NIHR | HealthTech Research Centre
Devices, digital and robotics

MD-TEC
Medical Devices Testing and Evaluation Centre

Work with us

Information and guidance for technology developers on how to collaborate with the NIHR HRC-DDR

This document should be read in conjunction with the collaborative project proposal form.

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Introduction

Who we are

The National Institute for Health and Care Research HealthTech Research Centre in Devices, digital and robotics (NIHR HRC-DDR) is one of 14 HealthTech Research Centres (HRCs) in the UK.

The NIHR funds, enables and delivers world-leading health and social care research to improve people's health and wellbeing and promote economic growth. The HRCs are funded by the NIHR to support safe, effective and efficient translation of new healthcare technologies into routine care for NHS patients and follow-on social care.

The NIHR HRC-DDR is hosted by University Hospitals Birmingham NHS Foundation Trust (UHB). Our work aims to improve the efficiency and success rate of HealthTech uptake into health and social care. We provide a national service to support partners through the innovation ecosystem and build collaborations with expert academics and clinicians from leading organisations and infrastructures.

What we do

We help technology developers towards the regulatory approval and adoption of their health technologies (HealthTech) by generating evidence that will advance its technology readiness level (TRL).

Working in areas of unmet need, we aim to support technologies that align with our core themes and national strategic priorities while improving the expertise and knowledge of the medical device development pathway.

Our strategies, programme and project work are informed by patients and the public and align with NIHR strategies for Equality, Diversity and Inclusion (EDI), research inclusion and sustainability.

Our research themes

Core themes

Our core themes are medical devices, data and digital, and robotics and autonomous systems. Each theme is led by experts in their field who provide expertise and insight into innovation opportunities in these fields.

Cross-cutting themes

We work closely with our partners to accelerate technologies towards regulatory acceptance and clinical adoption by generating evidence within our cross-cutting themes, which are:

- Human factors and usability.
- Health economics and value proposition.
- Regulation.

We are co-located and partnered with the Medical Devices Testing and Evaluation Centre (MD-TEC), a state-of-the-art clinical usability testing facility, that allows technology developers to evaluate their products and prototypes in clinically realistic settings.

Our services

We support collaborative partners with the following services and offerings:

- **Clinical expert reviews**: Innovators can gain expert insight into the unmet clinical need, design and functionality requirements of early-stage health technologies through our clinical expert review process.
- **Grant application support**: We can help innovators to identify suitable funding opportunities and support grant writing by providing insight and feedback on applications. Working in collaboration with innovators, we can develop work packages to generate evidence to increase technology readiness.
- **Human factors and usability testing**: Through collaborative work packages, we can conduct iterative usability tests across the product lifecycle in realistic environments with patient simulators (working human models) within the MD-TEC facility, in compliance with international standards.
- **First-in-human clinical investigations:** We can support the preparation of study documentation and submission for regulatory approval to assess essential safety and performance.
- **Patient and public involvement and engagement (PPIE)**: Our dedicated PPIE Manager offers enabling support, advice and guidance to help innovators engage effectively with members of the public, ensuring the patient voice is heard throughout technology development.
- **Health economics**: Develop value proposition calculations, build optimal pricing strategies and conduct model-based economic analyses with support from our dedicated health economist.

- **Regulatory support**: Understand the appropriate regulations with consideration of evidence generation requirements needed for regulatory approval, where required.

Technology developers who are interested in a partnership can submit a collaborative project proposal during our regular open calls. More information about submitting a proposal is detailed in the Call for collaborative projects and Completing the collaborative project proposal form sections.

Call for collaborative projects

We have recently launched a call for collaborative projects to support technology developers effectively access our services and develop new partnerships for funding applications.

The aim of the process is to identify opportunities where we can add value and work in partnership with innovators to generate evidence to support the future acceptance of their technology.

The collaborative project proposal form and presentation meeting provides a mechanism by which we can understand the status of technologies and the support being sought. We are unable to offer support to HealthTech that is outside of our remit.

Following the presentation meeting, innovators with proposals that are within our remit and suitable for partnership will be provided with further information to begin the process of setting up a collaboration.

Overview

Figure 1 - Overview of the call for collaborative projects process.

