Accelerated Access

Review of innovative medicines and medical technologies supported by Wellcome Trust

Accelerated Access Review: Final Report

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An independently chaired report, supported by the Wellcome Trust

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Letter from Sir Hugh Taylor, independent chair of the Accelerated Access Review, to Lord Prior, Parliamentary Under-Secretary of State for Health

Dear Lord Prior

In November 2014 the government asked me to chair a review of how we could speed up access to innovative drugs, devices, diagnostics and digital products to NHS patients. I was pleased and proud to accept the challenge. Since then we have sought views from over 600 people and organisations, ranging from clinicians, NHS commissioners and patient groups and charities, to the life sciences industries and academia, to the national bodies that influence the innovation pathway.

The resulting report sets out an ambitious framework for how we can transform our NHS, pulling innovation – medical technologies, diagnostics, digital and biopharma products alike – through the system for the benefit of patients and improving the international competitiveness of our country. .

Countless people have contributed to the ideas contained within the report. In particular I would like to thank the review's champions: Dr Stuart Dollow, Professor Richard Barker, Richard Murray, Rob Webster and Hilary Newiss, as well as John Jeans and Charles Lowe. I would also like to thank Dr Nicole Mather, Director of the Office for Life Sciences; the AAR team; the Wellcome Trust, which has supported the review right from the start, and George Freeman MP, who originally commissioned the review and whose enthusiasm was a great asset as we took it forward.

Special thanks go to our advisory group and in particular its chair, Professor Sir John Bell. John has provided valuable guidance and wisdom throughout the review and I think it is fitting for him to provide an introduction.

Sir Hugh Taylor

Introduction from Professor Sir John Bell, Regius Professor of Medicine at the University of Oxford and chair of the review's external advisory group.

This report addresses one of the most important issues the National Health Service is confronting; how best to access innovation for the benefit of patients and to improve health care efficiency. The approach to accessing innovation in the NHS has become increasingly challenging; creating frustration for innovators who see the NHS as an interesting environment for demonstrating the value of their products, for patients who often have to wait long periods of time before life-saving therapies are available, and for clinicians who are frustrated by the multiple barriers to both approval and adoption. We wanted to obtain the views of these varied constituencies and create a new and more agile approach to the prioritisation and adoption of NHS innovation. Now more than ever, with a tidal wave of exciting new technologies approaching, the system needs a way to do this.

The difficulties encountered by the NHS's previous attempt to resolve this issue through *Innovation, Health and Wealth* meant that it was crucial for us to obtain strong support from NHS England as the sponsor of this new framework. Success will be highly dependent both on their actions centrally and throughout NHS organisations locally. We welcome the recognition NHS England has given to the importance of this agenda and I am particularly pleased that Simon Stevens, the Chief Executive of NHS England, has demonstrated this commitment in his letter on page 10.

It was our intention to propose a new system for accelerating access to all types of innovation in the NHS, including drugs, medical devices and diagnostics and digital tools. We saw opportunities for acceleration at every stage of approval and adoption. We have recommended a **process for identifying and pulling transformative innovations into the NHS quickly**, using the range of emerging regulatory pathways and facilitating the generation of patient data that define the benefits of innovation to both outcomes and pathways. We have also encouraged a much more streamlined approach to reimbursement for innovators, both through conditional licensing and through a new mechanism for pricing individual products using a range of new pricing tools. Why should a large single payer not benefit from volume-based contracts, from paying based on outcomes, or paying differentially in different diseases where the efficacy of a treatment might vary?

Collaboration and early dialogue between innovators and the NHS will be critical to enable agreements that exploit this more streamlined approach and the opportunity of new agreements being reached to deliver a win for both parties. For the NHS, we recognise the importance of NHS England being able to work with NICE as part of this process. Finally, we have encouraged the creation of incentives in the system both locally and nationally to enable the rapid adoption and diffusion of these new products. At each stage *acceleration* has been an important focus and this should greatly improve rapid access, particularly for transformative innovations.

A second important feature of this report is that it encourages the NHS to work more collaboratively with patients and innovators to provide the type of data all innovators and thus health care systems need to make decisions about the real benefits of innovation. The historical model where innovators simply throw new products at health care systems and allow them to layer these onto existing pathways is no longer viable. We believe that health care systems and innovators need to work together to demonstrate the way in which innovations change pathways

and improve outcomes. This is particularly true with digital, medtech and diagnostic innovations but has also been true for pharmaceutical innovations which have created enormous impacts on the way that patients with diseases such as vascular disease, inflammatory disease and cancer are treated. If the NHS is to see the continued benefits of such innovation it needs to contribute more actively to its development.

The beneficiaries of this new system should be:

- The NHS, creating a much more cost-effective and informed but dynamic system for pulling the required innovation intelligently into the health system to change the way it treats disease.
- Patients, who have often found the current approach to accessing new products in the NHS cumbersome, slow and bureaucratic. Patients have been among the strongest supporters of our work on these new pathways and clearly deserve a system where they are allowed to be more engaged participants.
- Innovators, who could also find this new approach to accelerating adoption transformative. They largely recognise that a state-funded health care system such as the NHS must take issues of affordability seriously but find the approach to innovation, the slow track to reimbursement, and low prices without generating wider diffusion and volumes, all make the UK a challenging market. With a different approach to generating the evidence of an innovation's value within a closed system and speeding up reimbursement and adoption, the UK could become a very attractive environment for the life sciences industry to flourish.

When we began this report, the UK was firmly in the European Union, and had a strong life sciences industry based on outstanding biomedical research in both world-class universities and internationally-renowned teaching hospitals. We also perceived the NHS as being a potentially crucial asset in further developing the life sciences industry. It was not unreasonable, we believe, to assume that some of the £120 billion spent annually on the NHS should be helping to drive success in this sector, fuelling economic growth and generating increased tax income on which to base our public services. Since the UK voted to leave the European Union, the importance of these principles have, if anything, been amplified. Given the uncertainty for the financial sector and heavy manufacturing in a future potentially outside the single market, it seems clear that **the life sciences industry will provide a crucial pillar for future economic growth**. This will, of course, require a targeted industrial strategy and may benefit from a future regulatory regime.

These 'sunny uplands' are not likely to be easily reached. More effort and resource will be needed to ensure the success of this sector both by creating a system in which the NHS is allowed to be a receptive market for useful innovations and by ensuring that the commercial entities that are required to support economic growth are viewed as partners in making the UK a global hub for innovation in healthcare.

The AAR therefore creates a first essential step in ensuring that the UK builds a capability in life sciences that leads to strong economic growth and also provides patients and the NHS with much needed tools and technologies at an affordable cost. A UK outside the EU, with no system for ensuring a dynamic market and a competitive research environment for one of its most important industries, could precipitate a decline in economic activity in the life sciences. It could also lead to a health care system that cannot ensure its patients benefit from the rapid advance of innovation and this risks taking us to the 'cloudy and windswept lowlands' pretty quickly.

There are a few important steps that need to be taken to assure the success of this report. NHS England needs to continue to engage at the highest level in this agenda; early signs are positive, though a sustained focus and engagement will be essential to realise the vision we set out. NHS Improvement also has a key leadership role to play as the lead agency for innovation, working closely with providers to enable local NHS economies to facilitate this programme. More integrated health systems and facilitation by a reinvigorated AHSN network will help, as will the engagement of the major academic teaching hospitals where creation and evaluation of innovation is already part of the culture.

Resource will be required to make this happen both centrally and locally. Some headroom may be created by accelerating the use of biosimilars and more active delisting of drugs and technologies that no longer have utility. These savings need to be captured in such a way that they can be re-targeted at the innovation agenda. If the programme is implemented as we recommend, there should be much better evidence of the efficiency gains from technologies, as used in the health system, that can be shared to enable faster uptake of innovation. Given the importance of this agenda to an industrial policy to support life sciences, additional resource to ensure a viable market should be seen as a high priority both within the NHS and more widely in government.

Finally, most of the major recommendations of this report will need enhancement of digital capabilities within the NHS. This is clearly in progress but must occur more quickly for the benefits of the AAR to be realised.

We are grateful to the many participants in the AAR programme who have given up their time to inform and advise us on this journey. Interestingly, we have not encountered anyone who believed that innovation adoption was not a problem that required a new solution and there are many patients, innovators and clinicians who will work hard to make this new model work. Ultimately, responsibility for success will lie with the leadership provided by NHS England and NHS Improvement. With this in place we see no reason for the benefits of innovation not to flow rapidly and widely to patients in the NHS, delivering a more efficient healthcare system, better outcomes and a thriving life sciences sector.

Professor Sir John Bell

Letter from Simon Stevens, Chief Executive Officer of NHS England

At a time of national debate and NHS pressure it's easy to forget an important truth: Health care is better than it's ever been. Cancer survival in this country is at an all-time high. Deaths from cardiovascular disease are down by over 40%. Worldwide, life expectancy is rising by five hours a day.

But, as the saying goes, 'better is possible'. One recent estimate suggests that humanity still only has around 500 viable treatments for more than 10,000 known health problems.

As a nation we therefore need to pursue at least three goals simultaneously.

First, we must actively support new discovery and further development of innovative treatments and care.

Second, we have no choice other than to drive value and affordability across the NHS if we're going to create headroom for faster and wider uptake of important new patient treatments.

And third, in the run-up to Brexit we need not only to secure - but actually enhance - our vibrant and globally successful UK life sciences sector.

Sometimes these three goals are thought to be in tension. By contrast, this Accelerated Access Review provides practical and welcome proposals for squaring the circle.

NHS England is fully committed to playing our part in doing so. We agree there needs to be better alignment between regulatory approvals, NICE HTA assessment, NHS England commissioning/reimbursement, and local innovation diffusion processes - encompassing the broad family of diagnostics, medicines, medtech and devices, and digital health.

We'll support the AAR's streamlined pathway to identify high value innovations. We'll then help pull them through into mainstream care - building on our AHSNs, innovation testbeds, and our new Innovation and Technology Tariff. And where it makes sense, we'll increasingly be open to agreeing innovative win/win product-specific reimbursement models, incorporating a mix of outcomes-based, annuity-based and volume-based pricing deals.

None of which is to pretend this is easy. Or that there aren't hard choices, and difficult trade-offs along the way.

But that shouldn't obscure the huge gains within our grasp, both for patients across the NHS, and for the wider success of our country.

Simon Stevens

A. Executive Summary

The Accelerated Access Review was asked to make recommendations to Government on how to accelerate access for NHS patients to innovative medicines, medical technologies, diagnostics and digital products, making our country the best place in the world to design, develop and deploy these innovations.

The Review's independent chair, Sir Hugh Taylor, published an interim report in October 2015, setting out the key themes emerging from the review team's engagement with a wide range of stakeholders. Since then the review team has been carrying out further engagement and refining the recommendations.

This report sets out the final recommendations of the Accelerated Access Review. We believe that these recommendations will enable our country 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. These recommendations will, of course, always need to be delivered within the budgetary envelope set by the Government for the NHS.

The recommendations are:

Chapter 1

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.

Chapter 2

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.

Chapter 3

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.

Chapter 4

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.

Chapter 5

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.

Chapter 6

16. An Accelerated Access Partnership should align national bodies around accelerating innovation.

Chapter 7

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.

B. The Vision

Getting the best technologies to patients more quickly and more cheaply, in a system that is quick to adopt innovation

This Accelerated Access Review sets out a bold new vision of better, cheaper and faster adoption of innovation, through:

- establishing **streamlined mechanisms for prioritising emerging technologies** and identifying strategically important innovations;
- working with innovators to **accelerate approvals**, speed up adoption and evaluate technologies efficiently using new data sources; and
- **aligning national organisations** to transform the NHS's ability to adopt the right innovations rapidly.

Patients, clinicians, the NHS and industry will all benefit and will need to work in partnership to deliver a win:win for all, improving the competitiveness of our country in life sciences and improving investment in the UK.

The offer to patients…

- Earlier access to important, life-changing innovations that improve outcomes, through an Accelerated Access Pathway.
- A greater say in determining what innovations are important to them.
- Participation at the earliest stage of the evaluation of new products so they can help influence the products that will go on to reach patients.
- A clear package of transparent information to help understand the impact that innovation has on patients and on the NHS.

The offer to innovators…

- The opportunity to collaborate with the NHS to collect real-world as well as clinical trial data to evaluate product outcomes and pathway changes, and use this data elsewhere.
- A simplified and streamlined system for market access, including:
    - earlier dialogue with regulators, NICE and the NHS;
    - faster and more integrated decision-making by national bodies;
    - the opportunity to engage at an early stage with key decision-makers on a realistic value proposition;
    - fast, reimbursed access to the NHS market for promising products whose development has been accelerated and where the evidence base is not yet mature; and
    - mechanisms for evidence collection and accelerated diffusion across the whole NHS.
- A clear signal of the needs of the health system, to which they can respond.
- Access to a strengthened AHSN network which can facilitate local evidence-collection and adoption of innovation.

The offer to clinicians…

- The opportunity to work in a flexible and empowered health system that works together to adopt the best new technologies for its patients.
- The ability to lead and publish world-class translational research and develop evidence of a product's performance in real-world settings.
- Better data on the impact of clinical pathway change on their patients' outcomes.
- Better professional recognition of innovation and clearer messages on best clinical practice.

The offer to the NHS…

- A quicker and simpler way of finding those innovations that can improve efficiency and patient outcomes.
- The opportunity to deliver the most transformative products to patients in a way that offers better value, within the budgetary framework set for the NHS by the Government
- Faster local and national spread of innovations by supporting the capacity and capability required to make the associated clinical pathway changes.
- Better ways of procuring products that generate greater value.
- Collaborations with innovators that will generate valuable evidence on the impact and efficacy of new innovations.
- Improved clinical pathways as a result of innovation adoption.
- A more efficient NHS that chooses the best innovations over interventions of lesser impact.

The diagram below sets out the Accelerated Access Review's vision of a faster and more streamlined pathway for innovation, driven by patients and clinicians and supported by an Accelerated Access Partnership.

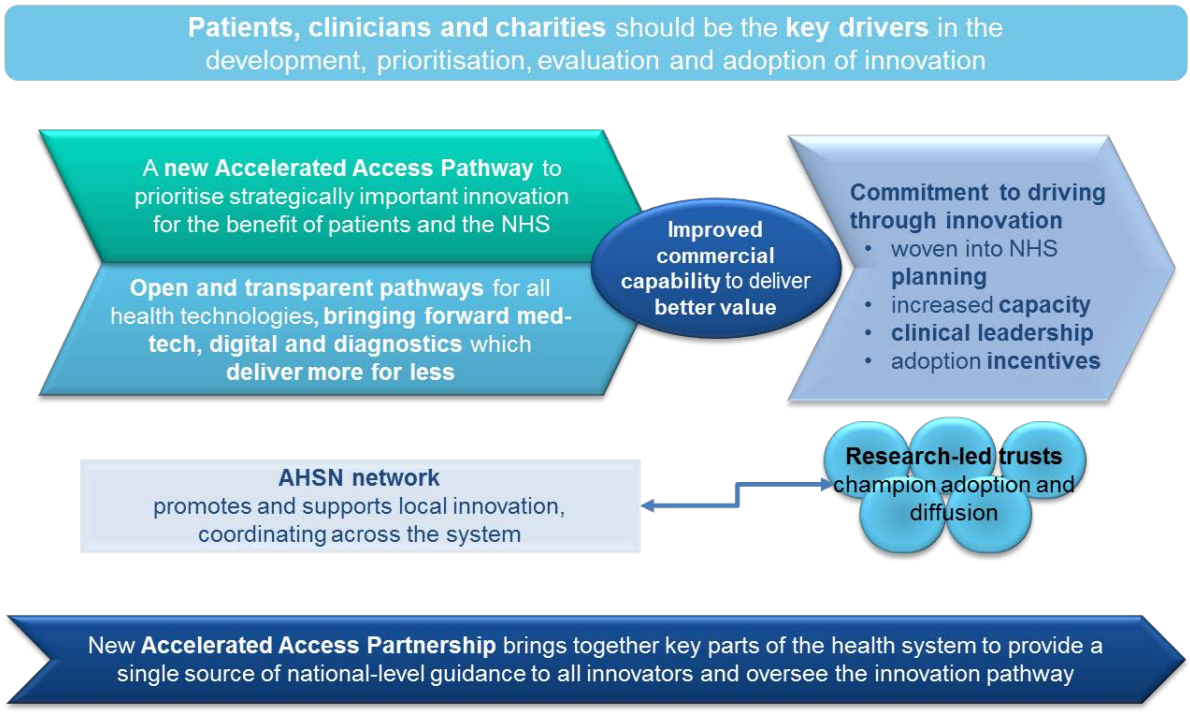

Figure 1: A summary of the Accelerated Access Review's proposed approach

C. The Challenge

Patients rightly expect the NHS to provide emerging, transformational innovations as soon as they become available and for our health outcomes to keep pace with those of other countries. Evidence shows, however, that we sometimes lag behind other countries in the adoption of innovation[1].

This situation cannot continue. Enabling clinicians, including doctors, nurses, healthcare scientists, pharmacists and allied health professionals, to access emerging innovations is essential if the NHS is to rise to meet its current and future challenges. Innovation has the potential to transform patient outcomes, modernise the delivery of care, make services more efficient, and help address some of the major challenges this country is facing, such as antimicrobial resistance. Our country is a world-leader in health research, our life sciences industry punches well above its weight internationally, and – in the NHS – we have the ideal infrastructure to test and adopt innovation. And yet throughout the review we have heard extensively from stakeholders how our health system currently struggles to prioritise even the best new products. Their frustrations are outlined in Sir John Bell's introduction.

Now is a critical time to address the health system's capacity to adopt innovation. In recent years the life sciences industry has generated an increasing number of transformative technologies. New technologies are coming down the pipeline at a rate we have never seen before: medical devices that use ground-breaking nano-technology or digital capability; drugs for chronic diseases that target specific sub-populations; diagnostics such as genomic sequencing that allow treatments to be targeted more effectively and curative medicines for diseases like Hepatitis C. The NHS needs to be ready to respond: flexing clinical pathways to get the most out of innovations, and generating datasets that allow a much more thorough evaluation of benefits and risks. Medicines regulators have already responded by adapting their processes to increase the speed of approval;[2] but these opportunities will be lost and patients will be disadvantaged if the rest of the healthcare system is not equally agile.

This report provides the NHS with the ability to make a clear and attractive offer to those innovators that are willing to work with us: a simplified and aligned system; dialogue with national bodies; accelerated diffusion across the whole health system; and the opportunity to gather the data they need to market their products around the world. In the face of a rising medicines bill, however, this report is clear that those innovators who benefit from this system must also be prepared to offer significant value to the NHS to enable change to be delivered at better value and within the overall budget for the NHS.

The UK's exit from the EU, far from altering the overall proposition set out in this report, gives us a chance to look afresh at our systems and identify steps to improve our international competitiveness in life sciences. We need to grasp the opportunities presented by leaving the EU

[1] https://www.gov.uk/government/publications/life-science-sector-data-2016
[2] For example the US's 'breakthrough designation', or PRIME in Europe

and – where possible – use any freedoms to create opportunities for our country: focusing on our global-leadership position in biosciences research and emerging industry subsectors; growing promising SMEs; building on our regulatory expertise and our reputation for health economic assessment; transforming the NHS into a system that welcomes innovation; and further developing our world-leading life sciences sector.

