**ITT ReSPONSE DOCUMENT**

**PROVISION OF CLINICAL RESEARCH ASSOCIATE SERVICES**

 **IN FRANCE, BELGIUM AND GERMANY**

Deadline for receipt of completed ITT is 13.00 on 22 June 2015

1. **CELL THERAPY CATAPULT**

The Cell Therapy Catapult was established in 2012 to grow the UK cell therapy industry, increasing health and wealth for all.

Cell-based therapies will play a vital role in the next generation of healthcare, and our aim is for the UK to become a global leader in their development and commercialisation. The past decade has shown that there is clear need for sustained translational resources to advance the technologies and products arising from the vibrant early-stage research base, and it is the role of the Cell Therapy Catapult to bridge this translational gap.

1. **SPECIFICATION OF REQUIREMENTS**

Cell Therapy Catapult requires Clinical Research Associate Services in the form of a single or multiple designated individual(s) (CRA) to act as the main interface between clinical sites and the Cell Therapy Catapult for a new clinical trial.

* 1. **Background**

The designated CRA/CRAs will be involved with novel, genetically modified Advanced Therapy Investigational Medicinal Product in a phase l/ll Oncology study in the therapeutic area of Haematology (Leukaemia). Four countries are planned to be involved including the UK, France, Belgium and Germany.

There will be a low double digit target number of subjects to be recruited to be split evenly amongst the sites. The required site selection visits have already been taken by the sponsor, so the role of the CRA will be in initiating the sites, routine monitoring, management activities and future close out of sites.

Time commitment is expected to be approximately 2 FTE (full Time equivalent staff) days per week for a CRA covering France and Belgium and approximately 2 FTE (full Time equivalent staff) days per week for a CRA covering Germany as indicated below.

* 1. **Requirement**

The Cell Therapy Catapult requires an experienced CRA (2+ years) who is fluent in both French and Belgian Dutch as well as English and an experienced CRA (2+ years) who is fluent in German as well as English.

The CRA will be responsible for progressing a Phase I/II Oncology study involving a cell based, gene modified ATIMP at assigned sites, from start-up providing training and support to site staff, conducting monitoring visits, and reporting and resolving or escalating problems and issues occurring at sites.

The CRA will be responsible for but not limited to the following responsibilities:

* Full responsibility for allocated country and sites, performing site initiation, routine monitoring visits and management, along with final close out activities as per Sponsor SOP’s, local regulations and GCP
* Production of accurate and complete monitoring reports following monitoring visits.
* Verifying compliance with the Clinical Trial Protocol, GCP, and other relevant requirements at the site
* Ensuring that non-compliance and any other problems and issues are detected promptly, and reported, resolved and escalated as required, in compliance with project plans and the Cell Therapy Catapult SOPs.
* Ensure that the Investigator Site File at the investigator site is maintained correctly and that the documents originating at the site (excluding documents that identify study subjects) are copied to the sponsor TMF as required.
* Reporting directly to the Sponsor Lead CRA and Project Manager with issues, actions, updates and status of sites or alternative
* Attending a 1 weekly call to discuss ongoing status of sites / study with Sponsor Lead CRA
* Quarterly visits required to Sponsor Head Office in London for ongoing training, updates and Trial Master File review work
* 1 visit / site / second month. Frequency of visits can be extended post discussion / approval with Cell Therapy Catapult Lead CRA and Clinical Project Manager.
* Travel arrangements will need to be made by the successful provider and invoiced to Sponsor as per terms of the contract.
1. **CONTRACT VALUE AND TERM**

CRA(s) will be required to work flexibly to meet the needs of the trial on a part time basis over a period of three years until July 2018. Approximately 2 FTE (full Time equivalent staff) days per week will be needed to cover France and Belgium and approximately 2 FTE (full Time equivalent staff) days per week to cover Germany. The number of days required may increase or decrease dependent on the timings of full approvals and site opening and individual site activity and this will be advised by the Sponsor, with appropriate notice given of changes in requirements.