Launch and webinar

The open call for collaborative projects is announced on the NIHR HRC-DDR website. The launch webinar, with information about what we do and the process for submitting a collaborative project proposal, will be held online including a Q&A session with our team.

Initial review

Collaborative project proposals are checked to ensure they are in remit. Proposals that align with our research themes and are feasible for us to support will be invited to present their project to representatives from our team and research themes.

Project presentation

Innovators will join an online meeting to present their project, providing information about the technology and potential collaborative work packages. The presentation will be followed by a brief Q&A with our team and clinical representatives. Project proposals will be reviewed based on their innovative opportunity and alignment with our support offering.

Next steps

Following the presentation meeting, all innovators will be contacted to confirm whether we are able to proceed with the collaborative project. Unsuccessful projects may be signposted to other HRCs or organisations that could support the technology.

Launch and webinar

Calls for collaborative projects are announced on our website. For each call, we will hold a webinar to provide guidance on submitting a proposal for a collaborative project and more information about our services.

The webinar is open to technology developers from all sectors and includes a Q&A session to provide an opportunity to ask questions about the engagement process and what to expect from a collaborative partnership. Registration is required to attend the webinar and will open when the call is announced.

Technology developers (innovators) who are interested in a collaborative partnership are strongly encouraged to attend the webinar.

Collaborative project proposal form

Innovators interested in a collaboration should complete a collaborative project proposal form. The information provided in the form provides us with a high-level overview of the potential project for an initial review.

The form will be made available in the Resource library on our website after the launch webinar. Completed forms should be sent to our engagement inbox HRCengagement@uhb.nhs.uk by 11.59pm on the date stated on our website.

For queries related to completing the form, please contact us by email on HRCengagement@uhb.nhs.uk.

Step-by-step guidance on the collaborative project proposal form is detailed below: Completing the collaborative project proposal form.

Initial review

All proposal forms go through an initial review process to check that they are within the remit of the HRC-DDR and that there are no major barriers to a potential partnership. Criteria in this initial review include:

- A due diligence check, to ensure we are able to collaborate with the entity that has developed the technology.
- The technology is checked to ensure it is within the scope of our core themes (devices, digital and robotics).
- The project proposal is checked to ensure it is within the scope of our cross-cutting themes (human factors and usability, health economics and value proposition and regulation) and aligns with the principles of public acceptability, accessibility and inclusion.
- An assessment that the project work is achievable and feasible.

Proposals that meet these criteria are invited to join a presentation meeting to discuss their technology with our team and relevant stakeholders.

Project presentation

Innovators who are invited to present their project will join an online meeting with representatives from our team that have a diverse range of expertise, who will provide their perspectives on the clinical need or technical area and public acceptability, accessibility and inclusion.

The purpose of the presentation is for the innovators to share more detail about their technology and its purpose, and the aims of the collaborative partnership. It provides the opportunity for our team to discuss the project in more detail with the innovators to understand how the partnership could proceed. Our team will also discuss any key points from the written proposal form that they would like to explore in more detail.

Innovators will be provided with a slide deck template containing an outline of the specific information they should include and guidance to the meeting. Presentations should be no more than 15 minutes to allow for a further 15-minute discussion with our team.

The date of the presentation meeting will be available on our website when the call for proposals opens. Following the triage process, we will email innovators who have submitted proposals to confirm their attendance at the meeting with their presentation time slot.

Due to the volume and breadth of proposals we receive, we invite multiple representatives from our team to discuss the projects. However, the purpose of the discussion is to collaboratively explore the potential collaborative partnership, not to act as a critical review panel.

Next steps

Following the review process, proposals that lead to a collaboration will be contacted to begin the next steps of engagement. This will include the organisation of a project ‘kick-off’ meeting with subsequent study management meetings throughout the project duration.

The aims of the kick-off meeting are to:

Introduce the project team, including the Project Research Officer who will lead the HRC contribution to the project.

- Review the objectives of the project and confirm timelines, proposed work packages and the project roles and responsibilities.

- Where grant application support is required, share and discuss a grant proposal support outline and agree the timeline for development and submission of the application.
- Where PPIE support is required, we will also share the PPIE enabling support information.

