GDAŃSKI UNIWERSYTET MEDYCZNY

AGENCJA BADAŃ MEDYCZNYCH

Gdańsk, 17.07.2024

Contractors in the procedure

public procurement procedure conducted in an open tender procedure, based on art. 132 of the Act of 11 September 2019 - Public Procurement Law (Journal of Laws of 2023, item 1605), (hereinafter referred to as the Public Procurement Act) entitled Supervision over the comprehensive implementation of a clinical trial (CRO) in Great Britain. GUM2024ZP0058.

The Medical University of Gdańsk, as the Ordering Party, based on art. 135 sec. 2 and 6 of the Public Procurement Act, provides answers to the questions received in this procedure.

1. Question

We kindly ask you to provide the study protocol (or summary) and the CRF project in order to estimate the complexity of the study and the amount of data, which translates into the calculation of the time allocated for monitoring.

Answer

The Ordering Party informs that the determinant of the degree of complexity of the study should be made on the basis of Annex No. 2 to the Request for Proposal (RFP) and adequately to the activities described therein, to which the given entries in the 'ORDER DESCRIPTION' refer.

2. Question

We kindly ask you to provide the Pharmacy and Laboratory Manual, in order to estimate the scope of work (translation).

Answer

The Ordering Party informs that the determinant of the degree of complexity of the study should be made on the basis of Annex No. 2 to the RFP and adequately to the activities described therein, to which the given entries in the 'ORDER DESCRIPTION' refer.

3. Question

According to the provision of RFP R.XVIII point 1, the person supervising the comprehensive implementation of the clinical trial should be employed by the Contractor on the basis of an employment contract within the meaning of the Act of 26 June 1974 - the Labor Code. This provision excludes the possibility of submitting an offer by a foreign entity with employees employed under local regulations. Please remove or modify this provision in a way that does not limit competition and allows the participation of entities not subject to Polish labor law.

Answer

Art. 95 sec. 1 of the Public Procurement Law obliges the ordering party to require contractors and subcontractors to ensure that persons performing activities indicated by the ordering party within the scope of the order are employed on the basis of an employment relationship, if the performance of these activities consists in performing work in the manner specified in Art. 22 § 1 of the Labor Code, and therefore contains the characteristics of an employment relationship.

According to the aforementioned provision, by establishing an employment relationship, the employee undertakes to perform work of a specified type for the employer and under his direction

DZIAŁ ZAMÓWIEŃ
SEKCJA ZAMÓWIEŃ PUBLICZNYCH
ul. M. Skłodowskiej-Curie 3a, 80-210 Gdańsk
| 58 349 12 23 / 58 349 12 34 | zp@gumed.edu.pl

and in the place and time designated by the employer, and the employer undertakes to employ the employee for remuneration.

Art. 22 § 1 of the Labor Code therefore directly specifies the constitutive characteristics of an employment relationship, which are:

1) performing work of a specified type for the employer;

2) performing work under the employer's direction,

3) performing work in a place designated by the employer;

4) performing work at a time designated by the employer,

5) the employer's obligation to employ the employee for remuneration.
Whether an employee remains in an employment relationship is determined by the features mentioned above, not the name of the concluded contract. In connection with the above, the provision of Chapter XVIII point 1 of the RFP does not exclude the possibility of submitting an offer by a foreign entity with employees employed under local regulations, provided that the method and form of employment ensure the maintenance of the above features of the employment relationship referred to in art. 22 § 1 of the Labor Code. The name of the legal relationship appearing in the legal transactions of the foreign entity is not significant in this respect.

4. Question

According to the provisions of RFP R.XVIII point 2, the Clinical Trial Monitor should be employed under an employment contract by the Contractor. In the draft agreement, par. 19 section 1, however, there is mention of employment by the Contractor or a subcontractor. Please indicate which of these provisions is binding and correct the documentation accordingly.

Answer

In response to the question, the Ordering Party amends the content of Chapter XVIII point 2 of the RFP, by giving it the following wording:
The duties of the Clinical Trial Monitor employed by the Contractor or a subcontractor under an employment relationship during the execution of the order will include, among others:
• supervision over the comprehensive implementation of the clinical trial (CRO) in Great Britain if the performance of these activities involves the performance of work within the meaning of the provisions of Art. 22 § 1 of the Act of 26 June 1974 - the Labor Code (consolidated text: Journal of Laws of 2023, item 1465)

Art. 22 § 1 - Labor Code: By entering into an employment relationship, the employee undertakes to perform work of a specified type for the employer and under his management and at the place and time designated by the employer, and the employer - to employ the employee for remuneration.

5. **Question**

In accordance with the provisions of the Draft Agreement, paragraph 5, the Ordering Party expects to establish detailed conditions for the final agreement with the Newcastle center within 14 days. The description of the subject of the order does not include contracting and negotiations with the

centers. Therefore, we ask for information on who will be responsible for selecting, contracting and negotiating the conditions of participation of the centers in the study. If it is the Contractor, please supplement the Detailed Cost Estimate and the 'ORDER DESCRIPTION' accordingly.

Answer

A preliminary agreement was concluded between the Sponsor and the Newcastle Center. The Ordering Party expects to establish detailed conditions for the final agreement with the Newcastle center within 14 days of concluding the agreement for Supervision over the comprehensive implementation of the clinical trial (CRO) in Great Britain.

6. Question

According to the provisions of the Draft Agreement, par. 2, section 1, point 4), the Contractor is obliged to:
conduct all activities documenting the Study in a secure, IT data storage system, providing access to data with the possibility of verifying the changes introduced; What IT system does the Ordering Party have in mind and will it be provided by the Ordering Party? Or is its provision and maintenance the Contractor's obligation and should it be included in the study cost estimate? If so, please supplement the detailed cost estimate accordingly.

