Innovation in the NHS: personalised medicine and AI

Response to the House of Lords Science and Technology Committee's call for evidence

Introduction to the organisation and the reason for submitting evidence

This is a response from the National Engineering Policy Centre (NEPC) on behalf of the Royal Academy of Engineering and the Institution of Mechanical Engineers. The NEPC, led by the Royal Academy of Engineering, is a partnership of 43 professional engineering organisations that cover the breadth and depth of the engineering profession. The NEPC brings engineering thinking to the heart of policymaking, creating positive impacts for society. Together we provide insights, advice, and practical policy recommendations on complex national and global challenges.

The Royal Academy of Engineering is the UK's National Academy for engineering and technology. We bring together leading engineers, researchers, innovators and business leaders to deliver public benefit through excellence in engineering. As a National Academy, we provide leadership for engineering and technology, and independent, expert advice to policymakers in the UK and beyond. Our work is enabled by funding from the Department for Science, Innovation and Technology, corporate and university partners, charitable trusts and foundations, and individual donors.

One of the ways the Academy contributes to policy development is by convening expertise from across our Fellowship, Awardee Excellence Community, Enterprise Hub, and wider networks, such as our Healthcare Community of Interest, including experts in biomedical engineering, medical technology, AI, data and systems thinking. This enables us to bring together perspectives from research, innovation and deployment to inform policy questions where engineering and technology are central.

We are submitting evidence to this inquiry because personalised medicine and AI raise a broader question of direct relevance to engineering policy: why promising innovations often struggle to move from research and validation into routine NHS use at scale.

Summary

For the NHS, the strongest near-term opportunities from science and technology innovation lie where there is already infrastructure, clear clinical need and a realistic route to deployment. These include AI-assisted imaging and diagnostics, risk stratification and prevention for long-term conditions, genomics-enabled stratification in cancer and rare disease pathways and the growing use of sensors and wearables where data can be integrated into care pathways.

On data and infrastructure, NHS digital and IT systems are a substantial barrier. The UK has major strengths in longitudinal health data, academic capability and secure research environments, but remains much better at creating research datasets than embedding data-driven tools into routine care. Interoperability,

uneven digital maturity, patchy linkage across settings, inconsistent annotation, basic data formatting incompatibilities and trust-by-trust governance requirements all slow deployment and increase costs. More mutually recognised governance approvals, clearer data access processes and stronger operational infrastructure are needed.

On translation and deployment, the NHS remains highly fragmented. Companies repeatedly face a "one hospital at a time" model, requiring repeated clinical pathway design, data governance, digital integration, contracting and local verification. This is especially damaging for SMEs. After several successful adoptions, there should be reusable templates for the clinical, business and governance case rather than repeated local re-approval. The NHS Innovator Passport could help if it is designed to support centralised evidence evaluation, standardised IT and information governance requirements and access to NHS staff and settings.

On regulation, there are concerns about regulators' capacity, clarity, duplication and insufficient engagement with innovators. The UK has important building blocks through MHRA, NICE, DTAC and NHS guidance, but regulatory and evaluation processes are often too slow, too sequential and insufficiently adapted to AI-enabled tools that evolve over time. Better coordination between regulatory approval, HTA and NHS evaluation, combined with stronger post-deployment monitoring and clearer accountability, would improve both safety and speed.

On health economics, strong technical and clinical evidence alone are often not enough to secure adoption. Innovations can fail because the NHS cannot clearly identify or capture the savings or service benefits they create. This is especially true for technologies that improve workflow, avoid deterioration or support prevention and early intervention rather than replacing an existing product. Procurement and commissioning need to be more closely joined to evidence generation from an earlier stage.

Strategically, the UK needs a more coherent route from validation to routine use. The most important interventions would be a clearer national adoption pathway joining up evidence, procurement, implementation and monitoring; more standardised data governance and interoperability; more proportionate and transparent evidence expectations; stronger translational workforce capability; and more effective regional or national mechanisms to spread adoption beyond a single trust or pilot site.

