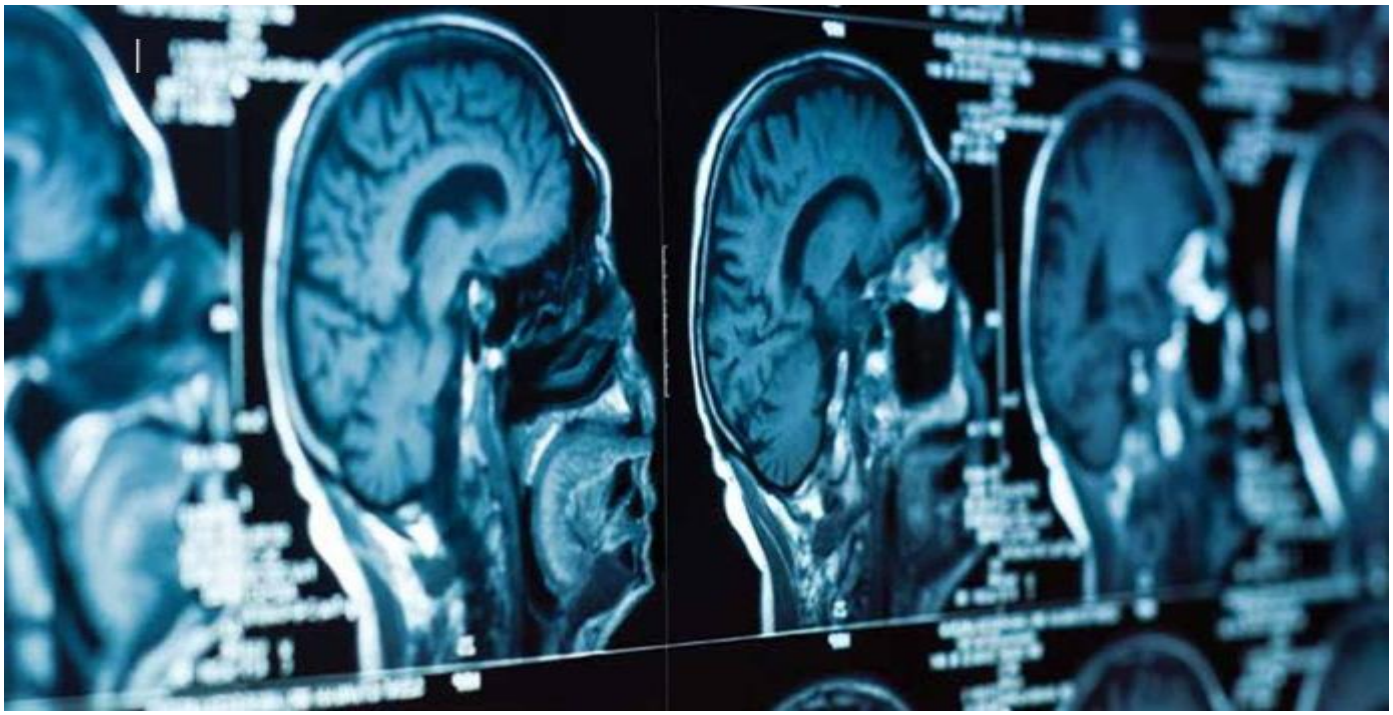
Department of Health

Department for Business, Energy & Industrial Strategy

Making a reality of the Accelerated Access Review

Improving patient access to breakthrough technologies and treatments in a cost-effective model



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Introduction

1.1. **The Government's ambition is that NHS patients should be among the first in the world to get life-changing treatments. Achieving this goal is only possible by working in close partnership with our world-leading life sciences sector. Our response to the Accelerated Access Review (AAR) sets out how we will work with industry and the health system to create a streamlined and sophisticated approvals system so that cost-effective breakthrough products – be they drugs, devices, digital or diagnostics – can get into the NHS as fast as possible.**

1.2. In autumn 2016, the independently-chaired AAR set out a vision of getting the best technologies to patients more quickly and more cheaply, in a system that is quick to adopt innovation. It urged the Government to take advantage of opportunities to streamline the pathways to patients for breakthrough products while delivering improved value to the taxpayer. The report echoed the Government's ambition to build an even more dynamic and forward-looking NHS, and to make sure the UK is the best place in the world to innovate and invest in new life sciences technologies.

