NATA Research Challenges: Improving the delivery of nucleic acid therapeutics

Total fund:
£8,000,000

Maximum award:
£8,000,000

Full application closing date:
27th April 2022 16:00 UK time

Table of contents

The Funding Opportunity

1. Who can apply

The opportunity is open to academic and industry organisations based in the UK or abroad. The lead organisation must be UK based.

To apply for funding you must be based at one of the following organisations:

- academic organisation
- SMEs
- eligible public sector research establishment (PSRE)
- UK Catapult.

Large industrial organisations can apply as investigators but not request funding.
Further information on eligibility to request funding is in section 7.

Projects must be collaborative. At least two organisations must be involved, including a minimum of one partner commercially active in the nucleic acid therapeutics (NAT) space in the UK.
Applicants will be required to demonstrate that the assembled team have the necessary experience, expertise and access to facilities to deliver the proposed research plan.

The principal investigator should have demonstrable experience in leading multi-investigator and multidisciplinary consortia or, at a minimum, applicants should demonstrate their potential to lead and manage a large-scale collaborative project.

Please refer to Section 1.3 of the **MRC Guidance for Applicants** for further information regarding people and organisations named on the grant. Applications may include researcher co-investigators (RCoI) as set out in the **MRC researcher co-investigator guidance**.

2. What we're looking for

This funding opportunity is part of the £30 million Nucleic Acid Therapy Accelerator (NATA) programme, funded by the **Strategic Priorities Fund**. The NATA programme supports multidisciplinary approaches to the development of NATs. The programme is delivered by **MRC**, part of **UKRI**, as part of a wider portfolio of support for advanced therapies.

The promise of NATs has been demonstrated in the clinic. However, their development and widespread use has been hindered by a lack of robust techniques to achieve targeted delivery to specific tissues, improve stability and facilitate uptake into cells, without compromising on safety or effectiveness.

This funding opportunity will support a consortium to tackle major barriers to safe and effective NAT delivery through the development of novel technologies, platforms and resources. To solve

these challenges, new approaches could arise from any scientific discipline or therapeutic modality.

Proposals must articulate a substantial, ambitious programme of work with clear potential to catalyse a step-change in UK NAT delivery, having downstream translatability and wide-ranging industrial utility. Applications seeking to address specific issues tied to an existing asset or development programme are not eligible for this call.

The potential impact of this funding opportunity is being expanded through co-funding provided by **LifeArc**, a medical research charity with interests including advanced therapies and rare diseases. **LifeArc is contributing £2m to the total budget for the Delivery Research Challenge.**

Up to **£8million** of funding (£6m UKRI, £2m LifeArc) will therefore be available for **up to 36 months** to a single consortium formed of eligible academic organisations, SMEs, PSREs and Catapults. Leveraged funding and contributions in kind from partners, particularly via staff time and access to facilities, are welcomed. Large commercial entities cannot request direct support.

The expansion in the total budget since the Expression of Interest stage will enable applicants to significantly enhance their programmes, partnerships, and intended outputs in line with the Panel feedback and the assessment criteria for the funding opportunity. The total funding request will need to provide value-for-money in terms of the impact and outputs.

3. Scope

To be within scope, proposals must articulate a substantial, ambitious programme of work with clear potential to catalyse a step change in the delivery of NATs. Transformative opportunities could include, but are not limited to:

- platform technologies or tools to enable more efficient, safe and effective delivery of NATs and more reproducible research and development
- activities enabling improved active uptake and intracellular trafficking of NATs
- innovative strategies addressing unmet needs in targeting of specific organs, tissues or cell types

Novel technologies or major patient-centred improvements enabling non-systemic delivery of NATs, in other words direct administration strategies, will be within scope where they have significant primary relevance to a broad pipeline of NATs.

Stage of research

While the focus of the consortium's research plan should be early-stage and applied pre-clinical research and innovation, proposals can include basic research where this would directly enhance the translational outputs of the consortium.

Outputs

Proposals should clearly articulate how the consortium's outputs will:

- have downstream translatability
- demonstrate wide-ranging industrial and academic utility
- improve the reproducibility of early stage research and innovation
- take account of:
    - safety and toxicity
    - scalability
    - manufacturing
    - cost
    - quality control
    - regulatory issues
    - other considerations relevant to the development of NATs destined for clinical administration
- benefit the UK NAT field.

