##

## **INVITATION TO TENDER: BIDDER INFORMATION DOCUMENT**

Invitation to tender 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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1. INTRODUCTION AND BACKGROUND
	1. The Sheffield Teaching Hospitals Trust (the "**Authority**") is issuing this Invitation to Tender ("**ITT**") Information Document in connection with the competitive procurement of Investigational Medicinal Products for IMPEDE-PKD drug trial. This document contains important information about the procurement process and the contract that the Authority intends to award.
	2. This Information Document contains further information about the procurement process.
	3. Bidders must respond to the ITT questions on the Atamis e-tendering portal. Each Bidder's response ("**Tender**") should be detailed enough to allow the Authority to make an informed award decision.
	4. All Tenders must be submitted no later than the deadline for receipt of Tenders specified on the front cover of this Information Document.
	5. The Authority is using the Atamis e-tendering portal to conduct the procurement process. This can be accessed at <https://health-family.force.com/login>. All communications (including submission of tenders) should be carried out via the portal.

# Contents of the ITT Information Document

* 1. This document consists of:

|  |
| --- |
| **Instructions and information** |
| 1 | Introduction and background |
| 2 | Tender timetable  |
| 3 | Instructions to Bidders  |
| 4 | Tender evaluation methodology and criteria |

* 1. Sheffield Teaching Hospitals NHS Foundation invites interested suppliers to tender for the provision of Investigational Medicinal Products for IMPEDE-PKD drug trial.

**STH - Who we are and what we do**

* 1. Sheffield Teaching Hospitals NHS Foundation Trust is one of the UK’s largest, busiest and most successful NHS foundation trusts. We provide a full range of hospital and community services for people in Sheffield, as well as specialist care for patients from further afield. We manage five of Yorkshire’s best known teaching hospitals including:
		1. Northern General Hospital
		2. Royal Hallamshire Hospital
		3. Charles Clifford Dental Hospital
		4. Weston Park Cancer Hospital
		5. Jessop Wing Maternity Hospital
	2. We have a long history of providing high quality care, clinical excellence and innovation in medical research.
	3. With around 16,000 employees, we are one of the biggest employers locally. We aim to reflect the diversity of local communities and are proud of our new and existing partnerships with local people, patients, neighbouring NHS organisations, local authority and charitable bodies.
	4. As well as being home to one of three Major Trauma Centres for the Yorkshire and Humber region, we have a number of specialist medical and surgical services, many of which we are internationally renowned for. These include cancer treatment, spinal injuries, neurology, cardiology and stereotactic radiosurgery to name but a few.
	5. Our long tradition of clinical and scientific achievements has been strengthened by developing one of the UK’s first Academic Health Science Networks. Through our partnerships with the University of Sheffield, Sheffield Hallam University, other health and social care providers and industry we remain at the forefront of advancements in clinical services, teaching and research.
	6. Our Vision is to be recognised as the best provider of health, clinical research and education in the UK and a strong contributor to the aspiration of Sheffield to be a vibrant and healthy city region.
	7. Further information about Sheffield Teaching NHS Foundation Trust can be found on our website; please visit <http://www.sth.nhs.uk/>

**Procurement Objectives**

* 1. IMPEDE-PKD is a global clinical trial, with a recruitment target of over 1000 participants (with 300 being recruited in the UK). It is a pragmatic, multi-centre, double blind parallel group randomised controlled trial of metformin versus placebo in patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD). The primary objective is to evaluate the long-term efficacy of metformin therapy in slowing the rate of kidney function decline in metformin versus placebo treated ADPKD subjects.

**Procurement Key Requirements**

* 1. As the Lead Trust, STH is seeking a bidder who can supply Metformin XR 500mg and a matched placebo. These must be labelled to our requirements set out in the specification, stored appropriately and distributed to 35-40 UK NHS Trusts as the trial develops.
	2. Full details of the Authority's requirements are set out in the Specification documents folder on the Atamis portal.

# Purpose and scope of this ITT

* 1. This ITT:
		1. invites Bidders to submit their Tenders in accordance with the instructions set out in the remainder of this ITT;
		2. sets out the overall timetable and process for the procurement;
		3. provides Bidders with sufficient information to enable them to submit a compliant Tender;
		4. sets out the award criteria and Tender evaluation model that will be used to evaluate the Tenders; and
		5. explains the administrative arrangements for the receipt of Tenders.

