ABHI response to consultation on Policy paper: A pro-innovation approach to AI regulation

June 2023

ABHI

Introduction

A pro-innovation approach to AI regulation
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CONSULTATION QUESTIONS

Our revised AI principles
Our framework is underpinned by five principles, which we expect to guide and inform the responsible development and use of AI in all sectors of the economy:
1) Safety, security and robustness
2) Appropriate transparency and explainability 3
) Fairness 4
) Accountability and governance 5
) Contestability and redress

See section 3.2.3 in A pro-innovation approach to AI regulation for more details.

1: Do you agree that requiring organisations to make it clear when they are using AI would improve transparency?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer				X		

We welcome the government's recognition that information should be provided "appropriately" by organisations using AI based on the intended use, level of risk and the target audience. We further agree that such as approach can help increase public trust. Such a targeted approach will be supported by sector regulators developing relevant transparency frameworks based on intended use, context of use and the end user. Particularly in the health context, where the end recipient (patient) is not the necessarily the user of the AI system, such transparency is particularly important to maintain trust in a highly sensitive use case.
It should be noted that transparency is as much about explaining an ethical decision-making process as it is about explaining model architectures, training results, and model parameters. The conversation and language have to balance the needs and understanding of stakeholders.

2: Are there other measures we could require of organisations to improve transparency for AI?
In medical devices and diagnostics MHRA labelling requirements already exist. These existing legislative requirements can be augmented through the proposed approach of guidance and utilisation of standards rather than creating a new framework. ABHI welcomes the proposed non-legislative approach and wherever possible alignment with existing international standards

and best practice guidance should be the leveraged. Where no such approaches exist we commend the approach of MHRA in proactively working with like-minded jurisdictions to develop common approached (Good Machine Learning Practice for Medical Device Development: Guiding Principles - GOV.UK (www.gov.uk))
Existing labelling frameworks for medical devices provide an effective mechanism for manufacturers to communicate the essential information needed for the safe and effective use of AI/ML-enabled software. Specifically, these labelling frameworks ensure that product information is provided in a clear and timely manner and shared in a way that best supports patients and health care professionals in understanding the benefits, risks, and limitations to safe and effective use of the product. Any modification or augmentation to existing labelling frameworks for medical devices should focus on those areas where AI/ML-enabled devices raise unique challenges as compared to other medical device technologies. In addition, consideration should be given to the type of AI, i.e., locked versus adaptive. Finally, we encourage the use of electronic instructions for use to help support more rapid update to labelling as the AI iterates.

3: Do you agree that current routes to contest or get redress for AI-related harms are adequate?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer				X		

Routes for contestability and redress for AI-related harms are adequately addressed for the medical device industry through current sectoral legislation, e.g. through medical technology vigilance/incident reporting, with robust processes in place for medical devices which should also be utilised for AI-enabled medical devices. The existing regulators are the most appropriate body to apply existing rules to various products and situations to adequately balance public interest and expectations of safety This will ensure that there is consistency across medical devices for affected parties to contest harmful outcomes or decisions.

4: How could current routes to contest or seek redress for AI-related harms be improved, if at all?

As stated above, we believe there is already a robust process for this in the medical device sector that should be leveraged for AI-enabled medical devices. Current routes to contest or seek redress are appropriate, including for AI-related harm. What may need to be done is to clarify that software is a product, and therefore subject to consumer protection legislation. To facilitate proving tort, consider for opaque systems the addition of automatic logging functionality to ensure the auditability of the AI system's operation and to facilitate the post-market monitoring. The logs will allow detection of when the AI system presents a risk. Such logging should be done in consideration of state-of-the-art standards.

5: Do you agree that, when implemented effectively, the revised cross-sectoral principles will cover the risks posed by AI technologies?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer				X		

The UK framework allows regulators to apply the framework within the remits of their sector, which will facilitate effective and appropriate implementation of the principles to encourage innovation while ensuring the safe and effective use of the AI systems. We would emphasize the need for relevant risk-benefit assessment - a fundamental concept in healthcare innovation - and each of the principles could be considered in that regard. The flexibility in the proposals in permitting regulators to interpret the framework as it applies to their relevant sector is welcome and will help ensure that the principles are applied in a manner relevant to each sector.

