National Institute for Health Research

Invention for Innovation (i4i)

Supporting Information for Applications

Product Development Awards, Challenge Awards and i4i Connect

Section 1: Introduction

This document contains information to assist applicants submitting an application to the NIHR Invention for Innovation (i4i) Programme. Applications for funding are made online through the CCF Research Management System (RMS). You must register or log-in to the RMS to complete and submit your application.

Please also ensure that you have read the guidance for applicants fully. Potential applicants are also encouraged to visit the programme website .

The following supporting information is available on the NIHR web pages:

Programme scope
Finance Guidance
Making a strong application

Word version of the Stage 1 and Stage 2 application form

1.1 Purpose

The NIHR i4i programme is a translational funding scheme which advances healthcare technologies and interventions for increased patient benefit in areas of existing or emerging clinical need. It supports research and development of medical devices, active implantable devices and in vitro diagnostic devices.

There are three funding streams: Product Development Awards, Challenge Awards and Connect. Product Development Awards support the research and development of medical technologies in any area of existing or emerging clinical need. Challenge Awards are based on themed calls in areas of existing or emerging healthcare need. Connect is aimed at small to medium-sized enterprises (SMEs) in need of a funding boost to reach the next stage in the development pathway. The expected output of i4i funding is an advanced or clinically validated prototype medical device, technology or intervention.

The objectives of i4i are to:

- Accelerate the development and uptake of innovative products, technologies and interventions for the benefit of patients in the NHS.
- Support collaborative English-led projects targeting unmet healthcare needs.
- Provide translational funding for projects which have demonstrated ‘proof of principle’ and have a clear pathway towards clinical adoption and commercialisation.
- De-risk projects and make them attractive to follow on funders and investors.

1.2 Essential requirements

All proposals must meet the essential requirements of the i4i programme.

- Projects must have already demonstrated ‘proof of principle’. Applicants are expected to have generated experimental data to support the case for further development and illustrate technical feasibility. Early stage research or discovery science is not fundable.
- For Challenge and Product Development Awards: A minimum of two organisations must be involved from an NHS Trust, NHS service provider, Higher Education Institution (HEI) or SME.
- For Connect: The lead applicant must be an SME. No collaborators are required, but collaborations are encouraged.
- Lead applicants must be based in England.
- Work packages must not include animal studies. If animal studies are required as part of the project, we expect applicants to seek parallel funding to cover such studies, details of which can be provided in the application form.

- Proposals must set out a commercial strategy that takes into account the regulatory pathway, IP management, commercial barriers, health economics and route to market.
- Proposals must present a plan for adoption of the technology into the NHS and other healthcare systems.

1.3 What we fund

Funded activities include the following:

- Research and development of medical devices, active implantable devices and in vitro diagnostic devices as defined by the relevant EU directives, across all areas of existing or emerging healthcare need (examples can be found here).
- Product development required to enable a technology for clinical use; work packages may comprise all aspects around manufacturing, intellectual property protection, freedom to operate analysis and market analysis, business case development, etc.
- Research and development of techniques or technologies from a different industry sector, which could have a potential impact if applied in a healthcare setting.
- Feasibility studies if a technology from a sector other than health is being developed.
- Studies to provide data relating to safety and effectiveness of a device, including first-in-man and pivotal studies.
- Health economic analyses and clinical utility studies, looking at a device's real-life implementation and use.
- CE marking and other regulatory requirements, including any associated safety trials.
- Activities associated with the adoption of new technology.
- Training associated with the implementation of new technology.
- Digital technologies such as machine learning or artificial intelligence that has shown robust proof of concept.

The i4i programme will not fund:

- Minor or incremental changes to technologies or interventions in current clinical use.
- Projects involving small molecule drugs and biologics, including vaccines and gene therapies.
- Projects involving stem cells.
- Projects involving cosmetic products.
- Projects that involve work on animals or animal tissue.
- Early stage or basic research.
- Evaluation or clinical trials of fully developed products or interventions, which have already been adopted within another NHS organisation or have a history of NHS use.
- Studies to improve the understanding of biological processes.
- Studies on the impact of interventions on service delivery and management.
- Products to be used only in hospital information, administration infrastructure and other related software.
- Methodologies clinically assessing or validating an existing or newly developed technique or technology.
- Wellness and prevention apps or stand alone apps.
- Professional training.
- Development of innovation or knowledge networks and healthcare technology cooperatives which aim to accelerate the development of innovative technology products.

