**MND Drug Repurposing Programme**

**Expression of Interest Application Form**

**SECTION 1 FURTHER GUIDANCE AND SCOPE**

Guidance on the scope of this funding call is provided below. Please also see the LifeArc website for further details [MND Drug Repurposing Programme - LifeArc](https://www.lifearc.org/strategy/neurodegeneration/motor-neuron-disease-translational-challenge/mnd-drug-repurposing-programme/).

LifeArc will work with you throughout your project funding journey, starting with the opportunity to receive 1:1 support prior to submitting your Expression of Interest (EOI). If you have a project that would fit the scope of this call, we would love to hear from you. Get in touch with us to discuss your application. [MND@lifearc.org](mailto:MND@lifearc.org)

**Project Scope**

**Projects that are in scope for funding:**

* Preclinical stage projects for MND using a repurposed drug or drug combination.
* Applications that can demonstrate evidence for a repurposed drug or drug combination and a relevant MND drug target.
* Earlier stage applications with target validation plans in the first milestone to evaluate repurposed drugs or drug combinations against a relevant MND drug target.
* Projects that also include biomarker guided approaches for repurposed drug-target engagement, mechanism and efficacy. We encourage applicants to consider the utilisation of biomarkers that may be suitable for future clinical research studies.

**Projects that are out of Scope**

* MND research that doesn’t involve drug repurposing; fundamental MND research, MND target identification.
* New drug discovery projects, including but not limited to unbiased drug screening, novel hit identification and novel hit-lead medicinal chemistry.
* Clinical phase drug research and development including experimental medicine and clinical trials of repurposed drugs.
* Other stand-alone technologies without a repurposed drug (e.g., diagnostics, delivery methods, biomarkers, model development).

In preparation for your submission, we would encourage you to read the following white paper [‘Guiding principles for drug discovery and development in amyotrophic lateral sclerosis’](https://www.myname5doddie.co.uk/assets/media/Guiding%20principles%20for%20drug%20discovery%20and%20development%20in%20amyotrophic%20lateral%20sclerosis_Final.pdf). Further information on the different stages of drug repurposing can also be found here [Repurposing medicines - Home](https://www.repurposingmedicines.org.uk/index.html)

**EOI submission deadline**

Submit your completed EOI form as a pdf by email to [MND@lifearc.org](mailto:MND@lifearc.org) by 23.59 on 10 May 2024.

**SECTION 2 APPLICANT ELIGIBILITY**

**Please delete (Y/N) as appropriate**

The Lead Applicant and point of contact must be based in an academic/research institution/SME.

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| **Are you (or will you be) based in an academic/research institution/SME?** | **Y / N** |

The Lead Applicant is expected to have a contract (fixed term or tenure) which covers the proposed duration of the grant. If the Lead Applicant does not hold a tenured appointment, the application must include a co-applicant that does.

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| **Do you accept this condition?** | **Y / N** |

Early Career Researchers (ECRs) are eligible to apply as a Lead Applicant provided that LifeArc receive appropriate assurances that the host institution is supportive. ECR led applications should include a tenured Co-Applicant from the host institution where the research will be conducted.

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| **Do you accept this condition?** | **Y / N** |

If the project uses animals, human participants and/or samples and requires regulatory and/or ethical approvals, the award is dependent upon the requisite approvals being granted.

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| **Do you accept this condition?** | **Y / N** |

All applications will be treated confidentially by LifeArc to assess the applicant’s eligibility for the call. If necessary, we may share information provided with external reviewers under confidentiality agreements.

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| **Do you consent to LifeArc sharing this form confidentially?** | **Y / N** |

We will need to collect some personal information to manage and assess your funding application, to communicate with you about your submission and the outcome of the assessment. We will handle personal data in like with UK data protection legislation and manage it securely. For more information, including how to exercise your rights, read our privacy notice [LifeArc Privacy Notice](https://www.lifearc.org/privacy-policy/#:~:text=We%20will%20not%20share%20your,request%20that%20we%20do%20so.&text=Some%20of%20our%20External%20Third,of%20data%20outside%20the%20UK.)

We also want to know if your project involves collecting personal data.