6: What, if anything, is missing from the revised principles?

The principles could highlight further the concept of risk-benefit balance and the ethical principal of 'beneficence'. A singular focus on safety risks missing the point of the performance of the system and delivering the foreseen benefits. Suggest adding to the foundation the idea of risk-benefit balance, including the risk of not using AI at all.

A statutory duty to have due regard to the principles.

The AI regulation framework will be implemented on a non-statutory basis at first. However, we anticipate that introducing a statutory 'duty to have due regard' on regulators might be needed to strengthen the framework at some point. A statutory duty would create a legal obligation on regulators to have due regard to the AI principles. See section 3.2.4 in A pro-innovation approach to AI regulation for more details.

7. Do you agree that introducing a statutory duty on regulators to have due regard to the principles would clarify and strengthen regulators' mandates to implement our principles while retaining a flexible approach to implementation?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer			X			

A cross-sectoral statutory duty on regulators should only be introduced when deemed necessary after collecting input from the regulators and the public following a period of non-statutory implementation period has been received. The medical device sector already has robust regulatory requirements in place and therefore may not need additional statutory requirements. Any statutory language should be flexible to ensure that regulators may implement the requirements as appropriate for the specific sector. For this reason, any statutory duty on regulators should allow regulators to provide exemptions where sectoral requirements or guidance exists.

We also reiterate the importance of joint guidance within a specific sector where more than one regulatory body may have jurisdiction. For example, the intersection between a sectoral

regulator, MHRA and a horizontal regulator such as the ICO. Existing regulators will have the best understanding of their capacity and ability to mitigate the AI risks relevant to their sector with existing authorities. The UK government should ensure that regulators have input into whether statutory language is needed to support the sectoral implementation of the principles in this framework and, if so, that such language is appropriate and flexible to the sector.

8. Is there an alternative statutory intervention that would be more effective?

Before launching any statutory intervention, the principles should be tested in real-world engagements to monitor whether those principles work among all stakeholders. In the meantime, guidance documents should be developed laying down the principles of AI and how it should be regulated within the respective sector, along with the adoption of relevant international standards and guidance.

New central functions

We intend to coordinate, monitor and adapt the framework through central mechanisms that will supplement and support the work of regulators without undermining their independence or duplicating existing activities. We will bring together a wide range of interested parties including regulators, international partners, industry, civil society organisations such as trade unions and advocacy groups, academia and the general public

See section 3.3.1 in A pro-innovation approach to AI regulation for more details.

9: Do you agree that the functions outlined in section 3.3.1 would benefit our AI regulation framework if delivered centrally?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Monitoring and evaluating the framework as a whole				X		
Assessing and monitoring cross-economy risks arising from the use of AI				X		
Scanning for future trends and analysing knowledge gaps to				X		

inform our response to emerging AI						
Supporting AI innovators to get new technologies to market (see section 3.3.4 for more detail)				X		
Promoting international alignment on AI regulation				X		

We agree that certain functions will benefit from centralized support where there is a need for cross-sector input, monitoring and evaluation of developments and assessment of the framework performance. This can help ensure that AI technologies bring substantial benefits to citizens while also ensuring that AI does not negatively impact safety or human rights.
The medical device sector already has robust frameworks for monitoring and risk assessments that are specific to risks related to medical devices. Therefore, we encourage the UK government to leverage MHRA's existing authorities for these functions.

10: What, if anything, is missing from the central functions?

Central functions should be required to consider input from the different sectors and sufficient autonomy to provide independent advice. The central function should also have a requirement to with other global and regional partners.

11: Do you know of any existing organisations who should deliver one or more of our proposed central functions?

Is there, for example, an academic research group that conducts AI horizon scanning or a think tank that gathers evidence on regulatory impact.

Yes	X	Consider both existing government entities and NGOs such as research groups and technology-focused think-tanks that can fulfil a robust advisory role in support of the central functions. Examples: • Alan Turing Institute • Office for AI
No		

12: Are there additional activities that would help **businesses** confidently innovate and use AI technologies?

