable) from the NC3Rs to support a collaborative project with the MDC. The MDC will contribute in-kind services (access to industrial expertise, facilities and equipment) equivalent in value to NC3Rs funding. Projects can be up to 24 months in duration.

This document provides a comprehensive guide to participants applying to the Technologies to Tools (T2T) competition. Awards made under this competition constitute *de minimis* aid.

1.1 Competition objectives

The overall aim of the competition is to support non-animal, human relevant models and technologies developed with NC3Rs funding in crossing the '3Rs valley of death' that exists between model development and wider uptake and impact. The expertise and capabilities of the MDC will help translate these models from academic prototypes into research tools that can be applied confidently in the pharmaceutical industry to support improved medicines discovery. These awards cannot be used to support R&D work that was not completed during the lifetime of a previous NC3Rs grant, and any proposal requesting funding for this purpose through this competition will be deemed ineligible.

The objectives of the awards are to:

- Accelerate and maximise the scientific, commercial and 3Rs impact of project outputs arising from NC3Rs response mode grants
- Support collaborative working to ensure the most promising technologies are identified, developed,
 validated and integrated in to industry product development processes
- Build confidence in 3Rs technologies and accelerate their path to market
- Increase knowledge exchange and co-creation between NC3Rs-funded researchers and the MDC
- Nurture talents and skills development of NC3Rs-funded researchers

Eligibility

- Open to any UK- based recipient of a grant awarded through NC3Rs response mode schemes that has developed a non-animal, human relevant in vitro or in silico model system.
- Prospective applicants must have completed, or be within the last year, of their NC3Rs grant.
- Only one application per eligible NC3Rs grant will be accepted.
- Applications to the scheme must be made in collaboration with the MDC.
- Awards made under this scheme constitute *de minimis* aid. Any one organisation cannot be provided with more than the *de minimis* funding threshold of €200k over a three-year fiscal period.

Application and review process

- Prospective applicants are required to present the outcomes of the NC3Rs grant, upon which the application will be based, to the MDC at a Research Showcase event organised by the NC3Rs.
- The MDC will select projects that fall within their remit and to which they can add value and work with the research team to develop a collaborative application for submission to the competition.
- Completed application forms must be submitted prior to the deadline.
- Applications are reviewed by an expert Panel convened by the NC3Rs.

Agreements and awards

- The lead applicant is informed by email of the decision of the Panel approximately one (1) week after the Panel meeting.
- The successful applicant's organisation is issued with an award document outlining the terms and conditions of the award. The document must be signed and returned to the NC3Rs before work on the award can commence
- Successful applicants may also enter into a separate agreement with the MDC.

Post-award

- Awards are milestone-driven with regular Project Management Team meetings to ensure the
 project is on schedule and any risks are managed accordingly. NC3Rs and MDC staff will form part
 of the Project Management Team, alongside the awarded research team.
- The lead applicant will be responsible for ensuring key deliverables of the funded project are met within agreed timeframes.
- All awardees are required to submit a final report and a final expenditure statement (FES) within three (3) months of the completion/ termination date.

The NC3Rs reserves the right to amend the application procedure.

1.2 Competition remit

Applications to the competition are expected to accelerate towards commercialisation a technology/ product that, through NC3Rs funding, has already completed the majority of R&D work required to produce a working prototype or demonstrator. Using the modified technology readiness levels (mTRL) defined by Phadke & Vyakarnam¹ as

¹ Taken from Phadke & Vyakarnam, Camels, Tigers and Unicorns: Rethinking Science and Technology-enabled Innovation, World Scientific Publications, 2017

guidance, a mTRL level of 2-4 is expected to be the minimum starting point for applying to the competition. The aim of the competition is to support activities towards mTRL 5-7 (Table 2).

Table 2: Modified Technology Readiness Levels (mTRL) and their definitions

mTRL 0	Research in progress Fundamental research activity before any potentially useful and validated science or technology has been established		
mTRL 1	Validated research: Start concept definition At the point at which the conceptual application of the technology has been defined in outline terms		
mTRL 2	Initial concept defined The conceptual application has now been converted to a definition of the product or service which can potentially be offered using the technology		
mTRL 3	Working prototype or demonstrator A working prototype or demonstrator has been built		
mTRL 4	Product or service testing and concept refinement The new product, service or technology has been refined/modified following feedback from the initial customer		
mTRL 5	Proven product or service The product or service is ready at a functional level, without the collateral around the product including the method of deployment and the proposed business model		
mTRL 6	Deployment with early customers in real commercial environment The product or service is now ready for use with early Customers, and so includes all the associated collateral, including a service infrastructure where relevant.		
mTRL 7	Product or service ready for testing in real user environment Early customer feedback has been used to define the modified product or service functionality, its required performance and critically, the chosen business model.		
mTRL 8	Techno-commercial refinement of product or service The refined product or service is now ready for deployment with mainstream customers.		
mTRL 9	Ready for commercial deployment with real customers The final product or service is now ready for commercial launch, including go-to- market collateral and proven business model. The challenge now is growing the mainstream customer base.		

