NHS Commercial Framework for Medicines: EMIG Quarterly Meeting

Monday 10th February 2020

NHS England and NHS Improvement

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Introduction

Meeting Objectives

- Bringing the commercial framework to life.
- Ensuring attendees have a good understanding of the commercial framework.
- Update on feedback
- Explain next steps

Process

- We will go through the framework section by section to discuss the key issues and concepts.
- There will be a dedicated section for questions and answers.

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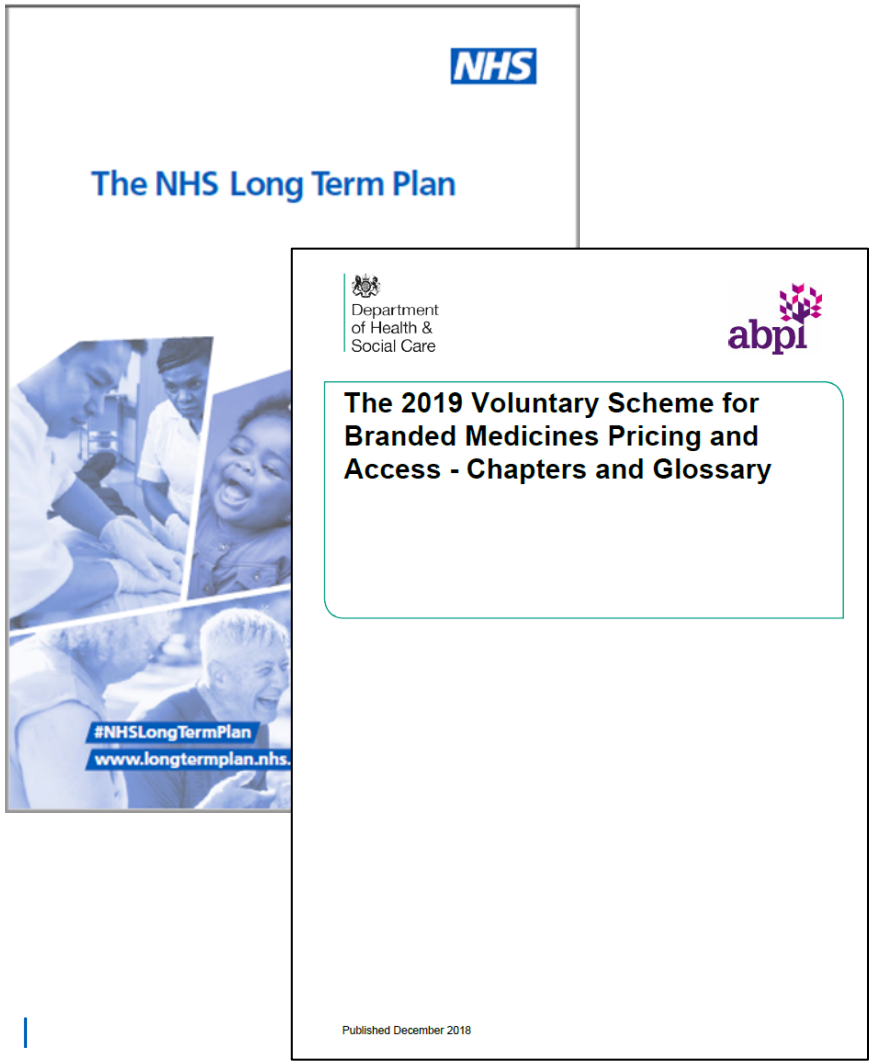
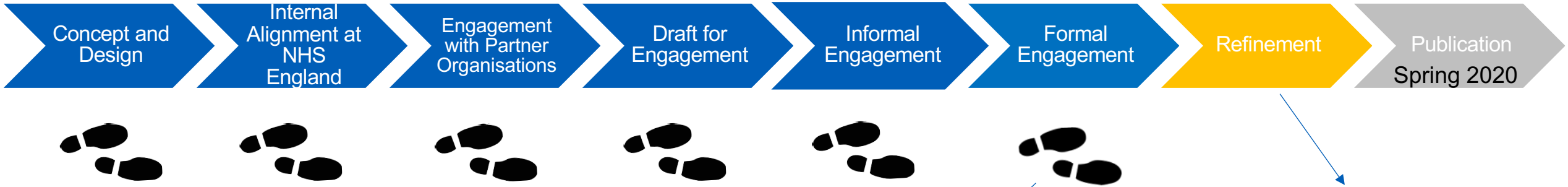
Context