The contract will be let on the basis of the terms and conditions provided by the supplier, please see section C.

The anticipated contract value for each part-time position is approximately £20,000 per annum (anticipated total value of £40,000 per annum) excluding expenses which will reimbursed at cost on a monthly basis. Mileage will be paid in accordance with local standard mileage payments or low cost airfares, to be determined in advance with the Sponsor.

1. **PURPOSE OF THIS DOCUMENT**

The purpose of this ITT is for Catapult to receive sufficient information from potential Suppliers interested in supplying the requirements to allow an assessment to be made of their capacity and suitability to supply the services.

Please respond in the format presented, with all responses made within the appropriate space provided, which may be expanded.

1. **CONFIDENTIALITY**

All information provided in this document shall remain confidential between the Supplier and the Cell Therapy Catapult. The Cell Therapy Catapult will not share this information with any other organisations or Public Bodies without the permission of the Supplier.

This document and the associated appendices are provided in confidence for the sole purpose of this tender for Project Management and Design Service and must not be provided to any third party or used for any other purpose without the express written permission of the Catapult.

1. **COMMUNICATION DURING THIS PROCUREMENT**

All contact regarding this procurement should be made via the email address tenders@ct.catapult.org.uk.

No approach is to be made to any other Catapult staff for information relating to this project.

Suppliers have been asked to include primary points of contact in their organisation for their response to this ITT. All communications will be made through the Primary Contact. The Catapult shall not be responsible for contacting the Supplier through any route other than the nominated primary contact. The Supplier must therefore undertake to notify any changes relating to the contact promptly.

1. **CLARIFICATION QUESTIONS**

The Catapult will not enter into detailed private discussion regarding the Services. Clarification questions about the procurement should be submitted through the tenders@ct.catapult.org.uk email address by 13.00 on 19 June 2015. Please clearly mark your email with “CON-0062 Clarification” in the subject line. The Catapult reserves the right to respond to clarification questions received after this deadline at its discretion. It shall normally reject questions raised after this deadline however will consider the importance of the question as a general concern to all Suppliers.

Where the Catapult considers any question or request for clarification to be of material significance, it may communicate both the query and the response, in a suitably anonymous form.

If a Supplier does not wish for a query or response to be disclosed to other Suppliers it must communicate this and the reason why to the Catapult with the query. The Catapult will consider the request but reserves the right to disclose the query and/or the response to other Suppliers.

1. **GENERAL NOTICES**

Any expenditure, work or effort undertaken by your Company prior to the award of a contract is a matter solely for your Company’s own commercial judgement.

The Cell Therapy Catapult reserves the right to terminate this contract award process at any time and not to enter into any contract. The Cell Therapy Catapult and/or its advisers shall not be liable for any costs, liabilities or expenses whatsoever whether incurred (directly or indirectly) by the bidding Company, advisers or sub-contractors, in connection with the preparation of the response to this ITT or in the event of discontinuance of this procurement.

1. **DISCLAIMER**

The Cell Therapy Catapult, (including, directors, officers, members, partners, employees, staff, temporary staff agents and contractors) do not make any representation or warranty (expressed or implied) as to the accuracy, reasonableness or completeness of the procurement documents and shall not be liable for any loss or damage (other than in respect of fraudulent misrepresentation) arising as a result of reliance upon information within the documents.

Any persons considering entering into a contractual relationship with the Cell Therapy Catapult in reliance of the information within the procurement documents should make their own investigations and should seek their own professional technical, financial and legal advice.

Suppliers are advised that nothing herein or in any other communication made by the Cell Therapy Catapult (written or oral) shall be taken as constituting a legally binding contract or agreement between the Cell Therapy Catapult and any other party (save for a formal award of contract made in writing on behalf of the Cell Therapy Catapult).

The Cell Therapy Catapult reserves the right to amend any information or any requirements contained in the documentation issued in connection with the procurement. Suppliers should form their own conclusions about the methods and resources needed to meet these requirements.

