**Translational Research Questions**

Please refer to the additional guidance document for translational research questions to help complete this section.

Please delete any excessive white spaces from the end of your answers

## Section 1: Further Applicant(s) Details

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| **Project Manager** (if applicable) |  |
| Institute/Organisation/  Company |  |
| Address |  |
| Telephone |  |
| E-mail |  |

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| --- | --- |
| **Technology Transfer Contact** |  |
| Position |  |
| Telephone |  |
| E-mail |  |

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| --- | --- |
| **University Administrator Contact** |  |
| Address |  |
| Telephone |  |
| E-mail |  |

## Section 2: Need and Proposed Solution

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| **Introduction to the disease,** please present the disease that is the subject of the application include age of onset,mortality, morbidity, demographic etc. |
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| **What is the rare disease health, clinical or product need you are seeking to address?** Consider including a Target Product Profile to explain what the solution needs to achieve. |
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| **Explain the current standard of care and unmet medical need.** |
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| **What is your proposed solution to this need and its advantages?** |
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| **Strategic position**  What are the competing solutions in development and their shortcomings? |
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## Section 3: Description of Proposed Project

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| **Scientific background**  Please explain the scientific rationale for your proposed intervention. Include data and experimental supporting evidence as an Appendix. |
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| **Key references**  Please include up to five key references to support the rationale. |
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| **List the objectives/milestones of the proposed project.** |
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| **Experimental design**  Explain the experimental design and provide a statistical justification for the numbers of patients/animals to be used. |
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## Section 4: Deliverability

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| **Describe the stages of the project, associated risks, how likely these risks are to occur and how the risks will be mitigated.** Use milestones and a flow diagram to show the project progression and stage the risks, a Gantt chart may be useful in illustrating the timelines. |
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| **What resources/skills sets are required to deliver the project and how will they be obtained? Please provide a full justification for all salaried posts and expenses sought.** |
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## Section 5: Intellectual Property

*Note that the generation of protectable intellectual property is not an essential requirement for this scheme however it is important to demonstrate that there is a credible route to the patient and that will not be impeded by the IP situation.*

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| **Does the proposal and the onward development have freedom to operate or does it require access to background IP? If access is required, what IP does the proposal need access to? Detail institutions or individuals holding relevant background IP.** |
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| **If access to background IP held by any third party is required, has access been agreed? If not, why do you believe you will be able to access the required IP on reasonable terms?** |
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| **What new IP or knowledge is the project expected to produce?** |
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| **How will project generated IP be managed and exploited to support the project in meeting its targeted need? Detail the organisations/individuals who will own any arising IP and any live, pending or envisioned agreements governing management or exploitation of that IP.** |
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| **Competitive landscape**  Please explain what other approaches are available/in development to address this medical need. Explain the advantages of the proposed approach. |
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## Section 6: Exploitation of the Project Deliverable(s)

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| **Please describe your plans and strategy for further development of the project outputs?** |
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| **How is the project going to be supported after the end of the project? List potential sources of further funding and comment upon the project’s compatibility with the individual fund’s defined remits.** |
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| **Route to market**  Outline the likely route to market/patient benefit. If licensing anticipated, list potential partners and describe the required data package to be offered for licensing. |
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| **Are there any existing or potential restrictions on exploitation of the project objectives(s)**? |
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## Section 7: Miscellaneous

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| **Previous funding**  Please give details of previous awards that have supported the project (funder, grant title, amount awarded, grant period). |
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| **Miscellaneous**  Please note any other issues not mentioned elsewhere in the application form. |
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