- The Long Term Plan and 2019 Voluntary Scheme for Branded Medicines and Pricing and Access provide the policy platform for the Commercial Framework.
- The NHS' commercial activity plays a pivotal role in ensuring patient access to the most clinically and cost-effective new treatments and technologies.
- There is also a requirement to maximise health outcomes for the people of England and value for money for taxpayers.
- The increased availability of confidential commercial flexibilities is expected to be beneficial for patients, individual pharmaceutical companies and the life sciences sector more broadly.
- There are mutual benefits of open and regular dialogue with pharmaceutical industry representatives and providing the opportunity for earlier engagement, advice, and signposting on the development of new products.

Development of the Commercial Framework

The development of the draft Commercial Framework has been a comprehensive exercise involving internal alignment at NHS England alongside the evolution of the Commercial Medicines Directorate.
Engagement with key stakeholders such as NICE, DHSC and OLS has been pivotal in its development.



Events held in London and Manchester

NHS England are considering all comments received during the engagement that relates to the engagement questions and publish a formal response based on a thematic approach, in due course.

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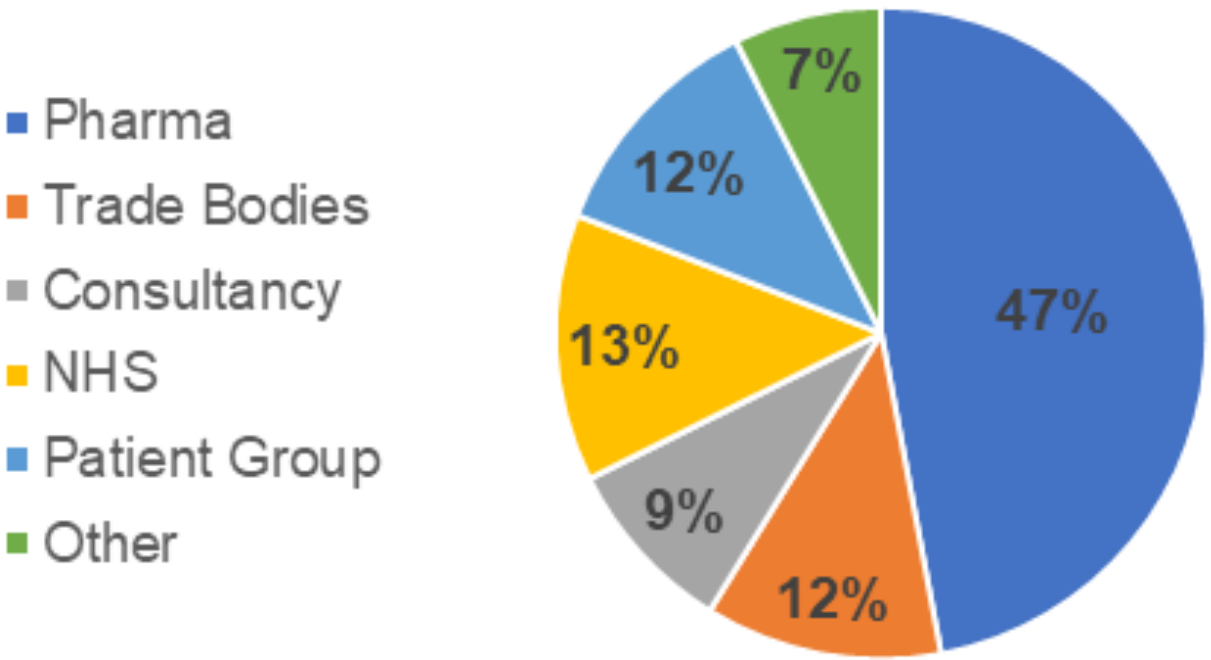
Feedback on draft

Responses (n=80) breakdown



- Engagement now closed
- Thematic analysis conducted, people are asking for:
  - Increased focus on patients
  - Clarity over language on thresholds
  - More detail on what PASLU, ODU and relationship with NICE and NHSE&I
  - More details on operational activity – how it all works
  - Push for MIP
  - Add in more commercial options
  - Escalation process missing
  - Data governance info missing
  - Timetable for review is missing
  - Rare diseases are not well served

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Aims of the Commercial Framework

This Framework sets out how NHS England will work together with NICE and the pharmaceutical industry on commercial medicines activity that is intended to support the introduction of clinically and cost-effective treatments into the NHS.

