**Document No. 02**

**Project title: NHS National Framework for Medical Retinal Vascular Treatments 1 August 2024**

**Offer reference number: CM/PHS/24/5707**

**Period of framework: 1 August 2024 to 31 July 2025, with an option or options to extend (at the Authority's discretion) for a period or periods up to a total of 24 months**

**Published By: Medicines Procurement and Supply Chain – NHS Medicines Value & Access, NHS England**

**Terms of offer**

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13. **Notice to Offerors**
    1. This Invitation to Offer ("ITO") document is being made available on the condition that the information contained within it is used solely in connection with this competitive process to procure **the Requirement** (as defined hereinafter) on behalf of NHS England (the "**Authority**") and for no other purpose.
    2. Whilst reasonable care has been taken in preparing the ITO, neither the Authority nor any of its advisers accepts any liability or responsibility for the adequacy or completeness of any information or opinions stated in this ITO. No representation or warranty, express or implied, is or will be given by the Authority or any of its representatives, employees, agents or advisers with respect to the ITO or to any information on which it is based. Any liability for such matters is expressly disclaimed
    3. In this ITO document, words such as “**anticipates**”, “**expects**”, “**intends**”, “**plans**”, “**believes**” and “**will**” (and words and terms of similar substance) indicate the Authority's present expectation of future events, which are subject to a number of factors and uncertainties that could cause actual requirements to differ materially from those described.
    4. Neither the issue of this ITO nor any of the information presented in it should be regarded as a commitment or representation on the part of the Authority (or any other person) to enter into a contractual arrangement. If an Offeror submits an Offer and/or proposes to enter into an agreement with the Authority, it must rely on its own enquiries and on the terms and conditions set out in the agreement(s) (as and when finally executed), subject to the limitations and restrictions specified in it.
    5. In so far as it is compatible with any relevant laws, the Authority reserves the right, without prior notice, to change the basis of, or the procedures for, the process for the award of the contract or to reject any or all Offers and to terminate discussions involving (directly or indirectly) Offerors at any time. In no circumstances will the Authority incur any liability in respect of the foregoing.
14. **Introduction**
    1. **Background**
       1. The Procurement relates to the supply of medical retinal vascular Anti Veg-F and Intravitreal Corticosteroid medicines used in medical retinal vascular services for the NHS in England.
       2. There are currently ten licensed Anti Veg-F and Intravitreal Corticosteroid medicines in England, these are:
          1. Aflibercept (Eylea®)
          2. Aflibercept (Eylea HD®)
          3. Brolucizumab (Beovu®)
          4. Dexamethasone Intravitreal implant (Ozurdex®)
          5. Faricimab (Vabysmo®)
          6. Fluocinolone acetonide Intravitreal implant (Iluvien®)
          7. Ranibizumab (Byooviz®)
          8. Ranibizumab (Lucentis®)
          9. Ranibizumab (Ongavia®)
          10. Ranibizumab (Ximulci®)
       3. Anti Veg-F and Intravitreal Corticosteroid medicines are currently used in the treatment of:
          1. neovascular (wet) age-related macular degeneration (AMD);
          2. visual impairment due to diabetic macular oedema (DME/DMO);
          3. visual impairment due to myopic choroidal neovascularisation (myopic CNV);
          4. visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central CRVO);
          5. proliferative diabetic retinopathy (PDR);
          6. inflammation of the posterior segment of the eye presenting as non-infectious uveitis; and
          7. prevention of relapse in recurrent non-infectious uveitis.

2.1.4 Age-related macular degeneration (AMD) remains a leading cause of sight impairment despite new treatment options. It is estimated to affect 600,000 people in the UK, with 39,800 patients developing “wet” AMD each year. <https://www.rcophth.ac.uk/news-views/national-ophthalmology-database-amd-audit/>

* 1. **National Eye Care Recovery and Transformation Programme**
     1. In recent years, the NHS has been seeking to reform care through pathway and service integration. Prior to 2020, this was through the National Outpatient Transformation Project, which began in 2018/19 which then grew into the National Pathway Improvement Programme.
     2. The NHS Pathway Improvement Programme brings together all NHS Improvement Programmes and aims to avoid duplication of effort, by coordinating resources so that transformation is delivered across the whole pathway.
     3. The National Eye Care Recovery and Transformation Programme will enable and support all local systems in England to deliver radical transformation of eye care services across primary, secondary and community care; driving the development of innovative, integrated, safe and sustainable ways of working.
     4. Through supporting local systems to develop and implement their plans for the immediate restoration and ongoing transformation of services, the program aims to:
* Support the immediate, rapid restoration of eye care services;
* Prevent unnecessary, irreversible sight loss and improve access to care for all driven by clinical need;
* Avoid all unnecessary face to face outpatient attendances; and
* Embed new ways of working and enable ongoing local transformation of outpatient eye care services across primary, secondary and community care.
  1. **Procurement Objectives**

2.3.1 This Procurement seeks to support delivery of the National Eye Care Recovery and Transformation Programme through the following key objectives.

1. **Reduction in unwarranted variation:** Reduce the number of patients that should be, and are not, treated and reduce the number of patients who are treated for whom treatment is inappropriate or ineffective;
2. **Maintain clinical choice:** Clinicians will continue to determine which medical retinal vascular treatments are clinically appropriate for each patient and will be able to access all available treatments.
3. **Make best use of NHS resources:** To support transformation into eyecare services, if a prescribing clinician and their patient identifies that there are multiple clinically appropriate treatment alternatives, they will be encouraged to choose the lowest cost option or one of the lower cost options.
4. **Overview of the Procurement**
   1. **Introduction** 
      1. The Authority is undertaking this Procurement in accordance with the Public Contracts Regulations 2015 (as amended) and will use the Open Procedure.
   2. **Procurement Approach**
      1. Offerors should note that this Procurement process is separate to and distinct from any guidance or processes the Authority may introduce with regard to commissioning decisions and/or recommendations.
      2. Section 11 of this ITO provides further details about the approach the Authority may take to determine any commissioning recommendations.
   3. **Overview of the Procurement Process**
      1. The Procurement process includes the following key steps:

a, Invitation to Offer;

b, Evaluation of Offers;

c, Contract Award;

d, Contract Finalisation and Mobilisation; and

e, Contract Start.