1.4 Applicant eligibility

For all i4i awards the lead organisation must be based in England. For Challenge and Product Development Awards, the lead organisation may be any of the types of eligible organisation listed below. For Connect awards, the lead applicant must be an SME. Overseas collaborators are permitted but will not be eligible to receive any funding. Their role must be clearly described in the application.

The following types of organisations are eligible for funding:

- SMEs (including start-up or 'spin-out' companies);
- NHS organisations (including NHS Trusts and NHS Foundation Trusts), and equivalent UK authorities;
- Universities, research institutes and not-for-profit organisations.

For Challenge and Product Development Awards a collaboration of two or more of the above is eligible. For Connect an SME may apply for the funding alone, however, collaborations with two or more of the above are encouraged. Applications which involve partnerships between a university and its associated NHS Trust are considered an eligible collaboration. If support for a clinical trial is requested, one of the partners must be an NHS organisation or other NHS service provider which has agreed to be the sponsor of the trial.

It is possible that an organisation outside England can request funding as a co-applicant, if an appropriate case is made. We would expect the application to make a strong case that the chosen co-applicant was the organisation best placed to provide input to the planned research.

Specialist services or expertise may be brought into the team through consultancy or sub-contract arrangements, however, appropriate justification must be provided. Sub-contractors may be based outside of England.

The day-to-day running of your project should be handled through a project manager. While it is acceptable for the lead applicant to act as the project manager, for larger consortia in particular we would expect you to employ a dedicated project manager on a part-time basis.

For projects with a strong clinical emphasis it is expected that project teams encompass all relevant expertise required for clinical development and implementation, including clinical trial methodologists, statisticians, nurses, allied health professionals and commissioners.

The involvement of SMEs and/or early-stage companies in applications is particularly welcome. Large companies may be involved, but are unlikely to be supported with i4i funds.

For all collaborations where a partner is providing in-kind contributions, the exact nature of the commitment of each partner must be clearly detailed.

Section 2: Privacy and Data Protection

The CCF Research Management System (RMS) is hosted by Pulsant (http://www.pulsant.com/). The Data Controller for the website is the Department of Health (DH). The Data Processor is the CCF, based at LGC.

The purpose for which personal information is collected through the RMS is to deliver the work of the CCF in relation to the operation of research programmes, faculty and infrastructure workstreams. Data will not be used for any other purpose without the consent of the supplier.

Use of the registration and application facility on the CCF RMS is entirely voluntary and the personal

information stored will be used solely by the CCF, its subcontractors and partners in order to respond to your enquiries and send information relevant to its work.

To prevent unauthorised access, maintain data accuracy, and ensure the correct use of information, the CCF has put in place appropriate physical, electronic, and managerial procedures to safeguard and secure the information it collects online. The information you provide will be held securely and in accordance with the Data Protection Act 1998. The Department of Health and Social Care, National Institute for Health Research (DHSC NIHR) is the Data Controller. Your personal details provided on registration will not be disclosed to third parties. Details that are provided on research application forms must necessarily be shared in confidence with third party individuals involved in making funding decisions.

Your information may also be shared with other DHSC NIHR bodies for the purposes of statistical analysis and other DHSC NIHR management purposes, including targeted communications with selected groups of researchers. In addition, information collected is used by the CCF, its subcontractors and partner organisations:

- To administer the grant application process
- To identify peer reviewers for grant applications
- To notify users about funding opportunities by email
- To notify relevant users about application deadlines by email
- To notify users of any issues of service interruptions, holiday closures and other situations affecting the operation of the CCF RMS.