1. **Core Objectives and Principles**: outlining the purpose and principles on which NHS commercial medicines activity will be based.
2. **Roles, Responsibilities and Engagement**: defining the roles and responsibilities of those involved in commercial medicines activity and detailing how pharmaceutical companies can engage with the NHS.
3. **Routes to Commissioning**: clarifying the routes to routine commissioning in the NHS, and where commercial activity can occur in those routes.
4. **Commercial Options**: outlining commercial flexibilities, and circumstances where they could be considered.

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The Commercial Framework has 3 Core Objectives

1. • **Drive earlier and more purposeful engagement** between the pharmaceutical industry, NHS England and NICE, to enable better planning at both individual company level and at a wider industry level.

2. • **Facilitate timelier and more streamlined discussions about value, affordability and transactability** so technology appraisal decisions, and ultimately patient access, are not unnecessarily delayed, to ensuring early and fast access to new medicines.

3. • **Clarify the commercial flexibilities that may be available to companies** where appropriate. This will ensure that all companies, in particular smaller and/or specialist ones with less experience, will understand the full range of commercial options available to them.

The Commercial Framework has 6 principles which underpin all activity

1	2	3	4	5	6
• NHS England's commercial medicines activity serves to support NICE's technology appraisal process, rather than act as a substitute or alternative to it.	• NHS England and NICE will work collaboratively to provide a joined-up way for pharmaceutical companies to engage with the NHS regarding technology appraisals.	• Commercial arrangements must be as simple as possible, minimising the burden on the NHS and front-line staff.	• 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.	• Bespoke commercial arrangements (commercial flexibilities) will be considered on a case-by-case basis.	• Commercially sensitive information will be kept confidential at all times.

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Section aims

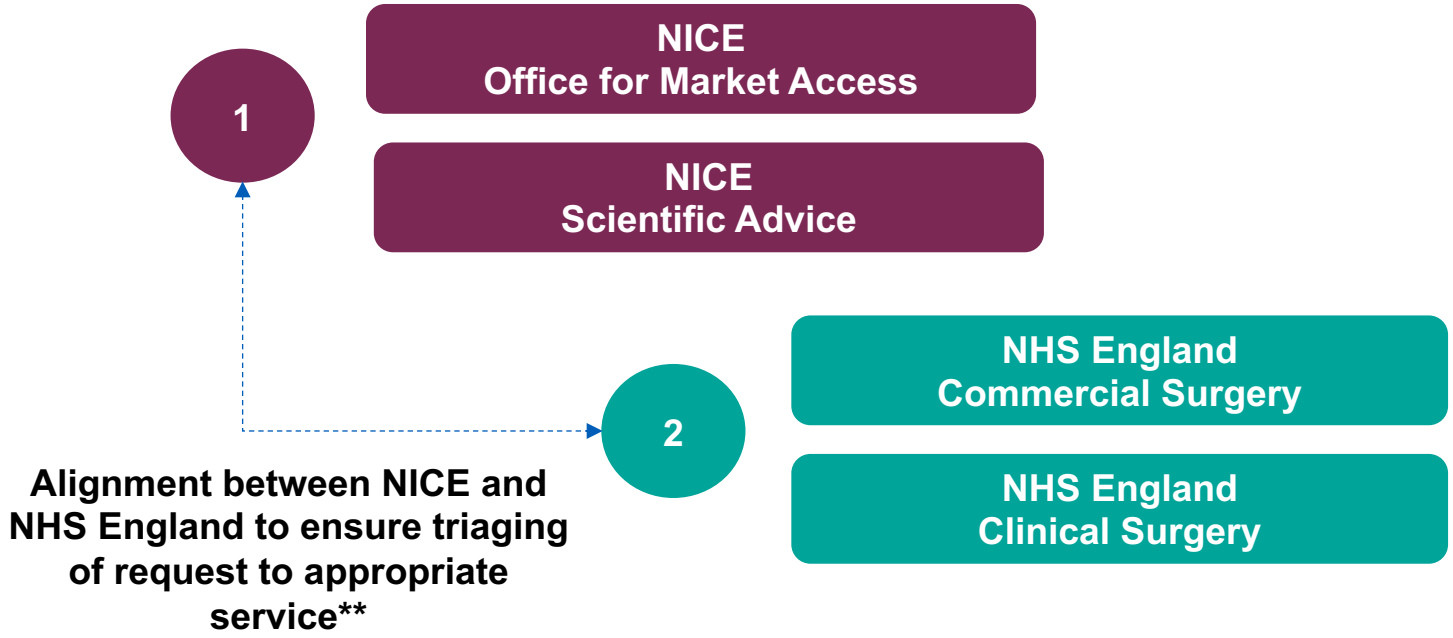
1. **Drive earlier and more purposeful engagement** between the pharmaceutical industry, NHS England and NICE, to enable better planning at both individual company level and at a wider industry level.