What we won't fund

The following activities are not within scope:

- small-scale applications seeking to address specific issues tied to an existing asset or development programme
- programmes focusing solely on the delivery of modalities that require the translation of the delivered product to exert a therapeutic effect
- programmes where the impact will be limited to a particular clinical indication
- programmes where the output will primarily support delivery of mRNA vaccines
- programmes focusing on delivery to hepatocytes
- programmes developing delivery systems without direct relevance to precision delivery of NATs
- programmes comprising mainly basic research or without a significant applied component
- late-stage development or clinical studies of NATs or delivery systems.

Applicant Workshop

Shortlisted applicants are required to attend a workshop on 2nd March 2022 prior to the submission of their full application.

Each shortlisted applicant will provide a non-confidential overview of their proposal, outlining the need and proposed solution, in addition to the proposed research objectives, team and additional opportunities for collaboration with external partners.

The workshop will be attended by representatives from leading academic and industry organisations and contact details will be shared for follow up conversations where potential partnerships can be explored.

The workshop will also be an opportunity to engage with the NATA Hub.

NATA Programme and Hub

NATA programme

The Nucleic Acid Therapy Accelerator (NATA) is a £30 million investment awarded by the UK's **Strategic Priorities Fund** to support and accelerate the development of NATs. The NATA works in partnership with international industry and academic organisations and is being delivered by MRC, part of UKRI, as part of a wider portfolio of support for advanced therapies.

The NATA programme consists of two main offerings to the UK research and innovation community:

- the NATA Hub, which offers world-leading, state-of-the-art NAT research infrastructure
- substantive consortium grants to address two focused research challenges representing major barriers to NAT development.

About the NATA Hub

NATA Hub is an MRC Unit and UK research centre based on the Harwell Research Campus, Oxfordshire. It comprises state-of-the-art chemistry and biology capability to address bottlenecks in NAT development. The Hub is disease agnostic, with an initial focus on short oligonucleotide therapeutics.

NATA Hub's toolbox and techniques will help answer the main questions about NAT translational development, including:

- consultation on sequence design and chemical modification patterns of oligonucleotides:
  - siRNAs
  - ASOs, gapmer and blockers
  - aptamers
- manufacture, purification and characterisation of natural and modified oligonucleotides, including:
  - new chemical modifications for nucleosides and nucleotides
  - new modalities, including new ligands and conjugation methods
  - detection and quantification of oligonucleotides in biological samples
  - detection and characterisation of trace impurities after synthesis using high-resolution mass spectrometry
- biological assessment of nucleic acid therapeutic efficacy, specificity and toxicology including:
  - establishment of relevant *in vitro*, *ex-vivo* and *in vivo* models

- analysis of spatial distribution within tissues – high resolution imaging
- analysis of cell type specific uptake and efficacy
- transcriptomics for off-target and toxicity profiling.

For a comprehensive overview of the Hub's capabilities and available equipment and to discuss your proposal, please email enquiries@natahub.org

Full Application Guidance

Following the Applicant Workshop shortlisted applicants will be invited to develop their full stage application, referencing the feedback provided by the expert Panel at the EOI stage.

Applicants may refer to the MRC Guidance for Applicants and Je-S handbook for general guidance as they complete their application, however please note that elements of this funding opportunity are significantly different from standard MRC funding schemes; specific guidance is detailed in this document.

4. Overview of documents required

A detailed Checklist of Application Documents is provided at **Annex 1,** with a brief summary provided below:

Mandatory documents

- Case for Support form
- Research Organisation form (one per non-academic organisation)
- Cover letter/Panel feedback response
- Supporting data, figures and tables
- Milestone form
- Gantt chart
- Signed letter of support from senior sponsor(s) within commercial organisations forming part of the consortium.
- Signed letter of support from the Technology Transfer Office (TTO) of each academic organisation within the consortium
- Signed letter of support from the lead commercialisation organisation
- Signed consortium Heads of Terms agreement
- Justification of resources
- Data management plan
- CV for each Principal-, Co- and Researcher Co- investigator
- List of publications for each Principal Investigator, Co-Investigator and Researcher Co-Investigator
- Letter(s) of support for Researcher Co-Investigator(s) (where applicable). Please note the detailed guidance online regarding Researcher Co-Investigator eligibility and letters of support.
- For companies requesting funding, additional documents requested in part B of the Research Organisation form (detailed in Annex 1)

Optional documents

- Additional letters of support from key collaborators or partners
- Risk table
- Proposed governance structures
- Minutes of discussion with regulators, or relevant emails

All documents have a maximum file size of 5MB except the Case for Support (10MB).

Please ignore the following Je-S upload document types when submitting your application: 'MICA Form' and 'Technical Assessment'.

Applicants should address the feedback provided by the expert Panel as they complete their full application, using the Cover Letter to indicate updates made from the Expression of Interest stage, while referencing the relevant sections of the Case for Support form, Supporting data document etc.

