

BS BIOTECHNA SA

Szlak 77 / 222,

31-153 Kraków

TAX IDENTIFICATION NUMBER [NUMER IDENTYFIKACJI PODATKOWEJ, NIP]: 945-222-64-86

CALL FOR PROPOSALS NO 4/2/FENG

In connection with the execution of a project as part of the European Funds for Modern Economy, Priority 1 Support for Entrepreneurs, Measure: SMART path, Call: FENG.01.01-IP.02-002/23, BS Biotechna SA, in line with the competition principle, announces tender proceedings in the form of a call for proposals.

1. Object of the Contract – performance of a clinical study at phase 1 unit sites

Contract Specification:

The Contractor shall guarantee access to at least 4 clinical study sites in Poland and abroad, shall handle active recruitment of patients that will last for approximately 180 days (6 patients per site - this number is indicative and may be changed in connection with the studies carried out) and shall perform a scope of works including:

- a. contact and assessment of the potential to perform a clinical study at selected sites (database, know how, networking of study sites)
- b. contracting sites and study team consisting at least of: principal investigator, sub-investigator, nurse
- c. patient recruitment
- d. performance of patient visits in accordance with the clinical study protocol and GCP guidelines
- e. visit settlement
- f. completion of CRF entries
- g. delivering data necessary for drafting the Clinical Study Report
- h. cooperation with clinical study experts from the BS Biotechna team
- i. cooperation with the central laboratory.
- j. Subcontractor management

Due to the need to protect a company secret, as defined under the provisions of the Polish Act on Combating Unfair Competition dated 16 April 1993 (Polish Journal of Laws of 2022, item 1233, as amended), a detailed contract specification shall only be shared upon the receipt of a signed non-disclosure agreement. A signed agreement (in scanned format or in the format of a document signed with a qualified electronic signature) must be sent to marcin.olczak@bsbiotechna.com. A detailed contract specification for the purposes of drafting a price quote shall be provided without undue delay, no later than within two working days. A template contract constitutes Appendix no. 2 to this call for proposals.

Place of contract performance shall be: entire Poland + abroad.

Common Procurement Vocabulary (CPV):

73111000-3 - Research laboratory services

73000000-2 - Research and development services and related consultancy services

2. Schedule:

Planned contract execution period: from 1 July 2027 to 31 December 2029. Proper performance is defined as performing the research in accordance with GCP guidelines and local legal regulations, allowing the BS Biotechna team to draft a final report.

The bidder undertakes to conclude a conditional contract for the service within 3 working days after the winning proposal is selected. The final contract shall be signed upon the condition that funding is secured, the previously assumed project results are achieved and all the requirements for the bidder have been met as of the moment of signing the final contract. Should no final contract be signed, this shall not give rise to any costs, penalties nor fees for the Contracting Entity.

3. Conditions for participation in the proceedings.

Note: The following conditions for participation in the proceedings must be met as of the moment of submitting a proposal, as of the moment of signing the final contract, as well as throughout the service provision period.

Bidders meeting the following conditions shall be admitted to take part in the proceedings:

- Hold licenses necessary to carry out the particular activity or activities, if such licenses are required under the applicable legal provisions.
- Have an economic and financial standing that allows for performing the contract by the indicated deadlines.
- Have the necessary knowledge and experience or ensuring subcontractors who have the necessary knowledge and experience to perform the contract.
- Have the appropriate technical potential or ensure subcontractors who have the appropriate technical potential to perform the contract.
- Have persons able to perform the contract or ensure subcontractors having persons able to perform the contract, including:
 - Principal investigator (1 person per site) - university medical education, specialization in oncology, at least 5 years of experience in clinical studies, GCP certificate and advanced knowledge of English. Experience in conducting clinical studies in the position of a principal investigator.
 - Investigator (1 person per site) - university medical education, at least a year of experience in clinical studies, GCP certificate and advanced knowledge of English. Experience in conducting clinical studies in the position of a sub-investigator.
 - Nurse (2 persons per site) - a degree in nursing, at least a year of experience in clinical studies, GCP and IATA certificate, as well as intermediate knowledge of English.
 - Site coordinator (1 person per site) - advanced knowledge of English, GCP certificate, experience in clinical studies in the position of a coordinator

