







Wrocław, 29.01.2025

Request for Proposal

Within the framework of the project entitled: "Discovery and development of a new clinical drug candidate for the eradication of cancer stem cell in the treatment of hepatocellular carcinoma, through degradation of oncofetal transcription factor - Stage II", Financed by European Funds for Smart Economy 2021-2027 (FENG), SMART Track - R&D module.

Order number: LL/2/25

Order name:

"Delivery of medical dictionary software for coding and data analysis for clinical trials"











SECTION I: CONTRACTING AUTHORITY

I.1. Name and address of the ordering entity

Captor Therapeutics S.A. 11 Dunska Street 54-427 Wrocław, Poland VAT Number: 8943071259

I.2 CPV code for the order subject

According to the Dictionary of Procurement Terms, the subject of the Order is defined as:

CPV code: 48000000-8 Software packages and information systems

SECTION II: SUBJECT MATTER OF THE ORDER

II.1. Mode of proceeding:

This procedure is conducted in the mode of invitation to submit a bid, according to the principle of competitiveness. The basis for the initiation of the following proceedings is the applicable Guidelines for the eligibility of expenditure for 2021-2027.

II.2 Defining the subject of the order:

The subject of the Tender is the supply of software/license for coding and analysis of drug-related data such as drug product information, active substance, trade names, therapeutic classification according to ATC (Anatomical Therapeutic Chemical). The product must be compatible with MedDRA (Medical Dictionary for Regulatory Activities), compliant with ICH (International Council for Harmonization), EMA (European Medicines Agency), WHO (World Health Organization) and FDA (Food and Drug Administration) guidelines. Detailed specifications are included in Appendix no. 2

II.2.1 Name of the order given by the Ordering Party:

"Delivery of medical dictionary software for coding and data analysis for clinical trials"

The Ordering Party envisages execution of the contract within the framework of the project: "Discovery and development of a new clinical drug candidate for the eradication of cancer stem cell in the treatment of hepatocellular carcinoma, through degradation of oncofetal transcription factor - Stage II". Financed by European Funds for Smart Economy 2021-2027 (FENG), SMART Track. FENG.01.01-IP.01-1001/23-00

II.2.2 Detailed description of the subject of the tender:

Website 2 z 13











- 1. The Bidder shall provide the Purchaser with software/access to a medical dictionary type database for analyzing, coding, reporting drug and therapy safety data in accordance with the requirements in Appendix 2.
- 2. Number of users (if applicable): min. 1
- 3. License/subscription term: for min. 12 months
- 4. Required to provide the software or login and password to online access to the software within 5 days of signing the Agreement or payment
- 5. The bidder will provide online technical support.
- 6. The Ordering Party plans to sign a contract with the selected Bidder in February 2025. It is required to provide validation documentation with the software.
- 7. The Ordering Party allows for the possibility of "Supplementary contracts". The Plan consists on the repetition of similar services i.e. Increasing the number of users/licences, extending the subscription time, activating additional modules, other activities to optimize the software etc. Supplementary contract may be concluded within 3 years from the date of signing agreement to a core project. In order to carry out the supplementary contracts' services The Ordering Party shall invite the Bidder to the new contract negotiations where the detailed scope of work remuneration, terms and conditions will be determined.
- 8. The Bidder shall allow the use of its own bid form, which should include at least: <u>Bidder's name</u> and address, contact information, Name of software offered, Net price.
- 9. The Ordering Party allows for the possibility of delays in the execution of the subject matter of the contract, caused by the occurrence of force majeure¹, the effects of which could not be prevented. In the event of a justified inability to execute the order within the period specified in the Agreement, the Contractor shall inform the Ordering Party of the expected delay.

II.2.3 Conditions

- 1. Possibility of submitting a partial bid is not admissible. The Ordering party treats the bid as a one continuous process.
- 2. Possibility of submitting a variant bid is not admissible.