This report sets out an approach to selecting, accessing, funding and adopting the best innovations. This will allow the NHS to work positively and collaboratively with innovators and provide reassurance that system-wide, innovation-led changes will have significant benefits in streamlining clinical pathways, improving patient outcomes and generating efficiencies. Developing such an approach to adopting cost-effective innovations at scale is an important component of our efficiency drive and critical in ensuring that the UK and the NHS retain their globally competitive position[3] in clinical research and investment.

The NHS is the ideal place to develop this new paradigm:

- It has the most integrated health research system in the world – the National Institute for Health Research – allowing access to defined population cohorts, providing research funding and world-class facilities and expertise that support early translational, clinical and applied health and care research across the pathway.
- It is the biggest and most integrated single payer healthcare system – a 'closed loop' where economic value can be quantified to allow the total impact of a product to be assessed.
- Our emerging health data and genomics platform will give us unrivalled capability in data collection and assessment, along with a host of diagnostic tools such as molecular pathology for improving the targeting of medicines.
- Our world-leading system of value for money assessment qualifies us well to lead rigorous evaluation.
- It has demonstrated a willingness to partner with innovators to test their product claims on real clinical pathways.

Our strong charitable sector will be an important voice for patients, carers and the public as we undergo this change. Patients not only have an interest in the availability of innovative products, but are ideally placed to influence the early development of these products so they can get what they need and go on to hold the NHS to account for uptake. The involvement of patients, their families, charities and the public will be critical to the successful implementation of this review's recommendations.

This report provides a model through which strategically important innovations can be identified early, tested in the NHS to generate evidence of their impact, evaluated, and have reimbursement agreed promptly using a set of novel tools that reward innovators appropriately, and then adopted

[3] Office for Life Sciences, *Life Science Competitiveness Indicators*, May 2016 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/523269/BIS-16-236-Office-for-Life-Sciences-OLS-life-science-competitiveness-indicators-report-May-2016.pdf)

and diffused across the NHS in a way that enables clinical pathway changes and generates efficiencies. A dynamic system like this needs to be flexible and rapid, and should be underpinned by good quality data. This will only be achieved if the life sciences industry and the NHS work together to deliver innovations that offer cost savings and patient benefits: accelerating access, rewarding the most innovative companies, and helping the NHS to manage its finite resources.

D. The Report

The review's analysis and recommendations

This report describes the pathway to market for both strategically-important innovations (section 2) and products with more incremental benefits (section 3), and makes recommendations for each**.** In describing these pathways, it uses the terminology of the six basic steps in that process, as described below. The *sequencing* of the steps will vary product by product. The report makes recommendations on how each of these steps could be streamlined and accelerated so that patients get access to the most innovative products more quickly and more cheaply.

Figure 2: The six steps in a product's pathway to market

1. Improved horizon scanning and targeting to identify the greatest potential benefits

The NHS should develop an enhanced horizon scanning process and clarify its needs to innovators

1.1. Improved horizon scanning to identify products that have the most potential to deliver improved outcomes or efficiencies.

1.1.1. It is difficult for the NHS to understand which innovations are likely to have the greatest benefit for the NHS and its patients from the multitude under development. Many of the existing horizon scanning systems only consider pharmaceuticals and not medical technologies, diagnostic, or digital products. We believe a simpler, more comprehensive and transparent system is necessary. We recommend that existing horizon-scanning mechanisms are brought together in a joined-up approach so that all major emerging products are considered consistently and thoroughly. The enhanced horizon-scanning function should include arrangements for medical technologies, diagnostics and digital products and should consider the wider financial and organisational potential of pipeline products. For example, cancer diagnostics that identify patients who would benefit from chemotherapy can avoid unnecessary treatments as well as save money for the NHS.

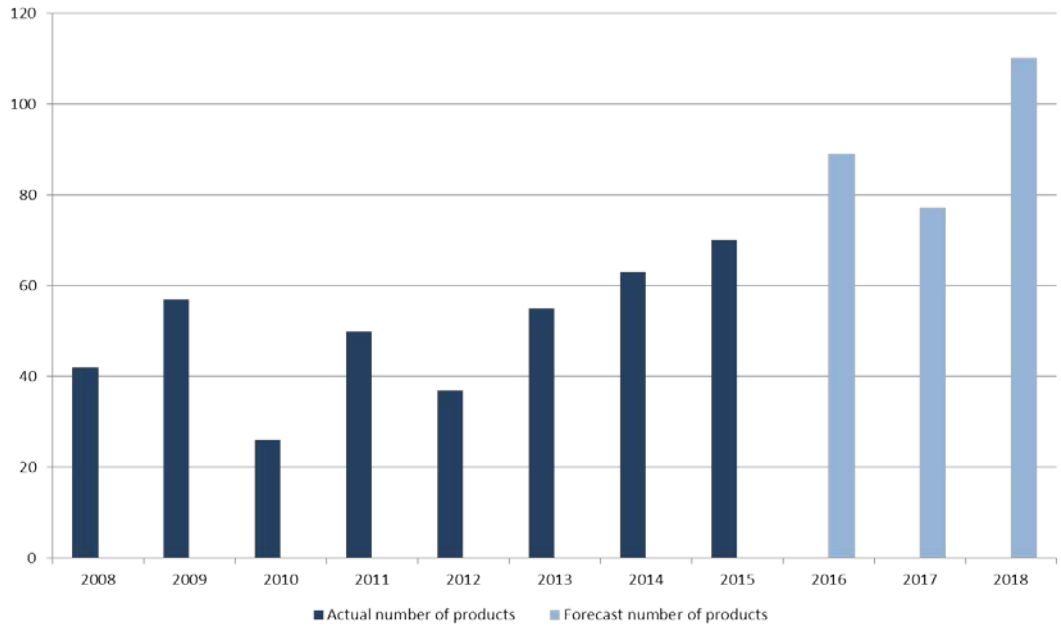

Figure 3: Forecast number of new chemical entities to launch between now and 2018[4]

[4] The period 2008-2015 is based on European Medicines Agency (EMA) data on NCEs (new chemical entities) and biologics. The figures from 2016 onwards are a forecast for NCEs provided by the Horizon Scanning Research and

1.2. Innovators need to understand the NHS's key priorities to help them focus on developing the right products – this should be one of the roles of an Accelerated Access Partnership.

1.2.1. Stakeholders have called for greater coordination across the innovation pathway and supported the proposal for a partnership model in the interim report[5]. This 'Accelerated Access Partnership' would bring together the main national organisations in this landscape – NIHR, MHRA, NICE, NHS England, NHS Improvement and the Department of Health, as well as patient and industry representatives – and is described further in section 7.

1.2.2. Amongst its other roles, the Accelerated Access Partnership should, building on the gaps in the technology pipeline exposed by horizon scanning and using the approach of the Small Businesses Research Initiative (SBRI), enable the NHS to articulate to innovators the technology requirements that would best support its needs. This is expected to be more effective for technologies than biopharmaceuticals.

SBRI Healthcare

The SBRI Healthcare programme co-develops technology with the NHS, working with clinicians to identify key challenges and priorities. The resulting technologies bring the opportunity to transform health and care, and grow economic value for the UK. The programme is led by the Academic Health Science Networks and in 2015/16 was able to disburse nearly £20m to almost 50 companies.

Solutions have been identified for a number of conditions. In diabetes, for example, Sedgefield-based Polyphotonix has developed a non-invasive treatment for macular eye disease using organic light-emitting diodes housed in a fabric mask which is worn overnight, avoiding costly outpatient visits. The mask (Noctura 400) can be used to prevent and treat diabetic retinopathy and Diabetic Macular Oedema and is currently undergoing phase III trials and a NICE assessment.

SBRI-backed companies are reporting jobs and trade growth, private investment of over £45m and a pipeline value to the NHS evaluated by health economists at over £510m.

1.2.3. In parallel, it will be vital to provide innovators with simple access to research infrastructure. To support this, the NIHR is combining its Healthcare Technology Co-operatives (HTCs) and Diagnostic Evidence Co-operatives (DECs) schemes in order to hold a single, new, open competition to fund new Medtech and In vitro diagnostic Co-operatives (NIHR MICs). NIHR MICs will work collaboratively with the NHS, industry and patients to both develop new concepts, demonstrate proof of principle and devise

Intelligence Centre (HSRIC) based on what products companies expect to launch. The EMA figures include combination products and certain blood products that have been excluded from the forecast; therefore the figures are not directly comparable. The forecast is a best case scenario and should be treated as an upper bound.

[5] *Accelerated Access Review: interim report*, October 2015 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/471562/AAR_Interim_Report_acc.pdf)

research protocols, for new medical technologies, and generate evidence on commercially-supplied IVDs. The review is supportive of this step.

1.3. A digital health technology catalyst should be established to deliver the digital solutions the NHS needs.

1.3.1. Some digital technologies offer the opportunity to deliver improved outcomes at lower cost. We therefore recommend that the government explores how a digital health technology catalyst could be funded. This should be modelled on the Biomedical Catalyst[6] and aligned with the work of Innovate UK.

1.3.2. A catalyst could provide matched public sector funding, alongside private investment, to address areas of failure in the digital healthcare market and support the growth of those promising small companies who are developing the digital technologies that the NHS and patients need and help bring their products to market.

Biomedical Catalyst

The Biomedical Catalyst is a competitive challenge fund, run in partnership by Innovate UK and the Medical Research Council. It supports the translation of research into therapies, devices and diagnostics into commercial success and increases the confidence of those private investors who can help support a product to reach the market. It is considered to be highly successful; during phase 1 of the catalyst, companies in its portfolio realised over £1bn in post-project financing, licensing deals and acquisitions.

The Biomedical Catalyst provides three main phases of funding:

- Feasibility awards to explore the commercial potential of a scientific idea
- Early-stage awards to evaluate feasibility in a model system
- Late-stage awards to demonstrate effectiveness in a relevant environment.

In the Accelerated Access Review's consultation process, stakeholders consistently identified a scarcity in funding for late-stage testing of digital health products in a real-world environment as a significant barrier to digital health innovation. Creating a digital health catalyst to address this issue would help provide a sustainable pipeline of digital health products designed to meet NHS needs and support the growth of UK companies.

[6] http://www.mrc.ac.uk/funding/science-areas/translation/biomedical-catalyst/

A new *transformative designation* should be applied to those innovations with the potential for greatest impact

1.4. A transformative designation should identify the most strategically important products (medical technologies, diagnostics, pharmaceuticals or digital innovations) that have the potential to deliver significant benefits in cost or outcomes.

1.4.1. The transformative designation should signal, within the UK and internationally, a product's strategic importance to the NHS. It should be reserved for the small number of products that have the potential to provide significant benefits in either patient outcomes or NHS costs. Its immediate practical effect should be to **act as a trigger for these strategically important innovations to enter an accelerated pathway to patients, receiving additional support and guidance to navigate the market and to reach patients**. This accelerated pathway for transformative products is a key plank of this report and is described in more detail in section 2.

1.4.2. Determining which products should receive a transformative designation will therefore be of critical importance, and the Accelerated Access Partnership should develop a transparent and robust process for this, bringing together skills in NICE and NHS England and drawing on a range of evidence of potential impact. For pharmaceuticals, the criteria should build on 'breakthrough designation' in schemes such as PRIME[7] in Europe and the UK's Early Access to Medicines Scheme (EAMS).[8] Criteria for designation could include:

- magnitude of health gain;
- impact on unmet need;
- alignment with NHS England's clinical priorities and other national priorities;
- impact on system efficiency;
- potential cost impact, from cost saving to significantly cost increasing;
- opportunity for clinical pathway transformation;
- innovative nature of the technology.

1.4.3. As well as considering the potential cost impact of individual products, the cumulative cost impact of all products should be considered, in the context of the budgetary envelope for the NHS set by the Government, with a view to ensuring overall affordability within that budget.

1.4.4. We expect that only around five to ten innovations per year would receive the transformative designation and not all of these will travel down the entire Accelerated Access Pathway as described in section 2; products can enter and leave at multiple points. While many products of strategic importance may be in specialised services, this designation should be applicable to all products, regardless of their commissioning

[7] http://www.ema.europa.eu/ema/index.jsp%3Fcurl%3Dpages/regulation/general/general_content_000660.jsp%26mid%3DWC0b01ac058096f643
[8] https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams

method, and available to medical technologies, diagnostics, pharma and biotech as well as emerging types of innovation such as cell therapies and digital health.

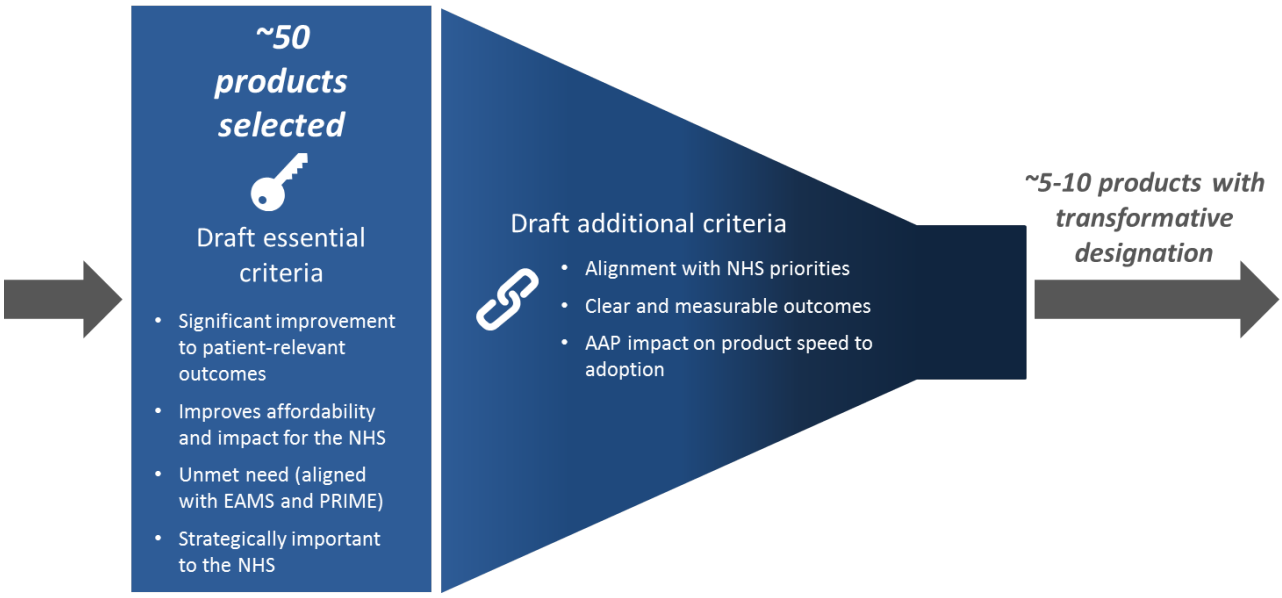

Figure 4: The Accelerated Access Partnership will identify a small number of strategically important products

Patients should be involved in horizon scanning and prioritisation, and this involvement should continue along the whole innovation pathway

1.5. The NHS should use a common set of principles describing what good partnership with patients and the public looks like along the whole innovation pathway.

1.5.1. We are seeing a shift from a one-size-fits-all model of blockbuster drug development to a new age of personalised medicine, enabling patients to take greater control in their health care. Patients' strong interest in the development and availability of new innovations means that their involvement, either directly or through charities, is critical, from influencing innovators to develop the products they need, participating in research, championing the uptake of innovations into the NHS to holding the NHS to account for the adoption and spread of the best innovations. This means that meaningful dialogue with patients has never been more important.

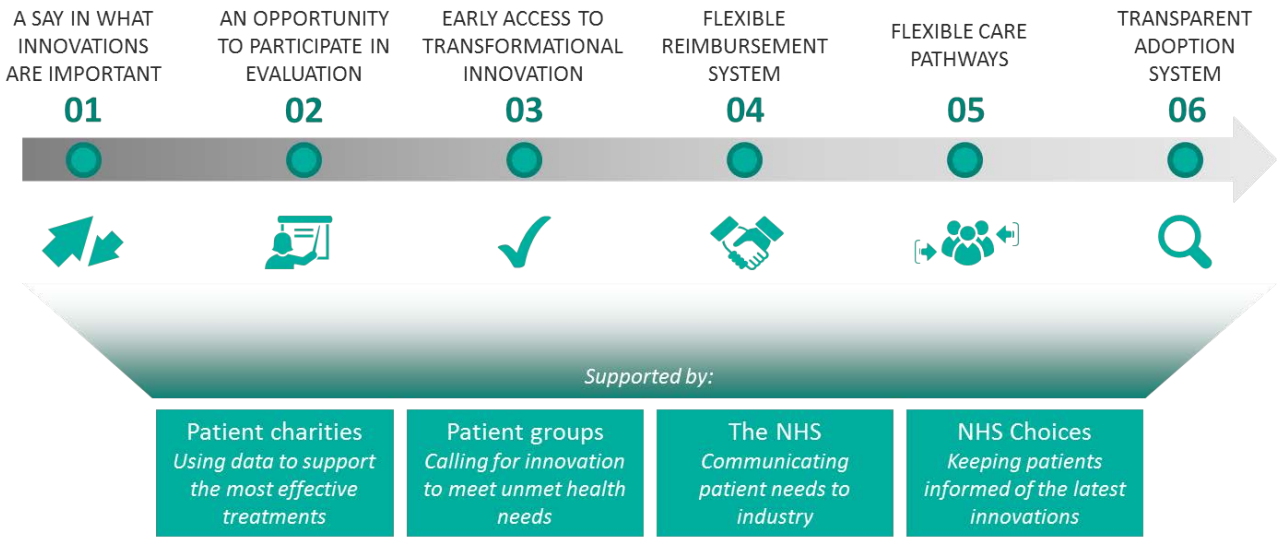

Figure 5: Greater patient influence at all stages of the innovation pathway

1.5.2. Alongside the review, National Voices, the coalition of health and social care charities, developed a set of principles or 'I statements' that describe what good collaboration with patients and service users throughout the innovation process looks like in practice.[9] We propose that NHS organisations – and other organisations involved with innovation – should develop their own set of principles, using the I statements as a basis, to underpin all stages of the innovation pathway and help everyone along that pathway to put the patient first.

1.5.3. This applies equally to the national bodies that form part of the Accelerated Access Partnership who, in addition, should consider how to best ensure patent involvement in the process of designing the criteria for transformative designations.

[9] http://www.nationalvoices.org.uk/publications/our-publications/involving-patients-and-service-users-i-statements-research-and

A collaborative approach in myeloma

In 2007, Myeloma UK developed an innovative approach to gain approval from NICE for bortezomib, a treatment for patients with relapsed myeloma. Although bortezomib had initially been turned down, Myeloma UK worked collaboratively with Janssen and NICE to develop the first patient access scheme of its type, which is still in operation today. It reduces the level of risk to the NHS by ensuring that the NHS only pays for patients that respond to the drug. Failure of a patient to respond means that the company reimburses the NHS for the costs of the drug.

Myeloma UK was pivotal in pushing compromise between all parties and ensuring that the outcomes data reporting systems were put in place so that the scheme operated effectively, with minimal additional burden to the NHS.