* + 1. Where an Offer for a product is determined to be successful (in accordance with the criteria and methodology set out below), then a separate award will be made for each such product and each such product will form the subject matter of a separate, single-supplier Framework Agreement.
  1. **Timetable**
     1. The indicative timetable for the Procurement is set out below. Whilst the Authority does not intend to depart from the timetable, it reserves the right to do so at its sole discretion.

|  |  |
| --- | --- |
| **Activity** | **Date** |
| Invitation to Offer Published (via Atamis) | 11/03/24 |
| Deadline for submission of Clarification Questions | 05/04/24 |
| ITO Submission Deadline | 10/04/24 |
| ITO Evaluation Completed | 26/04/24 |
| Approval to Award | 28/05/24 |
| Contract Award Notifications Published (via Atamis) | 03/06/24 |
| Completion of Standstill Period | 12/06/24 |
| Completion of Contract Finalisation & Mobilisation | 03/07/24 |
| Contract Commencement | 01/08/24 |

**Table 1 – Indicative Procurement Timetable**

* + 1. **Invitation to Offer Documents**
    2. Documents and information related to the Procurement are located in the Documents section of the NHS England Atamis E-Tendering Portal.
    3. The Authority may update the Procurement Documents and information from time to time. The Authority also reserves the right to amend or alter this Procurement process (upon reasonable notice and to the extent it is lawfully permitted to do so) and/or the subsequent commissioning guidance and/or processes.
    4. The Offeror's Authorised Representative will be notified of any changes to the Procurement Documents via the Atamis portal.
    5. Any difficulties or problems with access to the NHS England Atamis E-Tendering Portal or any of the documents or information contained therein should be reported via the Atamis Helpdesk.
    6. The Invitation to Offer includes:
       1. Document No. 01 - Invitation to offer covering letter
       2. Document No. 02 Terms of Offer
       3. Document No. 03 - Framework Agreement and Terms and Conditions
       4. Document No. 04a - Quality Assurance Process
       5. Document No. 04b - Assessment Criteria, Stability Protocol and Additional

Specification Requirements

* + - 1. Document No. 05a - Offer Schedule
      2. Document No. 05b - Prevent or Perfect Initiatives Template
      3. Document No. 06 - Form of offer
      4. Document No. 07a - Quality control technical sheet
      5. Document No. 07b - Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines v6 (Issued October 2023)
      6. Document No. 08 – Confidentiality Undertaking
      7. Document No. 09 – FOIA
  1. **Overview of the Offer Requirements**
     1. Offerors must complete the Selection Questionnaire (Qualification Envelope)
     2. Offerors must include within their Offer a Price for each product they wish to be considered for in accordance with the pricing requirements specified in paragraph 5.3.
     3. Offerors may include within their Offer a commitment to invest in Prevent or Protect initiatives.
     4. Offerors may include within their Offer details of any Prevent or Protect initiatives, however these will not be included in the evaluation process.
  2. **Overview of the Evaluation and Award Methodology**
     1. Subject to the Authority’s approval process, a compliant Offer that satisfies the Quality Assurance Assessment and Price Assessment will be awarded on to a single-supplier Framework Agreement
  3. **Overview of the process to determine commissioning recommendations**
     1. The process the Authority may undertake to determine any commissioning recommendations regarding the use of Anti Veg-F and Intravitreal Corticosteroid medicines is separate to and distinct from this Procurement process. Further details of this process are included in Section 11.
  4. **Deadline for submission of Offers**
     1. Offers and all documents relating to the Offers must be written in English and must be submitted to the Authority via the Authority’s Atamis E-Tendering Portal by **13:00hrs (GMT), 10 April 2024**
     2. Please note that Offers received after the closing deadlines may be rejected.

1. **Offer Requirements**
   1. **Documents to Submit**

5.1.1 An Offer must include the following documents, completed in full:

* + - 1. The Selection Questionnaire (see Qualification Envelope on the Atamis E-Tendering

Portal);

* + - 1. Document No.05a - Offer Schedule;
      2. Document No.6 - Form of Offer;
      3. Document No.08 - Confidentiality Undertaking; and
      4. Document No.09 - FOIA Declaration.
    1. In addition, Offerors may include within their Offer one or more Prevent or Protect Initiative Proposals in accordance with the Prevent & Protect Initiative Proposal template provided.
  1. **Compliant Offer**
     1. In order for an Offer to be compliant, it must:
        1. include the documents listed in 5.1.1, completed in full; and
        2. if submitted, include Prevent or Protect Initiative Proposals in accordance with the Prevent or Protect Initiative Proposal template; and
        3. comply with the requirements of 5.3; and
        4. comply with all other requirements of this Invitation to Offer.
  2. **Pricing**
     1. Each Offer must include a price for each product line (in respect of which drug molecule the Offeror is submitting an Offer) at which Participating Authorities can purchase such product lines under the Framework Agreement.
     2. Prices must be stated in Document No.05a – Offer Schedule and must be capable of being accepted by the Authority for 90 days from the closing date for the receipt of Offers.
     3. Prices must be fixed firm (i.e. not subject to variation) for the duration of any framework (and permitted extensions) that may result from this procurement exercise, subject only to any variation provisions contained in the framework agreement.
     4. Prices must be quoted in sterling (GBP) and exclusive of Value Added Tax.
     5. Offers must include a single price proposal for any presentation, strength, and indication across secondary care. Offers must include a single price and may include Prevent and Protect Investments.
     6. The pricing offered in an Offer must include commercial value to the NHS compared to current pricing arrangements in place with the Offeror, taking account of the following:
        1. any national rebates currently available to Participating Authorities in Secondary Care;
        2. any local rebates currently available to Participating Authorities in Secondary Care;
        3. any Commercial Access Agreements; and
        4. any other relevant pricing arrangements.

i.e., taking into account all of the above factors, the pricing proposed in an Offer must not be greater than the weighted average of current pricing arrangements available to the NHS for the relevant Products Offered.

