## **SUPPLIER TENDER RETURN: SUPPLIER RESPONSE DOCUMENT**

## Supplier Tender Return for the delivery of Investigational Medicinal Products for IMPEDE-PKD drug trial.

## Atamis Reference Number: C289889

## Deadline for receipt of Tenders to be received: 27/08/2024 13:00

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**SECTION1: FORM OF TENDER**

**DECLARATIONS BY THE BIDDER (TO BE SIGNED AND RETURNED BY THE BIDDER)**

**FORM OF TENDER, NON-COLLUSION, CONFLICTS OF INTEREST AND ANTI-CANVASSING**

**DECLARATIONS**

TO: Sheffield Teaching Hospitals NHS Foundation Trust

## PROPOSAL TO PROVIDE Investigational Medicinal Products for IMPEDE-PKD drug trial.

REFERENCE NUMBER: C289889

**Form of Tender**

We have examined the invitation to tender ("ITT") dated 25/07/2024 and all accompanying annexes and schedules. This Tender is made subject to the terms of the ITT, including but not limited to the instructions to Bidders.

We declare that to the best of our knowledge the answers submitted in response to the Eligibility Questions (including the self-declaration) are correct.

I/We agree to deliver the services outlined within the specification, on time and in full, to the reasonable satisfaction of the Trust for the period set out in the Invitation to Tender documentation, in line with the Terms of the Contract contained in Appendix C and Specification in Appendix B.

We tender against the requirements, and offer to enter into a contract with the Authority comprising the following:

* ITT Information Document
* Appendix A – Specification
* Supplier Tender Return
* Appendix B – Pricing Schedule
* Appendix C – NHS Terms and Conditions
* Appendix D – Confidential and Commercially sensitive information

Accordingly, this Tender is a contractual offer capable of acceptance by the Authority. If the Authority accepts this Tender, we will execute any agreement that the Authority produces to record in one place the offer and acceptance.

We undertake to keep the Tender open for acceptance by the Authority for a period of ninety (90) days from the deadline for receipt of Tenders.

We understand that you are not bound to accept the lowest priced, or any, Tender.

**Non-collusive tendering**

I/we the undersigned, in submitting the accompanying tender do hereby make the following statement that I certify to be true and complete in every respect:

1. this tender is made in good faith and is intended to be genuinely competitive, and that I understand that the accompanying tender will be disqualified if this Certificate is found not to be true and complete in every respect;
2. I am authorised by the Tenderer to sign this Certificate, and to submit the accompanying bid, on behalf of the Tenderer;
3. each person whose signature appears on the accompanying tender has been authorised by the Tenderer to determine the terms of, and to sign, the tender, on behalf of the Tenderer;
4. for the purposes of this form of tender, I understand that the word "competitor" shall include any individual or organisation, other than the Tenderer, whether or not affiliated with the Tenderer, who:
   * + - 1. has been requested to submit a tender in response to this call for tenders; or
         2. could potentially submit a tender in response to this call for tenders, based on their qualifications, abilities or experience;

and that the words “consultation, communication, agreement or arrangement” include any such transaction, whether or not legally binding, formal or informal, written or oral.

1. the Tenderer discloses that *(delete whichever of the following paragraphs (a) or (b), is not applicable)*:
   * + - 1. the Tenderer has arrived at the accompanying tender independently from, and without consultation, communication, agreement or arrangement with, any competitor;

*or*

* + - * 1. the Tenderer has entered into consultations, communications, agreements or arrangements with one or more competitors regarding this call for tenders, and the Tenderer discloses, in the attached document(s), complete details thereof, including the names of the competitors and the nature of, and reasons for, such consultations, communications, agreements or arrangements;

1. in particular, without limiting the generality of paragraphs 5 (a) or (b) above, there has been no consultation, communication, agreement or arrangement with any competitor regarding:
   * + - 1. prices;
         2. methods, factors or formulas used to calculate prices;
         3. the variation or the withdrawal of a tender after it has been submitted;
         4. the intention or decision to submit, or not to submit, a tender;
         5. the submission of a tender which does not meet the specifications of the call for tenders; or
         6. the intention or decision to submit, or not to submit, a tender in relation to any future call for tenders;

except as specifically disclosed pursuant to paragraph 5(b) above (where applicable);

1. in addition, there has been no consultation, communication, agreement or arrangement with any competitor regarding the quality, quantity, specifications or delivery particulars of the products or services to which this call for tenders relates, except as specifically authorised in writing by the Tendering Authority or as specifically disclosed pursuant to paragraph 5(b) above (where applicable);
2. the terms of the accompanying tender have not been, and will not be, knowingly disclosed by the Tenderer or any of its agents, consultants or employees, directly or indirectly, to any competitor, prior to the date and time of the official tender opening, or of the awarding of the contract, whichever comes first, unless otherwise required by law or as specifically disclosed pursuant to paragraph 5(b) above (where applicable);
3. the Tenderer has not paid, given, or offered to pay or give any money or other valuable consideration directly or indirectly to any competitor for doing or having done or causing or having caused to be done in relation to this tender, any act or thing of the sort described in paragraphs 6, 7 or 8 above;
4. the Tenderer has not been paid, been given or agreed to accept any money or other valuable consideration directly or indirectly by or from any competitor for doing or having done or causing or having caused to be done in relation to this tender, any act or thing of the sort described in paragraphs 6, 7 or 8 above;

1. I/we understand that if the Tenderer has done, or caused to be done in relation to this bid any act or thing of the sort described in paragraphs 6, 7, or 8 above, this could give rise to an infringement of Chapter I of the Competition Act 1998 and/or section 188 of the Enterprise Act 2002; and
2. I/we have read and I understand the contents of this Certificate, and I understand that knowingly making a false declaration on this form may result in legal action being taken against me.