Myeloma UK, reflecting on the first unsuccessful NICE appraisal, has developed a collaborative approach to health technology appraisals, ensuring engagement as early as possible with companies. This has meant successful appraisals of the majority of new medicines for myeloma. In addition, Myeloma UK established a clinical trial network to accelerate the set-up of and recruitment to a strategic portfolio of trials. This network also created the capability to partner with industry to generate real-world UK data alongside registration programmes to improve the evidence suitable for the UK assessment, and thus the value proposition, and increase data certainty ahead of the health technology appraisal.

2. An Accelerated Access Pathway for transformative products

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

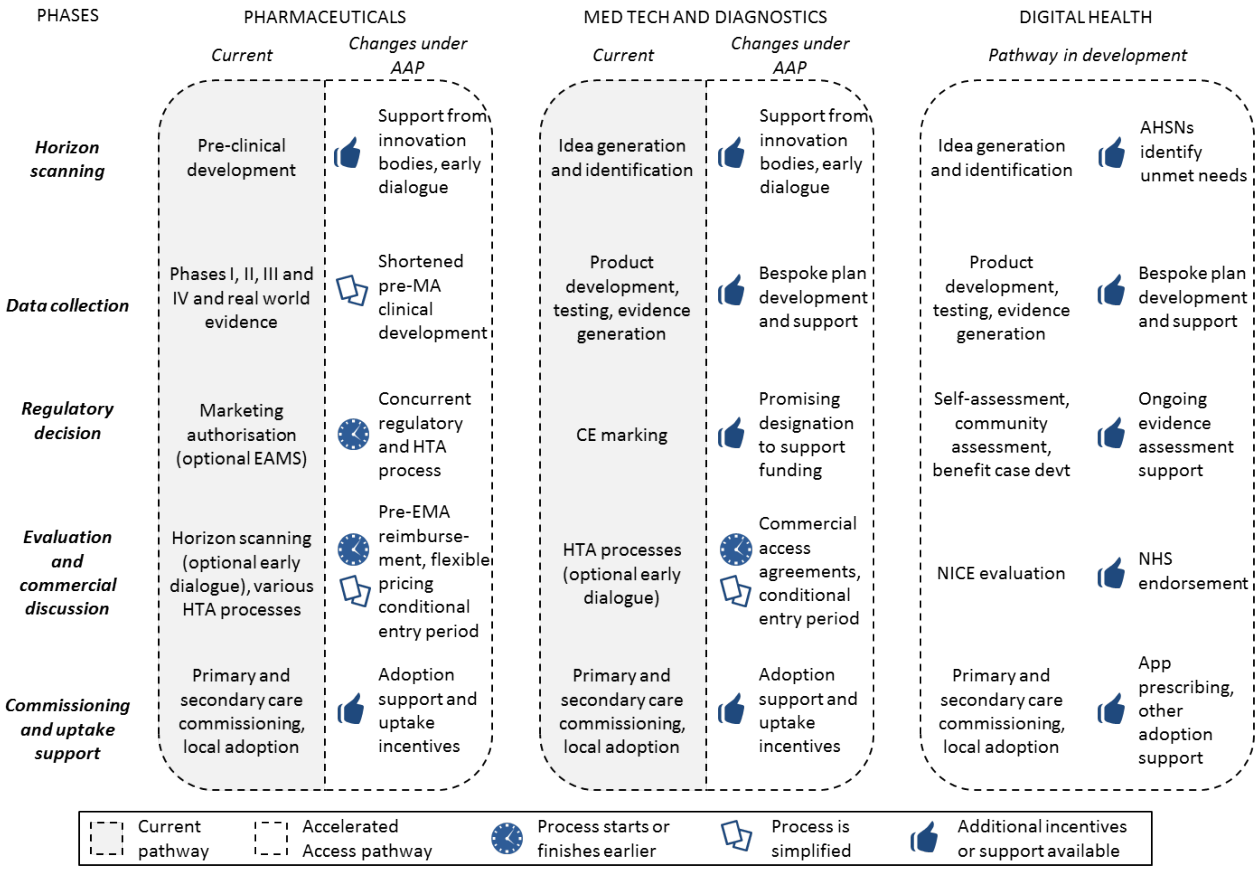

Figure 6: Key differences between existing pathways and the accelerated access pathways

2.1. Strategically important products should benefit from an Accelerated Access Pathway to patients.

2.1.1. The Accelerated Access Pathway should allow products with a transformative designation to meet regulatory requirements, agree commercial arrangements, receive revenue and achieve market access as quickly as possible. We expect that this could bring forward reimbursed access by up to four years in some cases (see section 2.3.2). This should be enabled by the Accelerated Access Partnership, which will provide specific, tailored support from an early stage of the pathway.

2.2. Strategically important products with a transformative designation should be given access to clinical research opportunities to support evidence collection, for the benefit of patients and industry.

2.2.1. The Accelerated Access Partnership should support innovators with strategically important products to navigate the system, hold early dialogue with national decision-makers such as NICE, NHS England, NHS Improvement and MHRA, and increase understanding of product impact. This should include:

- Using our state-of-the-art translational clinical research base to provide access to clinical research cohorts.
- Generating real-world, in addition to other, clinical trial data on the most responsive patient populations, using genomic sequencing and other personalisation tools to identify more precisely who can benefit from the intervention.
- Undertaking research in collaboration with the NHS, sharing cost and risk and allowing the NHS to benefit (for example through a lower price) if and when the product receives a licence.
- Gathering real world data on medical technologies and their impact on a clinical pathway through a 'commissioning through evaluation' type approach or a managed access agreement (described in more detail in section 2.9).

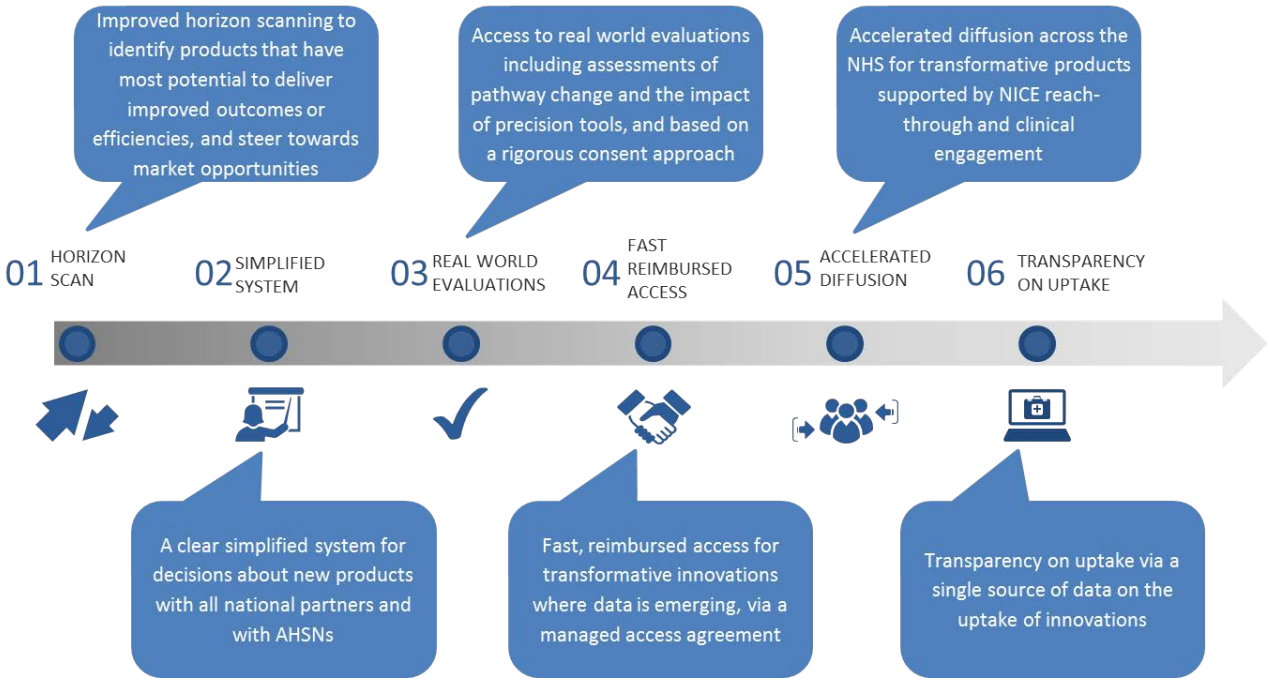

Figure 7: The innovator's perspective

2.2.2. Many innovations come to market with incomplete evidence of impact on patients, clinical pathways and efficiency. The NHS, as a single system where cost and outcomes data can be collected, can offer innovators significant value in building their evidence base. Combined with the scale and strength of its early translational and clinical research through NIHR, its emerging genomic sequencing capabilities through

Genomics England, and its strong health economic assessment skills in NICE, this provides a compelling opportunity to create global value for strategically important innovations.

Lessons from Ebola

The UK's rapid response to the licensing needs for the Ebola virus demonstrated not only the willingness of the population to participate in ground-breaking research, but also how our regulatory processes can be accelerated. The MHRA's Clinical Trials Unit (CTU) prioritised Ebola studies over other clinical trial applications. This resulted in approval timeframes of approximately one week compared to an average for phase I studies of about three weeks.

The MHRA CTU worked closely with the trial sponsors to provide *ad hoc* scientific advice and review prior to official submission of the application. The MHRA also sought independent expert advice from the Commission on Human Medicines' Clinical Trials, Biological and Vaccines Expert Advisory Group who supported the review through their willingness to provide expert input remotely and at short notice.

Trial sponsors ensured that any questions raised by the MHRA and independent experts were answered as quickly as possible, allowing a rapid approval without compromising the MHRA's stringent assessment standards. This demonstrates that MHRA is a world-leading regulator and has the ability to flex its resources and processes where necessary to enable a rapid response to public health emergencies.

Overcoming regulatory challenges in dementia

In dementia, interventions are more likely to be successful in the early stages of disease before symptoms present. But that means it can take years to generate the evidence of efficacy required for regulatory approval. Between 2002 and 2012, 99.6 per cent of clinical trials in Alzheimer's disease – the most common cause of dementia – failed due to a combination of scientific, trial design and regulatory challenges*. This enormous failure rate creates a risk that innovators will become reluctant to invest in this important area, and patients will lose out, unless new regulatory approaches are found.

Raj Long's 2015 report *Finding a path for the cure for dementia*** recognised the seriousness of this situation. Its recommendations were shaped by a collaboration of ten regulatory agencies from North America, Europe and Japan, which convened to draw attention to these challenges and find a solution. The report called for a radically new approach to drug development that takes into account the unique characteristics of dementia. It sets out a strategic solution, involving regulators, clinicians and academics, acting at multiple levels in the current regulatory framework. The specific recommendations include:

- Reconsidering previously rejected molecules to see if they can be developed in a different way;
- Embracing new approaches to drug development such as 'adaptive pathways' that can apply existing accelerated regulatory pathways to dementia;
- Employing a sensitive and patient-centric approach to the risk-benefit balance;
- Creating an advisory panel of research experts who can work in conjunction with regulators to advise on optimal development strategies.

Alzheimer's Research UK and the OECD are now taking forward the report's recommendations and appraising an integrated solution to the drug development challenges in dementia. This work aims to address the high failure rate and help bring effective new treatments to people living with dementia and potentially serve as a model for other diseases.

* Cummings et al (2014) Alzheimer's disease drug-development pipeline: few candidates, frequent failures. Alzheimer's Research & Therapy, 6:37

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https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/451874/DH_DementiaReport_acc.pdf

2.3. A number of early access or breakthrough schemes exist for pharmaceutical products: the Accelerated Access Pathway for medicines should fit seamlessly with these schemes and should allow time to be taken out of the process by better aligning regulation and evaluation.

2.3.1. The Accelerated Access Pathway for medicinal products should build on existing breakthrough designations such as PRIME and EAMS's 'Promising Innovative Medicine' (PIM) designation. The pathway should enable patients to access strategically important products early, through a NICE conditional recommendation where appropriate, and allow additional evidence to be collected to fully demonstrate the product's value and impact.

2.3.2. Closer alignment of regulatory and NICE data requirements and processes, including timing NICE's decision as close to the opinion of the Committee for Medicinal Products for Human Use (CHMP) as possible, will, alongside the other measures identified in this report, accelerate access to strategically important pharmaceuticals. Our analysis shows that patient access can be brought forward by up to four years where an EAMS scientific opinion is used (saving 12-18 months), and where there are no delays in the technology appraisal (which can take up to two years) or in NHS commissioning and adoption (which can take two years or even longer). Companies can also reduce clinical development timelines if decisions are taken at global level to use novel approaches to clinical trial evidence generation and regulators are showing increasing willingness to consider evolving datasets for high-impact products. Truly breakthrough products with promising early clinical trial results also tend to accelerate through clinical development.

The EAMS experience: bringing forward access to pembrolizumab

Through the Early Access to Medicines Scheme (EAMS), MHRA worked with MSD to ensure that UK patients with advanced melanoma were among the first in the world to access the breakthrough treatment, pembrolizumab. EAMS offers patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need.

Pembrolizumab was available through EAMS around a year earlier than if it had gone through all the conventional processes and MSD estimated that around 500 UK patients accessed it during the EAMS period. For pembrolizumab, the company proposed a patient access scheme (PAS) at the earliest opportunity after licencing which helped NICE to publish guidance as quickly as possible. EAMS helped accelerate routine patient access by seven to eight months through a combination of expedited NICE scheduling and a 30 day implementation period by NHS England rather than the usual 90 day period.

Following the successful implementation of the first EAMS scientific opinion, MSD is continuing to engage with MHRA and other stakeholders on further EAMS applications, including other indications of pembrolizumab.

2.3.3. There is always a balance to be struck between accelerating access to medicines and ensuring that patients can be confident those medicines are safe. It is therefore important to note that this review does not make any recommendations that change the evidentiary standards needed for regulation. In EAMS, medicines are only approved for use in the scheme if companies can provide good quality, clinical and non-clinical supporting data, along with a risk management plan, similar to that provided for marketing authorisation.

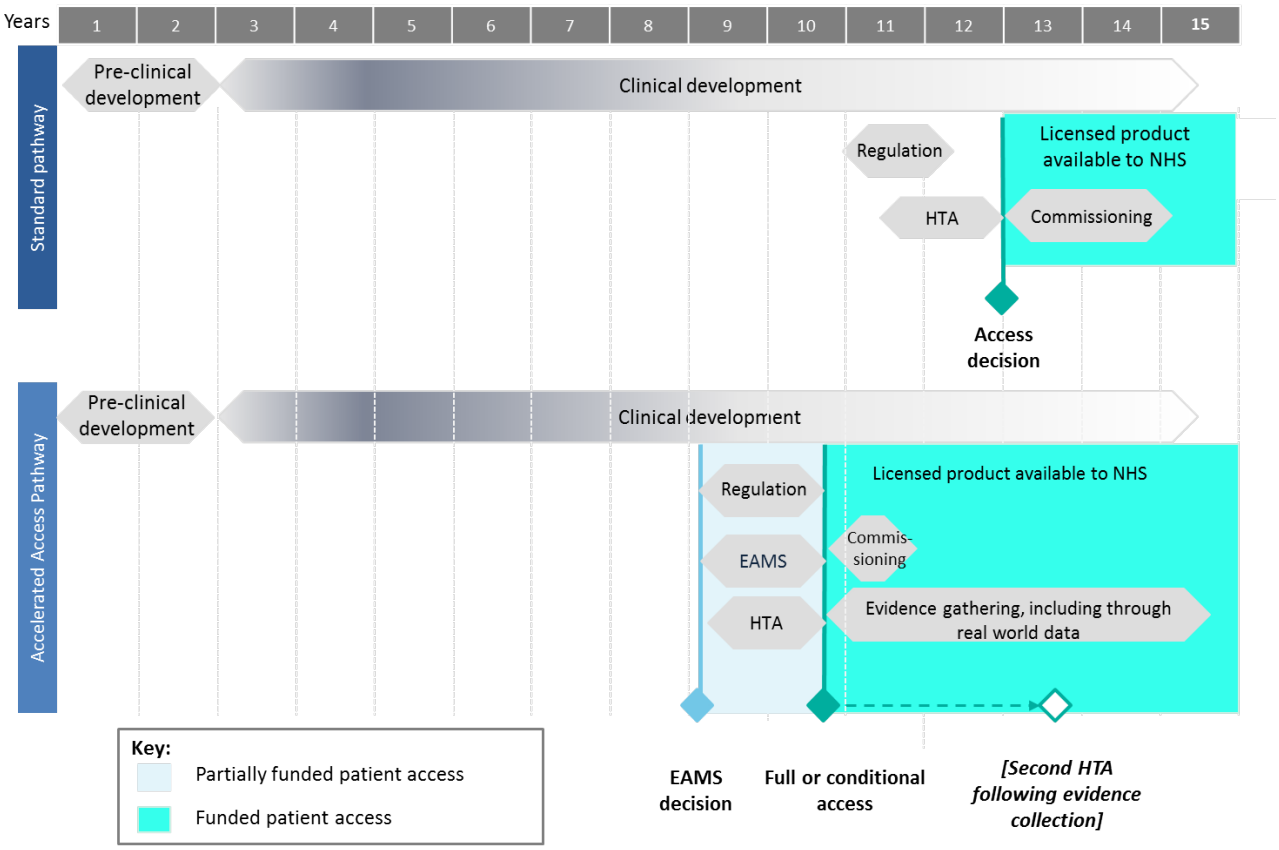

Figure 8: The Accelerated Access Pathway could enable widespread patient access to pharmaceutical products up to four years earlier

2.4. SMEs and not-for-profit organisations with products on the EAMS pathway should, in some cases, receive some funding.

2.4.1. EAMS continues to hold significant value for innovators on the Accelerated Access Pathway: giving patients access to medicines prior to marketing authorisation, accelerating the path to NICE evaluation, and shortening the time to reimbursement.

2.4.2. As part of the Accelerated Access Review, the government commissioned a review of EAMS. Following extensive engagement with stakeholders, this was published in March 2016 and makes seven recommendations that build on what EAMS has achieved to date.[10]

2.4.3. One of these recommendations relates to funding. The EAMS review's analysis suggests that, in order for the UK to remain internationally competitive, products participating in EAMS should receive some level of funding prior to NICE assessment. To direct monies most effectively, this funding could be focused on strategically

[10] Strategy&, *The Early Access to Medicines Scheme: An independent review*, 2016 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/509612/eams-review.pdf)

important products manufactured by SMEs and not-for-profit organisations. It could depend on the level of risk associated with the product and include risk-sharing arrangements where appropriate. We recommend that the government makes between £20m and £30m available for this support over five years.

The EAMS experience: bringing forward access to osimertinib

Osimertinib is an innovative product discovered and developed in the UK by AstraZeneca to treat lung cancer where there is high unmet medical need. Osimertinib went through the regulatory system using accelerated assessment and conditional marketing authorisation and was approved based on single arm studies. In addition, 22 UK patients benefited directly from the EAMS scientific opinion which allowed them earlier access. The conditional marketing authorisation came only eight months after the regulatory submission was filed at the EMA, and less than three years after osimertinib was first trialled in humans. In October 2016, osimertinib became the first medicine to be made available to NHS patients through the reformed CDF process, following a recommendation by NICE.