1.3. The life sciences sector is critical for developing medicines, medical and digital technologies and diagnostics that improve patients' lives. It is one of the key sectors for the UK economy with over 5,000 companies, nearly 235,000 employees and £63.5bn turnover in 2016[1]. It is a highly productive industry with employment distributed across the regions, in small, medium and global companies. The significant role that life sciences play in the UK economy and its future growth was underlined when the Government made it one of five priority sectors in its January 2017 Green Paper: *'Building our Industrial Strategy'.*

1.4. Sir John Bell was asked by the Government to convene the sector to bring forward an industry vision for the *'Life Sciences Industrial Strategy' (LSIS).* The LSIS sets out recommendations for Government to work with the sector for mutual benefit, paving the way for a Sector Deal later in the year. Sir John Bell is clear that the arguments in the AAR remain critical to delivering outstanding patient outcomes; building a collaborative environment between the public sector, industry and academia; and creating a dynamic ecosystem that encourages and rewards innovation.

[1] Office for Life Sciences (OLS) 'Strengths and Opportunities Report' 2016

1.5. In the year since Sir Hugh Taylor and his team published the AAR, Government and its partners[2] have fully considered the arguments and recommendations in the review, and the best way to implement them. In responding, it is critical that we take the opportunity to create a catalyst for change in the access landscape.

1.6. The case for change is compelling. The NHS faces significant challenges in dealing with demographic changes, the pace of scientific advances, and the evolution of more complex personalised medicines and technologies. As our demographics change and populations become older, overall and per capita healthcare costs continue to increase. Technology and the availability of data are facilitating behaviour change in patients, who are becoming increasingly engaged about the type and quality of care they should be receiving. And our ability to develop treatments for rare and previously unmet need creates increasing debate about access, affordability and cost-effectiveness.

1.7. In parallel with this shift in the health landscape, we are also embarking on a new relationship with the European Union, which we hope will be a deep and special partnership.

1.8. In this context, Sir John Bell urged Government to accept the AAR recommendations, and implement them; we broadly agree. We also support Sir John's view that our commitment to the AAR's implementation represents a key step in the Sector Deal. In turn, we look to industry to develop innovations and technologies that not only deliver better outcomes for patients, but do so with improved value for money.

[2] NHS England (NHSE), National Institute for Health and Care Excellence (NICE), National Institute for Health Research (NIHR), Medicines and Healthcare products Regulatory Agency (MHRA), NHS Improvement (NHSI), Academic Health Science Networks (AHSNs)

2. Accelerated Access Review recommendations

2.1. The AAR made a series of recommendations to enable the NHS to improve patient outcomes, leverage the UK's strong biosciences research and life sciences industrial base and enhance the international competitiveness of our life sciences industry. We endorse its vision.

2.2. In accepting the recommendations in the AAR, we are also accepting many of the powerful arguments that shaped those recommendations. We agree that more can and should be done to accelerate access to market; we recognise that the current commercial arrangements and pathways can be unnecessarily complex. We agree that we need a better understanding of unwarranted variation in uptake, and a system that maximises the appropriate use of innovative products. The recommendations will, of course, need to be delivered within the budgetary envelope set by the Government for the NHS.

