



Department  
of Health &  
Social Care

# Developing and testing innovative models for the evaluation and purchase of antimicrobials: subscription-based payment model

**March 2020**

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# Housekeeping

- Duration of webinar is approximately two hours
- All participants are muted by default
- Use the 'Q&A section' to send in your questions. You can click 'Send Anonymously' if you do not want the panellists to see your name. Questions will be seen only by the panellists who will read them out during presentation

# Agenda

1. Purpose of today
2. Background
3. Overview of Procurement
4. Competitive Dialogue Process
5. Award Methodology & Criteria
6. Payment Model
7. Contract
8. Health Technology Assessment
9. Specifications
10. Engagement
11. Next Steps

# Purpose of today

- Set out how the subscription based model will work
- Seek feedback on;
  - Award methodology,
  - Payment model,
  - Selection criteria, etc.

# Background

# Clinical context and need for action

- Antimicrobial resistance (AMR) is one of the most pressing global challenges we face this century
- Although the UK has made progress in reducing the use of antimicrobials in humans and animals in the past five years, drug resistant bloodstream infections in humans increased by 35% from 2013-2017 in England. <https://www.gov.uk/government/news/antimicrobial-resistance-uk-launches-5-year-action-plan-and-20-year-vision>
- For most antimicrobials, there are few replacements or alternative products in development and even fewer that target priority pathogens
- Investment in novel antimicrobials is widely seen as commercially unattractive – the high R&D costs and low returns have led to market failure

# Market failure

- The market for a new antimicrobial following launch may be limited in two main ways:
  - New products active against priority pathogens should be subject to strict stewardship and used on a last in line basis. In the absence of significant outbreaks of drug-resistant infections, sales could be minimal
  - New products offering alternative options to existing antibiotics, which could potentially be valuable as part of “cycling” stewardship regimes, tend not to be used due to their high cost compared to existing products (many of which are generics)

# Current pipeline

Only **42** new antimicrobial compounds in phase I-III clinical trials (March 2019)

<https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2019/09/tracking-the-global-pipeline-of-antibiotics-in-development>

*Compared with **3,876** immuno-oncology agents in development (September 2019)*

<https://www.cancerresearch.org/scientists/immuno-oncology-landscape>

**There is an urgent need to  
increase investment**



# Success

- An agreed HTA valuation framework and complete value assessment of two products
- An agreed payment framework that leads to successful negotiation of payments for the two products, supporting good stewardship
- Other countries test models that, together, achieve pull incentives for antimicrobials and stimulate companies to increase investment

# Progress

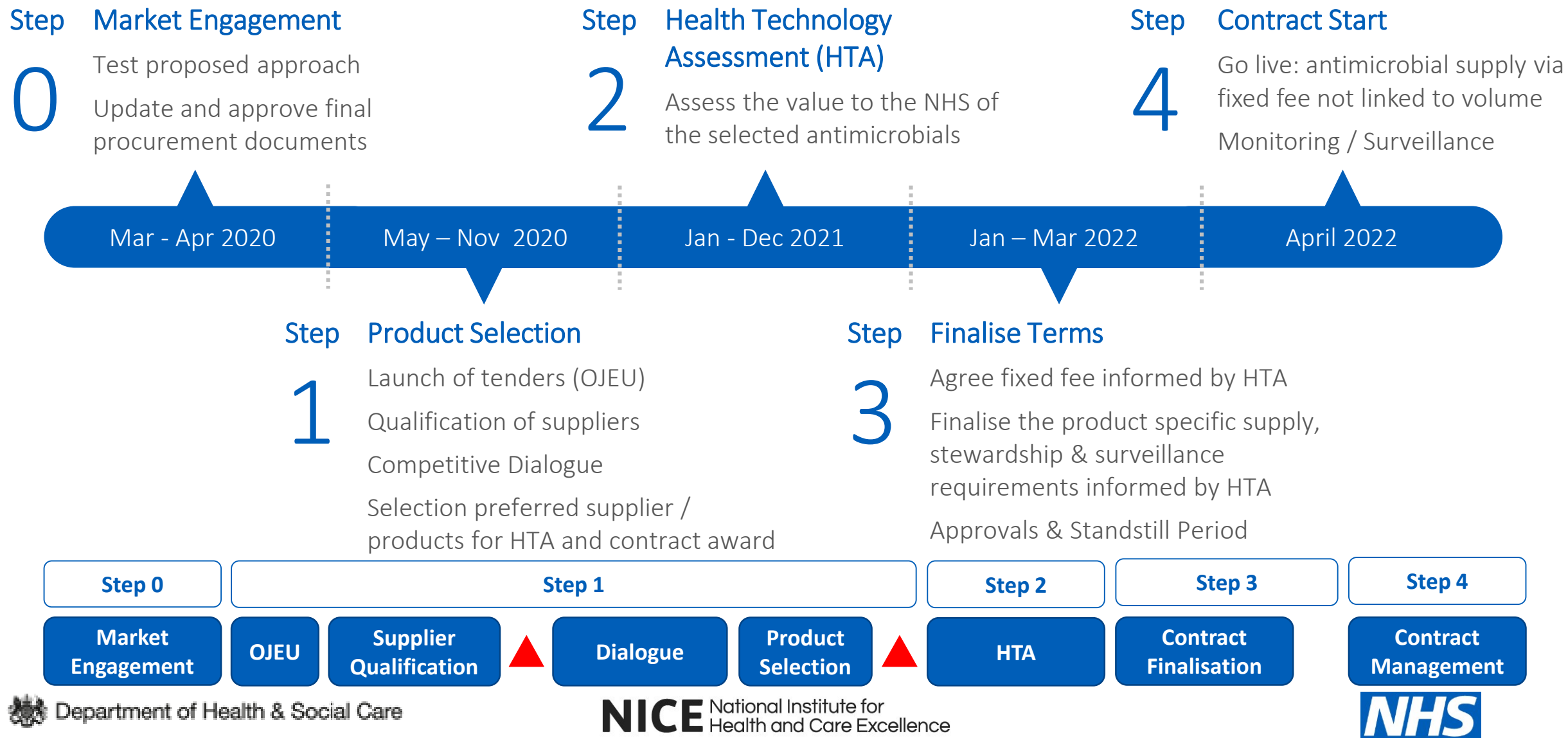
- **July 2019:** Project launched
- **September 2019:** Completion of stakeholder engagement on draft evaluation framework, product selection process and commercial model
- **November 2019:** Stakeholder webinar covering outcomes from the targeted engagement and outline procurement process
- **February 2020:** Project Advisory Group recruited
- **March 2020:** Draft documents for procurement process (via competitive dialogue route) shared with stakeholders
- **March 2020:** Webinars with companies and broader stakeholders to support market engagement

