VOLUME. 3
SEPTEMBER 2025

NIHR | HealthTech Research Centre Devices, digital and robotics

MD-TEC Medical Devices Testing and Evaluation Centre

TECHTALK
WITH HRC-DDR

AUTUMN EDITION

Welcome to the third edition of TechTalk. After a busy summer at the HRC-DDR, this autumn's newsletter contains updates from the team and facility, a new case study and exciting opportunities for MedTech. If you have any questions, please get in touch with us using the contact information below.

The NIHR HRC-DDR is a centre of excellence that supports the safe, effective and efficient translation of new healthcare technologies for NHS patients. Our aim is to improve the rate of success and uptake of HealthTech into health and social care.

HealthTechDDR@uhb.nhs.uk hrc-devices.nihr.ac.uk @DDRHRC nihr-hrc-ddr

VOL. 3
SEPT
2025

A MESSAGE FROM TOM...

Many research organisations slowdown in the heat of summer, but not us! The team have been working flat out, tackling complex usability studies, preparing for a challenging first-in-human clinical investigation, and managing multiple grant applications. It's been full throttle all the way.

We are delighted to report success as a co-applicant on another NIHR i4i PDA award and are also collaborating on a second-stage PDA application. Following a great deal of work, Olivia and colleagues have created an efficient triage process to handle the large number of support requests we receive. For those projects that are not the right fit for us, we make every effort to direct applicants to alternative HRCs who may be able to help.

The NIHR response to our annual report was exceptionally positive—thanks and congratulations go to Olivia, Sian, and the entire team for their efforts in making this possible.

As I write, we are in the midst of the inaugural West Midlands Life Sciences Week 2025, where our contributions include presentations on "Usability and First-in-Human Clinical Studies in Medical Devices" and "Digital Technology and the Essential Role of Patient and Public Involvement and Engagement." We have also been providing guided tours of the simulation facility. Members of team have been actively involved in many of the other events across the programme.

Our family of high-fidelity mannequins has expanded once again with the arrival of the new Laerdal SimMan® Critical Care. We are now one of the few centres in the UK with access to such an advanced system. Unlike simpler models with passive lungs, this simulator incorporates piston-based lungs using IngMar Medical's ASL 5000 technologies. Our non-clinical colleagues had a challenging (and entertaining) morning learning to intubate his trachea—most impressively, with great success!

We have recently launched our new series of free online webinars with our first session being "Navigating Complexities of the Medical Device Regulatory Pathway" presented by our Medical Devices Co-Theme Lead, Professor Liam Grover.

Finally, as the "Developing the Workforce" lead for the NIHR HRC Network, we have been involved in surveys and discussions to ensure all 14 HRCs can work together effectively to create a useful, sustainable, and impactful programme of workforce development.

Tom Clutton-Brock

VOL. 3
SEPT
2025

NIHR | HealthTech Research Centre
Devices, digital and robotics

MD-TEC
Medical Devices Testing and Evaluation Centre

OUR TEAM

Tom Clutton-Brock
HRC-DDR Director

Olivia Brookes -
HRC-DDR Programme Manager

Deb Milligan
Deputy Programme Manager

Sian Dunning -
Programme Manager

Amy Smith -
Portfolio Manager

Kulli Kuningas -
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Hannah Rooney -
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Project Support Office

Newton Chagoma
- Health Economist

Jeffrey Faint -
Project Research Officer

Charlotte Whitehouse -
Project Research Officer

LinkedIn®

Connect with us on LinkedIn to stay up-to-date with events, opportunities and other news from the HRC-DDR!

Go to: linkedin.com/company/nihr-hrc-ddr

VOL. 3
SEPT
2025

GOODBYE &WELCOME

We are sorry to say goodbye to our colleague Sandra and wish her every success in her new role. At the same time, we are delighted to welcome Deb to the team! Deb joins us from a previous role in life science innovations and she is looking forward to the pace, variety, and impact of HRC-DDR projects.

We would like to introduce the newest member of our team, Deb.

Deb's role as Deputy Programme Manager is to support the delivery and leadership of the HRC-DDR programme. Deb collaborates with key stakeholders, industry and academic staff to maximise the impact of NIHR HRC-DRR projects and activities. She supports the communications, research inclusion, patient and public involvement and engagement (PPIE) and training strategies of the HRC.

Deb joined the team in August and has a background in supporting the development and commercialisation of research across the biosciences. Deb gained her BSc at the University of Bath with pharmaceutical industry placement and completed her PhD in molecular biology at the Blizard Institute in London.