Yes	X	Global harmonisation including conformity assessment, audit programmes, standards and guidance. Particularly with significant trading partners such as EU and USA Facilitate data access. Make existing regulatory pathways more streamlined and transparent, rather than creating new ones. Ensure a minimum level of requirements are met by providers of foundation models and general-purpose AI (See note below). Note: Small and medium size companies struggle to comply with sectoral tech legislation (e.g., medical device legislations in EU, US, UK...), if a third-party component which they intend to integrate into their product and further train for their specific use case, does not meet a minimum set of requirements (e.g., having been developed using good machine learning practices) so that the product in which it is integrated can prove compliance with sectoral tech legislation. Many of these called "foundation model" or "general purpose AI" components are developed by big tech companies. These components are currently not subject to any (sectoral) legislation. The integrator company often can only prove the final product complies with sectoral tech legislation if it can demonstrate that the product, including its components, complies with the sectoral legislation. The small and medium size companies however struggle to impose contractual requirements on big tech for their foundation models and general-purpose AI to meet a minimum level of requirements. A legal framework that forces foundational models or general-purpose AI to comply with a minimum set of requirements, will ensure that UK companies can integrate these components, prove compliance with sectoral legislation and export them to the main markets around the world
No		
Unsure		

12.1. If so, should these activities be delivered by government, regulators or a different organisation?
A multi-stakeholder approach at the international level is required, to ensure that relevant AI legislation is not only harmonised. This will include government, regulators and importantly standards organisations.

13: Are there additional activities that would help individuals and consumers confidently use AI technologies? Please limit your response to 2-3 sentences.

Yes	X	General awareness and education of the general population on both the benefits and risks of AI and the guardrails that are in place. Ensuring basic levels of proficiency and understanding of relevant user groups through development of appropriate training curriculum. Making AI 'trustworthy', carefully managing data, making it usable for AI applications, communicating the benefits of AI and providing guidance on applying regulations to AI technologies. Appropriate post-market surveillance/monitoring obligations on economic operators Using guidance and standards to oblige providers to assess bias and caution users where bias may impact safety or performance
No		
Unsure		

13.1. If so, should these activities be delivered by government, regulators or a different organisation?

UK government has a critical role to play in communicating with citizens on the risks, benefits and guardrails for AI. Regulators should undertake a similar role within their sectoral responsibilities. Academia broadly will also need to address the introduction of AI with both broad-based education and vocational training. Medical Device Innovators have a statutory requirement to proving appropriate training on their products.

14: How can we avoid overlapping, duplicative or contradictory guidance on AI issued by different regulators?

This relates to your section on "Monitoring, assessment, and Feedback". We understand this as the central government function collaborating with sector functions to, in an iterative way, update the horizontal principles AND the sector legislations until definitions and requirements integrate well. This should be done carefully to avoid collapse of the vertical legislation and its supporting standards and guidance.

To do so, use guidance as a precursor to international standards. The central government function must work with sector functions to ensure that:

1. There is a common base layer with (A) minimum requirements and (B) aligned terminology, i.e.,
    A. Minimum requirements raise the bar high enough to create safe systems and trust, while not conflicting with requirements of sector legislation.
    B. Aligned terminology does not conflict with terminology of sector legislation.

The horizontal layer should act as foundation on which the sectors can build, i.e., vertical guidance reference them and add sector- or technology-specifics only if necessary.

2. If conflicts cannot be resolved through guidance, add a derogation for the sector until the horizontal principles or sector legislation are revised and can be aligned

UK government should continue its engagement with international harmonization forums and is encouraged to help develop harmonised AI regulatory requirements with other nations and international bodies.
Regulators need to be provided with adequate funding and resources, including forums to effectively discuss cross-sector coordination and, where relevant, jointly tackle issues.

Monitoring and evaluation of the framework

We will need to monitor the implementation of the framework closely to make sure that it is working as designed. We will monitor the regime to ensure it aligns with 6 key characteristics, these being: pro-innovation, proportionate, adaptable, trustworthy, clear and collaborative. See box 3.2 in A pro-innovation approach to AI regulation for more details.

