NIHR | HealthTech Research Centre
Devices, digital and robotics

Brochure

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Background

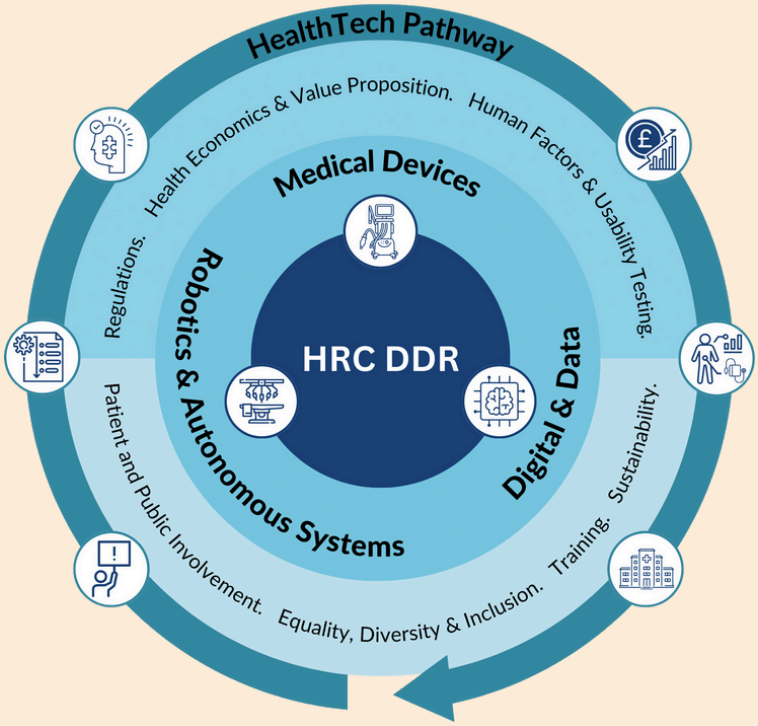
The National Institute for Health and Care Research (NIHR) HealthTech Research Centre in Devices, Digital and Robotics (HRC-DDR) builds on the previous successes of HealthTech research at University Hospitals Birmingham NHS Foundation Trust (UHB). The HRC-DDR is one of fourteen HealthTech Research Centres (HRCs) in the UK, funded by the NIHR and hosted by University Hospitals Birmingham NHS Foundation Trust.

UHB previously hosted the NIHR Trauma Management Healthcare Technology Co-operative (HTC) and NIHR Trauma Management MedTech Co-Operative (MIC). These infrastructures successfully supported evidence generation for medical devices and technologies to support regulatory approval and subsequent adoption.

Introduction

The vision of the NIHR HRC in Devices, Digital and Robotics is to be a national centre of excellence to support the safe, effective and efficient translation of new healthcare technologies into routine care for NHS patients and follow-on social care. This is achieved through a coherent, integrated set of themes led by experts in their fields. Our core themes of Medical Devices, Digital & Data, Robots & Autonomous Systems, and cross-cutting themes of Human Factors & Usability, Health Economics & Value Proposition, and Regulations, cover the major areas of unmet need in the translation of health and social care technologies.

Our work aims to improve efficiencies, and rate of success, of HealthTech uptake into health and social care. The NIHR HRC-DDR provides a national service supporting partners through the innovation ecosystem linking with expert academics and clinicians within our partner organisations and infrastructures, generating evidence to support uptake and adoption. We identify solutions unlikely to be adopted, allowing ideas to 'fail early' and subsequently reduce waste and resources.



The NIHR HRC-DDR plays a key role in identifying unmet needs, supporting prioritised technologies, and generating evidence across Technology Readiness Levels (TRLs) to support the evidence required for regulatory approval and adoption. We continue to improve the knowledge and expertise surrounding medical device development and regulations to provide specialised support for digital and data-driven solutions. Our strategies, programme and project work are informed by patients and the public and align with national strategies for Equality, Diversity and Inclusion (EDI) and sustainability.