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| **Will the research project involve collecting personal data?** | **Y / N** |

**SECTION 3 EXPRESSION OF INTEREST FORM**

**1. APPLICANT DETAILS**

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| **Details of Lead Applicant** | |
| Name: Full title, all initials and surname |  |
| Institution: |  |
| Present position: |  |
| Contact address: |  |
| Telephone: |  |
| E-mail: |  |
| **Role and expertise of Lead Applicant:** (250 words) | |
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| **Details of Co-Applicants**  Co-Applicant names and Institutions:  Use full titles, all initials and surnames and include Institution name. (List multiple Co-Applicants separately) |
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| **Collaborators/Project Partners**  If relevant, please give the names of any collaborating parties that are not named as applicants but would be collaborating (or providing services) on the project including names and type of organisation (i.e., charity, other not for profit or for profit/SME).  Briefly outline the expertise and experience essential to the project that each collaborator/ partner will contribute.  (List multiple Collaborators/ Project Partners separately). |
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| **Technology Transfer Office / Contracts Administrator contact**  Please provide the name and position of your Technology Transfer office contact and/or please provide the name and position of your Contracts Administrator.  (List multiple contacts separately) |
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1. **PROJECT TITLE AND TECHNICAL SUMMARY**

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| **Title of project (maximum 25 words)** |
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| **Technical Summary**  Please share a summary of your proposed project in about 300 words. Please summarise the overarching aim, the objectives you will undertake to achieve that aim, and the expected deliverables. |
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**3. THERAPEUTIC TO BE REPURPOSED FOR MND**

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| ***Guidance:*** *In this section we want you to describe the therapeutic(s) that you are planning to repurpose for MND and how it is used in the existing indication(s) – its name, the indication(s) for which it is currently in use; its stage of development for the existing indication (Repurposing candidates must have achieved a minimum of clinical Proof of Concept, successfully completing Phase 2 clinical trials or Market Authorised drugs for the existing indication); its structure and mechanism of action; dose and route of administration, and safety profile.*  (If drug combinations are being proposed, please list drugs and authorised indications separately.) |

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| **Name of drug(s):** |
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| **Stage of development in the existing indication:**  What stage of development is the therapeutic? Has Market Authorisation been granted for the existing indication(s), or is the therapeutic still in clinical development for the existing indication? (**250 words**)  (Repurposing candidates must have achieved a minimum of clinical Proof of Concept, successfully completing Phase 2 clinical trials or Market Authorised drugs for the existing indication) |
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| **Product description & mechanism(s) of action**  Briefly outline relevant background information for the therapeutic: substance type (e.g., small molecule chemical, biological); structure and mechanism of action; dose and route of administration; safety and tolerability (**250 words**)  (Please provide a Target Product Profile (TPP) for the drug if available and/or reference to official product information of authorised medicines). |
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**4. SCIENTIFIC RATIONALE**

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| ***Guidance:*** *In the previous section you have described the characteristics of your proposed repurposed therapeutic – tell us here why those characteristics make it a suitable candidate for use as a therapeutic in MND.*  ***We have divided this section into 3 parts.***  *In Part 1 we would like you to describe the underpinning rationale e.g., target, mechanism of action etc.*  *In Part 2 we would like you to describe any experimental evidence/supporting data, either that you have generated, or that is in the public domain, that supports the repurposing of this candidate(s) for MND.*  *In Part 3 we would like you to articulate the pre-clinical knowledge gaps that you believe need to be addressed before this candidate can progress to the clinic for MND.*  ***(Please use “Additional Information” to upload any figures, tables, and graphs)***  *You may wish to consult our Guiding Principles document for additional guidance.*  *Note: Applicants selected for the full application stage will be able to access support from LifeArc and our network of experts to develop a pre-clinical strategy to address knowledge gaps outlined.* |
| **Part 1: Underpinning rationale: (300 words)** |
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| **Part 2: Experimental evidence/ data that supports your rationale (300 words)** |
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| **Part 3: Pre-clinical knowledge gaps for MND (500 words)**  Considering the rationale and the supporting data presented above, what are the pre-clinical knowledge gaps that need to be addressed before this candidate can progress to clinic for MND? E.g., additional validation/ proof of drug efficacy and target engagement in a relevant disease model/ dose-ranging studies/ PK/PD studies relevant to MND/ GLP safety/ toxicity/ etc. |
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**5. PROJECT PLAN**