If we change our privacy policy, for example, in response to changes in legislation, we will post details of any changes on our website. This will help ensure that you are always aware of what information we collect, how we use it, and under what circumstances, if any, we share it with other parties. In some circumstances, explicit consent to continue use of the Services may be required. Otherwise, your consent to changes will be implied by your continued use of the Services. If you do not consent to the changes, then you must terminate your agreement as set out in section 12 of the NIHR CCF AND PRP CCF Grant Application System Terms and Conditions.

More information can be found at: http://www.nihr.ac.uk/funding-and-support/documents/Confidentiality-guidance.pdf

Section 3: Contact Details and Further Information

We wish to ensure that potential applicants fully understand what is needed in their applications before they submit them. We are happy to discuss the general principles of strong proposals prior to the deadline, although we cannot advise on the specific content of an application.

Enquiries may be made by email to i4i@nihr.ac.uk. Alternatively the i4i Secretariat can be contacted on +44 (0)20 8843 8015

NIHR can offer further support and advice on your application for funding through a number of its organisations, details of which are provided below:

NIHR Medtech and In vitro diagnostics Co-operatives

NIHR Medtech and In vitro diagnostics Co-operatives (MICs) build expertise and capacity in the NHS to develop new medical technologies and provide evidence on commercially-supplied in vitro diagnostic (IVD) tests. For more information visit:

https://www.nihr.ac.uk/about-us/how-we-are-managed/our-structure/infrastructure/Documents/medtech-and-in-vitro-diagnostic-co-operatives.htm

NIHR Research Design Service (RDS)

NIHR funds the Research Design Service (RDS) to provide design and methodological support to health and social care researchers across England to develop grant applications to the NIHR and other national peer-reviewed funding programme. Applicants may wish to seek advice on the content of an application via their regional RDS. It is advisable to make contact as early as possible to allow sufficient time for discussion and a considered response.

Section 4: Clinical Trials Unit (CTU) Support

CTUs are regarded as an important component of any trial application and can advise and participate throughout the process from initial idea development and design through to project delivery and reporting. However they may not be essential for all types of clinical research studies. If you feel this is the case please justify the reasons in your application in the appropriate section.

If you are looking for a CTU to collaborate with in your application, then the following sources can provide more help:

CTU Support Funding provides information on units receiving funding from the NIHR to collaborate on research applications to NIHR programmes and funded projects.

The UKCRC CTU Network provides a searchable information resource on all registered units in the UK, and lists key interest areas and contact information**.**

Section 5: Resubmission Policy

Although we do not prohibit the submission of applications which were submitted unsuccessfully in previous application rounds, applicants should recognise that the original applications were judged to be uncompetitive in that round, or significantly flawed, and are therefore likely to need substantive modification to have a realistic chance of being funded in future competitions. Previously unsuccessful applicants should therefore pay particularly close attention to any specific feedback provided prior to re-applying.

Section 6: INVOLVE/Public Involvement

INVOLVE has issued guidance for researchers about involving patients and the public in research.

Further information and resources can be found on the INVOLVE website. This includes a detailed definition of patient and public involvement in research, briefing notes for researchers on how to involve patients and the public and an involvement cost calculator and budgeting guide.

The NIHR Research Design Service also provide advice on developing research applications including involving patients and the public, and the James Lind Alliance has a step-by-step guide on involvement in research identification and priority setting.

Section 7: Publications

When a recipient of NIHR funding publishes their research findings we expect them to meet our publishing requirements and our policy on open access where we have adopted the 'gold' approach in common with the other principal biomedical research funders.

For any research supported by NIHR funds, the NIHR expects all publishing costs to be budgeted for when the research is commissioned. Therefore, NIHR will not routinely fund additional publishing costs separately. Please ensure when putting your grant application together that you include all expected costs of paid open access publishing. The average cost per paper is around £2,000 but can be much higher.

Section 8: Carbon Reduction Guidelines

Researchers applying for NIHR funding are asked to consider the carbon footprint of their research and take steps to reduce carbon emissions where appropriate. Advice on how to do this can be obtained from the Carbon Reduction Guidelines.