Meet The Team

Professor Tom Clutton-Brock

The NIHR HRC-DDR is led by Clinical Director, Prof Tom Clutton-Brock MBE. Tom qualified in medicine from Bristol University (UK) in 1980 and went on to gain an FRCP, FRCA and FFICM. Tom has been a clinical academic in Anaesthesia and Intensive Care Medicine at the University of Birmingham (UK) since 1990 and has maintained a career-long research interest in medical technology. In 2016 Tom was named as as one of the "100 most influential drivers of the health technology revolution, globally" and was awarded an MBE for services to the NHS during the COVID-19 pandemic in 2021. Tom currently chairs the Interventional Procedures Advisory Committee (IPAC) at NICE and the Interim Devices Working Group (IDWG) at the MHRA.

Core Team

Olivia Brookes - Programme Manager

Amy Smith - Portfolio Manager

Hannah Rooney - PPIE Manager

Jeffrey Faint - Project Research Officer

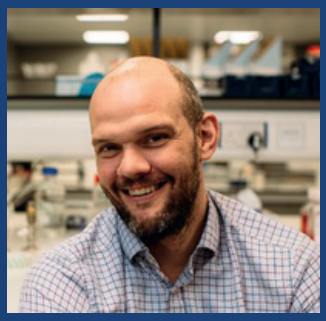
Charlotte Whitehouse - Project Research Officer

Amrita Cheema - Project Support Officer

The core team are vital in delivering the NIHR HRC-DDR's objectives and a wealth of expertise in programme and project management, medical device/ health technology research methods, industry engagement and development of strategic partnerships, and patient and public involvement and engagement.

The team is led by Programme Manager, Olivia Brookes, with support from Portfolio Manager, Amy Smith. We comprise of a Health Economist, several Project Research Officers, including Jeffrey Faint and Charlotte Whitehouse and a Project Support Officer, Amrita Cheema, who are crucial in delivering HealthTech research studies. The team have a dedicated Patient and Public Involvement and Engagement Manager; Hannah Rooney who's role is to ensure diverse insights and perspectives from patients and members of the public are central to the work of the HRC-DDR.

Core Theme 1: MEDICAL DEVICES



Prof Liam Grover
Theme lead and Director of the Healthcare Technologies Institute (UoB)

Prof Tom Clutton-Brock
Co-theme lead, Professor of Anaesthesia and Intensive Care Medicine

Medical devices play a key role in modern health and social care. With a £14.5bn medical device market in the UK today, projected to grow to £21bn by 2027, they represent approximately 89% of total health technology spend in the UK. The MHRA has over 1 million different types of medical devices registered with them. The medical device regulations in the UK are undergoing a major redevelopment, with consultation recently completed on the proposed new device regulations.

Healthcare provision is a significant contributor to the UK's carbon footprint. In 2019, this was estimated to be almost 5% of all UK carbon emissions. Medical devices contribute through discarded packaging, single use plastics and incineration of clinical waste. NHS England has updated best practice to support the NHS achieve their target of net zero by 2045. The HRC-DDR considers this when prioritising HealthTech to support.

NIHR HRC-DDR's Offering:

- Identify unmet clinical needs for medical devices, match unmet needs to potential solutions, and support prioritised technologies.
- Support evidence generation required for UKCA/ CE regulatory approval. Conduct pre-regulatory studies including expert reviews, formative and summative usability studies, first-in-human clinical investigations (preparation, set-up and delivery), and pre-market pivotal studies.
- Conduct post-regulatory real-world usability evaluations.
- Provide expert advice to help navigate the medical device regulations, reflecting the complexities involved with Software as a Medical Device (SaMD) and Artificial Intelligence as a Medical Device (AiMD).
- Support industry understand and develop evidence for supportive NICE guidance, including Medtech Innovation Briefings, Medical Technologies Guidance, Interventional Procedures Guidance, Diagnostics Guidance, Technology Appraisals and Real-World Evidence.