A new strategic commercial unit should be established in NHS England

2.5. A strategic commercial unit should have the capacity and capability to consider a range of flexible pricing models as part of a commercial dialogue with innovators.

2.5.1. Win-win scenarios, where innovators benefit from earlier, and, in some cases, guaranteed market access and the NHS and patients benefit from better value through a reduced price, are possible. They depend, however, on having the right expertise in place and require innovators and NHS England to undertake a commercial dialogue so that mutually advantageous commercial arrangements can be agreed quickly. They are more likely to be successful if all parties are willing to engage early in this dialogue.

2.5.2. We propose that NHS England creates a new strategic commercial unit (SCU) to enable the NHS to agree such commercial arrangements with companies. The unit should consider a product's overall affordability, and its dialogue with innovators should take into account the wider value of accelerated access, such as early approval from NICE, the potential for confidential commercial arrangements, increased – and in some cases guaranteed – volumes across England, and the generation of real-world observational data on top of clinical trials data. This offer to industry should be reflected in a cost proposition that delivers additional value for the taxpayer beyond that achieved through the current system.

2.5.3. Building the evidence base for a strategically important product is of value to innovators, and should be taken into account in the commercial negotiations described above. This could involve novel risk-sharing arrangements between the NHS and the innovator that enable both parties to benefit from a product's success.

2.5.4. The unit should be able to enter into a wide range of commercial arrangements that deliver better value, share the benefits of accelerated access and recognise any uncertainty in the evidence base. A large number of flexible pricing schemes are in use internationally, such as price-volume agreements, conditional reimbursement, deferred payments or annuity-based pricing, outcome-based payments, product-service

bundling and deferred payments, amongst others, and the SCU may wish to consider, for each product, whether using one or more of these schemes would deliver value and help a product to achieve reimbursement in an affordable way. The most appropriate scheme will depend on the product's value proposition and should be considered and modelled on a case by case basis. We would encourage flexibility and innovation in the type of arrangements that might be achieved to maximise the potential benefits for all parties. Over time, the commercial arrangements may change depending on the emergence of new evidence or changes in population size. Payment could be linked to the delivery of value, whereby no payment is made if the expected value has not been delivered.

2.5.5. As the unit develops its capacity and capability, we suggest that its scope could extend beyond strategically important technologies to cover a wider range of products. This would give NHS England the ability to reach agreements with companies that allowed it to manage its resources more effectively. We note that NHS England and NICE are currently consulting on proposals that include entering into commercial access agreements with companies where products exceed a budget impact threshold[11], and we propose that the way this consultation is taken forward is aligned with the implementation of this review.

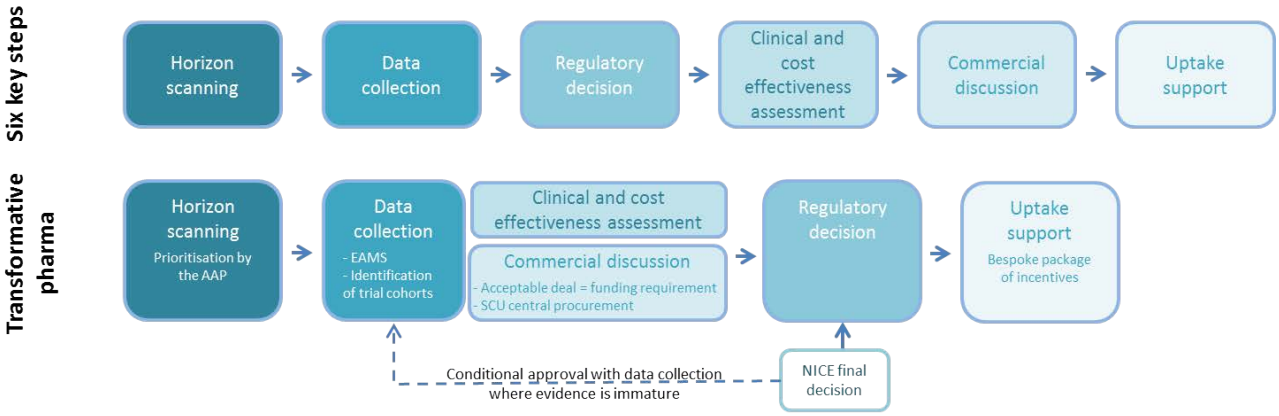

Figure 9: The sequencing of the Accelerated Access Pathway for strategically important pharmaceuticals

2.6. SCU commercial dialogue should be informed by NICE and should take place before final guidance is issued.

2.6.1. The SCU should hold commercial dialogue with the small number of companies whose product has a transformative designation, in parallel with that product's assessment by

11 NICE and NHS England, *Proposals for changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE's technology appraisal and highly specialised technologies programmes*, October 2016 (https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/consultation-on-changes-to-technology-appraisals-and-highly-specialised-technologies)

NICE. The discussions should include the level and timing of reimbursement and, as with the new Cancer Drugs Fund (CDF),[12] the resulting commercial arrangements should be able to remain confidential. As outlined in section 2.5.2, the discussion should take into account the benefits to the company of the Accelerated Access Pathway and the opportunity to enter into confidential, flexible arrangements, and as a result should aim where possible to achieve a significantly higher level of cost effectiveness. Final NICE guidance on these strategically important products should ideally not be published until after SCU's commercial dialogue has concluded, and the three month funding requirement should apply where SCU agrees a mutually acceptable commercial deal with the innovator and NICE guidance recommends the product for routine use. Where the SCU fails to reach a commercial deal, the NICE guidance would be based on the price agreed with the company under existing rules and, in the event that this would result in a positive recommendation, NHS England could ask NICE to consider varying the funding requirement where they had concerns about resources, including budget impact.

2.6.2. Should a company choose not to take advantage of the benefits of the Accelerated Access Pathway they should be able to opt out of their transformative designation and proceed down the standard pathway as they would have done under normal circumstances.

> *"Immunocore supports the NHS in its initiative to treat high medical unmet need patients earlier than traditionally possible. In a collaborative partnership, Immunocore will invest alongside the NHS in improving pathway efficiency (for uveal melanoma patients) that expedites earlier access to treatment, improves patient care and shares financial benefits that align with the benefits of expedited access to patients."*
>
> Eliot Forster, Chief Executive, Immunocore

2.6.3. Where a product's evidence base is immature but shows strong potential, NICE should be able to issue a conditional recommendation leading to a period of managed access, building on the approach for the new CDF. This should only be available to those strategically important products whose development and regulatory timetable has been accelerated, and should also be dependent on NHS England reaching satisfactory commercial arrangements with the company. In a managed access period, the commercial arrangements for these products should reflect the uncertainty of their evidence base to limit the financial risk being borne by the NHS. It would be reasonable for products with uncertainty to be tested against more stringent requirements than those products where benefit is well understood.

2.6.4. CDF monies should be used to fund any managed access agreements for licensed cancer products on the accelerated access pathway.

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[12] NHS England,
Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund): A new deal for patients, taxpayers and industry, July 2016 (https://www.england.nhs.uk/cancer/cdf/)

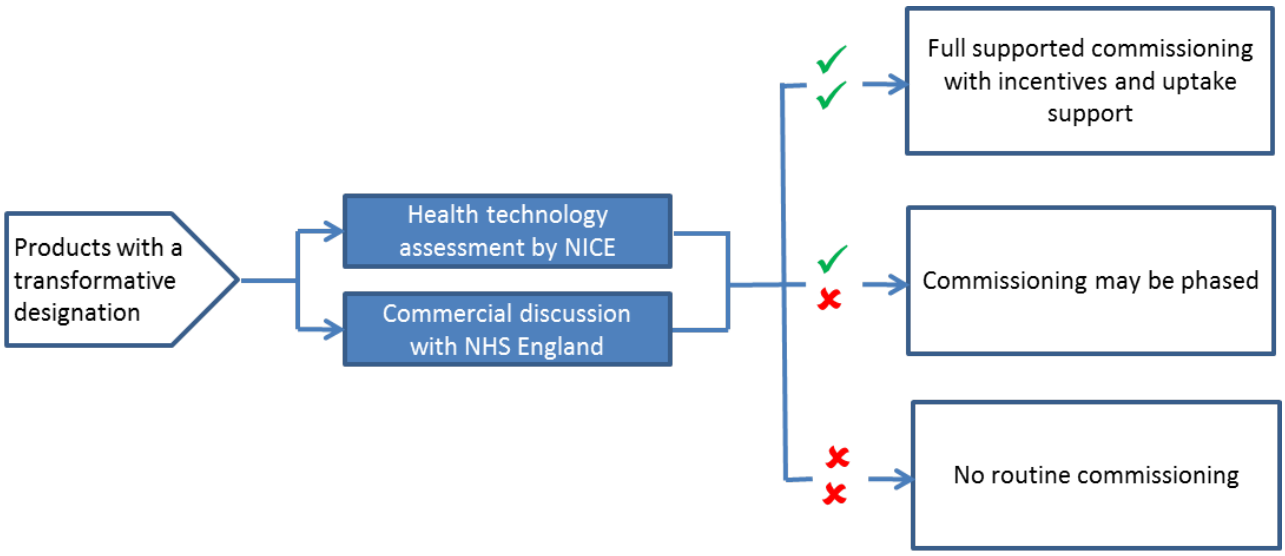

Figure 10: Products that reach a commercial deal will move swiftly to reimbursement

2.7. Industry should seek advice from MHRA and NICE to trial cancer medicines in early stage disease where QALY benefits may be more easily demonstrated.

2.7.1. Cancer medicines are typically first trialled on patients with late stage disease, where it is challenging to significantly extend life. These patients are also seriously ill and it would deliver more health gains if products were able to extend life, potentially for longer, for patients before their condition has seriously deteriorated. Treating patients with early stage cancer could reduce the number of treatments they need over time and be a significant opportunity for innovators to improve outcomes for patients and demonstrate more value from their products. Industry should work with MHRA and NICE to understand whether more cancer medicines can be tested to support a first-line indication, where this can be justified for ethical and scientific reasons.

The Accelerated Access Pathway should be suitable for medical technologies, diagnostics and digital products, as well as medicines and emerging forms of treatment

2.8. Strategically important medical technologies may require support for data collection.

2.8.1. For medical technologies, diagnostics and digital products, the pathway may look slightly different to the pathway for strategically important pharmaceuticals. Medical technologies will often come to market with a less formed evidence base than medicines due to the different regulatory requirements. This means that a transformative designation is more likely to be given after a CE marking, and products may need further clinical and cost effectiveness data before the NHS can be clear about their benefits. These benefits will usually arise due to the product's impact on a clinical pathway.

2.8.2. Innovative med tech products frequently fail to achieve reimbursement and adoption because the small firms involved have limited resources for the additional clinical testing required to generate the evidence to inform cost-effectiveness decisions. We propose that a small amount of funding – around £20m to £30m over five years – would support the commercialisation of disruptive innovative technologies that significantly change care pathways and have the potential to improve outcomes and create efficiencies. The funding should be targeted at SMEs to promote a vibrant and varied industry.

Six key questions that medical technology innovators should ask

- How will this innovation change clinical pathways and establish a new standard of care?
- What will be the clinical, social and economic impacts from this new standard of care?
- How will we measure the impacts with sufficient precision to provide evidence for adoption?
- What changes in workflow will be required?
- How will the re-engineering of this workflow be resourced?
- How can the benefits be spread across and between healthcare delivery systems?

2.9. Support for strategically important medical technologies from the Accelerated Access Partnership should be aimed at post-CE mark data collection

2.9.1. This data collection should focus on demonstrating the product's impact on the system. One way of approaching this is through a commissioning through evaluation pathway, where complex medical technologies or diagnostic products that significantly change clinical pathways are rolled out in a number of specialist providers who are well-placed to collect impact data and build expertise around pathway change. Following this period, should the technology prove its value after assessment by NICE, it should enter routine commissioning and benefit from supported uptake, driven by AHSNs.

2.9.2. The best evidence of costs and benefits to the health system will arise in settings where data is collected digitally and is integrated across the whole health economy. This is explored further in section four

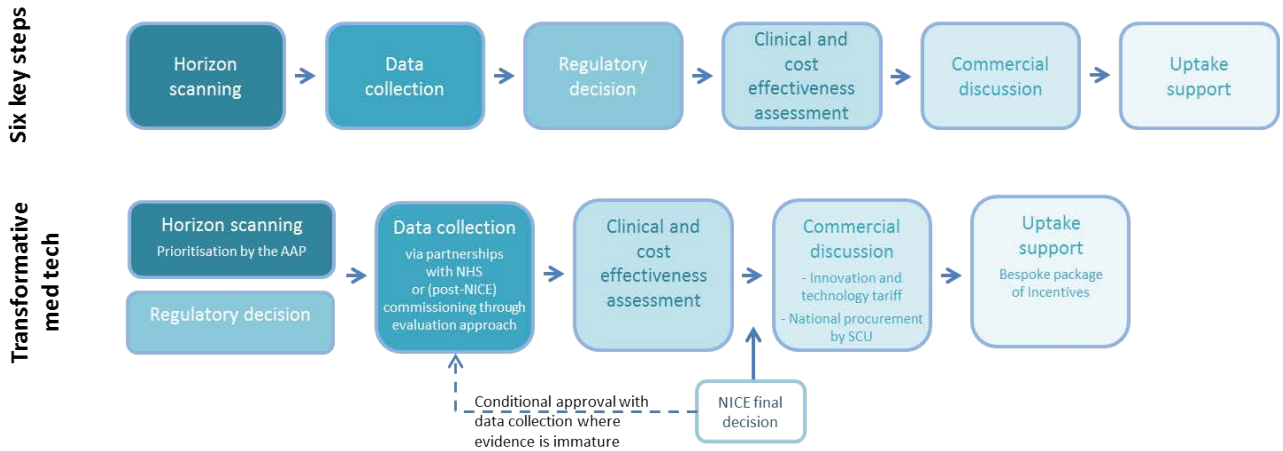

Figure 11: The sequencing of the Accelerated Access Pathway for strategically important medical technologies

2.9.3. The new Innovation and Technology Tariff, announced by the Chief Executive of NHS England in June 2016,[13] provides a reimbursement route for a selected number of value-proven, strategically-important medical technologies and digital products, including standalone digital technologies such as apps, removing the need for multiple local price negotiations.

How innovative diagnostics can save money and improve patient experience

Innovative diagnostic tools have the potential to improve patient experience and save operational costs. High sensitivity troponin assays, for example, can rule out or confirm a type of heart attack.

In 2014 NICE recommended the use of Elecsys Troponin T high-sensitive (Roche Diagnostics) and ARCHITECT STAT High Sensitive Troponin-I (Abbott Diagnostics), alongside other investigations, to help emergency clinicians determine whether patients experiencing chest pain are having a heart attack. Both these tests measure the level of troponin, a protein released into the blood when heart muscle is damaged. Standard cardiac troponin tests have to be carried out on admission and 10-12 hours later, but the high-sensitivity troponin tests are able to detect a change in levels of troponin much earlier, within as little as three hours.

Ruling out heart attacks earlier means patients can be discharged from A&E sooner and fewer patients need to be admitted to hospital for observation while the testing is carried out, saving the cost of unnecessary admissions. It reduces length of hospital stay and improves patient experience by reducing waiting time for results and putting patients on the appropriate treatment pathway sooner. Based on NICE's assessments and industry data, it is estimated using these tests with the earlier discharge protocol has the potential to save the NHS £30 to £40 million per year.

2.9.4. As with medicines, the costs of adoption of strategically important medical technologies should be negotiated centrally through the SCU (see section 2.5) in order to secure

[13] https://www.england.nhs.uk/2016/06/treatment-innovations/

value for the NHS as a whole. The Accelerated Access Partnership should be able to refer particular products for procurement within the NHS Supply Chain programme where they deem this more appropriate, and should ensure that new procurement and supply chain arrangements due to be in place from 2018 become the default procurement process for strategically important products coming through the Accelerated Access Pathway. The Accelerated Access Partnership may also submit some medical technologies for inclusion in the model hospital proposals as set out by Lord Carter in his review of operational productivity.[14]

Episcissors: an innovative approach to procurement

The NHS identified an opportunity to improve care and make savings by the national use of Episcissors-60, an innovation which was supported by the NHS's National Innovation Accelerator. Episcissors take away human error in estimating safe episiotomy angles during childbirth. Data suggests that obstetric anal sphincter injuries, which occur during vaginal childbirth, have a direct cost to the NHS of £48.75m per year, and an additional indirect cost of £3.1m per year in litigation costs. Trials at Hinchingbrooke and Poole Hospitals NHS trusts suggest that use of Episcissors-60 reduces the risk of obstetric injury by up to 20 per cent and they have reduced the risk of obstetric injury at Croydon University Hospital by nearly 50 per cent.

The Department of Health instructed NHS Supply Chain to bulk purchase this innovative surgical instrument through an upfront commitment contract. This commercial agreement is delivering:

- improved patient outcomes
- significant upfront savings from bulk purchasing
- savings over time from reduced harm to patients
- an easy route for the product to the NHS market, to stimulate demand
- reduced investment risk for the company.

This innovative partnership model also benefits the taxpayer by paying the Department of Health a royalty on all international sales of Episcissors-60.

2.10. Each strategically important innovation and associated clinical pathway should have a bespoke incentive package for the NHS, developed alongside NICE guidance, to support collaboration and track adoption.

2.10.1. The Accelerated Access Partnership should take every step to support uptake and diffusion of products on the accelerated access pathway for the benefit of patients. It should ensure that NICE's guidance for strategically important innovations includes a bespoke incentive framework that supports diffusion across the NHS. This could include national tariffs or proposals for local changes to support collaboration across organisations. NICE should track uptake of the products and publish this information.

[14] *Operational productivity and performance in English NHS acute hospitals: Unwarranted variations: An independent report for the Department of Health by Lord Carter of Coles*, February 2016 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf)

3. Simpler national and local routes to get products to patients

There should be a single set of clear national and local commissioning arrangements to get medical technologies, diagnostics, pharmaceuticals and digital products to patients

3.1. The current range of national commissioning routes is complex and difficult to navigate. The new routes should be clearer, fewer in number, and there should be transparency about the time each step is expected to take. They should enable well-organised innovators to reach patients quickly through the most appropriate route.

3.1.1. Whilst all commissioning routes will be based around the six steps identified earlier, the sequence of the steps may vary depending on product type. It is not feasible for every product to be evaluated nationally, so local routes should be available.

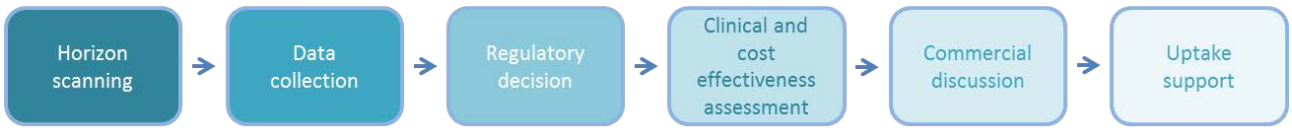

Figure 12: The six steps in a product's pathway to market

3.1.2. Section two described the accelerated routes through which strategically important products will reach patients. However, products whose benefit is incremental, rather than transformative, should also have a small number of clearly-defined arrangements that are easy for the health system to articulate and for innovators to understand. These routes should be clearly laid out for all stakeholders to see.

