

Regulatory Innovation Office

One Year On

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01: Foreword from Our Chair

It is with great pride that I introduce the Regulatory Innovation Office’s (RIO) report on our first year’s work.

The Government set up RIO last October with a clear remit: to ensure that regulation enables innovation in science and technology rather than obstructing it. New technologies are key to future growth, higher living standards and better public services. They should not be held back by regulations which protect old ways of doing things. Our task at RIO is to work with regulators so that they are tech positive and attach proper weight to the benefits technology and innovation can bring.

Over their first twelve months, the RIO team have worked energetically to turn a bold idea into an organisation which now occupies a unique place in the UK’s science and technology landscape. Since my appointment as Chair in March 2025, I have been working with officials and ministers to shape the direction of this new organisation.

Working in close partnership with regulators, outside experts, government departments, technology entrepreneurs, and investors—to whom we express our sincere thanks and gratitude—we have translated ambition into action, and action into results. We have heard at first hand the obstacles facing innovators and followed up on what we have learnt. This work has been iterative, creative, and constructive. Regulators themselves want to tackle these obstacles, and we can provide advice, support, encouragement and sometimes funding.

We have invested in regulators’ science and tech capabilities. Through the Regulators’ Pioneer Fund and AI Capability Fund, the RIO is backing pro-innovation regulators to experiment, to speed up processes with artificial intelligence (AI), and to collaborate with businesses to build expertise regulating at the scientific frontier.

We have started with four priorities: space, engineering biology, drones and other autonomous technology, and AI in healthcare. We have promoted pro-innovation reforms, accelerating the path to market for innovative businesses as diverse as novel foods and drone deliveries for the NHS. This is just the beginning. These first steps have given us invaluable lessons which will serve to amplify our impact going forward.

The next phase of the RIO will involve even deeper collaboration, sharper focus, and greater ambition. We are upgrading our internal capacity and improving our mechanisms for listening to and addressing the needs of technologists and businesses. Benefiting from relationships across government and industry and drawing on the expert advice of our excellent Regulatory Horizons Council, we will help to reshape the regulatory landscape to make the UK the partner of choice for investors and innovators.

This report is both a reflection and a call to action. We would be delighted to hear from readers about regulatory barriers that you have encountered in science and technology so that we can consider ways to assist you.

With your help, and the efforts of the ministers we serve and the regulators we work with, I am confident we can position the UK as the global leader in regulatory innovation. Doing so will deliver enormous benefits for the British people.



The Rt Hon Lord Willetts FRS
Chair, Regulatory Innovation
Office

+150

Businesses engaged with to surface regulatory barriers across Science & Technology

+40

UK Regulators worked with to unlock regulatory barriers to innovation

“The first year of the RIO has been a testament to progress. A small, nimble team with strong leadership has been able to cut through the regulatory sludge startups often get trapped in. There is plenty more to do and Startup Coalition is glad to see that clear front door emerging. The groundwork has been laid now we can really start pushing on the gas.”

Startup Coalition

“The Regulators’ Pioneer Fund has been instrumental in helping the UK Civil Aviation Authority explore how it can enable innovators to develop new products and services..”

CAA

Highlights from our 1st year

+£100bn

of combined Gross Value Added (GVA) across our priority sectors...

4



Highlights so far...

In Space a RIO supported sandbox that is enabling safe testing of new mission types to help unlock a £2.7 billion market by 2031

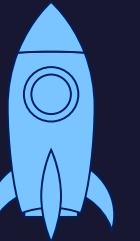
In Drones, RIO’s work is keeping drones in the skies for longer to enable NHS blood deliveries to be cut down from +30 minutes by van to just 2 minutes by drones

In AI in Health, funded by the RIO, the MHRA is developing AI-powered tools to help regulatory experts make faster, decisions, so patients can access safe, effective treatments sooner

In Engineering Biology RIO-funded projects are expected to cut novel foods approval timelines by 50%

What we’re doing next...

In Space, we are prioritising space and satellite services, which support £454 billion of UK economic activity, and position the UK to capture a small-satellite market expected to reach \$12 billion by 2030¹



RIO will continue unlocking the projected £103 billion (by 2050)* to the UK economy from future flight technologies by expanding drone use through pro-innovation regulation



In AI in Health, RIO is focusing on unlocking one of drug development’s biggest challenges: 90% of drugs fail in clinical trials²



In Engineering Biology, we are targeting novel therapeutics, spanning innovations that can tackle difficult to treat infections or diseases like cancer



Our mission is to transform the
UK's approach to regulation so
that it becomes the best place
in the world to invest in and
commercialise new
technologies

02: About the RIO

Who we are and what we do

In October 2024, the Regulatory Innovation Office (RIO) was established to deliver a key government commitment: transforming the UK's approach to regulation so that it becomes the best place in the world to invest in and commercialise new technologies.

By identifying and working with regulators to tackling regulatory barriers and support a more agile regulatory environment, the RIO aims to give UK science and technology businesses the confidence and certainty they need to attract investment, scale up, and develop the next generation of products and services right here in the UK.

As set out in the UK's Modern Industrial Strategy and Chancellor's March 2025 Regulation Action Plan, it is critical that our regulatory system adapts to keep pace with innovation.³ As such, the RIO is key to delivering government's regulatory reform agenda.

Today, HM Treasury and the Department of Business and Trade are publishing an update to the Plan, setting out the tangible progress that has been made to deliver that vision and where Government will go further and faster to do so.⁴

Within the cross-government drive to reduce regulatory red tape and encourage pro-growth regulation, RIO provides support to regulators, departments and businesses. It works with regulators to ensure regulation is pro-innovation and supports fast-developing, high growth potential, science and technology sectors while protecting safety and preserving regulatory independence.

In its first year, RIO has become a catalyst for change within the UK's regulatory landscape, helping British businesses bring world-leading products and services to market faster and more safely.



02: About the RIO: Continued

The RIO addresses regulatory barriers to innovation, responding to the following challenges identified by the **Government Chief Scientific Adviser in 2023**:⁵

Capacity and skills:

Regulators need the bandwidth and funding to engage in innovation-enabling activities like regulatory sandboxes. They also need the skillset and expertise to tackle regulation of novel technologies and use digital and data to make regulation more effective

Our work with the Food Standards Agency (FSA) gets to the heart of this challenge. Our support and funding have led to the launch of the FSA's Market Authorisation Innovation Research Programme in September 2025 – boosting their scientific knowledge on assessing the safety of innovative foods and providing direct support to innovators on how to apply for approval in Britain without compromising safety.⁶

Fragmentation:

Overlapping remits between regulators can mean innovators face a challenge in knowing where to go, particularly for general purpose technologies like AI, where one application could have multiple uses, in domains overseen by multiple regulators

The RIO is supporting the Digital Regulation Cooperation Forum (DRCF) – a collaboration between Ofcom, the Information Commissioner's Office, the Financial Conduct Authority and the Competition and Markets Authority – to provide a joined-up service to help businesses navigating digital regulation. On 4 September, RIO provided the DRCF with £800k funding to prototype a unified digital library.⁷ This library will give innovators 'one stop' access to digital policy and regulations, making the system easier to navigate and helping to free up businesses to focus on growth and innovation.

