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NHS Commercial Framework & Sovereignty of NHS Data

EMIG Market Access Meeting

5th December 2019

Summary of NHSE CF Engagement Questions
Please use post-its to put your thoughts down on Q4-6

1. Are the objectives and principles underpinning the Commercial Framework for Medicines clear? Is anything missing? (**Section 2**)
2. Are the respective roles and responsibilities and the processes for engaging with NICE and NHS England clear? Where would further clarity be helpful? (**Section 3**)
3. Are the routes to commissioning and funding new treatments within the NHS clear? (**Section 4**)
4. Is the framework of commercial options available clear? Where might further clarity be helpful? (**Section 5**)
5. What is missing from the Commercial Framework?
6. What additional information could be included?
7. Are you aware of any impact this framework might have on health equalities?

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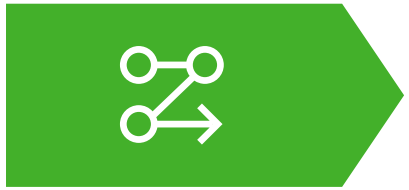
Three Central Issues the Framework Aims to Address

Ensuring treatments are **clinically and cost-effective** and represent a good use of NHS resources

Ensuring the introduction of clinically and cost-effective treatments are **affordable** for the NHS now and in the future



Ensuring that any commercial arrangements are **transactable** within the NHS so that the value is realised and the burden on the NHS is minimised

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Principles of the Commercial Framework

Principle 1: NHS England's commercial medicines activity serves to support NICE's technology appraisal process, rather than act as a substitute or alternative to it

- **Where issues arise in relation to the economic evidence, whether in relation to cost-effectiveness or affordability, the NHS is able to consider whether commercial arrangements may be able to help resolve those issues**

Principle 2: NHS England and NICE will work collaboratively to provide a joined-up way for pharmaceutical companies to engage with the NHS regarding technology appraisals

Principle 3: Commercial arrangements must be as simple as possible, minimising the burden on the NHS and front-line staff

- Complex arrangements will only be considered once simple discounts have been fully demonstrated to be unsuitable
- Where there is a case for more complex schemes, these will need to be carefully scrutinised, avoiding complex monitoring, disproportionate additional costs and be consistent with NHS financial flows, accounting rules and commissioning arrangements

Principles of the Commercial Framework

Principle 4: Confidential complex commercial arrangements are expected to be considered only for products which represent value at or below the lower end of the standard NICE threshold or other applicable thresholds

- The standard cost effectiveness threshold used by NICE will be retained at the current range (£20,000 – £30,000 per Quality Adjusted Life Year [QALY]) and not changed for the duration of the Voluntary Scheme
- Enhanced commercial arrangements would normally correspond to medicines that would be expected to have value propositions **at or below the lower end of the standard NICE cost effectiveness threshold range**, with greater flexibilities made available for value propositions at even greater levels of cost effectiveness, taking into account any applicable QALY weightings

Principle 5: Bespoke commercial arrangements (commercial flexibilities) will be considered on a case-by-case basis

- Although the types of commercial schemes that may be available to companies are described in this Framework, the different challenges facing different treatments (value, uncertainty, affordability) demands consideration on a case-by-case basis
- No previous deals are an indicator of future deals and discretion on whether an acceptable offer has been made and to agree a commercial arrangement ultimately rests with NHS England

Principle 6: Commercially sensitive information will be kept confidential at all times

- NHSE recognises the critical importance of this to industry. **Notwithstanding this principle**, and consistent with the Voluntary Scheme, **NHSE will work with companies and the Devolved Administrations to confidentially share**, wherever possible, commercial arrangements, recognising the reach of the NHS across the UK and the interests of UK taxpayers

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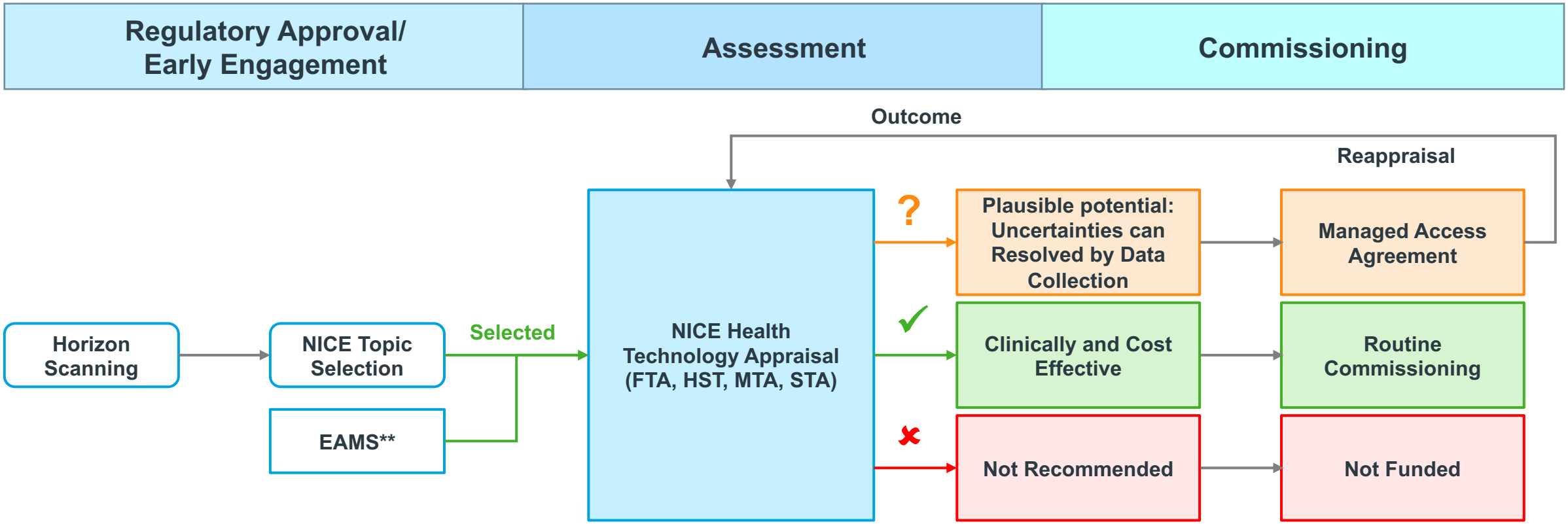
Routes to commissioning in the NHS in England for new medicines



