

REQUEST FOR PROPOSAL

RFP 060672 – MONITORING OF THE PIVOTAL BIOEQUIVALENCE STUDY OF THE NEW ORAL SOLUTION FORMULATION

As a result of obtaining a grant for project no. POIR.01.02.00-00-0072/18 “Development and implementation of a new generation drug in the form of an easily applicable oral solution used in treatment of nicotine addiction” submitted under Activities 1.2. of the Intelligent Development Operational Programme 2014-2020, acting on the basis of Article 12 of the financial project support contract, Adamed Pharma S.A. invites to submit tenders for the below-defined service.

Subject of the Tender:

Monitoring of pivotal, 3-arm, 3-period, bioequivalence study under fasting conditions following a single administration in healthy volunteers (54).

The study will be carried out at the Quinta-Analytica s.r.o., Prague (Czech Republic).

Study Sponsor (Contracting Authority): **Adamed Pharma S.A.**

I. The following activities shall be conducted:

1. To perform the study monitoring in accordance to the requirements of ICH GCP.
2. To prepare written report after each visit.
3. To prepare Monitoring Plan.
4. The collection of the copies of documents for Sponsor's TMF may be required during the visits.
5. To provide 100% source data verification (CRF vs SD), 100% of review of ICF, 100% review of AE and verification of the investigational product's accountability at the Centre.
6. During the offer preparation and calculation of the monitoring visits number an experience of the Supplier shall be used to select the most suitable monitoring scheme, which should ensure:
 - review of screening documentation,
 - verification of compliance with inclusion/exclusion criteria,
 - monitoring on dosing days,
 - review of dosing compliance and compliance with sampling schedule,
 - check of the queries,
 - verification of AE reporting,
 - verification of IMP dispensing and accountability.
7. The offer should be presented in a way that:
 - includes the site initiation visit, inclusion/exclusion criteria check visit, monitoring visits on the dosing days, in-between dosing days monitoring and close-out visit and additional monitoring visits in case the Tenderer deems necessary to carry out them to ensure the appropriate quality of supervision of the study.
 - is adjusted to the specifics of the study and experience with documentation of Quinta-Analytica s.r.o., clinical center (if such experience exists).
 - includes the costs of additional activities that must be taken due to the COVID-19 pandemic.
 - Costs associated with shipping TMF to Sponsor

Quotations to the offer should be presented in **Appendix 1.**

II. Timeframe for the implementation of services:

1. The offer shall take into account the following assumptions:
 - a) Study dates:
Initiation visit: December 2022/ January 2023
ICF meetings with volunteers: January 2023
 - b) As the dosing can be also performed during the weekends, the Monitor's availability during the weekend has to be taken into consideration.
 - c) The tenderer reserves the right to change the study dates.

III. Conditions for participation in the proceedings:

1. Orders cannot be awarded to entities affiliated personally or financially with the Contracting Authority. Through financial or personal connection, we understand the interactions between the Contracting Authority or persons authorized to enter into commitments on behalf of the Contracting Authority or persons performing on behalf of the Contracting Party activities associated with the preparation and the procedure for selecting Suppliers and Supplier, in particular by:
 - a) participation in the company as a partner or partnership,
 - b) owning at least 10% of the shares,
 - c) the functions of a member of the supervisory or management, proxy,
 - d) remaining married in consanguinity or affinity in a straight line, second-degree consanguinity or affinity of the second degree in the collateral line or by adoption or guardianship.

In order to fulfill this condition a Tenderer is obliged to send with the offer signed statement about the lack of connections - **Appendix 2.**

2. This offer is addressed to:
 - a) entities (CROs) having experience in the monitoring of bioequivalence/bioavailability studies
 - b) having possibility to perform monitoring in the specified clinical centre in the presented timelines
 - c) confirming conduct of their work in accordance with GCP requirements
 - d) having introduced quality system (SOPs).

The Supplier is obliged to send a relevant statement confirming that this criterion has been met – **Appendix 3.**

3. The offer should document the essential knowledge and experience as well as the tenderer's ability to provide the required services in accordance with all RFP requirements. To confirm this, the Tenderer should send information on the company's history, quality assurance system and describe its experience in monitoring of bioequivalence/bioavailability studies – **Appendix 4.**
4. The monitors involved by the tenderer in the performance of the contract subject should:
 - a) have **min. 1 year** of experience in monitoring of the bioequivalence/bioavailability studies or experience in monitoring at least 5 bioequivalence / bioavailability studies in the last year (the requirement applies to the main monitor, but not to the assistant monitor – in case they will be involved in the study monitoring)
 - b) be properly trained,

- c) should possess the scientific and / or clinical knowledge necessary for the proper monitoring of bioequivalence/bioavailability studies
- d) should be fluent in spoken and written English and Czech language, level of knowledge: very good

Monitor qualifications should be documented by enclosing to the offer the CV of monitors involved in the performance of the subject of the contract. CV should include information that allows to verify criteria a) – d) - **Appendix 5**.