Case Study

SPO-TOO Study

Working in collaboration with SurePulse Medical Limited

Background

The NIHR HRC-DDR (formerly Trauma MIC) collaborated with SurePulse Medical Ltd (SurePulse), a UK-based medical device company, on the development of a new pulse oximeter intended to measure blood oxygen levels (oxygen saturation, SpO2) in newborn babies. Current pulse oximeters used with newborn babies take a few minutes before readings are available and their values can be inaccurate; without quick and efficient care these babies are at risk of poor health outcomes.

The NIHR NIHR HRC-DDR conducted a formative usability study for SurePulse's heart rate monitor (SurePulse VS), where clinical staff highlighted the importance, and unmet need, for SpO2 monitoring in newborn babies. The NIHR HRC-DDR set-up and delivered a clinical investigation in healthy adult volunteers to assess the essential safety and performance of the SurePulse VSP, their novel pulse oximeter, which intends to wirelessly and accurately monitor neonatal SpO2.

Our involvement and support included:

- Identification of a clinical unmet need which supported a successful grant application to Medilink East Midlands
- Development of documentation for a clinical investigation study of 20 healthy adult volunteers and facilitation of PPIE review of all participant-facing documentation. Completion and submission of an IRAS form for the necessary approvals (REC and HRA approval, MHRA Letter of No Objection), and progression through local R&D approvals.
- Delivery of an oxygen desaturation study completed in line with the internationally agreed standard, ISO80601-2-61:2017, within the NIHR Birmingham Clinical Research Facility (CRF). Study delivery involving an inclusive recruitment strategy cognisant of skin tone and gender.

Core Theme 2: DIGITAL DATA

Prof Theo Arvanitis
Theme Lead and Head of Electronic, Electrical & Systems Engineering (UoB)

Dr Jonathan Gregory
Co-theme Lead and Honorary Research Fellow, Imperial College of Science Technology

Data driven care and digitally delivered care, both with and without artificial intelligence (AI), are going to be the cornerstone of healthcare delivery. Approximately 30% of the world's total data volume is generated by the healthcare industry. AI offers solutions that may help to address gaps in workforce, help with administration and triage of tasks, provide quality assurance and support for clinical teams. There is a need to review the evidence for digital, data and AI driven technologies to confirm that they deliver meaningful patient and clinical benefits, and that they can be accommodated into current care pathways. It is also crucial to understand the clinical pathway changes required to leverage the benefit of these products. The NIHR HRC-DDR are keen to be involved throughout the innovation pipeline to support product development and evidence generation so that health and social care access well developed products generating meaningful benefits and that are safe and robust.

NIHR HRC-DDR's Offering:

- Identify unmet NHS needs and work with the wider digital healthcare landscape to respond to these needs, prioritising innovations that will assist the NHS in delivering its health and care priorities.
- Support innovation development throughout the Technology Readiness Levels (TRLs), assist in generating evidence and meeting NHS requirements for adoption within the health and care system. Conduct usability/ human factors studies throughout the development process, first-in-human clinical investigation set-up and/or delivery, premarket pivotal studies, and real-world studies.
- Assess early designs and prototypes, highlighting key future standards to ensure that early decisions will support successful development and deployment.
- Conduct cost-benefit analysis for digital innovations as applied to specific use cases, e.g., using the NICE Evidence standards framework (ESF) for digital health technologies, and risk-benefit assessments considering both technical and clinical assurance.
- Develop new methodologies where current methods and techniques do not provide the framework required.

directed SYSTEMS

Case Study

Hypotension Decision Assist-USE

Working in collaboration with Directed Systems Limited

Background

The NIHR HTC-DDR (formerly Trauma MIC) collaborated with Directed Systems Ltd to develop software called Hypotension Decision Assist (HDA), a new tool to aid clinical decision making by anaesthetists during surgery. Keeping blood pressure stable during an operation is important and a drop (hypotension) can be associated with poorer post-operative outcomes. During surgery, the anaesthetist gives the patient medicines/fluids to stabilise blood pressure, currently relying on their skills and experience to make decisions. HDA provides additional information to assist decision making and uses an algorithm to predict changes in blood pressure likely to occur in the next few minutes, giving the anaesthetist more time to decide how to treat the patient

Our involvement and support included:

- Collaborated on a successful Innovate UK grant application.
- Delivery of a PPIE work package with patient and public advisory group at regular intervals throughout developing the grant application and delivery of the project.
- Delivery of formative and summative usability studies in a realistic, simulated environment to assess the ease of use and understand training requirements. Completed comprehensive reports summarising study outcomes and participant feedback, highlighting minor system amendments early in development, and provided edited video footage.
- Development of documentation for a clinical investigation study of HDA in 30 real-time operations and facilitation of PPI review of all participant-facing documentation. Completion and submission of an IRAS form for the necessary approvals (REC and HRA approval, MHRA Letter of No Objection), and progression through local R&D approvals.
- Delivered the clinical investigation within UHB, concluding that HDA could accurately record patient vital signs and provide helpful information to anaesthetists in real-time.

Core Theme 3: ROBOTICS & AUTONOMOUS SYSTEMS

Prof Simon Bach
Theme Lead and Professor of Colorectal Surgery, Director of Royal College Surgeons (Eng) Robotic and Digital Surgery initiative

Prof Samia Nefti-Metziani
Co-Theme Lead and Director of the Birmingham Robotics Institute, UoB

Robotics and autonomous systems can play a key role in safely and efficiently delivering aspects of health and social care. Waiting times for residential care and delays in hospital discharge have increased by 40% and 180% respectively since 2010, and NHS staff shortages in England could exceed 570,000 by 2036. Long-term sustainability will be delivered through reduced healthcare costs and increased quality; this value-based 'smart healthcare' combines standardisation of care with the use of technology to deliver the best possible outcome at lowest cost. Pharmacy and surgical robots are already used in the NHS but there are many areas where robots, including autonomous robots, could play a much larger role. Their successful deployment in the real world, including operational safety, low-cost and efficacy, needs to be carefully considered. Robotic interfaces also enable digitalisation of physical tasks to yield data that may be collected and evaluated to specify improvements in pathways and care.

NIHR HRC-DDR's Offering:

- Identify priorities for robotics and autonomous systems, working with the wider landscape to respond to NHS needs.
- Explore current training approaches, identify training and methods required for successful robotics and autonomous systems adoption.
- Support evidence generation for regulatory approval and subsequent adoption into the health and care system. Conduct pre-regulatory studies including expert reviews, formative and summative usability studies, first-in-human clinical investigations (preparation, set-up and delivery), and pre-market pivotal studies.
- Conduct post-regulatory real-world usability evaluations.
- Explore the barriers and facilitators to adoption of robots and autonomous systems and disseminate learning to improve translation and uptake efficiency.

Case Study

Health & Social Care Robotics Simulation Centre

Background

The NIHR HRC-DDR (formerly Trauma MIC) successfully leveraged SBRI funding to deliver a detailed specification for a testing and evaluation centre to support robotic development and deployment in health and social care. The project conducted interviews with a variety of stakeholders to understand the current landscape of robotic innovation, identify the unmet needs in robotic development and implementation, and scope a robotic test centre.

Our involvement and support included:

- Arranged and conducted semi-structured interviews with 69 stakeholders and potential end-users within two months to scope a potential robotic test and evaluation centre. Key stakeholder groups included users and purchasers of robotics, wider infrastructure, and other HRC/MICs, allowing a well-informed specification to be developed.
- Transcribed interviews and completed qualitative analysis, whereby key themes and comments were identified.
- Agreed key elements for inclusion in a robotics simulation centre and proposed the centre's outputs for collaborators.
- Delivered a written specification for a highly configurable robotic simulation centre covering a range of health or social care environments. The specification highlighted the need for robotics within health and social care but noted a current lack of infrastructure and processes to support rapid and successful development and implementation. The specification highlighted the need for a physical centre and ecosystem of relevant people to bridge the 'valleys of death' in both gaining regulatory approval and subsequent uptake.
- Pursued discussions with local Government and other funding bodies to support the centre's development.