Applicants may add, remove or make amendments to research objectives and work packages outlined at the Expression of Interest stage, where this strengthens the application and aligns with Panel feedback. Consortium members and partners may be added or changed to support the effective delivery of the final research plan.

5. Milestones

In order to support and appropriately de-risk this funding opportunity, the consortium's progression in research plan delivery will be contingent on passing a series of milestones which will gate funding. These milestones should be articulated in full within the Milestone form and discussed briefly within the relevant section of the Case for Support form.

Milestones will articulate clear go / no-go decision points with clearly articulated and quantified success criteria. You should note that:

- Milestones must be SMART – that is: Specific, Measurable, Achievable, Relevant, and Time-framed.
- Applicants may include more than 3 milestones within their Milestone form when this is required, with the final milestone being the Project End.
- Success criteria should be based on outputs that, at the given point, need to be achieved in order to justify continued consortium support. Success criteria should align to critical aims and objectives.
- For each success criterion, please specify a quantified target value that you will seek to attain and a quantified acceptable value, which, if achieved, would support programme progression.

- Milestones should be consecutive, not concurrent or overlapping. Work packages do not necessarily need to align with milestones.
- Please do not include management meetings or other process-related tasks as milestone success criteria.
- Your estimate of the milestone criteria being met should assume that the preceding milestone was achieved.
- You should provide justification for the proposed set of criteria and for the proposed target values.

This award is contingent upon meeting the progression milestones set out at the full application stage. Failure to meet progression milestones may result in termination of the award at the discretion of MRC. Spending on the grant should be limited to work detailed within the programme plans for the active milestone.

Without specific prior written approval, MRC will not reimburse the host institution for the costs of any work contributing to a later milestone should it be decided that the criteria of an active milestone have not been met.

6. Risk identification and management

Within the Case for Support form you should list the key risks to the programme, and, for each risk, indicate the likelihood (e.g. low, medium, high) and the consequences and impact this could have on the programme (e.g. minor, moderate, severe). Describe how the risk will be managed and any risk mitigation plans that are in place. The applicants should also consider risks and mitigation strategies with respect to the protection of arising IP (and for protecting background IP if existing/required for downstream exploitation) and downstream commercialisation.

Risks, Impact and Mitigations may be set out as free text within the respective section of the Case for Support form or, **alternatively**, a 1-page Risk Table may be uploaded as 'Other Attachment', and the comment "Please Refer to Risk Table" written in the Case for Support.

7. Funding and industry involvement

Research Organisations (RO) that are eligible to receive standard UKRI funding are set out within the MRC Guidance for Applicants (1.1) and UKRI website, including briefly:

- Higher education institutions - Costs associated with research activities taking place at UK HEIs will be eligible to receive 80% full economic costs (fEC) in line with UKRI policy. Universities based outside of the UK will normally be eligible to request costs of up to 80% fEC; requests for funding to meet the full economic costs of research conducted in non-UK based universities may be eligible and should be discussed with the funding call lead in advance of submission.

- Independent research organisations
- Public sector research establishments (PSREs) – PSREs already confirmed as eligible to receive UKRI funding are listed on the UKRI website. If a PSRE is not on this list, you must allow sufficient time to apply for eligible PSRE status before the application is submitted. Please discuss this with the funding call lead.
- MRC institutes, units and partnership institutes
- Institutes and units funded by other research councils
- Research and technology organisations, i.e. Catapults

Company funding eligibility

In supporting this funding opportunity, the MRC is keen for industry to be actively involved in consortia. Whilst we expect that large companies would support their own costs in participating in a consortium, we are willing to consider requests for funding from small/medium companies involved in the consortia. Companies will need to meet the definition of a small or medium sized enterprise (SME), as set out in the UK Gov Companies Account website (Sections 11.1), to be eligible to apply for funding to cover research costs.

Eligible companies requesting funding will be assessed on a case-by-case basis and will need to complete PART B of the Research Organisation form. Companies will need to detail within their full application:

- why the involvement of the company is essential to the success of the consortium
- how funding to the company will be used to support the objectives of the consortium
- why the company is not able to support the costs themselves.

Subsidy control (and State aid where applicable)

This funding opportunity must provide funding in line with the UK's obligations and commitments to Subsidy Control. These include:

- UK Subsidy Control regime (see **Department for Business, Energy and Industrial Strategy (BEIS) guidance**)
- **World Trade Organisation (WTO) rules**
- the EU-UK Trade and Cooperation Agreement (TCA) (see **EU-UK TCA summary**)
- EU State aid regulations where relevant (for example under the **Northern Ireland Protocol** (GOV.UK)
- other bilateral **UK Free Trade Agreements (FTAs)** where relevant.