02: About the RIO: Continued

The RIO addresses regulatory barriers to innovation, responding to the following challenges identified by the **Government Chief Scientific Adviser in 2023**.⁵

Pacing:

Regulatory systems often lag behind the speed of technological development, but regulating too early can stifle innovation. Effective regulation lies in striking the balance between the two. The RIO sponsors the Regulatory Horizons Council (RHC), who support regulators and departments to understand when and how to regulate new technologies

The RHC's Quantum report positioned the UK as the first country in the world to set out a pro-innovation regulatory framework for quantum technologies and led to establishing the Quantum Regulators' Forum to coordinate regulatory engagement and enable collaboration.⁸

Risk aversion and incentives:

Regulators are rightly focused on the safety of activities that fall under their remit and play a critical role in ensuring that unsafe activities never pose an undue risk to the public. But it is important that regulators act to balance these core responsibilities against the goal of enabling innovative, socially positive use cases

The Civil Aviation Authority (CAA) recently approved, and then extended, the UK's most complex drone trial, flying blood samples across central London.⁹ In consulting stakeholders, the CAA placed particular weight on the clear public benefit arising from a project that supports the NHS, and the potential for it to act as a trailblazer for wider adoption of an innovative approach to public service delivery, even though this carried the risk of generating an adverse stakeholder reaction or potential appeals against the approval, for example in relation to noise complaints. The CAA is now working with RIO, DfT and other colleagues across government to take this innovative project from a trial phase to national scale.

02: About the RIO: Continued

Since our launch, the RIO has focused primarily on four fast-growing technology sectors. These sectors offer significant potential to drive economic growth and improve lives:

- Space
- Drones
- Artificial Intelligence in Healthcare
- Engineering Biology

Our work supports the Treasury and Department for Business and Trade to deliver the government’s key goal of reducing the complexity and burden of regulation, including the commitment in the March 2025 HMT Regulation Action Plan to cut the administrative costs for business by the end of the Parliament.¹⁰

We do this through:

Funding Regulatory Innovation: We fund regulators and local authorities to trial new and innovative regulatory approaches, enabling businesses to bring tech enabled products and services to market quicker and encouraging business investment. In October 2025, the RIO awarded circa £8.9 million to successful applicants of the Fourth Round of the Regulators’ Pioneer Fund (RPF), which will deliver pioneering projects.

Through the **Regulatory Horizons Council (RHC)**, we take a systems-thinking approach to regulatory reform. The RHC identifies future regulatory needs to support the safe and rapid introduction of new technologies.

Building regulator capability: We also invest in building regulator capability, helping regulators adopt tools like AI to speed up approvals and reduce compliance burdens, with £3.6million awarded this year through our AI Capability Fund.¹¹

Business Engagement: We listen to businesses to clarify the regulatory challenges holding back their products.

Strategic Support: We support ministers in engaging with regulators on enabling innovation (for example the April 2025 letter from Ministers Vallance and Kane to the Civil Aviation Authority on priorities for the drone sector).¹²

Deep Dives: We work closely with regulators and businesses to identify and unblock specific barriers in priority areas of the economy.

02: About the RIO: Continued

We draw lessons from our work to support wider government efforts to drive system-wide regulatory change, for example:

- **Scaling successful models** – insights from sandboxes or pilots can be applied across regulators and sectors. This could include working with sponsor departments, HMT and DBT to take forward changes to regulation or interpretation of regulations from sandbox outcomes.
- **Driving regulatory updates** – when we identify regulations that may need sector specific amendments, we work with sponsor departments, DBT and HMT to prompt wider reviews across similar regulations, ensuring that reforms are proactive, not reactive.
- **Measuring impact** – using insights and metrics from our work, we monitor and inform departments and regulators on regulatory performance and help scope future priorities.

We are committed to working with regulators to speed up decisions and driving a culture of innovation within the UK's regulatory system, while preserving the independence of regulatory decision-making. By doing so, we are helping to ensure that the UK remains at the forefront of global innovation, delivering economic growth and providing new opportunities for the British public to benefit from science and technology.



PRIORITY SECTOR IMPACT

SPACE

DRONES

AI IN HEALTHCARE

ENGINEERING BIOLOGY

SPACE

“The willingness of RIO to listen to operators and drive targeted, practical reform is exactly what the UK space sector needs. Removing repetitive information requests would be a win-win, easing the burden on both industry and the regulator, and ensuring licensing focuses on the satellite mission itself. It’s a clear example of how smart regulatory reform can support growth and maintain the UK’s leadership in a competitive global space market.”

Eutelsat (OneWeb)

03: Priority Sector Impact – Space

Space plays a vital role in our economy and our national security. Every day, satellites orbiting above us help keep the UK connected, safe, and informed – enabling everything from accurate weather forecasts and GPS navigation to global communications and scientific breakthroughs. The UK is well-placed to seize this economic opportunity, with a thriving industry spanning satellite manufacturing, launch services, and data-driven applications. Reflecting this, the Government’s Industrial Strategy identifies space as a frontier industry, with the sector set for significant growth: one projection sees the global space economy growing from \$596 billion in 2024 to \$944 billion by 2033.¹³

Regulatory barriers

Despite the UK’s thriving space industry, and the great steps the CAA has already taken to improve its licensing and regulatory functions, persistent regulatory challenges risk constraining the speed of further growth. For many UK space companies – especially startups and smaller firms – the journey to launch or satellite orbit has been slowed by complex and repetitive licensing processes across multiple regulators. These often require applicants to submit the same information multiple times, leading to delays and extra costs that can be especially challenging for new entrants.

At the same time, space operators are calling for clearer, faster guidance from regulators and government on how new types of missions – like In-Orbit Servicing and Manufacturing (ISAM), where satellites are repaired or assembled in space – will be regulated. Without this clarity, businesses face uncertainty, which can hold back investment and slow the growth of these exciting, high-potential markets.



03: Priority Sector Impact – Space

How we've tackled these barriers:

The Regulatory Innovation Office (RIO) has partnered with the Civil Aviation Authority (CAA), the Department for Transport (DfT), and the UK Space Agency to help create a more efficient and supportive regulatory environment for the space industry whilst maintaining standards of safety, security and sustainability, helping domestic companies get to market more quickly and attract more investment into the UK space sector.

Progress over the past year includes:

- **Supporting innovation:** The RIO has supported the delivery of the £2 million Rendezvous, Proximity Operations (RPO) sandbox which is helping regulators and companies such as Astroscale, ClearSpace and D-Orbit, to safely test new mission types, creating a regulatory pathway to increase the UK's share of the In-Orbit Servicing (IOS) market, representing a USD 18.2 billion cumulative revenue opportunity over the next decade.¹⁴ The CAA has been key in delivering the sandbox and is working with DSIT on proposals for a new sandbox next financial year.
- **Simpler guidance:** The RIO have worked with Department for Business and Trade (DBT) who are revamping the space regulation pages on GOV.UK, making it much easier, especially for startups and new entrants, to quickly find and understand exactly what regulatory steps they need to take to comply.

Rendezvous, Proximity Operations (RPO) sandbox

Astroscale is at the forefront of the UK's rapidly growing in-orbit servicing sector, aiming to deliver essential services such as satellite life-extension, inspection, and active debris removal. By pioneering these capabilities, Astroscale and other space operators are positioning the UK as a global leader in emerging space activities that are set to become highly valuable markets in the coming decades.

To accelerate progress, Astroscale helped deliver the first stage of the Rendezvous, Proximity Operations (RPO) sandbox as part of a consortium (ClearSpace, D-Orbit, DSIT) with participation from CAA, UK Space Agency, and Ofcom. This sandbox provided a safe environment to rigorously test and refine the UK's legislative and regulatory framework for novel space missions. The result: greater clarity and confidence for UK space businesses, their clients, and investors, helping to unlock new investment and growth opportunities.

Through the sandbox the consortium worked to:

- Develop and test a minimum viable product (MVP) for licensing new RPO mission types,
- Identify and map gaps in the UK's licensing regime,
- Lay the groundwork for future policy, legislative, and regulatory reforms.