AAR Recommendations
1. *The NHS should develop an enhanced horizon scanning process and clarify its needs to innovators.*
2. *A new transformative designation should be applied to those innovations with the potential for greatest impact.*
3. *Patients should be involved in horizon scanning and prioritisation, and this involvement should continue along the whole innovation pathway.*
4. *An Accelerated Access Pathway for strategically important, transformative products should align and coordinate regulatory, reimbursement, evaluation and diffusion processes to bring these transformative products to patients more quickly.*
5. *A new strategic commercial unit should be established in NHS England.*
6. *The Accelerated Access Pathway should be suitable for medical technologies, diagnostics and digital products as well as medicines and emerging forms of treatment.*
7. *There should be a single set of clear national and local routes to get medical technologies, diagnostics, pharmaceuticals and digital products to patients.*
8. *National routes to market should be streamlined and clarified.*
9. *Many products will benefit from regional and local routes to market, which should be enhanced to operate consistently across the NHS.*
10. *The route for digital products should build on the Paperless 2020 simplified app assessment process.*
11. *The digital infrastructure should enable the system to capture information on the use of innovations and associated outcomes.*
12. *The process of assessing emerging technologies should be evolved so that it is fit for the future.*
13. *A range of incentives should support the local uptake and spread of innovation, enabling collaboration and with greater capacity and capability for change.*
14. *AHSNs, tertiary academic teaching hospitals and clinical leaders across the NHS should drive and support the evaluation and diffusion of innovative products.*
15. *Improved accountability and transparency around uptake of innovation should be supported by NICE.*
16. *An Accelerated Access Partnership should align national bodies around accelerating innovation.*
17. *The Accelerated Access Partnership should be established immediately.*
18. *Implementation of the report's recommendations should be led by the Accelerated Access Partnership and clinicians.*

3. Making a reality of accelerated access to innovation

3.1. Our vision for change is ambitious, but there is evidence across the system that it is becoming a reality. At the heart of this vision is a system which can embrace the innovations our patients need: delivering faster patient access to life-changing innovations. There is energy and hunger for innovation, with much already in train and even more in prospect.

3.2. Across the NHS there are many examples of innovation in clinical practice:

- New oral treatment for Hepatitis C will reduce mortality by around 10% and liver transplants for these patients by around 50%. Alongside the clear patient benefits, driving competition between companies has allowed the NHS to save millions, enabling the treatment to be made available to 25% more patients in the last year. So far, at least 20,000 patients have already benefited from this life-changing approach.

- World-leading advances in genetic technology mean that babies at risk of mitochondrial diseases could now have DNA that is clear of those inherited conditions.

- By 2019, more than 6,200 brain tumour patients a year will benefit from the use of stereotactic radiosurgery and radiotherapy, meaning that they are undergoing less invasive and cheaper treatments.

- The NHS Clinical Entrepreneur Programme has supported the creation of 50 clinician-led start-ups.

3.3. We are also seeing new and innovative partnership arrangements. Last January we launched the **Test Bed** programme, demonstrating how industry and the NHS can work in collaboration. Through this unique approach we have established seven sites across the country, supported 40 innovations and have about 4,000 patients enrolled. Test Beds demonstrate success throughout the innovation pipeline: from supporting the development of devices and technologies, integrating them in new ways, and working with health professionals to adapt and develop new clinical and care pathways. It is early days for the test beds, and by the very nature of innovation, we expect that some will be more successful than others, but the evidence shows compelling signs of improvement to patient care outcomes. NHS England and Government have committed further funding to support the extension of the programme for another two years.

3.4. We know that innovation can mean the need for changes to clinical pathways and that this can be a barrier to adoption. Government is providing the **£6m Pathway Transformation Fund** to target these barriers, helping adoption and integration into everyday practice. The **NHS Innovation Accelerator** has also already supported 25 innovators to spread their innovations into over 700 NHS organisations. We hope for the

same excellent outcomes from the third cohort of innovators that will be announced by early 2018.

3.5. In addition to world-class R&D supported by the Research Councils and Innovate UK, the Government invests over £1bn each year in the National Institute for Health Research (NIHR) to improve the health and wealth of the nation. NIHR provides an internationally renowned environment for collaboration between the life sciences industry, charities, academia and the NHS, supporting the development of therapeutics, medical technologies and diagnostics. NIHR has recently invested £950m in new research infrastructure in the NHS, including £14m for **NIHR Medtech and In Vitro Diagnostic (IVD) Co-operatives (MICs)**. These centres of expertise will develop new medical devices and technology-dependent interventions, and catalyse the generation of the robust evidence that is required by the NHS and industry to enable rapid uptake of commercially-supplied in vitro diagnostics.