Cross Cutting Theme 1:

HUMAN FACTORS & USABILITY TESTING

Prof Tom Clutton-Brock
Theme Lead, Professor of Anaesthesia and Intensive Care Medicine

Fran Ives
Co-Theme Lead, Chartered Human Factors Specialist – Health Innovation West Midlands

Reports from medical device regulators worldwide have repeatedly shown that human error in technology usage is a much more common cause of adverse incidents, including patient harm, than actual technology failure. Investigating user errors at all stages of device development is now embedded in most device regulatory systems.

Well-designed usability studies support industry in two important areas. Firstly, the MHRA ask for usability testing to be undertaken and the results included as part of the risk assessment section of the Technical File. These studies, in line with IEC 62366-1:2015, should be performed in a "realistic environment" but "not on real patients". Secondly, early usability studies provide insight into future clinical uptake and greater understanding of the complex realities of work carried out in busy and ever-changing clinical environment. This allows design amendments to be made to support future adoption and for "fail early" decisions. Pre-regulatory studies in simulation, not requiring Regional Ethics Committee (REC) or a letter of no objection from the MHRA, allows rapid and value for money research that doesn't place patients or volunteers at risk.

- Conduct expert reviews by engaging with relevant clinical and non-clinical staff to collect feedback at the concept/early design stage on proposed features and functions, exploring what is important to users.
- Deliver bespoke formative and summative studies for physical and software-based products to test novel health tech in a realistic clinical environment with real end users, in compliance with published standards including IEC 62366-1:2015. Provide formal written reports with design recommendations and a supporting video of participant sessions.
- Engage with patients and the public to develop study protocols and materials and involve patients as end users when testing technologies used in the home.
- Conduct post-regulatory human factors/ usability studies in the real-world.
- Develop novel testing protocols to support real world technology evaluations.

Cross Cutting Theme 2:

HEALTH ECONOMICS & VALUE PROPOSITION

Prof Richard Lilford
Theme Lead, Professor of Public Health & NIHR ARC-WM Director

Prof Tracy Roberts
Co-Theme Lead, Professor of Health Economics & Institute Director for IAHR

Many devices that are developed are not used or do not achieve sustained uptake because any need they meet is not comparable with their financial and opportunity costs. Preliminary health economics evaluation can highlight critical gaps in current evidence and predict the likely drivers that will affect decision making required for funding and uptake into the NHS. Funders are increasingly looking for early-stage health economic work and value proposition calculations, and industry must consider the cost of development and the required return on capital. Work conducted on the value of investment and pricing of devices will benefit companies and investors, resulting in benefits to the economy by channelling investment where it is most advantageous.

Previous work shows that failure to allow for diverse preferences in health economic models can greatly distort cost-effectiveness estimates. It is vitally important that health economic work considers equity and diversity, therefore analysis will be conducted to provide distributional breakdowns of who gains most and who bears the largest burdens by equity-relevant social variables, e.g. socioeconomic status, ethnicity and location, and disease categories.

- Provide health economic consultancy and support for value proposition calculations in grant funding applications.
- Undertake model-based, supply side, economic analyses to compare potential cost effectiveness of proposed interventions with existing alternatives. Examine under what assumptions technology could provide cost-effective.
- Provide value of investment and pricing for companies and investors, working with companies on the implications of the model and the assumptions included.
- Calculate optimal pricing strategies.
- Where applicable, provide distributional breakdowns of who gains most and who bears the largest burdens by equity-relevant social variables.
- Assist companies in the assessment of profitability of sales in other countries with different healthcare funding models.
- Develop new methodologies for health economic approaches related to HealthTech.

Cross Cutting Theme 3: REGULATIONS

Prof Alastair Denniston
Theme Lead, Consultant Ophthalmologist and Honorary Professor, specialising in AI and Digital Health Technologies (UHB & UoB)

Regulations in healthcare are critical to care quality and patient safety. The UK is currently reforming their medical device regulations and updating these to account for the rapid pace of technological development and increase in Software as a Medical Device (SaMD) and Artificial Intelligence as a Medical Device (AIaMD). It is important for developers of technologies to understand, early in development, the relevant regulations and regulatory pathways required for market access and adoption. Utilising close links with the NIHR Incubator we will be able to provide industry with access to a 'safe space' to supply direct feedback to regulators, helping the MHRA, NICE, HRA, and CQC to develop regulations and guidance that is fit-for-purpose, accelerating responsible innovation.