She previously worked in life science innovations, as a Business Development Manager at Queen Mary University of London and as a Programme Manager at the National Centre for the Replacement, Refinement and Reduction of Animals in Research UK.

WEBINAR SERIES

Thank you to everyone who joined us for the first in our series of discussions with experts on key topics in the translation and adoption of health and social care technologies.

The webinar will soon be available to watch on our website along with other resources for training and education.

COMING SOON

VOL. 3
SEPT
2025

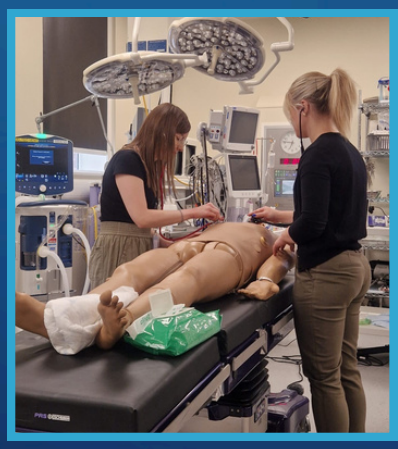
NEW & IMPROVED

Critical Care Simulator - available to use now!

We have recently purchased a SimMan® Critical Care, one of the most advanced emergency care simulators available for medical simulation.

SimMan® Critical Care enables us to provide advanced, realistic clinical scenarios in respiratory care, critical care, and anaesthesia practice. It creates a safe and realistic environment, with the ability to simulate any respiratory condition, enabling us to provide technology developers with a cutting edge simulated clinical environment for usability studies.

Throughout the summer period the team completed Laerdal training to implement SimMan® Critical Care and prescribe multiple clinical scenarios.



Features of SimMan® Critical Care and offerings to innovators:

- **Pre-built lung models:** Access pre-built lung models, each offering variable severity to enhance the breadth of simulation scenarios.
- **Custom lung models:** Create custom lung models tailored to the specification of your technology.
- **Breathing control**: Exercise precise control over patient work of breathing with variable patient effort settings, providing a nuanced and true-to-life experience, including spontaneous breathing response.
- **Ventilation changes:** Switch between ventilation modes, transitioning from volume to pressure control on the same patient without adjusting settings or interrupting the simulation flow.

VOL. 3
SEPT
2025

HEALTHTECH PUBLIC ADVISORY GROUP

HealthTech
PUBLIC ADVISORY GROUP

If you have any questions regarding our public advisory group, please contact PPIE Manager, Hannah Rooney:

h.rooney@bham.ac.uk

We are delighted to welcome four new advisers to our HealthTech Public Advisory Group!

The new starters join our growing Public Advisory Group which provides valuable insights to research projects from a patient and public perspective. Jane, Mala, Mazen and Rebeka were selected for their diversity of lived experience, including their personal experience as patients or family carers.

They complement the group's established membership and provide guidance to researchers about how accessible and acceptable new health technology is likely to be to a public audience.

We are looking forward to working new public advisers and learning from their insights.

Find out more about them via their personal profiles below.

Mazen is a medical engineering master's student from Egypt who brings a younger person's perspective to our research projects. Mazen is passionate about research and how technology can be used to improve patient care.

Mazen's lived experience includes caring for his grandfather who was a prostate cancer patient and accessing services regularly for osteomalacia ("soft bones" where people experience bone pain, muscle weakness and increased fracture risk) as a child/young person.

Mazen Muhammad

VOL. 3
SEPT
2025

OUR NEW MEMBERS

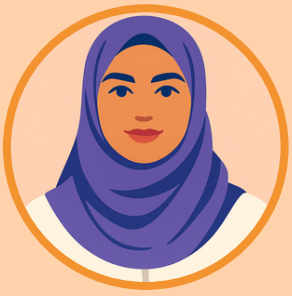
Mala Thapar

Mala brings lived experience as a neurodivergent, South Asian woman with long-term disabilities and physical health conditions, specifically asthma and autoimmune conditions.

Her patient experience includes navigating complex care systems, managing multiple conditions, and helping to tackle the barriers that racialised and disabled people face in accessing equitable healthcare.

Mala has contributed to diverse health research projects in digital health, asthma self-management, and autoimmune conditions, advising on study design, participant materials, accessibility, and intersectionality. She has a particular interest in ensuring research is inclusive, relevant, and meaningful for under-represented communities.

Mala's advisory skills and collaborative work with researchers, health professionals, and fellow public contributors have successfully strengthened communication, equity, and accessibility for patients.