Activities in remit for this competition include:

- Developing the core technology/approach to a point where it can be deployed with customers (mTRL5 and 6).
- Demonstrating the core technology/approach is fit for purpose, to minimise risk and increase customer confidence (mTRL7).
- Developing new applications of the core technology/approach to create novel means of impact generation (mTRL5-7).

Establishing confidence (scientifically and commercially) to operate in the market (mTRL6 and 7).

Activities not in scope for this competition include:

- Consultancy, for example, advice on business/commercialisation strategy, business development, pitching for investment and market analysis.
- Marketing to attract potential investors and customers including website design, travel, academic publications, conference and exhibition fees.
- Research and development work not completed during the original funding period.
- Merchandising and advertising activities and materials.
- Export activities.

1.3 Eligibility criteria

- The T2T competition is open to any UK-based recipient of an NC3Rs response mode grant that has developed a non-animal, human relevant *in vitrol in silico* model system and who has completed, or is within the last year, of their NC3Rs grant.
- Prospective applicants must have a contract of employment that will outlast the duration of the proposed project and be based at either a Higher Education Institution (HEIs), Independent Research Organisation (IROs or Research Council (RC) Institute.
- Prospective applicants are required to present the outcomes of their NC3Rs grant, upon which the application will be based to the MDC at a Researchers Showcase event hosted by the MDC and organised by the NC3Rs.
- Following this event, MDC staff will select projects that fall within their remit and to which their expertise can add value and work with the research team to compile a collaborative application for submission to the T2T competition.

MDC criteria for selecting projects to submit a collaborative application with include:

- Ability to add value with their available expertise and technologies and move the technology to the desired mTRL
- Fit with MDC priority to make humanise preclinical research more readily available to SMEs
- Alignment with MDCs goal of developing novel in vitro approaches for drug discovery
- Potential for the project to impact more widely across MDC programmes
- Expertise of the team
- Potential for the project to significantly improve current standard used for drug discovery
- Does the proposed work fit with the project budget?
- Only one application per eligible NC3Rs grant will be permitted.
- Under European Commission Regulation 1407/2013 (De Minimis Regulation), T2T 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 T2T 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.

2. The application process

2.1 How to apply

Applicants are expected, before applying, to have discussed their proposal with their own organisation or any other body whose co-operation will be required in the conduct of the project. By applying, applicants are confirming that the information provided in the application is complete and true, that they are actively engaged in the project and will be responsible for its overall management, and that they agree to administer the award if made.

General Guidance

Applications must be made using the application form provided. Completed applications must be sent by email to 3rsgrants@nc3rs.org.uk. All applications are treated in confidence.

- Application forms and attachments must be submitted as PDF files.
- Failure to complete mandatory fields on the application form and to submit all required attachments may result in the application being rejected.
- The application form should be completed using a font size no smaller than 10pt (Arial) and text limits must not be exceeded.
- The use of acronyms should be kept to a minimum.

Attachments

Supporting information can be provided in the form of separate attachments as indicated within this guidance and the application form. Attachments must:

- Be submitted as separate PDF files and not added or pasted within the application form.
- Be named appropriately: Document type—Lead applicant's name i.e., 'CVs Dr A.N. Other'.
- Be completed using a font size no smaller than 10pt (Arial).

Only provide attachments as specified in the application form and in this guidance. Any additional materials or documentation submitted will not be considered and may result in your application being rejected or returned without review.

Questions about the application process should be addressed directly to the NC3Rs via email 3rsgrants@nc3rs.org.uk or call +44 (0)20 7611 2233.

2.2 The application form

This section contains guidance on how to complete the application form. Sub-sections are numbered as they appear in the application form.

- Application details
- (i) **Project title:** Please provide your own title for the project. This should be both clearly descriptive and concise. It should contain keywords relevant to the project.
- (ii) **Project duration:** Applicants can request up to the maximum duration of 24 months.
- (iii) Proposed start date: Please specify the date upon which activities will commence.