- Clinical research associate (1 person) - university education, advanced knowledge of English, proficiency with various types of computer software and the ability to quickly learn and operate internal databases
- Subcontractors coordinator (1 person) - advanced knowledge of English, experience in cooperation with subcontractors.

Moreover, the selected contractor should have the necessary human resources and be able to contract companies/persons able to perform the study

- Not meet any of the prerequisites for exclusion (as per the scope of exclusions included in the call for proposals).
- Submission of a printout from the *Register of Entities Performing Medical Treatment Activities*, confirming that the contractor has been an entity performing medical treatment activities for at least 4 years or in the case of entities from outside the Republic of Poland, another equivalent register appropriate for the contractor's country (if any).

In order to confirm that the above-mentioned conditions have been met, the Contracting Entity requires the following documents to be submitted:

- 1) Submit a proposal using the proposal form (Appendix no. 1) that includes the following elements:
 - Name, address, e-mail and tax identification number (NIP) of the Contractor
 - Proposal drafting date
 - Details allowing to assess the proposal and assign a score according to the criteria
 - Proposal validity date
- 2) Include the following statements on the proposal:
 - The Contractor hereby represents that they know and accept the terms and conditions for performance of the contract, as stated in the call for proposals, and reports no reservations nor comments within this scope.
 - The Contractor hereby represents that they hold the licenses necessary to carry out the particular activity or activities, if such licenses are required under the applicable legal provisions.
 - The Contractor hereby represents that they have the necessary knowledge and experience or shall ensure subcontractors who have the necessary knowledge and experience to perform the contract.
 - The Contractor hereby represents that they have the appropriate technical potential or shall ensure subcontractors who have the appropriate technical potential to perform the contract.
 - The Contractor hereby represents that they have persons able to perform the contract or shall ensure subcontractors having persons able to perform the contract, including:
 - Principal investigator (1 person per site) - university medical education, specialization in oncology, at least 5 years of experience in clinical studies, GCP certificate and advanced knowledge of English. Experience in conducting clinical studies in the position of a principal investigator.

- Investigator (1 person per site) - university medical education, at least a year of experience in clinical studies, GCP certificate and advanced knowledge of English. Experience in conducting clinical studies in the position of a sub-investigator.
- Nurse (2 persons per site) - a degree in nursing, at least a year of experience in clinical studies, GCP and IATA certificate, as well as intermediate knowledge of English.
- Site coordinator (1 person per site) - advanced knowledge of English, GCP certificate, experience in clinical studies in the position of a coordinator
- Clinical research associate (1 person) - university education, advanced knowledge of English, proficiency with various types of computer software and the ability to quickly learn and operate internal databases
- Subcontractors coordinator (1 person) - advanced knowledge of English, experience in cooperation with subcontractors.

Additionally, appropriate human resources or ability to contract companies/persons able to perform the study