# Overview of the Procurement

# Procurement Headlines

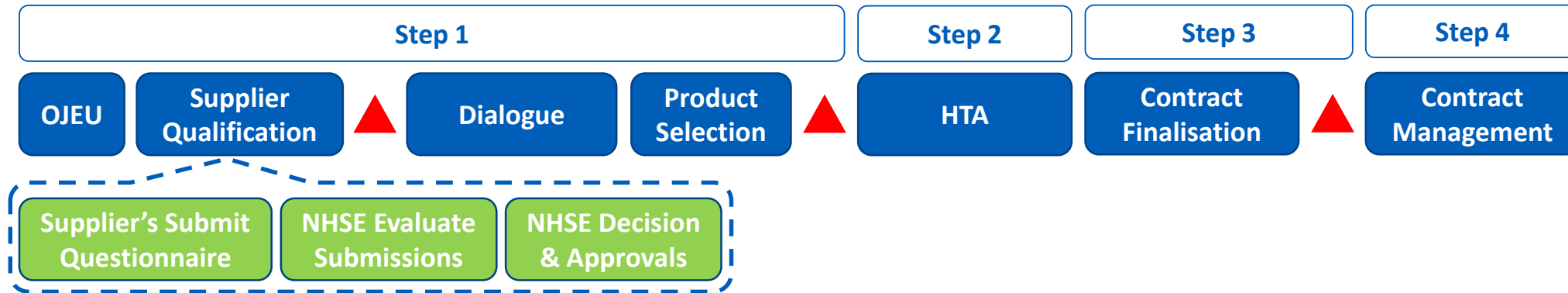
- 2 Separate Procurements – 1 for Existing Antimicrobials, 1 for New Antimicrobials
- 1 Product selected per Procurement
- 5 Key Steps: (Qualification, Product Selection, HTA, Finalise Terms, Contract Start)
- 3 Year initial contract, extendable to 10 years
- £10m per annum maximum fixed fee (Subject to HTA outcome)
- Fixed fee contingent upon achieving performance requirements (e.g. availability, stewardship, etc)
- Public Contract Regulations 2015 Competitive Dialogue process
- Final tender documents will be informed by feedback from this market engagement

# Summary Process & Timetable



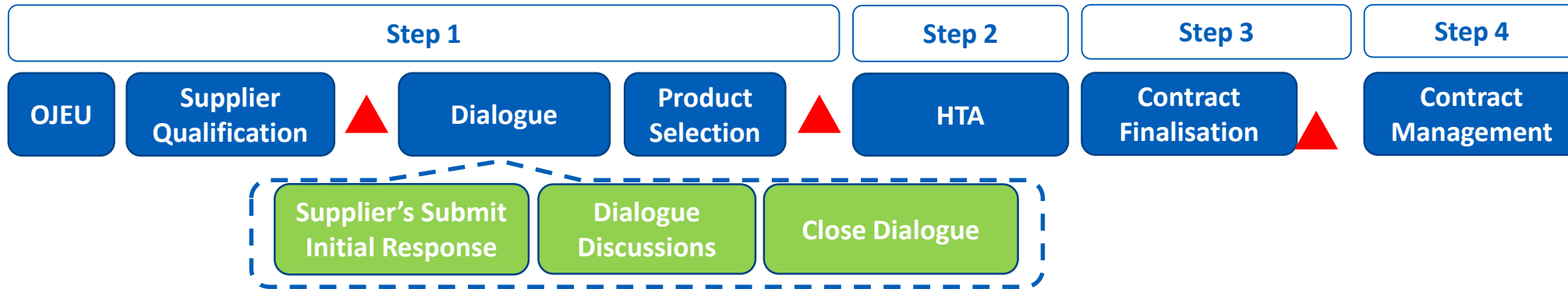
# The Competitive Dialogue Process

# Competitive Dialogue Process – Qualification



<b>OJEU Notice</b>	The procurement will commence with publication of the Contract Notice in the Official Journal of the European Union
<b>Procurement Documents</b>	Suppliers will be able to register their interest and access the Qualification Questionnaire via the NHS England BravoSolution eTendering Portal at: <a href="https://nhsengland.bravosolution.co.uk/web/login.html">https://nhsengland.bravosolution.co.uk/web/login.html</a> Suppliers will also be able access a <u>draft</u> version of the Invitation to Participate in Dialogue
<b>Supplier Qualification</b>	Suppliers interested in participating in the procurement must complete and submit their response to the Qualification Questionnaire prior to the specified deadline (c30 days from OJEU publication)
<b>Decision Point</b> ▲	<b>ONLY</b> suppliers that pass the Qualification Criteria will be invited to participate in dialogue. Suppliers will be notified at this point if they have been successful or unsuccessful

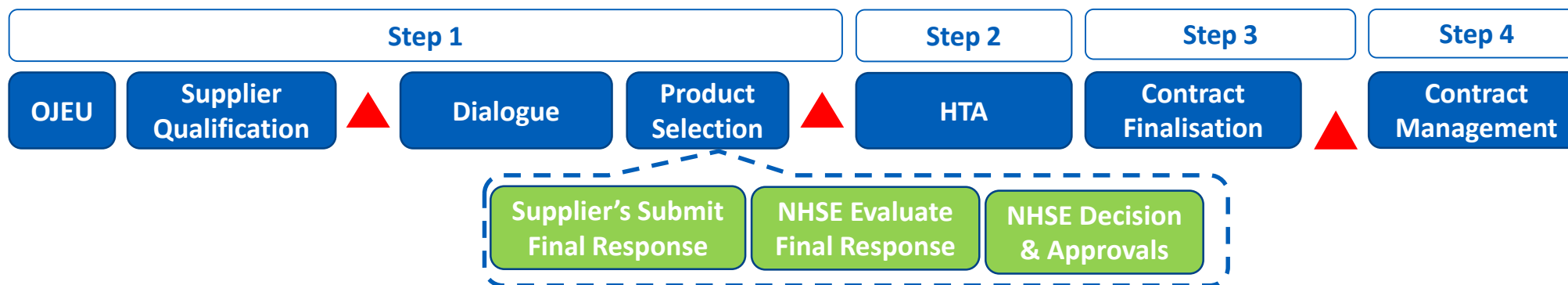
# Competitive Dialogue Process – Dialogue




<b>Invitation to Participate in Dialogue (ITPD)</b>	Suppliers that pass the Qualification Criteria will be invited to participate in dialogue be able to access the <u>final</u> Invitation to Participate in Dialogue documents at: <a href="https://nhsengland.bravosolution.co.uk/web/login.html">https://nhsengland.bravosolution.co.uk/web/login.html</a>
<b>Initial Response</b>	Suppliers will be required to submit an initial response to describe how they will meet the requirements and satisfy the award criteria. The initial submissions will not be evaluated, nor will they result in Suppliers being down selected. These submissions will form part of dialogue.
<b>Dialogue</b>	We anticipate dialogue to include discussions regarding product characteristics; payment mechanism; performance criteria; commercial terms; antimicrobial access, stewardship and surveillance; and contract monitoring & performance. Suppliers may propose additional topics
<b>DRAFT ISFT</b>	The Authority may enable Bidders to prepare and submit a draft final tender response
<b>Close Dialogue</b>	Once satisfied that the solutions(s) proposed by Suppliers substantially meet all the requirements, the Authority will declare Dialogue to be concluded