These concrete steps are paving the way for the UK to lead in RPO missions, ensuring that innovative companies can bring new services to market faster, safely, and with greater certainty.

"The RPO sandbox is a great example of how the UK is taking a proactive and collaborative approach to shaping and clarifying the legislative and regulatory frameworks needed for the next generation of space activities. Working with DSIT, the CAA, the UK Space Agency, Ofcom, and industry partners allowed us to examine legislation and regulations in depth, align policy and regulatory objectives with the legal framework, and ensure that the approach adopted is clear, consistent, streamlined, and supports the safe, secure, resilient, and sustainable conduct of UK-licensed space activities."

Vinicius Aloia, Head of Legal, Regulatory Affairs and Space Policy, Astroscale

03: Priority Sector Impact – Space

The government has announced the following new commitments to improve the regulatory environment for space activity in the UK, following work between the CAA, DfT, DSIT and RIO:

- **Streamlined, digitalised licensing:** Over the next six months, CAA will work with HMG to explore with industry the potential of licensing operators rather than individual missions, and other options, such as licensing constellations, that may achieve similar outcomes. The CAA aims to deliver a more flexible regulatory framework by early 2027. In addition, by January 2026, the CAA will deliver a Discovery Project, exploring options to update IT systems for licensing and monitoring applications from space operators, to help deliver greater efficiency, transparency, and responsiveness to industry.
- **Clarity and Transparency:** Starting from the beginning of 2026, the CAA will publish key performance metrics, such as average licensing times, to give businesses clarity to inform business planning. They will also review and improve orbital licence terms, conditions, and reporting requirements, and publish clear licence templates for orbital activities. This will help to remove compliance uncertainties and make it easier for industry to understand and meet their obligations.
- **Streamlined environmental information requirements:** In the next six months, the RIO will work with all relevant government departments, devolved administrations, and regulators, including the CAA, to improve coordination among regulators on environmental information requirements across UK spaceports and launch activities, supporting increased UK launch capacity and reducing regulatory barriers for operators.

RIO's future work in the space sector

Together with our partners—the CAA, DfT, HMT, and UK Space Agency—we are now exploring financial reforms, including to third-party liability and insurance requirements and licence application fees for orbital operations, with the aim of attracting further investment into the UK space sector while protecting the safety and sustainability of operations.

Our regulatory reforms will support the UK space industry to continue its rapid growth, securing the economic benefits of the UK's space leadership for the public.

“ADS has long supported and advocated for the establishment of the Regulatory Innovation Office. We warmly welcome the progress made for the space industry in the Office’s first year, particularly its constructive engagement with industry and pragmatic efforts to streamline duplicative processes across government. This package is a positive starting point towards reducing regulatory burdens and building an environment of growth.

— ADS Group

There is, of course, further work to be done, and we hope the Office continues to draw on the expertise of industry to achieve this. We look forward to ongoing collaboration to strengthen the UK’s global competitiveness.”



DRONES

RIO helped “overcome a significant regulatory obstacle that would have otherwise required years of arduous regulation resulting in substantial annual losses of approximately £200 million in crop yields for the sector. The RIO’s willingness to engage in collaborative partnerships with industry to address challenges exemplifies the progressive approach essential for facilitating and developing this rapidly evolving sector.”

Autospray Systems

03: Priority Sector Impact – Drones

Drones could transform life in the UK, saving lives in search and rescue missions, and boosting economic growth by permitting safe, scaled deliveries in urban and rural areas. Future flight technologies like drones and other aviation systems could contribute as much as £103 billion to the UK economy by 2050, with thousands of manufacturers, operators, and service providers leading the charge.¹⁵

RIO has worked with the Department for Transport (DfT) and the Civil Aviation Authority (CAA) to explore how regulation can support the growth of this key sector of the economy. In April, the Department for Transport (DfT) provided an additional £16 million to support the Civil Aviation Authority's (CAA) efforts on drone regulation and have set a target for routine scaled Beyond Visual Line of Sight (BVLOS) operations by 2027.¹⁶

Regulatory barriers

Many of the greatest barriers facing UK drone operators relate to beyond visual line of sight (BVLOS) operations which allow drones to fly further than a pilot can see. Unclear rules can result in slow, inconsistent approvals, limiting innovation where drones can make the biggest difference, from spraying crops to moving urgent medical supplies.

To break down these barriers to opportunity, the RIO has become a key partner in cross-government efforts to transform the UK's drone regulatory environment.



03: Priority Sector Impact – Drones

How we've tackled these barriers

Working with the Department for Transport (DfT), the Civil Aviation Authority (CAA) and the Health and Safety Executive (HSE), we have focused our efforts on:

- **Enabling safe BVLOS:** Expansion of the CAA's atypical air environment policy, which enables the use of drones Beyond Visual Line of Sight (BVLOS) in low-traffic airspace, such as to inspect powerlines.
- **Securing faster, clearer approvals:** The introduction by the CAA of a single, standard risk assessment (SORA) process to cut approval times for complex drone operations. This has already reduced approval times by more than 60%.
- **Creating greater certainty:** Development by the CAA of a new pathway to allow drone operators to secure airspace change approvals for up to two years, providing greater certainty and scalability.
- **Paving the way for safe, shared airspace:** Consultation by the CAA on a policy for electronic conspicuity, which explores how drones and crewed aircraft can broadcast their locations to improve safety and integration.

These changes are giving innovators and investors the confidence to invest, operate, and scale within the UK.

- **Infrastructure:** Enabled by the CAA's atypical policy, Sees.ai secured a £23 million National Grid contract to inspect power lines BVLOS, keeping workers away from high-risk environments and reducing maintenance costs.
- **Health:** Apian are expanding BVLOS routes between Guy's and St Thomas' hospitals, delivering urgent blood samples to the lab for testing. A journey that took 30 minutes by road can now take less than 2 minutes by air, with emissions down by 99%.

Agriculture

In 2025, a UK company were given the UK's first permanent approval to fly BVLOS but agricultural drones companies also needed HSE authorisation to apply pesticides using drones. Thanks to RIO's work with HSE, drones can now apply, on an experimental basis, slug pellets quickly and precisely, potentially cutting carbon, improving yields and reducing risks to workers and the environment. This is an important initial step to bringing choice and competition to the pest, weed and disease control market and opening up the UK crop protection drone sub-sector.



03: Priority Sector Impact - Drones

The RIO is committed to continuing to support DfT and CAA's efforts to remove barriers to scaling-up drone operations. As part of this:

- Following close collaboration with HMT, DBT, DfT and the RIO, the Civil Aviation Authority (CAA) has published an investor-focused commercial road map for launching private drone operations in the UK, sending a clear message to industry that the Government is working with key regulators to align its frameworks, infrastructure and services to market needs.
- Based on data gathered from existing operations and elsewhere, the CAA will continue to update the atypical air environment policy concept, to ensure industry are able to conduct more operations where it is safe to do so.
- The CAA will publish and report against a transparent set of metrics and published statistics and use them to target improvements where they are needed to proactively build momentum and drive growth of drone use across sectors. These metrics will include:
 - The volume and complexity of SORA applications.
 - Average time to complete SORA approvals and SORA user satisfaction.
 - The split of processing time between the CAA and applicants.
 - Growth in new use cases captured through case studies.
 - Total applications, approvals and the overall UK drone market size.

How RIO's funding mechanisms are supporting the drone sector...

We continue to build on our impact and pro-innovation approach to the Drones sector through the Regulators' Pioneer Fund.