Section 9: Transparency Agenda

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information can be found at transparency agenda.

Section 10: Guidance on Completing the Application Form

To submit an application, you must complete all the relevant sections of the online form available within the **Central Commissioning Facility Research Management System (CCF RMS).** This can be accessed through this link.

The **'System Help'** document found on the CCF RMS's web pages provides extensive step by step instructions on how to make use of the CCF RMS.

Registration
Only registered users of the CCF RMS can apply. Applicants new to using the CCF RMS should register as a new user. Once logged into your account the RMS home page is the starting point to create applications, access co-applications and to update contact information and professional details.

Managing my details
Lead applicants and co-applicants can manage their basic contact information and curriculum vitae (CV) through the **'Manage my Details'** link on their RMS home page. Lead and co-applicant contact information and CV details are integrated by the RMS into the relevant fields during the application process. Please note that only lead applicant CV details are mandatory at Stage 1 while basic contact information is required for co-applicants. At Stage 2, lead and co-applicant CV details are mandatory. For i4i Connect the Lead applicant's CV is not required until Stage 2.

Creating an application
The lead applicant must initially create the new application. Clear instructions on how to start a new application can be found in the '**System Help**'. The research team can collaborate with the lead applicant to edit the content in the application by being invited to be a co-applicant through the co-applicant section of the application form.

The lead applicant can use the search tool to find co-applicants and then to invite them to join the application. The RMS will automatically dispatch an email inviting the co-applicant to confirm their participation in the application. Co-applicants can then decide whether to accept the invitation and consent to the application being submitted jointly in their name. They will need to log into the RMS and follow the links to **'Confirm**' their involvement on the co-application summary page. Once confirmed, the co-applicant will be granted access to edit the online application form.

All co-applicants must not only '**Confirm'** but also **'Approve'** their invitation to participate in the application electronically on the co-application summary page in advance of the submission deadline. Co-applicants participating in the i4i Connect application process are only required to accept their invitation prior to the Stage 2 deadline.

Completing an application
From the application summary page, the application can be edited by clicking on the **'Edit**' button. The different sections of the application form can then be accessed via the list of hyperlinked buttons on the left-hand side of the RMS webpage. You can move from page to page either by using the '**Previous**' and '**Next**' buttons, or using the list on the left-hand side of the web page.

Most questions are associated with contextual help buttons and clicking on them will open up pop-up

windows containing brief guidance notes that supplement the published guidance for applicants. It is strongly advised that applicants refer to the published guidance first and then use contextual help  as they complete and review each question as contextual help is not designed to replace it. Mandatory questions are flagged with a red dot.

The system will prevent your co-applicants accessing your application at the same time as you. This stops applicants and co-applicants inadvertently making changes to the same part of the application at the same time and overwriting each other's work.

For more details on the electronic approvals required from official representatives of the host organisations in advance of submitting your application, please refer to the published guidance for applicants.

Remember to save your work
You will be prompted to save your work if you leave the browser in application editing mode. We recommend you save your work regularly to minimise the risk posed by any local computer or internet problems. You can save and return to the application form as often as you like prior to submission.

Exiting and returning to work on your form
Should you wish to exit your form, you can return at any time; simply log in using your username and password and select **'My Applications'** from the menu. You will then be presented with a list of all the applications you are currently involved with as well as providing details as to their stage in the submission process.

Validation and submission of the form
The lead applicant can review the progress of their application at any time by selecting the '**View/Print**' option on the application summary page to generate the application as a PDF File.

When the application form has been completed, the lead applicant must use the '**Validate form**' tool within the online application form. The validation step is a check run by the RMS to assess whether all the mandatory questions contain information. It will provide a list of links to any parts of the form where corrections or additional content are needed.

Once the application has been validated successfully and no further corrections are needed, the lead applicant can submit the application by clicking on the **'Submit**' button on the lower right-hand side of the application summary page.

Following submission
A programme specific reference number will be assigned to the application once it has been submitted. After the relevant competition round closes, the application will automatically enter the process of being considered for funding.