



MHRA Strategy to 2030: What it means for innovators and academics

Our 2030 Strategy sets out how we will support the safe and timely development of innovative medicines, medical devices and technologies, while maintaining high standards of safety, quality and effectiveness. For innovators and academics, this means a clearer and more predictable regulatory environment, with earlier access to regulatory expertise and greater clarity on the evidence needed to support development.

We want to engage with researchers and innovators earlier to make regulatory requirements clearer. Through scientific advice, more flexible approaches, and closer alignment with the wider health system, we aim to make it easier to navigate the pathway from research and development through to approval and patient access.

We will work with universities and research organisations to build the evidence, skills and regulatory approaches needed for the next generation of healthcare innovation. By sharing learning, supporting regulatory science and working with academic and industry partners in the UK and internationally, we aim to create an environment where promising new ideas can be tested, developed and translated into safe and effective products for patients.

Supporting clinical practice across the product lifecycle

Our priority What it means for innovators and academics

Earlier support for emerging innovation

We will strengthen horizon scanning and introduce an **MHRA Innovation Accelerator**, helping innovators navigate the regulatory system and connect earlier with the right expertise and support.

New ways to test novel approaches

We will continue to introduce **regulatory sandboxes** where innovators and regulators can generate evidence and test new approaches safely. As well as further developing our AI Airlock programme with its focus on AI as a Medical Device technologies, we will also continue to develop our regional AI sandboxes for pre-market products and introduce a sandbox focussed on the use of AI in pre-clinical testing.

Stronger regulatory science partnerships

We will work with partners to continue to develop the **UK Centres of Excellence for Regulatory Science and Innovation (CERSI)**, drawing on academic and clinical research strengths to develop regulatory approaches for emerging technologies.

More innovative approaches to evidence and clinical research

We will expand our ability to assess **in-silico evidence**, publish guidance on digital twins and enable hybrid trials using digital twins and synthetic data. We will also support human-relevant methods, including organoids and organ-on-a-chip technologies. This will contribute to the government's ambition for the UK to rise from fifth to third globally for Phase 1 clinical trials **by 2030**.

Support for priority technologies

We will strengthen expertise in emerging areas including oligonucleotides, AAVs, CAR-T, mRNA technologies and cancer immunotherapies, alongside real-world data, AI, computational modelling and innovative biomarkers. **In 2027**, we will publish an **AI Medicines Development Action Plan**, setting out a coordinated UK-wide approach to AI across medicines development.

A more connected research and health system

We will work with UK partners to better connect regulation, research, health technology assessment and adoption. Closer alignment between MHRA licensing and NICE value assessment could enable patients to access some new medicines **three to six months earlier** than under previous sequential pathways.