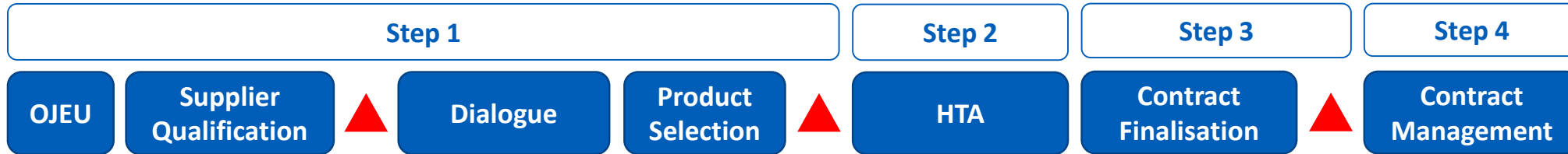


# Competitive Dialogue Process – Selection



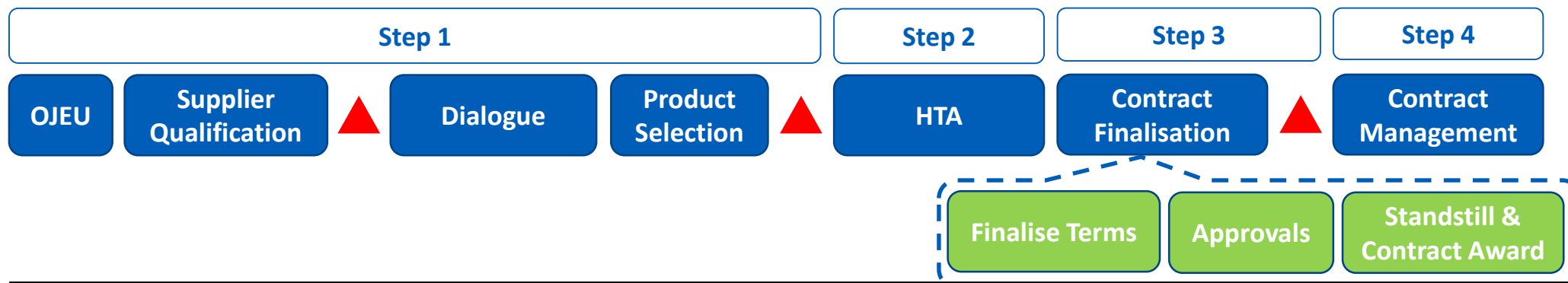
<b>Invitation to Submit Final Solutions (ISFS)</b>	Once dialogue has been closed, the Authority will issue the Invitation to Submit Final Solutions. The ISFS will reflect the final requirements and contractual terms against which Suppliers will prepare their final proposals.
<b>Submit Final Response</b>	Suppliers will typically have a couple of weeks after dialogue to finalise their proposal and to submit them via the Portal at: <a href="https://nhsengland.bravosolution.co.uk/web/login.html">https://nhsengland.bravosolution.co.uk/web/login.html</a>
<b>Evaluation</b>	The final responses will be evaluated by the Authority in accordance with the published award methodology and award criteria. The evaluation process will recommend a single Supplier to proceed to HTA and contract finalisation.
<b>Decision Point</b> 	<p>The recommendation from the evaluation process is subject to approval via the Authority's governance processes.</p> <p>Suppliers will be notified of the evaluation outcome. However this does not yet constitute the award of a contract or a promise or decision to award a contract.</p>

# Competitive Dialogue Process – HTA



To be covered later in presentation

# Competitive Dialogue Process – Finalisation



## Finalise Terms



Contract finalisation will conclude:

- The annual fee to be paid to the supplier (contract value);
- Limited adjustments to the service, stewardship and surveillance requirements to reflect the HTA recommendations;
- Limited adjustments to the contract performance criteria (KPIs) to reflect the HTA recommendations.

## Approvals

Confirmation that both the Authority and Supplier agree and accept the final contract terms

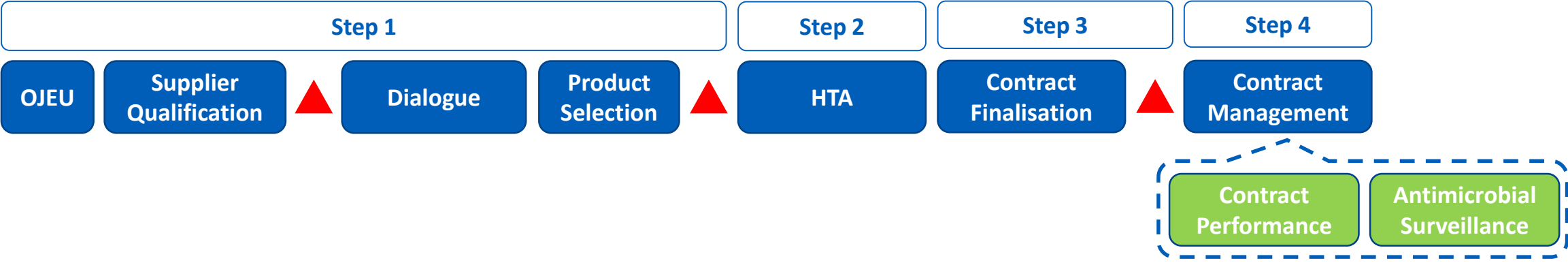
## Standstill Period

Once the Authority has reached a decision in respect of contract award it will notify all Bidders of that decision and provide a standstill period of 10 calendar days before entering into the Contract with the Winning Bidder.

## Contract Award

Once the Standstill period has concluded, the Authority will exchange contracts with the winning Bidder

