



Warsaw, 09/03/2018

REQUEST FOR PROPOSAL NR 8/ 2018- IBD

I. ZAMAWIAJACY

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II. OBJECT FOR THE REQUEST:

Good Clinical Practice audit

The order carried out as a part of the project titled:

— **IBD:** „PRE-CLINICAL AND CLINICAL RESEARCH OF CANDIDATE FOR INNOVATIVE DRUG IN ASTHMA AND INFLAMMATORY BOWEL DISEASES THERAPY” (POIR.01.01.01 00-0168/15)

co-financed by the European Union Funds and because of the competitiveness principle

III. THE FORM OF THE ORDER:

- III.1 The request is not made under The Public Procurement Law (Journal of laws of 2013, item 907 as mentioned).
- III.2 This order is carried out in accordance with the principle of competitiveness, openness, transparency and equal access.
- III.3 The Ordering Party reserves the right to cancel this procedure without providing reasons and also to complete the procedure without choosing the winner tender.
- III.4 In the course of examination and evaluation of the offers the Ordering Party may require Contractors to present explanations concerning the content of submitted bids.
- III.5 The Ordering Party reserves the right to change the content of this request. If the changes can affect the content of tenders submitted in the procedure, the Ordering Party shall extend the tender submission deadline. Any changes made shall be provided promptly to all tenders to which the request was sent and shall be binding on them.
- III.6 This procedure does not set the obligation for OncoArendi Therapeutics SA to sign any formal contracts.
- III.7 It is not possible to make and offer for part of order.

IV. CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS:

- IV.1 The Request for offers relates to potential Contractors whose scope of business activity is in full

compliance with the subject of this Request.

IV.2 The offers may be issued by parties who:

- 1) Have the necessary qualifications to carry out the described activity and have the appropriate technical potential and personnel capable of performing the contract.
- 2) Are in a good economic and financial standing, which assures proper execution of the project in the declared time.
- 3) Will pursue the contract in a way that is beneficial to the environment by minimizing the consumption of materials, raw materials energy, etc. (with environmental certificates such as ISO 14001:2015)

As a proof of the above, the Ordering Party requires that the Contractor submit, along with the tender, a statement about fulfilling conditions for participation in the proceedings. The model statement is attached as Appendix 2 to this request for proposal.

IV.3 Regarding knowledge and experience, the Ordering Party requires that the Service Provider:

1. Has at least 4 years of experience in performing clinical trial audits, in accordance with GCP standards, for third parties
2. Performed at least three audits of phase I clinical trials with the use of innovative investigational products.

The fulfillment of the above conditions will be evaluated on the basis of the statement of the Service Provider, a model statement is attached as Appendix 2 to the Request for the Offer.

IV.4 Regarding human resources, the Ordering Party requires the Service Provider to engage an expert With well documented experience meeting the following requirements:

- Has performed for third parties at least 30 clinical trial audits in accordance with GCP standards, within the last 4 years, and prepared the same number of clinical trial audit reports, basing on the guidelines established by ICH (*International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use*), EMA (*European Medicines Agency*), FDA (*Food and Drug Administration*)
- Has performed at least 5 GCP audits within last 12 months
- Performed at least three audits of phase I clinical trials with the use of innovative investigational products.
- Has a documented training in GCP, version dated 09Nov2016

Fulfillment of the above conditions will be evaluated on the basis of:

- a) statement of the Service Provider, a model statement is attached as Appendix 2 to the Request for the Offer,
- b) CV's of the expert with the record of training

IV.5 Excluded from the proceedings shall be those contractors who are personally or equity related to the Ordering Party by in particular:

- 1) participation in the company, in a civil or limited partnership;
- 2) holding at least 10% shares or interests;
- 3) serving a function of a member of the supervisory organ, a member of the management organ or proxy;
- 4) having family ties, such as by marriage, by lineage at first or second degree, by adoption, guardianship or custody.

As a proof of the above the Ordering Party requires that the Contractor submit, along with the tender, a statement about not being related to the Ordering Party. The model statement is attached as Appendix 3 to this request for proposal.