How we consider collaborative partnerships

The content of the collaborative project proposal form and project presentation meeting will be used to explore the potential collaboration within three overarching themes:

- Clinical need and technical innovation.
- Public acceptability, accessibility and inclusion.
- Alignment with our remit and strategic priorities.

Clinical need and technical innovation

We are particularly interested in projects that support the development of technologies that:

- Address a clear and/or urgent unmet clinical need.
- Offer an improvement on the current standard of care and improve patient outcomes and experience.
- Could feasibly be integrated into clinical practice and support the health and social care workforce.

Public acceptability, accessibility and inclusion

We support proposals with projects and teams that:

- Recognise the importance of PPIE and include PPIE activities in the project with consideration of how diverse perspectives will be sought, including the resource required to achieve this.
- Acknowledge the importance of research inclusion and demonstrate how the technology will benefit patients from diverse communities.
- Have identified any health inequalities that may be caused by the technology and barriers to its accessibility or acceptability and, where possible, how to address these.

We are particularly looking to support technologies that:

- Are likely to be received positively by and are accessible to patients and family carers, including protected characteristics and underserved communities.
- Aim to reduce or address health inequalities.
- Have potentially undertaken some PPIE activities that have informed technology development.

Alignment with our remit and strategic priorities

We support technologies that align with our research themes, which are:

- Medical devices.
- Digital.
- Robotics.

We are particularly interested in collaborating with innovators that have developed technologies that aim to support the three major shifts for the NHS outlined in the Fit for the future: 10 Year Health Plan for England:

- From hospital to community – more care will be available on people's doorsteps and in their homes.
- From analogue to digital – new technology will liberate staff from admin and allow people to manage their care as easily as they bank or shop online.
- From sickness to prevention – reach patients earlier and make the healthy choice the easy choice.

We are also particularly interested in technologies that align with one of the CORE20PLUS5 priority areas, which is a national NHS England approach to support the reduction of health inequalities at both national and system level. The approach defines a target population cohort and identifies five focus clinical areas requiring accelerated improvement, which are:

- For adults:
  - Maternity.
  - Severe mental illness.
  - Chronic respiratory disease.
  - Early cancer diagnosis.
  - Hypertension.
- For children and young people:
  - Asthma.
  - Diabetes.
  - Epilepsy.
  - Oral health.

- Mental health.

Technologies that do not align with any of the three major shifts or CORE20PLUS5 priority areas may still be eligible for partnership where another unmet clinical need has been identified, and the innovation has the potential for significant improvement.

Completing the collaborative project proposal form

General guidance

The form is intended to provide a high-level overview of the technology and proposed project. Further detail about the project and its potential impacts related to the three themes discussed above (How we consider collaborative partnerships) can be shared and discussed during the presentation meeting.

Please complete each section of the form, providing clear and concise information. If there are areas where you are unsure, please indicate that the information is not available or the technology is too early stage for the information to be known. Forms with blank sections are unlikely to proceed to the presentation meeting.

For example, if you are not sure of the regulatory status, please indicate what classification may apply but that guidance is sought in this area. If the technology is at an early or concept stage and therefore no evidence has been generated, please indicate this too.

The proposals will be treated as confidential and not shared outside of our team and internal advisors. However, they are subject to the Freedom of Information Act and the Data Protection Act. Please do not include any commercially sensitive information.

International organisations

We are able to form collaborative partnerships with organisations based outside of the UK. However, it is important to consider how these projects will be funded due to the eligibility criteria of many grants available from UK funders.

Contact details

- Include the contact details of the project lead, their organisation and, where appropriate, information about any parent organisations.
- Indicate the type of organisation the lead contact is from. An SME is defined as an enterprise that satisfies two or more of the following criteria: a headcount

of less than 250, an annual turnover of less than £36m and/or a balance sheet of less than £18m. Larger businesses are classed as 'Industry'.

- If you have previously engaged with the HRC-DDR, MD-TEC or other NIHR HRCs, please indicate this (specifying which HRC if appropriate).
- If the proposed project will require the support of grant funding, specify which scheme(s) the funding is being sought from (for example, NIHR i4i FAST May 2025).
- If you are already supported by grant funding, please provide information about the funding received to date.
- If you have been involved with or benefitted from regional funding or accelerator programmes, such as the West Midlands Health Tech Innovation Accelerator or Local Innovation Partnerships Fund, please indicate which schemes you have been involved with and when this took place.