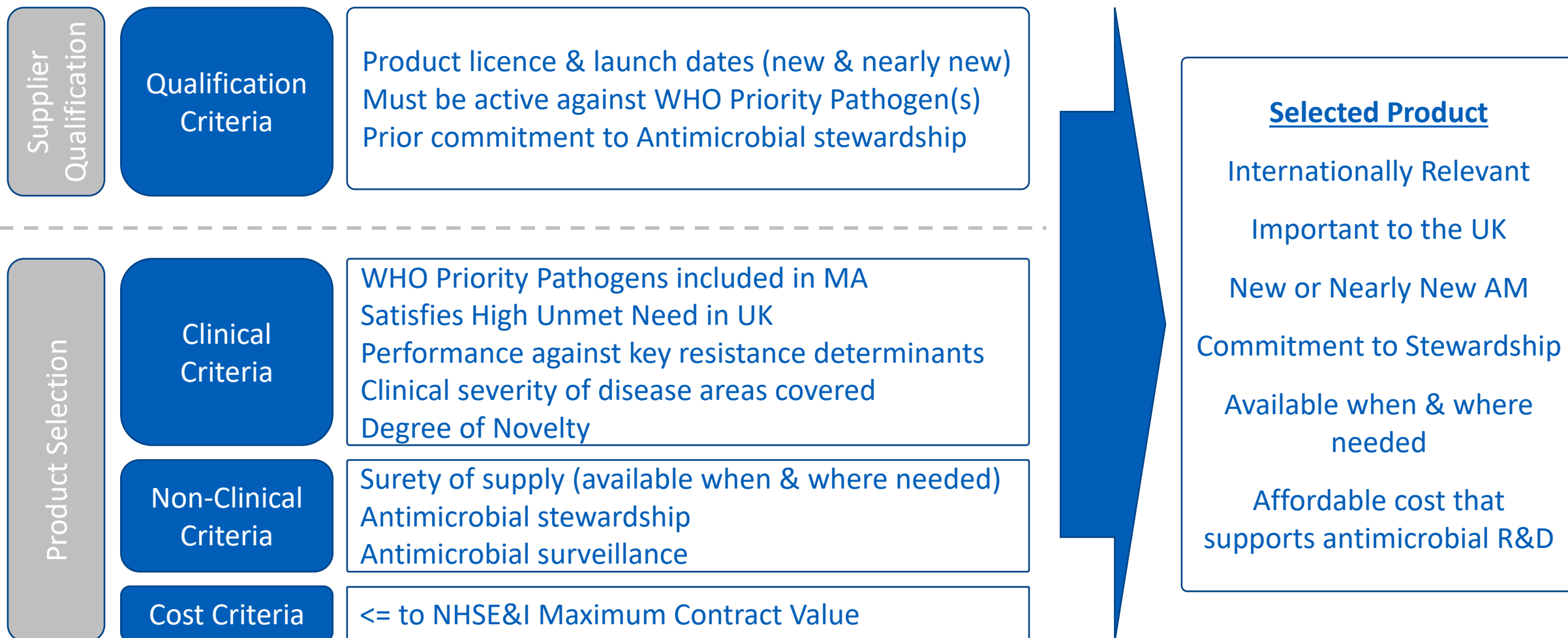
# Contract Management



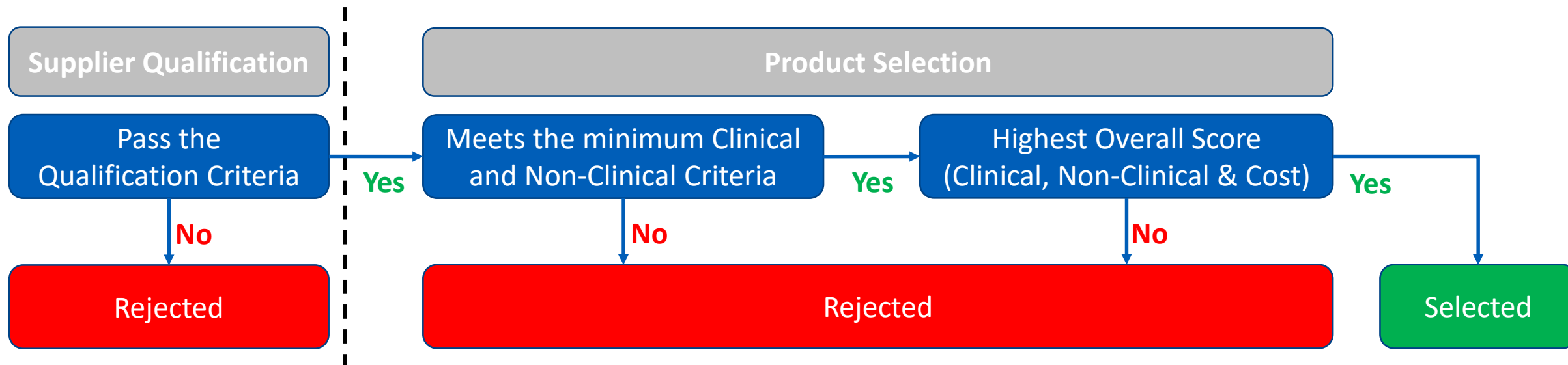
Contract Performance	Monthly Supplier Deliveries Report Quarterly Supplier Performance Report Quarterly Contract Management Meeting
Antimicrobial Surveillance	Monitor usage Monitor emergence of resistance

# Award Methodology & Criteria

# Qualification & Product Selection: Criteria



# Qualification and Award Methodology



Suppliers must pass the Qualification Criteria to be considered;

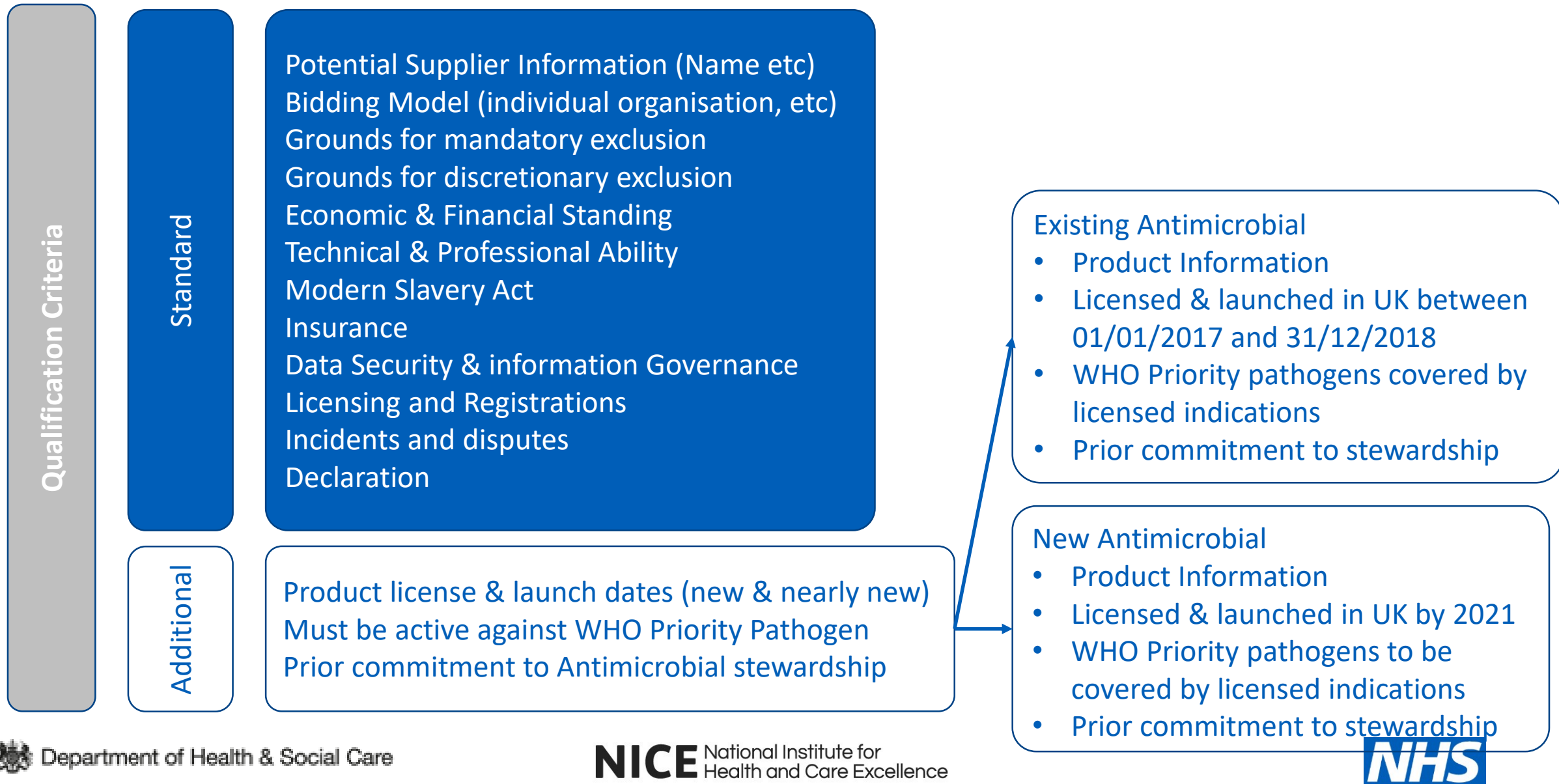
The criteria select products that score highest against the clinical and non-clinical criteria;

Only products that achieve a minimum clinical and non-clinical score are considered for award;

The thresholds can be reduced in defined steps if no product meets the initial thresholds;

Of those products that meet the minimum clinical and non-clinical scores, the product that achieves the highest overall score (clinical, non-clinical & cost) is selected