The MRC is unable to award funding to organisations that are considered to be in financial difficulty. We will conduct financial viability and eligibility tests to confirm this is not the case during the full application review stage.

If you are unsure about your obligations under the UK Subsidy Control regime or the State aid rules, you should take independent legal advice. We are unable to advise on individual eligibility or legal obligations.

Companies based in Northern Ireland should make it clear whether Article 10 of the Northern Ireland protocol applies to them and their participation in the consortium, and therefore whether any funding request would need to be considered under EU State Aid regulations.

Companies based in the EU must be compliant with the General Block Exemption Regulation (GBER) principles to request funding, and funding requested must be at the appropriate aid intensity.

Companies based outside the UK and EU should take into account relevant Free Trade Agreements and WTO rules when requesting funding.

If the companies requesting funding within the consortium are doing so at different funding intensities (for example company 1 is requesting funding at 80% FEC and company 2 at 50% FEC), the consortium is asked to collectively consider and outline in their application why this is necessary and what steps would be taken to minimise any potential distortion of competition.

If there are any changes to the above requirements (including within developing UK Subsidy Control legislation) that mean we need to change the terms of this funding opportunity, we will tell you as soon as possible.

8. Project costs and funding requests

The *total request to the MRC* should not exceed £8 million. The total *project cost* represents the total value of all the funding (the full economic cost (fEC)) plus contributions, cash and in-kind, required to carry out the project. This may be more than £8 million.

UK academic organisations are expected to apply for 80% fEC in line with standard MRC guidance.

MRC requests that companies eligible to receive funding consider whether they are able to request costs of up to 80% fEC, in line with academic organisations. Should this not be feasible, eligible companies will be able to request support for their full economic costs should the rationale be adequately justified and evidenced in the full application. All funding should be requested **at cost** by eligible companies and in line with relevant subsidy control regulations.

Please note that Je-S automatically calculates 80% of the full economic cost as default. Costs entered in the Directly Incurred - Exceptions category are requested at 100% of the fEC (see guidance on Exceptional costs below). Where a partner wishes to request an alternative percentage of the fEC (neither 80% nor 100%), please contact the funding call lead to discuss this.

Eligible costs

Eligible costs will include labour, purchase, rental or licensing of any new equipment, facilities, platforms or consumables required by the consortium, subcontracting costs where necessary or travel and subsistence costs.

Labour costs are of course eligible and should be linked to the details of employed staff working directly on the research programme and all listed staff should be on your payroll and subject to PAYE. Costs should be calculated for each staff member based on their time dedicated to the programme, on the basis of their day rate based on their working days per year less bank holidays and your organisation's annual leave entitlement. You can include costs for any staff time which directly supports the research programme (such as budgeting, project reporting and recruiting).

Gross employee costs should be calculated based on your PAYE records, including gross salary, National Insurance (NI), company pension contribution, life insurance or other non-discretionary package costs.

Ineligible labour costs include:

- Use of blended labour rates inclusive of overheads
- Discretionary bonuses or performance related payments of any kind
- Dividend payments
- Forecasted pay increases.

Equipment

You may request funding for new equipment (including computers and software), the costs of equipment repairs and major spares, the costs of external maintenance agreements and the cost of equipment relocation and installation, where required by the proposed research. Please refer to section 3.2.2.2 of the Guidance for Applicants for details of how to include requests for equipment in your application.

Exceptions

Exceptions are costs that may be funded by MRC at 100% full Economic Cost (fEC), unlike the standard 80% fEC support provided to eligible Higher Education Institutions (HEIs) that receive dual support from Research England or Devolved Nation equivalents.

For this call, MRC would consider requests for 100% fEC for the following:

- Eligible research costs incurred by a commercial organisation within the consortium that is classified as an SME (UK or non-UK based), where this is compliant with any applicable subsidy control funding intensity requirements. Requests must be supported

by adequate rationale detailing why the organisation is unable to request 80% fEC support

- Eligible research costs being conducted in a non-UK based research organisation, where it can be demonstrated the required expertise cannot be sourced within the UK
- Costs in excess of £50,000 for sub-contracts with CROs may be paid at 100% fEC should the activities meet all three of the criteria outlined below:
    - Are required to be undertaken to regulatory standards by a competent authority to allow clinical evaluation
    - Do not involve creativity/intellectual input to the development of the entity by the CRO
    - Require access to skills and resources not available in academia, where this can be robustly justified.

Those costs being requested at 100% fEC in your application should be entered on Je-S in the 'Exceptions' category.