**Conflicts of interest**

We acknowledge that we are responsible for ensuring that no conflicts of interest exist between us (and our advisers) and the Authority.

So far as any possible conflict of interest has arisen, we have notified the Authority promptly in writing of that potential conflict of interest and have taken any steps agreed with the Authority to avoid the conflict.

We acknowledge that if we fail to comply with this requirement, we may be disqualified from the procurement at the discretion of the Authority.

**Anti-canvassing confirmation**

We have not canvassed or solicited any member, officer or employee of the Authority, in connection with the proposed contract award and to the best of our knowledge and belief nor has any person employed by us or acting on our behalf done any such act.

We further undertake that we will not in the future canvass or solicit any member, officer or employee of the Authority, in connection with the proposed contract and that no person employed by us or acting on our behalf will do any such act.

Name of person duly authorised to sign tenders:

Date: .............................................................................

Name: .............................................................................

in the capacity of: ................................................................

duly authorised to sign tenders for and on behalf of:

............................................................................................

**SECTION 2: FREEDOM OF INFORMATION EXCLUSIONS SCHEDULE**

Tenderers should complete this exclusion schedule with information that they believe can be excluded under the Freedom of Information Act 2000.

Tenderers should be aware that requests for information under the Freedom of Information Act 2000 are considered individually and that the decision as to whether the requested information will be disclosed lies solely with the Trust.

|  |  |  |  |
| --- | --- | --- | --- |
| **Section of the Tender** | **Description** | **Reason for FOIA Exemption** | **Exemption Period to be Applied** |
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In all cases the Trust may publish (either proactively or in response to a request) after Contract award the following information:

* The identity of all Tenderers
* Overall contract value of the contract awarded
* The value of all tenders received (but not necessarily correlated to the identity of the Tenderers)
* General performance standards to be achieved under the Contract
* Performance and progress monitoring arrangements.

**SECTION 4. STANDARD SELECTION QUESTIONAIRE**

**Potential Supplier Information and Exclusion Grounds: Part 1 and Part 2.**

**otential Supplier**

The Standard Selection Questionnaire is a self-declaration, made by you (the potential supplier), that you do not meet any of the grounds for exclusion[[1]](#footnote-1). If there are grounds for exclusion, there is an opportunity to explain the background and any measures you have taken to rectify the situation (we call this self-cleaning).

A completed declaration of Part 1 and Part 2 provides a formal statement that the organisation making the declaration has not breached any of the exclusion grounds. Consequently, we require all the organisations that you will rely on to meet the selection criteria to provide a completed Part 1 and Part 2. For example, these could be parent companies, affiliates, associates, or essential subcontractors, if they are relied upon to meet the selection criteria. This means that when you are joining a group of organisations, including joint ventures and partnerships, each organisation in that group must complete one of these self-declarations. Subcontractors that you rely on to meet the selection criteria must also complete a self-declaration (although subcontractors that are not relied upon do not need to complete the self- declaration).

When completed, this form is to be sent back to the contact point given in the procurement documents along with the selection information requested in the procurement documentation.

**Supplier Selection Questions: Part 3**

The procurement document provides instructions on the selection questions you need to respond to and how to submit those responses. If you are bidding on behalf of a group (consortium) or you intend to use sub-contractors, you should complete all of the selection questions on behalf of the consortium and/or any sub-contractors.

If the relevant documentary evidence referred to in the Selection Questionnaire is not provided

Upon request and without delay we reserve the right to amend the contract award decision and award to the next compliant bidder.

**Consequences of Misrepresentation**

If you seriously misrepresent any factual information in filling in the Selection Questionnaire, and so induce an authority to enter into a contract, there may be significant consequences. You may be excluded from the procurement procedure, and from bidding for other contracts for three years. If a contract has been entered into you may be sued for damages and the contract may be rescinded. If fraud, or fraudulent intent, can be proved, you or your responsible officers may be prosecuted and convicted of the offence of fraud by false representation, and you must be excluded from further procurements for five years.

**Notes for Completion**

1. The “authority” means the contracting authority, or anyone acting on behalf of the contracting authority, that is seeking to invite suitable candidates to participate in this procurement process.

2. “You” / “Your” refers to the potential supplier completing this standard Selection Questionnaire i.e. the legal entity responsible for the information provided. The term “potential supplier” is intended to cover any economic operator as defined by the Public Contracts Regulations 2015 (referred to as the “regulations”) and could be a registered company; the lead contact for a group of economic operators; charitable organisation; Voluntary Community and Social Enterprise (VCSE); Special Purpose Vehicle; or other form of entity.

3. Please ensure that all questions are completed in full, and in the format requested. If the question does not apply to you, please state ‘N/A’. Should you need to provide additional information in response to the questions, please submit a clearly identified annex.

4. The authority recognises that arrangements set out in section 1.2 of the standard Selection Questionnaire, in relation to a group of economic operators (for example, a consortium) and/or use of sub-contractors, may be subject to change and will, therefore, not be finalised until a later date. The lead contact should notify the authority immediately of any change in the proposed arrangements and ensure a completed Part 1 and Part 2 is submitted for any new organisation relied on to meet the selection criteria. The authority will make a revised assessment of the submission based on the updated information.

5. For Part 1 and Part 2 every organisation that is being relied on to meet the selection must complete and submit the self-declaration.

6. All **sub-contractors** are required to complete Part 1 and Part 2[[2]](#footnote-2)

7. For answers to Part 3 - If you are bidding on behalf of a group, for example, a consortium, or you intend to use sub-contractors, you should complete all of the questions on behalf of the consortium and/ or any subcontractors, providing one composite response and declaration.