Scope of the response

The Committee's inquiry is framed around personalised medicine and AI. The evidence gathered by the Academy identifies important opportunities in personalised medicine, including genomics-enabled stratification, diagnostics, risk stratification, sensors and wearables. However, most contributors focused on the broader challenge of translating AI-enabled, data-driven and technology-

enabled innovation into routine NHS use. This response therefore places particular emphasis on the practical barriers to deployment: data infrastructure, evidence generation, regulation, procurement, health economics, workforce capacity and scale-up. This reflects the focus of the evidence received, rather than a view that personalised medicine is of limited importance.

Response

1. What is the current state of the science underpinning personalised medicine – including genomics, AI-driven diagnostics, and advanced genomic therapies? What are the most significant near-term opportunities for patients to benefit in the NHS?

The strongest near-term opportunities lie where the NHS already has infrastructure, clear clinical need and a realistic route to deployment. In diagnostics, AI-assisted imaging in radiology, pathology, dermatology, ophthalmology and cancer pathways is among the most advanced areas of AI deployment. Further, AI-assisted image analysis in endoscopy for polyp detection, may offer lessons for analogous tasks across other specialties where visual assessment is central, although deployment depends on the wider clinical workflow and the availability of trained staff. More broadly, there are opportunities for AI to support diagnosis by synthesising data from multiple sources, treatment planning and workflow planning, including discharge and resource management. In surgery, personalised approaches using 3D imaging and 3D printing show promise for planning and tailoring interventions. Digital twins show promise too, but further validation is needed before their clinical impact can be assessed with confidence.

More focus needs to be placed on bridging the implementation gap. As the 10 Year Health Plan for England drives a focus on prevention and care closer to home, there is a need to support different implementation settings, not only traditional laboratories and hospitals. There is a strong case for investing in living labs that create conditions for industry, academia, health and care and end users to co-design and evaluate technologies using mixed methods and for evaluation using frameworks such as the Idea, Development, Exploration, Assessment and Long-term study (IDEAL), as well as greater use of real-world evidence (RWE), rather than defaulting to randomised controlled trials (RCTs) that are often ill-suited to rapid iteration cycles.

b) What possibilities exist for personalised medicine in the medium and long-term, and what is needed to unlock these opportunities? Are there examples of specific areas of UK practice, or practice overseas, which we should learn from to help deploy personalised medicine?

Medium-term possibilities include genomics-enabled prevention at population scale, point-of-care testing incorporating wider biomarkers, gene-silencing

techniques, tissue engineering and nanomedicines for more precise targeting. Unlocking these opportunities will require better access to linked, high-quality data, greater interoperability across NHS systems, and attention to patient accessibility, especially for preventative genetic screening, where questions around consent, privacy, anxiety and use of risk information may affect uptake.

Data access in Scotland and Wales appears more clinically useful, and there may be lessons to learn from their approaches. The institutional separation of prevention between the NHS for primary and secondary care and local authorities creates barriers to the shift from sickness to prevention that technology could enable.

2. a) Where do you think existing AI tools could be most effective at advancing personalised medicine, for example across genomic analysis and drug discovery? Are there standout examples that could be more widely deployed? What is preventing more widespread adoption of promising tools?

AI-assisted image analysis across specialties is one of the clearest near-term opportunities, particularly where workflows, infrastructure and evidence pathways are already relatively mature. However, there are potentially larger gains in areas such as diagnosis from multiple data sources, treatment planning, workflow planning, home testing or remote monitoring where data can be integrated into care pathways.

What prevents adoption is rarely the technology itself. Barriers include fragmented procurement requiring trust-by-trust engagement; hospital IT infrastructure making integration slow, expensive and bespoke; different data governance requirements; and the absence of clear evidence thresholds that innovators can plan against. In some areas, particularly where AI is expected to support more personalised prediction or risk stratification, the datasets needed to produce robust and clinically meaningful results are likely to be extremely large, making data access, linkage and validation a major practical constraint.

3. Personalised medicine depends on large scale genomic and health data being accessible and linked together. What further research infrastructure, in terms of data accessibility, compute etc. – is needed to support the development of personalised medicine and AI? Where are the gaps in current provision? How should the Government help ensure that its health data infrastructure is fit to deliver on this promise?