Argyll & Bute Council, has been awarded funding through the fourth round of the RPF, to build on its successful NHS and postal pilots and run targeted trials, subject to approvals, under the CAA's new Atypical Airspace framework, with the aim to make drone services a routine part of life in rural UK communities. These trials directly support the RIO's mission to unlock economic growth in the drone sector while enabling faster, more accessible public services.

Projects that we have funded to advance the sector in previous rounds include...

Milton Keynes City Council trialed drone deliveries for urgent medical supplies and environmental monitoring to help emergency responders and healthcare providers get what they need faster, whilst reducing emissions and traffic congestion.

Coventry City Council and Midlands Aerospace Alliance, supported by Skyfarer, developed and demonstrated a Regulatory Framework to address non-aviation regulatory barriers to support local authority use of drones in urban areas, delivering benefits to consumers, businesses and the organisations themselves.



“The Regulatory Innovation Office has shown how industry and government can deliver together. RIO's work with the Civil Aviation Authority to prioritise streamlining airspace changes and the SORA authorisation process will accelerate sustainable commercial drone delivery, unlocking growth and enabling Apian to provide resilient, on-demand NHS logistics.”

– Alec Jackson, Head of
Policy and Public Affairs,
Apian



AI in Healthcare

“We are really excited to enter this groundbreaking collaboration with RIO and the MHRA. Predicting complex drug/drug interactions remains a major clinical challenge and through the use of AI, computational modelling and model validation using the unique humanised platform PhaSER has developed we believe we can make significant inroads into resolving this clinical issue. Embedding the models into regulatory submissions will accelerate the use of new safer drugs in the clinic and allow medicines to be prescribed in a truly personalised manner.”

PhaSer Biomedical

03: Priority Sector Impact – AI in Healthcare

Artificial intelligence (AI) has the potential to revolutionise healthcare by reducing the time spent by clinicians on paperwork, improving the speed and accuracy of medical tests, and accelerating drug discovery and development.

The UK, with its world-class research base and strengths in data and AI, is uniquely positioned to lead globally in harnessing these opportunities to improve patient outcomes while maintaining rigorous safety standards. Doing so will be key to achieving the Government's missions for growth and building an NHS fit for the future.

Regulatory barriers

Realising the transformative potential of AI in healthcare requires not only cutting-edge technical innovation but also a regulatory environment that is agile, adaptive, and capable of validating and scaling new AI-driven approaches at pace. The NHS 10 Year Health Plan and Life Sciences Sector Plan both emphasise the importance of fostering such a regulatory ecosystem to enable safe, responsible adoption of AI technologies.¹⁷ By evolving regulatory frameworks to keep pace with innovation, the UK can ensure patients benefit from faster access to breakthrough treatments and technologies, while safeguarding public trust and safety.



03: Priority Sector Impact – AI in Healthcare

How we've tackled these barriers

The RIO has partnered with the Department for Health and Social Care (DHSC), the Medicines and Healthcare products Regulatory Agency (MHRA), and representatives of academia and industry to ensure that the UK regulatory environment supports the use of AI in healthcare while protecting safety:

- **AI Airlock:** Building on the Government's response to the Regulatory Horizons Council's (RHC) report on the regulation of AI as a medical device, RIO has been working with the MHRA on unlocking the benefits of AI enabled medical devices, including by supporting the launch of a second year of the AI Airlock, a regulatory sandbox to address challenges arising when regulating AI as a medical device.¹⁸ Led by the MHRA, the Airlock is helping businesses and innovators to understand the regulatory challenges for AI technologies, adapt their approaches and ultimately create greater certainty for the sector. The first round of Airlock funded projects, explored the use of AI in developing radiology reports and in developing personalised management plans for cancer patients. The second phase of the AI Airlock, announced on 16 October, includes clinical AI assistant technologies to clarify when features move from documentation support to diagnostic or decision-support functionality.
- **Medical device regulation:** The RIO is working with DHSC and MHRA to explore regulatory issues shared by businesses and clinicians around the regulatory treatment of AI enabled medical devices. This includes challenges linked to ambient scribe technologies, some of which are regulated under the Medical Devices Regulations 2002. Ambient scribe technologies will be one of the first issues to be considered by the MHRA's new National Commission into the regulation of AI in healthcare, which will be chaired by Professor Alastair Denniston (member of the RIO's RHC).¹⁹
- **AI in drug development:** The RIO is working with the MHRA, industry and academic partners to explore how advanced technologies including human-relevant in vitro systems, in silico modelling, and AI-driven predictive tools could safely accelerate drug development, reduce reliance on animal testing, and improve predictive accuracy. The RIO also convened a workshop with the Academy of Medical Sciences, bringing together industry and academic partners to tackle clinical challenges in AI drug development. These collaborations are shaping government strategy and strengthening partnerships across the sector.