Due diligence

Due diligences are carried out as part of the University Hospitals Birmingham NHS Trust (UHB) Research, Development and Innovation (RD&I) process to review any published evidence that the entity, any predecessor of the entity or any member of the entity has been associated with relating to a set of 'controversies' within the last five years. These include, but are not limited to, controversies related to:

- Ethics or human rights.
- Litigation or fraud.
- Financial irregularities.
- Illegalities and breaches listed on the ICO register.

Disclosure of any controversies will not automatically decline involvement. The purpose of the due diligence assessment is to inform UHB RD&I in the decision-making process and mitigate potential risk to joint collaborations.

Technology details

Briefly describe what the technology is

Provide a few sentences that describe if the tool is a device, app, software, or other type of technology, what its clinical application is and the target user, how the technology will be used and what the benefit of the technology is. For example:

We have developed a wearable medical device to continuously monitor glucose in the bloodstream and a corresponding app that collects the data to manage diabetes. Patients with type 1 diabetes can use the device and app 24/7 at home for continuous monitoring

and share data with clinicians to improve care pathways. This technology allows continuous, accurate monitoring without the need for finger-pricking and early identification of hypo/hyper-glycemia to allow for immediate action.

What is the technology readiness level, regulatory status and level of evidence generated to date?

Technology readiness levels (TRLs) are ways to describe the maturity of a technology. There are ten levels, with TRL-1 being the earliest and TRL-10 being a technology which is freely available and fully developed for market. The levels are outlined in **Table 1**.

Table 1 - Technology readiness levels.

TRL	Remit	Definition
TRL-1	Basic research	Idea, unproven, concept, no testing.
TRL-2	Basic research	Concept and application formulated.
TRL-3	Pre-clinical research	First laboratory tests are completed.
TRL-4	Pre-clinical research	Small-scale prototype built in a laboratory.
TRL-5	Manufacturing validation and late pre-clinical research	Large-scale prototype tested in an unintended environment or simulation suite.
TRL-6	Clinical research	Performance-scale prototype testing in an intended environment close to expected performance.
TRL-7	Clinical research	Demonstrate innovation operating in an operational environment at pre-commercial scale, gaining regulatory approval.
TRL-8	Regulatory clearance and market preparation	First-of-kind commercial innovation. Manufacturing and integration process outlined, gaining regulatory approval.
TRL-9	Regulatory clearance and market preparation	Full commercial application: innovation available for customers
TRL-10	Post-launch	Innovation marketed: generation of real-world evidence and impact evaluation

The regulatory status of HealthTech is determined by the intended use of the technology and the potential risks to the patient when it is used. If possible, include the regulatory classification of the technology as a medical device or if this is not yet known. Guidance on regulatory requirements and classification for medical devices is available in the NHS Innovation Service Regulation stage guidance document.

Please let us know if you have done any testing or evidence generation to date as this will help us understand the level of support you might need. However, if the technology is at an early or concept stage and no testing has been done, please state this on the proposal form.

Clinical need and impact

What is the unmet clinical need the technology will address, and which patient groups will benefit?

Use this section to describe the problem you will solve with your technology. Include where possible:

- The gap in health and social care where patient outcomes and/or experience could be improved or their needs are not being addressed, where the technology could prevent, diagnose, treat or manage health conditions and/or improve their experience of accessing care and support.
- The patient groups that will benefit if the technology were successfully implemented.
- A high-level estimation of the size of the need, for example, the number of patients or size of population, and any health inequalities.
- The context of where and how the technology will be used, for example benefit of the device if it is successfully deployed in GP practices for use by community nurses to treat women over 65 years old.

Have you engaged with healthcare professionals during research and development? If so, please describe the engagement activities.

We offer clinical expert reviews and other services to provide input from healthcare professionals on health technologies. It is important to outline any engagement that has already taken place with healthcare professionals so we can identify where our services could add value to your project, which may be building on existing data.