Key: EAMS – Early Access to Medicines; FTA – Fast-track Technology Appraisal; HST – Highly Specialised Technology; MTA – Multi-Technology Appraisal; STA – Single Technology Appraisal

*All New Active Substances in their first indication, and extensions to their Marketing Authorisation to add a significant new therapeutic indication, will undergo and appropriate NICE appraisal, except where there is a clear rationale not to do so. NICE expects to achieve this by April 2020

: .EAMS allows **access to medicines that do not yet have a marketing authorisation when there is a clear unmet clinical need. Voluntary

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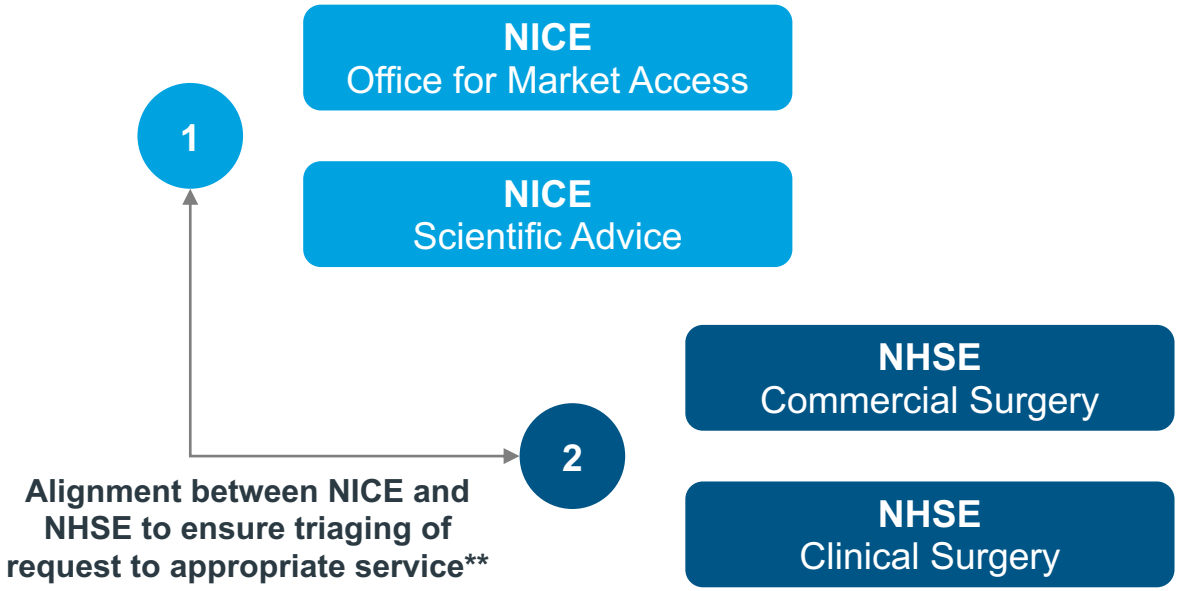
Engagement Opportunities with NICE and NHS England

Engage Early



There is broadly a two-step process for engaging with NICE and NHSE

Step	Detail
1	• Initial engagement on emerging market access challenges for individual & group treatments • Structured multi-stakeholder interaction enabling shared understanding and initiating solution focused co-working • Comprehensive scientific advice on evidence generation
2	• Future targeted discussion on commercial and clinical issues, building on from Step 1 interactions wherever possible • Surgeries tend to be closer to appraisal and focus on practical, commissioning related issues

*Both NICE and NHSE&I offer advice at later stages of the product lifecycle and requests are triaged appropriately
**Acknowledging that confidentiality plays a role in what information can be shared

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Commercial Framework Goals

The framework of potential commercial options has been designed to:

Support companies in presenting a value proposition to NICE that is considered clinically and cost-effective at the relevant threshold

Offer companies the potential opportunity to enter into complex and confidential agreements, beyond a simple discount, where that results in an enhanced value proposition being presented to NICE **that is at or below the lower end of the relevant clinical and cost-effectiveness threshold**

Offer companies the opportunity to discuss the potential for a confidential commercial solution where there may be unusual or unique circumstances that makes launching a product particularly challenging or commercially unviable

Provide companies with a confidential commercial mechanism where NICE believe there is significant uncertainty surrounding the clinical and/or cost-effectiveness of a treatment and **there is plausible potential for that treatment to be clinically and cost-effective**

Support companies and NHS England in working together to identify confidential commercial solutions for addressing NHS affordability challenges that may arise from otherwise clinically and cost-effective treatments

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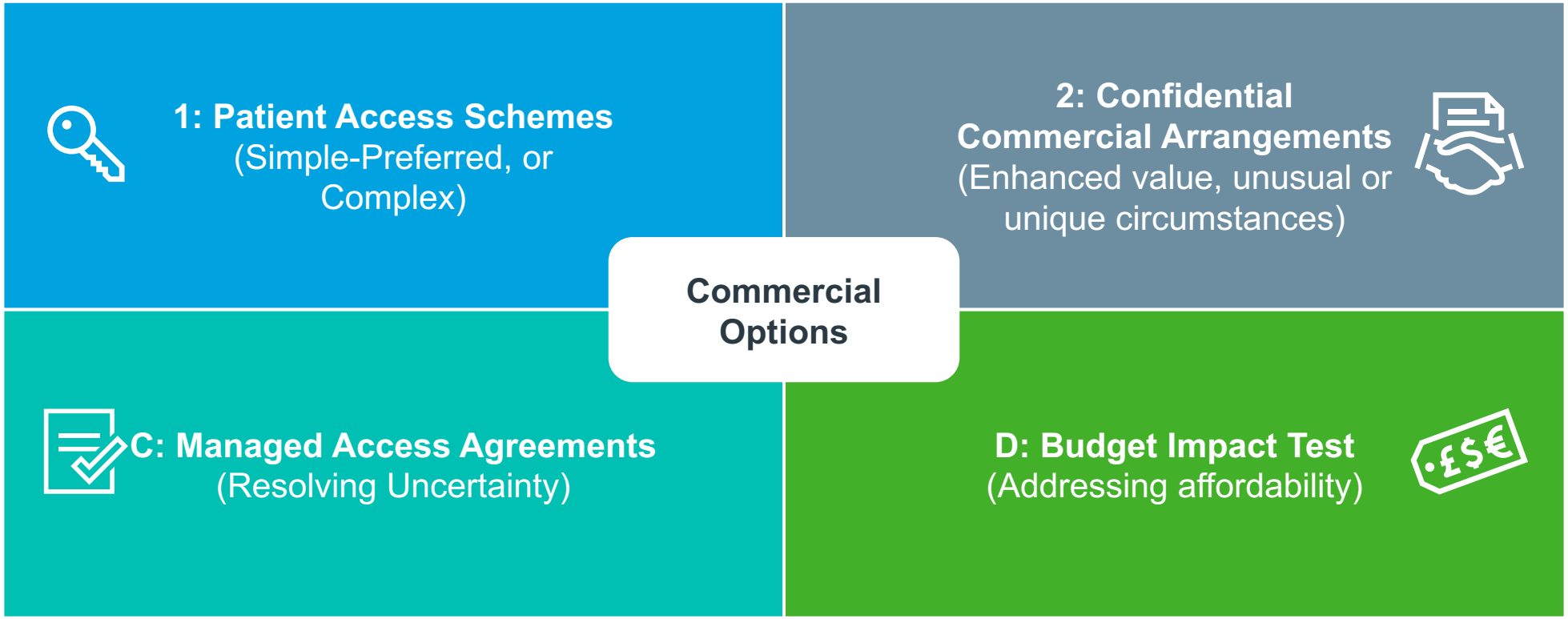
Commercial Framework Options



1. Patient Access Schemes

1. Patient Access Schemes (Simple and Complex)

- Patient Access Schemes (PAS) are **the starting point** or default option for companies to consider **when developing their value proposition for appraisal by NICE.**
- Their purpose is to provide a mechanism for companies to improve the cost-effectiveness of a treatment under appraisal beyond that driven by its list price
- Unless a treatment is to be considered by NICE at list price, then **companies should always include a PAS when making their initial evidence submission to NICE** to ensure sufficient time for full consideration in advance of the Appraisal Committee meeting
- There are two types of PAS

  1a: Simple PAS (confidential)

  1b: Complex PAS (transparent)