Rebeka Sultana

Rebeka is a parent carer of a child with autism and learning disabilities with significant sensory, language and communication needs. Rebeka has worked with children and young people with profound multiple disabilities, adults with neuro-diverse conditions, and communities whose first language is not English.

Rebeka's experience has taught her a lot about the lives of people living with long-term health conditions and neurodiversity, including what matters most to them and how important it is for them to receive treatment and care that is effective, evidence- based and easy to access.

Rebeka is a Muslim woman with a biomedical sciences background. She has been involved with embedding patient and public involvement within health research for five years.

OUR NEW MEMBERS

Jane Southam

Jane has lived experience of long-term musculoskeletal pain and associated mental health issues, and she is a carer for an older relative who has Alzheimer's disease.

In addition, Jane has seven years patient and public involvement experience with the NHS, universities and her local Midlands Partnership University NHS Foundation Trust (MPFT). She has supported research and implementation projects, shared lived experience, participated in advisory groups and has been a co-applicant.

Jane is also is a lay member at Keele University and the Midlands Public Health RESearch for Health Consortium (PHRESH). Jane recently helped to trial and launch a mobile phone app to assist patients in the self-management of low to medium back pain which is currently being used in GP practices.

Jane is passionate about closing the gap between research and healthcare to enable people to manage their health and wellbeing in a positive way.

VOL. 3
SEPT
2025

NIHR | HealthTech Research Centre
Devices, digital and robotics

MD-TEC
Medical Devices Testing and Evaluation Centre

Case Study

Addressing the Unmet Need in Diabetic Neuropathy: Insights from Experts and Patients on the Sensetic Device

Dynamis MedTech is advancing research into painful diabetic peripheral neuropathy (pDPN) with the Sensetic device, an innovative non-pharmacological treatment designed for patients who cannot tolerate or have exhausted standard therapeutics. The device delivers targeted electrical impulses intended to relieve symptoms to help patients regain quality of life.

Working with the NIHR HRC-DDR to conduct a preliminary expert review and a Public and Patient Involvement and Engagement (PPIE) session has been instrumental in consolidating and focusing the next steps of device innovation.

Unmet Need:

pDPN is a debilitating diabetic complication, causing persistent burning or stabbing sensations, often in the feet (NICE, 2022). Of 589 million people with diabetes worldwide, about 147 million have pDPN, yet current treatments like duloxetine, pregabalin and TENS relieve pain in only half of diagnosed patients; leaving 74 million still affected (IDF Diabetes Atlas, 2025).

The Solution:

The Sensetic device is designed to provide sustained pain relief for pDPN patients, potentially improving sleep and overall well-being. Unlike many in-clinic treatments, the device is designed to be used at-home, eliminating the need for daily hospital visits. The device's core value proposition lies in its promise of long-term relief - **"10 days of treatment delivers 3 months of pain relief."** This would be a major breakthrough compared to existing devices which only provide "in-the-moment" relief.

NIHR HRC-DDR Collaboration:

The NIHR HRC-DDR has supported this project from its inception, guiding its development and ensuring a patient-centric approach. This support was key in the delivery of a preliminary expert review and PPIE sessions, providing valuable insights into the unmet need of the device and potential challenges for consideration.

Expert Review Outcomes:

- There is a clear critical unmet need, while highlighting the importance of demonstrating a clear advantage over existing technology/therapeutics.
- There is a need to address practical factors such as cost, funding, maintenance and at-home usability.
- Participants agreed the Sensetic device offers a promising non-drug, at-home alternative for those with limited treatment options potentially improving patient quality of life.

VOL 3
SEPT
2025

NIHR | HealthTech Research Centre
Devices, digital and robotics

MD-TEC
Medical Devices Testing and Evaluation Centre

PPIE Outcomes:

- Patients valued the convenience of using devices at home, reducing the need for hospital visits, and expressed interest in understanding more about the research and usability of the device (e.g., how easy it is to press the buttons).
- It was suggested that providing video instructions, alongside standard written materials, would better support to patients in learning to use the device independently.