3.6. Over 95% of companies in the UK life sciences sector are small and medium sized enterprises (SME) and so we are prioritising help for SMEs to get their innovative products to patients. We know from the AAR analysis, and our ongoing stakeholder engagement, that SMEs are sometimes unable to provide sufficient real-world evidence to inform and/or support NHS commissioning and adoption decisions – preventing their innovations from helping patients. In addition to the portfolio of support available through current research funding, the Government is delivering a new **£6m scheme to support SMEs** in obtaining an effective evidence base for their medtech products (including IVDs and digitally enabled devices) or medicines qualifying for the **Early Access to Medicines Scheme (EAMS)**. We are also providing £35m over four years to encourage and support innovators to develop world-leading digital solutions. The **Digital Health Technology Catalyst** will support SME-led projects to develop the evidence base required to launch their products in the NHS.

3.7. **The 15 Academic Health Science Networks (AHSNs)** are providing local support for NHS adoption of the right innovations and tackling some of the causes of unwarranted variation in uptake. This capacity will be boosted by the £39m Government has committed to improve local adoption and uptake of innovative medical technologies. New **Innovation Exchanges** will establish greater collaboration between the 15 AHSNs, and support innovators, clinicians and patients to navigate the system to meet their needs. We know that many exciting innovations may be better supported at local level first, and Innovation Exchanges will increase AHSN capacity and capability to assess the local value of new technologies and promote diffusion of those products that deliver real benefits to patients.

3.8. Innovation Exchanges will work in partnership with NHS **Innovation National Networks (INNs)** that will connect AHSNs with clinical and national policy leads, bringing in relevant expertise to help identify and support the highest potential products. Together, Innovation Exchanges and INNs will provide a fertile ground for the uptake and spread of innovation.

3.9. NHS England's new **Innovation and Technology Tariff (ITT)** is supporting the uptake of technology across the health system, and has helped to procure digital innovations such as the myCOPD app across the NHS. Over 30,000 patients are benefitting from being able to self-manage their severe or very severe Chronic Obstructive Pulmonary Disease (COPD) symptoms. To extend the scope of the ITT, NHS England announced the **Innovation and Technology Payment (ITP)** in June 2017, supporting a wider range of medical devices, digital platforms and technologies, including in primary and community care systems. The ITP is expected to go live in April 2018.

3.10. Horizon scanning is a key capability required for a forward-looking NHS that can articulate its priorities to industry, and prepare to deliver against those priorities. **PharmaScan** currently enables horizon scanning for pharmaceutical products, and NHS England is currently building on these capabilities to create a parallel system suitable for medical technologies. The recently established **NIHR Innovation Observatory (NIHRIO)** is now applying state of the art data analytics to explore trends in health innovation across drugs, medical technologies, diagnostic tools and healthcare services.

3.11. There is a focus on streamlining routes to market and improving process across the system. In spring, NICE introduced 'Fast-Track' appraisals for the most clinically and cost-effective products[3], for which the time it will take to receive funding after NICE guidance publication is reduced from 90 to 30 days. NHS England and NICE have also developed a more streamlined and integrated commercial dialogue for the **Cancer Drugs Fund (CDF)** and **Highly Specialised Technologies (HST)** programme. NICE will continue to focus on earlier engagement with industry, ensuring that their evaluations continue to meet the needs of a rapidly changing healthcare system. NHS England's **Regional Medicines Optimisation Committees (RMOCs)** will also reduce duplication in NHS evaluations and play a role in decommissioning outdated medicines to help the NHS live within its means and creating headroom for new interventions.

3.12. We are doing more to better understand uptake across the system through the strengthened Innovation Scorecard and new research. This helps us to understand what is happening across the system and give patients an informed voice. We are improving the content and accessibility of the **Innovation Scorecard** to include medical technologies and provide a better view of what is happening across the wider innovation landscape. We will also commission further research to improve our policy response, and to give us a better view of how our uptake of innovation compares with other similar countries.

3.13. **NHS RightCare** is addressing variation in clinical practice across the country, working in partnership with a wide range of organisations, national programmes and patient groups to shine a light on performance, optimise use of medicines and other technologies, and design optimal care pathways.