# Questions about this ITT

* 1. You may submit, by no later than Friday 20/08/2024 13:00 any queries that you have relating to this ITT. Please submit such queries via the e-Tendering Portal.
	2. Any specific queries should clearly reference the appropriate paragraph in the ITT documentation and, to the extent possible, should be aggregated rather than sent individually. The Authority may decline to answer queries received after the above deadline.
	3. Answers to the questions received by the Authority will be circulated to all Bidders via the e-Tendering Portal. Answers will not reveal the identity of the individual Bidder that asked a particular question. The Authority may decide not to disclose answers, or parts of answers, which would reveal confidential or commercially sensitive information in relation to a particular Bidder.
1. TENDER TIMETABLE

# Key dates

* 1. The procurement will follow a clear, structured and transparent process to ensure a fair and level playing field so that all Bidders are treated equally.
	2. The key dates for this procurement are currently anticipated to be as follows:

|  |  |
| --- | --- |
| **Event** | **Date** |
| ITT issued | 25/07/2024 |
| Deadline for the receipt of clarification questions | 20/08/2024 |
| Target date for responses to clarification questions | 23/08/2024  |
| Deadline for receipt of Tenders | 27/08/2024 13:00 |
| Evaluation of Tenders | 28/08 – 19/09/2024 |
| Notification of contract award decision | 20/09/2024 |
| Standstill period | From 21/09/2024 to midnight on 30/09/2024 |
| Contract award | 01/10/2024 |
| Contract work starts  | 01/10/2024 |

* 1. Whilst the Authority does not intend to depart from the timetable, it reserves the right to do so at any stage.

# Deadline for receipt of Tenders

* 1. Bidders must submit their Tenders in the manner prescribed in section 3 below no later than the date and time specified on the front cover of this ITT.
	2. Any Tender received after the deadline or by any method other than via the e-Tendering Portal may not be considered. The Authority may at its discretion extend the deadline and in such circumstances the Authority will notify all Bidders of any change.

**Standard Selection evidence**

* 1. Bidders are required to provide information about their eligibility for this procurement and some of that information will be self-certified as accurate. During the standstill period, the Authority will require the successful Bidder to provide the following:
		1. Self-Certify as required in the Public Contracts Regulations 2015, Regulation 60(4) or (5), that none of the mandatory or discretionary grounds of exclusion referred to in the Standard Selection Questionnaire and responses section found in the Supplier Tender Return document applies;
		2. Proof as required in the Public Contracts Regulations 2015, Regulation 60(6), that you have the minimum level of economic and financial standing;
		3. Self-certify the required insurances as set out in Part 8 of the Standard Selection Questionnaire and responses section found in the Supplier Tender Return document applies;
		4. A copy of your health and safety Policy;

**Contract award**

* 1. Contract award is subject to the formal approval process of the Authority. Until all necessary approvals are obtained and the standstill period completed, no contract(s) will be entered into.
	2. Once the Authority has reached a decision in respect of a contract award, it will notify all Bidders of that decision and provide for a standstill period in accordance with the Public Contracts Regulations 2015 before entering into any contract(s).
1. INSTRUCTIONS TO BIDDERS

# Formalities for submission of Tenders

* 1. Bidders must submit their Tenders by completing the questions within the Requirements envelope on Atamis. Completed Tenders must be submitted using the e-Tendering Portal. Bidders should ensure that they allow plenty of time to upload the Tender, particularly where there are large documents.If Bidders have any problems with [the electronic tendering portal], they should contact the helpdesk on 029 2279 0052 or email: info@atamis.co.uk. As noted above, any Tender received after the deadline may not be considered.
	2. The Authority does not guarantee that you will be able to upload files, particularly at busy times. For this reason it is recommended that Bidders should ensure files are well prepared and allow plenty of time to upload, so they have enough time to resolve any technical difficulties before the deadline.
	3. *Bidders must adhere to the following standard requirements when submitting their Tenders*:
		1. *Do not embed documents within other documents. Instead provide separate electronic copies of the documents, clearly labelled and referenced if necessary.*
		2. *The Tender must be in English and drafted in accordance with the drafting guidance set out in this ITT.*
		3. *[Each Tender (whether a reference bid or a variant bid) must be uniquely named or referenced.] [– delete if variants are not permitted]*
		4. *The Tender must be fully cross-referenced and include a table of contents.*
		5. *The Tender must include a list of all supporting material.*
		6. *Electronic copies of the Tender shall be in* relevant *Microsoft Office* Package, e.g. Word *or* Excel.
		7. *No PDF documents should be included unless otherwise agreed via clarification.*
	4. Where a word count limit is specified, Bidders should state how many words their response contains. The Authority reserves the right not to consider any part of a response exceeding the word limit. Words included within diagrams or other graphic representations will count towards the word limit.
	5. The Tender must be clear, concise and complete. The Authority reserves the right to mark Bidders down or exclude them from the procurement if their Tenders are ambiguous or lack clarity. Bidders should submit only such information as is necessary to respond effectively to this ITT. Unless specifically requested, do not include extraneous presentation materials.
	6. Tenders will be evaluated on the basis of information submitted by the deadline. Where information or documentation submitted appears to be incomplete or erroneous or specific documents are missing, the Authority reserves the right to request the Bidder to submit, supplement, clarify or complete the information or documentation.
	7. The Tender must be signed by a duly authorised representative of the Bidder.