IV.6 Issuing the offer represent the full acceptance of the rules set in this Request.

II. DETAILED DESCRIPTION OF THE OBJECT OF THE REQUEST:

CPV Code: 73200000-4

The subject of the order is a service of performing a GCP audit of a clinical trial in an investigative site.

The order includes:

1. Preparation to the audit, basing on the guidelines established by ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use), EMA (European Medicines Agency), FDA (Food and Drug Administration)
2. Preparation of an audit plan and announcing the audit to the site, the CRO and the study sponsor
3. Auditing the site, basing on the guidelines established by the ICH, the EMA and the FDA, untill the end of May 2018
4. Follow-up letter preparation, to be received by the site, the CRO and the study sponsor
5. Preparation of clinical trial audit report for the study sponsor, with the list of all identified findings
6. The evaluation of the responses to clinical trial audit report, prepared by the CRO in cooperation with the investigative site, that include the proposal of corrective and preventive actions for identified findings. The process may be repeated until a satisfactory response or a corrective/preventive action is agreed for all identified findings.
7. The auditor will be requested to consider the fact that the study sponsor will be present onsite at the time of the audit. Therefore, the auditor should include in the plan of his/her work onsite the time needed to answer possible inquires of the study sponsor about the audit process and potential findings.

The language of the audit process will be English (Polish will be only of secondary importance and used only if absolutely necessary, for informative purpose)

The Appendix 5, which contains confidential information regarding the scope of the order (clinical site address and other details necessary to estimate the value of the order), will be disclosed on the Contractor's demand only after signing the confidentiality agreement available as an Appendix 4 to this Request (8/2018-IBD).

The scan of completed and signed confidentiality agreement should be send by email to a.lipinska@oncoarendi.com, CC: j.lipner@oncoarendi.com. The Appendix 5 will be disclosed within 48 hours from receiving of the agreement.



III. EVALUATION OF THE OFFERS:

III.1 Price – weight: 90% (90 pts.)

1) In this criterion points will be calculated according to the formula below:

$$P_c = \frac{C_{min}}{C_{evaluated}} \times 90$$

P_c – Points received

C_{min} – The smallest Net price

C_{evaluated} – Net price of the offer being evaluated

90 – weight of the criterion (90%)

III.2 Payment deadline– weight: 10% (10 pts.)

In the payment deadline, points will be awarded according to the formula:

10 points - when the payment deadline is at least 60 days from the invoice delivery date

5 points - when the payment deadline is at least 30 days from the invoice delivery date

0 points - when the payment deadline is less than 30 days from the invoice delivery date

10 – weight of the criterion (10 %)

III.3 In the case of two or more tenders with equal number of points awarded, to guarantee performance of the contract in a manner favorable to the environment, by providing minimize the consumption of materials, raw materials, energy etc. any environmental certifications will be taken onto consideration (eg. ISO 14001:2015).

If the abovementioned does not allow to choose the best offer, the Ordering Party shall call Contractors who submitted equally evaluated offers to submit, within the period specified, additional offers. Contractors cannot offer higher prices than offered in the tenders.

IV. HOW TO PREPARE AND SUBMIT THE OFFER:

IV.1 The offer should be signed by the person authorized to represent the institution.

IV.2 Each contractor may submit only one offer.

IV.3 Costs of the offer preparation shall be incurred by the offering party.

IV.4 Offers must be submitted no later than: **23/Mar/2018 23:59** CET and must be written on the form as in Appendix 1 to the request for proposals.

IV.5 Offers shall be issued only via email to: a.lipinska@oncoarendi.com.

IV.6 The date of receiving the email shall be considered as a date of issuing the offer.

IV.7 Offers that do not meet the deadline, are incomplete or sent to the wrong email address will not be taken into consideration.

