# Enhancing the role of UK medicine regulation

# Contents

“An internationally competitive regulatory framework is crucial for attracting investment and positioning the UK as a global leader for Life Sciences. By optimising and streamlining the regulatory framework we can attract increased investment, foster economic growth, and support the NHS. These changes will help impS. The

# Foreword

The ABPI wants the UK to be the best place in the world to research, develop and use the medicines and vaccines of the future. Continued UK excellence in regulation is key to the success of our sector, as it underpins the high trust and regard patients have for our products, and enables us to rapidly bring new innovations to those who can bene t most.

As the Medicines and Healthcare products Regulatory Agency (MHRA) embarks on a new phase in its leadership, and the new government seeks to improve UK regulatory standards across the board, this report brings together our industry's contribution to shaping a globally leading UK regulatory framework for innovative medicines. Central to our recommendations is an ambition to rebuild the UK's world-class reputation in regulatory science, medicines' development and licensing, which has unfortunately seen a number of setbacks and challenges in recent years.

The MHRA has a critical role in the wider UK life sciences ecosystem. We continue to believe it can be among the best regulators in the world at both regulating innovation and innovating regulation, despite a period of recent challenge.

Our 12 detailed recommendations are found at the end of this report and are framed under these main themes:

- Enhanced communications, transparency and accountability: Pharmaceutical companies depend on  nding regulatory and technical information quickly and easily and require access to performance metrics that inform the planning of product launches. Companies also need to have dedicated points of contact that provide relevant and timely information, particularly for scienti c and technical advice and procedural queries, facilitated via stronger internal and external accountability mechanisms.
- Resourcing and expertise: Regulatory authorities need to provide expert opinion and consistency in approach, keeping up to date with evolving technological advances. A well-resourced regulatory authority should provide predicable and reliable services and ensure that the right capacity exists to focus delivery on key regulatory statutory functions.

- Regulatory function and o ers: Growth in clinical trial activity depends on timely approvals and acceptability of innovative approaches. Regulatory reliance o ers better use of resources and potential leadership in particular areas with horizontal agreements and positioning of the MHRA as a reference regulator. Early access exibilities are crucial for patients with high unmet medical needs and these pathways need to be attractive to industry. Horizon scanning that feeds directly and measurably into resourcing and regular reviews of practice and future regulatory science challenges and opportunities are essential.

We believe that implementing these recommendations is essential for supporting the government's growth agenda, drive greater inward investment into UK life sciences, and facilitate earlier patient access to innovative medicines. Building con dence and predictability in the regulatory framework will help ensure that the ambitions of UK to be the best place in the world to research, develop and use the medicines and vaccines of the future can be fully realised.

