



# National Institute for Health Research

## Invention for Innovation (i4i) Programme

### i4i Connect Expression of Interest

### Guidance for Applicants

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## 1. Introduction

### 1.1 Purpose

The Invention for Innovation (i4i) Programme is a translational funding scheme which advances healthcare technologies and interventions for increased patient benefit in areas of existing or emerging healthcare need. It supports research and development of medical devices, active implantable devices and in vitro diagnostic devices to a point where they are de-risked for follow on investment.

i4i 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. Offering between £50,000-£150,000 over a 6 - 12 month period, its primary aim is to help SMEs get to a point where they can apply for further funding, in particular for a full [i4i Product Development Award \(PDA\)](#), or to support projects at any stage of the translational research and development pathway to further de-risk them for follow on investment. This will enable accelerated development of promising medical technologies, in line with recommendations from the Government's [Accelerated Access Review](#).

### 1.2 Essential Requirements

- Lead applicants must be from an SME.
- Lead applicants must be based in England.
- Projects must be £50,000-£150,000 in value.
- Projects must be 6-12 months in duration.
- Project start dates must be between **01 January 2019 and 01 March 2019**.
- Upon acceptance of i4i Connect funding, applicants agree to be bound by the terms of the [NIHR standard research contract](#) and are expected to sign the contract within 4 weeks of the award notice or the award may be withdrawn.

### 1.3 Eligibility

**i4i Connect funded activities can include:**

- Generation of data to support an application to [i4i Product Development Awards](#) or any other funding stream.
- 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 needs (examples of what we have funded previously can be found [here](#)) at any stage of the translational research pathway, including but not limited to:
  - Product design
  - Manufacturing and scale up
  - User requirement assessment
  - Intellectual property strategy, including freedom to operate analysis
  - Development of commercialisation strategy and market analysis
  - Business case development
  - Studies to provide data relating to safety and effectiveness of a device
  - Health economic model development or analyses and clinical utility studies, looking at a device's real-life implementation and use

- CE marking and other regulatory requirements, including any associated preparation for a future clinical trial application
- Activities associated with the adoption of new technology
- Training associated with the implementation of new technology

**i4i Connect will not fund:**

- Basic research
- Minor or incremental changes to technologies or interventions in current clinical use
- Projects involving small molecule drugs, stem cells or cosmetic products
- Projects that involve work on animals or animal tissue
- 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 on the impact of interventions on service delivery and management
- Products to be used only in hospital information, administration and infrastructure
- Methodologies clinically assessing or validating an existing or newly developed technique or technology
- Professional training
- Development of hospital information, administration, infrastructure and other related software

## **1.4 Applicant Eligibility**

**The lead organisation must be an SME registered in England**, have a staff headcount no greater than 250 and annual turnover no greater than €50 million (including start-up or spin-out companies). Companies must be registered on Companies House prior to applying to i4i Connect to be eligible for funding.

**There is no requirement to have formed a collaboration prior to application**; however, applicants seeking post-award i4i PDA funding will be expected to identify a collaborator/s as a deliverable within the project.

The following types of organisations are eligible to collaborate with the lead SME:

- SMEs with a staff headcount no greater than 250 and annual turnover no greater than £50 million (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

A collaboration of two or more of the above is accepted. 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 if the required expertise or service cannot be reasonably contracted from within England.

We cover 100% costs for SME and NHS trusts and 80% FEC for academic partners. There is no set rules on the split between collaborators, however, as the contracted organisation, the lead applicant

will receive funding payments and would be required to distribute to co-applicants/contractors where applicable.

## **2. Assessment Criteria**

Expression of Interest applications will be assessed against the following criteria:

- **Unmet patient need**
- **Proposed solution**
- **Benefits to patients and the healthcare system**
- **Spending plan**
- **Applicant and team details**
- **Company information**

Each of these criteria constitutes a separate section on the application form and must be addressed according to the guidance below. The maximum word count for each of these sections is 300 words.

### **Unmet Patient Need**

Please provide details on the scale of the clinical problem to be addressed both in the UK and globally and on the limitations in current clinical practice.

### **Proposed Solution**

Please provide a clear explanation of the device, technology or intervention and the benefits it provides over competing technologies. A consideration of the proposed barriers to clinical adoption must also be clearly articulated, as well as a description of the level of innovation of the proposed technology and Intellectual Property (IP) position.

### **Benefits to Patients and the Healthcare System**

Please provide a clear case of how the proposed device, technology or intervention will change clinical practice and provide benefit to patients (such as reduced mortality or morbidity, improved quality of life, reduced misdiagnosis, improved patient outcomes and experiences). Potential cost savings for the NHS should also be provided, along with details of the expected involvement of patient/and or public representatives during the product development process.

### **Spending Plan**

Please provide details of the work to be conducted and how funds will be allocated. This section must adequately address the main objectives of the project. Project objectives must be realistic in terms of time and resources requested.

### **Applicant and Team Details**

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 to the expected project end point.

### **Company Information**

Full details of the company are to be provided including company number, name, address and contact details. A summary of the company's activities should be provided, including, if applicable, other products in development, any synergies of the proposed project with an already existing portfolio, or any other relevant information.

## **3. Application Process**

i4i Connect operates a two stage application process:

### **Stage 1 – Expression of Interest**

### **Stage 2 – 15 page (maximum) Business Plan and a 3 minute video pitch**

The first stage requires applicants to submit an [Expression of Interest form](#). Applicants shortlisted for Stage 2 will be required to submit a business plan with a maximum of 15 pages and a 3 minute video pitch which will be reviewed by our i4i Connect Selection Panel. The i4i Connect Panel comprises of commercial, clinical and academic experts drawn from the existing i4i Product Development Award Panels.