The authority confirms that it will keep confidential and will not disclose to any third parties any information obtained from a named customer contact, other than to the Cabinet Office and/or contracting authorities defined by the regulations, or pursuant to an order of the court or demand made by any competent authority or body where the authority is under a legal or regulatory obligation to make such a disclosure.

**Part 1: General information**

Please answer the following questions in full. Note that every organisation that is being relied on to meet the selection must complete and submit the Part 1 and Part 2 self-declaration.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Part 1** | | | | | **Potential Supplier Information** | | |
| **Question Number** | | | | | **Question** | | **Response** |
| 1.1(a) | | | | | Full name of the supplier submitting the information | |  |
| 1.1(b) | | | – (i) | | Registered office address (if applicable) or head office | |  |
| – (ii) | | Registered website address (if applicable) | |  |
| 1.1(c) | | | | | Trading status   1. public limited company 2. limited company 3. limited liability partnership 4. other partnership 5. sole trader 6. third sector 7. other (please specify your trading status) | |  |
| 1.1(d) | | | | | Date of registration (if applicable) or date of formation | |  |
| 1.1(e) | | | | | Registration number (company, partnership, charity, etc if applicable) | |  |
| 1.1(f) | | | | | Charity registration number (if applicable) | |  |
| 1.1(g) | | | | | Head office DUNS number (if applicable) | |  |
| 1.1(h) | | | | | Registered VAT number | |  |
| 1.1(i) | – (i) | | | | Are you registered with the appropriate professional or trade register(s) specified for this procurement and as set out in the procurement documents in the country where your organisation is established? | | Yes ☐  No ☐  N/A ☐ |
| - (ii) | | | | If you responded yes to 1.1(i) - (i), please provide the relevant details, including the name of the register and registration number(s) and, if evidence of registration is available electronically, please give the website address, issuing body and reference number. | |  |
| 1.1(j) | – (i) | | | established for you to: a) possess a particular authorisation, or b) be a member of a particular organisation, to provide the requirements specified in this procurement? For procurements for **services only**, is it a legal requirement in the country where you are | | Yes ☐  No ☐ | |
| – (ii) | | | If you responded yes to 1.1(J) - (i), please provide additional details of what is required and confirmation that you have complied with this and, if evidence of compliance is available electronically, please give the website address, issuing body and reference number. | |  | |
| 1.1(k) | | | | Trading name(s) that will be used if successful in this procurement | |  | |
| 1.1(l) | | | | Relevant classifications (state whether you fall within one of these, and if so which one)   1. Voluntary Community Social Enterprise (VCSE) 2. Sheltered Workshop 3. Public service mutual | |  | |
| 1.1(m) | | | | Are you a Small, Medium or Micro Enterprise (SME)**[[3]](#footnote-3)**? | | Yes ☐  No ☐ | |
| 1.1(n) | | | | Details of Persons with Significant Control (PSC)   * Name * Date of birth * Nationality * Country, state or part of the UK where the PSC usually lives * Service address * The date he or she became a PSC in relation to the company; * Which conditions for being a PSC are met: * - Over 25% up to (and including) 50% * - More than 50% and less than 75% * - 75% or more   (Please enter N/A if not applicable) | |  | |
| 1.1(o) | | | | Details of immediate parent company:   * Full name of the immediate parent company * Registered office address (if applicable) * Registration number (if applicable) * Head office DUNS number (if applicable) * Head office VAT number (if applicable)   (Please enter N/A if not applicable) | |  | |
| 1.1(p) | | | | Details of ultimate parent company:   * Full name of the ultimate parent company * Registered office address (if applicable) * Registration number (if applicable) * Head office DUNS number (if applicable) * Head office VAT number (if applicable)   (Please enter N/A if not applicable) | |  | |
| 1.2(a) | | – (i) | | Are you bidding as a single supplier or as part of a group or consortium? | |  | |
|  | | If you are bidding as part of a group or consortium (including where you intend to establish a legal entity to deliver the contract), please tell us:  a) The name of the group/consortium.  b) The proposed structure of the group/consortium, including the legal structure where applicable.  c) The name of the lead member in the group/consortium.  d) Your role in the group/consortium (e.g. lead member, consortium member, subcontractor). e) If you are the lead member in the group/consortium, whether you are relying on other consortium members to meet the selection criteria (i.e., are you relying on other consortium members for economic and technical standing and/or technical and professional ability?) and, if so, which criteria you are relying on them for. | |  | |
| 1.2(b) | | – (i) | | Are you or, if applicable, the group of economic operators proposing to use sub-contractors? | | Yes ☐  No ☐ | |
| – (ii) | | If you are proposing to use subcontractors/a supply chain please provide the following details for each subcontractor/supply chain member;   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Name |  |  |  |  | | Registered address |  |  |  |  | | Trading status |  |  |  |  | | Company registration number |  |  |  |  | | Registered VAT number |  |  |  |  | | Type of organisation |  |  |  |  | | SME (Yes/No) |  |  |  |  | | The role each sub-contractor will take in providing the works and /or supplies e.g. key deliverables |  |  |  |  | | The approximate % of contractual obligations assigned to each sub-contractor |  |  |  |  | | | | |

**Contact details and declaration**

I declare that to the best of my knowledge the answers submitted and information contained in this document are correct and accurate.

I declare that, upon request and without delay I will provide the certificates or documentary evidence referred to in this document.

I understand that the information will be used in the selection process to assess my organisation’s suitability to be invited to participate further in this procurement.

I understand that the authority may reject this submission in its entirety if there is a failure to answer all the relevant questions fully, or if false/misleading information or content is provided in any section.