* + 1. If the Authority considers that an Offer does not satisfy the requirements of paragraph 5.3.6, then that Offer may be disqualified.
    2. If the Authority considers that any pricing proposed by an Offeror as part of any Offer is abnormally low, the Authority may require the Offeror to provide further information to explain and justify its pricing proposals (or any aspect of these). If after assessment of any information, explanation or evidence provided by the Offeror, the Offeror does not, in the opinion of the Authority, satisfactorily account for the low level of prices proposed and so leads the Authority to the conclusion that the Offer is abnormally low (so as to put the sustainability and satisfactory delivery of any contract over its term at risk), the Authority reserves the right to reject such Offer.
  1. **Prevent & Protect Investments**
     1. Offerors may include within the Offer Schedule, a financial commitment to fund Prevent or Protect initiatives.
     2. Any financial commitment to fund Prevent or Protect initiatives may be expressed as an investment per Unit supplied.
     3. Where a financial commitment to fund Prevent or Protect initiatives is made it will be a debt owed to the Authority.
     4. The debt may be discharged through funding Prevent or Protect initiatives approved by the Authority or via a rebate to the Authority.
  2. **Prevent & Protect Initiatives**
     1. Offerors may propose, for consideration by the Authority, Prevent or Protect initiatives.
     2. Proposals for Prevent or Protect initiatives may be submitted with the Offer or during the term of the Contract.
     3. Proposals for Prevent or Protect initiatives must be treatment agnostic.
     4. Such initiatives must seek to:
        1. Reduce referrals into secondary care through managing ongoing lower risk care in the community (Prevent); and/or
        2. Improve access and increase capacity through high flow diagnostic and injection services, including in-hospital and community settings (Protection)
     5. Proposals for Prevent or Protect initiatives must be submitted using Document No.05b – Prevent and Protect Initiative Template
     6. The Prevent or Protect initiatives will **not** be evaluated as part of the procurement process but, if approved by the Authority, will form part of any Contract subsequently awarded.
     7. Outside of the procurement process and separate to it, the Authority will consider the Prevent or Protect initiatives proposed and confirm which are approved and if deployed will debit the committed Prevent and Protect investment.
  3. **Form of Offer**
     1. The Products Offered must comply with the requirements of this Invitation to Offer including Document No.03 – Framework Agreement and Document No. 04b - Assessment Criteria, Stability Protocol and Additional Specification Requirements.
     2. The Form of Offer and other documents referred to in paragraph 5.6.1 above must be completed in full. Any Offer may be rejected which:
        1. contains gaps, omissions, or obvious errors; or
        2. is received after the closing time and date for the receipt of Offers
        3. seeks to alter or amend the stated terms and conditions of contract (including without limit the minimum pricing period and/or price variation clauses) issued with this invitation; or
        4. seeks a solus or exclusive arrangement to exclude other medical retinal vascular treatments from other Offerors from being appointed to the framework; or
        5. seeks a “basket deal” to include products that may be available from other sources (for example; parallel importers and wholesalers).
     3. Offerors must not submit with their Offer any documentation which has not been specifically requested by the Authority. If an Offeror does submit such additional documentation which has not been specifically requested by the Authority, this will be disregarded by the Authority.

1. **Instructions**
   * 1. **Clarification Questions**
     2. Offerors can raise clarifications regarding the Procurement only via the NHS England Atamis E-Tendering Portal and until the clarification deadline specified in Table 1.
     3. Offeror clarifications received after the clarification deadline may not receive a response.
     4. Please note that any clarification questions raised by Offerors and the responses to those questions by the Authority may be published anonymously to all Offerors in order to ensure transparency, fairness and equal treatment of Offerors throughout the procurement exercise. If you are concerned that your query and/or the response to it may disclose confidential information or information which is commercially damaging to you, then you may submit the query marked "Confidential" and setting out clearly the reasons why you believe that the query and/or the response are or will be confidential or commercially damaging. The Authority will consider your request and make its decision at its sole discretion. If the Authority determines that the query or response should not be disclosed to other Offerors, it will answer your query and not disclose it or the response (as appropriate) to the other Offerors. If the Authority determines that the query and/or the response should be disclosed to other Offerors, it will give you the chance either to withdraw your query or have it answered. If the latter, then the Authority will disclose the query and the response to all other Offerors.
   1. **Selection Questionnaire** 
      1. Offerors are required to submit information to support their Offers by completing the Response form on the Atamis website – found under “My Response”, which must be satisfactorily completed as indicated therein. The Authority reserves the right to reject an Offer where the Offeror has failed to complete the Selection Questionnaire satisfactorily or where the Offeror fails to meet (or where required, evidence adequately that it meets) any requirement set out in the Selection Questionnaire. This requirement covers Part I, Part II, and Part III of the Selection Questionnaire.
      2. ***Exclusion Grounds - Grounds for mandatory rejection****:* If the Offeror answers “yes” to any of the questions in this section it will be rejected except in the circumstances outlined in Regulation 57(6) and 57(7) of the Public Contracts Regulations 2015.
      3. ***Exclusion Grounds - Grounds for discretionary rejection and tax compliance****:* If the Offeror answers “yes” to any of the questions in this section, the Offeror must provide evidence of measures taken by the Offeror to demonstrate the reliability of its organisation and measures taken to resolve the relevant matters or prevent them from recurring, despite the existence of a relevant ground for exclusion. If the Authority does not consider such evidence to be sufficient the Authority may reject the Offer.
   2. **Offer Schedule - Prices**
      1. Please see the instructions included in the Offer Schedule
   3. **Offer Schedule – Prevent or Protect** **Investments**
      1. Please see the instructions included in the Offer Schedule
   4. **Prevent or Protect** **Initiatives**
      1. Please see the instructions included in the Prevent & Protect Initiative Template.
2. **Evaluation Criteria and Award Methodology**
   1. **Introduction**
      1. Each individual National Product Code ("NPC") is deemed to be a separate lot for the application of the award criteria. There is no restriction on the number of lots that Offerors can offer for or be awarded.
      2. Any Framework Agreement(s) awarded as a result of this procurement will be awarded on the basis of the best price/quality ratio offer (most economically advantageous tender) determined in accordance with the criteria and methodology below. Where an offer for a product is determined to be successful (in accordance with the criteria and methodology set out below), then a separate award will be made for each such product and each such product will form the subject matter of a separate, single-supplier Framework Agreement. The award criteria described below shall be applied in relation to each product as set out below.
      3. Subject to receipt of compliant offers and its formal approval processes, the Authority intends to award framework agreements for the supply of each medical retinal vascular treatment.
   2. **Most Economically Advantageous Offer**
      1. The Authority does not intend to select the winning Offer based upon price alone. Any award will be made based upon the most economically advantageous Offer in accordance with the process set out in this Section 7.
      2. The Authority does not bind itself to accept the lowest or any Offer at all.
   3. **Award Process**
      1. The award process consists of the following key steps:
         1. **Compliance Gateway** – Confirm that Offers comply with the requirements set out in the Invitation to Offer;
         2. **Evaluation** – Evaluation of the Offers that have passed the Compliance Gateway in accordance with the methodology and criteria set out further below; and
         3. **Award Gateway** – Approval to proceed to Contract Award (award notifications, standstill and contract signing)