The UK has major strengths: rich longitudinal NHS data, strong academic data science capability, Trusted Research Environments and Secure Data Environments. But infrastructure remains a bottleneck when moving from research to live care. Common constraints include lack of interoperability across fragmented systems; uneven digital maturity across trusts; patchy data quality; incomplete linkage across settings; weak community and mental health data; inconsistent annotation and limited operational readiness in frontline services.

The UK is often better at creating research datasets than at embedding data-driven tools into routine operations.

a) What recommendations would you have for bodies like the Health Data Research Service, Genomics England, and the Genomics AI Network to capitalise on the opportunities presented by these technologies?

Data access is scattered across NHS trusts and boards, making it difficult to build comprehensive datasets. The value of data is frequently misunderstood: single-centre datasets are overvalued during licence negotiations, while the work needed to build on data and develop a usable medical device is not appreciated, leaving data unused. Faster, streamlined processes are needed for licences and documentation required for data use in commercial medical device settings. The separation of secure data environments into regional units risks geographical variation in access - some centralisation in guidance, access arrangements, curation and formatting would help.

c) To what extent does the NHS's digital and IT infrastructure represent a major barrier to the deployment of these treatments, and are the Government's current attempts to address this and ensure interoperability adequate?

This is a substantial barrier. Hospital networks, IT services and systems are highly heterogeneous, making device development and deployment more challenging, slower and more expensive. Limited coordination between IT and clinical teams can lead to a cautious approach to new tools with insufficient focus on identifying workable integration solutions. Requirements for data compliance vary by trust with no standard interoperability package a company can prepare in advance. Some companies have been told by clinicians not to integrate but rather to email a PDF with results. Infrastructure for simulation and controlled deployment environments is limited. Deployment outside hospital settings introduces additional governance and privacy challenges not yet adequately addressed.

4. a) What are the main barriers in moving personalised medicines and AI from the early-stage research to clinical trials and through to regulatory approval? To what extent is the national infrastructure for clinical trials able to keep up with developments in personalised medicines and AI?

The primary bottleneck is the transition from clinical validation to implementation and routine use. Technologies are often developed without sufficient early integration into clinical pathways, leading to poor alignment with workflows and limited clinician uptake.

Stakeholder engagement is frequently too late in development. Multidisciplinary teams bringing together design, formulation, engineering and computing are needed to scale up effectively but rarely come together. Ethics approval processes can create significant delay, with innovators often having to navigate multiple overlapping processes across universities, IRAS, NHS bodies and

individual hospitals. Clinical-industry and academia contract agreements, particularly around IP, add further friction.

A related barrier concerns clinical trial site recruitment. New sites have little direct incentive to participate in studies: the work falls on R&D offices and nursing staff, rarely resulting in tangible benefit for them beyond reputational gain for the principal investigator. Even small financial incentives, such as a fast-setup fee and a modest per-patient payment to participating nurses, could transform recruitment dynamics.

b) Is there a concern that innovative start-ups, SMEs and industrial partners in this space will move efforts overseas owing to failures in NHS procurement, support for scale-up, sluggish regulation, or other factors? If so, what could be done to address this?

Yes. The distinction between UK Conformity Assessed (UKCA) and Conformité Européenne (CE) marking, alongside evolving frameworks, leads many companies, especially innovative startups, to prioritise the US market, where the Food and Drug Administration (FDA) and the wider regulatory and commercial environment is often perceived as more predictable. The current regulatory environment can appear overly complex with uncertain requirements, slower procurement, weaker scale-up mechanisms and less clarity about eventual adoption, that can deter UK-first launches. Venture capital firms don't typically invest where the NHS is the primary market for a product. There is an opportunity for the NHS Innovator Passport to be designed to act as a signal to investors and international markets that the NHS is a viable route to adoption.

5. Translating cutting-edge medical science into routine NHS treatment has long been recognised as a problem. Considering personalised medicine and AI as an example, what are the key systemic barriers, such as procurement processes, workforce, or IT infrastructure, that prevent or delay the deployment of proven innovations across the NHS? Which of these barriers are the most important in practice?