[3] Products which are £10,000/QALY or less

3.14. These measures are being implemented in England. Our ambition is to align them closely with activities in the devolved administrations to ensure systems are joined up and navigable.

4. A new route for breakthrough products

The Accelerated Access Pathway

4.1. At the core of the Accelerated Access Review is the proposal to get strategically-important, cost-effective products into the NHS as rapidly as possible within NHS resource constraints. We endorse this approach, which should be focused on affordable products which can dramatically improve efficiency, fill an unmet need or make a step-change in patient outcomes.

4.2. From April 2018, we will introduce an **Accelerated Access Pathway (AAP)**. This will be a new route to market that will streamline regulatory and market access decisions; getting those innovations that we believe will be truly transformative to patients more quickly. We will make the process from bench to bedside quicker, cheaper, and easier for innovators and the NHS. The Government's ambition is to bring forward by up to four years patient access to these selected, highly beneficial and affordable, innovations.

4.3. The need to balance our commitment to accelerating patient access to life-changing innovations, with the financial sustainability of the NHS means that accelerated access must be cost neutral for the NHS. This has been a key design principle for the AAP. We anticipate that ~5 products a year will receive breakthrough product designation and go onto the new pathway, subject to satisfactory commercial negotiation. Across this basket of products, any products placed on the AAP that are cost additive will need to be offset by products that deliver cost savings, beyond those already factored into NHS plans . Medicines, medical technologies, diagnostics, and digital products at any stage will be eligible to benefit from the AAP, including repurposed medicines where a new indication is found for an existing product. Efforts will be focused on those products that will deliver the greatest benefit to patients and improve value for money.