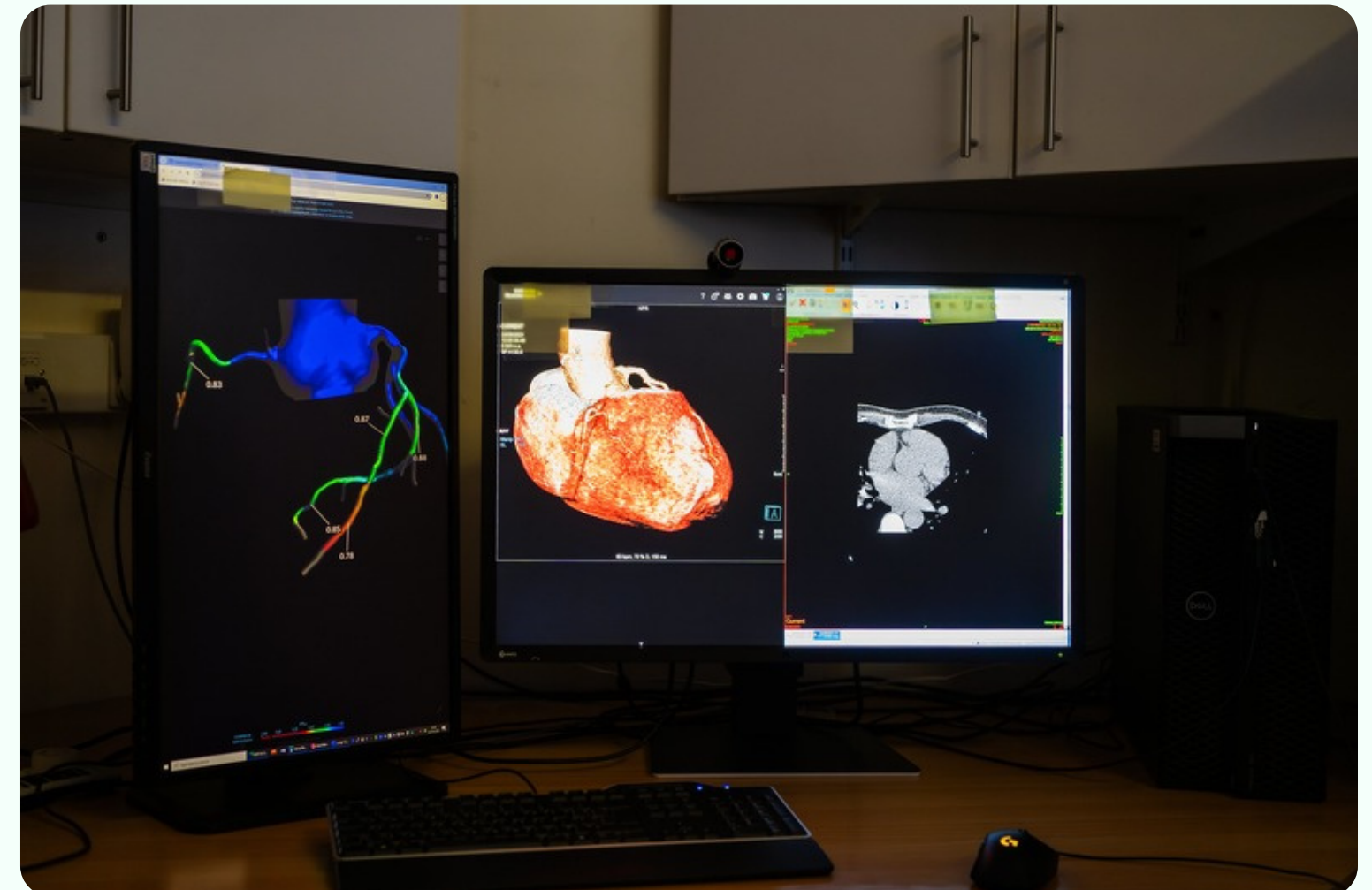
RIO'S FUTURE WORK IN AI IN HEALTHCARE

We are enhancing our impact with targeted funding for interventions through our Regulators' Pioneer Fund and the AI Capability Fund:

- Backed by **RIO funding**, the **MHRA is piloting AI assisted tools** to support experts in scientific advice, clinical trial assessments, and licensing to improve efficiency and consistency, while keeping all decisions in human hands.
- As part of our work on **AI drug development**, **RIO is providing funding to the MHRA** to explore how new AI-enabled methods can accelerate safe access to new medicines, including an AI tool to validate drug-drug interactions in cardiovascular patients. The Regulators' Pioneer Fund has provided further funding for MHRA to pilot the safe use of synthetic data in clinical trials.
- The Regulators' Pioneer Fund is providing funding to the **Care Quality Commission** to deploy Ambient Voice Technology in inspections, providing valuable real-world use cases.

These investments follow previous rounds of Regulators' Pioneer Fund funding which supported MHRA research into the transparency and explainability of AI in medical devices.

The RIO is helping to position the UK as the partner of choice for AI in healthcare innovators and investors so that patients can benefit from revolutionary new technologies and treatments sooner.



“We support the Regulatory Innovation Office’s mission to simplify the regulatory landscape by streamlining processes that can lead to enhanced research and development opportunities and benefit patients in accessing new treatments at pace.

We look forward to continuing our partnership with government and regulators to make the UK the best place in the world to research, develop, and deliver innovative medicines.”

– The Association of the British
Pharmaceutical Industry (ABPI)

ENGINEERING BIOLOGY

“RIO has worked to provide tailored support to companies navigating regulatory challenges, demonstrating a deep understanding of the barriers faced by industry.”

Alternative Proteins Association

03: Priority Sector Impact – Engineering Biology

Engineering biology has transformative potential for sectors across the economy. Whether it's turning factory waste into low-carbon fuels, or treating genetic conditions through personalised medicines, the UK's engineering biology companies are showing just how impactful these new technologies can be for our economy, health, and environment.

At the frontier of novel foods, businesses are developing products that could give UK consumers a wider choice of healthy and sustainable products while strengthening our food supply.

These innovative products include meat and dairy grown from cells (much like how yoghurt cultures grow) or produced by fermentation. Modern food science is building on techniques that have been safely used since the 1980s. Most cheese today uses enzymes made through precision fermentation – the same principle that is now driving new food innovation. Producing these foods can use up to 83% less land than conventional proteins, helping to meet environmental goals.²⁰ This growing sector could help to achieve the Government's Growth Mission, with a projected global industry value of up to \$150 billion by 2050.²¹

Regulatory barriers

Early in our engagement with the engineering biology sector, innovative foods emerged as a cluster of high growth potential technologies facing clear regulatory barriers and so became the focus of the RIO's work during our first year. Until recently, there was no clear regulatory pathway for these products in the UK, despite the fact they are already on supermarket shelves in countries across the globe. Foods not commonly consumed before 1997 – the year the regulations came into effect – are regulated as “novel foods” by the Food Standards Agency (FSA).

So that these exciting, environmentally friendly new foods can safely come onto the market, the FSA is putting them through their paces via a rigorous, in-depth assessment of their safety. Through this process, the FSA will ensure that these innovative foods are as safe as any other product you can buy at the supermarket before they can enter the market – maintaining the very highest standards of food safety that the UK public expect.

03: Priority Sector Impact – Engineering Biology

How we've tackled these barriers:

The RIO has played a key role in cross-government efforts to capture the benefits of the most innovative novel foods.

Working with the Food Standards Agency (FSA), RIO has helped create a regulatory path through the robust legislation for the most innovative novel foods. We have provided £3 million (which includes £1.6 million through the Engineering Biology Sandbox Fund) to ensure the FSA has the skills and the knowhow to enable these products to come to market quicker and ensure that the British public has access to safe, innovative, and more sustainable foods – all without changing the UK's strict requirements on food safety.²²

- **Accelerator for innovative foods:** The FSA has launched a new Business Support Service for the most innovative products: cell-cultured and precision-fermented foods. The FSA now offers one-to-one conversations with businesses, both before and after submission – cutting delays and helping businesses submit the highest quality applications.
- **Regulatory clarity:** For a food business, proving taste is essential. Regulation around taste trials have previously been unclear and uncertain. By December, companies will know the steps to organise taste tests without risking a breach of the law. FSA are also publishing answers to key regulatory and safety questions, like what companies should do to test for allergens and assess the nutritional value of their products.
- **Centralised guidance:** A Guidance Hub to help innovators submit a strong application that the FSA can progress quickly.
- **UK-led global network:** An advisory network of international regulators to draw on best practice from overseas and provide leadership on the world stage. By disseminating UK best practice, we aim to export our pro-growth approach to regulating innovative products and create more opportunities for British companies.

These changes are giving innovators and investors the confidence to invest and operate in the UK.

- **2x faster approvals for innovators.** RIO-funded projects are expected to cut approval timelines by 50% for relevant novel food categories (cell cultivation and precision fermentation), without compromising food safety.
- **Businesses now have greater confidence in their timelines to regulatory approval.** By February 2027, the FSA will complete scientific risk assessments for the first two cell-cultivated products – putting these new products through a rigorous process of identifying and managing hazards that ensures the very highest standards of food safety. This means the first cell-cultivated products could be on the market within the next three years.
- **Businesses are seeing the benefits of the faster approval times, without compromising consumer safety.** In the last 6 months, 7 innovative precision fermentation businesses have moved to the next stage of FSA's authorisation process, thanks to dedicated resource for the most innovative novel foods.
- **New innovators are submitting applications to the FSA, in recognition of the expertise and capacity that FSA is building.** Applications for cell-cultivated products in the FSA pipeline have nearly doubled. Three new businesses who previously did not plan to apply in the UK have now submitted applications, with more on the way.
- **With greater confidence in the regulatory pathway, businesses are investing to scale in the UK.** For example, in September this year, precision fermentation company Clean Food Group announced its purchase of a manufacturing facility in Liverpool to scale up its activities.²³

RIO'S FUTURE WORK IN ENGINEERING BIOLOGY

As part of our work with the FSA, we have agreed a set of Key Performance Indicators so we can work together to monitor progress and troubleshoot pinch points that arise. These include the time taken for companies to pass through each stage of the approvals process; qualitative and quantitative feedback from businesses; and the number of businesses passing through each stage of the approvals process.