NHS procurement is one of the single biggest obstacles. Nearly 200 acute trusts operating independently force innovators to repeat clinical pathway design, data governance, digital integration, contracting and local verification at every site, despite national regulatory approval. Companies report average timelines of 18 months from clinician request to patient access. This fragmentation is especially damaging for SMEs. Small companies can exhaust their funding navigating the administrative landscape before signing a single contract.

Additional barriers include absence of sustainable post-pilot funding models, fragmented commissioning mechanisms, lack of protected clinician time or incentives for implementation, information silos restricting communication and workforce readiness issues. When technologies create value through efficiency,

prevention or safety gains, a clear budget holder or procurement pathway may be lacking or may not be obvious, making it harder to support their adoption.

a) Why have previous attempts to address this not succeeded? What would be effective in addressing these problems?

Based on the expert consultation the Academy has conducted, previous attempts have not succeeded primarily because they have not addressed structural fragmentation and the practical realities of implementation:

- Efforts have tended to focus on innovation generation rather than adoption pathways, while processes remain duplicative and sequential, particularly across regulation, health technology assessment (HTA), and local evaluation, and a lack of standardisation across Trusts prevents scaling.
- There has also been insufficient focus on early integration into clinical pathways. Data access and governance challenges persist despite policy attention, and evidence requirements remain unclear and inconsistent, particularly for novel technologies.
- The system is also highly risk-averse, and decision-makers can default to established products from large incumbent firms.

Promising approaches would include:

- The NHS Innovator Passport could help address some of the barriers highlighted in this response through centralised evidence evaluation so that once passed, a technology is pre-approved across trusts; standardised IT, IG and DTAC passports not requiring renegotiation at each hospital; the Passport acting as a 'visa for engagement' formalising access to NHS staff; and a regional adoption model through ICBs and Health Innovation Networks. After several trusts have successfully adopted an innovation, a reusable template covering clinical case, business case and governance should be accepted by subsequent trusts without repeated local re-approval.
- Where AI-enabled healthcare deployments straddle multiple regulatory regimes (for example, medical device requirements, NHS governance, data protection and confidentiality) innovators face case-by-case, multi-regulator approval journeys with duplicated documentation. A cross-economy AI Growth Lab could convene relevant regulatory bodies around joint trial protocols, providing a more coherent view than separate engagements would sequentially. It could also turn the similar performance and safety questions that different regulators and NHS trusts ask about AI systems into tested, reusable blueprints that can be adapted rather than reinvented in each setting. Beyond regulators, local bodies such as NHS trusts often determine whether trials proceed. The AI Growth

Lab could standardise MOUs, risk-sharing and consent templates with visible support from relevant regulators.

- Aligning regulatory approval, HTA and NHS evaluation so that they occur in parallel rather than sequentially would significantly reduce delays and unnecessary repetition.
- Technologies being integrated into clinical pathways at an early stage, with engagement involving clinicians, patients and service managers during development to ensure real-world usability.
- The development of simulation environments and controlled deployment settings would support safer and faster implementation, alongside enabling iterative development through rapid iteration approaches.
- Support for adoption, alongside defined pathways for technologies that create new categories of care, would address current financial and structural gaps.

b) What are examples of good practice within the NHS of adopting these innovations that should be learned from and could be deployed more widely? What would need to happen to make that a reality?

The NHS Research Passport is an example of a system designed to reduce repeated checks when a researcher needs to work with multiple NHS organisations. Innovation pathways should follow a similar principle: where checks have already been completed and recognised, they should not be repeated from scratch in every organisation.

Health Innovation Networks should play a stronger role in regional scale-up, and the emerging thinking around regional adoption via ICBs is promising, because it could reduce duplication across individual trusts and provide a more realistic route from local pilots to wider scale-up.

Trusted Research Environments, particularly Safe Havens in Scotland, have improved access to data for development and validation. Some regions have developed integrated datasets and strong academic-NHS collaborations.

There is established use of AI in imaging and diagnostics where workflows and infrastructure are relatively mature, as well as early examples of approaches that embed evaluation and learning into care delivery.