15: Do you agree with our overall approach to monitoring and evaluation?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer				X		

ABHI agrees with the need to monitor the implementation of the framework and to ensure it is working as designed as well as the need to gather diverse input. Government should consider already existing frameworks, such as that of the MHRA for medical technology, to oversee certain functionalities, such as the development and monitoring of metrics and the effectiveness of the framework in mitigating unacceptable risks.

16: What is the best way to measure the impact of our framework?

Finding suitable metrics is challenging considering there are often many confounding variables that impact the metrics. We encourage aligning with other legislators across the world to develop and use a common methodology that ensures the metrics are comparable across jurisdictions.

Possible KPIs to consider: consumer trust and satisfaction, rate of innovation, time to market, complaints/adverse events, litigation, compliance costs etc. Specifically in health, clinical and financial outcomes should be captured alongside patient reported outcomes and experience.

17: Do you agree that our approach strikes the right balance between supporting AI innovation; addressing known, prioritised risks; and future-proofing the AI regulation framework?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer				X		

ABHI agrees with the need to monitor the implementation of the framework and to ensure it is working as designed as well as the need to gather diverse input. Government should consider already existing frameworks, such as that of the MHRA for medical technology, to oversee certain functionalities, such as the development and monitoring of metrics and the effectiveness of the framework in mitigating unacceptable risks.

18: Do you agree that regulators are best placed to apply the principles and government is best placed to provide oversight and deliver central functions?

Yes	X	We broadly agree with this proposal. Regulators are best placed to apply the principles in practice and build upon already existing sectoral frameworks as needed. Development of the central function should have due regard to existing entities and avoid duplication/reinvention.
No		Please describe:
Unsure		

Regulator Capability

While our approach does not involve extending any regulator's remit, regulating AI uses effectively will require many of our regulators to acquire new skills and expertise.

19. As a regulator, what support would you need in order to apply the principles in a proportionate and pro-innovation way?

No response

20: Do you agree that a pooled team of AI experts would be the most effective way to address capability gaps and help regulators apply the principles?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer					X	

Strongly support the proposals though should come from different fields (regulators, industry, academia, auditors, public, etc) to ensure good representation and adequate skill sets to define and apply the principles. It should be clear that the group is advisory and not a regulator in its own right. The expert group composition should be reviewed on a regular basis to ensure it is current and comprehensive.

Tools for trustworthy AI

Assurance techniques and technical standards will play a critical role in enabling the responsible adoption of AI and supporting the proposed regulatory framework. These techniques include impact assessment, audit, and performance testing along with formal verification methods.

See part 4 in A pro-innovation approach to AI regulation for details.

21: Which non-regulatory tools for trustworthy AI would most help organisations to embed the AI regulation principles into existing business processes?

Please limit your response to 2-3 sentences.

Education and balanced communication of the benefits and risks together with the strategy behind the framework should be embedded into existing business processes. This should be supported by a strong emphasis on ethical and accountable approaches.

Final thoughts on the framework

22: Do you have any other thoughts on our overall approach? Please include any missed opportunities, flaws, and gaps in our framework.

We agree with the UK government that non-legislative initiatives, such as guidance or the utilization of standards, is the preferred method. The development of stringent legislative frameworks stifle innovation since legislation will be unable to accommodate new learnings stemming from increased experience with AI. This could have negative effects on patients in the healthcare sector.

Allowing sectorial regulators to better determine the balance between horizontal requirements and a vertical benefit/risk conversation in their own sector is a very practical approach though care has to be taken to ensure there is effective oversight so as to avoid undesirable divergence between sectors on interpretation of the framework principles.

It is important to avoid contradiction with other global legislation and the development of standards which may add obstacles to the delivery and access of AI solutions that demonstrate clear benefit v. risk. We therefore encourage the UK government to leverage international standards and continue UK's international engagement to further global harmonization of AI-enabled medical device regulation to encourage innovation and patient access to medical device technologies while ensuring safety and effectiveness of AI systems. We support continued work to harmonize requirements and policies for the medical device sector, such as through UK's international engagement and collaboration and engagement at IMDRF (International Medical Device Regulators Forum) level.