2. **Facilitate more timely and streamlined discussions about value, affordability and transactability** so technology appraisal decisions, and ultimately patient access, are not unnecessarily delayed.

- This section sets out the respective roles and responsibilities of NICE and NHS England and how we will work together to enable pharmaceutical companies to engage with the NHS about introducing their new medicines and building partnerships.
- This engagement can happen in different ways across the product lifecycle, and clarity is given about the timing, opportunities and nature of the advice available at these different points.

There are a number of engagement opportunities at NICE and NHS England

Horizon Scanning → Pre-Launch → Appraisal → Adoption and Uptake*



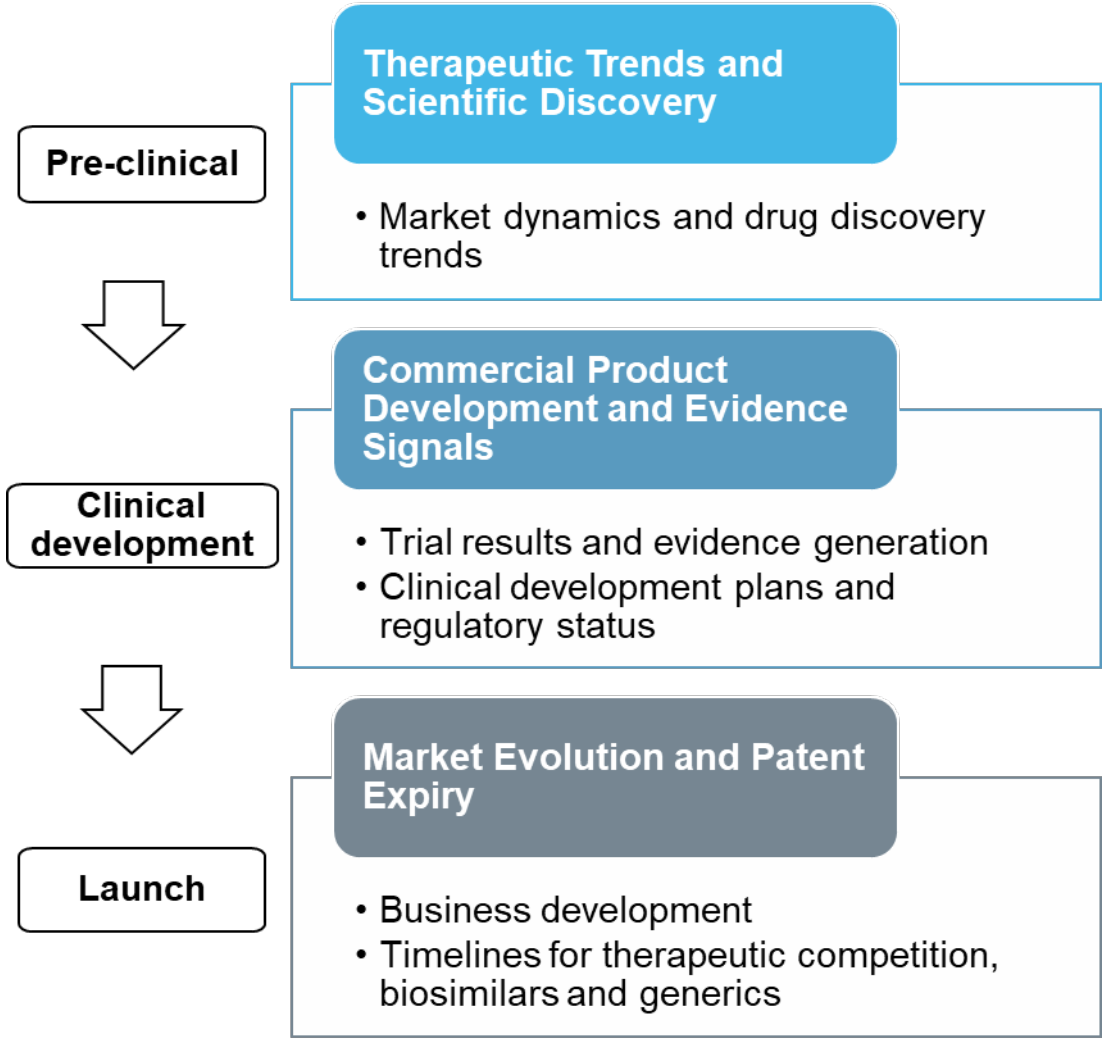
There is broadly a two-step process for engaging with NICE and NHS England