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| ***Guidance:*** *With this strategy in mind, set out the proposed plan of work for which you are seeking funding. Please list the planned objectives, milestones and deliverables including the associated success and no-go criteria if possible. We have provided a suggested template to guide your completion of this section.*  *Note: Applicants selected for the full application stage will be able to access support from LifeArc and our network of experts, who will provide guidance in designing milestone based experimental plans for the full application. Applicants will also be able to outsource defined parts of the project to Contract Research Organisations (CROs).* |
| **Project Plan** |
| Objective 1: Months   * + Objective 1.1: Months X-X   + Objective 1.2: Months X-X   + Objective 1.3: Months X-X   Leading to:   * Milestone 1: Month X   + Success criteria:     - Ideal:     - Acceptable:     - No-go |

**6. PROJECT DELIVERY**

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| **Project team**  How are you and your team equipped to deliver this solution.Please include evidence of how you and your team have the appropriate scientific track record, relevant experience and the right balance of skills to cover the proposed work and achieve the goals of the project. (**250 words**) |
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| **Collaboration**  Applicants are encouraged to take a collaborative approach to their application, aligning with key players and initiatives in MND. Please outline how the proposed research project fits within the current MND landscape (**250 words**) |
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| **Project Partners / Outsourcing**  LifeArc recognises that not all applicants will have the internal resources and pre-existing relationships required to deliver on all aspects of the preclinical project.  There will also be the opportunity to outsource defined parts of the research plan to specialist Contract Research Organisations (CROs) with appropriate expertise and capabilities. Outline project objectives, milestones and deliverables that would require outsourcing. (**250 words**) |
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| **Regulatory/ clinical advice obtained**  Outline any previous and/or planned interactions with regulators, clinicians, or other advice, obtained to support the scientific rationale and project plan for MND. (**250 words)** |
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| **Commercial interactions / IP**  As a charity LifeArc needs to be informed of the likelihood of IP being created to capture the outputs and impact of research it funds and to ensure research outputs are correctly monitored, protected, managed and exploited to benefit society.  **Does the project have freedom to operate, or does it require access to any Background IP (including know-how, materials, or technologies)? (delete Y/N as appropriate)** |
| Freedom to Operate (Y/N) |
| **If access to Background IP is required:**  What Background IP (including materials, data, know-how, or technologies) does the project need access to and has access been agreed? If not, why do you believe you will be able to access the required IP, materials, know-how, data, or technologies on reasonable terms? How do you plan to access the proposed therapeutic/s? Detail all institutions or individuals holding relevant background IP and detail any agreements in place or envisioned. (**250 words**)  *Note: LifeArc will be able to provide technology transfer support to applicants and their organisations selected for the full application stage.* |
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| **Patient / public involvement**  What engagement with end users and patients has already been undertaken, or will be undertaken, in the development of the project plan? (**250 words**) |
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| **Outline costs**  Applicants apply for up to £750,000 GBP. Funding Awards shall cover 100% of the direct costs of the project as permitted expenditure, evidenced and directly incurred in the Project. Typically, this will cover FTE; consumables directly related to funded work; access to specialist equipment/reagents; Contract Research Organisation work; reasonable travel and subsistence. Receipt of funding will be linked to achieving milestones. and standard payment terms will be quarterly in arrears.  Provide an estimate of Total Project Costs that should not exceed £750,000. Total Project Costs include costs for outsourced CRO work. Please do not include full economic costings. As a registered charity, LifeArc will not cover indirect costs such as administrative or other overheads (for example maintenance costs). Indirect costs of research in universities can be supported by the Charity Research Support Fund ([CRSF](https://www.amrc.org.uk/charity-research-support-fund-crsf)). |
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**7. REFERENCES**

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| **List the references you have used to support your application.**  To support the scientific assessment of your proposal, please list up to three key outputs that provide a rationale for the proposed project. The outputs may or may not be your own work. |
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**8. ADDITIONAL INFORMATION**

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| Please append supporting figures, graphs, and tables to the end of your EOI form. Figures and additional information **should not exceed 2 A4 pages**. Please clearly label figures and refer to these labels within section 4. |