I am aware of the consequences of serious misrepresentation.

|  |  |  |
| --- | --- | --- |
| **Part 1** | **Contact Details and Declaration** | |
| Question number | Question | Response |
| 1.3(a) | Contact name |  |
| 1.3(b) | Name of organisation |  |
| 1.3(c) | Role in organisation |  |
| 1.3(d) | Phone number |  |
| 1.3(e) | E-mail address |  |
| 1.3(f) | Postal address |  |
| 1.3(g) | Signature (electronic is acceptable) |  |
| 1.3(h) | Date |  |

**Part 2: Exclusion Grounds**

Please answer the following questions in full. Note that every organisation that is being relied on to meet the selection must complete and submit the Part 1 and Part 2 self-declaration.

|  |  |  |
| --- | --- | --- |
| **Part 2** | **Grounds for Mandatory Exclusion** | |
| Question number | Question | Response |
| 2.1(a) | **Regulations 57(1) and (2)**  The detailed grounds for mandatory exclusion of an organisation are set out on this [webpage](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/551130/List_of_Mandatory_and_Discretionary_Exclusions.pdf)[[4]](#footnote-4), which should be referred to before completing these questions.  Within the past five years, anywhere in the world, have you or any person who  ● is a member of the supplier’s administrative, management or supervisory body; or  ● has powers of representation, decision or control in the supplier 16 been convicted of any of the offences within the summary below and listed in full in Annex D | |
| Participation in a criminal organisation. | Yes ☐  No ☐  If Yes please provide details at 2.1(b) |
| Corruption. | Yes ☐  No ☐  If Yes please provide details at 2.1(b) |
| Fraud. | Yes ☐  No ☐  If Yes please provide details at 2.1(b) |
| Terrorist offences or offences linked to terrorist activities | Yes ☐  No ☐  If Yes please provide details at 2.1(b) |
| Money laundering or terrorist financing | Yes ☐  No ☐  If Yes please provide details at 2.1(b) |
| Child labour and other forms of trafficking in human beings | Yes ☐  No ☐  If Yes please provide details at 2.1(b) |
|  | Any other offence within the meaning of Article 57(1) of the Directive as defined by the law of any jurisdiction outside England, Wales or Northern Ireland. | Yes ☐  No ☐  If Yes please provide details at 2.1(b) |
|  | Any other offence within the meaning of Article 57(1) of the Directive created after 26th February 2015 in England, Wales or Northern Ireland | Yes ☐  No ☐  If Yes please provide details at 2.1(b) |
| 2.1(b) | If you have answered yes to question 2.1(a), please provide further details.  Date of conviction, specify which of the grounds listed the conviction was for, and the reasons for conviction,  Identity of who has been convicted  If the relevant documentation is available electronically please provide the web address, issuing authority, precise reference of the documents. |  |
| 2.2 | If you have answered Yes to any of the points above have measures been taken to demonstrate the reliability of the organisation despite the existence of a relevant ground for exclusion? (Self-Cleaning) | Yes ☐  No ☐ |
|  | **Grounds for Discretionary Mandatory and Discretionary grounds relating to the payment of taxes and social security contributions Exclusion** | |
|  | The detailed grounds for mandatory and discretionary exclusion of a supplier for non-payment of taxes and social security contributions, are set out in Annex D, and should be referred to before completing these questions. | |
| 2.3 | Please confirm that you have met all your obligations relating to the payment of taxes and social security contributions, both in the country in which you are established and in the UK. |  |
|  | If documentation is available electronically, please provide- - the web address, - issuing authority, - precise reference of the documents. |  |
|  | If you have answered NO to this question, please provide further details including the following:   * Country concerned * the amount concerned * how the breach was established, i.e., through a judicial or administrative decision or by other means * if the breach has been established through a judicial or administrative decision please provide the date of the decision * if the breach has been established by other means please specify the means |  |
|  | Please also confirm whether you have paid or have entered into a binding arrangement with a view to paying the outstanding sum including, where applicable, any accrued interest and/or fines. |  |
| Please Note: We reserve our right to use our discretion to exclude your bid where we can demonstrate by any appropriate means that you are in breach of your obligations relating to the payment of taxes or social security contributions | | |