It is expected that work on successful projects will commence promptly and within eight (8) weeks of returning the signed award document

- (iv) Total project cost: Applicants can request, from the NC3Rs, up to a maximum total cost (inclusive of VAT where applicable) of £50k. Requests for more than this sum will be rejected.
- (v) Contact details of Lead Applicant: Please include the name of the lead applicant, current position and contact details including organisation's name and address.
- (vi) Contact details of Lead MDC Scientist: Please include the name of the lead MDC scientist on the proposal, current position and contact details.
- 2. Previous NC3Rs grant details
- (i) Project number and title: Please provide the number and title of the NC3Rs grant upon which the current proposal is based.
- (ii) Grant type: Please select from the drop-down menu under which NC3Rs funding scheme the previous award was made.
- (iii) Project start date: Date on which the project commenced.
- **(iv) Project completion date**: Date on which the project completed or if still in progress, the date on which the project is due to complete.
- 3. Project summary

Please describe the proposed project in language to be understood by a non-specialist audience. Please include the potential 3Rs impacts of the project.

- 4. Commercial opportunity
- (i) Market opportunity: Please describe the unmet need, size of the market opportunity and potential customers for the technology/model. The maximum word limit for this section is 300 words.
- **Competition**: Please describe competing technologies/models and the competitive advantage of your approach. The maximum word limit for this section is 200 words.
- (iii) Intellectual property: Please provide details of any existing patents or other forms of intellectual property (i.e. know how, trademark) that have arisen from the NC3Rs-funded grant upon which this application is based. In addition, please indicate any anticipated IP, which may arise in delivering the project and how this would be handled i.e. the proposed arrangements for ownership. Please provide details of any freedom to operate searches conducted to date (or plans for the future) and any restrictions this may impose on the dissemination and exploitation of the technology/product. The maximum word limit for this section is 200 words.

Associated attachment (optional): Summary of patent filings.

(iv) Business model: Please describe the business model and route to commercialisation of the technology/model. Please include the barriers and key risks to commercialisation and how you plan to address them. Please also describe any interactions with potential customers and/or investors, together with any feedback received. The maximum word limit for this section is 300 words.

Associated attachment (compulsory): Letters of support/intent from potential customers/end users.

5. Financial planning

Please explain in detail the proposed use of T2T funds including milestones, timelines, costs and where the work will be carried out. Describe how the funding will de-risk the translation of your NC3Rs-funded technology/model into industry consumable products and/or services. Describe what modified technology readiness level (mTRL) your technology/ approach is currently, and what mTRL you aim to achieve by the end of the project. Please include what contributions MDC will provide and how these will support achievement of the intended mTRL. Please outline your future plans (milestones, timelines, costs and longer-term financing plans) following successful completion of your award. The maximum word limit for this section is 600 words.

Please note: Should your application include the use of animals, please contact the <u>NC3Rs office</u> before submitting an application.

Associated attachment (compulsory): Project milestones/Gantt chart (maximum two sides of A4).

6. Team and Expertise

Please provide a detailed description of the current team (skills, expertise and track record). Identify any gaps in your team/experience where additional support is anticipated in the future. Please include any previous experience of generating impact from academic research. The maximum word limit for this section is 600 words.

Associated attachment (compulsory): The CVs of up to five (5) principal team members should be combined and included as a single attachment (maximum one (1) side of A4 per team member).

7. Project costings

T2T awards are non-Full Economic Costing (FEC) and as such, applicants can apply for **100% directly incurred costs.** Please provide a summary of the overall costs requested by the Lead Applicant (7a) and the costed MDC contributions (7b). Costs requested should be inclusive of VAT, as appropriate².

Direct Costs

These are costs that are specific to the project, including:

- Labour costs for all non-MDC staff contributing to the project broken down by individual
- Material costs, including consumables for research/validation work relevant to the project and conducted within the lead applicant's own institution
- Travel and subsistence costs
- Other costs specifically attributed to the project

Itemisation of costs and methods of calculation may be requested to support the application at a later date.

In addition, please provide justification for the resources required to undertake the proposed project.

Any other costs (e.g. equipment/service costs, technician time, etc.) will be covered by the MDC within reasonable limits and pre-agreed with the MDC.

² It is the responsibility of the lead applicant to determine whether VAT should be paid; if VAT should be paid, the total award amount, including VAT, will not exceed £50k.

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 organisation, 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.