- The Contractor hereby represents that their economic and financial standing allows for performing the contract by the stipulated deadline.
- The Contractor hereby represents the following:
 - a. they are not subject to exclusion from the proceedings based on the provisions of Article 5k of Council Regulation (EU) No. 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (Official Journal of the EU No. L 229 of 31 July 2014, p. 1; hereinafter: Regulation 833/2014), as amended by Council Regulation (EU) 2022/576 amending Regulation (EU) No. 833/2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (Official Journal of the EU No. L 111, 8 April 2022, p. 1; hereinafter: Regulation 2022/576);
 - b. the prerequisites for exclusion from the proceedings based on the provisions of Article 7 section 1 of the Polish Act on special solutions to prevent support for the aggression against Ukraine and to protect national security (Polish Journal of Laws, item 835) are not applicable to them;
 - c. any and all information provided in the above representations are up to date and true, and they have been presented fully aware of the consequences of misleading the Contracting Entity when presenting this information. At the same time, the Contractor undertakes to immediately provide the Contracting Entity with any updates for the above representations in case of any relevant changes.
- The Contractor also represents that they have no personal nor equity connections with the Contracting Entity. Personal and/or equity connections are defined as mutual connections between the Contracting Entity and/or the persons authorized to draw liabilities on behalf of the Contracting Entity and/or persons performing activities related to the drafting and performance of the contractor selection procedure and the Contractor, consisting in, but not limited to:
 - a. participation in an enterprise as a partner of a civil law partnership or a partnership, holding at least 10% of shares or stock, performing the function of a member of a supervisory body or management body, holder of the commercial power of attorney, attorney in fact;

- b. marriage, direct consanguinity or affinity, or secondary consanguinity or affinity of up to the second degree or an adoptive relationship, custody or guardianship or cohabitation with the contractor, their legal successor or members of the management bodies or supervisory bodies of contractors applying for the award of the contract;
 - c. a legal or factual relationship with the contractor that could give rise to justified doubts as to whether they are impartial or independent in connection with the proceedings for the award of the contract.
- The Contractor hereby represents that they operate a registered business related to clinical studies and that their main object is classified under PKT 72.19 Other research and experimental development on natural sciences and engineering for at least 5 years or, in the case of entities from outside the Republic of Poland, are registered in another register appropriate for the contractor's country (if any).
- 3) Submission of a printout from the *Register of Entities Performing Medical Treatment Activities*, confirming that the contractor has been an entity performing medical treatment activities for at least 4 years or in the case of entities from outside the Republic of Poland, another equivalent register appropriate for the contractor's country (if any).

4. Description of the manner of drafting a proposal:

A proposal must be submitted using the proposal form (Appendix no. 1 to the call for proposals). A proposal must be drafted in Polish in a legible manner. Each proposal must bear the name and address of the bidder. The Contracting Entity requires the proposal to be signed by a representative of the Bidder. Scanned documents bearing wet ink signatures or documents signed by electronic means shall be accepted. In their proposal, the Bidder should indicate the price for complete performance of the object of the contract on the terms and conditions stipulated in the call for proposals; moreover, the bidder should attach to their proposal all the documents indicated in the body of the call for proposals. In the submitted documents, the Bidder should also confirm meeting the abovementioned admission requirements. The price offered should include performance of all the works and activities covered by the contract, as well as include any and all costs related to the performance of the contract over the period and subject to the terms and conditions stipulated in the Bidder's proposal and the Call for Proposals. The price should be indicated in monetary units.

The Contracting Entity does not allow for the submission of partial nor variant proposals; only proposals covering the entire scope of the object of the contract shall be considered.

Proposals that fail to meet the formal requirements and/or those that do not include the full scope of the object of the contract shall be rejected.

5. Deadline and manner for submission of proposals:

- All Proposals should be submitted by electronic means through the Competition Database (function available for logged in users).
- Deadline for submission of proposals shall be: 15 June 2023

The date of submitting the proposal through BK2021 shall be decisive for the timely submission of a proposal.

Any and all questions regarding the object of the call for proposals may be submitted by no later than 08 June 2023. Questions may only be asked by electronic means through the Competition Database (function available for logged in users). The Contracting Entity reserves the right to refuse to provide answers to questions submitted after the above deadline.

Proposal validity date: at least 14 days after the proposal submission deadline.

6. Proposal assessment criteria:

The proposals shall be assessed by the Contracting Entity based on the following criteria:

Proposal assessment criteria	weight	maximum score
<i>net prices</i> ¹ (in PLN/other currency)	100%	100

¹ in the case of a proposal quoted in a foreign currency, the average exchange rate of the National Bank of Poland from the last working day preceding the drafting of the proposal selection protocol by the Contracting Entity shall be used for the conversion.

