

Pioneering UK partnership to accelerate patient access to new neurotechnologies

A pioneering new partnership between Newcastle University and the Medicines and Healthcare products Regulatory Agency (MHRA), funded by the Advanced Research and Invention Agency (ARIA), will develop clear and comprehensive guidance on the regulation of neurotechnologies, designed to accelerate access to these cutting-edge devices for UK patients.

Novel neurotechnologies are ushering in a new era of understanding the human brain and treating neurological conditions. Realising the potential of neurotechnology to improve health, further scientific discovery, and deliver economic benefit, requires the UK's regulatory pathways to enable global scientific study and translation of new neurotechnologies.

This project will undertake a comprehensive review of existing regulations and guidance pertaining to neurotechnologies, such as implanted brain-computer interfaces, neurostimulators and wearables and will develop new guidance for emerging neurotechnologies. This will ensure the UK's capacity to rapidly and safely support current and next generation neurotechnology innovation.

The partnership will draw expertise and insight from a consortium of stakeholders throughout the UK and global neurotechnology ecosystem, including people with lived experience, academics, clinicians, charities and industry.

The partnership is led by Principal Investigator, Dr. Luke Bashford, Newcastle University and Newcastle Hospitals NHS Foundation Trust, and co-investigators Prof. Anne Vanhoostenberghe, Kings College London and Prof. Tim Denison, Oxford University.

Dr Luke Bashford said:

“We will ensure the regulatory pathway for translating neurotechnology innovation to widespread patient benefit is relevant, appropriate, and easily accessible to all stakeholders. It demonstrates the UK as a neurotechnology leader from first-in-human and research studies to pivotal and post-market clinical trials. It should be seen as a global invitation to advance neurotechnologies here in the UK.

Our team at Newcastle University and Newcastle Hospitals NHS Foundation Trust are proud to lead this truly collaborative project and deliver the outputs openly and equitably. This work demonstrates the community's continued commitment to research and ensuring people can access the latest clinical care for neurological conditions.”

The initiative aligns with the MHRA's focus on UK life sciences and patient safety and addresses key recommendations of the Regulatory Horizons Council: Neurotechnology Regulation Report (2022).

Mark Grumbridge, Head of Clinical Investigations, Science Research & Innovation group, who leads the initiative within the MHRA, said:

“The UK is uniquely positioned to lead in neurotechnology – combining world-class neuroscience and med-tech with the NHS, which provides an unparalleled platform for research and real-world application.

To unlock the UK’s full potential, we must strengthen understanding of existing regulatory frameworks so that developers are clearer on how to get their products to market as quickly and safely as possible.

This new partnership will help do exactly that, and I look forward to working with researchers, industry, policymakers, and patients to help create the conditions for a thriving neurotechnology ecosystem that delivers real benefit for patients.”

Jacques Carolan, Precision Neurotechnologies Programme Director at ARIA, said:

“Pioneering new neurotechnology is not just about research and development; we also have to pioneer the pathways that bring it to the world safely and effectively. What makes this project so exciting is that it brings everyone to the table—researchers, clinicians, industry, and the regulator, and most importantly, the patient perspective and experience. This is how we will build a world-leading ecosystem founded not just on brilliant science, but on trust, clarity, and a shared vision for improving lives.”

For more information about the partnership, to explore ways to be involved and/or contribute please contact Dr Luke Bashford (luke.bashford@newcastle.ac.uk).