# Qualification Criteria





# Product Selection Criteria

2020-03-25 NHS AMR Market Engagement Briefing-Final

Page 25

Product Selection Criteria	Question	Focus	Scoring	Maximum Points
	AMR1	Who Priority Pathogen	Priority 1, 2 and 3 Pathogens	11,250
		Unmet need in England	High, Medium & Low	6,000
		Key Resistance Determinants	High, Medium, Low & None	6,000
		Disease Setting	High, Medium & Low	6,000
	AMR2	Degree of Novelty	New Class	2,000
			New Pathogen Target	1,500
			New Mode of Action	15,00
			Reduced Susceptibility	1,500
			No Cross Resistance	1,000
			Additional Benefits	500
	AMR3	Surety of Supply	Confidence Minor Concerns Concerns Major Concerns	5,000
	AMR4	Antimicrobial Stewardship		5,000
	AMR5	Antimicrobial Surveillance		5,000

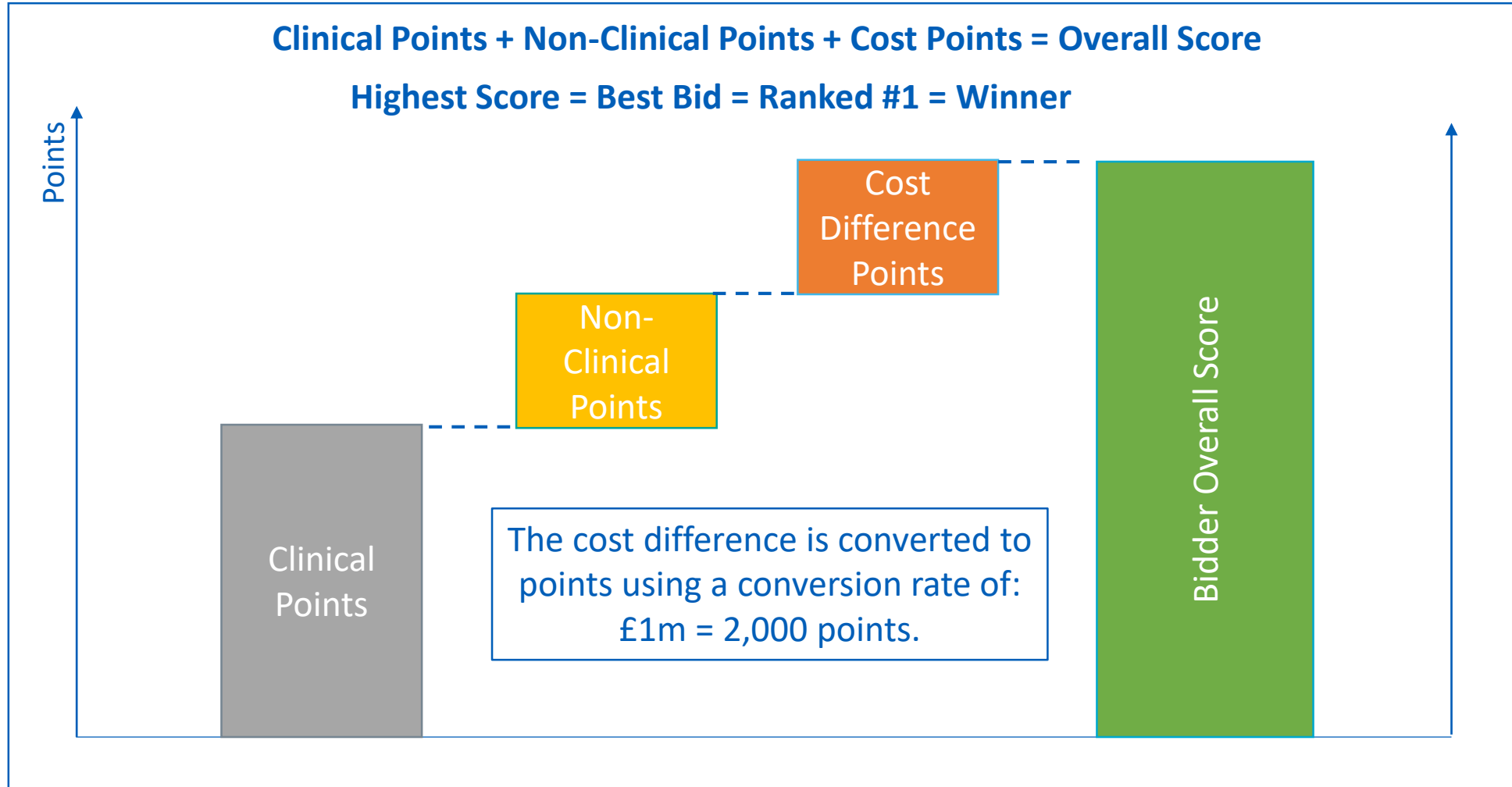
# Minimum Clinical & Non-Clinical Scores

If no Bidder achieves the minimum scores for the clinical and non-clinical criteria at the Final Tender stage, then the Authority may reduce the thresholds until one or more Bidders satisfy the revised threshold.

	Clinical Score Threshold	Non-Clinical Score Threshold
<b>Initial Threshold</b>	Greater than or equal to 24,200 points (c67% of the Maximum Score)	Greater than or equal to 3,500 points for each of AMR3, AMR4 & AMR5
<b>Revised Threshold 1</b>	Greater than or equal to 21,800 points (c60%)	Average of AMR3, AMR4 & AMR5 is greater than or equal to 3,500 points
<b>Revised Threshold 2</b>	Greater than or equal to 19,600 points (c54%)	
<b>Revised Threshold 3</b>	Greater than or equal to 18,100 points (c50%)	
<b>Revised Threshold 4</b>	Less than 18,100 points	

However, Bidders should note that the Authority may abandon the procurement if it considers that the offered products provide insufficient value to the NHS in England