1a: Simple PAS Schemes

- Simple PAS are confidential and involve the provision of **a simple percentage** discount on the list price that is applied at source. These are **always the preferred option** as, they require less monitoring for all parties and minimise the administrative burden on NHS organisations. They also ensure that where VAT is incurred it applies at the lowest level of the effective net price
- Simple discounts apply consistently across all indications for a given technology
  - This is consistent with the Voluntary Scheme, which confirmed that the health service in England **does not operate blended pricing or pricing by indication**
  - In **practice, this means that a simple PAS discount may increase the discount within an existing PAS** i.e. where the technology being appraised for a particular indication is already routinely commissioned for a different indication
- **NICE Commercial Liaison (Patient Access Scheme Liaison Unit [PASLU]) advise NHS England on the feasibility of a PAS**
  - As a simple PAS involves a more rapid review than a complex PAS, both the NICE Commercial Liaison Team's (PASLU) advice and NHS England's approval is **faster**
  - Agreement by NHS England to a PAS should not be seen as a willingness to pay at the proposed level of discount
    - › **The advice from the NICE Commercial Liaison Team (PASLU) informs the decision on whether the proposed PAS can be considered as part of a NICE technology appraisal**
    - › It is for NICE to determine whether the level of discount being offered by the company represents a clinically and cost-effective use of NHS resources

1b: Complex PAS Schemes

- **A complex PAS is not confidential**
  - By definition, it will involve a more complex reimbursement proposal that, in turn, will be more complex to administer within the NHS
  - The requirement for transparency is **to ensure the administrative burden and cost to the service of implementing such schemes is minimised** and helps ensure the value of the treatment, as determined by NICE, is achieved
- If a company chooses to propose a complex scheme, there needs to be a strong rationale to justify its use and an **indication of how the associated risks will be shared equitably between the company and NHS England**
  - VAT consequences associated with the proposed scheme must also be accounted for within the proposal
- As with a simple PAS, the NICE Commercial Liaison Team (PASLU) will advise NHS England on the feasibility of implementing the proposed scheme
  - For a complex PAS this will inevitably be a more involved process, including consultation with the NHS and an operational review of commercial arrangements to ensure the benefit can be realised
- PASs extant as at 31 December 2018 have been maintained in accordance with their terms as per the 2014 Pharmaceutical Pricing Regulation Scheme

2. Confidential Commercial Agreements (CCA's)

Confidential Commercial Agreements

Unlike complex PAS, which are transparent, Confidential Commercial Agreements are, by definition, confidential

- Such agreements are at the discretion of NHS England with the default arrangement of offering a PAS (simple or complex) always being available to companies

There are currently two circumstances when NHS England may be prepared to enter into a Confidential Commercial Agreement with a company:

1. **Where the company wants to propose an enhanced value offer; and/or**
2. **Where there are unusual or unique circumstances that mean launching a product is considered particularly challenging or commercially unviable**

CCA's : Enhanced Value Offers

Enhanced Value Offers

The Voluntary Scheme sets out the following:

'Enhanced commercial arrangements may include complex confidential commercial arrangements, where deemed appropriate by NHS England and ***reserved for where companies aspire to deliver greater levels of health gain relative to cost***

Arrangements would normally correspond to medicines that would be expected to have value propositions ***at or below the lower end of the standard NICE cost effectiveness threshold range****, with greater flexibilities made available for value propositions at even greater levels of cost effectiveness, plus any applicable QALY weightings'*

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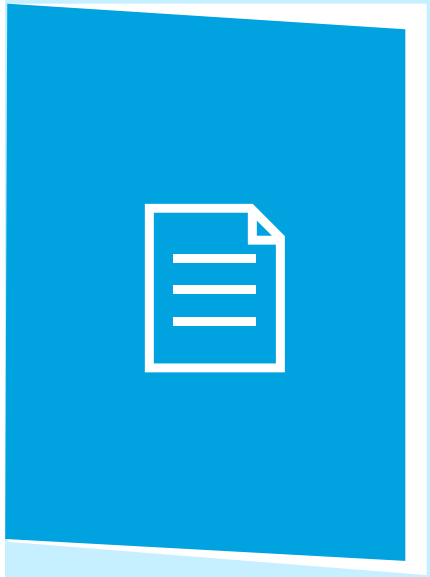
CCA's : Unusual or Unique Circumstances

Unusual or Unique Circumstances



- Unusual or a unique set of circumstances surrounding the NICE appraisal of a particular treatment that makes its launch challenging or commercially unviable.
- EG: The Voluntary Scheme acknowledged that there may be instances where uniform pricing would lead to a reduction in total revenues for a medicine overall from the introduction of additional indications
  - In such a circumstance, and where **medicines have a strong value proposition and the level of clinical effectiveness is highly differentiated and substantial in all indications under consideration, commercial flexibility can be considered**
  - These arrangements would normally correspond to medicines that would be expected to have value propositions at or below the lower end of the standard NICE cost effectiveness threshold range, with greater flexibilities made available for value propositions at even greater levels of cost effectiveness, plus any applicable QALY weightings