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	• Further 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 NHS England offer advice at later stages of the product lifecycle and requests are triaged appropriately

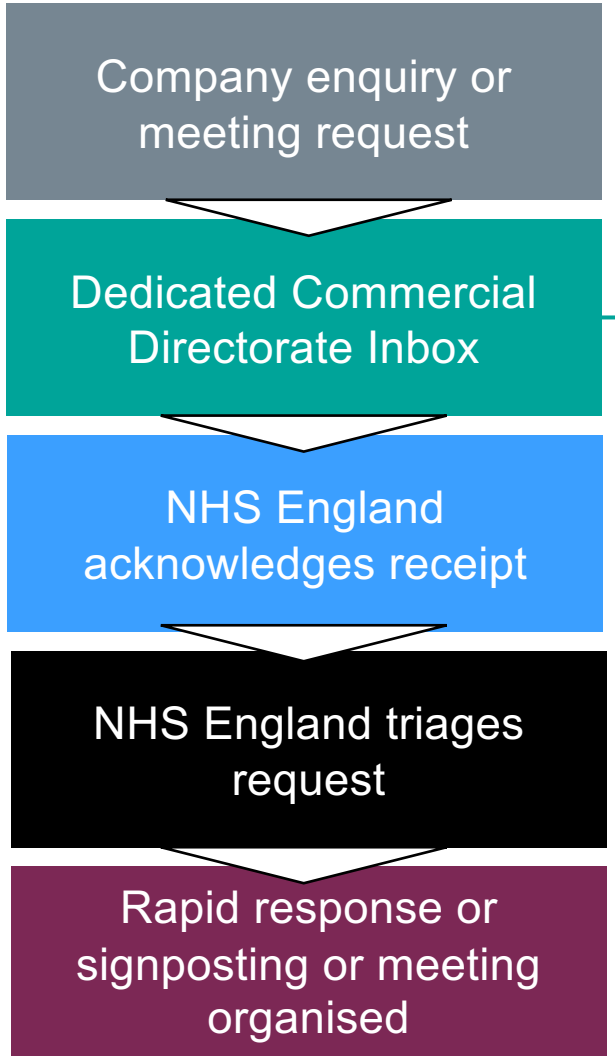
** Acknowledging that confidentiality plays a role in what information can be shared

Effective horizon scanning is an essential element of the Commercial Framework



- Pharmaceutical companies are encouraged to make information available at all stages of product development, which can then be used to inform horizon scanning.
- Companies are expected to submit timely and accurate information to the fullest extent on products in development using UK *PharmaScan*.
- A cross-functional Horizon Scanning Steering Group (HSSG) has been set up and is working to enhance and optimise the NHS' horizon scanning ability, reaffirming the commitment set out in the Scheme.
- The National Institute for Health Research Innovation Observatory (NIHRIO) will work alongside stakeholders such as the NHS Specialist Pharmacy Service (SPS) to provide a central horizon scanning platform for intelligent, timely analysis and aligned to AAC goals.

