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**NIHR Themed Call for CF Development Group Application Form**

**Investigator details:**

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| --- | --- |
| **Principal Investigator:** |  |
| **Host Institution:** |  |
| **Co-Investigators (Name, Institution):** |  |
| **Contact details:** |  |
| **Signature:** |  |
| **Date submitted to the Application Development Group:** |  |
| **Planned submission date for NIHR programme:** |  |

**Proposal details:**

|  |  |
| --- | --- |
| **Project title**: |  |
| **Study type:** | Translational research  Phase 1  Phase 2  Phase 3  Phase 4  Other (please describe) |
| **Research type:** | Primary research  Secondary research  Evidence synthesis  Clinical trial/ investigation  Other (please describe) |
| **Approximate number of participants required (if applicable):** |  |
| **Approximate number of UK recruitment centres (if applicable):** |  |

**Research Plan: a maximum of 2 pages addressing the key points below:**

* A clear demonstration of the need and importance of the research
* A brief overview of existing literature (primary research)
* An outline of the research question to be addressed, including aim(s) and objectives
* A short summary of the proposed project/ study plan outlining the study design and methods.

**For trials:** please list trial phase, primary outcomes, secondary outcomes (please list first 3), UK recruitment target, approximate no. of UK sites and the patient population (age, genotype etc)

* A clear description of team member roles and contribution
* Consideration of appropriate and relevant involvement of representatives from the CF community (PPI)

**Application development details:**

Which NIHR programme do you wish to submit your proposal to?

|  |  |  |
| --- | --- | --- |
| **NIHR programme** | **NIHR deadline** |  |
| Programme Grants for Applied Research (PGfAR) | 25 November 2020 |  |
| Efficacy and Mechanism Evaluation (EME) | 1 December 2020 |  |
| Health Technology Assessment (HTA) | 6 January 2021 |  |
| Programme Development Grants | 13 January 2021 |  |
| Health Services and Delivery Research (HS&DR) | 4 February 2021 |  |
| Research for Patient Benefit (RfPB) | 10 March 2021 |  |

What help would you like from the Application Development group/s:

|  |  |
| --- | --- |
| Scope of Research |  |
| Guidance on proposed research question |  |
| Engagement with CF community |  |
| Study design |  |
| Recruitment |  |
| Collaborators |  |
| Alignment with other proposals |  |
| Abbreviated protocol review |  |
| Other (please describe below) |  |

**Definitions** (taken from NIHR definitions and glossary)

**Study Type:**

**Phase 0:** Human micro dosing studies involving a small number of subjects to gather preliminary data on a drug’s pharmacokinetics and pharmacodynamics.

**Phase I:** A clinical trial to project the pharmacology of a medicinal product when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial.

**Phase II:** Trials that test the treatment in larger number of people with a given disease or condition. They aim to find out how well the treatment works in larger numbers, identify common side effects, and refine the dose and length of treatment.

**Phase IIa:** Exploratory (non-pivotal) project that has clinical efficacy, pharmacodynamics or biological activity as primary endpoint, conducted in patients.

**Phase IIb:** Definite dose range finding project in patients with efficacy as primary endpoint.

**Pilot:** Pilot studies are a smaller version of the main study used to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure that recruitment, randomisation, treatment, and follow-up assessments all run smoothly.

**Feasibility:** Feasibility Studies are pieces of research done before a main study in order to answer the question "Can this study be done?". They are used to estimate important parameters that are needed to design the main study.

**Other Study:** Other project to investigate a novel intervention to compare interventions, including devices, screening and diagnostics studies. This should not include phase III or IV trials.

**Research Type:**

**Primary research:** Experimental studies generating new data (cf. secondary research, which analyses existing data).

**Secondary research:** A review of individual, existing (primary research) studies. A systematic review is a secondary study.

**Evidence synthesis:** Evidence synthesis involves the development of techniques to combine multiple sources of quantitative and qualitative data to derive best evidence for use in healthcare.