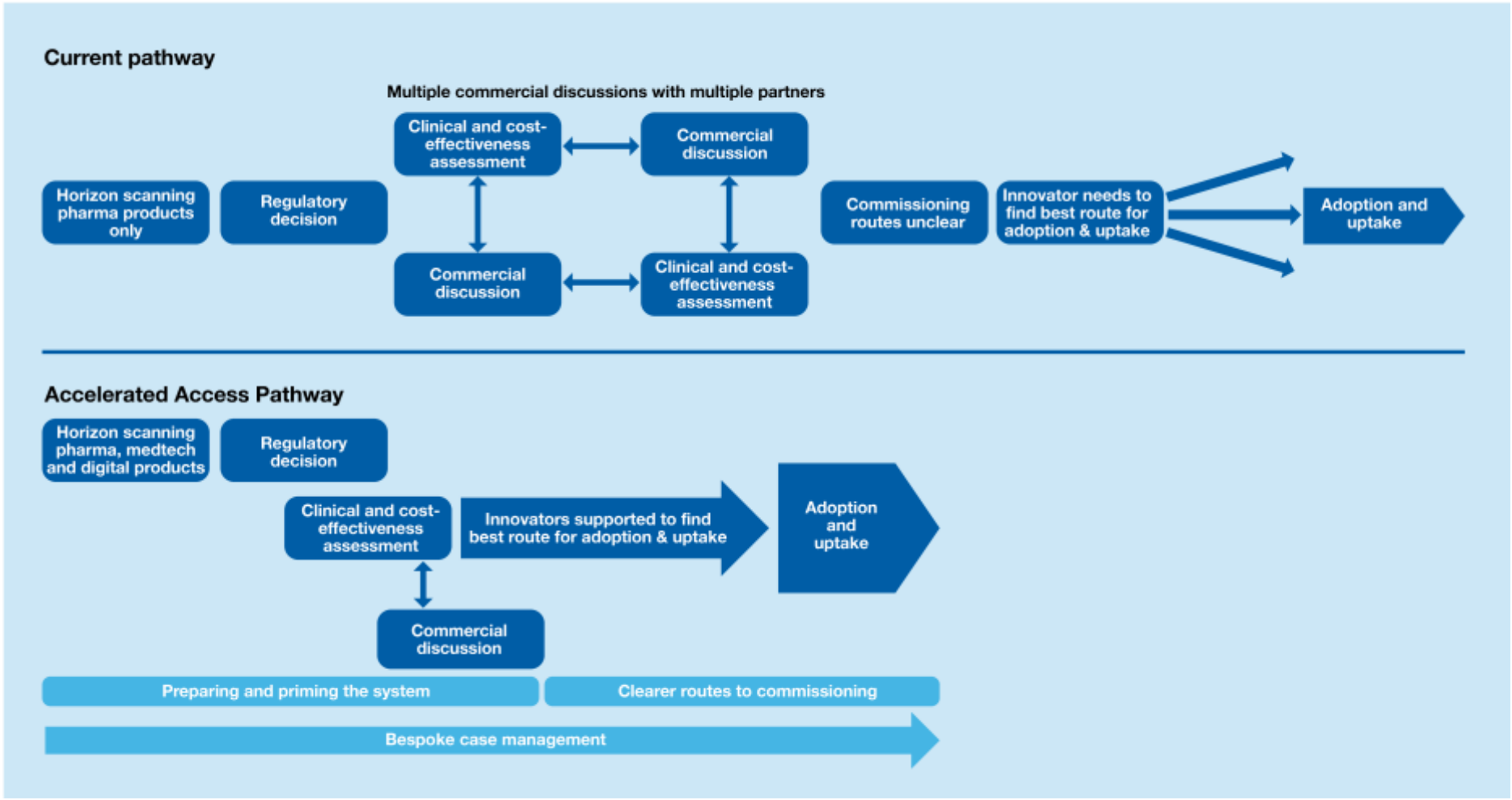

Figure 1: Comparison of current pathway and the Accelerated Access Pathway

The AAP will align the actions of key national bodies around the principle of accelerating access to innovations that patients need, streamlining regulatory and market access decisions and driving a better and more flexible deal to benefit patients, the NHS and innovators. It will have links to local networks and infrastructure for transformation including Sustainability and Transformation footprints. The AAC will be independently-chaired and will report to Ministers.

This diagram is for illustrative purposes only, the exact details will depend on the type of technology.

4.4. The AAP encapsulates our vision for partnership working across the system to deliver wins for industry, the NHS and its partners. Our new pathway will deliver faster access and support for uptake through features such as:

- Horizon scanning for new technologies to identify a subset of potential breakthrough products that could benefit from the AAP.
- Streamlining the pathway from market authorisation through to patient use for designated breakthrough products.
- Generation of real-world evidence in addition to clinical trials data.
- Early price negotiation and the potential for flexible commercial arrangements.
- Pharmaceutical products may also participate in the EAMS while on the AAP.
- Support for adoption and diffusion through the AHSN network and the Pathway Transformation Fund[4].

4.5. Each breakthrough product will benefit from bespoke case management, which will co-ordinate across partners to streamline the journey. In return for these commercial benefits, we expect industry to come forward with a cost proposition that delivers additional value for patients and the NHS beyond that achieved under the current system, and is affordable.

4.6. The AAP will complement existing activity. It will build on existing initiatives such as NICE's Fast Track Appraisal Process, the NICE/NHSE budget impact test, EAMS and the CDF. Intelligence and learnings from the delivery of the early and managed patient access schemes will be used to better understand impact and implementation challenges. This learning will be built into the AAP. Furthermore, products from other schemes that require further support with adoption and diffusion could be supported.

4.7. It will never be the case that the AAP is the right route for every product, but we will review and evaluate its impact, and consider whether other categories of product might be suitable for inclusion in the future. We will also aim to deploy more widely any improvements or learning that is identified through the AAP, where there is clear evidence that it will deliver patient benefit elsewhere, improvements in value for money, and meet our financial objectives. There will be implementation challenges to ensure that AAC is empowered to deliver within the requirement for no additional NHS cost, and to ensure that all AAP products deliver improved value to the taxpayer.

4.8. We agree that there is also more to do to streamline existing access routes, and we remain committed to continuing to improve these for digital and medical technologies.