Manners for scoring a particular proposal assessment criterion:

- The score for assessing the *net price in PLN/other currency* criterion shall be assigned according to the following formula:

$$A n = (C \min / C r) \times 100$$

C min – minimum price in the set

C r – price of the analyzed proposal

A n – number of points assigned to the proposal

A proposal for the performance of the contract may be awarded a maximum of 100 points.

7. Information concerning the selection of the most beneficial proposal:

- The Contracting Entity shall award the contract to the Bidder whose proposal corresponds to all the above mentioned requirements and obtains the highest total number of points based on the proposal assessment criteria indicated above.
- Information on the selection of the most beneficial proposal shall be provided to the Bidders by the Contracting Entity in the manner corresponding to that used for the publication of the call for proposals.
- Should the selected contractor withdraw from signing the contract, the Contracting Entity may conclude the contract with the contractor who obtained the second highest number of points as part of a properly executed proceedings for the award of the contract.

7. Information about the scope of exclusion from executing the contract.

- Entities that have personal or equity connections with the Contracting Entity shall be excluded from performing the contract. Personal and/or equity connections are defined as mutual connections between the Contracting Entity and/or the persons authorized to draw liabilities on behalf of the Contracting Entity and/or persons performing activities related to the drafting

and performance of the contractor selection procedure and the Contractor, consisting in, but not limited to:

- a. participation in an enterprise as a partner of a civil law partnership or a partnership, holding at least 10% of shares or stock, performing the function of a member of a supervisory body or management body, holder of the commercial power of attorney, attorney in fact;
- b. marriage, direct consanguinity or affinity, or secondary consanguinity or affinity of up to the second degree or an adoptive relationship, custody or guardianship or cohabitation with the contractor, their legal successor or members of the management bodies or supervisory bodies of contractors applying for the award of the contract;
- c. a legal or factual relationship with the contractor that could give rise to justified doubts as to whether they are impartial or independent in connection with the proceedings for the award of the contract.

2) The following entities shall be excluded from performing the contract:

- a. those who are subject to exclusion from the proceedings based on the provisions of Article 5k of Council Regulation (EU) No. 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (Official Journal of the EU No. L 229 of 31 July 2014, p. 1; hereinafter: **Regulation 833/2014**), as amended by Council Regulation (EU) 2022/576 amending Regulation (EU) No. 833/2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (Official Journal of the EU No. L 111, 8 April 2022, p. 1; hereinafter: **Regulation 2022/576**);¹
- b. the prerequisites for exclusion from the proceedings based on the provisions of Article 7 section 1 of the Polish Act *on special solutions to prevent support for the aggression against Ukraine and to protect national security* (Polish Journal of Laws, item 835) are applicable to them.²

¹ According to the wording of Article 5k section 1 of Regulation 833/2014, as amended by the Regulation 2022/576, it shall be prohibited to award or allow to continue the performance of any public contract or concession falling within the scope of the Public Procurement Directives, as well as within the scope of Article 10 section 1, 3, 6 letters a to e, section 8, 9 and 10, Articles 11, 12, 13 and 14 of Directive 2014/23/EU, Articles 7 and 8, Article 10 letters b to f and h to j of Directive 2014/24/EU, Article 18, Article 21 letters b to e and g to i, Articles 29 and 30 of Directive 2014/25/EU and Article 13 letters a to d, f to h and j of Directive 2009/81/EC that are performed for the benefit of or with the involvement of:

- a) citizens of the Russian Federation or natural persons or legal persons, entities or bodies with their registered seat in the Russian Federation;
- b) legal persons, entities or bodies that have more than 50% of their ownership held directly or indirectly by one of the entities mentioned under letter a) of this section; and/or
- c) n or legal persons, entities or bodies acting on behalf of or under the control of one of the entities mentioned under letter a) or b) of this section,

including subcontractors, vendors or entities whose capacity is relied upon, as defined in the Public Procurement Directives, if more than 10% of the contract value is assigned to them.