With over 400 potential applications of engineering biology technologies, we know there is more to be done in the wider engineering biology sector. Innovators are producing novel medicines that can help tackle difficult-to-treat infections or cure rare diseases, but they face challenges bringing these products to the public. For example, as medicinal products using genetic modification, engineered therapeutics need to navigate regulatory regimes across the Medicines and Healthcare products Regulatory Agency (MHRA), the Health and Safety Executive (HSE) and Defra.

RIO will partner with the MHRA, the Office for Life Sciences (OLS) and DHSC to help these and other innovative engineering biology medicines reach the public safely and more quickly.

The RIO is also working with MHRA, Defra and HSE to look across the regulation of innovative genetic technologies and clarify regulatory pathways. And our expert committee, the Regulatory Horizons Council, is exploring the frontiers of early-stage assisted reproduction technologies that could transform fertility treatments for people who couldn't otherwise have children, shaping the regulatory pathway for when these technologies mature.

DSIT continues to convene the Engineering Biology Regulators Network, which brings together 12 regulators involved in regulating engineering biology products. The network meets regularly to share knowledge and best practice on pro-innovation regulation and identify common challenges to tackle. We are seeing increasing examples of collaboration between regulators as a result of this group. DSIT will also shortly be announcing the winners of round 2 of the Engineering Biology Sandbox Fund.



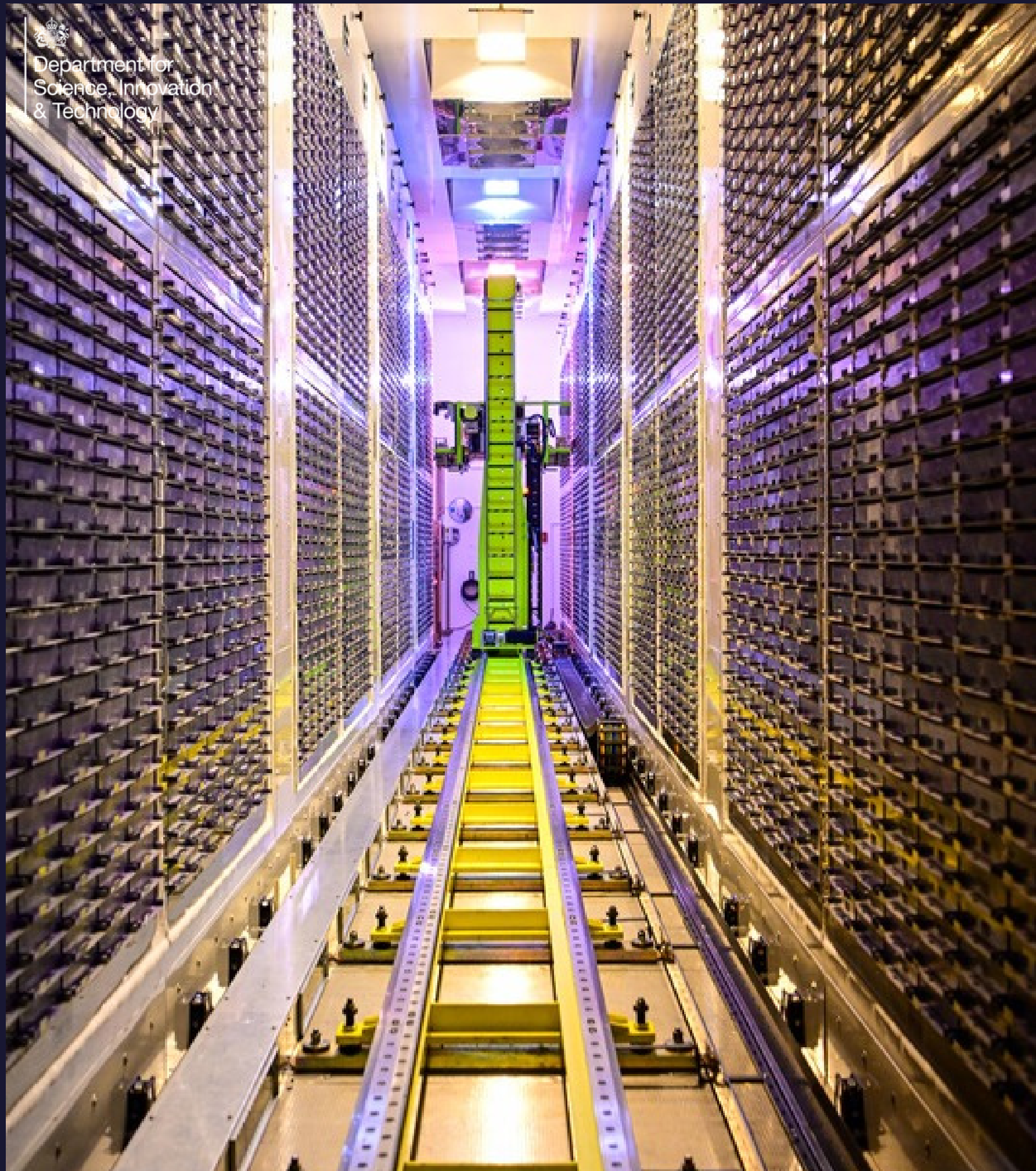
The RIO is helping the UK benefit from exciting developments in engineering biology. We will enable safe and tasty novel foods to arrive on supermarket shelves – bringing new jobs, cleaner growth, wider choices for consumers, and home-grown food security

“The regulatory sandbox is already making an impact on attracting innovative companies like ours to the UK market.”

— Mosa Meat

“RIO’s role has been critical, with the purview to look at regulation holistically and to consider how overlapping frameworks affect the innovation pipeline.”

— BioIndustry Association



Funding for Regulators and Local Authorities

“Artificial intelligence is already helping to simplify regulatory compliance for businesses across the economy. We’re looking forward to hosting the Regulatory Innovation Office hackathon so that more businesses and regulators can benefit from the opportunities created by AI.”

Dr Nicola Hodson, Chair, IBM UK and Ireland

- ◆ We are determined to create new pro-innovation pathways and scale support for businesses in the year ahead. Funding is one critical lever for us to achieve these goals and accelerate the route to market for innovators.
- ◆ Through the Regulators' Pioneer Fund and the Artificial Intelligence (AI) Capability Fund, we are backing regulators and local authorities to upgrade their capabilities and trial new approaches that can be scaled across the country and the economy.
- ◆ By making these investments, the RIO will help our partner organisations to improve the quality of the services they provide to businesses and the public, allowing all of us to benefit from new technologies quickly and safely.

AI Capability Fund

Advances in AI have created extraordinary opportunities to support more efficient and responsive regulation, including of new technology applications.

The RIO's AI Capability Fund is providing up to £3.6 million of funding to deliver a series of novel and experimental AI projects.²⁴ These awards will enable regulators to test how AI can increase their productivity and impact — boosting economic growth and improving the lives of the public.

In **aviation**, the Civil Aviation Authority (CAA) is applying AI to analyse air accident investigation reports, supporting data-driven, proactive safety oversight. The CAA will also trial AI assistants and simulators as part of the Future of Flight programme to make it easier for new drone technologies to be approved safely. This will help more drones take to our skies faster.

In **energy**, Ofgem is developing an AI tool to accelerate the delivery of up to £30 billion in funding for critical national infrastructure projects, cutting down bureaucracy to enable faster delivery of innovation in our energy systems. The Office for Nuclear Regulation is delivering a regulatory sandbox to accelerate the safe deployment of AI in nuclear installations.

In **digital and data**, the Digital Regulation Cooperation Forum is prototyping a digital library to provide businesses with a 'one stop' access to digital policy and regulations. The Information Commissioner's Office will lay the foundation for real-world testing of innovative AI data protection technologies, enabling innovators to develop products in compliant, safe ways that protect consumers.