A diagram of a process

Description automatically generated.

* 1. **Gateway Requirements**
     1. Each Offer must satisfy the requirements of the Compliance Gateway or be disqualified.
     2. To pass the Compliance Gateway, an Offer must:
        1. Pass the Selection Questionnaire;
        2. Complete in full all information required in Document No.05a – Offer Schedule, in the format requested; and
        3. Satisfy any other requirements included in the Invitation to Offer
  2. **Award Criteria** 
     1. The Award Criteria is set out in Table 2

|  |  |
| --- | --- |
| **Award Criteria** | **Scoring Methodology** |
| Quality Assurance Assessment | Pass / Fail |
| Price Assessment | Pass / Fail |

**Table 2 – Award Criteria**

* + 1. **Quality Assurance Assessment** – In order to achieve a pass for the Quality Assurance Assessment, an Offer must be for products that are confirmed by the evaluation panel as “Low Risk” or “Medium Risk” according to the approach documented in Document No.04a – Quality Assurance Process.
    2. Any product that is confirmed by the evaluation panel as “High Risk” will only be awarded a Framework Agreement in the absence of any other qualifying Offers (and subject to satisfying all other award criteria).
    3. If the Offeror is submitting an Offer in respect of a product which is already in regular supply to the NHS in England and that product has previously passed the assessments in Document No.04a, then the Authority, at its sole discretion, may deem that product to have passed the assessments in Document No.04a.
    4. **Price** - Price refers to the offered Price per Unit.
    5. In order to achieve a pass for the Price Assessment, Offerors must submit a Price within Document No. 05a – Offer Schedule) for each product they wish to Offer. The Offer must comply with the requirements of paragraph 5.6.
  1. **Award Principles**
     1. Compliant Offers that pass the Quality Assurance Assessment and the Price Assessment will, subject to the Authority’s approval process, be awarded a single-supplier Framework Agreement.

1. **Contract Finalisation and Mobilisation**
   1. **Contract Finalisation**
      1. Once the Authority has completed its evaluation and subject to the approval process, the Authority will issue Award Notifications to each Offeror and commence the standstill period. The Authority will also commence finalisation of the single-supplier Framework Agreement(s) with a view to executing those agreements as soon as possible after the Standstill Period.
   2. **Mobilisation**
      1. Mobilisation will commence, subject to agreement, following execution of the Framework Agreement and will end at contract commencement. The Supplier(s) may commence mobilisation prior to the contract execution date but this will be at their risk and cost.
   3. **Contract Commencement** 
      1. The Authority anticipates that contract commencement will be 1 August 2024, or such other date as agreed between the Authority and the Supplier.
2. **Legal**
   1. **The Authority and Participating Authorities**
      1. The Authority is conducting this procurement exercise as a central purchasing body to establish the Framework Agreement(s) for and on behalf of itself and the Participating Authorities with whom the suppliers appointed to the Framework

Agreement ("**Successful Offerors**") will ultimately enter into contracts under the Framework Agreement for the supply of the goods and/or services.