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| **Part 3** | | | **Grounds for Discretionary Exclusion** | | | | | | | | |
| Question Number | | | Question | | | Response | | | | | |
| 3.1 | | | The detailed grounds for discretionary exclusion of an organisation are set out in Annex D[[5]](#footnote-5), which should be referred to before completing these questions.  Within the past three years, anywhere in the world, have any of the situations summarised below and listed in full in Annex D applied to you? | | | | | | | | |
| 3.1(a) | | | Breach of environmental obligations?  To note that environmental law obligations include Health and Safety obligations. See Annex D. | | | Yes ☐  No ☐  If yes please provide details at 3.2 | | | | | |
| 3.1 (b) | | | Breach of social law obligations? | | | Yes ☐  No ☐  If yes please provide details at 3.2 | | | | | |
| 3.1 (c) | | | Breach of labour law obligations? | | | Yes ☐  No ☐  If yes please provide details at 3.2 | | | | | |
| 3.1(d) | | | Bankrupt or is the subject of insolvency or winding-up proceedings, where the organisation’s assets are being administered by a liquidator or by the court, where it is in an arrangement with creditors, where its business activities are suspended or it is in any analogous situation arising from a similar procedure under the laws and regulations of any State? | | | Yes ☐  No ☐  If yes please provide details at 3.2 | | | | | |
| 3.1(e) | | | Guilty of grave professional misconduct? | | | Yes ☐  No ☐  If yes please provide details at 3.2 | | | | | |
| 3.1(f) | | | Entered into agreements with other economic operators aimed at distorting competition? | | | Yes ☐  No ☐  If yes please provide details at 3.2 | | | | | |
| 3.1(g) | | | Aware of any conflict of interest within the meaning of regulation 24 due to the participation in the procurement procedure? | | | Yes ☐  No ☐  If yes please provide details at 3.2 | | | | | |
| 3.1(h) | | | Been involved in the preparation of the procurement procedure? | | | Yes ☐  No ☐  If yes please provide details at 3.2 | | | | | |
| 3.1(i) | | | Shown significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, a prior contract with a contracting entity, or a prior concession contract, which led to early termination of that prior contract, damages or other comparable sanctions? | | | Yes ☐  No ☐  If yes please provide details at 3.2 | | | | | |
| 3.1(j) |  | | **Please answer the following statements:** | | | | | | | | |
| – (i) | | The organisation is guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria. | | | Yes ☐  No ☐  If Yes please provide details at 3.3 | | | | | |
| – (ii) | | The organisation has with held such information. | | | Yes ☐  No ☐  If Yes please provide details at 3.3 | | | | | |
| – (iii) | | You are not able, without delay, to submit supporting documents if/when required. | | | Yes ☐  No ☐  If Yes please provide details at 3.3 | | | | | |
| – (iv) | | You have undertaken to unduly influence the decision-making process of the contracting authority to obtain confidential information that may confer upon you undue advantages in the procurement procedure, or to negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award | | | Yes ☐  No ☐  If Yes please provide details at 3.3 | | | | | |
| 3.2 | | | You are a relevant commercial organisation subject to Section 54 of the Modern Slavery Act 2015 if you carry on your business, or part of your business in the UK, supplying goods or services and you have an annual turnover of at least £36 million. If you are a relevant commercial organisation, please confirm:  ● you have published a statement as required by Section 54 of the Modern Slavery Act  ● that the statement complies with the requirements of Section 54 | | | Yes ☐  No ☐  If Yes please provide details at 3.3  Yes ☐  No ☐  If Yes please provide details at 3.3 | | | | | |
| 3.3 | | | If you have answered Yes to any of the above, explain what measures been taken to demonstrate the reliability of the organisation despite the existence of a relevant ground for exclusion? (Self Cleaning) | | |  | | | | | |
|  | | | | | | | | | | | |
| **Part 4** | | **Economic and Financial Standing** | | | | | | | | | |
| Question Number | | Question | | | | | Response | | | | |
| 4.1 | | Are you able to provide a copy of your audited accounts for the last two years, if requested?  If no, can you provide **one** of the following: answer with Y/N in the relevant box. | | | | | | Yes ☐  No ☐ | | | |
| (a) A statement of the turnover, Profit and Loss Account/Income Statement, Balance Sheet/Statement of Financial Position and Statement of Cash Flow for the most recent year of trading for this organisation. | | | | | | Yes ☐  No ☐ | | | |
| (b) A statement of the cash flow forecast for the current year and a bank letter outlining the current cash and credit position. | | | | | | Yes ☐  No ☐ | | | |
| (c) Alternative means of demonstrating financial status if any of the above are not available (e.g. forecast of turnover for the current year and a statement of funding provided by the owners and/or the bank, charity accruals accounts or an alternative means of demonstrating financial status). | | | | | | Yes ☐  No ☐ | | | |
| **Part 5** | | **If you have indicated in the Selection Questionnaire question 1.2 that you are part of a wider group, please provide further details below:** | | | | | | | | | |
| Name of organisation | | | |  | | | | | | | |
| Relationship to the Supplier completing these questions | | | |  | | | | | | | |
| 5.1 | | Are you able to provide parent company accounts if requested to at a later stage? | | | | | Yes ☐  No ☐ | | | | |
| 5.2 | | If yes, would the parent company be willing to provide a guarantee if necessary? | | | | | Yes ☐  No ☐ | | | | |
| 5.3 | | If no, would you be able to obtain a guarantee elsewhere (e.g. from a bank)? | | | | | Yes ☐  No ☐ | | | | |
| Part 6 | | Technical and Professional Ability | | | | | | | | | |
