BIA policy submission
December 2024



BIA response to survey on the 10 Year Health Plan for England

Background

The Government is seeking views on its plans to build a health service fit for the future, through the development of a 10 Year Health Plan. The consultation closes on Monday 2 December, and is <u>available here</u>.

About you

The BioIndustry Association (BIA) is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world changing innovation. Our members include start-ups, biotechnology and innovative life science companies, large pharmaceutical companies, universities, research centres, tech transfer offices, incubators and accelerators, and a wide range of life science service providers: investors, lawyers, IP consultants, and IR agencies. We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably.

The 10 Year Health Plan for England

Q1. What does your organisation want to see included in the 10-Year Health Plan and why?

The BIA welcomes the opportunity to input into the development of the 10-Year Health Plan. The plan should be ambitious in setting out clear objectives for the transformation of the NHS over the next decade. It must also be perfectly aligned with the life sciences sector plan; we are pleased to see the structures established by the Office for Life Sciences to do this.

Crucial to the success of both plans will be making sure that the NHS is fit for the future by keeping pace with advances in medicine, medical devices and other technologies. Innovations in the life sciences sector have the potential to transform patient care, including by diagnosing patients earlier, targeting interventions to prevent ill-health, and treating the root cause of diseases that were previously incurable. The NHS has a key role to play in both



developing and delivering these innovations, and, in doing so, supporting the growth of the UK life sciences sector and delivering the government's economic growth mission.

Key to the success of the NHS in the next 10 years will be collaboration and partnership with the life science sector. The UK life science sector has established and successful working partnerships with the UK government through the Life Science Council and the Office for Life Sciences. These should be strengthened as part of the Industrial Strategy and ten year plan. Furthermore, the NHS already has a strong foundation in working closely with industry to deliver the best care for patients and support research and innovation. It is important that the 10-Year Health Plan considers how this collaboration can be further developed as advances in medicine and medical technologies progress. Plans for this should involve bodies including the Medicines and Healthcare products Regulatory Agency (MHRA), National Institute for Health and Care Excellence (NICE) and the National Institute for Health and Care Research (NIHR), as well as the NHS.

A key area of partnership between the NHS and industry is the delivery of clinical trials.

Clinical trials are an essential part of the development of new medicines, and provide opportunities for UK patients to have early access to innovative treatments. The UK has a strong track record in this area, which was exemplified during the COVID-19 pandemic. However, in recent years, the UK has fallen behind in its commercial clinical trials activity. Lord O'Shaughnessy's independent review, published in May 2023, set out 27 recommendations to improve the environment for commercial clinical trials. Some progress has been made in implementing the recommendations, but it is necessary to maintain momentum so that outstanding issues are addressed, including around trial recruitment and delivery. The 10-Year Health Plan provides an opportunity to set out how the NHS will work with industry to continue to support trials and research into innovative new treatments and technologies.

A further area of industry-NHS partnership will be on the use of health data. This is a vital resource that the NHS holds that can be used to fuel innovations across the sector, for the benefit of patients and public. By unlocking this valuable resource for industry of all sizes, companies will be able to scale in the UK, on data relevant to UK populations. Furthermore, industry will be a key partner in realising the true value of this data. Technical solutions across the whole pipeline, from data capture to curation, analysis, storage and federation are being refined and enhanced within in the life science and techbio sectors. By working with colleagues in industry the value of data can be truly harnessed, for the benefit of the NHS, research and industry alike.



Industry engagement, primarily through trade associations, should be done early to identify subsectors and technologies that might help deliver the NHS's three main **objectives**. Start-ups and scale-ups are the primary source of innovation and growth in life sciences and should be prioritised in the industry engagement. In addition to this, the following sub sectors should be included in the plan:

- **Precision and preventative medicine** is a key sector for the future for the NHS. The term encompasses a variety of tools and techniques which seek to predict, diagnose and treat disease in a far more sophisticated manner than in the past. If the NHS is to succeed in shifting to prevention and to better using technology in healthcare, the government needs to work in partnership with companies in this subsector. Precision medicine tools can play a key role in identifying patients most at-risk of developing specific complications, providing them with actionable information about their risks, and helping target interventions to them before they experience the most serious complications. These tools can also ensure that patients receive the right treatments, at the right time, in the right volumes, lessening side effects and improving effectiveness.
- **Cell and gene therapies** have demonstrated their potential to transform patient outcomes for patients with diseases that were previously incurable. These treatments sometimes referred to as advanced therapy medicinal products (ATMPs), involve using cells or genetic material to affect changes inside patients' tissue, cells or DNA. Cell and gene therapies may offer longer-lasting effects than traditional medicines and have the potential to address complex diseases for which there are currently no effective treatments. The NHS is already delivering CAR-T treatments for leukaemia and lymphoma, and gene therapies for life-limiting rare diseases such as Spinal Muscular Atrophy (SMA) and metachromatic leukodystrophy (MLD). Over the next decade, we expect to see more cell and gene therapies approved for a wide range of diseases, potentially including dementia and Crohn's disease.
- Artificial intelligence (AI), machine learning (ML) and technology in life sciences (techbio) are key tools that have the potential to revolutionize the way we understand biology, discover and develop medicines and treat disease. These technologies can be used to improve the detection and diagnosis of disease, speed up the discovery of new drugs and support clinical trial design. They can greatly improve our health, while vastly improving efficiency and growth in the key areas of health and life sciences.

The intersection of two key growth-driving sectors has significant opportunity in the UK, which is seen as a leader in both AI and life sciences. As an example, Alphabet has chosen to



set up their AI and drug discovery company – Isomorphic Labs – not in Silicon Valley, but in London.

• **Genomic medicine** has already demonstrated itself as a key tool for the NHS. Genomics has wide applicability, from use in screening, diagnosing rare disease and supporting the treatment of cancer. This subsector has huge opportunity to be scaled across the NHS to support the 10-year plan. The UK is widely seen as the home of genomics and boasts a world-leading commercial genomics sector, predominantly composed of innovative small and midsize enterprises (SME's). These companies are working on cutting edge innovations which will support the adoption of genomics across the spectrum of healthcare.

Q2. What does your organisation see as the biggest challenges and enablers to move more care from hospitals to communities?

A key enabler in the shift in care to the community will be the use of digital and data sharing technologies. These technologies will allow for patient data to be shared between different care providers and empower patients with their own data. It also enables decentralised research in communities and collection of real world evidence to inform innovation and better delivery of care.

Q3. What does your organisation see as the biggest challenges and enablers to making better use of technology in health and care?

The low level of digitalisation in the NHS is one of the key challenges in making better use of technology in healthcare. Taking data as just one example, there are many different systems and standards in place which makes data sharing difficult. Ensuring all clinical professions have all the digital equipment they need, including an appropriate network connection, will be a big first step in the adoption of technology.

The UK's innovative life science sector will be a key enabler in facilitating the shift towards technology. The UK is home to a wealth of innovations which support various elements of healthcare, from better handling clinical data through to the use of AI in diagnosis and prevention. Collaborating with the life science sector will help bring the benefits of these innovations to patients.

A joined-up approach to the use of **precision medicine, techbio, and genomic** technologies will enable the adoption of technology in the NHS. This not only aligns with the NHS 10-year plan but also helps support this burgeoning sector to flourish. The correct



incentives are needed so that tech providers are seen as worthwhile investments, that will alleviate costs elsewhere in the system.

An innovation friendly approach to **regulation** is another key enabler for technology in healthcare. Currently, the UK has adopted a flexible approach to regulating AI, this is important within the life sciences as it allows AI to be applied in low-risk settings with proportional regulation. However, as technology is adopted more within the NHS, a clear agile framework for regulating technology in healthcare is needed, so that innovations can be developed and brought to patients in a safe but competitive manner.

Access to health data is another key area where investment is needed to support the tech shift. The trend of fragmenting health data in multiple, siloed, Secure Data Environments (SDEs) which lack unifying data representation and quality standards prevents research and innovation. Health data should be accessed by streamlined and standardised access processes, which are clear and transparent. Data should be secured in SDEs which are technically flexible and provide IP protection to innovators, which are standardised and interoperable, where appropriate, to support interconnected or federated data analysis.

The recommendations of the Sudlow review need to be implemented in close collaboration with innovators in the life science sector, this will help support the transition to using technology in the NHS, while also making the system more sustainable.