3.1.3. The routes for incremental products should include:

- a national route to specialised commissioning via NHS England or NICE;
- a national route to secondary and primary care via NICE; and
- a local route to secondary and primary care via regional medicines optimisation committees or AHSNs.

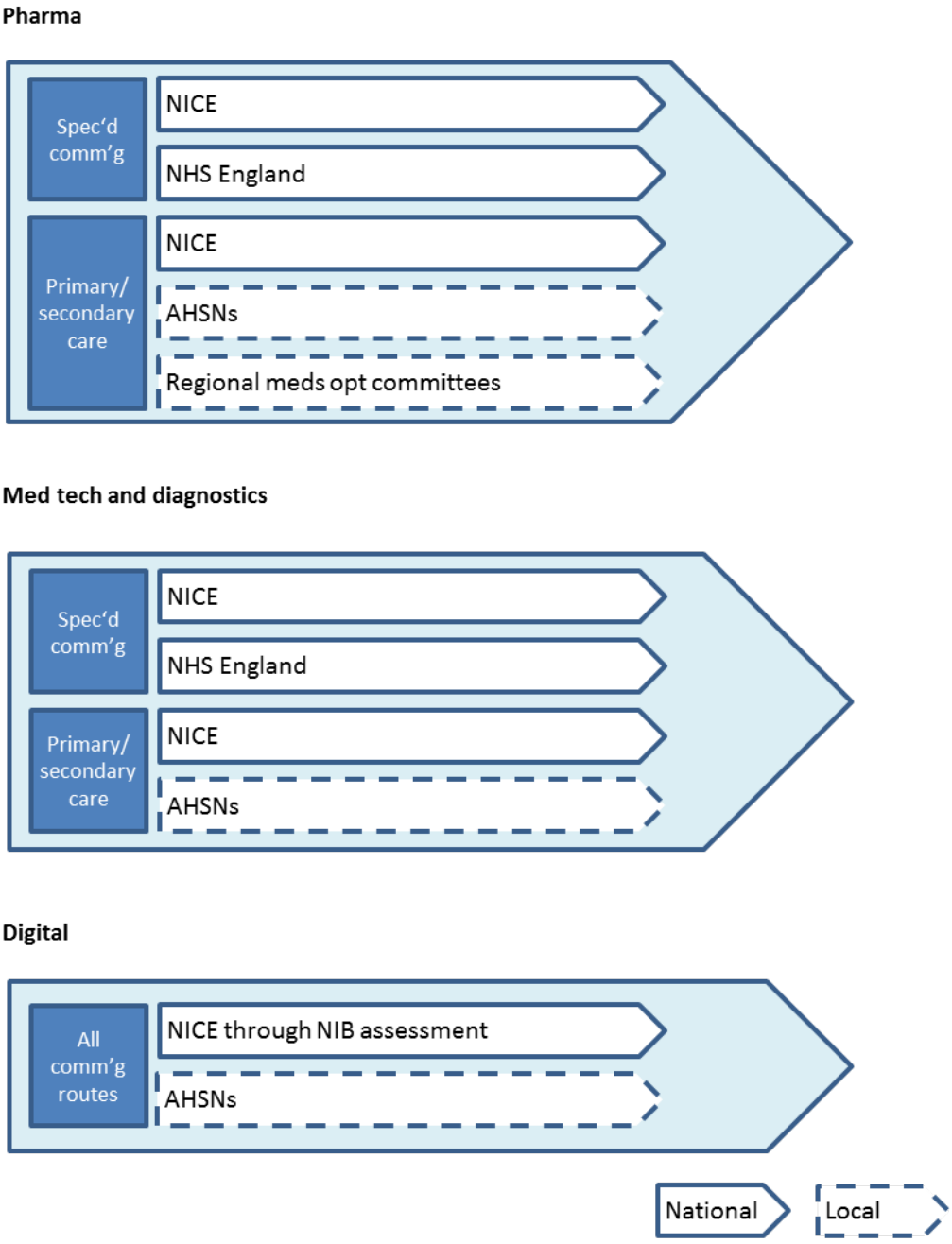

Figure 13: National and local routes will be available to products of more incremental benefit

3.2. A 'how to' guide should support innovators, particularly SMEs, in navigating national and local paths to market.

3.2.1. We have received extensive feedback that the arrangements for getting products to patients are too complex and opaque. A 'how to' guide, available online,[15] will enable

[15] https://www.gov.uk/government/publications/innovation-pathway-for-nhs-products

innovators to see clearly how their products can best navigate the system to reach patients.

3.3. NHS England should vigorously pursue its work to streamline local medicines assessment.

3.3.1. Companies have reported that local medicines assessment hubs sometimes increase bureaucracy without adding value. We therefore strongly support the work already underway within NHS England to streamline local medicines assessment into four hubs, using a standardised assessment approach. The hubs should not duplicate any activity that is being carried out nationally, for example by NICE.

3.3.2. Local uptake support for medicines should be enabled by AHSNs, underpinned by incentives that promote collaboration. This is detailed in section five.

National routes to market should be streamlined and clarified

3.4. National evaluation and commissioning should be aligned across NICE and NHS England.

3.4.1. Pharmaceuticals, medical technologies and diagnostics that are not selected for the accelerated pathway but which require national assessment should undergo a streamlined process that is aligned across the system.

3.4.2. Currently, products that form part of specialised services may be evaluated by NICE through a technology appraisal, assessed by NHS England's Clinical Priorities Advisory Group, or tested in a small number of centres through the *Commissioning through Evaluation* programme. We propose that NHS England and NICE work together to ensure that their separate topic selection processes are better integrated. Whilst it is not feasible for one national body to assess every specialised commissioning product, it is essential that NICE and NHS England are clear about their decision-making processes and criteria and that they clearly articulate to innovators the circumstances in which products would take each route. It is important that no groups of products can 'fall between the cracks' and struggle to find a decision-making process.

3.4.3. Products that form part of primary care or CCG-commissioned services that are suitable for national assessment should be assessed by NICE. Products that are not referred to NICE should be assessed only once, by NHS England's regional medicines optimisation committees.

3.4.4. These pathways should be described simply and clearly and reflected in the next iteration of the *how to* guide.[16]

[16] *A guide to navigating the innovation pathway in England*, May 2016 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/525787/AAR_how_to_guides.pdf)

Many products will benefit from regional and local routes to market, which should be enhanced to operate consistently across the NHS

3.5. Many innovations will be unsuitable for national evaluation but have the potential to create value in the healthcare system and should be tested and adopted locally into the NHS.

3.5.1. Many of these innovations will be medical technologies and digital products or tools that enable incremental improvements to clinical pathways and processes.

3.5.2. Evaluation of these innovations is best done at a regional level, in collaboration with providers who can flex local pathways in the manner of the NHS test beds, to provide clinicians and the NHS with evidence of utility, value and pathway redesign. This in turn provides innovators with the data they need to commercialise their products.

New and innovative commercial partnerships to support the delivery of better care in a more efficient way

Medtronic Integrated Health Solutions is a partnership between Medtronic and the NHS that supports access to capital infrastructure facilities and decreases costs to the NHS. In the UK, Medtronic has partnered with NHS organisations to modernise their catheterisation laboratories (cath labs), moving away from the traditional, transactional, supplier-customer relationship to build a shared risk-and-reward model that delivers value under a long term service agreement through a fee per-procedure approach. The partnerships have resulted in reduced waste and increased activity in NHS trusts.

3.5.3. We believe that a refreshed network of AHSNs, alongside local clinical leaders, should help identify the innovations that are suitable for this local pathway and establish evaluative studies that follow a nationally agreed format and standard. For medtech and diagnostics in particular, AHSNs should support the formation of partnerships with local NHS organisations to build a cost-effectiveness case and a body of knowledge around pathway change, and should signpost to the right kinds of specialist support such as the regional Medilink organisations[17] or NHS Innovation Hubs. This structured evidence gathering would allow effective innovations of all types to be badged with an 'NHS warrant', recognised by commissioners and procurement teams across the NHS, and be diffused across the system via the national AHSN network and with patient input. The AHSNs should act as innovation exchanges, working with their local health economies to understand local areas of unmet clinical need and then working with innovators to meet those needs, providing advice and support throughout product development.

3.5.4. Medical technology innovators using this local pathway should be able to apply for their product to be included in the Innovation and Technology Tariff and the product should be considered for inclusion in the NHS Supply Chain products catalogue. Some

[17] http://www.medilinkuk.com/about-us/medilink-uk-member-organisations

products may benefit from national procurement and in such cases the NHS Supply Chain could take a lead role in negotiating bulk deals.

Innovative medical technologies with cost saving potential

NeoTract's UroLift system is recommended by NICE for treating the symptoms of benign prostatic hyperplasia, a condition where an enlarged prostate can make it difficult for a man to pass urine, which can lead to urinary tract infections and, in some cases, renal failure.

Existing treatments involve cutting away excess tissue, which risks loss of sexual function and requires a hospital stay. The UroLift system uses implants to move excess tissue away and prevent it from blocking the flow of urine. NICE's Medical Technology Advisory Committee concluded that, as well as benefiting patients, for example by preserving sexual function, it could also save up to £286 per patient through, for example, carrying out the surgery as a day procedure. The treatment can also be delivered under local anaesthetic, thus avoiding the risks of general anaesthesia and further reducing costs.

The route for digital products should build on the Paperless 2020 simplified app assessment process

3.6. AHSNs should play a key role in digital health, advising innovators on local areas of unmet need and working with providers, CCGs and clinicians to generate evidence of the utility of digital products.

3.6.1. AHSNs should build on their role as innovation exchanges to ensure that digital product development meets the NHS's needs. They should have a specific mandate to identify, test and disseminate digital technologies, particularly those that are demonstrating locally the potential to deliver efficiencies. This should build on AHSNs' current work to support demand and supply needs in digital health, such as DigitalHealth.London, a collaboration between the three London AHSNs, the three London AHSCs, NHS England and the Greater London Authority.

3.7. Digital products' route from idea generation to patients should be clarified.

3.7.1. The pathway for healthcare apps requires improvements in assessment, commissioning, procurement and prescribing. It should be suitable for fast-moving technology areas and products developed by SMEs.

3.7.2. The Paperless 2020 app assessment process, due to be launched in early 2017, provides a comprehensive mechanism for app evaluation that assesses efficacy, cost impact and usability. This will increase commissioner, clinician and patient confidence in digital products. The Crown Commercial Service, in partnership with NHS Digital, NHS England, the Department of Health and other system and technology partners, should consider how best to develop an accessible, simple and swift competitive process for procuring digital products from SMEs. There would be benefit in aligning the processes for medical technologies and digital products, and both these technology

types should benefit from the new procurement and supply chain arrangements due to be in place from 2018.

3.7.3. Additionally, some of the apps evaluated by NICE as part of the Paperless 2020 process could be made available through the new Innovation and Technology Tariff. This will provide a national route to market for a small number of technologies and will incentivise providers to use digital products with proven health outcomes and economic benefits.

3.7.4. NHS England, working with NHS Digital, should develop a generic framework for app prescription that obviates the need for multiple, local systems and is as easy to use as existing prescribing systems for medicines. This will clarify the mechanism that health care professionals should use and the wrap-around services required to enable patients to access suitable digital products.

3.7.5. The final stage of the Paperless 2020 app assessment process, the NICE independent evaluation, should include specific advice on how the app should be adopted by the system and delivered to patients. This advice should be developed in collaboration with the Accelerated Access Partnership. It may also identify where the product should be used within the existing NICE care pathway and how this might change other aspects of the care pathway.

3.7.6. A representation of the digital pathway is included in technical annex C.

Using digital health to redesign care delivery

Digital health products can transform models of care to simultaneously provide excellent patient outcomes and NHS cost-savings. Big White Wall is a digital platform and community offering a range of therapeutic mental health interventions to support members to self-manage their care with support from clinicians, care-givers and peers. It allows members to access mental health services instantaneously and anonymously, eliminating waiting times. Recovery rates for Big White Wall therapy services in the UK are 12 per cent above the national average and 8 per cent above the national target. An independent review of the economic savings to the NHS from Big White Wall's support network service found an average saving of £36,935 per 100 members. Due to its clinical and economic benefits, it has been widely commissioned; it is currently available to 31 per cent of the UK adult population.

4. Future capabilities: evidence generation and NHS evolution

The digital infrastructure should enable the system to capture information on the use of innovations and associated outcomes

4.1. Systems that collect electronic information on prescribing, procurement, dispensing, pricing and outcomes will be essential in enabling improvements to patient care.

4.1.1. This report's recommendations cannot succeed without a significant improvement in digitisation across the NHS, including electronic patient records and e-prescribing. The need for this digitisation to be properly resourced and phased, with the appropriate workforce to support it, is clearly set out in Robert Wachter's recent report on harnessing the power of health information technology[18]. We wholeheartedly support the recommendations in Professor Wachter's report and in particular the focus on ensuring regional then national interoperability of systems.

4.1.2. In parallel, the National Information Board is undertaking work on secondary uses of pharmacy data under its programme 18. Without the right information on prescribing, dispensing and pricing – linked to outcomes – systems of conditional approval, new pricing models and real-world data collection will not be possible, and this review therefore strongly supports the National Information Board's work in this area. In order to assess costs and benefits across the whole system it will also be critical to link primary, secondary, tertiary and community care data – something that is already in progress in several areas of the UK.

4.1.3. Our ability to generate data on product impact, at scale, will be a significant selling-point for the NHS and, critically, it will also give the NHS information about product value with which it can negotiate fair reimbursement levels with companies. Existing disease registries and their relevant patient groups provide ideal opportunities to pilot this approach. These registries should be linked with patient records to provide trials cohorts and support the evaluation of products.

4.1.4. In his report, Professor Wachter recognises the importance of striking a balance between an individual's right to privacy and the enormous opportunity for patient benefit through the systematic secondary use of the NHS's valuable data. We strongly agree, and the Accelerated Access Review's recommendations will need to be underpinned by clear standards for data consent and guardianship. Whilst it is not the job of this review to develop these standards, we are supportive of the approach

[18] Robert Wachter, *Making IT work: Harnessing the power of health information technology to improve care in England*, September 2016 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/550866/Wachter_Review_Accessible.pdf)

advocated by Dame Fiona Caldicott's review,[19] which recommends new data security standards and a new consent model for sharing patient confidential data.

4.1.5. A robust approach to the quality and privacy of digital patient records will have a range of benefits, including giving patients increased confidence to share their data for research purposes. Charities and patient groups can play a key role in explaining the benefits of giving consent for sharing health data, and in clarifying how the NHS is working to keep confidential data safe.

Digitisation to support better patient care

The Hampshire Health Record (HHR) brings together key patient information from hospitals, general practice, community care and social services. This data can be accessed in a range of clinical environments to help deliver enhanced patient care, and anonymised data is analysed to identify where improvements in patient care can be made.

The process of assessing emerging technologies should be evolved so that it is fit for the future

4.2. NICE should review its health technology assessment processes and methods to ensure they are fit for purpose to assess new types of emerging products and enable access to the products the NHS needs.

4.2.1. This review is extremely supportive of NICE as a global leader in health economic evaluation and evidence-based guidance. Since its inception, NICE has continued to evolve so that it can best consider the innovations that it is asked to assess. This review sees NICE technology appraisals as continuing to form the basis of value assessment, but suggests that NICE should now undertake a review of its methods and processes to ensure they are fit for purpose to enable access to the products the NHS needs most. This should include:

- Changes that support NHS England in agreeing commercial arrangements for strategically important products.
- Evolution of NICE's processes to support acceleration, allowing products with sound evidence of increased efficiency to undergo a lighter-touch process.

4.2.2. Given the value to industry of a technology appraisal, we endorse the recommendation in NICE's triennial review[20] that NICE should consider recovering the costs of their assessments.

[19] National Data Guardian for Health and Care, *Review of data security, consent and opt-outs*, July 2016 (https://www.gov.uk/government/publications/review-of-data-security-consent-and-opt-outs)

4.3. NICE should develop a flexible health technology assessment pathway that can be tailored to a product's value proposition.

4.3.1. NICE's pathway for health technology assessment should be open to all innovations, be they medical technology, diagnostics, digital or pharmaceutical. It should be flexible, able to be tailored to a product's value proposition, and should anticipate future types of healthcare innovation.

4.4. NICE should refocus its work to place more emphasis on medical technologies, diagnostics and precision medicine tools, and a funding requirement should apply for those products that improve efficiency.

4.4.1. The majority of NICE's technology appraisals are focused on pharmaceuticals, with relatively few assessments of medical devices, diagnostics or digital products such as apps. When NICE does issue positive guidance for a medical technology or diagnostic, it does not carry a funding requirement because it has not been assessed within the technology appraisal programme.

4.4.2. NICE should rebalance its work towards products which, accompanied by appropriate changes in clinical pathways, can improve system efficiency whilst delivering equivalent or better patient outcomes. This is likely to include more medical technologies, diagnostics, including companion diagnostics for precision medicine, and digital products. It could also include those products that support national and international priorities, such as new, rapid diagnostics that inform the use of antimicrobials. NICE's review of its methods and processes should consider how funding requirements could be introduced for innovations that improve outcomes and improve efficiency.

4.5. NICE should support uptake by extending its role beyond evaluation

4.5.1. NICE should build on the work of its NICE Implementation Collaborative (NIC) to develop a new role that reaches beyond the evaluation of a technology into its subsequent clinical pathway. Its guidance, for example, could include proposed structured incentives or tariffs to support the uptake of innovative technologies. The details of these incentives should be developed through the Accelerated Access Partnership with advice coming from NHS England and NHS Improvement on their areas of responsibility.

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[20] Department of Health, *Report of the triennial review of the National Institute for Health and Care Excellence*, July 2015 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/447317/NICE_Triennial_Review_Report.pdf)

4.6. NICE, NHS Improvement and NHS England should have a greater focus on disinvestment, and outdated products and services should be made less attractive in the national tariff.

4.6.1. In order to create headroom for the cost of new innovations, there should be a greater system emphasis on disinvesting in outdated products or pathways.

4.6.2. NHS England's medicines optimisation programme aims to improve value and patient outcomes from medicines use, including safe and effective prescribing and de-prescribing of medicines, improved medication review and monitoring, as well as working with patients to understand their beliefs about medicines which in turn supports better adherence. This approach has helped to deliver significant efficiencies. The programme should be accelerated through NHS Right Care and should focus on eliminating those products and procedures that are not cost-effective or are outdated, supporting the concept of 'value exchange' where headroom for important new innovations is found by removing less impactful activities.

4.6.3. NICE should take a greater role in this value exchange, expanding on its list of cost savings opportunities and implementing them through the NHS Right Care programme. NHS Improvement should also support value exchange, for example including consideration of whether tariff amendments would support providers in prioritising more cost-effective products.