^{3.} natural disasters, such as earthquakes, floods or others, as well as those declared in accordance with the laws of the country of the natural disaster;



¹ By "force majeure" the Parties shall mean an event (i) beyond the control of the affected Party, and (ii) preventing the proper performance by a Party of one or more material obligations under the provisions of the request for proposals (contract), and (iii) external to the affected Party, and (iv) which the affected Party, acting with due diligence, could not have foreseen or counteracted, and (v) the consequences of which could not have been avoided or reversed. Provided that the prerequisites indicated in the preceding sentence are met, force majeure events of a Party include, in particular:

^{1.} Extraordinary disorders of collective life (including war, including on the territory of another country, if warfare affects the situation in Poland (especially sanctions), state of emergency, other armed actions, invasions, mobilizations, requisitions, terrorism), pandemics, epidemics;

^{2.} The occurrence of radioactive radiation and contamination caused by such radiation;









- 3. The bid is valid for: 30 days from the deadline for submission of bids, with the first day of the bidding period being the day on which the deadline for submission of bids expires. day of the bid binding period is the day on which the deadline for submission of bids expires.
- 4. The Procuring Entity reserves the right to cancel the proceedings without stating reasons, and may do so at any time without liability to the Bidders who submitted the Bids.

II.3 Requirements for Bidders:

The Contracting Authority stipulates that only Bidders who:

- 1. Have the power to perform a specific activity or service, if the law imposes an obligation to have them, to perform the activity covered by the contract,
- 2. have the right to sell the software offered. Bidders who are not producers of software are obliged to attach documentation confirming the right to resale to the offer,
- 3. will submit a statement on the absence of ties between cooperating entities (Appendix no 1).

From the contractor selection procedure are excluded bidders who are personally or financially related to the ordering entity. Financial or personal ties are understood as the relationship between the bidder and the ordering entity or the persons authorized to incur liabilities on behalf of the ordering entity or persons performing on behalf of the ordering party activities related to the preparation and conduction of contractor selection procedure, consisting particularly of:

- a) participation in a company as a partner in a civil partnership or partnership, holding at least 10% of shares (unless a lower threshold is required by law), serving as a member of a supervisory or management body, proxy, attorney,
- b) being married, in a relationship of consanguinity or affinity in a direct line, in a relationship of consanguinity or affinity in a collateral line, or in a relationship of adoption, custody or guardianship, or being in cohabitation with the contractor, his legal deputy or members of the management or supervisory bodies of contractors competing for the contract,
- c) remaining with the contractor in such a legal or factual relationship that there is reasonable doubt as to their impartiality or independence in connection with the procurement procedure.

In order to demonstrate the fulfillment of the condition for participation in the proceeding, the Bidder is required to submit a statement, the content of which is contained in item 4. of the Bid Form, which constitutes Appendix No. 1 to the request for proposal.

The evaluation of the fulfillment of the aforementioned conditions will be made on a meet/not meet basis. Bids that fail to meet at least one of the conditions described in Section II.3 will be excluded from the proceedings.

II.4. Submission of bids:

II.4.1 Basic requirements











- 1. Each Bidder may submit only one bid.
- 2. The bid should be prepared according to the requirements specified in this request.
- 3. The bid must be signed by persons authorized to represent the Bidder.
- 4. The authorization of the persons signing the bid must directly result from the documents attached to the bid. This means that if such authorization does not directly arise from an excerpt from the appropriate register (an excerpt from the Register of Entrepreneurs of the National Court Register or information on entry in the Central Register and Information on Business Activity or any other document that is issued in the country where the Bidder has its registered office) then the bid should be accompanied by the original or a certified for conformity with the original copy of the relevant power of attorney granted by the persons authorized to do so. Power of attorney sent electronically in the form of a scan of a signed document or other documentary form (referred to in Article 77³ of the Civil Code electronic documentary form), that is, electronic files bearing, in particular, a qualified electronic signature, trusted signature, personal signature, docuSign, signature mapping are treated as originals.
- 5. The cost of preparing and delivering the bid shall be borne by the Bidder.