Q4. What does your organisation see as the biggest challenges and enablers to spotting illnesses earlier and tackling the causes of ill health?

A significant challenge is the way in which new health interventions are valued and paid for in the NHS. This is in part because the current health system incentivises treating sickness with 'one size fits all' drugs or therapies, rather than early diagnosis or targeted therapies. Another factor is that many innovative therapies which tackle the root cause of disease, such as cell and gene therapies, have high upfront costs and benefits which accrue over a lifetime. These challenges are often exacerbated for medicines for rare diseases where there is inevitable uncertainty due to low patient numbers. A 2023 BIA/ABPI survey of members actively engaged in the discovery, development, and commercialisation of treatments for rare diseases found that around half of approved rare disease products are not being reimbursed for patients in England.

A refreshed approach to adoption of innovation in the NHS is needed to enable the shift to prevention. This should include reform of NICE's methods for evaluating the cost-effectiveness of new technologies which currently fail to recognise the full socioeconomic value of health interventions in treating and preventing disease. Such reform could also



enable aligned incentives to encourage R&D in areas of unmet need, such as many rare diseases, and route funds to innovations that bring down the overall cost of healthcare. This would include new frameworks that evaluate the full costs and benefits of health interventions and account for long term impacts. Dedicated funding for precision and preventative health technologies would better support companies that align with the prevention agenda.

Precision medicine is a key enabler of prevention as it helps identify patients most at-risk of developing specific complications, providing them with actionable information about their risks, and helping target interventions to them before they experience the most serious complications. For example, precision medicine diagnostics can help predict type-II diabetes patients at risk of chronic kidney disease. This cohort is most likely to experience renal failure, leading to hugely expensive and life-limiting dialysis and/or transplant. Impacting just 25% of these patients would reduce the burden of disease on the NHS significantly and save over £1B per year.

Accurately diagnosing patients and revealing the mechanisms underpinning their form of the disease is at the heart of precision medicine. New functional genomics technologies like epigenetics, proteomics, transcriptomics, metabolomics, liquid biopsies, and gene editing give us new insights into the causes and effects of disease.

Expanding our understanding of complex diseases to consider multiple mechanisms, diverse populations and environmental factors will be essential to realizing the benefits of precision medicine approaches. This can only be achieved with consistent, high quality multi-modal patient data and a new generation of AI-based tools to interpret them.

The routine use of genomics technologies will also be a vital tool in the shift to prevention. The integration of genomics into routine care offers an exciting opportunity to better prevent, detect, and treat disease. The current NHS genomic infrastructure is not set up for routine diagnostic and decision-making and as such is over capacity. A new strategy for the use of genomics throughout the care pathway should include screening to enable early diagnosis and prevention of disease. Genomics England's Generation Study has the potential to transform the diagnosis and treatment of rare genetic conditions, and it is important that the outputs of the study are used to inform the use of whole-genome sequencing in population-level newborn screening. The new plan should also consider the storing and use of genomic data for research and innovation, so that its use can be further expanded over time.



Q5. Please use this box to share specific policy ideas for change.

Please include how you would prioritise these and what timeframe you would expect to see this delivered in, for example:

Quick to do, that is in the next year or so:

- Invest in all core frontline digitalisation
- Commit to long-term funding the NHSE Data for R&D programme
- Continue to adopt data and technology standards across the NHS
- Invest in data and digital skills in the NHS
- Commission a review on reimbursement mechanisms
- Commission a new strategy for the use of genomics in healthcare
- Implement the recommendations of Lord O'Shaughnessy's review of commercial clinical trials
- Review NICE's methods and processes to enable the shift to preventative healthcare by evaluating the full, long-term costs of benefits of health interventions

In the middle, that is in the next 2 to 5 years:

- Share cases of best practice technology uses
- Federation of subnational health data assets for research and development
- Embed the use of whole genome sequencing in population-level newborn screening for treatable rare diseases
- Develop joined-up mechanisms to incentivise early prognosis and diagnosis of disease and enable targeted, early intervention
- Implement changes to NICE's methods and processes to enable the shift to preventative healthcare by evaluating the full, long-term costs of benefits of health interventions