IV.8 Any questions concerning the Object of the tender should be addressed to a.lipinska@oncoarendi.com (+48 573 900 610) no later than 20 Mar 2018 15:00 (CET). Contact person is: Anna Lipinska

- IV.9 Any questions concerning the formal issues of the tender should be addressed to m.skrzek@oncoarendi.com (+48 22 552 67 24) no later than 20/Mar/2018 15:00 (CET).
- IV.10 The offer should include the validity date (at least 30 days from the submission deadline).
- IV.11 The price should be set in both Net and Gross.
- IV.12 The values in the offer (Net and Gross) should be rounded to two decimals with the mathematical rule of rounding the numbers (according to § 5 section 6 of the regulation of Ministry of Finance of 28 November 2008 (Journal of Laws of 2008, No. 212, item 1337, as mentioned).
- IV.13 The offer price should include VAT. The correct determination of VAT is responsibility of the contractor – in accordance with the provisions of the Act of 11 March 2004 on Goods and Services Tax (Journal of Laws of 2004 No. 54 item. 535 as mentioned).
- IV.14 The offer shall not be prepared in price variants.
- IV.15 The financial settlements between the Ordering Party and the contractor may be made in PLN, EUR, USD or GBP.

V. TENDER RESULTS:

Bidder will be informed about choosing his offer via email. Formal results will be also published on the Ordering Party's website (www.oncoarendi.com) and concurrency database.

VI. MOST IMPORTANT PROVISIONS OF THE AGREEMENT:

- VI.1 Service provider will be obligated to enter into the agreement including all conditions presented in the Request for the Offer in the place and time specified by the Ordering Party.
- VI.2 It is not possible to introduce significant changes to the content of the agreement in relation to the content of the offer, which was the base for the Service Provider selection, unless:
- 1) The amendments concern performing additional services by the Service Provider, not covered by the basic contract, provided they are necessary and the following conditions are met:
 - i. The change of the Service provider cannot be made due to to the economic or technical reasons, in particular concerning the interchangeability and interoperability of equipment, services or installations, ordered as part of basic contract.
 - ii. The change of the Service Provider would cause significant inconvenience or substantial cost increase to the Ordering Party.
 - iii. The value of any subsequent changes do not exceed 50% of the basic contract value.
 - 2) The amendment does not lead to change in the nature of the contact and the following conditions are met:
 - i. The need for the contract change is brought about by circumstances which the Ordering Party, acting with due diligence, could not foresee.
 - ii. The value of a change does not exceed 50% of the basic contract value.
 - 3) The amendment does not lead to change in the nature of the contract and the total value changes is less than 209 000 EUR, and at the same time is less than 10% of the basic value.

Any contract amendment must be done in writing, otherwise will not be valid.



VI.3 Information regarding contractual penalties:

- 1) If the offered project execution time (as defined in the offer) extends for at least 15 days, the Service Provider shall pay the Ordering Party a contractual penalty of 1,5% of the net offer price for exceeding the time limit, and then another 2% of net offer price for each additional 15 days of delay. Moreover, the Ordering Party will gain a right to withdraw from the contract of the project execution time is exceeded by at least 60 days. The Ordering Party may withdraw from the agreement until 31st Dec 2019.
- 2) Due to the termination or withdrawal from the Agreement by either Party for reasons caused by the Service Provider, the Ordering Party will change a contractual penalty of 25% of net offer price.
- 3) The formal basis for changing contractual penalties will be a debit note the Ordering Party delivers to the Service Provider. The Ordering Party shall be entitled to deduct contractual penalties from payments due to the Service Provider.
- 4) The Ordering Party has the right to claim damages in the amount exceeding contractual penalties based on general principles.
- 5) The Ordering Party has the right to claim damages in the amount exceeding contractual penalties based on general principles.
- 6) Contractual penalties sum up.

VII. APPENDENCIES:

- 1) The offer form.
- 2) Statement concerning fulfilment of all the requirements set out in part IV of the Request for offers.
- 3) Statement concerning persona or/and capital connections between the Service Provider and the Ordering Party.
- 4) The confidentiality agreement form
- 5) The Appendix 5, which contains confidential information regarding the scope of the order