The ITT documentation and the information contained within it are the property of the Cell Therapy Catapult; all rights, including intellectual property rights, are reserved. Suppliers and other authorised recipients of the documents have a limited licence to reproduce the information. Suppliers may make it available within their organisation solely for the purposes of preparing a bona fide response to a document for the provision of goods and services. The Supplier is to ensure that all such parties are made aware of the confidentiality obligations and take such steps as to guarantee compliance with it.

Suppliers may not modify their ITT once it has been submitted. Suppliers may withdraw their responses at any time prior to accepting the notification of award by sending a notice of withdrawal to the Cell Therapy Catapult.

By participating in the procurement process, Suppliers shall be deemed to have agreed to be bound by the notices and undertakings in the procurement documents and no purported rejection, variation or addition to these notices and undertakings by the Supplier shall have any affect.

1. **THE EVALUATION APPROACH**

Proposals will be evaluated on the basis of the most economically advantageous tender which meets our technical and Quality requirements and will be assessed against the methodology proposed. Evaluation will include interviews with the contracting organisation and the relevant CRAs proposed for the contract. Interviews may be held either face to face or by video conference/Skype.

The Table below contains a list of all criteria and the relevant weighting for each.

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **Title** | **ITT Section** | **Weighting** |
| A | Supplier Organisation Information | Section A | Not Scored |
| B | Financial Information | Section B | Pass/Fail |
| C | Technical Information - Meeting the Specification | Section C | 60% |
| D | Pricing Information | Section D below | 40% |
| E | Quality Questionnaire | Appendix 1 | Pass / Fail |
| **TOTAL** | 100% |

**Criteria Weighting**

The marking scheme used to score against each requirement is detailed below.

|  |  |
| --- | --- |
| **Marking Scheme (0-10)** | **Grade** |
| ***Fully meets the requirement and offers added value -*** *The evidence demonstrates that the requirement is fully met and provides deliverable added value.* | 10 |
| ***Fully meets the requirement -*** *The evidence demonstrates that the requirement is fully met.* | 7 – 9 |
| ***Almost meets the requirement -***  *Evidence provided shows that the requirement is met but MINOR reservations exist about the quality or extent of the evidence provided* | 4 – 6 |
| ***Partially meets the requirements -***  *Evidence provided shows that the requirement is met but SIGNIFICANT reservations exist about the quality or extent of the evidence provided* | 1 – 3 |
| ***Fails to meet the requirements -***  *Failed to demonstrate or provide evidence of an ability to meet the requirement* | 0  |

**11.2 Marking Criteria - Price**

Prices submitted should be fully inclusive (Ex VAT & in GBP), fixed, current and not subject to variation.

Price elements of tender responses will be evaluated against the lowest tender price. The bidder who has submitted the lowest price will be awarded a score of 100. All bids will be scored relative to the lowest price using the formula below:

Expressed as:

 ***Price Score = (TL / Tt) x 100***

 Where: TL = Lowest Tender Price

 Tt = Actual Tender Price

The commercial and technical scores will be combined with the technical being worth 60% and the commercial being worth 40% to determine the most economically advantageous tender.

**Marking criteria – Technical**

Technical elements of the tender response will be evaluated on the basis of demonstrated ability to provide European CRAs to meet the requirements outlined in Section 2.3.

In addition, please provide the following information as it will be taken into account:

* Number of CRAs currently employed /contracted by the organisation and annual CRA turnover
* Approximate number of clinical trials the organisation was involved in last year,
* Approximate spread of clinical trial work by phase of development (Phase 1, Phase 2, Phase 3, other) and type of sponsor (eg big pharma vs SME)
* High level outcome of any EU Regulatory agency inspections related to clinical trial work in the last 3 years
1. **RESPONSE REQUIREMENTS**

Please detach page 10 onward from this document and return by email to tenders@ct.catapult.org.uk by 13.00 on 22 June 2015. Please clearly mark your email with “CON-0062 ITT Response” in the subject line. Responses will not be opened until after the deadline.