II.4.2 Form of the offer

- 1. The bid must be prepared in Polish or English.
- The bid and its attachments must be signed by persons authorized to represent the Bidder. If the authorization of the signing person does not arise from the document stating the legal status (e.g. KRS), the appropriate authorization must be attached to the offer.
- 3. The contracting authority allows the submission of a tender in written form bearing the contractor's handwritten signature, document form (as referred to in Article 77³ of the Civil Code electronic document form), that is, electronic files bearing, in particular, a qualified electronic signature, trusted signature, personal signature, docuSign, signature decryption.
- 4. The contracting authority accepts documents sent electronically in the form of a scanned signed bid, electronic form, document form or bearing a qualified signature.
- 5. The contracting authority may require the submission of an original or notarized copy of a document only if the copy of the document submitted by the Bidder is illegible or raises reasonable doubts as to its veracity, and the Contracting Authority cannot verify its its veracity in any other way.

II.4.3 Contents of the bid

The offer should include at least:











- If the documents are signed by person(s) other than the one(s) indicated in the excerpt from the
 relevant register, a power of attorney to represent the Bidder in the procurement procedure or
 to represent the Bidder in the procedure and to conclude the procurement contract must be
 attached to the bid. The forms of power of attorney permitted by the Contracting Authority are
 specified in II.4.1. item 4."
- 2. Current extract from the appropriate register or information from the Central Registration and Information on Business Activity or other institution, depending on the seat of the Bidder, issued no earlier than 6 months before the deadline for submission of tenders (the Contracting Authority allows confirmation of the timeliness of the attached documents by signing the documents by the Bidder with the current date or a statement). It is acceptable to submit in the bid, the document in the form of a printout from the website. If a copy of the register can be obtained by the Contracting Authority from publicly available databases (www.ms.ekrs.gov.pl, www.ceidg.gov.pl), the Bidder will not be required to attach a copy of the register to the bid, the Contracting Authority will download the relevant document from the website itself.
- 3. Appendices signed by authorized persons:
 - a) bid form with statements regarding the Bidder,
 - b) Appendix No. 1 statement on the absence of ties between cooperating entities,

II.4.4 Place, date and manner of bid submission

- 1. The deadline for submission of bids is 06.02.2025 at 11:00 am.
- 2. The offer should be submitted <u>electronically through the BK2021 Competitiveness Database platform https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/</u> by attaching a scan of the signed offer with attachments or in the form of documentary documents (referred to in Article 77³ of the Civil Code electronic documentary form), that is, electronic files bearing, in particular, a qualified electronic signature, trusted signature, personal signature, docuSign, signature mapping.
- 3. Bids that are received after the deadline will not be evaluated.

II.5. Mode of consideration of bids:

- 1. The Contracting Authority shall evaluate the submitted (in accordance with the requirements outlined in Section II.4.4.) bids, according to the evaluation criteria specified in Section II.7.1.
- 2. The bid that received the highest number of points (according to II.7.1) is analyzed on the merits, in order to verify the compliance of the offered products with the technical specification presented in Appendix No. 2. The Purchaser, during the analysis of the bid, may request additional explanations or supplements from the Bidder, if the information contained











in the bid does not allow an objective evaluation of the bid. The Contracting Authority shall reject the bid of the Bidder who has not submitted explanations within the prescribed period, or if the evaluation of the explanations confirms that the bid does not comply with the technical specification. In this situation, the Contracting Authority shall evaluate the next-best bid according to the score obtained according to Section II.7.1.

- 3. The Contracting Authority shall examine whether the bid that has received the highest score according to item II.7.1 and has passed the substantive evaluation (according to II.7.2) meets the formal conditions. The Contracting Authority may call upon the Bidder to supplement formal deficiencies of the offer, such as: lack of company registration documents, unless a copy of the register can be obtained by the Contracting Authority from publicly available databases (www.ms.ekrs.gov.pl, www.ceidg.gov.pl), the Bidder will not be obliged to attach a copy of the register to the offer, the Contracting Authority will download the appropriate document from the website itself, power of attorney, statement of lack of connections between cooperating entities, etc. The Contracting Authority shall reject the bid of the Bidder who has not submitted supplements within the prescribed period or if the response received confirms that the bid does not meet the formal conditions. A bid that does not meet at least one condition described in points II 2.3, II.3., II.4. shall be rejected or the Bidder shall be excluded, and the Contracting Authority shall examine the next highest evaluated bid.
- 4. In the event that the Procuring Entity calls on the Bidder to provide answers, related to the clarification or supplementation of the bid, the Procuring Entity shall grant the Bidder a reasonable period of time to supplement or clarify the documents, but not less than 2 working days from the date of delivery by the Procuring Entity of the inquiry/request for clarification or supplementation.
- 5. Waiver of communication through BK2021 is permitted to the extent that it is not possible to comply with the method of communication in BK2021. In such situations, the Contracting Authority shall allow communication by email.
- 6. After evaluating the bids, the Contracting Authority will inform about the selection of the most favorable offer through the competitiveness database.

