National Institute for Health Research

Invention for Innovation (i4i)

Supporting Information for Applications

Product Development Awards and Challenge Awards

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 two funding streams: Product Development Awards and Challenge Awards. 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. 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. Challenge Awards must include at least one collaborator from an NHS Trust or NHS Service Provider. .
- 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.

The duration and research funding limits for each i4i stream are as follows:

- Challenge awards: Maximum duration of 5 years. There is no upper funding limit, but all costs must be sufficiently justified and proposals must provide value for money.
- PDA awards: Maximum duration of 3 years. There is no upper funding limit, but all costs must be sufficiently justified and proposals must provide value for money.

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. 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. 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. Application Process

The i4i programme operates on a two-stage application process.

2.1 Stage 1 Applications

Refer to the terms and conditions under which the award will be made prior to applying for funding. These terms are set out in the NIHR standard contract and are broadly non-negotiable. The contract will be concluded between the lead organisation and the Department of Health, which will be managed by the NIHR Central Commissioning Facility.

Stage 1 applications should be submitted on the RMS **before 1pm** on the advertised closing date.

2.2 Shortlisting

Assessment of Stage 1 applications is made by an expert Selection Panel which is comprised of academic, clinical and commercial expertise. Applications are scored against the i4i programmes assessment criteria.

Stage 1 applications will be shortlisted and successful applicants will be invited to prepare and submit a Stage 2 application form. Details of the Stage 2 application process will be provided at that time.

2.3 Full applications and interviews

All invited Stage 2 applications are subject to independent peer review. Applicants will see the anonymised peer reviewers' comments and will have the opportunity to respond in writing. The application form, peer reviews, presentation and the applicant's rebuttals are all taken into consideration by the Selection Panel in reaching their funding decision.

Stage 2 applications should be submitted on the RMS **before 1pm** on the advertised closing date.

All Stage 2 applicants must present their project proposal in person to the Selection Panel at a Selection Panel meeting. The interview takes the form of a short presentation followed by a question and answer session.

Applications are treated as confidential and all steps are taken to ensure confidentiality is maintained. In line with Department of Health policy, i4i will publish summary minutes of Selection Panel meetings. Please refer to our Confidentiality Guidance for further details.

2.4 Post award process

Funding offer

Once your application has been recommended for funding, we will provide feedback as agreed with the Selection Panel. Successful applicants are expected to start their project within four months of the funding notification, subject to satisfactory completion of due diligence and a fully signed contract. The Department of Health reserves the right to withdraw the funding offer at any time after six months of the funding notification.

Due diligence

The due diligence process starts after submission of stage 2 applications. Its purpose is to highlight any potential areas of weakness within the project, allowing the Selection Panel to make recommendations how to address these weaknesses and to identify the level of project monitoring that will be required. Projects recommended for funding will have to satisfy all conditions imposed by the Selection Panel and the i4i secretariat before the funding agreement can be put in place.

In addition to any changes to the work plan that may be requested by the Selection Panel, further information may be requested on project finances, project management, intellectual property and commercialisation. Funded applicants may be required to engage with an independent advisor for the revision of the project plan or any other project elements.

Section 3: Assessment Criteria

Stage 1 and stage 2 applications will be assessed against the following criteria:

- Clinical need, health economic case and impact on the NHS and patients
- Level of innovation
- Case for further development based on work to date and evidence from the literature
- Quality of the project plan, including the technological content and risk mitigation strategy
- Strength of the project team and management arrangements
- Intellectual property (IP) and commercialisation strategy
- Value for money
- Patient and public involvement

3.1 Clinical need, health economic case and impact on the NHS and patients

The proposed research must be highly relevant to the needs and healthcare priorities of the NHS. A clear case has to be made how the proposed device, technology or therapy might influence clinical practice. The clinical need and advantages over the current gold standard and any constraints in adoption must be clearly articulated. Evidence must be presented that a novel technology, a novel intervention or a novel clinically adopted technology will be the ultimate output of the project, delivering a clear benefit to patients and/or practice within the NHS.

3.2 Level of innovation

Applicants must demonstrate how the proposed device, technology or intervention presents a significant level of innovation, providing an advance over currently commercially available products. The application must contain an explanation of how adoption of the technology would change clinical practice and how the project will generate data to drive adoption.

3.3 Case for further development based on work to date and evidence from the literature

Applicants will need to provide evidence to support the case for further development. Applicants are encouraged to provide details of key data generated in prior studies and that support the project in the appendix of the application form, and any claims or assertions made about the technology in the Case for Support section, including the plain English summary, must have references provided.

3.4 Quality of the project plan, including the technological content and risk mitigation strategy

The proposed project must be focused on a specific clinical application, with the characteristics of the proposed technology or intervention clearly defined. Project aims and objectives must be realistic in terms of time and resources requested. It is vital to add as much detail as possible on research design and methodology. The project plan must adequately address aims and objectives, identify the main technical and regulatory barriers and key risks to successful completion of the project and propose appropriate steps to mitigate these risks. If a favourable ethical opinion is required to carry out the project, evidence for approval must be provided before project start or before start of the respective work package. If ethical approval is only required in later stages of the project, it will be a distinct deliverable of the project and part of a funding stage gate.