Additionally, it is vitally important to address inclusivity and equity by design. The NIHR HRC-DDR support access to inclusive data resources at regional and national level, helping to ensure that data-driven technologies such as AIaMD are trained and tested on datasets that are diverse and representative of the wider UK population.

- Advise and guide innovators through the appropriate regulations, generating safety and efficacy data to support approvals. This will include outlining what regulations apply to technologies and mapping out the regulatory pathways, e.g. Medical Devices, In Vitro Diagnostics, SaMD, AiMD.
- Communicate and provide training on the latest regulations within Medical Devices, In Vitro Diagnostics, SaMD and AIaMD.
- Support applicants with relevant applications for approvals from regulatory bodies to generate the safety and efficacy data required for pre-regulatory clinical studies.
- Help applicants address inclusivity and equity by design, taking a 'safety for all' approach, including supporting access to inclusive data resources, e.g. PIONEER, INSIGHT, PATHWAY, wider HDRUK network and Secure Data Environments for Research.
- Support regulatory policy that supports responsible innovation, capacity building in regulatory science, and efficient, safe, accelerated approval and adoption of health technologies.

Medical Devices Testing & Evaluation Centre

The NIHR HRC-DDR is co-located with the Medical Devices Testing and Evaluation Centre (MD-TEC). Set up initially with part funding from European Regional Development Funds, MD-TEC is a dedicated medical device and technology usability testing facility. Aligned activity alongside the shared oversight of Clinical Director Professor Tom Clutton-Brock means that the NIHR HRC-DDR and MD-TEC are ideally placed to support companies and clinical entrepreneurs navigating the complex journey of health technology development.

Situated within the Institute of Translational Medicine, MD-TEC is a state-of-the-art facility with a fully equipped operating room with the latest in surgical and anaesthetic equipment, a configurable ward area which can be set up as a critical care unit, an emergency department, or a more general ward. There is a large open space which can be configured as an outpatient clinic, physiotherapy unit or a domestic living space.

Extensive use is made of HD/4K video recording from multiple angles with remote viewing and streaming capabilities. Usability testing involves the latest technology patient simulators and phantoms, minimising study requirements and allowing companies the ability to evaluate product iterations whilst avoiding costly design mistakes and condensing the design time frame. Clinical scenarios to assess medical device usability are simulated and involve healthcare professionals specific to the product's end user and market.

Sian Dunning
MD-TEC Programme Manager

Kulli Kuningas
Project Manager

Lola Afelumo
Research Fellow

Sandra Remsing
Project Support Officer

Patient & Public Involvement and Engagement

Patient and Public Involvement and Engagement (PPIE) is important in improving both the quality and relevance of our research. Throughout the programme we are building upon PPIE developed over recent years as the NIHR Trauma Management MedTech Co-operative (MIC). Technology must be accessible and acceptable and there is an opportunity in the development of new health technologies to tackle health inequalities. Our core HRC PPIE group brings together a diverse membership to shape research priorities, develop PPIE plans and inform research design through meaningful involvement and engagement ensuring that new health technologies meet the needs of patients, clinical staff and society.

The recent equity in Medical Devices independent review highlighted the health impact of potential ethnic and other biases in medical devices and the HRC follow recommendations to develop more equitable technologies. In addition, the NIHR HRC-DDR develops training packages for both patients and the public, industry and clinical partners, enabling informed and non-tokenistic involvement and engagement.

Our vision and priorities for PPIE can be found in our 2024-2029 strategy; outlining meaningful aims and objectives, alongside inclusive and supportive approaches to patients, public and community partners.

Our six core aims are:

Establish a HRC PPIE community that is representative of the diverse population we serve, respecting and championing equality, diversity and inclusion.

Build capacity and capability for PPIE within HealthTech Research Co-develop plans to capture and share the impact of our PPIE activity.

Develop a sustainable PPIE community who feel respected, supported and confident to shape our research and decision-making.