If the technology is at an early or concept stage, so there has not yet been any engagement with healthcare professionals, please state this and consider how engagement may benefit the research and development process. If you are interested

in engaging with healthcare professionals, indicate which staff groups you would like to engage with. Please also include if members of your team (not the lead contact) are healthcare professionals.

Market opportunity and competition

What is the standard of care, intervention, treatment or technology currently used in health and/or social care?

Identifying the current standard of care that your technology seeks to improve upon is a key step in developing its value proposition. Understanding how the current intervention, treatment or technology that is used in practice does not meet the needs of the patient helps towards the development of an effective solution to address this gap.

Use this section to provide information about current clinical practice or care pathways for the clinical need you are targeting. If this information is not available, consider if further research into current practices would support the development of value proposition and whether this will be included into the project.

To your knowledge, are there other innovations in development or commercially available that would compete with your technology?

HealthTech is a busy sector, and it is important to be able to define the unique selling point (USP) of your technology. Understanding the technologies that compete with your innovation is fundamental to defining the USP.

Please include, to the best of your knowledge, high-level information on the technologies that could compete with your innovation. These may be commercially available but not yet clinically adopted, in the process of regulatory approval or in development. If possible, please briefly describe why your technology is different from the competing technologies, for example our mobile app provides personalised care through tailored patient support, whereas the current app is a fixed care pathway.

Patient and public involvement and engagement (PPIE) and research inclusion

Have you engaged with patients and the public to develop technology that is inclusive and accessible?

PPIE is fundamental to understanding whether a new health technology is likely to be acceptable and accessible to patients and patient families. Public engagement has an important role in ensuring that technology is inclusive and beneficial for the whole

patient population, including people from diverse communities and the different protected characteristic groups outlined within the Equality Act 2010.

Innovators are expected to engage with patients and communities to understand whether their innovation is fit for purpose from a patient or public perspective, and to apply this feedback during the development of their technology to make patient-led improvements. Further information about the importance of embedding public involvement throughout research studies is available from:

- The NHS Health Research Authority – The Shared Commitment to Public Involvement in health and social care.
- The UK Standards for Public Involvement, developed over three years by a UK-wide partnership including the NIHR.

We offer PPIE enabling support in the form of advice, guidance and resources to help innovators to conduct PPIE effectively. Outlining the activities that have already taken place will help us to understand how we can add value to the project.

Briefly outline the PPIE activity that has taken place, the headline outcome from this work. If PPIE activities have not yet started, please detail how diverse patient and public perspectives will be sought and included during the development process in question below.

How do you plan to involve patients and the public throughout your project in the future?

Please provide an overview of your plans to conduct future PPIE activity throughout the duration of the project. Where possible, include if you are seeking guidance on a specific activity or objective.

Does the innovation directly address any specific health inequalities?

If the innovation aims to directly reduce or address any specific health inequalities, please describe what the health inequality is and how the innovation will reduce it. More information about health inequalities is available from the NHS website.

Have you identified any groups or communities that may face barriers to use or access your technology? How will these be addressed?

Are there any groups or communities that may face barriers to use or access your technology? If so, please provide information on how these will be addressed.

Proposed work packages

Please provide a high-level overview of the support you are seeking based on our themes and services.

Using the list of our services as a guide, briefly describe the support you are seeking from a collaboration. Note that not all technologies will require all the services offered, which is dependent on the stage of technology readiness, evidence generated to date, resource availability and technology type.

If you are unsure about the type of support that is most appropriate for your technology, please describe the desired outcome from the collaboration.

Contact us

For any enquiries about the call for collaborative project proposals, please contact us by email at HRCengagement@uhb.nhs.uk.

Abbreviations

Abbreviation	Meaning
EDI	Equality, Diversity and Inclusion
HealthTech	Health technologies such as medical device, digital technology, diagnostics and *in vitro* diagnostics
MD-TEC	Medical Devices Testing and Evaluation Centre
NIHR	National Institute for Health and Care Research
NIHR HRC-DDR	National Institute for Health and Care Research HealthTech Research Centre in Devices, digital and robotics
PPIE	Patient and public involvement and engagement
RD&I	Research, development and innovation

TRL	Technology readiness levels (see **Table 1**).
UHB	University Hospitals Birmingham NHS Foundation Trust
USP	Unique selling point