Feedback Implementation:

The expert review and PPIE feedback has been vital in shaping a clear path forward for the Sensetic device. It confirmed the unmet need and validated the appeal of a non-pharmacological, at-home treatment. Based upon the findings, the project team are now focused on:

- Gathering robust clinical data: The feedback highlighted the critical need for evidence to support the device's claims, particularly the promise of long-term relief. This has solidified the decision to prioritise and accelerate clinical trials to generate the necessary data.
- Differentiation from existing devices: The panel's concerns about how the Sensetic device compares to TENS units have prompted a renewed focus on clearly demonstrating its added value. Ongoing feedback from experts and patients continues to inform the development of a clearer narrative and the need of data to highlight these differences.
- Addressing usability and logistical concerns: The practical feedback on cost, maintenance and ease of use (e.g., battery type, bulkiness) is directly informing the device's final design and business model. The team is exploring different power source options, engaging with healthcare system administrators to understand potential funding and maintenance pathways, and planning future usability studies to ensure the device meets patient needs in real-world settings.

HRC-DDR Collaboration - Next Steps

Building on the insights from PPIE session and expert review panel, the project will now focus on targeted work packages to support device development and adoption. The application of an upcoming NIHR I4i Product Development Award will enable a continued collaboration with the HRC-DDR and, if successful, will deliver the following work packages:

Formative Usability Studies: Early-stage testing with patients and clinicians to gather real-world feedback on comfort, usability and functionality, feeding into design refinements.

Summative Usability Study: Comprehensive assessment of the finalised design to ensure it meets all user, regulatory and safety requirements before clinical rollout.

First-in-human clinical investigation: Preparation to conduct a randomised controlled trial to generate robust clinical data proving the device's effectiveness and long-term benefits compared to existing treatments.

Cost Analysis: Develop a financial model outlining cost, maintenance and replacement plans to support engagement with healthcare commissioning groups and demonstrate value.

Device Refinement: Refine to be more user-friendly, comfortable and practical for at-home use. This includes selecting a reliable, easy-to-manage power source and streamlining training for patients and clinicians.

DYNAMIS MEDTECH
BREAK THE CYCLE

References
1. National Institute for Health and Care Excellence (NICE). (2022). Diabetic foot problems: prevention and management (NICE guideline NG19). Available at: https://www.nice.org.uk/guidance/ng19 [Accessed 7 May 2025].
2. IDF Diabetes Atlas. (2025). 11th Edition ed. [online] Belgium: International Diabetes Federation. Available at: diabetesatlas.org [Accessed 15 May 2025].

VOL. 3
SEPT
2025

MEDTECH OPPORTUNITES

Innovate UK Biomedical Catalyst Accelerator - Medtech Venture Kickstarter

The new Innovate UK Biomedical Catalyst Accelerator is an intensive, structured four-month (Nov 2025 to Feb 2026) programme to provide MedTech ventures the confidence to proceed at pace in taking their innovation to market.

Funded by the Innovate UK Biomedical Catalyst, the programme is:

- **FREE** for all ventures selected through a highly competitive application process.
- Welcomes ventures commercialising a medical device to apply.
- Open to ventures from across the UK.
- Aims to de-risk and accelerate the commercial readiness of your medical device.

Successful ventures will participate in weekly activities including masterclasses, workshops, and bespoke guidance from in-house translation experts in regulatory and quality management, health technology assessment, clinical translation and more. Each venture will be matched with a dedicated Expert-In-Residence (EiR), who will act as a strategic navigator with MedTech expertise, supporting your venture.

Important note: Ventures completing the programme will be eligible to apply for a closed feasibility grant competition by Innovate UK.

For additional information please review their website and apply here!

UKRI Innovate UK

Application Form

NIHR | HealthTech Research Centre
Devices, digital and robotics

MD-TEC
Medical Devices Testing and Evaluation Centre

FUNDING OPPORTUNITES

Invention for Innovation (i4i) FAST - September 2025

Status	**OPEN**
Opening Date	10th September 2025
Closing Date	2nd October 2025

The NIHR HealthTech Research Centre Network, invites applications to support the **development of technology-assisted workforce solutions that prevent the progression of a chronic condition to multi-morbidity in community, home and care settings.**

- This is a one-stage commissioned funding opportunity.
- Applications need to be clearly aligned with the Department of Health and Social Care's area of research interest 3 and support at least one of the three critical healthcare transitions identified as government priorities, thereby reducing the long-term burden on the NHS.
- Awards made under FAST September 2025 may receive between £50k to £100k of funding for 6 to 12 months.

For further information and to review the eligibility criteria please go to the **NIHR website**.

Key dates for your diary

- 16th September 2025, 12pm - Application Support, Q&A session
- 2nd October 2025, 1pm - Application Closing
- November 2025 - Application Funding Decision

VOL. 3
SEPT
2025

REGULATION ROUND UP

IMPORTANT

Press release

MHRA announces proposals to improve access to world's best medical devices for patients and to boost economic growth in Britain's med tech sector

The MHRA has announced new steps to secure access for patients to the latest medical technologies available in Europe and other advanced countries. The proposals will reduce duplicative regulatory costs and instead focus on the domestic approvals route (UKCA) on first-in-market innovative technologies.