# Overall Score



# Payment Model

# Payment Model

Fixed Fee per annum

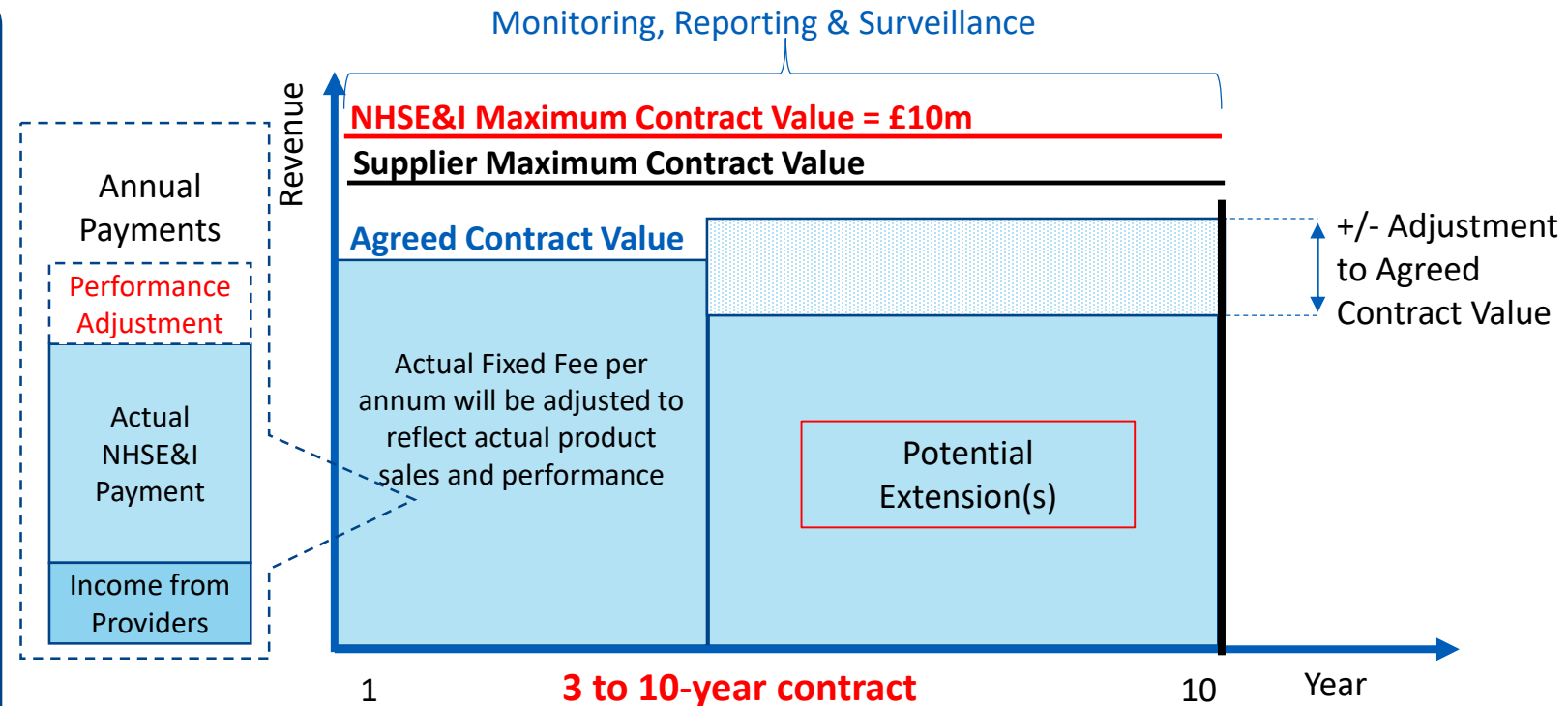
Fixed Fee is capped at lower of NHSE&I or Supplier Maximum Contract Value for term of contract

Agreed Fee is informed by outcome of NICE HTA

Fee paid is performance dependent & minus cost of supplies to hospitals

Performance Requirements (Draft):

- Surety of supply
- Antimicrobial Stewardship
- Good AM manufacturing practice
- Good AM environmental practice
- Monitoring & reporting
- Antimicrobial Surveillance



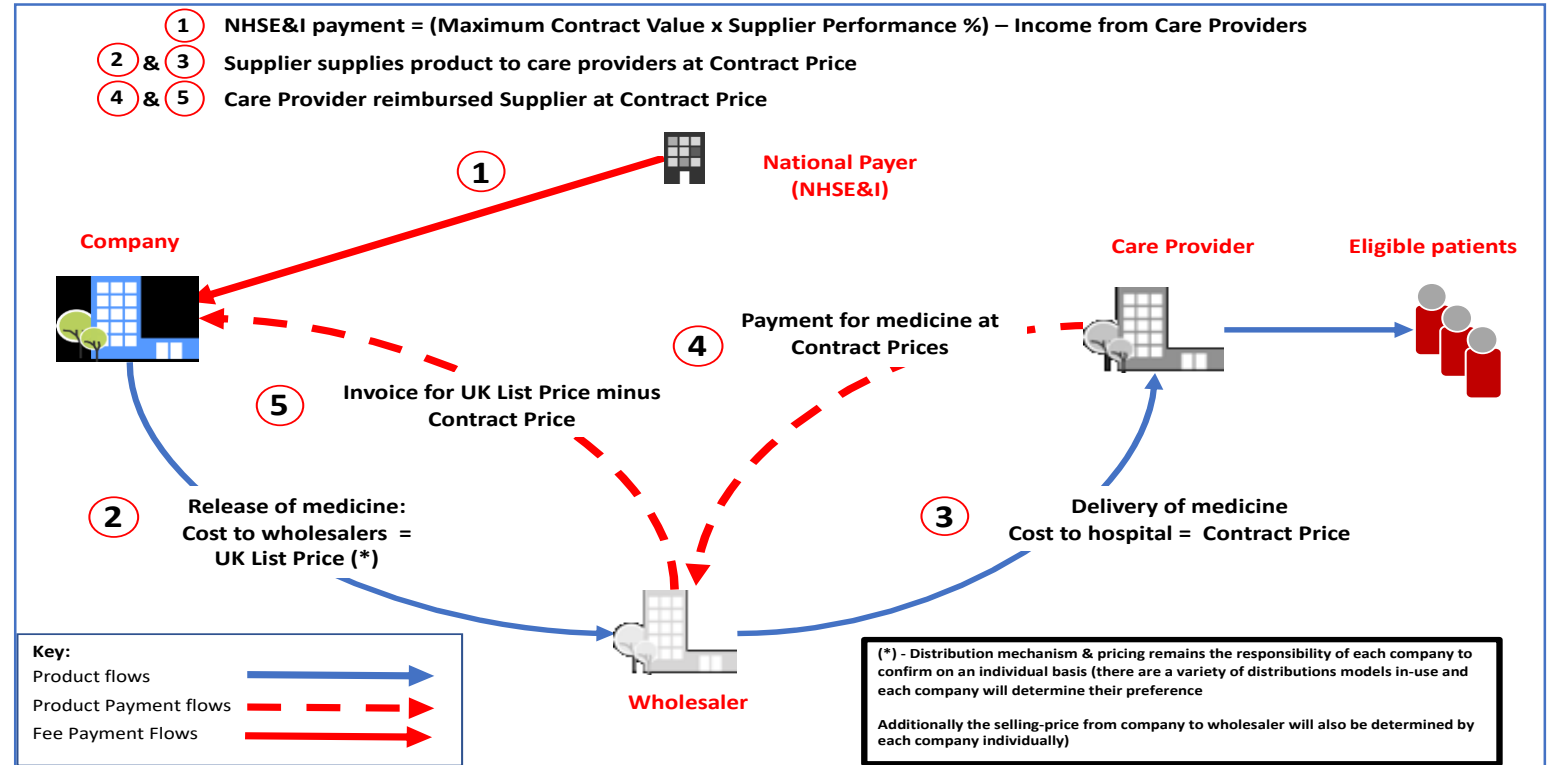
The Agreed Contract Value, adjusted for performance and care provider purchases, will be paid in quarterly instalments.

# Payment Flows

NHSE&I pays the supplier the agreed fee in quarterly instalments, adjusted for performance and minus any adjustments for product supplied to care providers;

The supplier provides the product to the care provider at the Invoice Price (via a wholesaler if that is their current / preferred delivery model);

The care provider reimburses the supplier (if needed via a wholesaler) at the Invoice Price



A national list price will be maintained for the purposes of international reference pricing.

An Invoice Price will be agreed with each Bidder as part of the procurement process. All NHS care providers will purchase the product at the agreed Invoice Price.

# Contract Review

The Authority may initiate a contract review if:

- the supplier significantly or repeatedly underperforms against the service or stewardship requirements; or
- if, in the opinion of NHSE&I, there has been a material change to the assumptions used within the HTA; or
- if, in the opinion of NHSE&I, there has been a material reduction to the unmet need addressed by the product.

A Review may result in:

- reduction of the Maximum Contract Value (subject to the agreement of the supplier);
- adjustment of the performance requirements or the performance criteria;
- adjustment of the data capture and reporting requirements;
- termination of the contract.