Scaling is often constrained by limited interoperability across the NHS, inconsistent data and governance standards, lack of consistent mechanisms to share implementation learning across trusts and routine requirements for local revalidation.

c) To what extent are issues in adopting innovation in the NHS down to an overstretched workforce, particularly of clinical academics, and what needs to be done to address this?

Workforce pressures are a significant constraint. Clinical teams often lack protected time and institutional incentives for innovation-related activities, and there is limited AI literacy and confidence in some settings. There is a shortage of translational roles, particularly clinical academics who can bridge research and practice. Addressing this requires investment in digital and AI training, dedicated implementation teams and translational leadership roles.

The NHS Innovator Passport could act as a 'visa for engagement', formalising access to NHS staff for validated innovators. A directory or network of innovation-engaged clinicians grouped by specialty would help, alongside protected time for clinicians, clinical engineers, medical physicists, pharmacists and senior nurses to engage with implementation.

6. How should the NHS and relevant regulators, including the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE), as well as professional and clinical bodies, balance the need to evaluate new personalised and AI-driven treatments with making innovative treatments available to patients? To what extent is the regulatory framework around personalised medicine and AI appropriate and proportionate, and where could it be improved?

The UK has important building blocks through MHRA, NICE, DTAC and NHS guidance. The MHRA is doing a credible job of balancing regulation against stifling innovation, and the UK is ahead of the EU where many innovations face prohibitive high-risk classification. But AI tools evolve faster than frameworks built to assess them. The result is not over-regulation but fragmentation, uncertainty and delay. There is a risk-balance issue, whereby the current level of risk to patients within the existing NHS is underappreciated. There is a need for government, regulators and the NHS to work together to ensure that regulatory and evaluation processes strike the right balance between timely access to innovation and appropriate assurance, including a more considered approach to the risks of delay and non-adoption of technologies where the evidence is still emerging.

a) Does the MHRA, under new leadership, have sufficient regulatory capacity to assess the newest developments in personalised medicine and AI? What can we learn from regulatory regimes in other countries?

Regulators can be understaffed and underfunded. Access to the MHRA innovation team has been particularly difficult for hardware innovators.

Regulatory timelines are longer than necessary. Alongside increasing capacity, there is also a case for continued upskilling and maintaining specialist excellence within regulatory teams, particularly where they are assessing AI-enabled and rapidly evolving technologies.

We support the ambition to halve the time for medtech regulatory approval, analogous to clinical trial approval ambitions. The UK should continue

recognising CE and FDA clearance to prevent unnecessary additional UKCA clearance requirements.

b) Is the MHRA's framework for software and AI as a medical device appropriate and keeping up-to-date with the latest developments?

The Academy's response to the government's AI Growth Lab call for evidence argued that legacy safety regimes assume deterministic, fixed-function systems and treat software or model updates as full re-approval events. This can create update paralysis and discourages iterative improvement central to AI development. For AI-enabled medical devices, approval journeys are often bespoke, one-hospital-at-a-time with limited reusable pathway from trial to scaled deployment. There can also be uncertainty around evidence requirements for adaptive algorithms and continuously learning systems. A model such as a cross-economy AI Growth Lab could help by convening regulatory bodies around joint trial protocols and producing reusable evidence blueprints. There is an opportunity to enable iterative model updates within agreed operational parameters without retriggering full approvals for every minor change.

7. One major barrier to personalised medicine is that it can be expensive and it may vary in effectiveness depending on individuals. This means it may not fit within NICE cost-effectiveness models and the NHS's desire to standardise the care people receive. Are current appraisal frameworks and commissioning models for the NHS appropriate for personalised medicine? What are the health economics implications of personalised medicine

The least developed aspect of health-technology evaluation is typically economic assessment. Innovations therefore often fail because it is challenging to capture the financial benefit. This is particularly true for prevention. An example was shared of an AI tool that successfully predicted which hospital patients were most likely to deteriorate and, as a result, prevented ICU admissions. However, if one ICU bed was saved, the bed was filled by someone else and the benefit isn't quantifiable. Evaluating innovation requires a stronger focus on where savings materialise or whether improved outcomes can be delivered without increasing cost.

a) What prospects are there for reducing the costs of personalised medicines as they are deployed more widely across the NHS? How effectively can we forecast how the cost of treatments might evolve? Is there fragmentation in the way that personalised treatments can be commissioned and funded in the NHS which create barriers to adoption?