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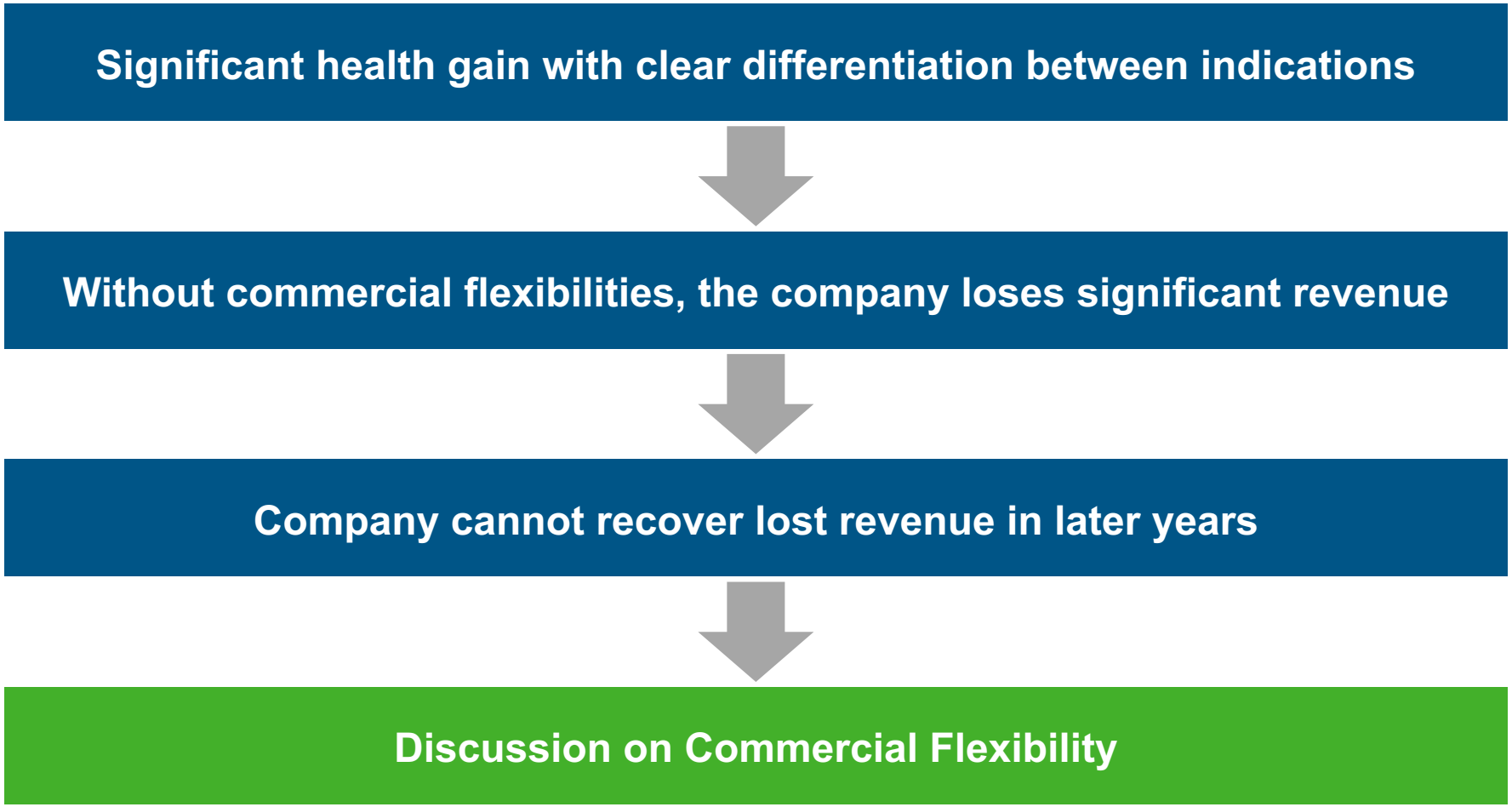
Considerations for Non-uniform Pricing Flexibilities: All criteria below chart need to be met before a potential discussion on commercial flexibility can be considered



Example Formats for Commercial Arrangements*

Scheme Type	Description
Budget Cap	Maximum budget impact for a product (or products) beyond which a central rebate is payable
Price/Volume Agreement	Price agreed for set volume of patients and then staged reductions based on additional patient numbers or company pays back the full amount (similar to budget cap)
Cost-Sharing	The company will fund initial cost of therapies such as offering the first month for free
Stop/Start criteria	Rules on eligibility criteria for when patients should start/stop therapy
Outcomes-Based Agreement/ Payment by Results	Discount or rebate applied if a product does not perform as expected or for non-responders

*NB: List is not exhaustive, and a combination of schemes can be applied

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3. Managed Access Agreements

Managed Access Agreements

- There are situations where uncertainty exacerbates the challenge in health technology appraisal. In general, there are two main sources of outstanding uncertainty at the time of appraisal:
  - **Clinical uncertainty; and**
  - **Financial uncertainty**
- Where such uncertainty exists, NICE is able to recommend that a MAA is explored between the company and NHS England
  - This would only happen when there is plausible potential for a drug to satisfy the criteria for routine commissioning, and there is uncertainty surrounding the clinical data and consequently the cost effectiveness estimates to make such a recommendation
- **MAAs consist of two key components**
  - **a Data Collection Agreement to mitigate clinical uncertainty (as defined by the NICE Appraisal Committee)**
    and either
  - **(a) Commercial Access Agreement or (b) a PAS discount**