* + 1. The Authority is not responsible or accountable for and shall have no liability whatsoever in relation to;
       1. The conduct of Participating Authorities in relation to the Framework Agreement;
       2. The acts or omissions of a Participating Authority in connection with a contract between a Successful Offeror and a Participating Authority entered into pursuant to the Framework Agreement; or
       3. The performance or non-performance of a contract between a Successful Offeror and a Participating Authority entered into pursuant to the Framework Agreement.
    2. Offerors taking part in this competition consent to the terms set out in this Invitation to Offer (including the Framework Agreement) as part of the competition process.
  1. **The Framework Agreement**
     1. This Procurement exercise concerns the conclusion of a Framework Agreement under which Successful Offerors will be appointed to supply Goods and/or Services (as described on Document No.05a – Offer Schedule) to Participating Authorities who may place orders for such Goods and/or Services from time to time and in accordance with the call-off terms set out in the Framework Agreement.
     2. The Authority cannot mandate the Participating Authorities to place any orders or any level of orders, nor can it require them to place orders with particular Successful Offerors. It follows that the Authority can give no warranty that any Successful Offeror will receive any business or any level of business under the Framework Agreement.
     3. Any volume estimates provided to Offerors by the Authority are statements of opinion, provided in good faith and based on experience and market knowledge, but they should not be relied upon by Offerors in formulating their Offers.
     4. By submitting an Offer, an Offeror is deemed to acknowledge and agree that:
        1. The supply of goods and/or services under any Framework Agreement resulting from this procurement exercise is not an exclusive arrangement;
        2. Notwithstanding the establishment of any Framework Agreement pursuant to this procurement exercise, the Authority and/or any of the Participating Authorities may at any time purchase goods and/or services from (and/or enter into other contracts and framework agreements with) any third party that are the same as, or similar to, the Goods and/or Services described in Document No.05a – Offer Schedule;
        3. The Framework Agreement prices will supersede any previous pricing arrangements Offerors may have with the Authority or Participating Authorities for medicines in Document No.05a – Offer Schedule;
        4. The Offer applies to all current and future product indications; and
        5. If after the ITO response deadline, an Offeror subsequently makes an offer to any Participating Authority that, in the opinion of the Authority is better than its Offer submitted in response to the ITO, then
        6. the Offeror agrees that the Authority may replace its Offer with the better offer; and (if the Authority chooses to do so)
        7. the Authority may invite all other Offerors (if Framework Agreements have not yet been entered into) or Successful Offerors (if Framework Agreements have been entered into) to update their Offers.
  2. **Contract Duration**
     1. As a result of this procurement, the Framework Agreements to be entered into with the Successful Offerors will have an initial term **expiring on 31 July 2025** (with an option for the Authority to extend the Framework Agreement for a period or periods up to **twenty four (24) months**.
  3. **Contract Award and Signature**
     1. Within one month of the Authority notifying the Offeror of the Authority’s decision to proceed to award of contract, the Offeror must:
        1. enter into the Framework Agreement with the Authority; and
        2. enter into all necessary contractual arrangements to put in place the sub-contracting arrangements and/or consortium arrangements which formed part of the Offeror's ITO submission, including forming any legal entity, and provide evidence of the foregoing to the satisfaction of the Authority.
     2. The Authority may abandon the Procurement or abandon the award to an Offeror if the Offeror does not meet the requirements of paragraph 9.4.1 above or where the Authority enters into the Framework Agreement with the Offeror but terminates this Framework Agreement due to failure by the Offeror to meet the mobilisation requirements and /or conditions precedent set out in the Framework Agreement.
     3. No offer or bid is deemed accepted until the relevant contractual documents have been duly signed on behalf of the Authority, the Offeror and all other relevant parties and declared unconditional. No dialogue or communication with the Authority whether prior to, during or subsequent to the submission of any bid implies acceptance of any offer or constitutes an indication that the Offeror will be awarded the contract. Only the express terms of any written contract(s) which is finally agreed and signed for and on behalf of the relevant parties and which is duly declared unconditional shall have any contractual effect.
  4. **Conditions of Offer**
     1. A response to this Invitation to Offer is an irrevocable offer by the Offeror and the Offeror separately undertakes with the Authority that the Offer will remain open for acceptance by the Authority for up to 90 days from the ITO submission deadline.
     2. In submitting its ITO submission, the Offeror warrants, represents and undertakes to the Authority that:
        1. all information and representations made to the Authority by the Offeror, its staff or agents in connection with or arising out of the Selection Questionnaire ("SQ"), ITO and/or associated documents, are true, complete and accurate;
        2. it has made its own investigations and undertaken its own research and due diligence and has satisfied itself in respect of all matters (whether actual or contingent) relating to the SQ, ITO and associated documents and that it has not submitted its Bid Submission in reliance upon any information, representation or assumption which may have been made by or on behalf of the Authority (save in respect of any information which is expressly warranted by the Authority); and
        3. where there is a change to the information provided to the Authority at any time the Offeror must advise the Authority as soon as practicable, even if this is prior to the date of submitting the Offer / Final Offer submission and disclose such changes in full.
     3. The Authority reserves the right to retain all and any of the information supplied to it by the Offeror(s).

1. **Contract Management**
   1. **Authority Monthly Report** 
      1. The Authority shall provide to the Supplier, a report summarising;
         1. the quantity of the Supplier's Product dispensed in the reported month;
      2. The Authority shall provide the Authority Monthly Report for the first month, by the last day of the fourth month, and then monthly thereafter.
      3. The report will be based upon the NHS Define data
      4. The Authority will also use its reasonable endeavours to include details of any reduction in usage of the Supplier’s Product due to patients who have ceased treatment.
   2. **Supplier Monthly Report** 
      1. The Supplier shall provide to the Authority by the last day of each month, a report summarising product delivery for the prior month. The report shall include the description of the Product and the quantity supplied to each Participating Authority (secondary care), and any other information reasonably requested by the Authority.
   3. **Contract Review**
      1. The contract review shall take place monthly, or at such other frequency as specified by the Authority, with the purpose of:
         1. Monitoring performance of the Framework Agreement;
         2. Monitoring performance of any Protect or Protect Initiatives;
         3. Ensuring prompt identification and resolution of any issues;
         4. Confirming any rebate due.
      2. In the event that the any issue, including the rebate due, cannot be resolved or agreed, via the Contract Review meetings, then the Dispute Resolution process shall apply.
      3. The contract review can take place via e-mail and via meetings.
2. **Commissioning Recommendations**

**Note to Bidders: this Section 11 does not form part of the criteria or the Procurement and is for information only.**

* 1. The process the Authority may undertake to determine any commissioning recommendations regarding the use of Anti Veg-F and Intravitreal Corticosteroid medicines the ("**Commissioning Process**") is separate to and distinct from this Procurement process.
  2. The Commissioning Process will be conducted following completion of the Procurement and may be informed by the outcome of the Procurement and the Offers received.
  3. The Commissioning Process may consider a number of factors, including but not limited to:
     + 1. the objectives of the Procurement;
       2. the Offers received;
       3. the overall value offered to the Authority;
       4. implications for patients;
       5. implications for local commissioners
       6. if the value offered is greater than that offered by current arrangements;
       7. an assessment of the cost versus benefit to the Authority;
       8. an assessment of the risk versus benefit to the Authority; and/or
       9. an assessment of deliverability (e.g. the operational and administrative requirements to implement Offers)
  4. As part of the Commissioning Process, the Authority may seek feedback from stakeholders including but not limited to:
     + 1. Clinicians;
       2. Eyecare Transformation Programme; and/or
       3. NHS Clinical Commissioners.
  5. Provided, in the opinion of the Authority, there is a clear rationale for doing so, the Authority may issue one or more commissioning recommendations covering topics, including but not limited to:
     + 1. Prevent and Protect Initiatives;
       2. Access to Anti Veg-F and Intravitreal Corticosteroid treatments;
       3. Clinical choice;
       4. Use of any preferred treatment options (from the clinically appropriate options available);
       5. Switching patients to a biosimilar, where clinically appropriate;
       6. Switching patients between treatments where clinically appropriate; and/or
       7. Improvement opportunities.
  6. If the Authority decides to issue any commissioning recommendations, then the Authority will provide the commissioning recommendations to Offerors but will not provide any further details regarding the Commissioning Process.