# Performance Criteria

<b>Stewardship</b>	No promotion of the product No sales team incentives
<b>Surety of Supply</b>	Product delivered with [xx] [hours][days] of order
<b>Manufacturing Practice</b>	[AMR Industry Alliance – Making Antibiotics Responsibly audit report indicates the supplier / their supply chain has not satisfied the minimum expectations] Initial Report to be provided by the Supplier to the Authority within first contract year
<b>Environmental Practice</b>	[AMR Industry Alliance – Making Antibiotics Responsibly audit report indicates the supplier / their supply chain has not satisfied the minimum expectations] Initial Report to be provided by the Supplier to the Authority within first contract year
<b>Monitoring &amp; Reporting</b>	Monthly Report Deliveries Supply chain status Key risks & issues together with proposed mitigations
<b>Antimicrobial Surveillance</b>	[Quarterly] Surveillance Report



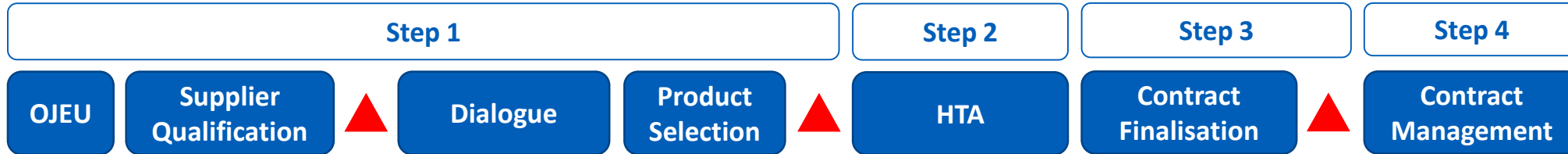
# Contract

# Contract

<b>Form</b>	NHS Standard Contract for the Supply of Goods and the Provision of Services (Contract version)
<b>Parties</b>	NHS England and the Supplier
<b>Key Provisions</b>	<p>The Contract will contain (amongst other 'local' terms):</p> <ul style="list-style-type: none"><li>• bespoke payment provisions;</li><li>• obligations on the Supplier to deliver the antimicrobial included in their Final Offer;</li><li>• obligations on the Supplier to comply with the performance requirements;</li><li>• obligations on the Supplier to comply with the specifications; and</li><li>• the standard Commercial Medicines Unit (CMU) provisions regarding the supply of pharmaceuticals;</li></ul>
<b>Duration</b>	Initial period of 3 years with the Authority having the option to extend for a period, or periods up to a total of 10 years
<b>Contract Start</b>	1 April 2022
<b>Transition</b>	In the event that contracts are awarded as a result of this procurement, then any existing framework agreements for the supply of the antimicrobial will be terminated.

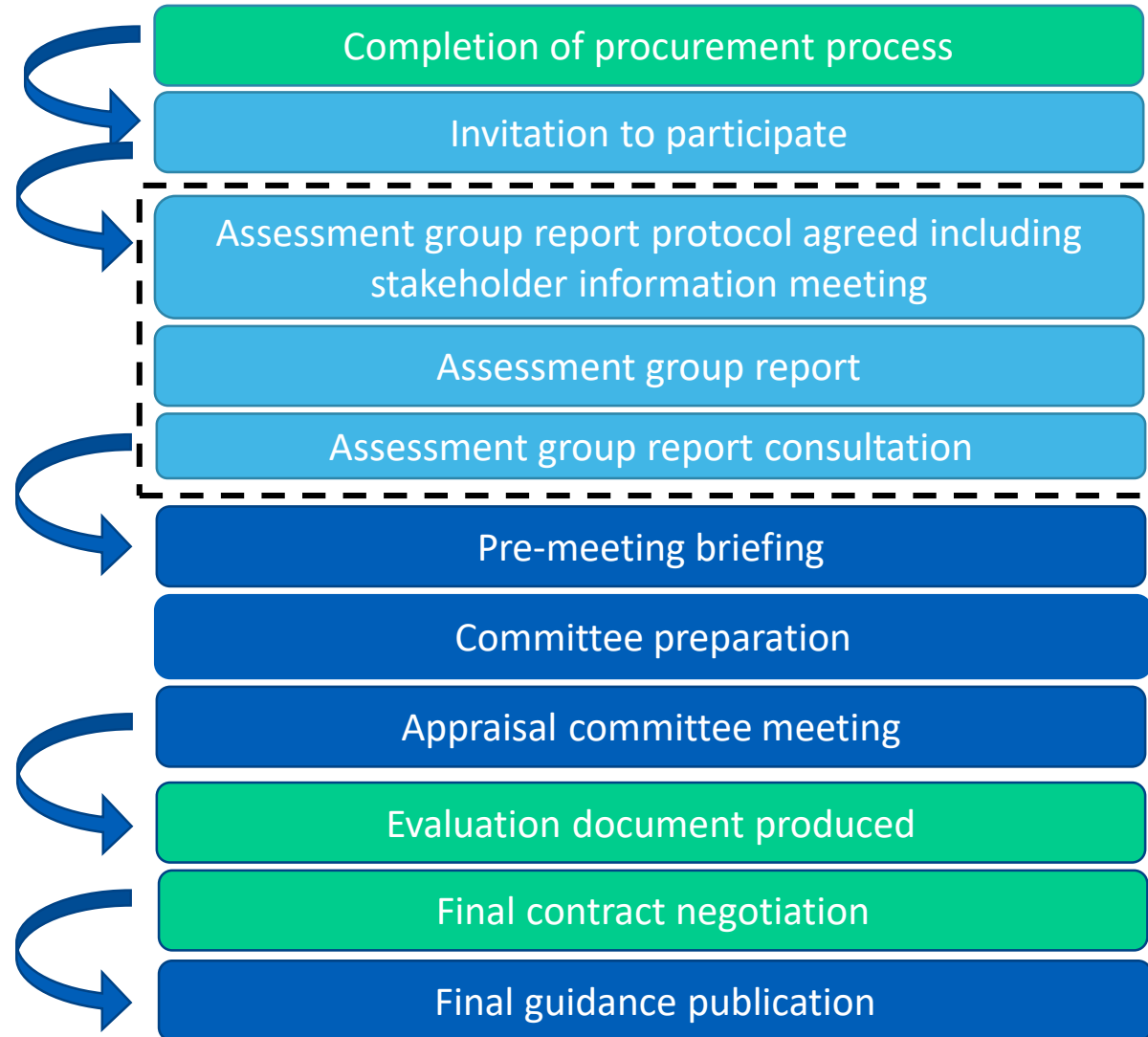
# Health Technology Assessment (HTA)