# Modification and withdrawal of Tenders

* 1. Except as set out in paragraph 3.6, no Tender may be modified after the deadline for receipt of Tenders.
	2. Tenders may be withdrawn at any time before the deadline for receipt of Tenders. Revised Tenders may be submitted up until the deadline for receipt of Tenders,

# Terms and conditions

* 1. The contract will include the NHS Terms and Conditions set out in Appendix C. It is vital that the Bidder reviews these carefully, and takes account of all information such as TUPE, key performance indicators and insurance requirements and that the Tender fully takes account of these. By submitting a Tender, Bidders are agreeing to be bound by the terms of this ITT and the NHS Terms and Conditions without further negotiation or amendment.

# Consortia and subcontractors

* 1. If the Bidder is a consortium or will rely on sub-contractors to deliver the contract, it must explain in its Tender precisely which entities will be the supplier.
	2. For the purposes of this ITT, the following terms apply:
		1. *Consortium arrangement -* Groups of companies come together specifically for the purpose of bidding for appointment as the supplier and envisage that they will establish a special purpose vehicle as the prime contracting party with the Authority.
		2. *Subcontracting arrangement -* Groups of companies come together specifically for the purpose of bidding for appointment as the supplier, but envisage that one of their number will be the supplier, the remaining members of that group will be subcontractors to the supplier.
	3. If the Bidder intends to sub-contract any material parts of the contract, it must explain which parts will be sub-contracted, who the sub-contractor is, confirm the sub-contractor has agreed terms of supply and what contractual commitment it has from the sub-contractor to deliver.

# Warnings and disclaimers

* 1. While the information contained in this ITT is believed to be correct at the time of issue, neither the Authority, its advisors, nor any other awarding authorities will accept any liability for its accuracy, adequacy or completeness, nor will any express or implied warranty be given. This exclusion extends to liability in relation to any statement, opinion or conclusion contained in or any omission from, this ITT (including its annexes) and in respect of any other written or oral communication transmitted (or otherwise made available) to any Bidder. This exclusion does not extend to any fraudulent misrepresentation made by or on behalf of the Authority.
	2. If a Bidder proposes to enter into a contract with the Authority, it must rely on its own enquiries and on the terms and conditions set out in the contract(s) (as and when finally executed), subject to the limitations and restrictions specified in it.
	3. Neither the issue of this ITT, 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.

# Freedom of Information Act 2000 and Environmental Information Regulations 2004

* 1. As a public body, the Authority is subject to, and must comply with, the Freedom of Information Act 2000 ("**FOIA**") and the Environmental Information Regulations 2004 ("**EIR**"). The Authority may therefore be required to disclose information submitted by the Bidder.
	2. In respect of any information submitted by a Bidder that it considers to be confidential or commercially sensitive the Bidder should:
		1. clearly identify such information as confidential or commercially sensitive;
		2. explain its reasons why disclosure of such information would be likely to prejudice or would cause actual prejudice to its commercial interests; and
		3. provide a reasoned estimate of the period of time during which the Bidder believes that such information will remain commercially sensitive.
	3. This information must be listed in **Appendix D** (Confidential and Commercially Sensitive Information), with a statement of which exemptions are relevant under FOIA and/or the EIR.
	4. Where a Bidder identifies information as commercially sensitive, the Authority will take those views into account. Bidders should note, however, that, even where information is identified as commercially sensitive, the Authority may be required to disclose such information in accordance with FOIA or the EIR. Accordingly, the Authority cannot guarantee that it will withhold information marked ‘confidential’, 'commercially sensitive' or otherwise exempt.