Note that the first £50,000 of CRO costs will be supported at 80% fEC and should be entered under the 'Directly Incurred' heading, with the remainder entered as Exceptions.

Applicants should discuss any Exceptions requests with the funding call lead before submitting their application.

Justification of Resources

Applicants will need to detail the costs sought from MRC and provide an attached Justification of Resources with their application, setting out how these resources will be used to support the objectives of the consortium. Guidance on writing a strong justification of resources (JoR) document is available on MRC's Guidance for Applicants (Section 2.2.4).

9. Intellectual property guidance

Intellectual property guidance

MRC recognises that intellectual property (IP) considerations will vary across each individual consortium and we support the formation of appropriate governance structures that principally facilitate the delivery of a programme's science, while managing background and arising IP for the benefit of the consortium and the UK.

As such, MRC will expect each consortium to put in place a collaboration agreement amongst all members of the consortium before MRC provides funding to the successful consortium. This agreement must be finalised an in place such that the award can start by 1st October 2022. Whilst the exact provisions included in the agreement will require discussion by the consortium,

MRC expects that the consortium takes into consideration certain principles in relation to the management and commercialisation of IP.

When completing the full application, in line with the principles set out below, the applicants should articulate a carefully considered IP management and commercialisation strategy that is tailored to the deliverables of their project, as far as these can be anticipated. Applicants should explain how their strategy aligns with the objectives of the Challenge, and more specifically how the project deliverables will be made widely accessible within the consortium and beyond.

Principles for management and commercialisation of IP

Background IP

a. No change in ownership of IP when entering the consortia;
b. Improvements to background should be classed as arising IP;
c. Rights to use will be granted by the owner/s to other members of the consortium for the purposes of research within the consortium; and
d. Consideration to be given as to how access to background will be achieved if needed for the commercialisation or future use of any arising IP.

Arising IP

a. IP to be owned by the party/parties that generate it;
b. Rights granted by the owner/s to other members of the consortium to use arising IP for the purposes of research within the consortium; and
c. Academic consortium members and the NATA Hub to be granted rights to use arising IP for academic research, sub-licensable to other research institutes.
d. It may be, dependent on contributions made, appropriate for industry consortium members to be granted rights to use arising IP for internal research purposes.
e. All consortium members and the NATA Hub to be granted non-exclusive option to take non-exclusive licence to arising IP that is of general applicability/utility for commercial purposes. MRC expects that most of the arising IP will fall under this category. However, licence terms should not place unreasonable financial burden upon an academic institute.

Management of IP

a. Consortium to establish a commercialisation committee with representation from all consortium members and the NATA Hub. The committee will co-ordinate and oversee implementation of the strategy for the protection and commercialisation of arising IP as articulated in the application form and collaboration agreement, including approval of commercialisation agreements and any revenue sharing provisions;
b. The consortium should elect a lead organisation who will be responsible for establishing the commercialisation committee and leading delivery of the commercialisation strategy;
c. MRC expects most of the arising IP to be of general applicability/utility and that it should be licensed non-exclusively to ensure widest possible impact;
d. Commercialisation agreements should reserve the rights for use in academic research and development and include clawback rights;

e. Industry consortium members may be granted an option to take licence to arising IP and to any unencumbered background IP that is required for the development/commercialisation of the arising IP; and
f. Owners of background may be granted option to take licence of arising IP that is an improvement of their background.

Heads of Terms and Collaboration Agreement

The application should include a Heads of Terms (HoT) document signed by all members of the consortium. The HoT, while not legally binding, should outline the intended principles and relative responsibilities in relation to governance, intellectual property rights, reporting, and access to data and materials before the project starts. The information in the HoT should align with that in the Case for Support form. Academic organisations should consult with their research contracts office and Technology Transfer Office or equivalent when the HoT is being developed prior to submission.

The HoT should be agreed between the consortium members and set out the following:

- Key tasks and responsibilities of the consortium members with respect to each work package
- Consortium management arrangements
- Access to background IP
- Ownership, protection and commercialisation of arising IP, including identification of the organisation that will lead responsibility for establishing the commercialisation committee and leading delivery of the commercialisation strategy
- Arrangements for publications and announcements
- Arrangements for withdrawal/change of control
- Principles for termination of the programme.

The HoT should be fully signed by all parties (including the NATA Hub where a consortium partner) and submitted alongside the application (uploaded as document type 'Head of Terms'). The HoT will be reviewed to ensure that the proposed arrangements are compatible with the principles outlined in the section above.