In **logistics**, the Centre for Connected and Autonomous Vehicles will conduct research to provide regulatory certainty for off-road autonomous vehicles (AVs). This could support the use of AVs in airports, maritime ports and factories, so that businesses can work safer and smarter.



Regulators' Pioneer Fund



In addition to supporting our priority areas, the fourth round of the Regulators' Pioneer Fund (RPF) will back a new cohort of regulators and local authorities to run regulatory experiments that will accelerate innovation across diverse sectors of the economy and across the UK.

In Housing

The Council for Licensed Conveyancers will pilot a Smart Property Data Framework, creating a secure, interoperable data framework to make home buying faster, safer, and less vulnerable to fraud.

Glasgow City Council will produce a regulatory guide for social landlords to adopt sensor technologies responsibly, improving housing safety while protecting tenant rights.

Northumberland County Council will trial an AI-supported regulatory approach to Flood Risk Assessments, aiming to deliver faster, safer planning decisions and accelerate housing development nationwide.

In Infrastructure

The **North Sea Transition Authority** aim to improve the accessibility and integration of offshore energy data through an enhanced data viewer and a pilot AI chatbot, which will improve decision-making, cut duplication, and unlock economic value in the offshore energy sector.

The **Greater London Authority** will test solutions to make it easier to repurpose disused underground infrastructure — including old water, power, and telecoms facilities — by removing regulatory barriers and encouraging cross-sector collaborations.

The **Environment Agency** will create a new digital platform using AI to help speed up and simplify the approval process for low-carbon heating systems for councils and businesses.



Regulators' Pioneer Fund



The fourth round of the RPF will run until September 2026, beyond which we will continue to work with regulators and local authorities to monitor real world and long-term impacts of their projects. All winning projects have committed to ensuring their project's benefits continue beyond the funding period and become part of regular practices. Previous RPF funding rounds have launched breakthrough trials and accelerated learning across sectors.²⁵

Support for Innovators

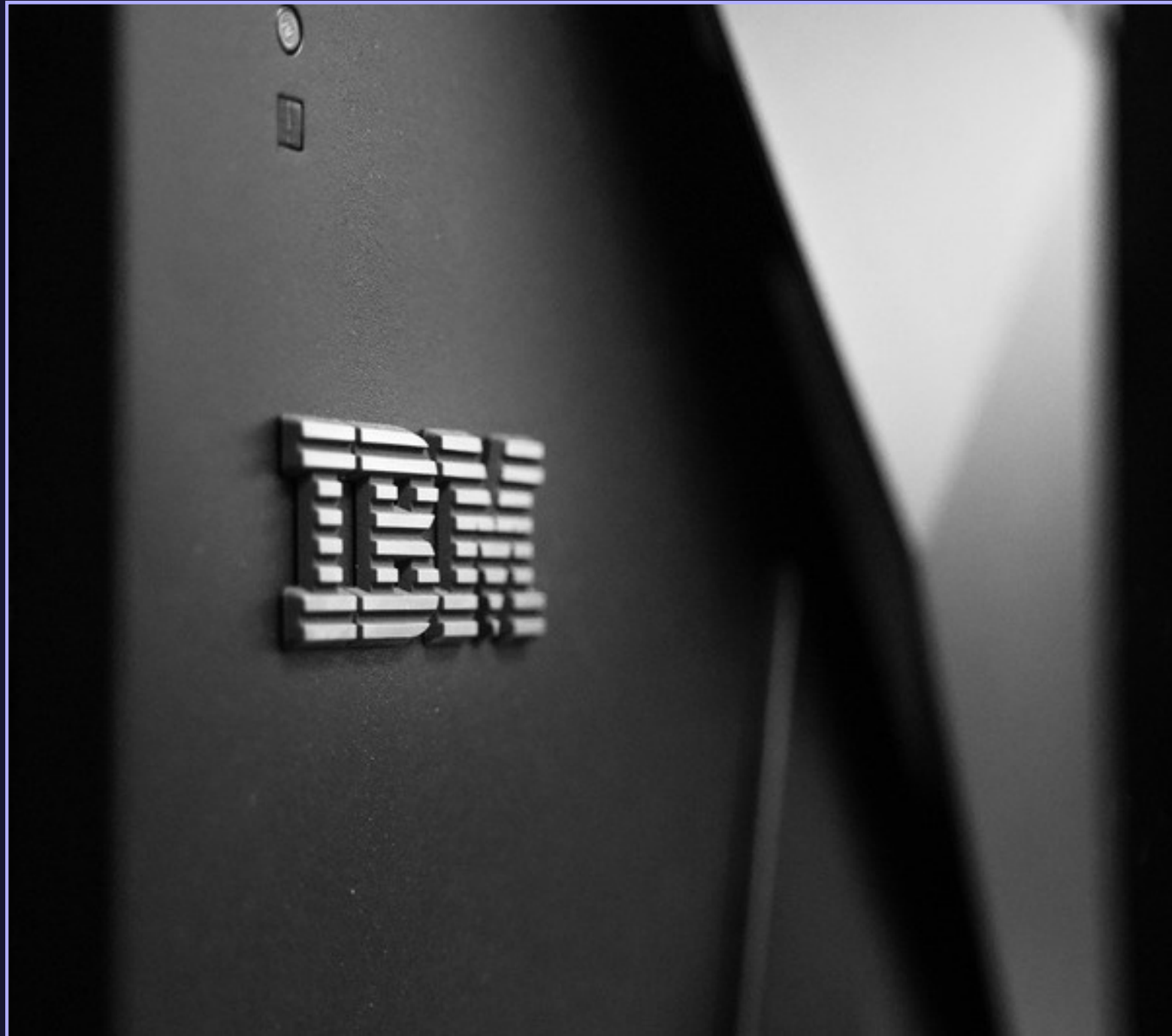
Cambridge & Peterborough Combined Authority are building an interactive Startup Support Platform to guide entrepreneurs and founders through incorporation and regulatory steps like company registration and IP protection, reducing delays and fostering a more inclusive startup ecosystem. This is expected to produce a replicable model to support startup formation across the UK.

Milton Keynes City Council are developing RoboPASS, a reusable licensing framework for deploying street robotics, starting with maintenance and repair robots, and creating a Smart City Testbed for future innovation. This could help to create a national regulatory blueprint to remove regulatory ambiguity.

Public Safety

London Fire Brigade will create an app that uses AI and smartphone cameras to identify hazards and provide real-time, personalised fire safety advice.

The **British Board of Film Classification** will develop an AI tool that generates regulator-grade metadata for video content, speeding up accurate age ratings for audiences and reducing compliance costs for businesses.



RIO x IBM Hackathon

- To help developers tailor products to the needs of regulators and businesses, we are preparing to hold a hackathon in Spring 2026, **partnering with IBM.**

Timed to coincide with the culmination of AI Capability Fund projects, this event will bring together regulators and experts to co-design AI tools that improve the regulatory experience for businesses and help to speed up approvals. For example, new tools could provide real-time feedback to businesses about applications, reducing costly delays.

“AI is central to building a world-leading smart, digital energy system that delivers maximum value for consumers. Ofgem welcomes this important government investment, which will support the development of an AI-powered tool to streamline approvals for clean energy infrastructure. This will help accelerate projects worth up to £30 billion, supporting the UK’s transition to a greener, more secure and resilient energy future.”