# Publicity

* 1. No publicity regarding the award of any contract will be permitted unless and until the Authority has given express written consent to the relevant communication. For example, no statements may be made to the media regarding the nature of any Tender, its contents or any proposals relating to it without the prior written consent of the Authority.

# Bidder conduct and conflicts of interest

* 1. Any attempt by Bidders or their advisors to influence the contract award process in any way may result in the Bidder being disqualified. Specifically, Bidders shall not directly or indirectly at any time:
		1. devise or amend the content of their Tender in accordance with any agreement or arrangement with any other person, other than in good faith with a person who is a proposed partner, supplier, consortium member or provider of finance;
		2. enter into any agreement or arrangement with any other person as to the form or content of any other Tender, or offer to pay any sum of money or valuable consideration to any person to effect changes to the form or content of any other Tender;
		3. enter into any agreement or arrangement with any other person that has the effect of prohibiting or excluding that person from submitting a Tender;
		4. canvass the Authority or any employees or agents of the Authority in relation to this procurement; and/or
		5. attempt to obtain information from any of the employees or agents of the Authority or their advisors concerning another Bidder or Tender (except for debrief information requests made through the e-Tendering Portal).
	2. Bidders are responsible for ensuring that no conflicts of interest exist between the Bidder and its advisers, and the Authority and its advisors. Bidders should notify the Authority promptly of any possible conflict and the proposed steps that the Bidder believes can be taken to avoid the conflict. Any Bidder who fails to comply with these requirements may be excluded from the procurement at the discretion of the Authority.

# Authority's rights

* 1. Subject to its obligations to act in a transparent, proportionate and non-discriminatory manner, the Authority reserves the right to:
		1. waive or change the requirements of this ITT from time to time;
		2. seek clarification or documents in respect of a Bidder's submission;
		3. disqualify any Bidder that does not submit a compliant Tender in accordance with the instructions in this ITT;
		4. disqualify any Bidder that is guilty of serious misrepresentation in relation to its Tender or the Tender process;
		5. withdraw this ITT at any time, or re-invite Tenders on the same or any alternative basis;
		6. choose not to award any contract as a result of the current procurement process; and
		7. make whatever changes it sees fit to the timetable, structure or content of the procurement process.

# Bid costs

* 1. The Authority will not be liable for any bid costs, expenditure, work or effort incurred by a Bidder in proceeding with or participating in this procurement, including if the procurement process is terminated or amended by the Authority.

# Language

* 1. Tenders, all documents and all correspondence relating to the Tender must be written in English.

# Transparency

* 1. In accordance with the Public Contracts Regulations 2015 and the Government’s policy on transparency, Bidders should be aware that the Authority intends to make the ITT and details of any subsequent contract publicly available, by publication on the Government's Contracts Finder portal.

# Governing Law and Jurisdiction

* 1. This ITT and any dispute concerning it (including non-contractual disputes or claims) shall be governed by English law and subject to the jurisdiction of the English Courts
1. TENDER EVALUATION METHODOLOGY AND CRITERIA

# Overview

* 1. This section of the ITT Information Document sets out the criteria that the Authority will use to evaluate Tenders.
	2. Bidders are required to submit a Tender strictly in accordance with the requirements set out in this ITT, to ensure the Authority has the correct information to make the evaluation. If a Tender is equivocal or unclear, the Authority may deduct marks when scoring it, or it may treat the Tender as non-compliant and reject it.
	3. The Authority will award the contract to the Tender that scores the highest marks, applying the methodology below. Scoring will be carried out as follows:
		1. The Bidder must pass all standard selection questions outlined in the Supplier Tender Return ITT ("**Standard Selection Questionnaire**").
		2. The Authority will then mark the Supplier Tender Return ITT Quality Questions for all Bidders that pass all the Eligibility Questions.
	4. The Authority will mark Standard Selection Questions as described in paragraphs 4.5 to 4.7 below. It will mark the Scored Questions as described in paragraphs 4.8 to 4.14

# Criteria – Eligibility Questions

* 1. The Authority will score Eligibility Questions on the following basis:

|  |  |
| --- | --- |
| **Standard Selection Questions**  | **Selection criteria** |
| Supplier information | For information only |
| Grounds for mandatory exclusion | Pass or Fail |
| Grounds for discretionary exclusion  | Pass or Fail |
| 4 Economic and Financial Standing] | [Pass or Fail] |
| 5 Organisation Profile | For information only |
| 6 Technical and Professional Ability] | Pass or Fail |
| 7. Modern Slavery Act | Pass or Fail |
| 8. Additional Questions | Pass or Fail |

