

BIA response Wellcome consultation on the oversight of emerging science and technology

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As the trade association for innovative bioscience companies in the UK, the BioIndustry Association (BIA) welcomes the opportunity to respond to Wellcome's consultation on the oversight of emerging science and technology.

It is vital that current and future approaches to oversight ensure that the UK continues to be an attractive destination for top global talent to conduct their research and innovative companies to start-up and grow. Ultimately, this will safeguard the UK as a country in which science and technology can be developed to the benefit of society. If the UK continues to be outward-looking in this regard, there will be positive benefits in all the areas highlighted by the questions below.

Q1. Thinking of approaches in the UK and internationally, what are the key elements of good oversight that should be in the UK's approach for emerging science and technology?

To ensure responsible innovation, it is important that the UK's approach to the oversight of emerging science and technology follows the below principles:

- Allows innovation to flourish through flexibility.
- Stimulates public engagement and debate.
- Provides confidence to the public.
- Issues clear communications.
- Provides scientific advice to industry (e.g. as provided by the MHRA).
- Fosters a collaborative mindset and partnership between industry, government and academia.
- Brings partners and stakeholders together for brainstorming and networking (e.g. workshops).
- Assembles expert panels, SMEs, and thought-leaders drawn internationally to provide guidance, recommendations and oversight to ensure regulators are in step with the latest thinking internationally, e.g. to ensure patients have timely access to the latest innovative treatments.
- Listens attentively to feedback from learned societies and trade associations.

Q2. From your perspective, what current oversight/regulatory processes of emerging science and technology could be improved?

As scientific knowledge advances and societal views evolve, oversight of the following areas of emerging science and technology should be monitored and considered for reform if innovation and commercial development is being impeded.

- Functional genomics (includes gene-editing, genetic manipulation, stem cell-based approaches and other cell-based and in-vitro strategies).
- In-silico approaches (includes artificial intelligence, machine learning, predictive sciences) in biomedical sciences.
- Access to and management of scientific data for use in biomedical sciences.
- Approaches involving the use of cell and gene therapy and genetic manipulation in disease therapies.
- The minimisation of reliance on animal models in human cell-based therapies.
- Industrial biotech.
- Drug safety prediction.
- Biomechanical devices.
- Access and benefit sharing of genetic resources. Under the Nagoya Protocol currently in place, the regulation is very ambiguous and creates numerous uncertainties for bioscience companies (SMEs in particular).

Q3a. Thinking in the longer term about what may present challenges to existing regulation, which areas of science and technology still in their early stages of development should the Government be aware of?

Below we have set out some areas of science and technology in their early states of development of which the government should be aware. We have also included areas of science and technology that are more developed, but which nonetheless pose oversight challenges.

- Development and application of in-silico approaches (includes artificial intelligence, machine learning, predictive sciences) in biomedical sciences.
- Alternative disease-relevant scientific strategies that look to reduce, replace and refine animals in research e.g. complex in-vitro cellular models.
- Development of cell and gene therapy approaches to treating diseases.
- Novel biomedical strategies to address bacterial drug resistance.
- Novel strategies for addressing dementia therapy.
- The use of big data in drug discovery and development.
- The rapid advance in gene-editing, especially using germline cells.
- The use of additional cell types and sub-types for targeted immunotherapy (NK cells, Macrophages, CD4 sub-types, etc).

Q3b. In the future, how do you think the Government should ensure that it is aware of emerging areas of science and technology in good time?

Companies that are on the frontier of emerging areas of science and technology are often small with limited resources to feed into Government horizon-scanning. Trade associations, research institutes and universities that work with these companies are well-placed to contribute to horizon-scanning. There may

be opportunities for government to engage proactively with these organisations to conduct horizon-scanning exercises.

Researchers, businesses and policymakers have a shared responsibility to contribute to an informed public debate to ensure that the wider society is well-informed of the benefits of emerging areas of science and technology and how any potential risks are mitigated. For the bioscience sector, it is important this debate includes a discussion of bioethics so that we, as a society, can take advantage of emerging technologies and have consensus on what might not be appropriate. Future regulations may then be derived from such a bioethical framework. Engaging with these debates will help to ensure the government is well-placed to evaluate and support developing areas of research in a timely manner.

In addition, the government should consider the following principles to ensure it is aware of emerging areas of science and technology in good time:

- Build network of experts and thought leaders drawn from industry, academia, regulators and biotech – to define key future challenges and potential solutions.
- Establish global network of ‘seekers’ to scout future areas in biomedical sciences.
- Use of diverse platforms including relevant social media platforms (e.g. LinkedIn).
- Sponsor selected labs and groups to run pilots and proof-of-concept experiments to test applicability, utility and readiness of emerging scientific areas.