II.6 Rejection of bid, exclusion of Bidder

- 1. The contracting authority shall reject the bid if:
 - a) Its content does not correspond to the content of this request for proposals,
 - b) Its submission constitutes an act of unfair competition within the meaning of the provisions of the on unfair competition,
 - c) the bidder did not submit clarifications / additions to the content of the submitted bid, when called upon by the Contracting Authority,
 - d) was submitted by a Bidder that does not meet the criteria of this proceeding or by an excluded Bidder,
 - e) is invalid under separate regulations.











- f) The bid was received through a channel other than the BK2021 Competitiveness Database platform.
- 2. Bidders who are excluded from the procurement proceedings are:
 - directly performed activities related to the preparation of the proceedings or used persons participating in the preparation of the bid in carrying out these activities, unless the participation of these contractors in the proceedings will not hinder fair competition,
 - b) have submitted false information that affects or may affect the outcome of the proceedings,
 - c) failed to demonstrate the fulfillment of the conditions for participation in the proceedings,
 - d) are related personally or by capital to the Contracting Authority;
 - e) if the Contracting Authority can establish, on the basis of credible grounds, that the Bidder has entered into an agreement with other bidders or the Contracting Authority aimed at distorting competition, in particular if they belong to the same capital group within the meaning of the Act on Competition and Consumer Protection of February 16, 2007, and have submitted separate bids, partial bids or requests to participate in the proceeding, unless they prove that they prepared these bids or requests independently of each other, or if the Bidder has entered into an agreement with the Contracting Authority aimed at distorting competition. The period of exclusion based on the premise referred to in the preceding sentence is 3 years from the date on which the Contracting Authority becomes aware of the conclusion of an agreement restricting competition or from the date of the decision of the President of the OCCP.

The bid of an excluded Bidder shall be deemed rejected.

II.7. Bid Evaluation Criteria:

1. **Evaluation by scoring criteria** - The Contracting Authority shall evaluate the submitted bids, according to the following criteria:

Criterion - Price - weight of 100 points.

The number of points for the price criterion will be calculated according to the following formula (counting to two decimal places):

Number of —	minimum offered price PLN net	X 100
	price of the tested offer PLN	V 100
points. =	price of the tested offer 1 EN	points
•	net	•











Where,

the net bid price will be calculated as the price indicated in bid form, attached. The maximum bid can receive 100 points.

- 2. The evaluation will be based on the total net bid price in the currency Polish zloty with an accuracy of two decimal places. In the case of bids submitted in foreign currency, the average exchange rate of the National Bank of Poland as of the last day of bid submission will be used for currency conversion, with an accuracy of 4 decimal places.
- 3. **Substantive evaluation** the Contracting Authority shall evaluate whether the bid with the highest number of points (according to II.7.1.) is in accordance with the specifications presented in Appendix No. 2.
- 4. **Formal evaluation** the Contracting Authority examines whether the Offer meets the conditions described in points II 2.3, II.3., II.4.
- 5. The bid which obtains the highest number of points and which is in substantial compliance and meets the formal conditions specified in points. II.2.3, II.3, II.4.
- 6. If no bids are received during the publication of the announcement, or only unacceptable bids are received, or all bidders are excluded, the Contracting Authority has the right to award the Contract without regard to the Competitive Principle².