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[4] **£6m to help the NHS to adopt and integrate new technologies into everyday practice**, through the Pathway Transformation Fund

We also recognise opportunities to improve alignment, reduce duplication and grow the commercial capacity of the NHS. By April 2018, we will make significant improvements. This will include enhanced commercial capability in NHS England. There is clear demand from innovators for the type of win:win commercial deals that we expect to see through the AAP. The strengthened commercial function within NHS England will have the capacity to develop these types of arrangement. In parallel, the NICE commercial liaison team will support commercial engagement between companies and NHS England, creating a smooth interface for companies throughout the appraisals process.

4.9. For pharmaceutical companies, we have proposed improvements that will immediately streamline the pathway for access discussions. By transferring the role of agreeing future **Patient Access Schemes (PAS)** from the Department of Health to NHS England, we will ensure that from early 2018 companies need to begin only one dialogue for each medicine, including products that will undergo HST appraisal or enter the CDF each year. Addressing existing duplication and bureaucracy in developing deals for these innovative medicines will unlock the benefits of greater simplicity throughout the appraisals process, including removing the risk of delays to guidance, and grant earlier certainty for companies about the process of approval.

The Accelerated Access Collaborative

4.10. Selecting the best products for the pathway will be key, and we think, as proposed by Sir Hugh Taylor, it is right that this decision is taken by the national organisations responsible for regulating, evaluating and delivering new innovations to patients -- NIHR, MHRA, NICE, NHS England, NHS Improvement and Government -- with input from independent representatives for patients, industry and clinicians. This group will be referred to as the **Accelerated Access Collaborative (AAC)** [5]**.**

4.11. We shall seek representatives from industry and patient groups who have sufficient breadth of experience and independence to allow them to inform AAC discussions on the different technology types and conditions those technologies might benefit. The AAC will be headed by an independent chair, who will be accountable to ministers. We are delighted that the **first independent chair will be Sir Andrew Witty.** We will publish further details on the selection and membership of the AAC, which will be in place in late 2017, and first products will be identified from April 2018.

[5] It will not disrupt existing statutory accountabilities for managing the NHS budget.

5. Monitoring and measuring our impact

5.1. The Accelerated Access Collaborative aims to be a unique partnership between the NHS and industry that can deliver the world-leading innovation required to achieve better patient outcomes with two core objectives:

- The NHS to be one of the most pro-innovation healthcare systems in the world, and for it to be seen as such by patients and industry.
- Innovation will be delivered at a price that industry and the NHS think is affordable and fair.

5.2. As we implement our plans, it is vital that we understand and measure the impact that our policies are having. This will enable us to focus resource where we are making the biggest difference, and target gaps or emerging issues. In line with the AAR's recommendation, we believe that the AAC should be responsible for measuring and evaluating the impact of our accelerated access programme and on assessing the industry response to it. The views of the AAC will be informed by parties across the system, who will be represented in the group.

5.3. It will be for the AAC, in discussion with partners, to determine success criteria. We should, however, expect that they will consider indicators such as: level of industry interest in AAP; speed of product progression through the AAP; improved health and quality outcomes; increased affordability of new technologies and products; improved value for money; increased impact of AHSNs; and SMEs getting products to patients quicker and more easily.

5.4. In response to the AAC's views, and the opportunities and challenges that will arise through implementation, many of the policies within our programme will develop over time. Government and its partners will commit to provide appropriate updates to the wider system as this develops.