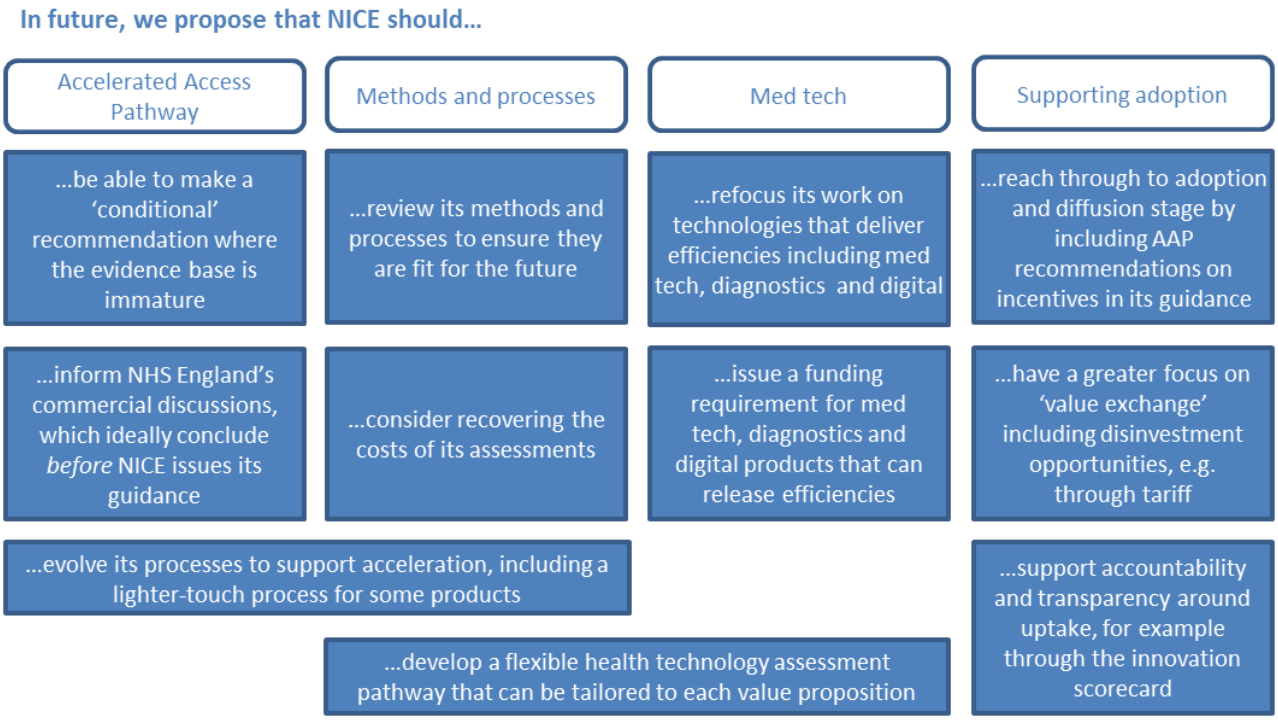


Figure 14: Proposed changes to NICE's methodologies

5. Incentives, local infrastructure and clinical leadership to enable the spread of innovation

A range of incentives should support the local uptake and spread of innovation, enabling collaboration and with greater capacity and capability for change

5.1. A package of coordinated incentives should support the changes outlined in this report.

5.1.1. We want to create an environment in which clinicians and local NHS organisations can rapidly adopt and diffuse innovations which are shown to transform the way care is delivered. Removing barriers, providing incentives and building local capacity and capability for change will be critical to the evolution of clinical practice.

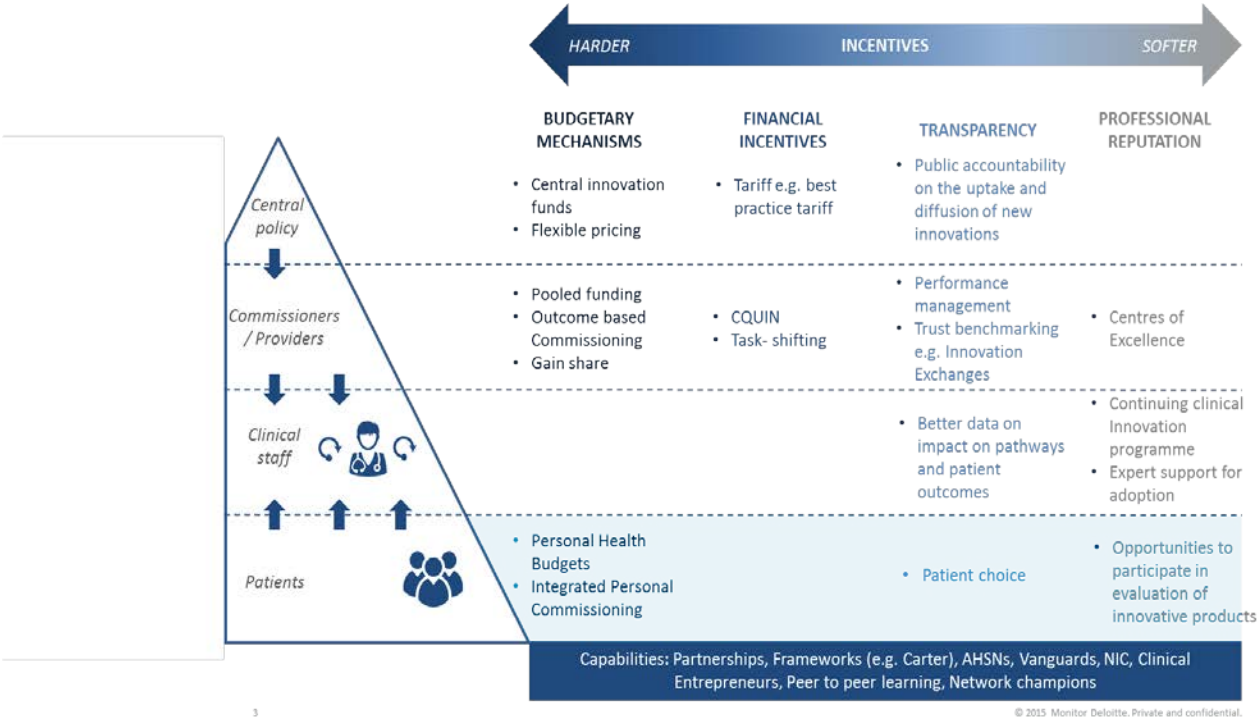


Figure 15: The four levels of approach to innovation adoption in the NHS

5.1.2. A range of different measures can incentivise the uptake of innovation. These incentives should focus on removing national or local barriers, providing capacity for change, and supporting cross-organisational collaboration. NHS Improvement with NHS England should take the lead in developing this package. Incentives could include:

- Budgetary incentives, such as centralised procurement as proposed by Lord Carter's review, gain-share arrangements whereby any efficiencies are distributed amongst the relevant organisations (at individual department level where appropriate), pooled budgets, or outcome-based payments. The NHS

vanguards[21] and Test Beds[22] are good examples of where pooled budgets are driving collaboration across a health economy.

- Financial incentives, such as the creation of best practice tariffs, the use of CQUIN, or – for medical technologies and digital products – inclusion in the Innovation and Technology Tariff. Tariffs for outdated or ineffective interventions could be removed or made less attractive, and the use of pass through costs as a route to reimbursement for these products could be controlled.
- Transparency, such as the better presentation of uptake information for an agreed set of products, and the wider use of data by charities and patient groups (see section 5.7).
- Professional or reputational, through the promotion of innovation within clinical excellence awards; through local health economies being at the cutting edge in adopting new technologies proven to improve local outcomes; or through empowering patients by enabling them to pioneer the use of new therapies and technologies.

AHSNs, tertiary academic teaching hospitals and clinical leaders across the NHS should drive and support the evaluation and diffusion of innovative products

5.2. A new mandate for AHSNs should support the local spread of adoption and enable a standard framework for local evaluation.

5.2.1. AHSNs, with their existing local networks that include NHS providers and commissioners, academia and industry, should play a vital role in supporting the testing and diffusion of technologies in the NHS. This role should be set out in a new charter with input from NHS England and NHS Improvement which clearly articulates what is expected from AHSNs and enables them to be held to account for delivery. AHSNs should galvanise and support local innovation partners to create a network of 'innovation exchanges', responsible for diffusing clinically- and cost-effective technologies across the system. Products with strong evidence of potentially transformative benefit should be routed to the Accelerated Access Partnership.

5.2.2. We recommend that AHSNs are more closely integrated with local health economies via the new sustainability and transformation footprints, and that the NHS Test Beds programme acts as a pilot for this new, strengthened remit for AHSNs. The Test Beds evaluation will provide a framework for assessing the impact of innovations in real-world settings; AHSNs should build on their current involvement in the Test Beds programme by using this learning for their own evaluation role and seeking to

[21] https://www.england.nhs.uk/ourwork/futurenhs/new-care-models/
[22] https://www.england.nhs.uk/ourwork/innovation/test-beds/

collaborate to promote mutual recognition of local evaluations using the national framework.

5.2.3. AHSNs are ideally placed to play a role in the post-CE mark testing and dissemination of medical technologies, diagnostics and digital products in particular, with a focus on determining their clinical utility, cost effectiveness and whole pathway benefits. AHSNs could, for example, work with clinicians to build on approaches such as the IDEAL[23] framework for medical technologies, or other methodologies, to rapidly develop high-quality evidence without delaying access.

5.2.4. AHSNs should be funded to a level that allows them to fulfil the role outlined in this report and to bring them all up to the level of the best. From 2017, we recommend that the government releases an additional £10m to £20m into AHSN baselines. Given budget constraints, further work should be carried out to determine the expected return on different levels of funding. We also recommend that NHS Improvement plays a greater role in leading AHSNs, including supporting them to undertake these activities.

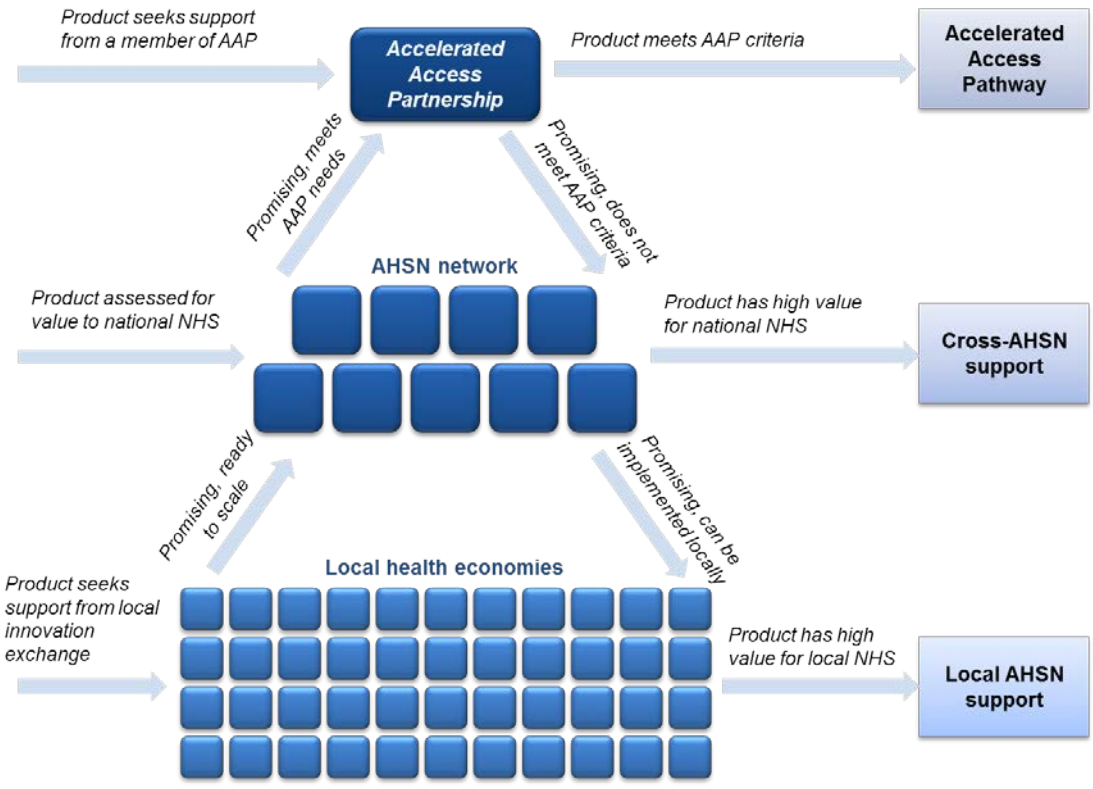


Figure 16: Local and national spread of innovation

[23] http://www.ideal-collaboration.net/

5.3. AHSNs should be responsible for providing support for delivering change.

5.3.1. Providing capacity and capability to deliver change will be critical. Change management capability is not available in all NHS organisations, and we recognise that additional capacity is required to undertake any reconfiguration following the implementation of a new technology. We propose that this additional capacity and capability is provided by and delivered through the AHSN network.

5.3.2. This change needs to be funded, in advance of AHSNs move to new licensing arrangements in April 2018. From 2017, we recommend that government makes available up to £30m per annum for this purpose. We recommend that the release of half of this sum should be conditional on the AHSNs matching it with funding from external sources such as industry or charities. This fund would need to be managed transparently and awards clearly linked to outcomes.

The NHS Test Beds Programme

The NHS test beds programme is supporting the testing and uptake of innovations across the NHS. Seven test bed partnerships between local healthcare economies, industry and the third sector are evaluating innovative combinations of digital technologies and new service delivery models. The innovations are being tested in real-world clinical settings to identify those interventions that offer better care and better patient experience at the same or lower overall cost.

For example, one area will test wearable devices linked into mobile technologies, implemented alongside technology-enabled housing, to help people with dementia to live in their own homes for longer. At the end of the programme, successful innovations will be available for other parts of the country to adopt and adapt to the particular needs of their local populations.

The NHS test beds programme shows how industry and the NHS can create partnerships and pool resources to enable change and innovation focused on local clinical challenges.

5.4. Tertiary academic hospitals that host Academic Health Science Centres (AHSCs) or Biomedical Research Centres (BRCs) should champion innovation and lead collaborations in their local health economies

5.4.1. We have heard throughout the review that clinical leadership is a key driver for rapid uptake of innovation. We want to build on this to maximise the potential of our highest performing tertiary and specialist providers to translate research and product innovation into cutting-edge clinical practice, recognising that the significant majority of innovations assessed by NICE form part of services that go through specialised commissioning.

5.4.2. At the same time it is vital to use the opportunity of place-based planning and the devolution of healthcare budgets to local geographies. Based on the NHS's sustainability and transformation plan footprints, we believe that using a combination of outcomes-based commissioning, an integrated budget across a whole health economy,

and joint decision-making would improve efficiency and outcomes by allowing the whole patient pathway to be considered holistically.

5.4.3. We believe that such change should be actively led by research-active tertiary hospital trusts, such as those that host AHSCs and BRCs. They should be active partners in the Accelerated Access Pathway: pioneering the evaluation and fast uptake of transformative products in their own organisations; championing the early adoption of these products in referring organisations and the health systems in which they work; acting as centres of excellence in innovation; capturing real-world evidence on how a product is used in a clinical setting, and supporting wider roll-out. This approach is exemplified by the role of Genomics Medicines Centres, which operate a hub and spoke model with their local delivery partners.

5.4.4. These trusts should be enabled and incentivised to act as local system leaders in innovation, and for this reason we recommend that, from 2017, £4m to £8m is made available to each centre.

5.5. Clinical revalidation processes and professional reward schemes should require demonstration of evidence-based innovative practice.

5.5.1. The medical royal colleges should support an increased focus on innovation by providing access to training and development which is then reflected in relevant clinical revalidation processes. Where health professionals are demonstrating evidence-based innovative practice, this should be recognised in appraisals, through awards schemes such as the Royal College of Nursing awards scheme, or through pay advancement such as that awarded by the Advisory Committee on Clinical Excellence Awards (ACCEA).

5.5.2. Innovative clinical practice can also be supported centrally. The National Clinical Lead for Innovation should host a network of innovation champions to develop a culture of continuous learning amongst their clinical colleagues. Trusts should identify a senior clinician who can participate in this network.

5.6. Professional leadership bodies, including Royal Colleges, should include adherence to NICE clinical guidance as a criterion for achieving professional standards in clinical care.

5.6.1. Professional leadership bodies can provide a clear picture of what good clinical practice looks like and support the uptake of innovation, by building on NICE clinical practice guidance and standards, and by ensuring that the promotion and use of the best, evidenced, value for money innovations is included within continuing professional development.

5.6.2. Healthcare professionals themselves are often the innovators, responding to the challenges they encounter in practice and finding practical solutions. These individuals should be identified and supported by employers locally.

Professional recognition of innovation

The Academy of Medical Royal Colleges is working with NHS England on the development of a 'Continuing Clinical Innovation Scheme' which provides a framework to identify how innovation can be recognised in appraisal processes and also as part of a doctor's continuing professional development (CPD). Recognising innovation as a professional development activity could be a vehicle that supports and facilitates the activity of frontline innovators. At the same time the Academy is seeking to ensure that innovation is recognised as part of the generic professional capabilities in quality improvement required of all doctors in training.

Improved accountability and transparency around uptake of innovation should be supported by NICE

5.7. There should be a single, accessible source of information on the uptake of technologies for the NHS, patients and industry.

5.7.1. Open, transparent and accessible data on the uptake of innovations, including those with a transformative designation, and their impact on patient outcomes, would be a powerful force for driving adoption and reducing unwarranted variation across the NHS. It would underpin the Accelerated Access Partnership's ability to hold the system to account for uptake and diffusion of innovation across the NHS.

5.7.2. Information on uptake can currently be found in the Innovation Scorecard,[24] but due to its format it is not widely used within the NHS. We propose that, in future, the Innovation Scorecard should be the single source of information on the use of innovation in the NHS. It should be owned by NICE and used by the rest of the Accelerated Access Partnership, particularly NHS England and NHS Improvement, to hold the system to account and assess the progress of local areas. Patients and clinicians, as well as NICE, the Department of Health and NHS England, should help to define the products and outcomes that are included, and there should be an emphasis on NICE-approved technologies. This information should be accessible to patients and the public.

[24] http://content.digital.nhs.uk/article/2021/Website-Search?productid=21974&q=innovation+scorecard&sort=Most+recent&size=10&page=1&area=both#top

6. Coordination and infrastructure to support delivery

An Accelerated Access Partnership should align national bodies around accelerating innovation

6.1. An Accelerated Access Partnership should coordinate the actions of key national bodies around the principle of accelerating the innovations we need, and provide a single point of access for innovators.

6.1.1. We are clear that a new body or a restructuring is not the right way to implement this review. We believe there is an opportunity for existing national bodies to work in strategic partnership, as part of an Accelerated Access Partnership, with clear links to local networks. This is borne out of experience with EAMS where each national body was able to work in alignment with other ALBs to deliver product acceleration.

6.1.2. The Accelerated Access Partnership should be a light-touch umbrella organisation that brings together the existing activities of NIHR, MHRA, NICE, NHS England, the Department of Health and NHS Improvement. It should align their innovation-related functions around the principle of accelerating patient access to key products, and also include a small number of new functions as laid out in section 6.2.

The Early Access to Medicines Scheme (EAMS) is coordinated by the Office for Life Sciences (OLS) and provides a valuable opportunity for early dialogue and collaboration between industry and government.