1. **Governance and Administration**
   1. **Definitions**
      1. For the purpose of this ITO, the capitalised words and expressions that follow have the meanings hereby assigned to them unless the context specifically requires otherwise

|  |  |  |
| --- | --- | --- |
| **Agreement** | the agreement to be entered into between the Authority and successful Offerors; | |
| **Authorised Representative** | the nominated person authorised on behalf of the Offeror; | |
| **Authority and / or Contracting Authority** | the NHS Commissioning Board, referred to as “*NHS England*”; | |
| **Compliant Offer** | an Offer which satisfies the requirements of paragraph 5.2; | |
| **Contract or Draft Contract** | the draft terms and conditions of contract and associated schedules set out in Document No.3 – Framework Agreement; | |
| **Goods and/or Services** | the goods and/or services specified in the Document No.05a - Offer Schedule; | |
| **Framework Agreement** | the framework agreement to be awarded pursuant to this procurement exercise; | |
| **FOIA** | the Freedom of Information Act 2000, the Environmental Information Regulations 2004, any regulations, guidance or codes of practice made or issued pursuant to the foregoing, decisions of the Information Commissioner and by courts and tribunals of competent jurisdiction concerning the foregoing; | |
| **Offer** | an offer submitted by an Offeror in response to this Invitation to Offer and "**Offers**" and "**Offered**" shall be construed accordingly; | |
| **Offeror** | an economic operator which submits an offer in response to this Invitation to Offer or which considers doing so or otherwise expresses interest or participates in this procurement process; | |
| **Open Procedure** | a procedure, pursuant to the Public Contracts Regulations 2015 as amended (the “Regulations”) by which the Authority will, with the aim of meeting its Requirements, conduct the procurement; | |
| **Participating Authorities** | the potential participating authority groups which are listed in Document No.03 – Framework Agreement; | |
| **Procurement** | this procurement process and all steps and actions associated with it, but not including subsequent commissioning decisions made by participating Authorities and/or individual clinicians; | |
| **Procurement Documents** | the documents referred to in this ITO and all associated Appendices, Annexes or other documents referred to therein; | |
| **Product** | any product included in an Offer and "**Products**" shall be construed accordingly | |
| **Regulations** | the Public Contracts Regulations 2015 (as amended); | |
| **Requirement** | The licensed Anti Veg-F and Intravitreal Corticosteroid treatment which the Authority wishes to procure, information and details of which are set out in 2.1.2 of this ITO document and “Requirements” shall be construed accordingly; | |
| **Secondary Care** | (whether or not capitalised) healthcare provided in hospitals. It includes amongst other things; accident and emergency departments, and outpatient departments; | |
| **Sub – Contract** | any sub - contract entered into by the Supplier or by any Sub - Contractor of any level for the purpose of the performance of any obligation on the part of the Supplier under this Contract; |
| **Sub – Contractor** | any sub - contractor, whether of the Supplier itself or at any further level of sub - contracting, under any Sub – Contract; |
| **Supplier(s)** | the Offerors that have entered into a Framework Agreement with the Authority to supply and deliver licensed Anti Veg-F and Intravitreal Corticosteroid treatments to the NHS in England; |
| **Update** | a written notification by the Authority to the Offerors. Updates may be issued during the ITO period to amend or to provide further clarification to any part of the ITO; and | | |

other capitalised terms have the meanings given in the relevant paragraphs or sections where they are defined in this ITO