Legal responsibility for AI

We recognise the need to consider which actors should be responsible and liable for complying with the AI principles. The ideal distribution of legal responsibility for AI may not be the same as the burden under current legal frameworks.

L1: What challenges might arise when regulators apply the principles across different AI applications and systems? How could we address these challenges through our proposed AI regulatory framework?

ABHI reiterates support for a model whereby expert sectoral regulators will implement the AI principles and are well positioned to integrate the principles in the existing framework and avoid a 'horizontal' application of the principles that would lead to conflicting provisions or legal uncertainty. The proposed AI regulatory framework should therefore explicitly mandate sectoral regulators to make their own assessment of to what extent the existing regulatory regime is already incorporating the proposed AI principles and allow them to address gaps only.

One area of challenge maybe on the boundaries of a sector and clarity of which technologies fall into a regulators purview. In the case of health and care there is a blurring between regulated medical devices and fitness and wellness applications and technologies. Equally there can be uncertainty on the interface between medical devices and some data/IT applications. There should be clarity on the scope of each regulator.

However we see more risk in duplication and unclear interplay between horizontal and sectoral regulations caused by the application of the principles by 'horizontal' regulators, especially if they choose not to leverage existing sectoral requirements existing in currently highly regulated sectors. We see value in a mandate to horizontal regulators to work together with sectoral regulators to develop joint guidance, where possible, to support industry compliance with the principles and relevant regulatory requirements. The central function should be able to bring balanced and comparable approaches to different regulators.

SMEs may struggle to prove compliance with (sectoral) legislation when integrating foundation model created by big tech not subject to the same (sectoral) legislation. International standards could be used to ensure foundation models comply with minimum requirements needed for SMEs to meet sectoral obligations.

L2.i: Do you agree that the implementation of our principles through existing legal frameworks will fairly and effectively allocate legal responsibility for AI across the life cycle?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer			X			

Given that the framework relies on the implementation and alignment of the principles into existing legal frameworks then there is a risk that the principles will add potential misinterpretation of where responsibility lies given already existing precedents from sectoral legal frameworks.

L2.ii: How could it be improved, if at all?

Where possible, each regulator should make an interpretative statement as to how the principles are incorporated into their existing framework and where if any interpretation of the existing framework changes or should be given greater focus. These statements should be aligned between sectoral and horizontal regulators. If there is to be change, then sufficient periods of implementation and consultation of impact should be allowed.

L3: If you work for a business that develops, uses, or sells AI, how do you currently manage AI risk including through the wider supply chain? How could government support effective AI-related risk management?

The medical device regulations already place extensive obligations on manufacturers of medical devices regarding quality management, risk management, traceability and vigilance to monitor and assure the safety of a device throughout its lifecycle. Therefore, existing medical device requirements should be leveraged for AI-related risk management. Risks are managed across the supply chain following the legislative obligations for manufacturers, importers, and distributors of medical devices.

Foundation models

Foundation models are an emerging type of general purpose AI that are trained on vast quantities of data and can be adapted to a wide range of tasks. The fast-paced development of foundation models brings novel challenges for governments seeking to regulate AI. See section 3.3.3 in A pro-innovation approach to AI regulation for detail.

F1: What specific challenges will foundation models such as large language models (LLMs) or open-source models pose for regulators trying to determine legal responsibility for AI outcomes?

Given the significant rate of growth of foundation models and foundation model providers we agree with the UK Government's views expressed in the White Paper that it is premature to make changes to life cycle accountability at this stage. Further stakeholder engagement at a sectoral level is recommended as current sectoral approaches, alongside general product liability and contractual liability regimes, may already provide for distinct roles and responsibilities that are relevant to LLM.

Within the sector issues of model architecture, training methods, and training and test data need to be addressed.

As highlighted in previous answers the lack of legally binding provisions applicable to foundation models and the difficulty for SMEs to contractually impose obligations on big tech providers of large language models so they can build these into their products in a way that complies with sectoral legislation.