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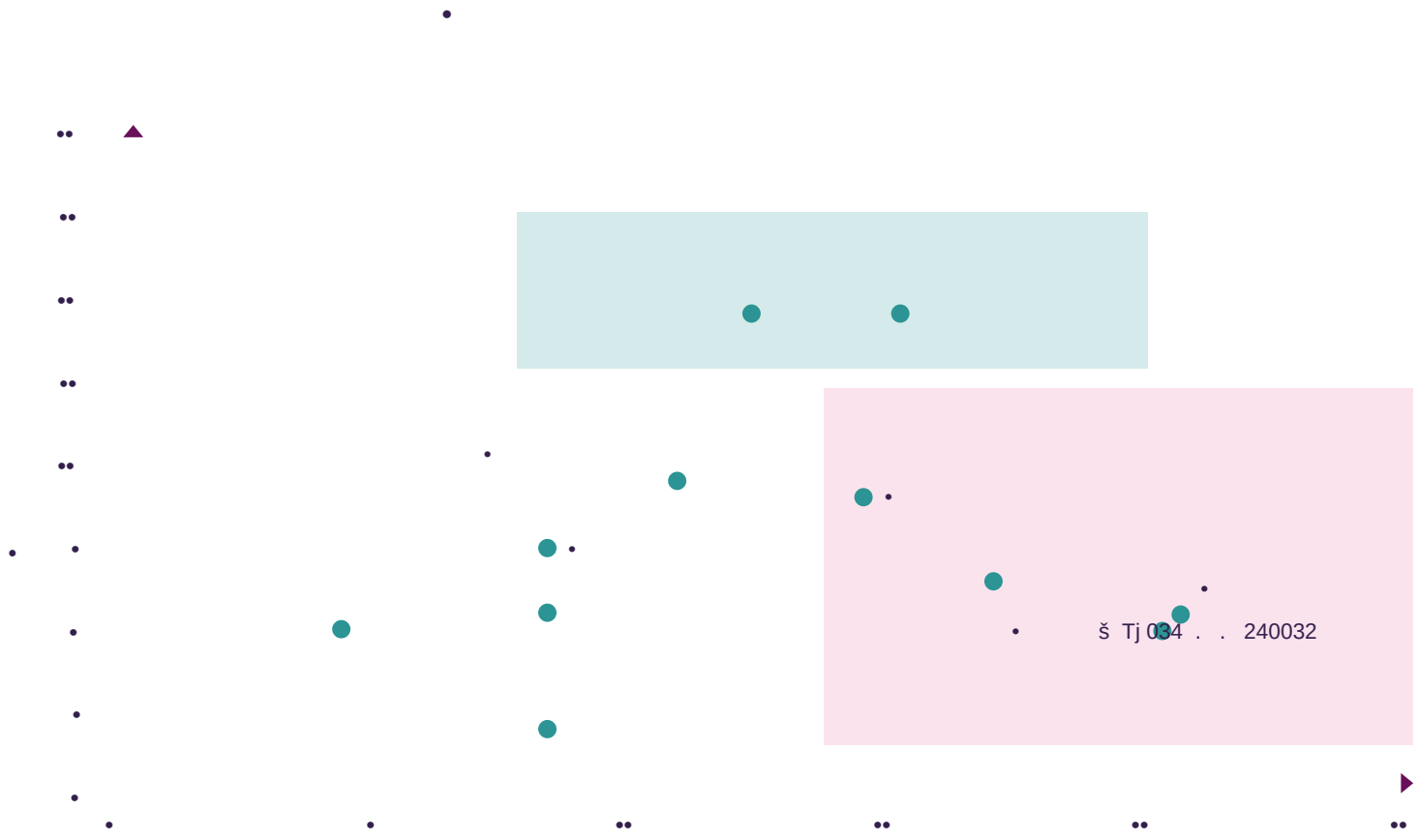
Chief Executive
The Association of the British Pharmaceutical Industry (ABPI)

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has earned a global reputation for its expertise and leading role in elements of regulatory practice.

Since the UK’s exit from the European Union, it has been necessary for the MHRA to reconsider and recon gure its role as a sovereign regulator. This has occurred against the backdrop of the COVID-19 pandemic and an extensive organisational restructure. While the agency continues to be a key and respected player in a global landscape, these challenges have impacted aspects of its regulatory performance.

In an ever more competitive global life sciences marketplace, multinational

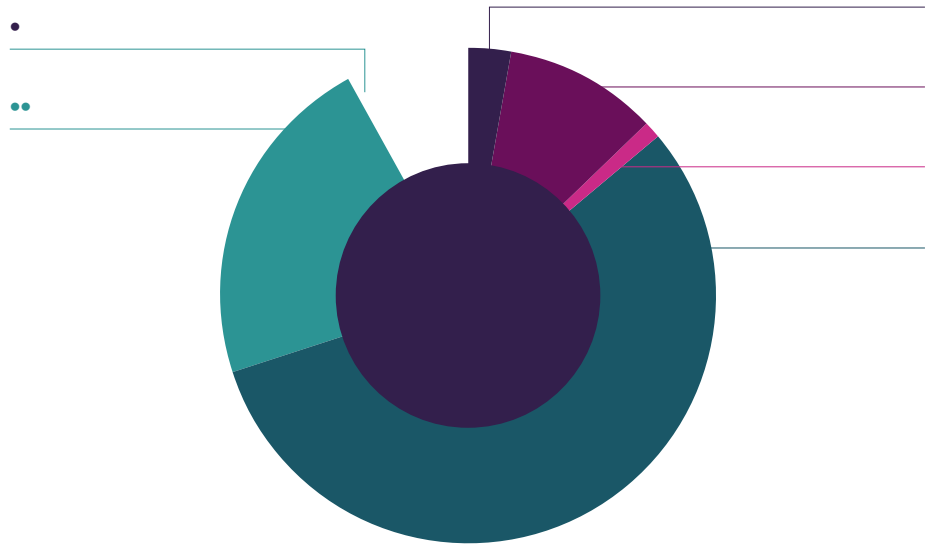
Over the past  ve years, the MHRA has been subjected