A triage function provides a single engagement point for all commercial queries



Objectives of the triage

- Resolve enquiries in a timely fashion
- Arrange a meeting or teleconference where appropriate
- Signposting and redirecting enquiries outside the commercial medicines directorate when necessary

Benefits:

- Single engagement point for all commercial queries
- Dedicated email address for enquiries and meeting requests
- Allows rapid response
- Ensures accurate and comprehensive response from subject matter experts

england.commercialmedicines@nhs.net

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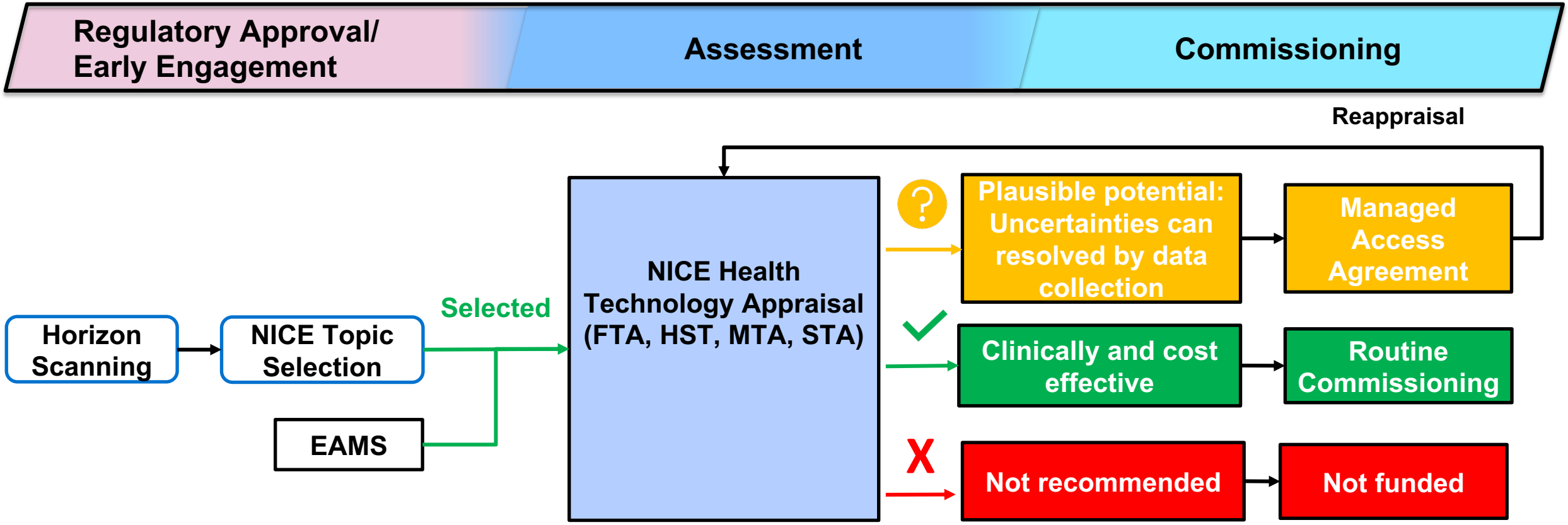
NICE appraisal is the central route for the routine commissioning of new medicines in England



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

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Commercial options may be available to companies in particular circumstances