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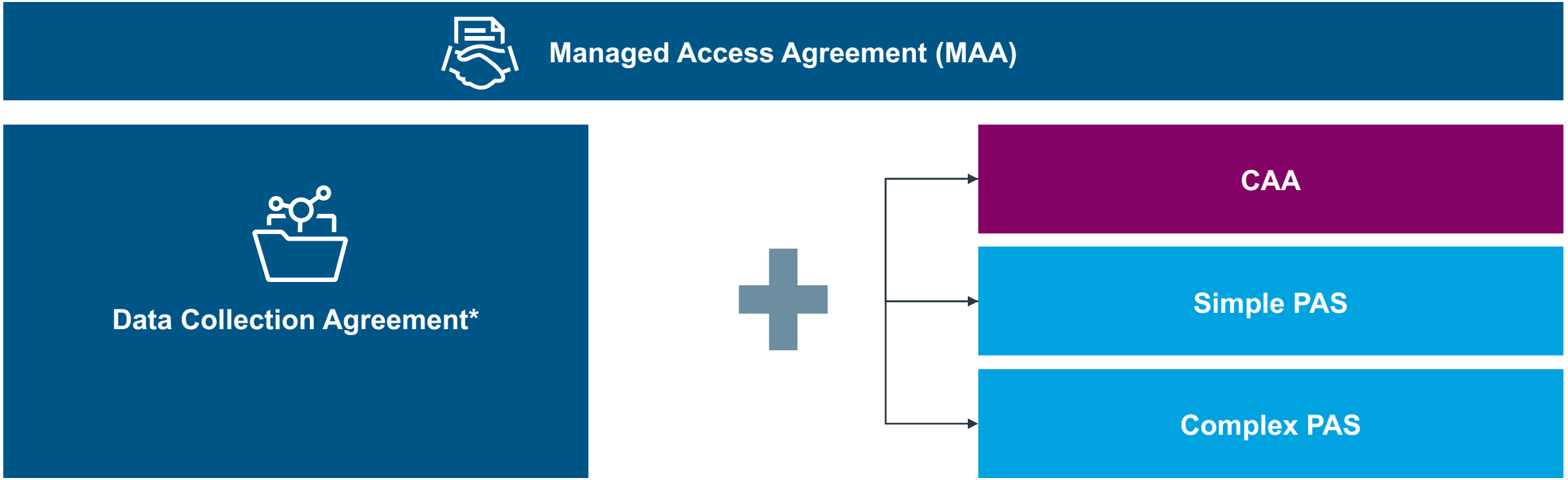
Managed Access Agreements Explained



*The time-limited clinical element of the MAA, i.e. not a commercial agreement which needs to be incorporated into the MAA

3. Managed Access Agreements

- MAAs are **an <u>interim</u> commissioning position** with a committed future date for reappraisal, which may result in routine commissioning; they are therefore time-limited
- MAAs require the agreement of the company to **offer the treatment at a cost-effective price for the duration of the MAA**. There are exit clauses in place as part of each MAA
- To date, MAAs have been most frequently used **in the context of cancer drug appraisal and within the NICE HST** appraisal process, where very small patient numbers can lead to significant uncertainty in the clinical evidence being presented
- Although MAAs have most commonly been seen within cancer and HST appraisals, this is not an exclusive position and it is possible that NICE may recommend that MAAs are explored in a broader set of circumstances in the future
- **However, one of the key constraints to overcome when considering the possibility of a MAA is <u>the practical data collection considerations and their link to health outcomes that will be critical to resolving any outstanding uncertainties</u>**

4. Budget Impact Schemes

The potential **net budget impact is expected to exceed £20 million per year in any of the first 3 years of a technology's use** in the NHS.
NHS England will engage in commercial discussions, with companies whose technologies are being appraised by NICE, **as an alternative to requesting a variation to the statutory funding requirement.**

The purpose of these commercial discussions is to mitigate the affordability challenge that immediately funding the technology would have on other NHS services

- If an agreement between NHS England and the company is not reached, NHS England may then request a variation to the statutory funding requirement

The degree of additional value expected from application of the Budget Impact Test (BIT) will take into account two main dimensions:

- **The overall cost impact to the NHS in each of the first three years; and**
- **Any likely direct competition or external impact to that market that may mitigate any spend by the NHS**

As an illustration, a new treatment expected to have a budget impact of £100m in any of the first 3 years with no or limited competitors, will require to provide more value than a technology with a budget impact of £21m in any of the first three years with multiple competitors entering the marketplace

Summary of Engagement Questions Brainstorm

1. Are the objectives and principles underpinning the Commercial Framework for Medicines clear? Is anything missing? (**Section 2**)
2. Are the respective roles and responsibilities and the processes for engaging with NICE and NHS England clear? Where would further clarity be helpful? (**Section 3**)
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Sovereignty of NHS Data

The UK has data at scale, but needs standards, access approval process and data linkage to “de-silo” the insights