– Ofgem

“The establishment of RIO was a positive signal to the nuclear industry on the UK Government’s support for innovation. ONR’s successful bid through the AI Capability Fund represents a great opportunity to accelerate discussions across the nuclear industry on applications of AI which can support the UK Government’s ambition on innovation and the wider growth agenda while maintaining safety and security. The RIO funded project will also give ONR the opportunity to support cooperation with other non-nuclear regulators as part of the UK Health & Safety Regulators’ Network, enabling learning between sectors.”

– Office for Nuclear Regulation (ONR)



Looking Ahead

“The RIO’s first year has shown real progress in making the UK’s regulatory system more supportive of innovation. By working closely with businesses, regulators, and trade associations like TechUK, RIO is helping to remove barriers, improve coordination, and harness new digital tools to speed up safe adoption of frontier technologies. Its continued focus on collaboration and learning will be vital to building a truly pro-innovation regulatory environment.

We look forward to continuing our partnership with RIO, and we are excited to welcome Lord Willets to our upcoming Tech and Innovation Summit in November.”

Antony Walker, Deputy CEO, TechUK

04: Looking Ahead

Over the past year, working with our Chair, Lord Willetts, we have directly engaged with more than 150 businesses and over 40 regulators to identify and unlock regulatory barriers facing frontier technologies. This engagement has shaped our first year's activities: helping us to identify rapid, practical interventions that address the needs of businesses, including connecting innovators with the right contacts in government, coordinating activity across departments, and convening regulators to discuss solutions.

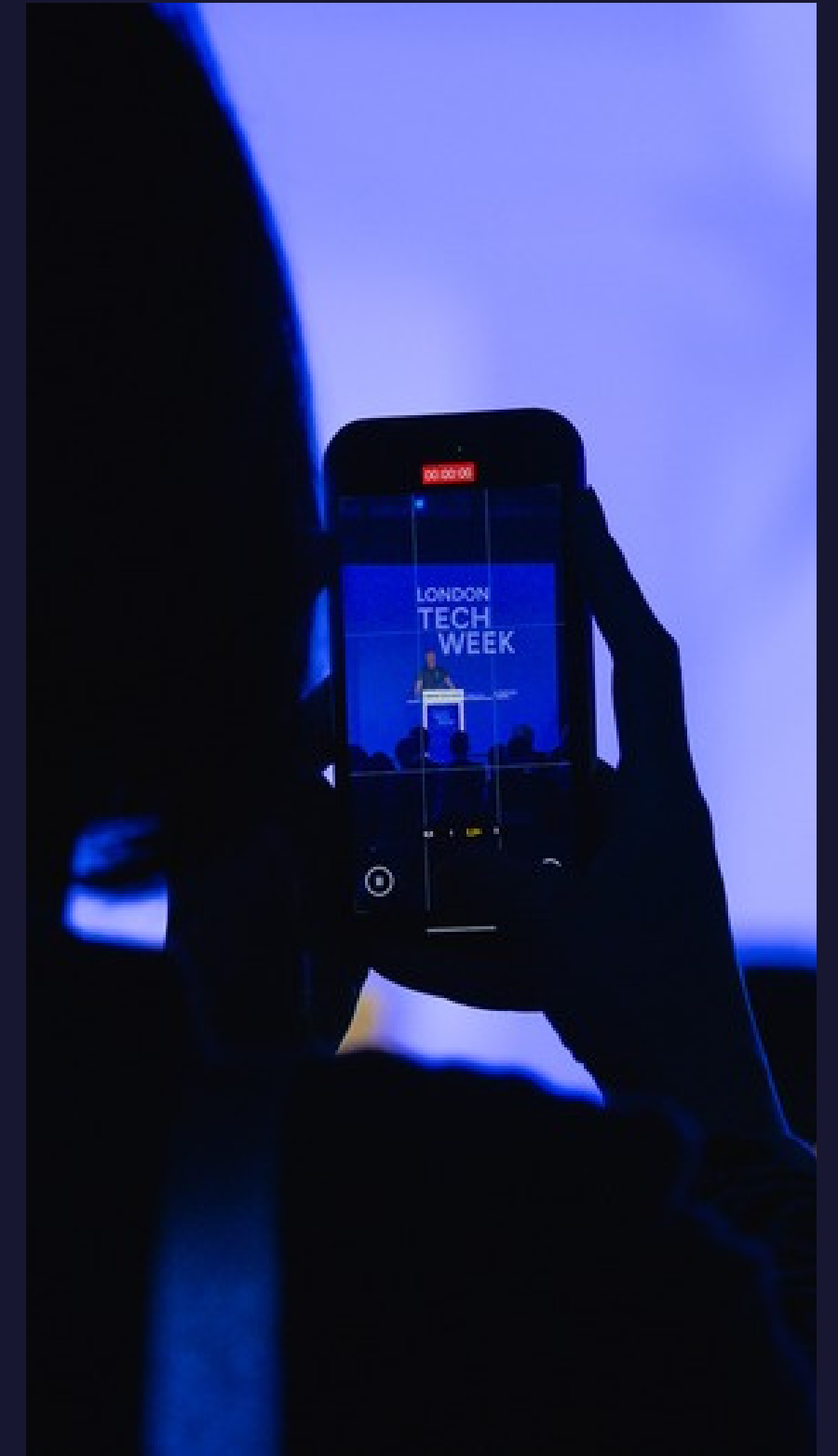
As we look ahead to the next year, we will learn from this first year of operation to maximise our impact.

System challenges

From our work in our four initial areas of science and technology, we have begun to identify challenges and opportunities that span multiple regulators, technologies and sectors.

Both regulators and innovators stand to benefit from enhanced pre-market engagement and other services that streamline the regulation of emerging technologies. New AI and digital tools are creating new opportunities to go further, offering cost effective ways for businesses to identify relevant regulations and improve their submissions to regulators. Given the similarities in processes and objectives across regulators, investments in these new tools can benefit sectors across the system.

In the next year, the RIO will continue to work closely with the Treasury, the Department of Business and Trade and other government departments, using what we have learned from our work in priority areas of the economy to identify the changes needed to embed a pro-innovation regulatory system in the UK.



How to contact us



So far, we've focused on four key sectors chosen for their growth potential, the presence of regulatory barriers, and where RIO could make the biggest difference. We've driven change through close collaboration with government departments and regulators, and importantly by working directly with businesses who are deploying frontier products within these sectors. With the Industrial Strategy now providing a clear framework, we will look for opportunities to expand our reach into more sectors where innovation is being held back. We intend to announce additional priority sectors in the autumn.

We're also working to make the RIO more accessible to innovators across the spectrum: from early-stage start-ups to established industry leaders.

Through www.gov.uk/government/organisations/regulatory-innovation-office we will provide a **direct route for businesses operating in one of our priority areas** – AI in healthcare, engineering biology, space, and drones and other autonomous technologies – to raise regulatory issues with the RIO.

We will continue to speak with a wide range of industry bodies across the science and technology Industrial Strategy sectors, to enable us to identify where we can have the most impact.²⁶ Our Chair and staff engage with business regularly, including through industry networks, events, and roundtables.

We also partner with trade associations, such as **TechUK, the CBI and Startup Coalition**, to identify regulatory issues in our priority areas and beyond. If you are a business operating in Science & Technology, including if you are not operating in one of our priority sectors, and you want to raise an issue, we encourage you to get in touch with your industry body or trade association.

Thank you to the many departments, regulators, and industry stakeholders who have worked with us this year and continue to work with us to unlock the potential of innovative technologies for UK public life and the economy.

To keep up to date with the progress of RIO and to find ways to get in touch with us please find us at:
www.gov.uk/government/organisations/regulatory-innovation-office

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