| 6.1 | | **Relevant experience and contract examples**  Please provide details of up to three contracts, in any combination from either the public or private sector; voluntary, charity or social enterprise (VCSE) that are relevant to our requirement. VCSEs may include samples of grant-funded work. Contracts for supplies or services should have been performed during the past three years. Works contracts may be from the past five years.  The named contact provided should be able to provide written evidence to confirm the accuracy of the information provided below.  Consortia bids should provide relevant examples of where the consortium has delivered similar requirements. If this is not possible (e.g. the consortium is newly formed or a Special Purpose Vehicle is to be created for this contract) then three separate examples should be provided between the principal member(s) of the proposed consortium or Special Purpose Vehicle (three examples are not required from each member).  Where the Supplier is a Special Purpose Vehicle, or a managing agent not intending to be the main provider of the supplies or services, the information requested should be provided in respect of the main intended provider(s) or sub-contractor(s) who will deliver the contract.  If you cannot provide examples see question 6.3 | | | | | | | | | |
| **Contract 1** | | | | | | | | | | | |
| Name of customer organisation | | | | |  | | | | | | |
| Point of contact in the organisation | | | | |  | | | | | | |
| Position in the organisation | | | | |  | | | | | | |
| E-mail address | | | | |  | | | | | | |
| Description of contract | | | | |  | | | | | | |
| Contract Start date | | | | |  | | | | | | |
| Contract completion date | | | | |  | | | | | | |
| Estimated contract value | | | | |  | | | | | | |
| **Contract 2** | | | | | | | | | | | |
| Name of customer organisation | | | | |  | | | | | | |
| Point of contact in the organisation | | | | |  | | | | | | |
| Position in the organisation | | | | |  | | | | | | |
| E-mail address | | | | |  | | | | | | |
| Description of contract | | | | |  | | | | | | |
| Contract Start date | | | | |  | | | | | | |
| Contract completion date | | | | |  | | | | | | |
| Estimated contract value | | | | |  | | | | | | |
| **Contract 3** | | | | | | | | | | | |
| Name of customer organisation | | | | |  | | | | | | |
| Point of contact in the organisation | | | | |  | | | | | | |
| Position in the organisation | | | | |  | | | | | | |
| E-mail address | | | | |  | | | | | | |
| Description of contract | | | | |  | | | | | | |
| Contract Start date | | | | |  | | | | | | |
| Contract completion date | | | | |  | | | | | | |
| Estimated contract value | | | | |  | | | | | | |
| 6.2 | | Where you intend to sub-contract a proportion of the contract, please demonstrate how you have previously maintained healthy supply chains with your sub-contractor(s)  Evidence should include, but is not limited to, details of your supply chain management tracking systems to ensure performance of the contract and including prompt payment or membership of the UK Prompt Payment Code (or equivalent schemes in other countries) | | | | | | | | | |
|  | | | | | | | | | |
| 6.3 | | If you cannot provide at least one example of previous contracts that are relevant to our requirement, in no more than 500 words please provide an explanation for this and how you meet the selection criteria relating to technical and professional ability e.g. your organisation is a new start-up or you have provided services in the past but not under a contract.  Where you intend to subcontract a proportion of the contract, please demonstrate how you have previously maintained healthy supply chains with your subcontractor(s). The description should include, but is not limited to, details of your supply chain management tracking systems to ensure performance of the contract and including prompt payment and whether you are a signatory of the UK Prompt Payment Code (or have given commitments under other equivalent schemes). | | | | | | | | | |
|  | | | | | | | | | |
| **Part 7** | | **Modern Slavery Act 2015:** **Requirements under Modern Slavery Act 2015** | | | | | | | | | |
| 7.1 | | Are you a relevant commercial organisation as defined by section 54 ("Transparency in supply chains etc.") of the Modern Slavery Act 2015 ("the Act")? | | | | | | | Yes ☐  No ☐ | | |
| 7.2 | | If you have answered yes to question 7.1 are you compliant with the annual reporting requirements contained within Section 54 of the Act 2015? | | | | | | | Yes ☐  Please provide the relevant url to view the statement.    No ☐  Please provide an explanation. | | |
| 7.3 | | If you are a non-UK bidder, please provide a link to your published modern slavery statement in your own jurisdiction or to a relevant company document containing the same type or level of information.  Your statement or documents should comply with the requirements contained within Section 54 of the Modern Slavery Act 2015 and associated guidance including information relating to:  a. the organisation’s structure, its business and its supply chains;  b. its policies in relation to slavery and human trafficking;  c. its due diligence processes in relation to slavery and human trafficking in its business and supply chains;  d.the parts of its business and supply chains where there is a risk of slavery and human trafficking taking place, and the steps it has taken to assess and manage that risk;  e. its effectiveness in ensuring that slavery and human trafficking is not taking place in its business or supply chains, measured against such performance indicators as it considers appropriate;  f. the training and capacity building about slavery and human trafficking available to its staff. | | | | | | |  | | |
| 7.4 | | Detail how through the delivery of this contract, you will proactively tackle modern slavery within the organisation and supply chain | | | | | | |  | | |
| 7.5 | | Please describe your organisations approach and policy with regards to modern slavery. Please include any information about policies held or adhered to and what methods of escalation your organisation follows to eradicate it. | | | | | | |  | | |
| **Part 8** | | **Additional Questions** | | | | | | | | | |
| **8.1** | | **Insurance** | | | | | | | | | |
| 8.1 (a)a. | | Please self-certify whether you already have, or can commit to obtain, prior to the commencement of the contract, the levels of insurance cover indicated below: | | | | | | | | | |
| Employer’s (Compulsory) Liability Insurance = £**10m** | | | | | | | | | Yes ☐  No ☐ |
| Public Liability Insurance = £**10m** | | | | | | | | | Yes ☐  No ☐ |
| Professional Indemnity Insurance = £ **10m** | | | | | | | | | Yes ☐  No ☐ |