Strengths

- **Universal healthcare system** provides whole population perspective
- NHS number provides **unique patient ID**
- National coverage of **hospital inpatient administrative data** (Hospital Episode Statistics)
- Well-developed **ecosystem of registries** (e.g. cancer, stroke)
- Large scale **primary care electronic medical records** for research (e.g. THIN, CPRD)
- **Community prescribing** and dispensation data
- Emerging **unique data assets** (e.g. Genomics England)

Gaps

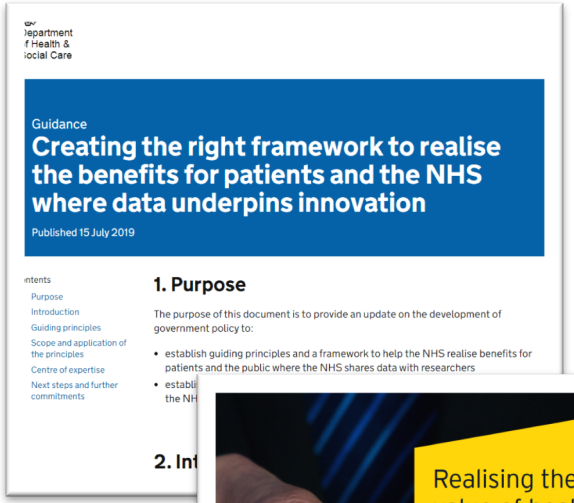
- Poor coverage of **hospital outpatient activity** in administrative data
- No routinely available national data about **hospital prescribing**
- Poor coverage of **outcomes data** (with the exception of mortality data), and early investment in **PROs** has not been sustained
- Prescribing and dispensation data **not routinely linked** to other data sources
- Primary care, secondary care and community care **data sources are often siloed**
- Some initial progress on interoperability, open standards and data access but **implementation has been slow**

Background to Sovereignty of NHS Data Agenda

The Exam Question: 'What Value do commercial organisations deliver back to the NHS in return for the de-identified patient data they access for clinical trials RWE studies, AIML and wider insights?

1. The 'Fair Value' Agenda:
The UK Government is seeking to establish a Value return from users of NHS patient data over the next 2 years

2. Industry Imperative:
To establish an evidence-based position and narrative with key messages to support all its research and data use programmes in the UK


Department of Health & Social Care

Guidance
Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation
Published 15 July 2019

Contents
Purpose
Introduction
Guiding principles
Scope and application of the principles
Centre of expertise
Next steps and further commitments

1. Purpose

The purpose of this document is to provide an update on the development of government policy to:

- establish guiding principles and a framework to help the NHS realise benefits for patients and the public where the NHS shares data with researchers
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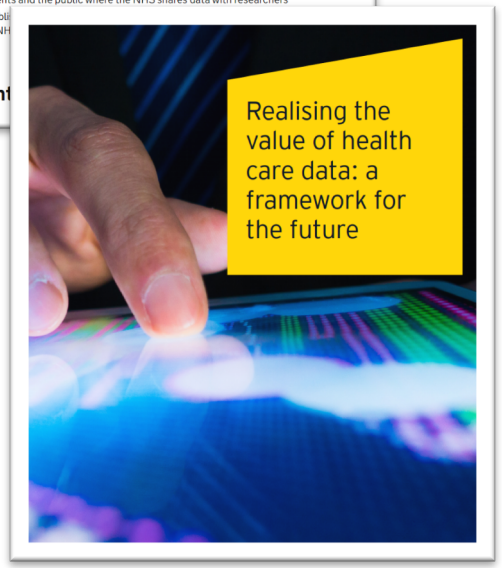

July 2019 saw the publication of the final draft of the ***'The Guiding principles and framework to help the NHS realise benefits for patients and the public where the NHS shares data with researchers'***[1] setting out a Principle that ***'fair value'*** for data extracted must be received by NHS organisations supplying health data to commercial researchers**. It didn't define 'fair value'.**

July 2019, **Sensyne** commissioned its strategic partner E&Y Report.
'***How can we place a value on health care data?***'[2]
The EY Report laid out the platform for the Government on which this theme will run, offering an estimate of the economic gain from NHS data proposing two primary approaches to quantifying the value of data:

1. A market-based approach, calculating the implied "per record" valuation multiples of comparable data assets or valuation multiples of companies with significant patient data assets
2. An income-based approach, which quantifies value based on the economic benefit to be generated from the curated data se

EY estimated that the **55 million** patient records held by the NHS today may have an indicative market value of several billion pounds to a commercial organisation[2]:

'***we estimate also that the value of the curated NHS data set could be as much as £5bn per annum and deliver around £4.6bn of benefit to patients per annum.***'

1. EMIG December 2019

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Media Coverage (1)

Why the drugs giants are thirsty for your health records (Aug 2019)

*There is a new **multibillion-pound** mining industry in Britain, and it does not involve coal. Pioneers from the world's biggest drugmakers and tech firms are hunting for treasure in the National Health Service.*

*The prize is huge: the medical histories of **65m** patients, from cradle to grave, which could provide the key to discovering new blockbuster medicines, identifying diseases years before symptoms appear, or finding patients perfectly suited to a clinical trial.*

At the forefront of the revolution is Sensyne, it has struck deals with NHS trusts, mining them for data it then makes available to big pharma. Last month, Sensyne signed up its first customer, Bayer.