A Government-Industry Stakeholder Task Group, coordinated by OLS, brings together key stakeholders from the bio-pharmaceutical industry, NHS, the government and arm's length bodies including MHRA and NICE, on a regular basis. OLS leadership and coordination, as well as the clear alignment of goals across ALBs, is critical in driving progress and collaboration across the ALBs involved in access pathways. It is a forum for industry to raise questions and discuss issues with the national bodies and helps ensure the smooth uptake of EAMS products in the NHS.

6.2. The Accelerated Access Partnership should provide strategic planning and operational advice to the national bodies and should have an independent chair who is accountable to ministers.

6.2.1. The Accelerated Access Partnership's strategic activities should include:

- horizon scanning for and prioritisation of strategically important products;
- designing the selection criteria and process for making a transformative designation; and
- articulating the healthcare system's priorities to innovators to help them focus their investment.

6.2.2. Its operational activities should include:

- overseeing the Accelerated Access Pathway;

- helping innovators navigate and collaborate with the system;
- providing guidance on pathways to market; and
- enabling the use of the products the NHS wants through commercial arrangements we can afford.

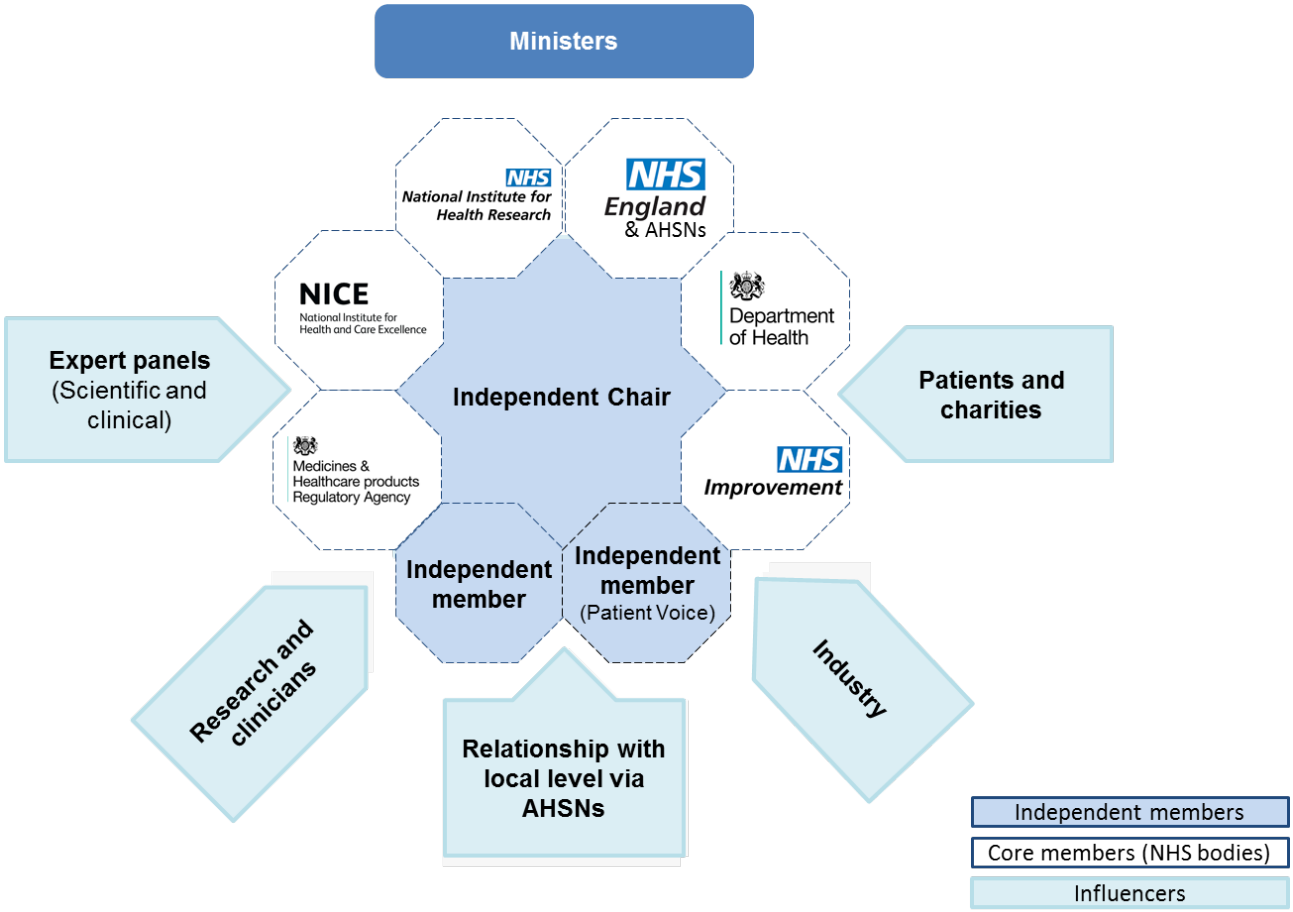


Figure 17: The Accelerated Access Partnership's proposed structure

6.2.3. The Accelerated Access Partnership should have an independent chair, responsible to ministers, who holds each member to account for delivery through a concordat that describes the partnership's vision and objectives and the roles and responsibilities of each organisation. This will be discharged through the Accelerated Access Partnership.

6.3. The Accelerated Access Partnership should build on the Five Year Forward View infrastructure and collaborate with AHSNs.

6.3.1. In implementing this review, the Accelerated Access Partnership should align itself with the local infrastructure for transformation, including the Sustainability and Transformation footprints, and should build on existing programmes such as the New Models of Care, RightCare, the NHS Test Beds and the Carter implementation programme.

6.3.2. The Accelerated Access Partnership should have strong links to the local innovation exchanges facilitated by the AHSNs, so that there can be an exchange of information from national to local level. The refreshed network of AHSNs should be aligned with the emerging sustainability and transformation footprints as well as local clinical senates.

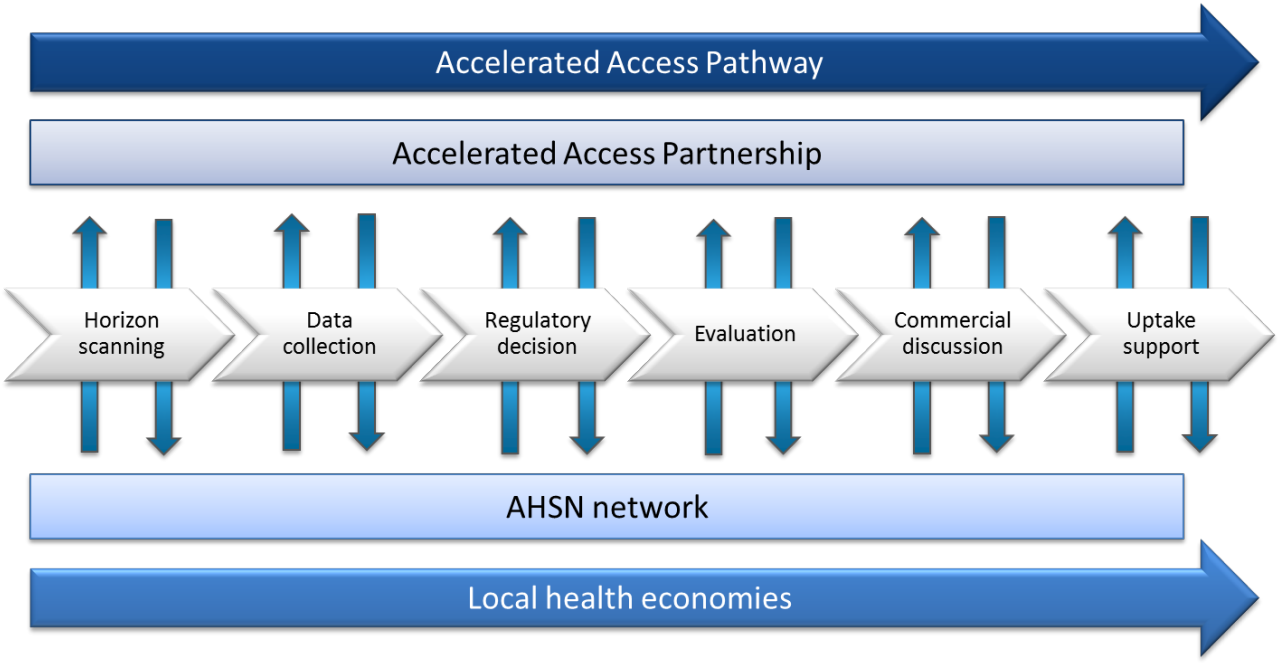


Figure 18: The relationship between AHSNs and the Accelerated Access Partnership

7. Recommendations for implementation

The Accelerated Access Partnership should be established immediately

7.1. The Accelerated Access Partnership should be set up immediately so that the collective leadership can be effective in 2016/17, along with a priority programme to reshape the AHSNs.

7.1.1. This will enable work to begin on coordination and collaboration across the system, criteria for prioritisation, operational advice to companies, and tools to support transparency and accountability. We recommend that a small amount of additional resource should be provided to enable AHSNs to provide the capacity and capability for change during 2017/18, building upon the Test Beds approach.

Implementation of the report's recommendations should be led by the Accelerated Access Partnership and clinicians

7.2. Implementation should begin immediately and be led through the Accelerated Access Partnership with visible leadership from NHS England and NHS Improvement and a strong mandate to engage clinicians and patients.

7.2.1. Clinicians are the front-line decision-makers on innovation and must be at the heart of this system transformation.

7.2.2. During the review we have engaged with clinical leaders and have consistently heard that there needs to be much greater clinical influence and better co-ordination in the development, adoption and diffusion of innovative products.

7.2.3. Each product's journey along the accelerated pathway should be supported by clinical engagement and leadership from National Clinical Directors (NCDs) and their colleagues; overseeing and directing the right clinical engagement during development, integrating the use of new innovative technologies and therapies into clinical pathways, and promoting the diffusion of the most effective and innovative new products amongst their peers.

7.2.4. This programme will not succeed without a strong commitment from NHS England to working in an integrated way with the rest of the system. It has much to gain: improved patient care; efficiencies created by transformed care pathways; greater negotiating power to collaborate with companies; a pre-emptive system to anticipate patient demand; and more proactive disinvestment to provide capacity and release funding.

7.2.5. In leading this work, the Accelerated Access Partnership should work closely with NHS Improvement which is the lead agency for promoting innovation and the adoption of evidence-based technologies by NHS providers. NHS Improvement has a key role in providing leadership across all steps in the innovation pathway and galvanising local NHS organisations to prioritise, test and adopt transformative new technologies.

7.2.6. Patients, carers and charities provide crucial advice on what innovations are needed, their value to patients and how best to pull them into use. Integrating the patient voice at all points in the pathway will be essential.

7.3. Some immediate actions could demonstrate that the proposed model can deliver change.

7.3.1. The AAR team has worked closely with NHS England to support its vanguards of new models of care to develop partnerships with those companies whose products align with their priorities. These relationships, brokered by AHSNs, are helping these vanguards act as early adopters of the AAR proposals by, for example, devising new innovative clinical pathways for respiratory disease, supporting the frail and elderly, and promoting medicines optimisation. As these projects begin to show results over the next few months, NHS England and the Office for Life Sciences should promote their success and share emerging good practice.

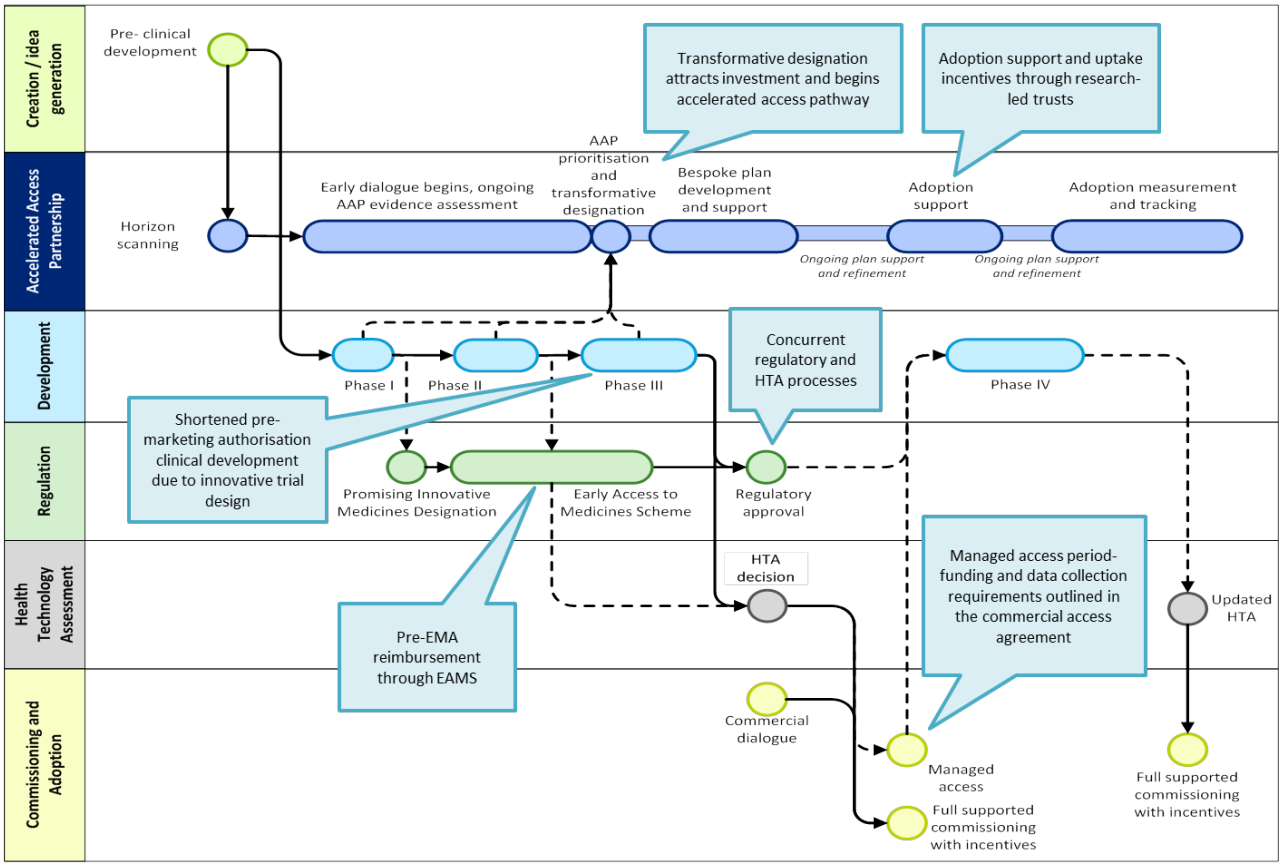
Glossary

AAP	Accelerated Access Partnership
AAR	Accelerated Access Review
ACCEA	Advisory Committee on Clinical Excellence Awards
AHSC	Academic Health Science Centre
AHSN	Academic Health Science Network
ALB	Arm's length body
App	"App" is shorthand for application software, which may include either a mobile app, a web-based application or in certain cases a digital service.
BRC	Biomedical Research Centre
CCG	Clinical Commissioning Group
CDF	Cancer Drugs Fund
CHMP	Committee for Medicinal Products for Human Use
CPD	Continuing Professional Development
CQUIN	Commissioning for Quality and Innovation
CTU	Clinical Trials Unit (part of MHRA)
DEC	Diagnostic Evidence Co-operative
EAMS	Early Access to Medicines Scheme
EMA	European Medicines Agency
EU	European Union
HSRIC	Horizon Scanning Research and Intelligence Centre
HTA	Health Technology Assessment
HTC	Healthcare Technology Co-operative
IVD	*In vitro* diagnostic
MA	Marketing authorisation
MHRA	Medicines and Healthcare products Regulatory Agency
MIC	Medtech and In vitro diagnostic Co-operative
NCD	National Clinical Director
NCE	New Chemical Entity
NHSI	NHS Improvement
NIB	National Information Board
NIC	NICE Implementation Collaborative
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
OECD	Organisation for Economic Co-operation and Development
OLS	Office for Life Sciences
PIM	Promising Innovative Medicine designation (part of EAMS)
PRIME	PRIority MEdicines (EMA scheme)
QALY	Quality-adjusted life year (used as part of a cost effectiveness calculation)
SBRI	Small Business Research Initiative
SCU	Strategic Commercial Unit
SMEs	Small and medium-sized enterprises
SO	Scientific Opinion (part of EAMS)
STP	Sustainability and Transformation Plan

Annexes

Annex A: The Accelerated Access Pathway for medicinal products

This diagram and accompanying narrative describe the new accelerated access pathway for medicines (including pharmaceuticals, biopharmaceuticals and advanced therapies such as cell and gene therapies) from the perspective of products that have successfully navigated the pathway.



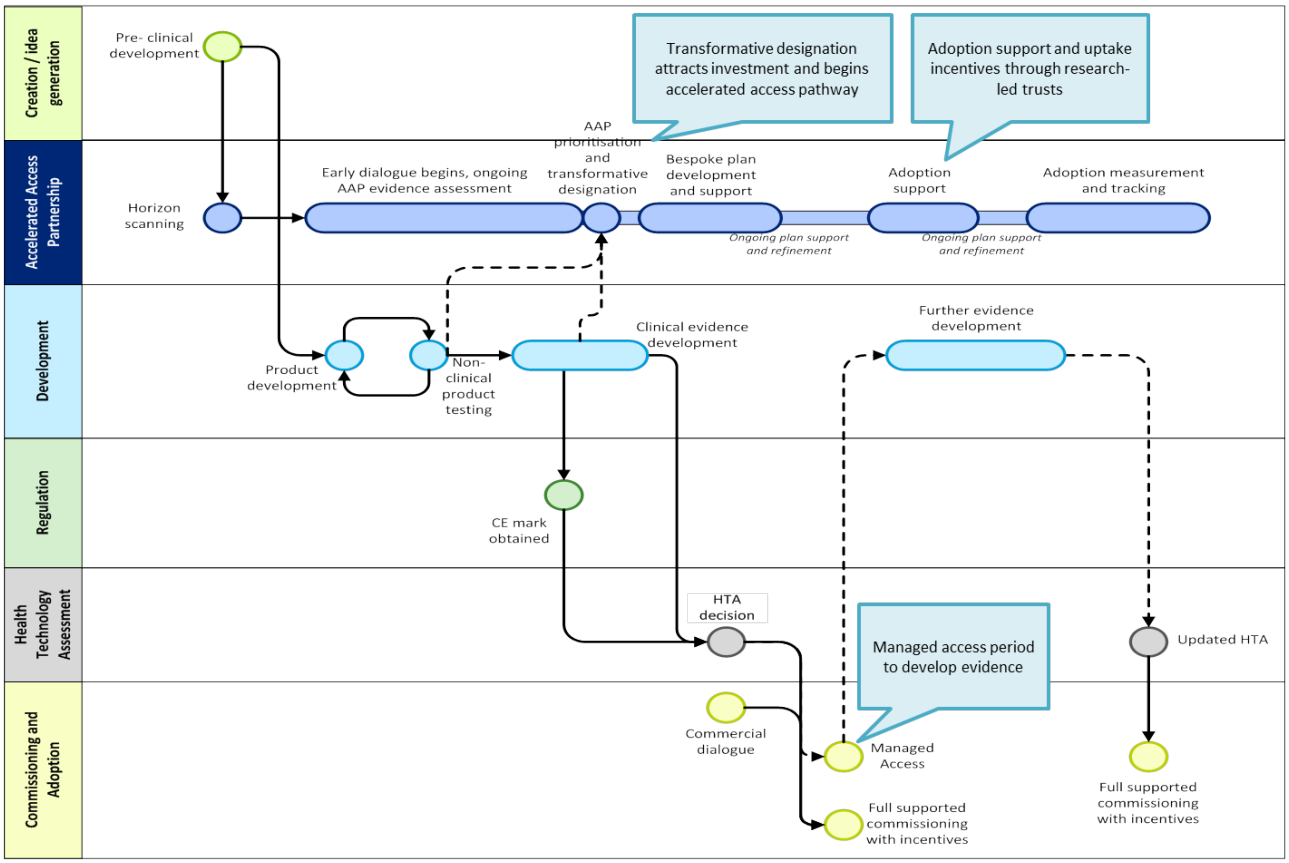
Stage of development	***Process***
Creation / idea generation:	Pre-clinical development is carried out in an academic or a commercial setting. Although there is little formal regulatory interaction during this time, developers will be able to approach the Accelerated Access Partnership to discuss initial development of their product, the pathway it might follow and any unique challenges they might face. Innovators can use information on system priorities, as set out by the AAP, to ensure they develop products that should meet the NHS's needs.