|  |  |  |
| --- | --- | --- |
|  | **Supplier** | **Buyer** |
| **COMPANY NAME:-** |       | Cell Therapy Catapult  |
| **CONTACT NAME:-** |       | Lisa Slade |
| **EMAIL ADDRESS:-** |      @      | Lisa.slade@ct.catapult.org.uk |

**SECTION A - SUPPLIER ORGANISATION INFORMATION**

Please note this section is for information only and ***will not be evaluated***. Please ensure that you complete the questions relevant to your organisation.

|  |  |
| --- | --- |
| **A1** | Full name of the organisation submitting the ITT: |
|       |

|  |  |
| --- | --- |
| **A2** | Please confirm the status of the Supplier to be considered: |
| GUIDE | *A response to this question is mandatory and is for the Catapult information to understand the Supplier.* |
| **A** | Your organisation is bidding to provide the services required itself *(if you tick yes, go to question A5)* |  |
| **B** | Your organisation is bidding in the role of Prime Contractor and intends to use third parties to provide some services *(If you tick yes go to question A3 and A4)* |  |
| **C** | The Potential Provider is a consortium *(If you tick yes go to question A3)* |  |

|  |  |
| --- | --- |
| **A3** | If your answer to **A2** was **b or c**, please indicate in the table all sub-contractors or members of the consortium which will be responsible for each element of the requirement.  |
| GUIDE | *If you have answered ‘yes’ to question b or c, the response to this question is mandatory. If your organisation is unable to confirm all sub-contractors please answer A4.* |
| Element of Requirement | Company / Organisation | How much of the requirement will they directly deliver (%) |
|  |  |  % |
|  |  |  % |
|  |  |  % |

|  |  |
| --- | --- |
| **A4** | If your answer to **A2** is **b** and you are **unable to confirm all sub-contractors** in **A3** at this stage, you will need to demonstrate a satisfactory methodology and track record of delivering a supply chain. If you do not have a track record of delivering a supply chain, please demonstrate how you would achieve this. Please give a brief outline on policy regarding the use of sub-contractors and, if applicable, the extent to which it is envisaged they may be used in any contract (**max 300 words**). |
| GUIDE | *A response to this question is mandatory if you are unable to confirm all sub-contractors in* ***A3*** |
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| --- | --- |
| **A5** | Details about the organisation named in **A1** (organisation submitting the ITT): |
| GUIDE | *A response to these questions is mandatory if applicable to your organisation* |
| **A** | Company Registration Number |       |
| **B** | Date of Registration |   /  /   |
| **C** | Place of Registration |       |
| **D** | Charities or Housing Association or other Registration number (if this applies). Please specify registering body and registration number |       |
| **E** | Registered address and postcode |       |
| **F** | VAT Registration Number |       |
| **G** | Please select which of the following applies to your organisation:  | 1 | a public limited company | [ ]  |
|  |  | 2 | a limited company | [ ]  |
|  |  | 3 | a sole trader | [ ]  |
|  |  | 4 | a partnership | [ ]  |
|  |  | 5 | a Limited Liability Partnership | [ ]  |
|  |  | 6 | a consortium | [ ]  |
| **H** | Website address | www.      |
| **I** | Name of (ultimate) parent company (if this applies): |       |
| **J** | Company Registration Number of (ultimate) parent company (if this applies): |       |

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| --- | --- |
| **A6** | Please provide full contact details of a primary contact to whom future correspondence is to be sent in connection with this ITT: |
| GUIDE | The person listed as Primary Contact should be the person that has registered their interest in this procurement and will be the person that receives communications accordingly. A response to this question is mandatory. |
|  | Primary Contact |
| Name |       |
| Position |       |
| Address |       |
| Telephone number |       |
| E-mail address |      @       |

**SECTION B – FINANCIAL INFORMATION**

The following questions have been designed to evaluate the financial standing and strength of an organisation and the risk they pose to the Catapult.