² According to the provisions of the Act *on special solutions to prevent support for the aggression against Ukraine and to protect national security* dated 13 April 2022, the following entities shall be excluded from the proceedings for the award of a public procurement contract or a competition held under the provisions of the Public Procurement Law Act:

1) a contractor or participant of the competition mentioned in the lists stipulated under Regulation 765/2006 and Regulation 269/2014 or entered into the list based on a decision on entering onto a list that is decisive for the application of the measure mentioned under Article 1 item 3 of the Act;

2) a contractor or participant of the competition, where the beneficial owner, as defined under the provisions of the Act on the prevention of money laundering and terrorist financing dated 1 March 2018 (Polish Journal of Laws of 2022, item 593 and 655) is a person included on the lists stipulated under the Regulation 765/2006 and Regulation 269/2014 or entered onto the list or being such a beneficial owner since 24 February 2022, provided that they have been entered onto the list based on a decision on entering onto a list that is decisive for the application of the measure mentioned under Article 1 item 3 of the Act;

9. Conditions for amending the contract:

The Contracting Entity reserves the right to amend the conditional contract and final contract to be concluded as a result of conducting the Call for Proposals in the following cases:

- a) as a result of the occurrence of circumstances that are independent from the Contracting Entity and the Contractor (assuming that they have exercised due diligence) that result in the inability to perform or considerable delays in the performance of the contract, including, but not limited to the temporary market shortage of the resources necessary to perform the object of the contract;
- b) occurrence of Force Majeure that prevents performance of the object of the contract by the deadlines stipulated under the Contract. "Force Majeure" shall refer to every external phenomenon that is unpredictable, unexpected and beyond the control of the Parties, occurring after the Contract is signed and preventing the discharge of obligations arising under the Contract;
- c) in the case of changes in the project execution schedule, including, but not limited to cases where it is necessary to extend/shift the deadlines for execution of the individual tasks and stages, resulting from objective factors, independent from the Contracting Entity and the Contractor, preventing the performance of the contract by the initially stipulated deadlines, impacting the quality of performance of the object of the contract;
- d) in the case of circumstances that are independent from the Contractor, at their justified request, provided that the change results from circumstances that the Contractor could not have anticipated at the time of submitting the proposal and for which they are not to blame;
- e) should it be necessary to introduce amendments that the Contracting Entity could not have anticipated when concluding the Contract, by the time necessary to introduce these amendments;
- f) amendments to the generally applicable legal regulations within the scope that impacts the performance of the Contract;
- g) where there are discrepancies and/or doubts as to the interpretation of the terms used in the Contract that cannot be resolved in another manner and the amendment will allow to remove the discrepancy and provide additional details for the Contract in order to ensure an unambiguous interpretation of its provisions by the Parties, where there is also no change in the nature of the Contract;
- h) the amendment does not lead to a change of the nature of the Contract and the total value of the changes is below 140,000 EUR and is at the same time below 10% of the value of the contract stipulated initially in the Contract;
- i) the amendments refer to the execution of additional services or from the previous contractor, not included in the basic scope of the contract, provided that these have become necessary and the following conditions have been met jointly:

3) a contractor or participant of the competition, whose parent undertaking as defined under the provisions of Article 3 section 1 item 37 of the Accounting Act of 29 September 1994 (Polish Journal of Laws of 2021, item 217, 2105 and 2106), is an entity mentioned on the lists stipulated under the Regulation 765/2006 and Regulation 269/2014 or entered onto the list or being such a parent undertaking since 24 February 2022, provided that they have been entered onto the list based on a decision on entering onto a list that is decisive for the application of the measure mentioned under Article 1 item 3 of the Act.