SECTION III: ADDITIONAL INFORMATION

III.1 Project Funding:

The ordering party informs that the project intends to implement within the framework of European Union funds under the European Regional Development Fund.

III.2 Forms of communication

1. Due to the need to protect sensitive information, which cannot be sufficiently guaranteed using BK2021, the Contracting Authority allows communication by email for sharing of clinical trial timetable. In order to obtain a detailed description of the subject of the contract (Appendix No. 2), contact the Procuring Entity by e-mail: pmo@captortherapeutics.com. All other correspondence related to the preparation of the bid, including formal and technical questions should be asked through the BK2021* Competitiveness Database platform. The Contracting Authority will respond to questions within 3 working days of receipt of the inquiry, provided that the questions are received no later than 3 working days before the date of submission of tenders (the 3-day period does not include the day of submission of tenders). When counting the deadline flowing from the date of the question, please note that the day on which the question is received is not included - the first day of the deadline is the next business day after receipt of the question.

² - In accordance with the Eligibility Guidelines 2021-2027Section 3.2.1. point 4. Website 9 z 13











The deadline ends at the end of the last business day. Answers will be provided by the Contracting Authority through the BK2021 Competitiveness Database.

- 2. The contracting authority is not obliged to conduct the proceedings according to the Public Procurement Law.
- 3. The content of the inquiry is available on the European Funds Competitiveness Database https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/.
- 4. If the answers to questions or problems raised involve a change in the terms and conditions of the contract, information about the change will be provided in the European Funds Competitiveness Database. In such a situation, the Contracting Authority may extend the deadline for submission of tenders.

III.3 Contract completion date

- 1. Implementation will begin after the signing of the contract. The Ordering Party plans to sign the contract in February 2025.
- 2. The selected Bidder will be obliged to implement the contract at the time and under the conditions specified in the Agreement.

III.4 Material provisions of the contract for the parties

- 1. Once the results of the Bidding process have been completed and made public, the Ordering Party and the Bidder will sign an appropriate Cooperation Agreement. If the Bidder whose Bid has been selected evades the conclusion of the Agreement, the Contracting Authority may select the next most advantageous bid from among the remaining Bids.
- 2. The Ordering Party reserves the right to amend the contract concluded with the Bidder selected in the course of the proceedings, in the event of the occurrence of one or more of the circumstances listed below, subject to the conditions specified for their introduction:
- 2.1 The completion date of the contract is subject to change in the following situations:
 - the occurrence of force majeure, (understood in accordance with item II.2.2.9. of the request for proposal), preventing timely execution of the subject matter of the Agreement, whereby the Bidder is obliged to inform the Ordering Party and specify the force majeure causing the inability to execute the contract on time and indicate the impact that this event had on the course of the contract execution
 - occurrence of extraordinary circumstances other than force majeure, preventing timely execution of the subject matter of the Agreement, which the Parties, exercising due diligence, did not foresee when concluding the Agreement and are not at fault;
 - c) suspension of contract execution by the Ordering Party due to the occurrence of technical or organizational reasons that make it impossible to continue execution of the subject matter of the Agreement, by the time of suspension. The Contracting Authority shall notify the Bidder of the suspension of contract execution, indicating the reason for the suspension;











- d) occurrence of changes in the Project implementation schedule, for which the approval of the Project Financing Authority is required
- e) when, for reasons beyond the Bidder's control, the subject of the order will be temporarily unavailable, the Parties may extend the time for the execution of the order by the period of unavailability of the subject of the order or a part thereof;
- f) when a change in the deadline for the execution of the subject of the contract is necessary due to changes in the research process of the research conducted under the Project. Due to the experimental nature of the research, it may be necessary to extend the deadline by the time necessary to complete all tasks that make up the Project. In such a situation, the term of the subject of the contract will be extended by the time necessary to complete the research.

If the prerequisites contained in letters a-b above are fulfilled, the Bidder shall be obliged to demonstrate the impact of the occurrence of the indicated circumstances on the execution of the subject matter of the contract, in particular to provide justification. The order completion date will be extended by the duration of the obstacle and the time necessary to remove its consequences.