Please note that this guidance document is for Expression of Interest applications only. Shortlisted applicants must refer to the i4i Connect Business Plan guidance document which will be made available on the [NIHR i4i website](#) prior to Stage 2 launch.

### **3.1 Registration and Creating an Application**

Applications to both stages of the process must be submitted online using the NIHR Central Commissioning Facility's [Research Management System \(RMS\)](#). For Stage 1 Expressions of Interest, the lead applicant must register on the RMS, providing contact details and a CV, in order to be able to create and complete the application.

To update your ORCID ID number, log in to the CCF research management system, go to 'Manage my details' and select 'Update CV'. In this section you will be able to login to the ORCID ID site and create an account if you do not already have one. Your unique number will automatically pull through to your Connect application form

### **3.2 Validating and Submitting your Application**

When the application form is complete it must be validated prior to submission. This will highlight any omissions in the form and allow these omissions to be corrected. After successful validation the lead applicant may submit the application. Once you have submitted your application, an i4i specific reference number will be generated. The application will be automatically considered for funding once the funding call closes.

### 3.4 Shortlisting

Assessment of EoI applications is carried out by the i4i Secretariat. Applications are scored against the [EoI assessment criteria](#). EoI applications will be shortlisted and successful applicants will be invited to Stage 2 of the process. Guidance for creating and submitting your business plan for Stage 2 of the application process will be made available on our [website](#) at this time.

### 3.5 Confidentiality

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

### 3.6 Post Award Process

#### Funding Offer

Once your application has been recommended for funding, we will provide feedback as agreed with the Panel. Successful applicants are expected to start their project between **01 January 2019 and 01 March 2019**, subject to satisfactory completion of due diligence and a fully signed contract. **The contract must be concluded by 21 December 2018 or the funding offer may be withdrawn.**

#### Due Diligence

Due diligence is carried out by the i4i Secretariat as part of the funding process to highlight any potential areas of risk or weakness within a project. This allows for recommendations to address risks or weaknesses in the project 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 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 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.

A face to face meeting between funded applicants and an i4i Secretariat member is strongly encouraged to address key questions and allow quick conclusion of the funding contract.

#### Finances

The project finances will be scrutinised to ensure that all requested costs meet the NIHR finance guidelines, any costs that cannot be fully justified may have to be adjusted. The Department of Health and Social Care reserves the right to negotiate the price it is prepared to pay for the work, based on the cost of the application and its operating constraints.

For collaborative partnerships where a partner is providing in kind contributions, the exact nature of the commitment of each partner must be clearly detailed. SMEs and/or early-stage companies may

be required to provide accounts and cash flow forecasts in order to demonstrate their capability to support a project throughout its lifetime.

### **Contracting**

Once due diligence has been completed, the NIHR standard contract will be put in place between the lead organisation and the Department of Health and Social Care; this process will be managed by the NIHR Central Commissioning Facility. Applicants should 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 non-negotiable. Upon acceptance of i4i Connect funding, applicants agree to be bound by the terms of the NIHR standard contract.

As part of the contracting process, a reporting and a payment schedule will be negotiated with the lead organisation, based on the proposed deliverables and milestones. The contract will be managed by the NIHR Central Commissioning Facility; all i4i projects will be actively monitored.

## **4. Post Award Monitoring**

### **4.1 Progress and Financial Reports**

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

As payments will be made monthly in arrears, you will also be required to provide monthly expenditure reports and an annual statement of expenditure. Lead applicants are required to issue invoices at the end of each payment period; 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 and Social Care or set off against any future payments. In such situations, a new payment schedule will be issued.

### **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 Social Care and an income- or equity-based revenue share will be agreed. We may consider requests for early agreement of commercialisation terms. At this time, the terms as set out in the NIHR commercialisation agreement will form the basis for negotiation.

## 5. Key Dates

The key dates for i4i Connect Call 2 are shown below:

<b>Event</b>	<b>Date</b>
Call Launch	07 August 2018
Stage 1 (EoI) Deadline	11 September 2018
Stage 2 Launch (Business Plan)	02 October 2018
Deadline for Submission of Business Plan	23 October 2018
Submission Outcome	November 2018

## 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 encourage discussion of proposals prior to the deadline, although we cannot advise on the specific content of an application.

Enquiries may be made by submitting a [pre-submission form](#) online. Alternatively, the i4i Secretariat can be contacted on +44 (0)20 8843 8015.



## Appendix A: Expression of Interest Form

An example of the EoI application form is provided below:

The screenshot displays the 'Research Management System' interface for 'CC Grant Tracker'. The main title is 'Research Management System' and the user is logged in as 'CC Grant Tracker'. The page is titled 'i4i Connect 2 Expression of Interest 20386'. On the left, a navigation menu includes 'Introduction', 'Research Details', 'Lead Applicant Details', 'Expression of Interest' (selected), and 'Validation Summary'. Below the menu are links for 'System Help' and 'Applicant Guidance'. The main content area is titled 'Expression of Interest' and contains three text input fields: 'Unmet Patient Need', 'Proposed Solution', and 'Benefit to Patients'. Each field has a rich text editor toolbar with options for bold, italic, underline, text color, background color, bulleted list, numbered list, indent, and outdent. The status bar at the bottom of each field indicates 'Paragraphs: 0, Words: 0/300'. Navigation buttons 'Previous', 'Next', 'Save', and 'Save and Close' are located at the top right of the form area. A note above the first field states: 'Please refer to the i4i Connect Guidance located on the [NIHR i4i website](#) for further information.'