| Product Liability Insurance = £ **5m** | | | | | | | | | Yes ☐  No ☐ |
| \*There is a legal requirement for certain employers to hold Employer’s (Compulsory) Liability Insurance of £5 million as a minimum. See the Health and Safety Executive website for more information: http://www.hse.gov.uk/pubns/hse39.pdf | | | | | | | | | |
|  | | **Health and Safety** | | | | | | | | | |
| Q8.5 (a) | | As an employer do you follow the Health and Safety at work act 1974 | | | | | | | | Yes ☐  No ☐ | |
|  | | **As was detailed in the Invitation to Tender, it is a requirement for this contract that the successful organisation is SSIP compliant or equivalent.** | | | | | | | | | |
|  | | Is your organisation a member of Safety Schemes in Procurement?  If **‘Yes’** please provide the date of approval and expiry:  If **‘No’** please answer questions Q8.5 (b) and Q8.5 (c): | | | | | | | | Yes ☐  No ☐ | |
| |  |  | | --- | --- | | Date of approval |  | | Date Accreditation expires |  | | | | | | | | | | |
| Q8.5 (b) | | Has a member of the Safety Schemes in Procurement (SSIP) assessed your organisation’s Health and Safety as compliant?  **If ‘yes’ please provide details and evidence to support your answer.** | | | | | | | | Yes ☐  No ☐ | |
|  | | | | | | | | | |
| Q8.5 (c) | | Are you willing to become SSIP compliant at no additional cost to the Trust and in a timely manner so not to adversely affect the commencement date of the contract as this will need to be in place before the contract commences.  If **‘Yes’** please provide indicative timetable for approval: | | | | | | | | Yes ☐  No ☐ | |
|  | | | | | | | | | |
| Q8.5 (d) | | Has your organisation or any of its Directors or Executive Officers been in receipt of enforcement/remedial orders in relation to the Health and Safety Executive (or equivalent body) in the last 3 years?  If ‘**Yes**’ please provide details below of any enforcement/remedial orders served and give details of any remedial action or changes to procedures you have made as a result.    **Note:** Bidder(s) that have been in receipt of enforcement/remedial action orders, may be excluded from the process under **Grounds for discretionary exclusion**. unless the bidder(s) can demonstrate to our satisfaction that appropriate remedial action has been taken to prevent future occurrences or breaches | | | | | | | | Yes ☐  No ☐ | |
|  | | | | | | | | | |
| Q8.5 (e) | | If you use sub-contractors, do you have processes in place to check whether any of the above circumstances apply to these other organisations? | | | | | | | | Yes ☐  No ☐ | |
|  | | **Data Protection**  Please note this information will be used to determine if you abide by Data Protection Legislation. If the Authority deem you do not have the necessary procedures and policies in place you may be excluded from the process under **Grounds for discretionary exclusion**. | | | | | | | | | |
| 8.6 (a) | | Please confirm that you have in place, or that you will have in place by contract award, the human and technical resources to perform the contract to ensure compliance with the UK General Data Protection Regulations and to ensure the protection of the rights of data subjects. | | | | | | | | | Yes ☐  No ☐ |
| 8.6 (b) | | Please provide details of the technical facilities and measures (including systems and processes) you have in place, or will have in place by contract award, to ensure compliance with UK data protection law and to ensure the protection of the rights of data subjects. Your response should include, but should not be limited to facilities and measures:   * to ensure ongoing confidentiality, integrity, availability and resilience of processing systems and services; * to comply with the rights of data subjects in respect of receiving privacy information, and access, rectification, deletion and portability of personal data; * to ensure that any consent-based processing meets standards of active, informed consent, and that such consents are recorded and auditable; * to ensure legal safeguards are in place to legitimise transfers of personal data outside the UK (if such transfers will take place); * to maintain records of personal data processing activities; and * to regularly test, assess and evaluate the effectiveness of the above measures. | | | | | | | | |  |
| **Response:** | | | | | | | | | |
| 8.6 (c) | | Have you been subject to any enforcement action(s) by the ICO, in respect of data protection compliance in the last three years?  If the answer is **YES**, please give details below and give actions.  **Note:** Bidder(s) that have been prosecuted or served penalty / enforcement notice(s) in the last 3 years, may be excluded from the process under **Grounds for discretionary exclusion**. Unless the bidder(s) can demonstrate to our satisfaction that appropriate remedial action has been taken to prevent future occurrences / breaches. | | | | | | | | | Yes ☐  No ☐ |
| 8.6 (d) | | Please provide details of your Data Protection Officer. If you are not subject to this requirement please provide your nominated representative. | | | | | | | | | |
| **8.7** | | **Business Continuity / Risk Management / Disaster Recovery** | | | | | | | | | |
| 8.7 (a) | | Does your organisation have a Business Continuity / Disaster Recovery / Risk Management Plan that ensures that the described services are delivered in the event of a disruption affecting your business and ensures continuity of supply/service from your critical Tenderers? | | | | | | | | | Yes ☐  No ☐ |
| If “**Yes**” please describe its main aims and characteristics  If “**No**” please give reasons    **Note:** You will be required to provide a copy of your Business continuity plan prior to contract award / commencement. | | | | | | | | | |
| **8.8** | | **Information Concerning Possible Blacklisting** | | | | | | | | | |
| 8.8 (a) | | Has your organisation committed an act prohibited under the Employment Relations Act 1999 (Blacklists) Regulations 2010? | | | | | | | | | Yes ☐  No ☐ |
| If “**Yes**” If yes, when did the breach occur? | | | | | | | | | |
| 8.8 (b) | | Has your organisation taken measures to demonstrate its reliability despite the existence of this ground for exclusion (“Self-Cleansing”)? | | | | | | | | | Yes ☐  No ☐ |
| If “**Yes**” If yes, please describe the measures taken: | | | | | | | | | |