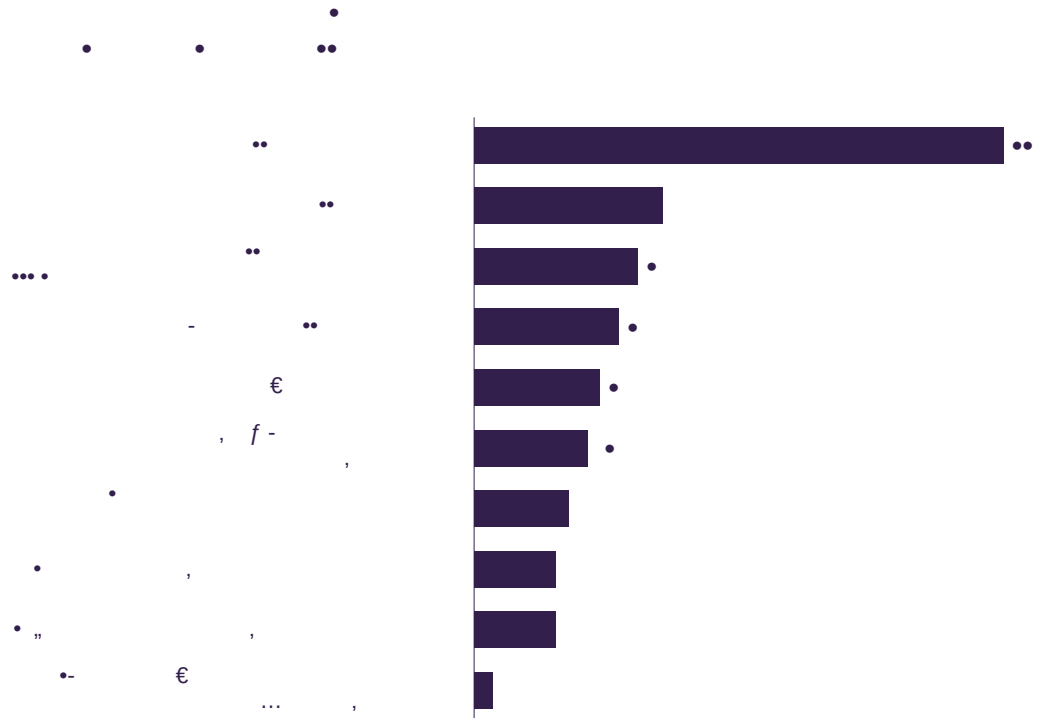


Survey respondents were asked to both assess MHRA performance and rate individual performance indicators in terms of their overall importance. A robust approach to the MHRA's independence and strong partnerships with peer regulators were areas judged as both e ective and important. Recommendations here seek chie y to buttress these strengths. Important areas of weaker performance included the need for revised performance indicators, clearer and more accessible processes, a greater focus on enabling innovation and a realistic and deliverable strategic approach. These are the areas where recommendations focus.

## The role and importance of the MHRA

- Regulatory performance is an important variable in decisions to invest or commit research and development resources to the UK. However, many reported that this was currently working as a disincentive, with respondents noting that the UK's regulatory environment had an unfavourable impact, attributed to the capacity and predictability of the MHRA.