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

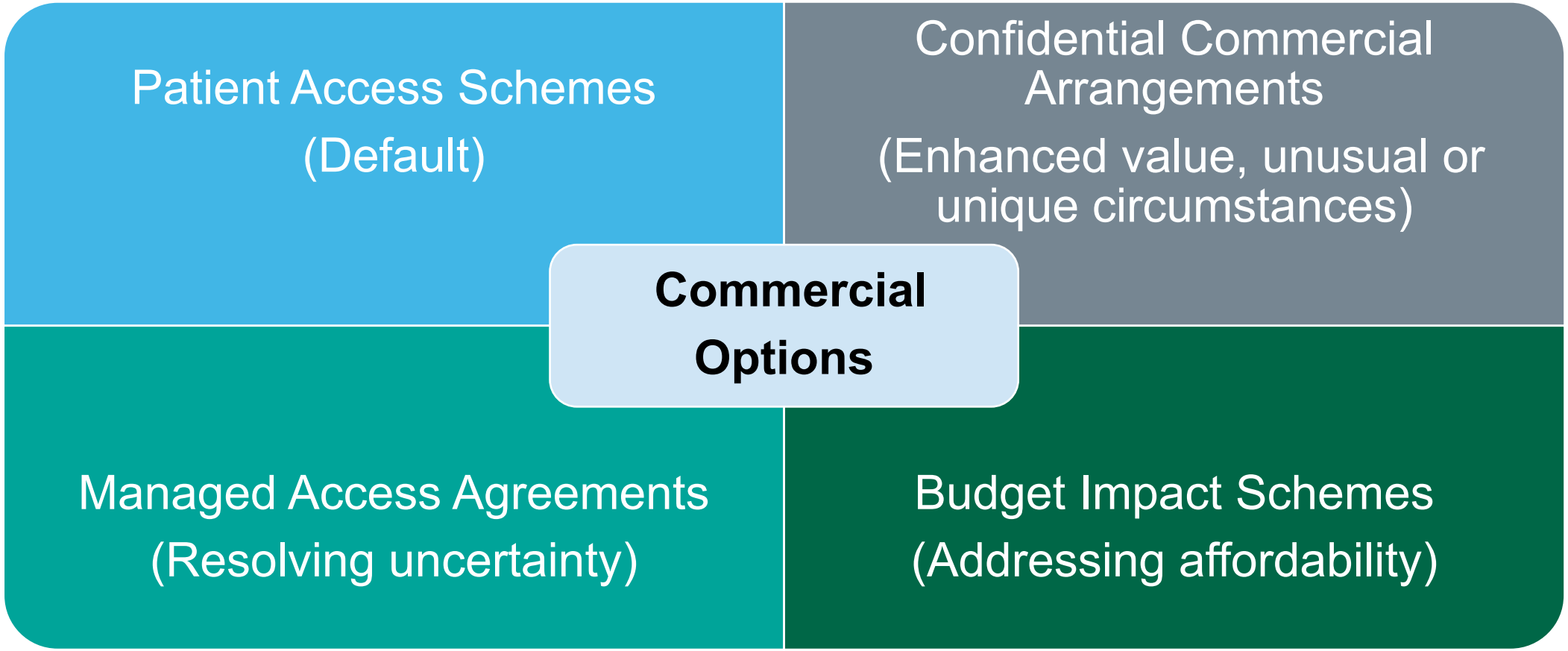
Offer companies the potential opportunity to enter into complex and confidential agreements, beyond a simple discount, where that results in an enhanced value proposition being presented to NICE that is at or below the lower end of the relevant clinical and cost-effectiveness threshold.

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.