* 1. **General** 
     1. By signing/submitting an Offer, the Offeror and each Relevant Organisations warrants that, save as disclosed in writing to the Authority within the Offer, any information supplied by it remains true and that it has:
        1. not passed a resolution, nor is it the subject of an order by the court, for the company’s winding-up otherwise than for the purposes of bona fide reconstruction or amalgamation, nor has it had a receiver, manager or administrator on behalf of a creditor appointed in respect of its business or any part thereof, nor is it the subject of proceedings for any of the above procedures, nor is it the subject of similar procedures under the law of any other states;
        2. not been convicted of a criminal offence relating to the conduct of its business or profession
        3. not been convicted of any of the offences listed in Regulation 57 “Mandatory exclusions” of the Public Contracts Regulations 2015;
        4. not been in any of the situations listed in Regulation 57 “Mandatory and discretionary exclusions for non-payment of taxes etc.” or “Discretionary exclusions” of the Public Contracts Regulations 2015, subject to the exercise of discretion, or acceptance of evidence of self-cleaning, by or on behalf of the Authority, as provided for under Regulation 57.
        5. not made any material misrepresentation in providing any of the information required in relation to the ITO; and
        6. not disclosed, copied, reproduced or distributed and will not disclose, copy, reproduce or distribute any information contained in the Procurement Documents or supplied by the Authority to any third party at any time except for the purpose of enabling a response to the ITO or to be prepared.
     2. The Authority may at its own absolute discretion extend the closing date and time for receipt of Offers in response to this ITO. Any extension granted will apply to all Offerors.
  2. **Guidance and Compliance**
     1. Offerors should read these instructions carefully before submitting a response to this ITO. Failure to comply with these requirements for completion and submission of the Offer may result in the rejection of the Offer. Offerors are therefore advised to acquaint themselves fully with the instructions and conditions set out in this ITO.
     2. All Offers received by the Authority will be checked for compliance with the submission requirements set out in this ITO. If an Offer is not considered compliant, the Authority will not be obliged to carry out any further evaluation and the Offeror may be eliminated from the Procurement. During this period, clarification of any aspect of the Offer may be sought.
     3. The Authority requires adherence to all instructions and conditions within this ITO from each of the Offerors and the participation in the ITO process by each Offeror shall be construed as unqualified acceptance of such obligations by and on behalf of that Offeror.
  3. **Offer Validity**
     1. All Offers submitted by Offerors must remain open for acceptance up to 90 Days from the ITO submission deadline. Offer Prices must be firm (i.e. not subject to variation) for the period of the Framework Agreement subject only to any variation provisions contained in the Framework Agreement.
  4. **Language**
     1. All documentation and communication shall be in English
  5. **Offer Preparation Costs**
     1. Each Offeror shall be solely responsible for all the costs it incurs in the preparation and submission of its Offer up to and including the award of any contract by the Authority. This shall also be deemed to cover the cost of attending any pre or post Offer meetings and dialogue and, should an Offeror be successful, the preparation of contract documents. The Authority shall in no event be responsible or liable for any such costs regardless of the conduct or outcome of the bidding process, and in this respect, the Offeror shall have no recourse to the Authority.
  6. **Variant Bids**
     1. Variant bids are NOT permitted.
  7. **Offeror’s Authorised Representative** 
     1. All communication relating to this Procurement will be sent via the NHS England Atamis E-Tendering Portal for the attention of the Offeror's Authorised Representative. The Authorised Representative must have full authority to represent the Offeror and attend any meetings on the Offeror's behalf. The Authority may, at any time, request documentary proof of such authority. Offerors shall notify the Authority of any changes to the Authorised Representative's contact details as soon as practicable.
  8. **Confidential Information** 
     1. Confidential information means all information which is supplied by the Authority to an Offeror whether in writing, orally or in any other form, directly or indirectly from or pursuant to discussions with such Offeror or which is obtained through observations made by such Offeror which is designated by the Authority as confidential or which is otherwise of a confidential nature. Each Offeror shall hold in confidence any confidential information, provided that such Offeror shall not be restricted from passing such information to its professional advisers, or its proposed sub-contractors (subject to obtaining appropriate confidentiality undertakings) but only to the extent necessary to enable it to prepare its Offer and participate in this procurement.
     2. The Authority may disclose detailed information relating to an Offer to the Authority's officers, employees, agents or advisers and they may make Offers available for private inspection by the Authority's officers, employees, agents or advisers.
     3. The Authority also reserve the right to disseminate information that is materially relevant to all Offerors, even if the information has only been requested by one Offeror, subject to the duty to protect any Offeror's commercial confidence in its responses.
     4. Should Offerors wish to avoid such disclosure (for example, on the basis that the request or response contains commercially confidential information or may give another Offeror a commercial advantage) the request must be clearly marked “In Confidence - not to be circulated to other Offerors” and the Offeror must set out the reason(s) for the request for non-disclosure to other Offerors.
     5. If the Authority considers that, in the interests of open and fair competition, it is unable to respond to the question or request for clarification or further information on a confidential basis, it will inform the Offeror who has submitted it. The Offeror must as soon as practicable thereafter respond in writing requesting that either the query be withdrawn or treated as not confidential. The Authority will deem that the question or request for clarification or further information has been withdrawn if the Authority is not contacted in writing via the Atamis e-tendering portal within 2 working days following the Offeror being so informed.
     6. The Authority will act reasonably as regards the protection of commercially sensitive information relating to the Offeror, subject always to the Authority's duties under the Freedom of Information Act 2000 (see paragraph 12.11 below).
  9. **No Inducement or Incentive**
     1. The Procurement Documents are issued on the basis that nothing contained in them shall constitute an inducement or incentive nor shall have in any other way persuaded an Offeror or Relevant Organisation to submit a Bid or enter into any contractual agreement.
  10. **Freedom of Information**
      1. Offerors are reminded that the Authority is subject to the requirements of the Freedom of Information Act 2000 ("FoIA") and the Environmental Information Regulations 2004 ("EIR"). Accordingly, the Authority may be required to disclose, on request, information submitted to it by Offerors in connection with the ITO. Information may be exempt from disclosure under FoIA where its disclosure would breach confidentiality or be likely to prejudice the commercial interests of any person, but the Authority can give no assurances as to whether or not information received from Offerors in connection with the ITO or would be disclosed in response to a request made under FoIA. In the event that such a request is received by the Authority, the Authority shall, in accordance with its obligations under the Code of Practice made under section 45 FoIA, consult with any party whose interests are likely to be affected by disclosure and take their views into account. However, the Authority shall be responsible for determining at its absolute discretion whether any such information is exempt from disclosure in accordance with the provisions of the FoIA or the EIR and whether any such information is to be disclosed in response to an information request. Even if the Authority initially refuses to disclose requested information, Offerors should be aware that disclosure may be enforced by the Information Commissioner or the Courts
  11. **Right to publish – Transparency agenda**
      1. By submitting an Offer, an Offeror is deemed to acknowledge and agree that, except for any information which is exempt from disclosure in accordance with the provisions of the FoIA, this Invitation to Offer and the content of any framework agreement resulting from this procurement exercise will be published in accordance with the Government's policies on transparency as expounded in the Guidance published by the Cabinet Office. Further information on transparency can be found at: <https://www.gov.uk/government/policies/buying-and-managing-government-goods-and-services-more-efficiently-and-effectively>
      2. The Authority shall be ultimately and solely responsible for determining whether any of the content of this Invitation to Offer and any Framework Agreement that is concluded as a result of this procurement exercise is exempt from disclosure in accordance with the provisions of the FoIA.
  12. **Copyright**
      1. Offerors are reminded that the copyright to this ITO rests with the Authority and its appointed advisors. This ITO may not either in whole or in part be copied, reproduced, distributed or otherwise made available to any other third party without the prior written consent of the Authority except in relation to the preparation of an Offer. All documentation supplied by the Authority in relation to this ITO is, and shall remain the property of the Authority and must be returned on demand, without any copies being retained.
  13. **Canvassing**
      1. Any Offeror who directly or indirectly canvasses any member of the Authority or any of its officials or representatives concerning the Procurement, or otherwise seeks to directly or indirectly influence the procurement or its outcome, may be disqualified.
  14. **Collusive Submissions**
      1. Any Offeror who:
         1. fixes or adjusts the Offer rates and prices quoted by it under or in accordance with any agreement or arrangement with any other person; or
         2. communicates to any person other than the Authority the amount or approximate amount of its proposed Offer (except where such disclosure is made in confidence in order to obtain quotations necessary for the preparation of the Offer for insurance or similar activity); or
         3. offers or agrees to pay or give, or does pay or give any sum of money inducement or valuable consideration directly or indirectly to any person for doing or having done or causing or having caused to be done in relation to this or any other Offer or proposed Offer, any act or omission; will be (without prejudice to any other civil remedies available to the Authority and without prejudice to any criminal liability which such conduct by a Offeror may attract) disqualified.
      2. The Offeror warrants that its Offer shall be bona fide and shall be intended to be competitive and that it has not done and will not do at any time any of the acts set out in paragraph 12.15.1 above.
  15. **Offeror Membership and Eligibility**
      1. The Authority must be notified in writing of any change in the control, composition or membership of a Offeror that has taken place subsequent to the Offeror’s ITO submission and of any other material change to the Offeror's response to the SQ, particularly any material change in the financial position of a Offeror. The Authority reserves the absolute right to withhold approval to any such changes and to disqualify the Offeror concerned from any further participation in the procurement process.
      2. Offerors are reminded of the eligibility requirements that apply to the procurement process at all times. In particular, these include the provisions set out in Regulation 57 of the Public Contracts Regulations 2016. Any change in the eligibility of an Offeror must be notified immediately to the Authority in writing and may result in such Offeror being disqualified from any further participation in the procurement process.
  16. **Authority's Advisors**
      1. Offerors should note that the advisers currently appointed on behalf of the Authority in relation to this procurement are:

**Legal - Blake Morgan LLP**

* + 1. The Authority may, at its sole discretion, appoint additional advisors.
    2. Each Offeror acknowledges that by virtue of submitting an Offer in response to the ITO it waives any right of objection which it has or may have in relation to the Authority's appointment of professional advisers. The Authority reserves the right to disqualify any Offeror which refuses to provide such a waiver.
  1. **Publicity**
     1. No publicity regarding the Procurement or the Requirement or the award of any contract will be permitted unless and until the Authority has given express written consent to the relevant communication.
  2. **Conflict of Interest**
     1. Offerors are instructed to ensure that their potential appointment as the Supplier to the Authority and the Participating Authorities for the provision of the Requirement has not and will not create any conflict of interest or any situation that might compromise or prejudice the Authority's duty to manage an open, fair, non-discriminatory and competitive procurement process. In the event of a conflict (or potential conflict) arising at any time during the procurement process, the affected Offeror must report the occurrence of an actual or potential conflict and the means for resolving it to the Authority as soon as reasonably practicable.
     2. Failure to declare any actual or potential conflict and/or failure to address such conflict to the reasonable satisfaction of the Authority may result in an Offeror being disqualified from this procurement.
  3. **Right to Disqualify Offeror / Reject Offers**
     1. The Authority reserves the right to reject an Offer and/or disqualify an Offeror where:
        1. an Offer is submitted late, is completed incorrectly, is materially incomplete or fails to meet the Authority's Requirements which have been notified to Offerors;
        2. the Offeror and/or a member(s) of its supply chain are unable to satisfy the terms of Regulation 57 of the Public Contracts Regulations 2015 (as amended) at any stage during the ITO process;
        3. the Offeror and/or a member(s) of its supply chain is/are guilty of material misrepresentation in relation to information provided by the Offeror during the selection stage and/or in connection with any Offer;
        4. the Offeror and/or a member(s) of its supply chain contravene any of the terms and conditions of this ITO or other document issued by the Authority; or
        5. there is a change in identity, control, financial standing or other factor impacting on the selection and/or evaluation process affecting the Offeror and/or a member(s) of its supply chain.
  4. **The Authority's Rights**
     1. Although it is intended that the remainder of this procurement will take place in accordance with this ITO, the Authority reserves the right to:
        1. waive the requirements of this ITO;
        2. disqualify any Offeror that does not submit a compliant Offer in accordance with the instructions in this ITO;
        3. annul the ITO process in its entirety;
        4. withdraw this ITO at any time, or to re-invite Offers on the same or any alternative basis;
        5. choose not to award any contract as a result of the current procurement process; and
        6. make whatever changes it sees fit to the timetable, structure or content of the procurement process and this ITO from time to time without prior (or any) notice being given by the Authority.
  5. **Interpretation**
     1. In the Procurement Documents, except where the context otherwise requires:
        1. words importing one gender include all other genders and words importing the singular include the plural and vice versa;
        2. enactment means any statute or statutory provision (whether of the United Kingdom or elsewhere), subordinate legislation (as defined by s.21 (1) Interpretation Act 1978) and any other subordinate legislation made under any such statute or statutory provision;
        3. a reference to any enactment shall be construed as including a reference to:

any enactment which that enactment has directly or indirectly replaced (whether with or without modification); and

that enactment as re-enacted, replaced or modified from time to time, whether before, on or after the date of the Procurement Documents.

* + - 1. the Definitions (paragraph 12.1), any abbreviations, the headings to the sections of the Procurement Documents and the Annexes thereto are for ease of reference only and shall not affect the construction of the Procurement Documents;
      2. any Appendices or Annexes to the Procurement Documents form part of the Procurement Documents and will have the same force and effect as if expressly set out in the body of the Procurement Documents; and
      3. in the event of any inconsistency between the provisions of the Procurement Documents and any previously issued documents, the provisions of the Procurement Documents shall prevail
  1. **Amendments to Invitation to offer**
     1. At any time prior to the closing time and date for the return of Offers, the Authority may modify the documents comprising the Invitation to Offer by notifying Offerors of the same in writing.
     2. The Authority may extend the closing time and date for the return of Offers to allow for significant amendments made by the Authority to be fully assessed and taken into account by Offerors.
  2. **Samples**
     1. Offerors may be required to submit samples of each item offered. Such samples shall be provided free of charge;
     2. Samples should be despatched under separate cover as and when required by the Authority.
     3. Any requested samples should be clearly marked with the name of the Offeror and the project code reference: C63060. Samples should be clearly labelled “NHS Framework Agreement for the supply of Medical Retinal Vascular Treatments for the NHS in England."
  3. **Governing Law**
     1. The laws of England and Wales, and the exclusive jurisdiction of the Courts of England and Wales, shall apply to this Procurement, ITO, the Requirement and, subject to applicable law, any dispute, including any non-contractual dispute arising therefrom.