# Proposed NICE HTA evaluation process and timelines

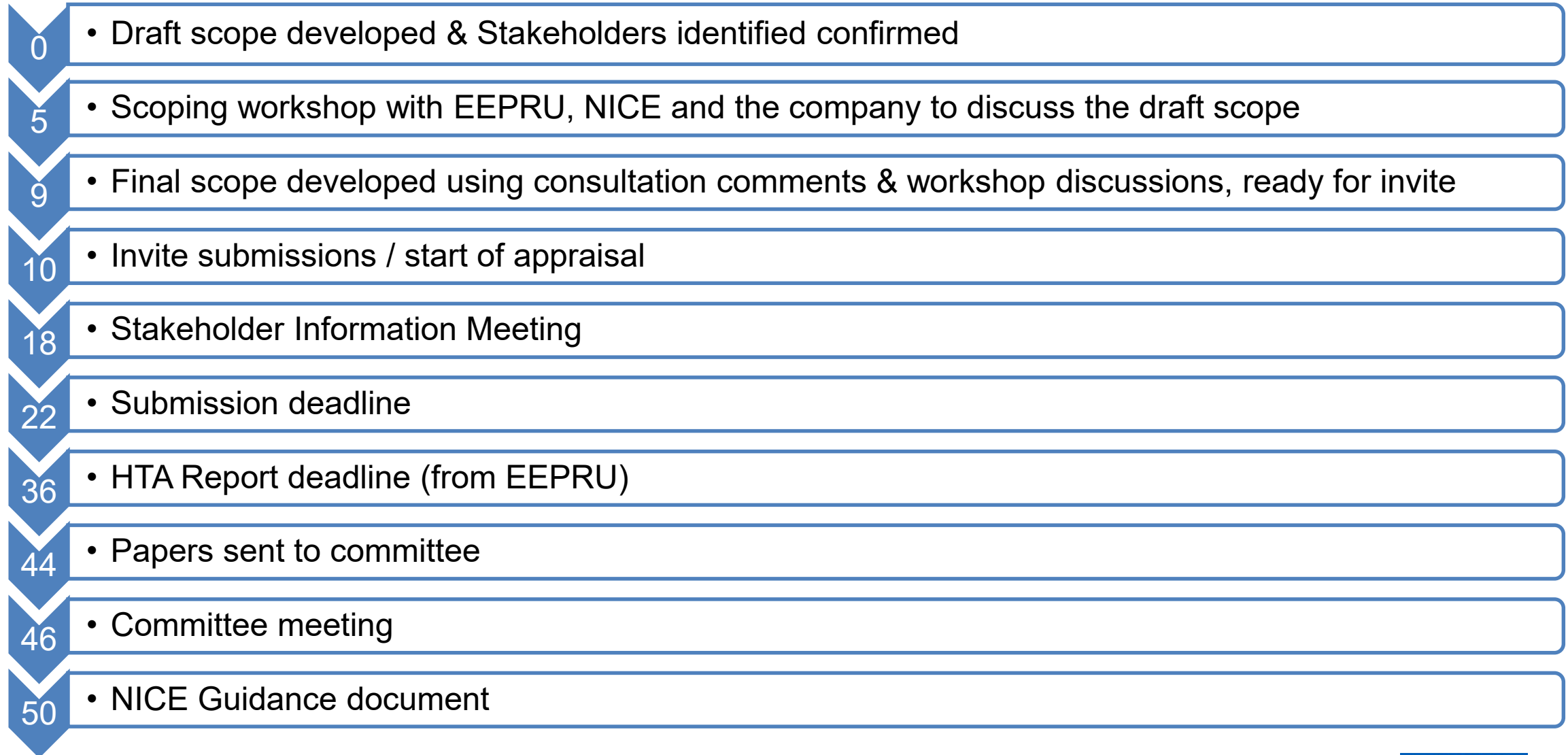


- Process based on Multiple Technology Appraisal process
- Special committee:
  - Approximately 10 members from current NICE committees with 6 additional members with specialist expertise
  - Chair: Gary McVeigh
  - Vice-chair: Amanda Adler
- Assessment Group report will be prepared by EEPRU
- Output of NICE process will be a guidance document used to inform final contract negotiations

# Evaluation process



# Proposed timelines in weeks



# Outline Specifications

## Surety of Supply

- Delivery within x [hours][days] of order
- Commercial Medicines Unit (CMU) Contract Technical Specification for Licensed Medicines for the NHS

## Antimicrobial Stewardship

- No product promotion
- No sales incentives
- Educational materials
- Evidence of complying with “AMR Industry Alliance – Making Antibiotics Responsibly”

## Antimicrobial Surveillance

- Monitor usage
- Monitor emergence of resistance

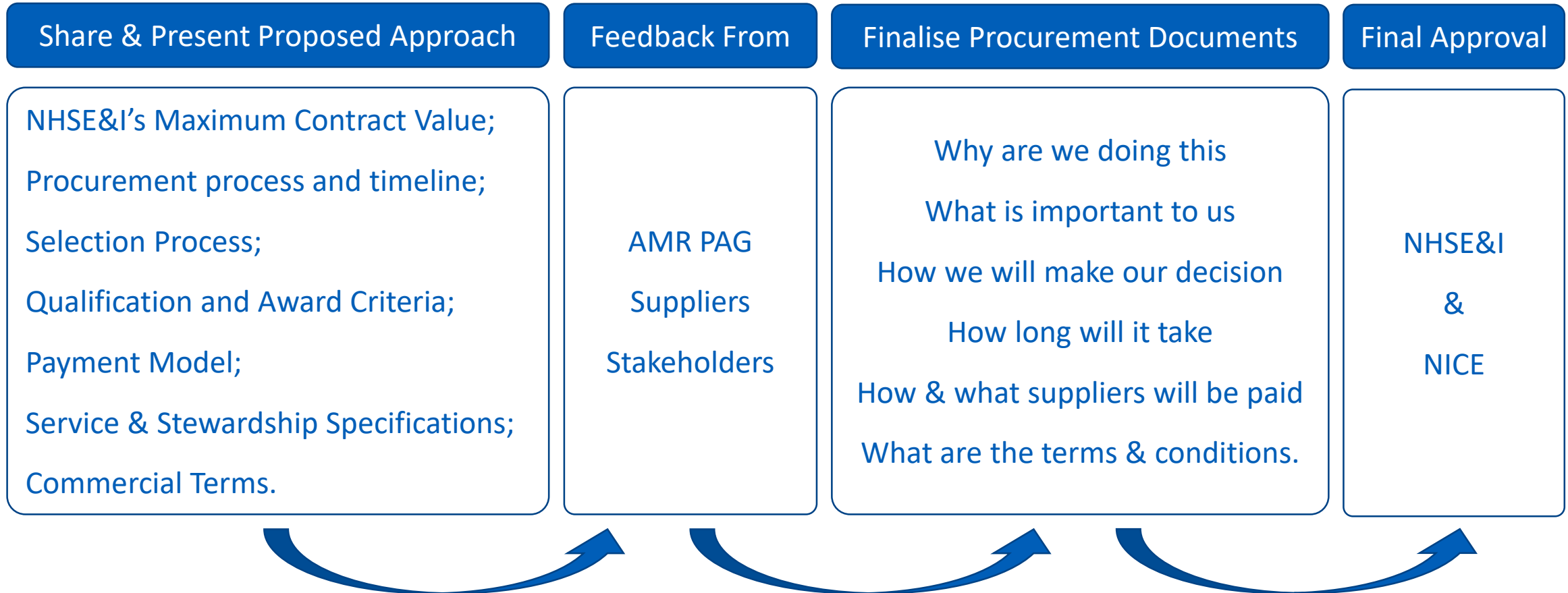
**We are keen to understand what suppliers and stakeholders would like and expect to see in these specifications**

**Please include any suggestions within your feedback**

# Market Engagement



# Market Engagement



# Next Steps

# Next Steps

1. Provide clarification question via [ABpaymentmodels@nice.nhs.uk](mailto:ABpaymentmodels@nice.nhs.uk).
2. Provide feedback on the form provided by 13:00 on Friday 17 April 2020 via [ABpaymentmodels@nice.nhs.uk](mailto:ABpaymentmodels@nice.nhs.uk).

Suppliers do NOT need to register interest or prepare responses yet

The OJEU notice to initiate the procurement and calling for expressions of interest will be launched in May – subject to the feedback received during market engagement

# Questions