A clear set of measurements which define the success of the project must be outlined; the key risks to delivering the research and the contingencies that will be put in place to mitigate them identified. Ideally a risk register should be maintained and updated during the timeline of the research.

All projects must adhere to the research governance framework for health and social care. Projects involving clinical trials should follow the MRC guidelines for good clinical practice in clinical trials. Researchers

designing or undertaking clinical trials are also encouraged to consult the Clinical Trials Toolkit. This NIHR resource is an innovative website designed to help researchers navigate through the complex landscape of setting up and managing clinical trials in line with regulatory requirements. Although the Clinical Trials Toolkit is primarily aimed at publicly funded Clinical Trials of Investigational Medicinal Products, it will also provide researchers and R&D staff working on trials in other areas with useful information and guidance.

3.5 Strength of the project team and management arrangements

Arrangements for managing the project must be adequate and roles of team members must be clearly described. Project teams are expected to have included expertise in all areas relevant to develop the proposed device, technology or intervention towards commercialisation. Any evidence of previous product development should be included. It is possible to request resources for external expertise, e.g. consultants for health economics or regulatory development. Teams are advised to appoint a Project Manager to coordinate and oversee project activities.

3.6 Intellectual property (IP) and commercialisation strategy

All background and any potentially arising foreground IP must be described in the application. An initial freedom to operate opinion must be provided, referencing any third parties' rights which may affect the development or commercialisation of your device or technology. A strategy should be put forward as to how third party rights will be managed to allow for further development and commercial exploitation.

IP arrangements between collaboration partners and with consultancies and sub-contractors must be regulated by appropriate agreements. The Lambert Toolkit provides model agreements for collaborations between universities and companies.

Market opportunities, both domestic and global, and the expected impact of the proposed technology or intervention must be described. A strategy for the commercial development of the technology or intervention must be presented. At the end of the project applicants must deliver an exploitation plan, including further IP and commercialisation strategy and potential sources of onward investment.

3.7 Value for money

All requested costs must be sufficiently justified and essential for the proposed work; however, it is expected that all applications aim at achieving real clinical impact, so the requested amount should allow for effective development of the device, technology or intervention. Taking into account the expected benefits of the proposed work and the level of funding requested, the proposal must provide value for money. Any funds requested for NHS support and treatment costs must be appropriate and justified.

3.8 Patient and public involvement (PPI)

The NIHR expects active involvement of patients and the public in the projects it supports. It is anticipated that most i4i projects will have a significant PPI component, which must be clearly and fully described. Applicants should identify the relevant patient/user group(s) for their application and engage with those groups at an early stage. To make the contents of your application and the implications of your project clear to members of the public, but also commissioning boards and reviewers, a plain English summary is required (see **Plain English summary** for further details). Further guidance and PPI resources can be found under **Patient and Public Involvement**.

Section 4: Post Award Monitoring

4.1 Progress and financial reports

i4i will oversee the management and progress of funded projects based on the deliverables and milestones agreed in the contract. An i4i project manager will be assigned to your project. We will use quarterly progress reports, email communication, phone calls and site visits to evaluate progress and the achievement of deliverables and milestones.

As payments will normally be made quarterly in arrears (at the end of March, June, September and December), you will also be required to provide quarterly expenditure reports and an annual statement of expenditure. Universities and NHS organisations will be paid as agreed in the payment schedule. Commercial organisations are required to issue invoices at the end of each quarter; any deviation from the scheduled payment in the contract must be thoroughly explained. Any funding not spent at the end of each financial year may be recovered by the Department of Health or set off against any future payments. In such situations, a new payment schedule will be issued.

When a scheduled payment is linked to a funding stage gate, the project team must clearly demonstrate that the contractually defined milestone has been achieved before any payment will be released. If a milestone is not achieved, payments may be withheld until the milestone has been achieved or an appropriate contingency plan has been agreed.

4.2 Return on investment

The NIHR funds a wide spectrum of health research and is keen to support the exploitation of products or treatments developed under its funded research to ensure that the benefits are not lost to UK patients and there is a return on its investment. The return on investment will depend on the nature of the funded project and the level of funding provided and will be agreed as part of the NIHR commercialisation agreement. Potential forms of return on investment include:

- Patient benefit, such as reduced morbidity or mortality, and improvements in quality of life
- Cost savings, resulting from innovative practice methods developed within the public health and social care systems funded by the NIHR
- Commercial return in the form of a share of revenues generated through IP licensing or consultancy, taking shares in new businesses created, or seeking product or service discounts, thereby generating cost savings
- Public good, such as a demonstration of the impact of NIHR funding on the health and prosperity of the nation

When a project team wants to make commercial use of any IP generated during an i4i project, whether during the life of the project or at any time after the project has ended and is ready for commercialisation, written consent must be obtained by the Department of Health and an income- or equity-based revenue share will be agreed. We may consider requests for early agreement of commercialisation terms. The terms as set out in the NIHR commercialisation agreement will form the basis for negotiation.

Section 5: 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 6: 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 7: 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 8: 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 9: 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 10: 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 11: 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 12: 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 13: 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.

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.

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.