Any award offer will be conditional upon MRC receiving a copy of a fully signed, legally binding Collaboration Agreement between the consortium members. This must be received and approved by the MRC before funding can be accessed and the project can start. Awards must start by 1st October 2022.

The terms set out in the Case for Support form, HoT and Collaboration Agreement should be consistent with each other, and any substantive post-award changes to the Collaboration Agreement, including changes of consortium members, will require prior MRC approval.

Commercialisation committee

You must establish a commercialisation committee with representation from NATA Hub and the project's research organisations that are actively involved in delivering the agreed research to coordinate the management and protection of IP, including approval of commercialisation agreements. The committee should meet at a frequency as required to fulfil its role.

Commercialisation committee membership should be agreed before the beginning of the award and MRC should be informed.

10. External advisory board

You must establish an external advisory board, or equivalent body, to act as a critical friend and provide advice on the running of the project, its research and related activities. This board must meet at least annually, and you must provide the external advisory board with an annual written report before the meeting detailing the project's:

- progress against programme objectives and milestones
- risks and mitigation strategies
- IP management/commercialisation strategy and updates
- research outputs
- training.

Each advisory board meeting will be chaired by the NATA Executive Director. NATA will provide secretariat for the external advisory board. The external advisory board Terms of Reference should be sent to the board Chair and the MRC Programme Manager for input prior to the first scheduled meeting; the Terms of Reference should include board membership.

11. Submitting your Full Application

Your full application should be submitted by 16:00 27th April 2022 via Je-S: https://je-s.rcuk.ac.uk/

All investigators will need to register with Je-S. Where an organisation does not yet have a Je-S account, co-investigators should use the 'Self-registration' function to add their organisation to the Je-S database before they attempt to create a 'proposal' level Je-S account. **You should allow up to 15 days for the organisation registration and account set-up to be completed.**

Please consult the Checklist in **Annex 1** before submitting your application.

To avoid possible document corruption, please ensure all documents are uploaded as PDFs. All documents should be completed in single-spaced, Arial 11pt font or similar-sized sans serif typeface.

Applying through Je-S

You must apply through Je-S at the full application stage**.**

When applying select:

- council: MRC
- document type: Standard Proposal
- Scheme: Biomedical Catalyst: DPFS Full
- call/type/mode: **INVITE ONLY Delivery Research Challenge nucleic acid therapeutics Full April 2022**

After completing the application, you must 'submit document' which will send your application to your host organisation's administration.

Applicants should allow sufficient time for your organisation's submission process between submitting your proposal to them and the call closing date.

Applicants should ensure they are aware of, and comply with, any internal institutional deadlines that may be in place.

Je-S Help

For general guidance on navigating and using the Je-S system, including creating accounts and self-registration for organisations, please refer to the Je-S Handbook.

For technical assistance with the Je-S system please contact the Je-S Helpdesk:

Email: JeSHelp@je-s.ukri.org
Phone: +44 (0) 1793 44 4164
Staffed Monday to Thursday 8.30am to 5pm and Fridays 8.30am to 4.30pm (excluding bank holidays and other holidays)

12. How we will assess your application

Full applications from shortlisted applicants will be peer reviewed and scored by an independent panel of leading international academic and industry experts, closely supported by MRC head office.

Financial and commercial diligence checks will be conducted before the applications are reviewed by the Panel, in addition to checks on the proposed management of IP, Heads of Terms agreement and any proposed commercialisation strategy.

Conflicts of interest will be managed according to MRC standard ways of working. External panel members will be under a non-disclosure agreement throughout the application process. Applications will not be sent for written peer review to experts in the research community.

Interviews

Applicants will be required to attend a short interview during the final Panel meeting in June 2022 to provide them with the opportunity to answer specific questions the Panel may have before scoring. Further details will be provided near the full stage Panel meeting.

Assessment Criteria

The assessment criteria at the full application stage will be consistent with the standard MRC Board and Panel Scoring Matrix.

A strong full application will:

- clearly articulate a specific delivery challenge and an innovative solution with potential to result in a step change in the field. The solution should have downstream translatability and broad industrial utility beyond the consortium members, and make a lasting impact on the sector
- set out how project outputs would unblock development pipelines, evidencing a substantial potential pipeline of activity which might be enabled
- demonstrate the novelty and competitive advantage of the proposed solution with reference to alternative approaches
- sufficiently consider factors crucial for future development of this solution and NAT delivery enabled by this solution, including safety, manufacturing, cost, quality control and regulatory requirements where relevant
- describe a credible approach and deliverable workplan, supported by appropriate milestones, risk mitigation strategies and governance and project management structures
- involve sufficient relevant expertise and appropriate leadership to give confidence in management of the consortium and delivery of the proposed workplan. The contributions and responsibilities of each partner towards the collective aims should be clearly articulated.
- have freedom to operate or a credible plan for obtaining freedom to operate, and a credible intellectual property and commercialisation strategy to enable the delivery of the proposal, wider dissemination and the wider utility of outputs
- demonstrate that the applicants are appropriately networked with the UK NAT landscape with particular reference to the NATA Hub
- explain how the programme of work and its outputs will appreciably benefit the UK NAT field
- present a clear opportunity for this amount and type of funding to make a significant impact, including the potential for leveraged input (financial or in-kind) to maximise the available resource.