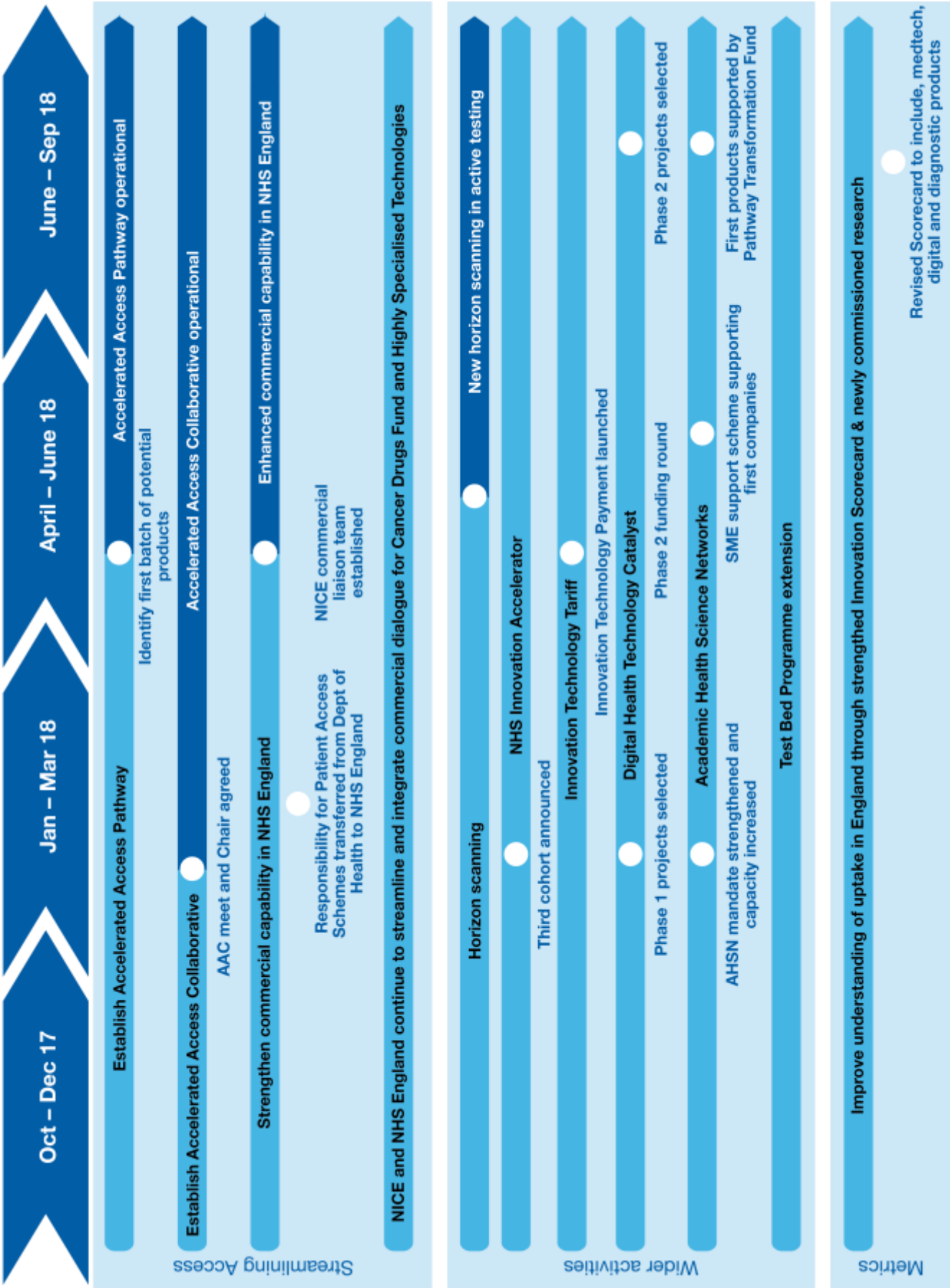

Figure 2: Summary of implementation milestones

6. Glossary

AAC	Accelerated Access Collaborative
AAP	Accelerated Access Pathway
AAR	Accelerated Access Review
AHSNs	Academic Health Science Networks
CDF	Cancer Drugs Fund
COPD	Chronic Obstructive Pulmonary Disease
EAMS	Early Access to Medicines Scheme
HST	Highly Specialised Technologies
INN	NHS Innovation National Networks
ITP	Innovation and Technology Payment
ITT	Innovation and Technology Tariff
IVD	In Vitro Diagnostic
LSIS	Life Science Industrial Strategy
MHRA	Medicines and Healthcare products Regulatory Agency
MIC	Medtech and In Vitro Diagnostic Co-operative
NHSI	NHS Improvement
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NIHRIO	NIHR Innovation Observatory
PAS	Patient Access Scheme
QALY	Quality-Adjusted Life Year (used as part of a cost-effectiveness calculation)
RMOCs	Regional Medicines Optimisation Committees
SMEs	Small- and Medium-sized Enterprises