- Two-thirds of respondents want the MHRA to be ambitious in de ning a global reputation and leadership role for itself. In interviews and survey responses, stakeholders often emphasised the importance of not adopting a model of excessive deference to other international regulators, but instead of continuing to aim to set precedents in important areas. This was linked to challenges in current capacity for strategic planning, rationale for decisions to focus on particular technologies or therapeutic areas and ability to translate horizon scanning into resourcing and internal knowledge development.

# Process, transparency and predictability

# Resourcing and expertise

- Only a small proportion of respondents considered that the MHRA is su ciently funded to meet its obligations. A potential reason attributed to the MHRA's lack of funding and resources is the removal its of trading fund status.
- Respondents indicate concern that the MHRA is struggling to attract and retain high-quality expertise. Additional open-ended responses suggested a clear negative feedback loop between failing to retain expertise and experienced personnel, and other aspects of regulatory performance such as high-quality interactions, capacity, responsiveness to scienti c advice and meeting statutory targets. The underlying causes for this are multi-faceted. Many reported that experienced assessors had left the agency as the MHRA struggled to compete with higher salaries, delivered its programme of restructuring and faced sta  and budget cuts

## Talent and expertise

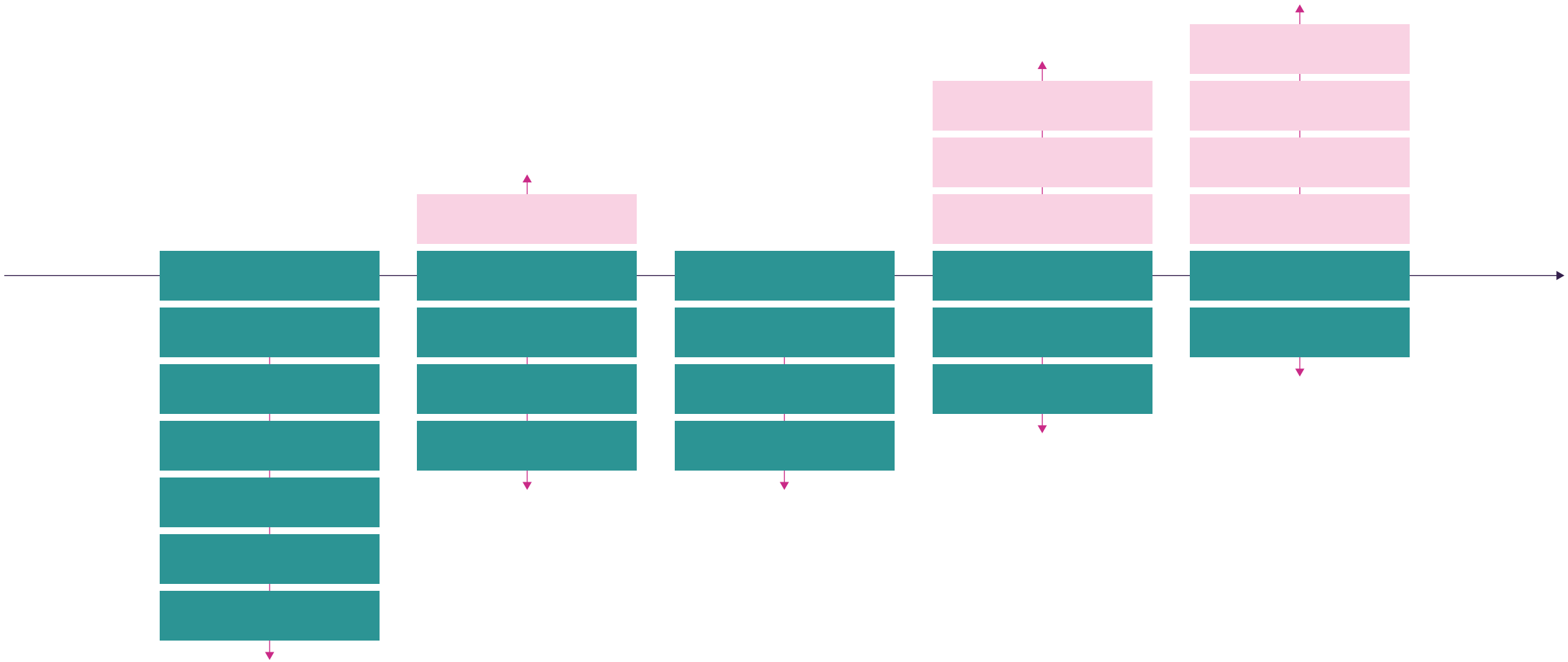
It was widely recognised by our survey respondents that retention of experienced and skilled sta  is absolutely critical to a world-class regulator. Experienced MHRA experts and assessors bring immense value to the regulator through their knowledge, pragmatism and judgement. They are comfortable engaging in a more dynamic dialogue with companies where less experienced sta  may be risk-averse and excessively procedural. Many respondents – across the survey, interviews and workshops – commented that the loss of a cohort of experienced sta  from the MHRA over the past  ve years had had a profound impact on its culture and e ectiveness.

