



MHRA Strategy to 2030: What it means for the life sciences industry

Companies developing medicines and medical technologies expect a regulatory environment that is rigorous, predictable and able to keep pace with scientific change. Our strategy aims to provide greater clarity and consistency across the development pathway, supported by earlier regulatory advice, transparent service standards and more joined-up working across the UK health system.

As advanced therapies, precision medicines, and AI-enabled technologies transform healthcare, we will adapt our regulatory approaches while maintaining robust standards of safety, quality, effectiveness and performance. We will strengthen expertise in priority technologies, improve the regulatory route to market and make better use of real-world data to support proportionate regulation throughout the lifecycle of medicines and medical devices.

Early engagement from industry will be essential. By sharing insight into emerging technologies, evidence challenges and development pipelines, companies can help us anticipate regulatory needs and provide clearer guidance. We will also work more closely with health system and international partners to reduce unnecessary duplication and help safe, effective medicines and medical technologies move more smoothly from development into patient care.

Supporting the development of medicines and medical technologies

Our priority

What we will deliver and what it means for industry

A faster, more predictable regulatory service

We will introduce new service guarantees, including initial assessment of first-in-human clinical trials within 14 days, first assessment of medicines licensing applications within 90 days, and Scientific Opinions within 90 days. Companies will be able to book licence application slots in advance, access expanded customer support and use an optional new customer relationship service offering concierge-style support. Eligible applicants will receive rebates if specified performance guarantees are not met.

Strengthened scientific and regulatory advice

We will introduce formal Scientific Opinions, providing companies with a documented MHRA view on a specific regulatory question. This will help companies make development decisions with greater confidence and demonstrate how earlier advice has been addressed in a subsequent application. We will also offer lighter-touch advice for more focused questions.

Pragmatic evidence requirements for innovative products

We will take a proportionate approach to evidence, identifying the most appropriate sources for new and innovative products while maintaining robust standards. We will begin by applying this approach to rare disease therapies, where small patient populations can require tailored evidence, including appropriate use of surrogate markers, real-world evidence and synthetic data.

New support for innovation

We will strengthen horizon scanning and introduce new initiatives including an MHRA Innovation Accelerator, Regulatory Innovation Corridors, regulatory sandboxes and a UK Centres of Excellence in Regulatory Science and Innovation (CERSI) model for regulatory science. These will help identify promising technologies earlier, test new regulatory approaches and connect developers with the right expertise earlier. See our explainer for Innovators

Specialist expertise in priority areas

We will build specialist expertise in areas where unmet patient need, UK readiness and national scientific strengths align. These include oligonucleotides, Adeno-Associated Viruses (AAVs), cell and gene therapies, mRNA technologies, cancer immunotherapies, AI-enabled products, advanced diagnostics, robotics, novel implants and neurotechnology. We will also strengthen capability in real-world data, digital twins, synthetic data, computational modelling and innovative biomarkers.

Modern, proportionate MedTech regulation

We will modernise medical device regulation, improve device identification and traceability, introduce new international reliance routes and, subject to parliamentary approval, increase the MHRA's assessment capacity. New initiatives will include an Early Access Service for Devices, expanded Predetermined Change Control Plans for AI-enabled devices and an MHRA Centre for AI and Digital Health. See our explainer for the MedTech industry.

Innovative evidence and clinical research

We will publish guidance on digital twins, expand our assessment of in-silico evidence and enable hybrid trials using digital twins and synthetic data. A new AI-enabled Clinical Trial Protocol Checker will help sponsors identify common reasons for non-acceptance before submission. We will also support appropriate use of human-relevant methods, including organoids and organ-on-a-chip technologies.

Stronger national partnerships

We will work with partners across the UK to better connect regulation, research, assessment and adoption. This includes closer working with the National Institute for Health and Care Excellence (NICE), the National Health Service (NHS), the Health Research Authority (HRA), the National Institute for Health Research (NIHR), the Health Data Research Service (HDRS), the Office for Life Sciences (OLS) and the devolved governments, helping companies navigate a more coordinated life sciences system.

Greater international alignment and partnership

We will aim for **convergence with our main international partners wherever possible, with divergence only where there is a clear purpose**. We will expand recognition, reliance and aligned assessment routes, with the ambition that companies can prepare high-quality submissions once and use them across trusted jurisdictions. We will also deepen collaboration through initiatives including the MHRA-United States Food and Drug Administration (FDA) Pioneer Programme, join the Medical Device Single Audit Programme, and strengthen the UK's influence in international forums, including by chairing the International Medical Device Regulators Forum in 2029.

More proportionate compliance

We will assess Outcomes Based Cooperative Regulation, exploring whether organisations that demonstrate sustained, proactive compliance can face a lower regulatory burden. By 2030, we will routinely use data and technology to focus inspections and compliance activity on areas of greatest risk.

More active safety monitoring

Working with the Health Data Research Service, we will use linked health data, genomics, real-world evidence and AI-enabled analysis to move towards more continuous safety monitoring. We will also modernise device registration and incident reporting and begin introducing a more conversational Yellow Card reporting interface from 2027.