Accelerated Access Partnership (AAP) • Horizon scanning • Early dialogue • Prioritisation • Bespoke plan development and support • Adoption support • Adoption measurement and tracking	The new Accelerated Access Partnership will manage the whole pathway and is overseen by an independent chair accountable to ministers. It is made up of the national organisations responsible for regulating, evaluating and delivering new innovations to patients including NIHR, MHRA, NICE, NHS England, NHS Improvement and the Department of Health. The partnership's initial role is in horizon scanning and prioritisation and it will continue to oversee the entire journey to patients, for strategically important products, including adoption support. Products can join the pathway at any time and will be considered on a case-by-case basis. Academic Health Science Centres (AHSCs) or Biomedical Research Centres (BRCs), provide a destination for medicines to be tested in a clinical trial or real world setting, providing evidence through clinical use and supporting wider adoption through local delivery partners and clinical networks. The AHSN Network will reduce barriers to entry, by directing pathway transformation funding to provide additional capacity/capability for providers, such as staff training, communication for service users, change costs and providing additional capacity. The Innovation Scorecard will collate information on the adoption and diffusion of medicines and present this information in an easy to understand format. This will allow innovators, patients and clinicians to call for additional support for the adoption and diffusion of transformative medicines, where this is low. It will also allow the AAP to strategically understand where further support is required.
Development: contains Phase I, Phase II, Phase III.	To obtain regulatory approval, innovators need evidence to demonstrate that a product is safe and performs as intended. The AAR does not change any of the evidentiary standards associated with medicine development. Innovators can enter into discussions with MHRA, NIHR and NICE around how novel clinical trial evidence-generation methodologies may improve or shorten global clinical development programmes.
Regulation: • Early Access to Medicines Scheme • Regulatory approval	**Early Access to Medicines Scheme (EAMS)** EAMS will be an integral part of the accelerated access pathway, providing pre-licence access, where appropriate, for strategically important products. The AAR proposes that SMEs and non-for profit organisations with products on the EAMS pathway should receive some funding to cover the cost of the product to recognise their commitment to early access. The Accelerated Access Pathway will also fit seamlessly with other early access schemes or breakthrough designations such as PRIME or adaptive licensing. **A marketing authorisation** (regulatory approval) can be issued from Phase II onwards depending on the evidence and level of unmet need. The AAR proposes concurrent regulatory and HTA processes (see below)
Transformative designation	This new designation made by the Accelerated Access Partnership will identify strategically important products that can deliver a step change in cost or outcomes and places the product on the accelerated access pathway. The designation will usually be made around the time of Phase III clinical trials when there is also some data on the product's value and affordability and will vary on a case-by-case basis. Following this designation, the Accelerated Access Partnership will develop a bespoke plan for each product, to support development.
Health Technology	Products with a transformative designation will be evaluated by NICE with a

Assessment (HTA) • Greater alignment of regulatory and HTA assessment timetables **NICE** • HTA decision • Mini HTA	timetable that begins earlier in the regulatory process. This will mean a HTA decision can be made soon after marketing authorisation, providing the company is able to supply data at a suitable time. In parallel with NICE's value assessment, NHS England will undertake the commercial discussion with innovators referred to below. NICE's evaluation will be based on the terms of any deal agreed between NHS England and innovators. Where a product's evidence base is uncertain because of accelerated development, and there is high potential, NICE will be able to give a conditional recommendation.
Commissioning and adoption:	**Commercial dialogue** A new strategic commercial unit within NHS England will consider a range of flexible pricing models as part of a commercial dialogue with innovators. **Managed access** Where NICE has issued a provisional recommendation and a deal can be reached with NHS England, a product can enter a period of managed access to collect evidence to satisfy the uncertainty. At the end of the managed access period, NICE can conduct a further appraisal to determine whether and under what commercial arrangements the product would enter baseline commissioning. **Full supported commissioning** Where the NICE technology appraisal recommends the product as clinically and cost-effective, and NHS England consider it affordable, a product will move into baseline commissioning with a funding requirement, supported by a bespoke package of incentives. This could be within specialised commissioning, commissioned by a CCG, or primary care. **Incentives** The Accelerated Access Partnership will develop a bespoke package of incentives along the pathway to ensure Accelerated Access Partnership organisations involved along the pathway of a transformative medicine are incentivised to support them and make them available to patients faster. This could range from increasing budgetary capabilities and providing new funding routes through to training and education.

Annex B: The Accelerated Access Pathway for medical technologies and diagnostics

This diagram and accompanying narrative describe the new accelerated access pathway for medical technologies and diagnostic innovations, from the perspective of products that have successfully navigated the pathway.



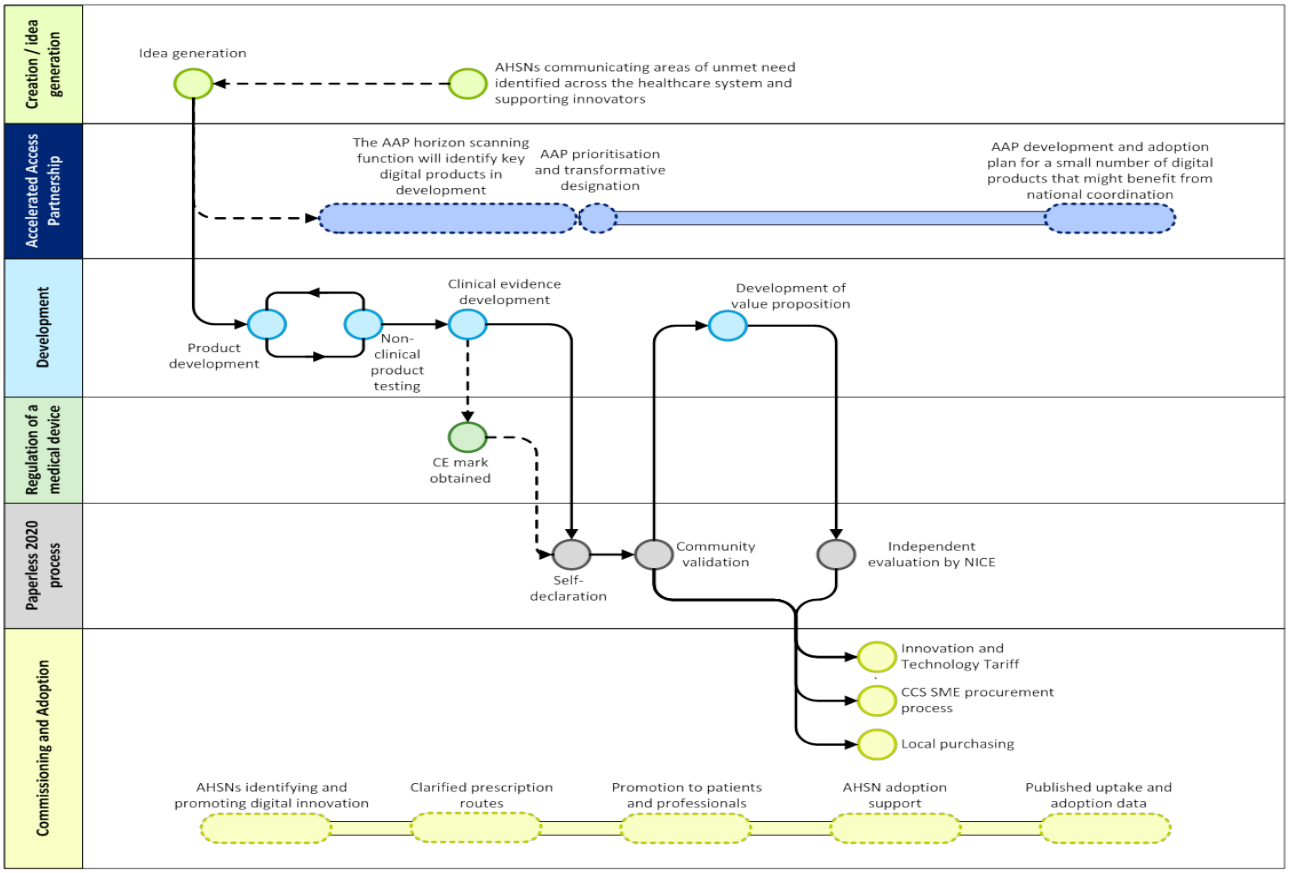
Stage of development	***Process***
Creation / idea generation:	Pre-clinical development is usually carried out in an academic or commercial setting. Although there is little formal regulatory interaction during this time, developers are encouraged to approach the new Accelerated Access Partnership (AAP) to discuss their product and the pathway it might follow. Innovators can use information on system priorities, as set out by the AAP, to ensure they develop products that should meet the NHS's needs.
Accelerated Access Partnership (AAP) • Horizon scanning • Early dialogue • Prioritisation • Bespoke plan development and support	The new Accelerated Access Partnership will manage the whole pathway and is overseen by an independent chair accountable to ministers. It is made up of the national organisations responsible for regulating, appraising and delivering new innovations to patients including NIHR, MHRA, NICE, NHS England, NHS Improvement and the Department of Health. The partnership's initial role is in horizon scanning and prioritisation and it will continue to oversee a strategically important product's entire journey to patients, including adoption support. Products can join or leave the pathway at any time and will be considered on a case-by-case basis.

• Commercial access agreements • Adoption support • Adoption measurement and tracking	The Innovation Scorecard will collate information on the adoption and diffusion of medical technologies and present this information in an easy to understand format. This will allow innovators, patients and clinicians to call for additional support for the adoption and diffusion of transformative medical technologies, where it is low. It will also allow the AAP to strategically understand where further support is required.
Development: • Product development • Non-clinical Product testing • Clinical evidence development • Further evidence development	The AAP will offer innovators a single point of contact to seek advice on development. Development continues after regulation, and when given a transformative designation by the AAP, a bespoke support package will be created to assist developers through the remaining process steps. Academic Health Science Centres (AHSCs) or Biomedical Research Centres (BRCs), provide a destination for medical technologies to be trialled in a real world setting, providing evidence through clinical use and supporting wider adoption through local delivery partners and clinical networks. The AHSN Network will reduce barriers to entry, by directing pathway transformation funding to provide additional capacity/capability for providers, such as staff training, communication for service users, change costs and providing additional capacity.
Regulation: • Regulatory approval	For products that meet the definition of a medical device, presence of a CE mark will indicate the device has gone through the relevant regulatory process. The shorter development times for medical technologies (compared to medicines) mean that the timing of CE marking is unlikely to change under the new pathway.
Transformative designation	A transformative designation will identify strategically important products that can deliver a step change in costs or outcomes and places a product on the accelerated access pathway. This is most likely to happen post CE mark for medical devices, and could happen at any point in a product's development. In particular it will support post-CE mark data collection that demonstrates a product's value to the system, and may also help attract outside investment in a product, particularly for SMEs.
Health Technology Assessment • NICE appraisal	Products with a transformative designation will be evaluated by NICE. In parallel, NHS England will undertake a commercial discussion with innovators (referred to below). NICE's evaluation will be based on the terms of any deal agreed between NHS England and innovators. Where the evidence base is uncertain, and there is high potential, NICE will be able to give a recommendation for the development of further evidence.

Commissioning • Commercial dialogue • Managed access • Full supported commissioning **Adoption** • Incentives	**Commercial dialogue** A new strategic commercial unit within NHS England will consider a range of flexible pricing models as part of a commercial dialogue with innovators. **Managed access** Where NICE has issued a conditional recommendation and a deal can be reached with NHS England, a product can enter a period of managed access to collect evidence to satisfy the uncertainty. A "commissioning through evaluation"-type approach will allow those complex medical technologies and diagnostic products that significantly change clinical pathways to be delivered through a number of specialist providers that have the expertise to gather impact data and build expertise around pathway change. At the end of the managed access period, NICE can conduct a further appraisal to determine whether and under what commercial arrangements the product could enter baseline commissioning. **Full supported commissioning** Where the NICE technology appraisal recommends a product as clinically and cost-effective, and NHS England considers it affordable, a product will move into baseline commissioning with a funding requirement, supported by a bespoke package of incentives. This could be within specialised commissioning, commissioned by a CCG, or primary care. **Incentives** The AAP will develop a bespoke package of incentives along the pathway to ensure agencies and actors along the pathway of a transformative product are incentivised to support them and make them available to patients faster. This could range from increasing budgetary capabilities and providing new funding routes through to training and education. **The new innovation and technology tariff** This provides a reimbursement route for selected value-proven, strategically important medical technologies and digital products, removing the need for multiple local price negotiations.

Annex C: The Accelerated Access Pathway for digital products

This diagram and accompanying narrative describe the new accelerated access pathway for digital products, including apps and wearables, from the perspective of products that have successfully navigated the pathway. The pathway incorporates relevant parts of the Paperless 2020 app assessment process due to launch in 2017. More detail will be included in revised versions of the 'how to guide' in due course.



Stage of development	***New process when Accelerated Access and Paperless 2020 assessment processes take effect***
Idea generation: includes pre-clinical development	AHSNs and, in a small number of cases the Accelerated Access Partnership, will identify the unmet needs of the NHS so that digital developers can respond to these needs. They will support them in building evidence about real world use and the most appropriate route to market. AHSNs will be key to ensuring that products can be taken up locally and move through the system quickly. AHSNs might refer products to the AAP that require national coordination and support if developers would find this useful.

Accelerated Access Partnership and horizon scanning	The new Accelerated Access Partnership will manage the whole pathway for strategically important products, and is overseen by an independent chair accountable to ministers. It is made up of the national organisations responsible for regulating, appraising and delivering new innovations to patients including NIHR, MHRA, NICE, NHS England, NHS Improvement and the Department of Health. The partnership's initial role is in horizon scanning and prioritisation but it will continue to oversee a strategically important product's entire journey to patients, including adoption support. Products can join or leave the pathway at any time and will be considered on a case-by-case basis.
Development: • Product development • Product testing • Clinical evidence development	Product prototyping is an iterative process. It is good practice for digital health technologies to develop clinical evidence around their safety and efficacy. In addition to this, some digital health technologies may be classed as medical devices which means clinical evaluation is required. The Paperless 2020 assessment process (see below) will include information about evidence development for app developers and their academic partners to use, such as studies types, economic evidence and case studies.
Regulation: • Regulatory approval	As at present, if a product meets the definition of a medical device it will need to be CE marked in accordance with the Medical Device Directives. For these products, a developer can still choose on a voluntary basis to undertake the Paperless 2020 assessment process, once the CE mark has been obtained. The Paperless 2020 assessment process itself is not a regulatory process.
Transformative designation	For a small number of strategically important digital products, that have the potential to deliver a step change in costs or outcomes and that would benefit from national coordination, a transformative designation will place the product on the accelerated access pathway. The Accelerated Access Partnership will consider the support required by transformative digital products on a case-by-case basis. The designation will usually be awarded after CE-marking for products that need medical device regulation.
Paperless 2020 assessment to identify high quality apps	The Paperless 2020 assessment process, due to launch in 2017, will identify high quality apps (and in the future other digital products) that are then promoted to patients, citizens, healthcare professionals and commissioners. The process, which will be digitally enabled, is designed to evaluate how well an app meets best practice standards for data security, safety, interoperability, usability and technical stability. It also considers the evidence on whether an app is effective, has a beneficial impact on cost and resource use in the health and care system, and positively influences factors important to users. The process is likely to require developers to register their digital product(s) and make a self-declaration against the set of best practice standards described above. Responses are then validated by an expert community. For a subset of the digital products considered, this process will also include a topic selection step based on the overall value proposition of the app to the health and care system and, for selected apps, an independent evaluation of the evidence by NICE. Transformative products that are prioritised by the Accelerated Access

	Partnership will be supported to complete the above Paperless 2020 assessment process by the AAP and all these transformative products will be evaluated by NICE as part of the process. Whilst the AAP may identify digital products to enter the Paperless 2020 assessment process, this process itself may identify promising digital products for the AAP to prioritise.
Evaluation by NICE	NICE will undertake a review of the evidence on the effectiveness of an app (clinical or behavioural effectiveness), its impact on cost and resource use in the health and care system, and how well it serves patients and users. The output of the NICE evaluation is a commissioner briefing to support local decision making. This evaluation will apply to all transformative products identified by the AAP and some of the other digital products from the Paperless 2020 assessment process.
Commissioning: • Local purchasing • Crown Commercial service SME procurement process • Innovation and Technology Tariff	The Crown Commercial Service will work in partnership with NHS England, the Department of Health and other partners to consider how best to develop an accessible, simple and swift competitive process for procuring digital health products from SMEs. NHS England will develop a new generic framework for app prescription that is easy to use and eliminates the need for multiple local systems. This will help healthcare professionals understand the mechanism they should use, and the wrap-around services required, to enable patients to access these products. The new Innovation and Technology Tariff will provide a reimbursement route for a selected number of value-proven digital products, removing the need for multiple local price negotiations.
Adoption	AHSNs will play a key role in supporting the adoption of the truly transformative digital products that it prioritises. Uptake and adoption data on digital health products will be published as part of the updated innovation scorecard to showcase where the most innovative digital technologies require more support and empowering innovators, patients and clinicians with this information to call for additional support. This will be further supported by uptake support activities that will accompany all digital products which complete the Paperless 2020 assessment process. This will include promotion through NHS websites, such as nhs.uk, in the context of specific conditions and targeted public communications, for example Public Health England's 'Stoptober' campaign.

Annex D: The Accelerated Access Review's champions

The following people provided advice and support throughout the review:

Policy:	Dr Stuart Dollow, Vermilion Life Sciences
	Professor Richard Barker, Centre for the Advancement of Sustainable Medical Innovation (CASMI)
	Richard Murray, The King's Fund
	Rob Webster, NHS Confederation (now South West Yorkshire Partnership NHS Foundation Trust)
Patients:	Hilary Newiss, National Voices
Medical technologies:	John Jeans, Life Sciences Advisor
Digital:	Charles Lowe, Digital Health and Care Alliance