The most recent accounts will be utilised to assess the financial standing and strength of your organisation. Accounts must be audited unless your organisation is exempt under the Companies Act. Where your organisation is deemed a potential risk to the Catapult, more information will be requested regarding your finances.

Organisations will fail where a Dun and Bradstreet report returns a significant risk of business failure.

|  |  |
| --- | --- |
| **B1** | Financial Statements |
| Please attach a copy of your most recent audited accounts  |  |

|  |  |
| --- | --- |
| **B3** | Conflicts of Interest |
| Is there any other work being undertaken or likely to be undertaken by your organisation (or consortium) which could give rise to a conflict of interest? If **Yes** please provide details below (**max words 300**) |  |
|       |
| **B4** | Complaints to Professional Bodies |
| Has your organisation (or consortium) had any substantiated complaints made against them to any professional body in the last **THREE years?** If **Yes** please provide details below (**max words 300**) |  |
|       |
| **B5** | Indemnity and Liability Provision |
| Please confirm that for the service being tendered your organisation **could** provide these insurances: |
| Professional Indemnity - £ 3M |  |
| Employers Liability - £ 5M |  |
| Public/Products Liability - £ 5M |  |

**SECTION C – TENDER RESPONSE REQUIREMENTS**

This section seeks to understand how your organisation can meet the requirements of the specification and how the equipment will meet Cell Therapy Catapults needs. This section is worth 60% of the overall marks

|  |  |
| --- | --- |
| C1 | User Requirement Specification  |
| **Please provide a proposal outlining how your organisation will meet the requirements of the specification in section 2.****The proposal should be no more than 6 pages in length.** Submissions will be scored in accordance with the bidder’s ability to meet the requirements outlined in the specification in section 2 and the technical marking criteria outlined in section 11.2.*This question is worth 60% of the overall marks.* |
|  |

|  |  |
| --- | --- |
| C3 | Terms and Conditions |
| Please confirm that you have attached your proposed terms and conditions for the Cell Therapy Catapult’s consideration.  Attachments should be labelled: CON-0061\_SupplierName\_C3 |  |

**SECTION D – COMMERCIAL AND PRICE INFORMATION**

The following section outlines the commercial and price offer based on the Specification in section 2. Bidders should note that this section is worth of 40% of the overall marks.

|  |  |
| --- | --- |
| **D1** | Price Schedule |
| Please enter your fixed cost per annum for the services listed in the table below. Expenses will be paid in accordance with a defined policy including mileage rates and use of low cost airlines and should be excluded This information will make up the price schedule of any contract.  |
| **£** |

**SECTION E – QUALITY QUESTIONNAIRE**

Bidders should note that this section will be evaluated using a pass / fail evaluation criteria.

|  |  |
| --- | --- |
| **E1** |  Quality Questionnaire |
| Please confirm you have attached a completed quality questionnaire. If not, please outline your reason in the space below.  Attachments should be labelled: CON-0061\_SupplierName\_E1 |  |
|  |  |

Please confirm you have completed and attached a copy of the Quality Questionnaire (Appendix 1). Bidders who have previously submitted a quality questionnaire to the Cell Therapy Catapult within the last two years will not be required to resubmit a quality questionnaire unless you wish to inform us about changes to your organisation. Please identify in the space below if you have attached a quality questionnaire.

|  |
| --- |
| UNDERTAKING |

To be signed by an Officer of the Supplier’s Company in their own name on behalf of the Company.

I certify that the information provided is accurate to the best of my knowledge and that I accept the conditions and undertakings requested in the ITT. I understand and accept that false information could result in rejection of the Company’s ITT.

|  |  |
| --- | --- |
| Signed for and on behalf of the CompanySIGNATURE |  |
| Name of person signing on behalf of the CompanyPRINT |  |
| Position/status in the CompanyPRINT |  |
| Company’s name and addressPRINT |  |
| Date |  |

For the purposes of this electronically transmitted ITT document it is sufficient that typed names are permitted rather than signatures. A typed name will be deemed to have been signed by a signature the person stated with the necessary responsibility required within the Supplier’s Company.