The commercial options that can be considered fall into four categories

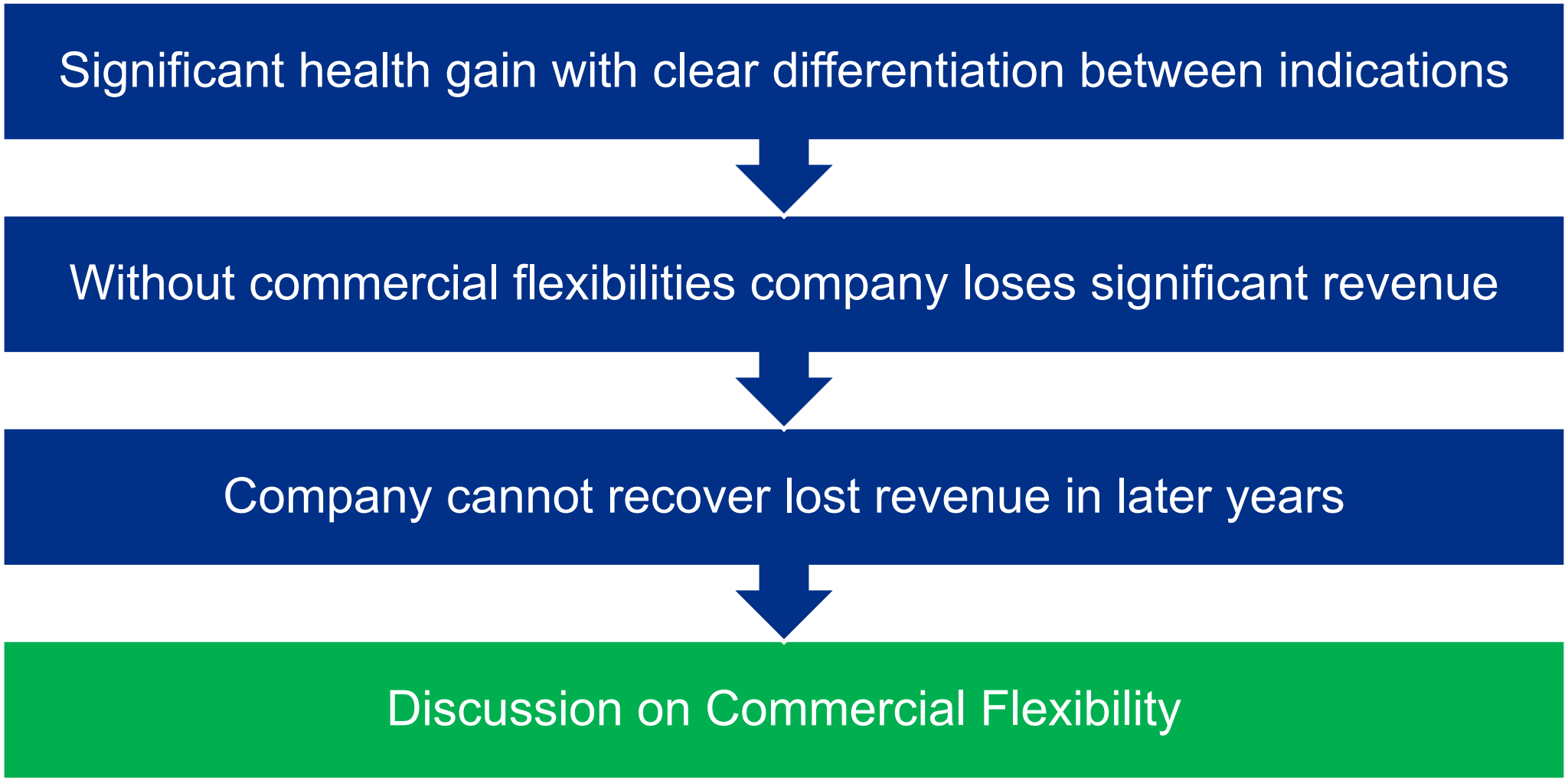


Example formats for confidential commercial arrangements

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.

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

Considerations for potential commercial discussions in unusual or unique circumstances

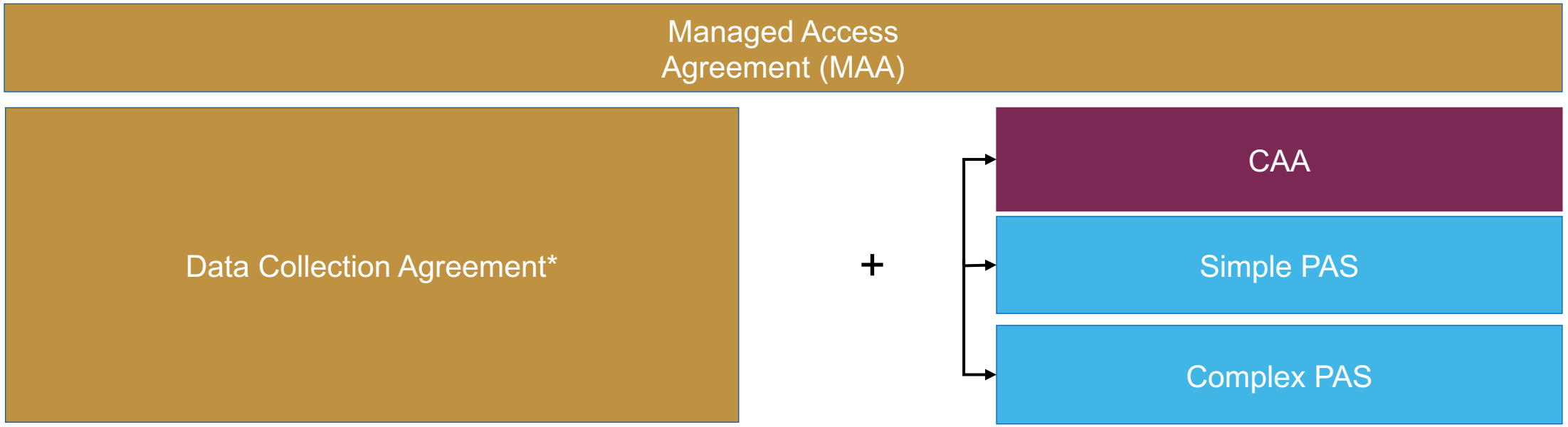


It should be noted that all criteria need to be met before a potential discussion on commercial flexibility can be considered

Managed Access Agreements Explained

A MAA consists of two components:-

- 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.



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

Revisiting workshop objectives

- ✓ Bringing the commercial framework to life.
- ✓ Ensuring attendees have a good understanding of the commercial framework.
- ✓ Update on feedback received.

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Thank you!

nina.pinwill@nhs.net