F2: Do you agree that measuring compute provides a potential tool that could be considered as part of the governance of foundation models?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer			X			

Assuming the main point is environmental, it could be one practical measure though care has to be taken to avoid measures of compute that lack granularity and are not balanced with the size of any organization or entity, their ability to deliver effective AI solutions to communities, and their ability to access the most efficient/optimum compute services. Measuring the number of

petaflops used during development, testing and use of AI can provide insight into a company's development efficiency, which is undesirable from a competition point of view.

F3. Are there other approaches to governing foundation models that would be more effective?
We agree with the UK Government's views expressed in the white paper that it is early in the maturity cycle of these technologies so we have no further comments at this time. Use legislation to define minimum requirements on foundation models. The bar should be high enough so SMEs can integrate and incorporate foundation models into their products in ways that allow the products to be compliant with sectoral legislation, such as medical device legislation.

Artificial intelligence sandboxes and testbeds

Government is committed to supporting innovators by addressing regulatory challenges that prevent new, cutting-edge products from getting to market. To deliver an effective sandbox, we would like to understand more deeply what service focus would be most useful to industry.

S1: To what extent would the sandbox models described in section 3.3.4 support innovation?

	Strongly prevent innovation	Somewhat prevent innovation	No impact on innovation	Somewhat support innovation	Strongly support innovation	Don't know
Single sector, single regulator (support innovators to bring AI products to the market in collaboration with a single regulator, focusing on only one chosen industry sector).					X	
Multiple industry sectors, single regulator (support AI innovators in collaboration with a single regulator that is capable of working across multiple industry sectors).				X		
Single sector, multiple regulator (establish a sandbox that operates in only one industry sector, but is capable of supporting AI innovators whose path to market requires interaction with				X		

one or more regulators operating in that sector).						
Multiple sectors, multiple regulators (a sandbox capable of operating with one or more regulators in one or more industry sectors to help AI innovators reach their target market. The DRCF is piloting a version of this model).			X			

A single sector, single regulator, sandbox model would support innovation, as the challenges posed by AI will vary by sector, it may not be feasible to establish one sandbox for all sectors. Involving multiple sectors and regulators might pose challenges around data protection/intellectual property.
We do however recognise that there could be cases where a sectoral regulator and a horizontal regulator may need to combine (Single sector, multiple regulator), for example on health technology, MHRA is the lead regular but may need to work with others such as ICO or Care Quality Commission.

S2: What could government do to maximise the benefit of sandboxes to AI innovators?
There should be regular reports and guidance from the sandboxes to inform innovators and future regulatory regimes to help 'create 'business-as-usual' processes. These should facilitate cross sector learnings and could be a role of the central function. The use of such sandboxes will also require specific staff expertise and technological capability from the regulator, the government should provide the resourcing to enable this.

Sandboxes must span market authorization and market access pathways. The market access pathways must extend to the end-customer. E.g., today, the EVA Pathway for medical devices provides a faster (<6 months) and more efficient approach through the National Institute for Health and Care Excellence (NICE) framework, for certain devices. Having passed NICE, the manufacturer however still needs to convince local NHS trusts to acquire the technology. To be successful sandboxes must span the entire pathway and ensure there are joined up processes to enable market deployment at scale.

S3: What could government do to facilitate participation in an AI regulatory sandbox?
The government could set clear criteria, guidance and expected benefits for entering or using sandboxes, as well as provide early incentives for participation. Ensure processes are integrated between regulatory sandbox and market access to support deployment at scale.

S4: Which of the following industry sectors do you believe would most benefit from an AI sandbox? Please select from this list the sectors your organisation works in or interacts with that would most benefit from a sandbox.

	Primary sectors (extraction of raw materials, farming, fishing)

	Secondary sector (utilities, construction, manufacturing)
	Financial services & insurance
	Communications
	Hospitality and leisure
	Real estate
	IT
	Legal services
	Retail
	Transportation
X	Healthcare
	Education
	Public sector
	Research and development
	Arts and entertainment
X	AI, digital, and technology
	Regulation
	Other

MHRA has already undertaken to establish sandboxes for AI within its AI and SaMD roadmap, an 'airlock process' in their terminology, we are highly supportive of this approach. The sector has existing experience and processes to support such approaches.