*Drayson came up with a model to ensure the NHS is rewarded, giving Trusts a **4%** share of future revenues and also handing them an equity stake in the business. In his view, when Sensyne benefits, the NHS benefits. However, the revenue share is capped — and there is no clear view on what value should be placed on the data.*

US tech firms want access to £10bn NHS health data *(Dec 2019)*

Media Coverage (2)

US tech firms want access to £10bn NHS health data

hilip Aldrick, Economics Editor

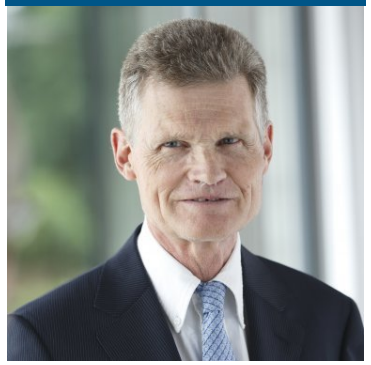
londay December 02 2019, 12.01am, he Times

Diluting data privacy rules after Brexit, as US negotiators have urged, could give companies access to 55 million health records

The Times-US-UK Trade Deal post Brexit 2/12/19 Diluting data privacy rules after Brexit, as US negotiators have urged, could give companies access to **55 million** health records.

The arrangements could give US companies unrestricted access to valuable UK data, one of the most promising of which is Britain's **55 million** health records. The leaked papers reveal that the US wants algorithms to be given full intellectual property protection and for restrictions on data localisation to be barred, which would allow UK data to be held in cloud servers based abroad.

Sir John Bell



The discrepancy in what big companies offer the NHS for access to data has sparked a debate over how Britain should ensure Silicon Valley giants do not plunder our health service for its data and bank all the profits.

"If we just let people come in and sift through the data and then run off to California, nobody gets anything out of it.

What sticks in people's throats is people come over, use NHS data to generate algorithms and then promptly say 'it's going to cost X amount to use the product'."

Some argue that the NHS should be granted a "golden share" of any drugs stemming from its co-operation. Others say there isn't a "one size fits all" solution.

There are many who question whether the private sector should be allowed access to patient data at all. GP apps Babylon and Push Doctor have struck deals with the NHS to treat patients — and they will be collecting data in the process.

"If you just have ad-hoc arrangements developed between individual trusts and private companies, and there's no standard being applied, we can end up handing over a resource of enormous value to the private sector and we have to avoid that,"

"The upside is massive, but there's a huge risk of lost opportunity if we don't get it right."

Norman Lamb

https://www.thetimes.co.uk/article/us-tech-firms-want-access-to-10bn-nhs-health-data-zpqwkj6pp

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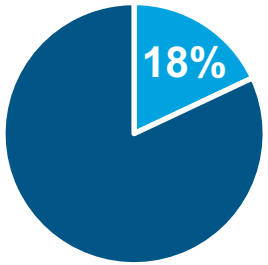
Public views on sharing anonymised patient-level data where there is a mixed public and private benefit

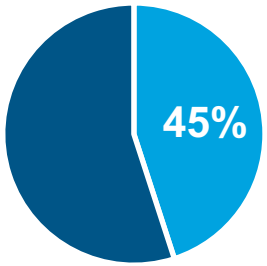
People readily accept NHS access to anonymous patient-level data for public benefit reasons other than the individual's direct care. However, people do not easily accept non-NHS access to this data

People's views change significantly if they are informed about the role that commercial organisations might play in developing data-driven services and products that might have a positive impact on healthcare



At the start of the research **18%** of participants felt that it would be acceptable to share anonymised patient-level data with commercial organisations for reasons other than direct care

At the end of the research this figure had grown to **45%**



Why the Change?

Participants reported that the view at the beginning of the day indicated their 'gut reaction' and that they changed their mind when exposed to information and discussion about particular ways that commercial organisations might be involved in developing healthcare products and services.

Participants unanimously felt that two conditions should apply where commercial organisations sought to access to patient data:

- The NHS should receive benefit in recognition of the role that the data played in the product's development.
- The NHS should be involved in the development of the product at all stages

How the NHS should benefit if the commercial organisations produced something of value?

Public View

Any product or service developed with patient data should be made available to the NHS at a preferential rate

The NHS should have unlimited access to any new knowledge or insights which arise from that company's work with the patient data

Public views on sharing anonymised patient-level data where there is a mixed public and private benefit HRA September 2019

2020 Fair Value for NHS data Agenda

Forward View

1. **The OLS is currently developing commercial templates, ahead of a 2020 consultation exercise on what represents fair value for NHS Data**

2. **Industry, through its trade bodies, needs to fully engage with this agenda**

3. **As an organisation:**

   a) *What data do you have appropriate access to?*

   b) *What is your position on fair value for NHS Data?*

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Thank You