- a change of the contractor cannot be introduced for economic nor technical reasons, including, but not limited to those pertaining to the exchangeability or interoperability of equipment, services or systems ordered as part of the basic contract;
 - a change of the contractor would lead to considerable hardship or significantly increase the costs to be borne by the Contracting Entity;
 - the value of the changes does not exceed 50% of the contract value stipulated initially in the Contract;
- j) the change does not lead to altering the general nature of the Contract and the following conditions have been fulfilled jointly:
- the need for introducing an amendment to the Contract results from circumstances that the Contracting Entity, acting with due diligence, could not have anticipated;
 - the value of the changes does not exceed 50% of the contract value stipulated initially in the Contract;
- k) the contractor that was awarded the contract by the Contracting Entity is to be replaced by a new contractor:
- as a result of succession, stepping into the rights and duties of the contractor, as a consequence of take-over, merger, division, transformation, bankruptcy, restructuring, inheritance or acquisition of the previous contractor or their enterprise, provided that the new contractor meets the conditions for participation in the proceedings and this does not entail any significant amendments to the Contract and is also not meant to circumventing the application of the competition principle and/or
 - as a result of the Contracting Entity taking over the obligations of the contractor towards their subcontractors - where a subcontractor is replaced, the Contracting Entity may enter into a contract with the new subcontractor without amending the terms for performance of the contract, taking into consideration the payments already made for works completed previously.

10. Disclaimers

- The Contracting Entity hereby reserves that in the contract to be concluded with the selected Contractor they shall include contractual penalties for culpable delay in the performance of the contract in the amount of 0.5% of the net value of the contract for each day of the delay in the performance of the contract, however not more than 10% of the net contract value, for which the Contractor consents by submitting a proposal in response to this call.
- The Contracting Entity hereby reserves that should in the course of performance of a subsidized project and the research performed as part of this project the testing results obtained indicate the need to change the scope and terms and conditions of the conditional contract/final contract, the Contracting Entity may terminate the conditional contract or final contract with immediate effect. The contract shall be terminated without incurring any additional fees or penalties.
- The Bidder shall bear all of their own costs associated with the preparation and submission of a proposal, regardless of the results of the proceedings.
- The Contracting Entity reserves the right to amend the call for proposals and the proposal form in case of errors in the call for proposals or the need to supplement the call for proposals; in such a case, the Contracting Entity:
 - informs about the scope of amendments in the call for proposals;

- informs all the Bidders who have submitted proposals about the amendments introduced;
- extends the deadline for submission of proposals by the time necessary to introduce changes in the proposals, if this is necessary due to the scope of the amendments introduced.
- When assessing proposals, the Contracting Entity may request the Contractors to submit explanations or supplement their proposals. In the case that it is not possible to communicate via BK2021, correspondence will be sent via e-mail.
- To complete the proposal assessment procedure, the Contracting Entity shall select the most beneficial proposal.
- Submission of a proposal as part of the Call for Proposals shall constitute acceptance of the terms and conditions stipulated in the call for proposals.
- In justified cases, the Contracting Entity shall be authorized to cancel the entire call for proposals or parts thereof at any time during the proceedings.
- Should the offered price or cost seem to be grossly understated compared to the object of the contract, i.e. differ by more than 30% from the arithmetic mean of the prices of all valid proposals that are not subject to rejection or give raise to doubts on the part of the Contracting Entity as to whether it would be possible to perform the object of the contract as per the requirements stipulated in the call for proposals or as results from separate regulations, the Contracting Entity shall request the Contractor to submit explanations by a designated deadline, including the submission of evidence concerning the manner of calculation of the price or cost. The Contracting Entity shall assess these explanations in consultation with the Contractor and may reject the proposal only where the explanations submitted along with the evidence do not substantiate the price or cost submitted in the particular proposal.

Appendices:

1. Proposal Form
2. Non-disclosure Agreement
3. Detailed Contract Specification