Post-Award

13. Feedback

All applicants will receive written feedback following the panel discussion of their proposal.

14. Additional conditions

Supplementary to the standard UKRI grant conditions, additional conditions will be added to the award offer. These will include but are not limited to the following conditions (wording may vary):

Milestones

This award is contingent upon meeting progression milestones. Failure to meet progression milestones may result in termination of the award at our discretion. Spend should be limited to work detailed in the research plan for the active milestone.

Without specific prior written approval, we will not reimburse you for the cost of any work contributing to a later milestone should it be decided that the criteria of an active milestone have not been met.

Changes to programme plan

If issues or problems arise prior to or during the course of the project that could potentially result in the inability to achieve the programme objectives or milestone, the issue, as well as proposed solutions, should be promptly communicated to us.

We require advance notification of any proposed change to the project plan, including changes in milestone criteria, grant duration or cost, in writing.

Changes must be approved by us prior to them being implemented. Please note, due to the milestone driven nature of the project, the process for change requests differs from other MRC schemes; these should be submitted via email and not through Je-S.

Expenditure against grants

Expenditure profiles will be agreed before the programme commences.

Reporting and expenditure profiles

You must provide MRC and NATA Hub with quarterly progress updates reporting the project's delivery against objectives, success criteria and milestones. Financial reporting on to-date and forecast expenditure, in addition to risks to delivery, will also be required quarterly.

It is your responsibility to ensure expenditure remains on the expected profile. You must inform us of material slippage or cost savings as soon as possible. We reserve the right to suspend or reprofile the grant if spend does not closely match allocation.

Final expenditure statement

It is the responsibility of the PI to submit a final expenditure statement and a Project End Report at the end of the grant. The final payment will be withheld until the final expenditure statement and the Project End report are received and failure to submit may result in financial sanctions.

Subsidies to companies

It is the responsibility of any company that receives a subsidy from this award to notify us immediately should any of the following arise:

- The company no longer meets the definition of an SME during the grant funding period, as defined by the UK Government (Companies Account website, section 11.1 onwards)
- The company or any of its board members are involved in any criminal prosecution, regulatory investigation or civil proceedings
- The company receives funding under a rescue and restructuring aid scheme, or enters insolvency proceedings / liquidation / other creditor voluntary arrangement.

We reserve the right to request further information, including grant expenditure details, during the grant funding period and following the end of the project. If a company does not co-operate then MRC has the right to terminate the funding.

We reserve the right to reduce the level of subsidy required, if necessary, in line with UKRI standard terms and conditions.

Evaluation requirements

This award is part of the NATA programme, funded by the Strategic Priorities Fund (SPF). You must adhere to any additional evaluation requirements set by the SPF.

Annex 1: Checklist of documents to be attached with your application

Attachment (in PDF format)	Attachment type on Je-S	Page limit or formatting
Mandatory		
Full Case for Support Form Complete 1 per consortium, using the template provided	Case for Support	N/A
Research Organisation Form Complete 1 per non-academic Research Organisation. Additional documents requested within PART B (**for commercial organisations requesting funding**) should be uploaded separately (in pdf or Excel format as stated), also under 'Other attachment'.	Other attachment	N/A
Cover/Feedback Letter Cover letter to the Panel, detailing your response to the Panel's comments from the outline submission of the proposal.	Feedback Letter	Up to 5 x A4 pages Font Arial, 11 point
CV for • Principal Investigator • Co-Investigator(s) • Researcher Co-Investigator(s) • Any named research staff Please refer to Section 2.2 of the MRC Guidance for Applicants for further information on CV requirements.	C.V.	Up to 2 x A4 pages each. Font Arial, 11 point
Publication list for • Principal Investigator • Co-Investigator(s) • Researcher Co-Investigator(s) • Any named research staff Please refer to Section 2.2 of the MRC Guidance for Applicants for further information on requirements for publication lists.	List of Publications	1 x A4 page each Font Arial, 11 point
Supporting information Can include data, figures and tables, and should show chemical transformations required.	Supporting Data	Up to 5 x A4 pages
Milestone Form 1 per consortium. See section 5 of this guidance document and the form itself.	Milestone Report	N/A