It was also recognised that retention at the MHRA must re ect both the inevitable constraints of public sector pay scales and competition from the private sector for skilled sta . For these reasons, the MHRA must be able to pay competitive salaries for assessors and other experts. Retention also needs to be built around more than  nancial rewards, such as opportunities for career development and training.

A regulator performing again at the top of its game internationally, with an established reputation for regulatory innovation, will attract and retain talented sta . Similarly, strong mechanisms for institutional knowledge transfer and the mentoring of new sta  by more experienced ones may help with retention. Respondents also felt that the MHRA could draw more on expertise from across the UK ecosystem of academics, researchers and industry.

- Results highlight visible improvements in performance in clinical trials after a period of challenge, but many respondents argued more can be done to build the attractiveness of the o er in a globally competitive environment. Areas to improve included better  exibility in processes for approving clinical trials and allowing changes to study design, and for speci c provisions to support phase I trials (e.g. 14-day turnaround for healthy volunteer trials). Stakeholders highlighted the outcomes of the Lord O'Shaughnessy Review as a catalyst for speeding up the MHRA's trial approvals and improving commercial clinical trial activity. They also emphasised that any improvements in the MHRA's performance to approve clinicals trials needed to be matched by other ecosystem partners.
- Respondents often reported that the MHRA's International Recognition Procedure (IRP) and international partnerships are functioning well. Of those respondents with experience of the IRP, around half believed it is functioning well. A  fth said it is either too soon to say or did not know. Similarly, those with experience of the Access Consortium reported that it was functioning "quite well".
- Of the MHRA's expedited national pathways, the Innovative Licensing and Access Pathway (ILAP) was commonly reported as not ful lling its ambition compared to the Early Access to Medicines Scheme (EAMS), which is viewed more favourably. Comments indicated that many respondents felt that ILAP was under-resourced and required an overhaul, though the principles of what it is trying to achieve are broadly welcomed by industry. EAMS was considered to have better performance but also to su er from capacity issues.
- For many respondents it is unclear what it means when the MHRA claims to have a focus on enabling innovation. A clearer strategic narrative regarding the MHRA's ambition in the innovation space would be welcomed, linked to visible speci c services, activities and outcomes that are measurable.

- Some respondents noted that horizon scanning to anticipate future demands on MHRA services could be better utilised. Respondents perceived that the MHRA could be using horizon scanning more e ectively to help inform future strategic decisions and workforce planning. UK



# Recommendations

The recommendations that follow are built directly on the evidence provided by our research and respond to the areas that could be strengthened and improved as suggested by stakeholders. They target the areas highlighted by respondents as both materially important to the future of the MHRA and most in need of action.