The aforementioned changes may not be the basis for an increase in remuneration. Any of the aforementioned changes may be associated with a reduction in remuneration.

- 2.2 The Ordering Party shall allow for the possibility of making changes to the subject matter of the Contract or for the Ordering Party to abandon the execution of part of the subject matter of the Contract in the event of:
 - a) when, during the course of the research conducted in the Project, after analysis of the research and analysis already carried out, the Ordering Party comes to the conclusion that a change in the manner of execution of the contract is necessary. The Contracting Authority shall be entitled to change the manner of execution of the subject matter of the Contract. A change in the scope indicated in the preceding sentence may result in a change in the term of execution of the subject of the contract. The Bidder shall be obliged to demonstrate to the Contracting Authority the impact of a change in the scope of the subject of the contract on the contract completion date;
 - b) the occurrence of a force majeure within the meaning of Section II.2.2.9 of the request for proposals, preventing the execution of the subject matter of the contract, whereby the Bidder shall be obliged to inform the Ordering Party and identify the force majeure causing the inability to execute the contract on time and indicate the impact that this event has had on the course of contract execution.
 - c) the occurrence of circumstances other than force majeure, preventing the execution of the subject of the Agreement, which the Parties, exercising due diligence, did not foresee at the Website $11 \ z \ 13$











- conclusion of the agreement and are not at fault of them, such as the occurrence of changes in the Ordering Party's research process, the occurrence of changes in the assumptions of the project,
- d) changes in applicable laws affecting the subject matter and terms and conditions of the agreement, as well as changes in the legal or factual situation of the Bidder and/or the Purchaser resulting in the impossibility of implementing the subject matter of the agreement
 - e) Agreement using other technical or material solutions due to changes in applicable law.
- 2.3 If in the course of implementation of the project implemented by the Contracting Authority, the competent Institution formulates recommendations for changes in the Project affecting the scope of this contract, the contract may be amended to the extent corresponding to the changes made in the Project.
- 2.4 In the event that the Contractor is unable to supply the product covered by the offer (for reasons beyond the control of the Contractor) it is possible to supply (with the consent of the Purchaser) a substitute with other trademarks, patents or origin, at a net price equal to or lower than that in the offer, but not with different properties and functionalities than those specified in the description of the subject of the contract. The above change is not an amendment to the contract and, therefore, does not require its annexation.
- 2.5 The Contractor shall not be entitled to claim for the execution of the entire subject matter of the contract in the event that the Ordering Party's needs in this regard are less.

2.6 Form of amendment:

- a) Initiation of changes at the written request of the Procuring Entity and/or the Bidder (letter of information).
- b) Annex to the contract with the Bidder in writing under pain of nullity.

Table of Attachments:

Attachment No. 1 - Statement of no relationship between cooperating entities

Attachment No. 2 - Detailed description of the subject matter of the contract











Attachment no. 1	
	(place and date)
(Bidder's name and address)	

Statement of no relationship between cooperating entities

I declare that the Bidder submitting the bid is not related personally or by capital to the Contracting Authority. A capital or personal relationship is understood as a mutual relationship between the Bidder and the Contracting Authority or persons authorized to incur liabilities on behalf of the Contracting Authority or persons performing activities on behalf of the Contracting Authority related to the preparation and conduct of the procedure for selection of the contractor in the procedure: LL/2/25 titled: "Delivery of medical dictionary software for coding and data analysis for clinical trials" consisting in particular of:

- a) participation in a company as a partner in a civil partnership or partnership, holding at least 10% of shares (unless a lower threshold is required by law), serving as a member of a supervisory or management body, proxy, attorney,
- b) being married, in a relationship of consanguinity or affinity in a direct line, in a relationship of consanguinity or affinity in a collateral line, or in a relationship of adoption, custody or guardianship, or being in cohabitation with the contractor, his legal deputy or members of the management or supervisory bodies of contractors competing for the contract,
- c) remaining with the contractor in such a legal or factual relationship that there is reasonable doubt as to their impartiality or independence in connection with the procurement procedure.

There are no relationships listed above between the Procuring Entity and the Bidder		

(stamp and signature of the Bidder)