Fragmented commissioning across trusts means there is no single procurement pathway. Many NHS clinical decisions are based on historic data that overlooks recent advancements and delays adoption. The separation of NHS budgets from local authority prevention budgets creates an institutional barrier to capturing the full value of technologies that support prevention and early intervention.

8. What should the Government do, at a strategic level, to strengthen the feedback loop between medical research, the life sciences industry, and the NHS, so that innovations developed domestically can be adopted at scale in the NHS, and clinical insights from the NHS can feed back into R&D and the life sciences sector? What would be the most important interventions you would prioritise to improve this process? What does the NHS most urgently need to do to position itself to benefit from innovations in personalised medicine and AI?

- The NHS Innovator Passport promises to simplify procurement. To achieve that, once a technology passes evidence evaluation, it should be pre-approved for use across all trusts. Standardised IT, IG and DTAC passports should not require renegotiation at each hospital. Adoption should be organised regionally through ICBs and Health Innovation Networks.
- Support core digital and data infrastructure, especially interoperability, linked data and the neglected community and mental health sectors. Standardise information governance across trusts. The Academy's response to the AI Growth Lab call for evidence recommended standardised MOUs and risk-sharing templates with visible regulatory support, directly applicable to NHS data governance.
- Easier access to realistic patient trajectory data, combined with better integration of research and operational data.
- Increase regulatory capacity and speed at MHRA. For example, a cross-economy AI Growth Lab could produce reusable evaluation artefacts and evidence blueprints that regulators can recognise across sectors.
- Support real-world evaluation at scale. Invest in living labs and implementation research infrastructure, particularly for technologies outside hospitals supporting prevention and early intervention.
- Support translational workforce capability, such as clinical academics, clinical engineers, medical physicists, implementation teams and innovation-engaged clinicians.
- Improve incentive structures for clinical trial site participation, including modest financial incentives for fast setup and per-patient payments to nursing staff, to support the patient-centric trial models the sector is moving towards.

a) Does the Government have the right structures in place to govern and oversee innovation in the NHS? Is it clear who has ownership of pushing research, innovation, and new technologies within the NHS? How effective are the links between projects like Genomics England, NIHR/MRC research, the Cell and Gene Therapy catapult, and NHS patient care? Are the Government's target-driven strategies, like the National Cancer Plan, effective at driving innovation?

Ownership of innovation within the NHS is fragmented and unclear. Multiple routes to regulatory approval, evaluation and procurement exist with limited

alignment. Multiple disconnected initiatives, including MHRA pathways, NIHR pilots and regional accelerators, can create confusion and inefficiency.

To address that, the Innovator Passport should integrate with, not sit separately from, current frameworks. In addition, the Academy's AI Growth Lab call for evidence response recommended a central coordination mechanism with regulator secondees or embedded teams from key regulators, retaining domain expertise while building the day-to-day capability to design joint trials and codify reusable patterns. A similar approach could be applied to NHS innovation governance.

The NHS should be more open about its innovation agenda and involve the wider research, innovation, user and patient communities in shaping priorities.

b) To what extent is fragmentation across trusts, integrated care boards, and national bodies, contributing to uneven or slow adoption of innovation? Are there any reforms that could realistically address this?

Fragmentation is a significant driver of slow adoption. One company consulted in the development of this response reported engaging with 140 NHS trusts that prescribe the relevant treatment, each requiring separate processes for clinical pathway design, data governance, digital integration, contracting and local verification. The average time from a clinician requesting the solution to it reaching patients is 18 months. This deprives patients of better outcomes, deprives the NHS of operational efficiencies and makes it difficult for UK innovation companies to grow. Regional adoption through ICBs and Health Innovation Networks, backed by centralised evidence evaluation and standardised governance, is a promising route to addressing this. Other reforms could include standardised data governance, interoperability and validation processes, combined with trust networks or regional groupings, a single evidence evaluation accepted across the NHS and a shift from document-heavy, email-only engagement to interactive channels such as innovation office hours and dedicated liaison support.