* 1. To score a "pass", the Tender must adequately address all key points and include adequate supporting evidence / examples / information. It must give a reasonable degree of confidence that the Bidder has the capability, resource and experience to properly perform the contract.
	2. Section 4 will be evaluated by reference to a financial credit check and scored as follows

|  |  |  |
| --- | --- | --- |
| **Credit Check Score** | **Description** | **Outcome** |
| A | Very low risk | Pass |
| B | Low risk | Pass |
| C | Moderate risk | Pass with reservations |
| D | High risk | Refer to Finance Team for further review |
| E | Not rated | Refer to Finance Team for further review |

* 1. A financial stability check will then be conducted using ratio analysis and the following scoring mechanism applied.

|  |  |  |
| --- | --- | --- |
| **Final Score** | **Description** | **Outcome** |
| 4 - 5 | Very low risk | Pass |
| 3 - 4 | Low risk | Pass |
| 2 - 3 | Moderate risk | Pass with reservations |
| 1 - 2 | High risk | Refer to Finance Team for further review |
| 0 - 1 | Very high risk | Fail |

* 1. Ratio analysis will be scored against liquidity, debt and profitability for the last 2 financial years.
	2. Bidders who are deemed to be financially at risk and who have a parent company will have the finances of the parent company assessed and if the parent company passes a Parent Company Guarantee will be required.
	3. Where a Bidder scores a "fail" for any question, the Authority will treat the Tender as non-compliant and it will not award a mark for the Scored Questions.

# Criteria – Scored Questions

|  |  |
| --- | --- |
| **Evaluation Criteria** | **Weighting** |
| Scored Quality Questions | 45% |
| Pricing Schedule | 45% |
| Social Value Questions | 10% |

# Criteria – Scored Questions: pricing evaluation

* 1. The rates shall allow for all general risks, liabilities and obligations as set out in the Conditions of Contract.

The Trust expects goods to be dispatched from a UK supply location where possible. In the event this is not possible all prices quoted MUST be inclusive of any additional import taxes, duty and fees (where payment liability sits with the Trust) in addition to the base price quoted. All values must be quoted in pound sterling (£). This is to ensure all Supplier responses submitted are evaluated on an equitable basis.

* 1. *Tender prices will be scored on a comparative basis, with the lowest compliant Tender (excluding any Tenders that the Authority rejects as being abnormally low or non-compliant) receiving 100% of the available marks(45% following weighting). All other Tenders will be compared against that lowest Tender using the formula*:

## *(A / B) x 100*

## *A = price of lowest compliant Tender*

## *B = price of the Tender being scored*

* 1. If it appears to the Authority that any Tender may be abnormally low then the Authority may ask the Bidder to explain its price or costs. If following the Bidder's explanations, the Authority is not satisfied with the Bidder's account for the low level of price or cost in the Tender, the Authority may treat the Tender as non-compliant and reject it.

# Criteria – Scored Questions: technical and quality evaluation

* 1. The technical evaluation will be scored in accordance with the table below:

|  |  |  |
| --- | --- | --- |
| **Grade label** | **Grade** | **Definition of Grade** |
| Unacceptable | 0 | Nil or inadequate response. Fails to demonstrate an ability to meet the requirement |
| Poor | 1 | Response is partially relevant but generally poor. The response addresses some elements of the requirement but contains insufficient/limited detail or explanation to demonstrate how the requirement will be fulfilled |
| Acceptable | 2 | Response is relevant and acceptable. The response addresses a broad understanding of the requirement but lacks detail on how the requirement will be fulfilled in certain areas |
| Good | 3 | Response is relevant and good. The response is sufficiently detailed to demonstrate a good understanding and provides details on how the requirement will be fulfilled |
| Excellent | 4 | Response is completely relevant and excellent overall. The response is comprehensive, unambiguous and demonstrates a thorough understanding of the requirement and provides details of how the requirement will be met in full and/or the information provided demonstrates the organisation is able to provide this element to the best in class level. |

**ANNEX A1
NHS TERMS AND CONDITIONS**

The Authority intends to enter into a contract with the successful Bidder on the NHS Terms and Conditions for the Supply of Goods (Services Version)

Appendix C contains the NHS Terms and Conditions, duly completed by the Authority so far as possible, including all relevant schedules, except schedule 5 (Specification and Tender Response Document) and schedule 6 (Commercial Schedule).

The Specification is set out in Appendix A within the Supplier Documentation in Atamis.