Consortium Heads of Terms agreement 1 per consortium, signed by all parties including the NATA Hub where a consortium member. See section 9 of this guidance document.	Head of Terms	N/A
Gantt Chart Should include: • Project tasks (these being short, achievable and measurable activities) with, where relevant, the party responsible for delivering the task and dependency relationships between tasks; and • The progression milestones (including the end goal). These should reflect the major specifically-timed decision points when a judgment will be made on whether or not to progress the programme based on the achievement/non-attainment of specific measurable targets.	Gantt Chart	1 x A4 page
Justification of Resources (JoR) One to be completed per consortium. Please refer to Section 2.2.4 of the MRC Guidance for Applicants for further information on the JoR.	Justification for Resources	Up to 2 x A4 pages Font Arial, 11 point
Data Management Plan (DMP) Please refer to Section 2.2.7 of the MRC Guidance for Applicants for further information on DMP requirements, including a DMP template. It is advised, although not mandatory, that applicants use the MRC's DMP template.	Data Management Plan	3 x A4 pages
Signed letter of support from senior sponsor(s) within commercial organisations forming part of the consortium This may be a Business Development / IP manager.	Letter of Support	Maximum of 2 pages each
Signed letter of support from the lead commercialisation organisation The lead commercialisation organisation should be well placed to establish the commercialisation committee and be responsible for leading the protection/management/ commercialisation of arising IP on behalf of the consortium. This letter may be from an academic TTO or a commercial organisation's Business Development / IP manager. Ideally the letter of support will provide information tailored to the application especially on strategy for IP	Letter of Support	Maximum of 2 pages

management and downstream development and exploitation.		
Mandatory if applicable		
Letter(s) of Support if the project includes a **Researcher Co-Investigator**(s) (RCo-I). Please note the detailed guidance online regarding Researcher Co-Investigator eligibility and support.	Letter of Support	Up to 2 x A4 pages each Font Arial, 11 point
Letter of Support from Academic Technology Transfer Office The letter should be signed by a member of the TTO from academic Research Organisations, and should indicate the role played in developing the application and supporting the project on an ongoing basis.	Letter of Support	Up to 2 x A4 pages Font Arial, 11 point
Additional documents required by commercial organisations requesting funding, as requested in the Research Organisation form • For Q 6.3, supporting evidence to verify the date of company incorporation • For Q 6.13, company governance and management structures including an organogram (if a description is not entered as free text) • For Q 7.1, full audited company accounts and annual reports for the last three years • For Q 7.2, projected Programme cash flow for the duration of the proposed Programme, to include the projected contribution of the company to the Programme and detailing the net funding requirement. (Do not upload to Je-S, instead email to challenges@natahub.org separately in Excel format)	Other attachment (unless otherwise specified)	N/A
Optional		
Risk table Detail project/programme risks in the case for support (Q 5.10) **or** upload a table. Should you choose to use the table instead of responding in the Case for Support form, write "Refer to Risk Table" in the relevant question box.	Supporting Data	1 x A4 page
List/table of background IP/patents To support question 6.1 in the Case for Support form. Please list all background IP (e.g. existing technologies, materials, know-how, patents or other IP rights) that will	Other attachment	N/A

be developed or utilised as part of the proposed research plan? For patents, please provide patent numbers and state whether they have been granted.		
Consortium composition and governance structure diagram This can optionally be used to supplement question 5.8 in the Case for Support.	Other attachment	1 x A4 page
CVs for consortium management staff (if already identified and applicable) or **job descriptions** if available. See question 5.9 of the Case for Support.	CV	For CVs, up to 2 x A4 pages each Font Arial, 11 point
Regulatory discussions Evidence of relevant discussion with regulators, in letter or email format.	Other attachment	N/A
Letter(s) of Support from key collaborators, Contract Research Organisations or other relevant parties where these add value to the application, or demonstrate any pre-arranged agreement relating to the availability and accessibility of resources.	Letter of Support	Up to 2 x A4 pages each

Please note:

- All attachments should be saved with a relevant document name for ease of identification.
- All attachments have a maximum file size of 5MB except the Case for Support (10MB).
- All attachments should be uploaded in pdf format, checking for document corruption in figures/tables before uploading.
- The following Je-S upload document types should be ignored when submitting your application: 'MICA Form' and 'Technical Assessment'.
- You should ensure that all figures and timelines given are consistent across all parts of the application, particularly between Je-S, the Case for Support, Milestone Form, Gannt chart and Justification for Resources.