The MHRA has now published the government's response to its public consultation on future routes to market for medical devices in Great Britain. The MHRA is also announcing its intention to consult later this year on the indefinite recognition of CE-marked medical devices. In parallel, new international reliance routes will be introduced to allow swifter access to medical devices from trusted regulators .

The announcement forms part of our broader regulatory reform programme for medical devices. Read the full article on the MHRA website.

Consultation outcome

Consultation on Medical Devices Regulations: Routes to market and in vitro diagnostic devices

The outcome of the consultation period of the proposed amendments to the Medical Devices Regulations 2002 regarding four specific pieces of assimilated EU law only have now been released.

The consultation ran from 14 November 2024 to 5 January 2025 and received 287 responses in total from various stakeholders, such as medical device suppliers and producers, healthcare professionals, trade associations, and individuals.
View the consultation documents online.

VOL. 3
SEPT
2025

REGULATION ROUND UP

UK MHRA leads safe use of AI in healthcare as first country in new global network

The HealthAI Global Regulatory Network is a new international platform bringing together health regulators to strengthen oversight of AI in healthcare. It aims to build trust, improve safety, and accelerate responsible innovation through shared learning, joint standards, and early warnings of emerging risks. Members will also have access to a global directory of registered AI health tools to support transparency and collaboration.

Ten 'Pioneer Countries' from diverse regions are being invited to shape the Global Regulatory Network. Each will work with HealthAI to develop stronger regulatory frameworks, support local innovation, and ensure AI technologies meet high standards of safety, effectiveness and equity.

AI Airlock is the world's first regulatory sandbox for AI medical devices, led by the MHRA. The pilot phase supported four breakthrough technologies to test how they perform in real-world settings under regulatory oversight.

More information can be found here.

VOL. 3
SEPT
2025

TEAM ACTIVITIES

Translational Research Symposium at the University of Birmingham

We recently attended the Translational Research Symposium which highlighted the breadth and impact of UoB research and its application for new medical techniques or technologies. Academics, clinicians and professional services from the University and its NHS partners shared their insights to foster a stronger translational research culture.

Key highlights for the team were discussions about navigating the complex regulatory landscape in product development and device commercialisation, including a demonstration of the the digital tools available to support medical device innovators.

West Midlands Life Sciences Week 2025

West Midlands Life Sciences Week is a pioneering programme that brings together professionals, researchers and businesses shaping the future of life sciences. The initiative explores the latest advancements, medical breakthroughs and innovative technologies. We took part in different events throughout Life Sciences Week 2025 in early September, sharing our work and connecting with stakeholders across the health technology landscape, including:

- Welcoming clinicians, researchers and hospital staff into the MD-TEC to showcase our facilities and capabilities during an open house.
- Connecting with innovators at the launch of the Birmingham Health Innovation Campus.
- Discussing the latest MedTech updates at the Innovation Day held in Partnership with Medilink Midlands at Aston Villa FC.
- Highlighting the regional impacts of the West Midlands Health Tech Innovation Accelerator in supporting the life science ecosystem and wider UK economy.

Would you be interested in participating in a clinical study assessing a new medical device measuring blood oxygen levels?

If you are a healthy adult aged 18 - 55 you may be able to participate.

The MD-TEC team together with NIHR HRC-DDR is based at the Queen Elizabeth Hospital site of University Hospitals Birmingham (UHB) NHS Foundation Trust. We support the development of new medical technologies and devices.

We are looking for healthy adult volunteers aged 18-55 to participate in a study assessing the accuracy of a new blood oxygen measuring device (pulse oximeter) which goes inside the ear. We aim to recruit an equal number of participants across all skin tones to ensure the device works accurately and effectively for everyone.

The study will involve having your blood oxygen levels temporarily altered (a process called controlled desaturation). Several small blood samples will be taken through an arterial tube in your wrist. You will be closely monitored and supported throughout the study in hospital by NHS medical staff. The study has been approved by a Research Ethics Committee.

Location:
Queen Elizabeth Hospital (UHB), Clinical Research Facility, Birmingham, B15 2TH

Duration:
1 on-site visit
3-4 hours

Expenses:
Reasonable travel expenses
£100 shopping voucher

October to December 2025

For further information, please contact us!

0121 371 8537

HealthTechDDR@uhb.nhs.uk