Involve the public in research management, regulation, leadership and decision making.

Work in partnership with patients, the public and local communities to deliver effective and inclusive communications and engagement activities.

The strategy will inform the HRC PPIE agenda from 2024 – 2029 and progress will be reported annually to NIHR.

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Devices, digital and robotics

Building capacity for HealthTech Research

The NIHR HRC-DDR deliver a programme of training to support a range of audiences to increase understanding of regulatory and translational pathways required for HealthTech. Our training streams are tailored towards different target audiences:

Innovator & Industry Education

The innovation landscape and pathway to regulatory approval, commercialisation and adoption is complex. The HRC-DDR deliver workshops, events, providing training and address challenges within the following topics:

- Health Economics & Value Proposition
- Human Factors and Usability testing
- Commercialisation and IP
- Health equality impact of novel technologies
- Regulations
- Patient and Public Involvement and Engagement in the development of Health Tech
- Sustainability considerations

A regular webinar series and the accompanying supporting materials are freely available through the website.

Patient & Public Contributors

The HRC-DDR deliver training and provide support to patients and public contributors as outlined in our **PPIE strategy.**

An induction and tailored training programmes are provided to ensure contributors feel supported and confident to shape our research and decision-making.

Clinician & Academic Education

Birmingham Health Partners (BHP):
The HRC-DDR supports training programmes and placement students in association with BHP, including: Internship programmes, Clinical Academic Research Partnerships and the New Consultant Scheme. Please see the BHP website for further information.

Placements & Work Experience:
The HRC-DDR offers a range of placement and work experience opportunities. We have existing relationships with the National School of Healthcare Science supporting clinical scientist training and students on the Scientist Training Programme. Additionally, we host students from the age of 16 interested in a STEM careers through to post-graduate students in a range of disciplines.

Undergraduate & Postgraduate teaching:
The theme and cross-cutting theme leads of the HRC-DDR continue to teach and supervise undergraduate and postgraduate students in health technology research programmes including:

- MSc Artificial Intelligence Implementation
- Undergraduate Digital Health Technology
- MSc Clinical Trials
- MSc Health economic evaluation, modelling and policy analysis
- MSci Novel Emerging Medical Technology Evaluation and Development.

MedTech Innovation Trainee Skills:
The HRC-DDR also supports the delivery of MedTech Innovation courses for healthcare professionals who are not yet research active but are interested in developing their Healthtech innovation skills and knowledge.

Birmingham Health Partners | Health Innovation West Midlands | MidTECH | Innovate UK Business Connect | ABHI | MEDILINK

NIHR HRC-DDR Offering

The NIHR HRC-DDR deliver a national centre of excellence to support the translation of new healthcare technologies safely, effectively and efficiently into routine care for NHS patients and follow-on social care. We achieve this by supporting industry, clinicians and academia to develop novel HealthTech with the aim of bringing patient benefits and improve healthcare efficiency. We provide the following key support to address unmet clinical needs:

Clinical Expert Reviews
Conducted early in the development process of HealthTech, expert reviews gain expert insight into the unmet clinical need and important design and functionality requirements.

Grant Application Support
Scoping for suitable funding opportunities, reviewing applications, and including work packages of support.

Human Factors Usability Testing
Conducted iteratively throughout the product lifecycle. with patient simulators in realistic environments. Testing completed in line with IEC62366, the reports can be used in regulatory technical files.

First in Human Clinical Investigations
These studies are designed to assess essential safety and performance of technology . Support preparing study documentation and completing IRAS form submissions for regulatory approval.

Patient and Public Involvement and Engagement
Identifying and engaging with relevant patient and public members, ensuring the patient voice is heard throughout technology development.

Health Economics
The NIHR HRC-DDR fund a dedicated health economist who can provide support including value proposition calculations, calculation of optimal pricing strategies and model-based, supply side, economic analyses.

Regulatory Support
Provide advice on the regulatory pathway, considering the appropriate regulations and evidence generation requirements for regulatory approval, where required.

If you are interested in discussing your technology with us please contact us using the details below.

Contact Information:

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