- 5. The Bidder must present a signed Confidentiality Statement - **Appendix 6** with the Contracting Authority. If the Bidder has previously signed a confidentiality agreement with the Contracting Authority, he may submit this agreement.

IV. Terms and methods of offer submission

- 1. The title of each correspondence should include the number of the procedure
- 2. **RFP 060672 – MONITORING OF THE PIVOTAL BIOEQUIVALENCE STUDY OF THE NEW ORAL SOLUTION FORMULATION - Company name**
- 3. **Deadline for submitting Offer is 15th of September 2022 at 23:59 CET.** The deadline for Answers submission may change, all Suppliers will be informed by e-mail.
- 4. Questions of the inquiry may be submitted on the website <https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>, to the Adamed Procurement System at <https://service.ariba.com> or by e-mail: [aleksandra.stojak\(at\)adamed.com](mailto:aleksandra.stojak@adamed.com), in the form of a completed **Appendix 7**. *Late submission of questions may result in lack of time to provide the required answer taking into account the above deadline for offer submitting.*
Answers to the question should be provided before the end of this tender process. In order to ensure equal access to information to all Tenderers participating in the proceedings, questions and answers (with hiding the author's questions) will be sent to all Tenderers.
- 5. Any Supplier may submit only one offer.
- 6. Partial bids are not allowed.
- 7. The offer should be prepared as **Appendix 1** to this offer. **If Appendix 1 is not attached, the offer will not be considered.** The Bidder can additionally prepare an offer in his own preferable format and upload into the system.
- 8. Offer along with the required attachments, may be submitted on the website <https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>, to the Adamed Procurement System at <https://service.ariba.com> or by e-mail: [aleksandra.stojak\(at\)adamed.com](mailto:aleksandra.stojak@adamed.com).
- 9. Supplier's Offer should be comprehensive in Polish or English, electronically.
- 10. The offer should include at least the following information: **Supplier name, address and TAX/registry number, date, bid inquiry number, price net (PLN/EUR/USD), delivery time (time required for delivery in hours), payment terms.**
- 11. The offer shall be valid min. 90 days.
- 12. If the prices in the offer are expressed in EUR, they will be converted using the exchange rate of 4,4536 PLN / EUR, in accordance with the Notice of the President of the Public Procurement Office of 3 December 2021 on the current EU thresholds, their PLN equivalent, PLN equivalent of amounts expressed in EUR and the average PLN / EUR exchange rate constituting the basis for converting the value of public contracts or design contests.
- 13. In the case of another currency, the average NBP exchange rate from the last day of submitting offers will be accepted for conversion.

14. Please attach filled out Appendices No. **1–6** and **9**. In addition please submit the attached checklist to confirm that all required documents will be delivered - **Appendix 8**.
15. Tenders submitted after the deadline will not be considered.
16. The Supplier before time-limit for receipt of tenders is entitled:
 - 15.1. to withdraw the offer by written notification by e-mail indicated for the submission of tenders,
 - 15.2. to change the offer – notification of the changes must be submitted by the same rules as the submitted offer, appropriately marked with the note "CHANGING THE OFFER".

V. Selection criteria and evaluation methods:

1. The Contracting Authority is entitled to reject the tender submitted by the Supplier who does not meet the conditions for participation in the proceedings, or if the offer is incomplete or incompatible with this request.
2. The Contracting Authority is entitled to reject the tender submitted by the Supplier if it has been documented that the tenderer, when performing the clinical trial monitoring service, did not comply with ICH-GCP or legal provisions regulating the performance of this activity or is an untrusted supplier, which was previously stated by the Sponsor - Adamed or Affiliate (for example in case of infringement of any confidentiality restrictions in the past or events of contract breach or timelines omission or poor quality of service). The obligation to prove of the above facts lies with the Purchaser. The proof provided by the Purchaser undermines having the level of qualification, competence and reliability required for proper performance of the contract, which is tantamount to a negative assessment of the Tenderer's ability to perform the contract properly and reliably under the conditions set out in the request for proposal.
3. Selection criteria:
 - a) **Net price** (PLN/EUR/USD), the weight criterion - 95%, shall include all the associated costs.
 - b) **Environmental criterion** - 5% of the overall assessment – assessment based on the Statement confirming compliance with the environmental criterion (**Appendix 9**) provided by the Tenderer
4. The Contracting Authority shall evaluate offers based on the result of the accumulated number of points calculated on the basis of above criteria and scores:

Criteria	Weight criterion [%]	Method of evaluation in accordance with the formula
Price	95%	net price of the offer with the lowest price/net price tested offer x 100 x 95 % = number of points
Environmental criterion	5%	removal of emission of pollutants into the environment by at least one of two means listed in the statement = 5 points

5. As the most advantageous offer will be considered that which obtains the highest number of points.
6. The results of the mathematical calculations carried out in the evaluation of tenders are rounded to the second decimal place. In case of equal scores for at least two offers the Contracting Authority will make the final choice of the offer more favorable when it comes to the impact on the environment. For this purpose, the Contracting Authority shall have the right to call the Suppliers, whose tenders have obtained the highest final points, to complete the offer by giving indicated by the Contracting Authority information about an impact of the offer on the environment. The deadline to complete the offer will be determined by the Contracting Authority, but it cannot be less than 3 working days from receipt of the request.

VI. The choice of Supplier and way of announcing:

1. The Contracting Authority will select the most advantageous offer on the basis of the selection criteria defined in this request for proposal.
2. The Contracting Authority will inform about the results of this request for proposal on website <https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/> and will send to each Supplier which has submitted its offer.

VII. General provisions

1. The Contracting Authority reserves the right to terminate the procedure at each stage without giving any reason.
2. In the case of cancellation of the contract the Suppliers are not entitled to claim for reimbursement of the costs of participation in the proceedings.
3. Submission of the application for registration in the process or tender implies acceptance without reservation all the conditions of the proceedings.
4. Withdrawal by the Contracting Authority from the conclusion of the contract after the notification the Supplier about the selecting the offer, cannot be the basis for claims of incurred costs of participation in the proceedings.
5. In the process of evaluating Offers the Contracting Authority may seek information from the contractors concerning the content of their documents.
6. If the application does not contain all the required elements, the Contracting Authority may in justified cases call the Supplier to complete it.
7. The Contracting Authority reserves the right to record sound during technical meetings with suppliers. Submission of the offer will be treated as giving consent to the recording of the meeting.
8. The Contracting Authority allows negotiations of the contract terms and conditions with the bidder.
9. The Contracting Authority reserves the right to negotiate the proposal with all Tenderers.. Negotiations may have several consecutive rounds with the possibility to invite bidder to submit the updated quotation after each round of negotiations
10. It is permitted to award the selected Bidder with supplementary orders, which are in line with the subject of this master contract, amounting to 50% of this order.
11. Terms of contract change: The contracting authority envisages the possibility of introducing significant changes to the contract concluded as a result of the conducted contract award procedure in relation to the content of the offer, on the basis of which the contractor was selected, in the event of the necessity to change the indicated scope of works specified in the offer:
 - 11.1. Necessary or justified changes in the design documentation resulting from unforeseeable reasons,
 - 11.2. The necessity or the technical-economic appropriateness of the use of equivalent materials and equipment,
 - 11.3. The necessity to make equivalent solutions resulting from technological or utility conditions,
 - 11.4. Financial constraints on the part of the Contracting Authority which cause the necessity to limit the scope of works included in the offer,
 - 11.5. Necessary or justified changes in the delivery time and conditions of the contract subject resulting from unforeseeable reasons
 - 11.6. Any changes and additions to the contract concluded with the selected Supplier will be made in the form of written annexes to the contract signed by both parties, under rigor of invalidity.

VIII. Cooperation and communication



Republic
of Poland



The National Centre
for Research and Development

European Union
European Regional
Development Fund



1. Any questions related to the subject matter of this request may be submitted using website <https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>, SAP Ariba Network or directed to the address: [aleksandra.stojak\(at\)adamed.com](mailto:aleksandra.stojak(at)adamed.com)
2. Checklist is provided in **Appendix 8.**
3. The person authorized to contact the bidders (Monday-Friday between 08:00-16:30) is Aleksandra Stojak [[aleksandra.stojak\(at\)adamed.com](mailto:aleksandra.stojak(at)adamed.com)]