Most are actions that can be undertaken independently by the MHRA within its statutory authority. A small number involve changes in the governance of the MHRA and require action from government, although no recommendations would change the nature of the MHRA's statutory role. The recommendations are underpinned by four themes that run through the survey responses:

- improving the transparency of the MHRA in ways that make it easier for stakeholders to understand and engage with its structure and processes
- improving the predictability and general delivery of the MHRA's statutory functions for the provision of scienti c advice, standard and expedited authorisation pathways and clinical trial approvals processes
- strengthening the MHRA's internal resourcing capabilities, development and retention of expertise and institutional knowledge base
- strengthening the MHRA's engagement with its ecosystem of stakeholders, including experts in regulatory innovation

The recommendations that follow sit beneath an overarching 'headline' recommendation that can be stated succinctly:

- The government and the MHRA should commit to establishing a world-class reputation in regulatory science, medicines development and licensing. The MHRA should play a critical facilitating role in leading the life sciences ecosystem and applying 21st-century technological advances. The MHRA needs to focus more on delivering its statutory regulatory duties and developing a culture of transparent, collaborative and predictable regulatory function. It must be among the best in the world at both regulating innovation and innovating regulation.

## 3.

The MHRA should develop ways to improve and encourage the transfer of institutional knowledge between experienced and newer MHRA sta , and between industry and the MHRA.

Regulatory authorities need to provide expert opinion and consistency in approach, keeping up to date with evolving technological advances. The MHRA needs to develop a more targeted strategy for knowledge transfer and talent retention. This strategy should involve the development of new training programmes where former or current long-serving MHRA assessors teach and mentor less experienced assessors.

## Regulatory function and o ers

## 4.

The MHRA must strengthen internal and external accountability mechanisms for the performance of statutory duties and the development of innovative regulatory o ers, helping to ensure consistent delivery of crucial regulatory functions.

The perception of a lack of accountability for external delivery was a persistent theme in survey responses, interviews and workshops. The MHRA's restructure in 2021 is often perceived to have contributed to this by displacing clear lines of accountability within a matrix structure. As a  rst step, an independent assessment should be made of the functioning of the organisational structure to evaluate its impact on regulatory performance.

## 5.

The government and the MHRA must ensure that the upcoming clinical trials legislation reinforces the strength of commercial clinical trial activity and keeps the UK globally competitive, maximising the unique attributes of the UK population and infrastructure, and opportunities for alignment of diagnostic regulatory framework.

Growth in clinical trial activity depends on timely approvals and acceptability of innovative approaches, particularly in the phase I setting and areas where the UK has strong expertise and attributes. While the backlog in trial approvals has been largely addressed, there are clear opportunities for the MHRA to move to a more e ective, streamlined, and world-class trials regulation. The proposed legislative changes for clinical trials need to sustain the momentum generated by the O'Shaughnessy review to accelerate trial approvals, remove unnecessary burdens and speed up trial recruitment. This recommendation also hinges on other parts of the ecosystem, such as NHS trusts, being able to manage any increases

## 6.

The government and the MHRA should continue to develop and champion international recognition and reliance protocols on a unilateral basis, and increasingly, a bilateral and plurilateral basis, with other countries across the globe, enhancing the reputation of the MHRA as a global leader.

Regulatory reliance o ers better use of resources and leadership in particular areas. Stakeholders generally rated the MHRA's partnerships and collaboration with international reference regulators positively. As such, the MHRA should continue to champion its existing routes (IRP, Project Orbis, Access Consortium) and sustain a strong commitment to international regulatory diplomacy, convergence in key standards and reliance in appropriate contexts. Given stakeholder preferences for the MHRA to be a ' rst approver' rather than 'fast follower' wherever it can, it should be emphasised that a proactive and pragmatic approach to recognition and deference should not come at the expense of ambition to be a rst mover and precedent-setter in key areas, where the MHRA is the reference regulator.

## 7.

The MHRA should commit to enhancing the operation of
creating an end-to-end access route for an EAMS marke
removing duplication and replication of regulatory proces

Early access exibilities are crucial for patients with high
needs and these pathways need to be attractive to indus
data and documentation submissions made in the contex
EAMS process must be duplicated when ultimately apply
authorisation. The MHRA should remove this duplication
applications to directly and formally support standard aut
applications.

# 11.