**Section 5: Technical Specification**

This section evaluates your organisation’s ability to deliver the key technical requirements outlined in Appendix A - specification. Please complete the Yes/No collum in relation to each key technical element.

Where your organisation has entered No, this will result in a fail and your organisation will be excluded form the evaluation process.

|  |  |  |
| --- | --- | --- |
| Reference number | Specification Conformance Requirement | Yes/no  Pass/Fail |
| SCR1 | The Supplier must confirm that they can meet the requirements as outlined within Appendix A - Specification |  |
| SCR2 | Key performance indicators  The Supplier will comply with the key performance indicators outlined in Performance and Contract Management sectionof Appendix A, page 11. |  |
| SCR3 | The authority must have access to view and audit the successful bidder’s policies, procedures and controls to ensure that they are acceptable, complete and up-to-date throughout the life of the contract. |  |

**SECTION 6: PRICING SCHEUDLE (STAGE 2)**

This section accounts for **45%** of the final evaluation score

Please complete and upload Appendix B – Pricing Schedule

**SECTION 7: QUALITY REQUIREMENTS (STAGE 3)**

This section accounts for **45%** of the final evaluation score.

The following questions relate to the Authority Quality requirements and are designed to establish your organisation’s understanding and proposals for how you will deliver them. **Please provide as full an answer as possible.**

There is a maximum word limit for each question. Please include your word count in the space provided. **Any words in excess of the word limit will not be considered**. All answers must be provided on this template.

The Trust will not be responsible for any errors or omissions due to changes to the document format

Should you need to supply graphics, tables etc. you should submit these as a separate document. For this supporting information to be considered you must clearly reference the supporting question and to clearly explain in your response (included in your word count) how and why the information supports your answer. Supporting information not clearly referenced as described here, will not be evaluated. Please note, this is only for graphics, tables etc, all written responses should be in the format supplied.

Please ensure you have read the evaluation criteria for all questions as set out in Invitation to Tender, Tender evaluation strategy and Example and you are aware how responses will be evaluated in this area.

|  |  |
| --- | --- |
| **Question 1**  **Question weighting 10%**  **Max word count: 750** | |
| **Question**  Please describe your Quality Assurance processes, as well as how you monitor, manage, and inspect your inventory to ensure that it meets required specifications and regulatory requirements. | **Question Guidance**   * please detail processes for storage * describe environmental and temperature monitoring processes * List processes for labelling and potential relabelling. * Assurance around third party vendor usage.. |
| Answer :  Word count: | |

|  |  |
| --- | --- |
| **Question 2**  **Question weighting 10 %**  **Max Word Count: 750** | |
| **Question**  Please describe how you will package and label the IMP and placebo into 3 bottles or blister packs of 128 tablets and then combine into kits of 3 packs, as well as detailing any features of note such as child-proofing or tamper-evidencing. | **Question Guidance**   * What packaging will be used * Describe how the kits will look * Detail all features * Detail how indistinguishable IMP and Placebo will look |
| Answer :  Word count: | |

|  |  |
| --- | --- |
| **Question 3**  **Question weighting 5 %**  **Max Word Count: 500** | |
| **Question**  This trial represents a multi-Trust collaborative project, involving the distribution of IMPs and Placebos to 35-40 NHS Trusts across the UK. Please detail how you would label, package and deliver trial medicines under temperature controlled conditions on a large-scale across multiple locations to meet the requirements of this contract.. | **Question Guidance**   * Detail stages involved * What records are kept * What courier services are used * What service level agreements you have with them with regard to temperature control * What delivery time scales can you gurantee |
| Answer :  Word count: | |

|  |  |
| --- | --- |
| **Question 4**  **Question weighting 10 %**  **Max Word Count: 750** | |
| **Question**  Please quantify what percentage of overages will be required for each production run to meet the requirements of this trial. Also detail how you plan to decrease this amount for each subsequent production run, once the number of participants on the drug or placebo at each location becomes clearer. | **Question Guidance**   * What data is required * What efficiencies can you provide * Detail your processes |
| Answer :  Word count: | |

|  |  |
| --- | --- |
| **Question 5**  **Question weighting 5 %**  **Max Word Count: 500** | |
| **Question**  Please give an overview of your organisation's resources and how you anticipate this will be allocated to deliver the requirements of this contract. | **Question Guidance**   * Who will be involved * How will they be involved * How long will they be involved * How will you minimise staff rotation to ensure consistency throughout the trial |
| Answer :  Word count: | |

|  |  |
| --- | --- |
| **Question 6**  **Question weighting 5 %**  **Max Word Count: 500** | |
| **Question**  Please provide and detail your organisations contingency arrangements and risk management arrangements that you have in place for manufacture of the IMP and placebo | **Question Guidance**   * List processes * Detail contingency plans around product recalls * How do you arrive at time frames around recalls * What support can you offer the Trust around recalls * Who will be involved |
| Answer :  Word count: | |

**SECTION 8: SOCIAL VALUE (STAGE4)**

This section accounts for 10% of the final evaluation score.

The following questions relate to Social Value and are designed to establish your organisation’s commitment in supporting Sheffield Teaching Hospitals NHS Foundation Trust in meeting their social value outputs and how you will deliver these over the term of the contract. **Please provide as full an answer as possible.**

There is a maximum word limit for each question. Please include your word count in the space provided. **Any words in excess of the word limit will not be considered**. All answers must be provided on this template.

The Authority will not be responsible for any errors or omissions due to changes to the document format

Please ensure you have read the evaluation criteria for all questions as set out in Invitation to Tender, Tender evaluation strategy and Example and you are aware how responses will be evaluated in this area.

|  |  |
| --- | --- |
| **Question 1**  **Question weighting 5 %**  **Max Word Count: 750** | |
| **Question**  Detail how, through the delivery of this contract, you will monitor and reduce the use of single-use plastics in both packaging and products? | **Question Guidance**   * How would you arrive at Base line plastic usage figures * What policies do you have in place to support this |
| Answer :  Word count: | |

|  |  |
| --- | --- |
| **Question 2**  **Question weighting 5 %**  **Max Word Count: 750** | |
| **Question**  Detail how, through the delivery of this contract, you will monitor and reduce the emissions produced by your storage and distribution network? | **Question Guidance**   * How would you arrive at base line figures * What policies do you have in place to support this. * What reduction levels would you commit to. |
| Answer :  Word count: | |

1. For the list of exclusion please see https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/551130/List\_of \_Mandatory\_and\_Discretionary\_Exclusions.pdf  [↑](#footnote-ref-1)
2. See PCR 2015 regulations 71 (8)-(9) [↑](#footnote-ref-2)
3. See EU definition of SME <https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en> [↑](#footnote-ref-3)
4. , 9, <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/551130/List_of_Mandatory_and_Discretionary_Exclusions.pdf> [↑](#footnote-ref-4)
5. <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/551130/List_of_Mandatory_and_Discretionary_Exclusions.pdf> [↑](#footnote-ref-5)