8. 3Rs impact

Please provide your own assessment of the 3Rs impact of the work, including qualitative assessment of the 3Rs benefits and quantitative estimates of the numbers of animals affected wherever possible. Please also consider the wider application of the technology/model beyond the current application and the 3Rs benefits of this. For guidance on writing effectively about the 3Rs visit the NC3Rs website. The maximum word limit for this section is 600 words

9. Declaration

The lead applicant is expected to have discussed the application within their own organisation and any other body whose co-operation will be required to deliver the project. If successful, the lead applicant will need to obtain consent from an authorised officer or appropriate signatory who will sign the award letter. By submitting the application you are confirming that the information given, in this application, is complete and that you are actively engaged in this project and responsible for its overall management and agree to administer the award if made. You are also confirming that you have read and understood this guidance.

Table 3: Summary of attachments

Application form section	Attachment name	Page limit (sides of A4)	Optional / compulsory
Section 4 (iii)	Summary of patents	Template provided in application form	Optional
Section 4 (iv)	Letters of support	1 per letter	Compulsory
Section 5	Additional milestones/ Gantt chart	2	Compulsory
Section 6	CVs (up to five)	1 per team member (5 in total)	Compulsory

3. Assessment procedure

Following submission, applications will be checked for remit and eligibility before review by the T2T Assessment Panel.

Table 4: Panel assessment criteria

Assessment Criteria

- Potential for T2T funding to progress technology to mTRLs 5-7 (as defined in Table 2)
- Potential 3Rs impact
- Scale of the market opportunity
- Value for money and justification for use of funds in achieving deliverables
- Expertise and track record of the team
- Eligibility of funding within the de minimis aid criteria

Membership of the Panel is published on the NC3Rs website. All panel members sign a confidentiality agreement upon appointment and are expected to abide by the principles set out in the Council and MRC boards.

Members also complete a Declaration of Interest form which is published on the NC3Rs website.

The Panel's decision is final and is not open to appeal.

3.1 Award starting procedures

The lead applicant is informed by email of the outcome of their application approximately one week after the Panel meeting. Awards are made to the lead applicant's organisation which then administers the award including return of signed documentation.

Work on the awarded project may only begin following receipt of the signed award document, which includes the award terms and conditions applicable to NC3Rs awards. These terms and conditions are non-negotiable. Award documents are expected to be finalised and signed **within two weeks** of receipt.

For successful applications involving more than one organisation, the lead applicant must agree to manage the award from the NC3Rs on behalf of the others (co-applicants). Co-applicants negotiate their agreements with the lead applicant directly.

It is expected that work on successful projects should commence promptly and within eight (8) weeks of returning the signed award document. Failure to comply will result in the award being terminated. To ensure rapid commencement of the work, all funding will be provided upfront.

The NC3Rs leads on award announcements. Award holders may be required to participate in media-related activities regarding the announcements.

4. Post award information

4.1 Intellectual property

The lead applicant and the MDC will each own the intellectual property (IP) they generate within the project, as described in the award document between the NC3Rs and the lead applicant. The MDC and the lead applicant shall between themselves agree written terms setting out ownership and rights of use of intellectual property, including but not limited to any commercialisation income or revenue share arrangement.

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.

4.2 Project management

The lead applicant will be responsible for ensuring key deliverables of the project plan are met within agreed timeframes. A project management team consisting of the lead applicant and relevant members of the project team, the NC3Rs and MDC will be established to oversee successful delivery of the project. The project management team will meet at quarterly intervals unless otherwise agreed.

4.3 Reporting

All competition awardees are required to submit a **final report** and a **final expenditure statement (FES)** within three (3) months of the completion/termination date. The final report should describe the work undertaken, the achievements and outcomes of the project and details of how the project advanced the 3Rs. The report template, FES and additional guidance will be sent to awardees four (4) weeks before the completion date.

Failure to provide the requested report and FES, within the specified timeframe, may result in funding being recouped. It is the responsibility of the lead applicant to manage the funds awarded responsibly and any additional costs incurred above the total amount awarded will not be reimbursed.

Researchfish and publications

Award holders are expected to disseminate their results by publishing in appropriate scientific journals and at relevant conferences. The UKRI policy on open access should be adopted. Award holders are required to report research outputs and outcomes on a regular basis using <u>Researchfish</u>. There is a mandatory annual collection period for the submission of data.

The NC3Rs support for the project should be acknowledged on all publications and presentations where such support has been significant. The NC3Rs should be informed of any publications or other promotional material or events arising from the award.

It is the responsibility of the lead applicant to keep the NC3Rs informed in a timely manner of outputs from the funded project.

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

Further information on reporting requirements can be found on the Researchfish website.