Answer

The eCRF created for the study will be provided by the Ordering Party.

7. Question

According to the provisions of the Draft Agreement, par. 2, sec. 1, item 5), the Contractor is obliged to make payments for the performance of the Study to the research centers. However, according to par. 5, sec. 1, the agreement is concluded between the Ordering Party and the center without the participation of the Contractor. Please clarify whether the costs of remuneration of the centers and Investigators are to be included in the costs of the offer? If the financing of the costs of the centers will come from the Ordering Party's budget, please describe the procedure for transferring these funds to the Contractor so that he can make payments to the centers. In addition, the Cost Estimate is missing an item related to the preparation and settlement of the centers. Please supplement or appropriately change the draft Agreement.

Answer

According to the regulations of the ABM, which finances this non-commercial clinical trial, the Foreign Centers and their Investigators do not receive remuneration. According to the arrangements and the preliminary agreement with the Center in Newcastle, the Center is obliged to make payments for the activities and studies performed.

8. Question

According to the provisions of the Draft Agreement, paragraph 2, section 1, point 6), the Contractor is obliged to prepare quarterly periodic reports and final study reports. What quarterly reports does the Ordering Party mean, to whom should they be addressed and what scope of information should they include? Please also clarify whether the term "final study reports" used in this sentence means the preparation of the Clinical Study Report or whether it refers to information on the completion of the study submitted to the regulatory body?

Answer

The final report from the clinical study (Clinical Study Report, CSR) is to be a detailed document containing the results, analyses and conclusions from the clinical study. The final report from the clinical study also includes information on the completion of the study, which is submitted to the regulatory body.

9. Question

In accordance with the provisions of the Draft Agreement par. 1, item 2, C – Pharmacovigilance, the Ordering Party expects the provision of Qualified Person Responsible for Pharmacovigilance (QPPV) services. According to the definition, the QPPV is the legal representative of the sponsor responsible for all studies conducted by him. Please confirm whether the Ordering Party expects the Contractor to provide such a person as part of this procedure, or whether by having such a person in its own structure it means appointing a representative delegated solely for this study.

Answer

As part of this procedure, the Ordering Party expects the Contractor to provide such a person for this study in the UK.

10. Question

In Annex No. 2 to RFP Detailed Cost Estimate, in item 5 "Supervision over the implementation of the Study..." in line 20 it is entered: "Estimated flat-rate fee for 60 months". Similarly in items 13 and 14. Meanwhile, 76 months are indicated in column E. Please explain this discrepancy and correct the entries accordingly.

Answer

76 months should be assumed. The Ordering Party makes appropriate corrections.

11. Question

In the Description of the Subject Matter of the Order, Stage II, the Contractor's tasks include: conducting all activities documenting clinical trials in a secure, IT data storage system, providing access to data with the possibility of verifying the changes introduced, eCRF

Is it correct to say that the Ordering Party expects at this point to maintain important documentation of the trial in an electronic system, i.e. to maintain the so-called Trial Master File? Did the Ordering Party perhaps mean eTMF, not eCRF? Please explain the context of using the term "eCRF".

Answer

eCRF is to be used to collect and store medical data and results of the clinical trial regarding individual trial participants. eCRF is connected to Cloud Solutions (Microsoft Azure) in order to enable data exchange between research centers. The implementation of the cloud resource takes into account limited access, security measures enabling full identification of users and integration with the eCRF system. For centers in Great Britain, the system has been adapted linguistically and regulatory. Additionally, the Ordering Party expects to maintain important documentation of the trial and project in Great Britain in an electronic system, i.e. to maintain the so-called Trial Master. The Ordering Party will provide access to the server where the Contractor will be able to store and organize documentation.

12. Question

Description of the Subject Matter of the Order, item 13 Supervision of eCRF, including providing a coordinator for data entry - please clarify the responsibilities related to supervision of eCRF.

Answer

Responsibilities related to supervision of eCRF include monitoring the correctness and completeness of data entered into the eCRF system, regular checking of entered data for compliance with the clinical trial protocol. Training and support for research staff in the field of correct data entry into eCRF. Providing technical and substantive support for eCRF system users. Reporting the status of data

entry and possible problems. Data Security in the eCRF system, Implementation of appropriate security measures to protect data from unauthorized access.

13. Question

Description of the Subject Matter of the Order, item 13 Supervision of eCRF, including providing a coordinator for data entry - does the Ordering Party expect the Contractor to enter data into the eCRF? Please explain the role and responsibilities of the coordinator entering data.

Answer

The coordinator is responsible for managing the data entry process, and for communication between the research team and the sponsor, and for supervising timely and accurate data entry, as well as for Data Quality control in the eCRF system - identifying and correcting errors and possible gaps in data.

14. Question

Description of the Subject Matter of the Order, item 20 Preparation and submission of annual reports
on the safety of medicinal products to the Regulatory Agency - is the Study being conducted solely in the UK or is it part of an international project? Will the Contractor be responsible for preparing the safety report only in the part concerning the UK?

Answer

Yes, only in the part concerning the UK.

15. Question

Description of the Subject of the Order, item 22 Cleaning and closing the database - please provide information:
- what eCRF platform will be used in the study and what functions does it offer in terms of supporting the data cleaning process and closing the database?
- is a data management team planned for the study and what is the scope of the Contractor's responsibility in the process of cleaning and closing the database?

Answer

- The eCRF platform used for the clinical trial in question is not a commercial solution. The eCRF used by the Sponsor is a dedicated proprietary solution manufactured to order.

- The Contractor is to report the need to close the database, prepare a form for closing the database regarding centers in Great Britain: verify queries and completeness of data in the eCFR system, verify the coding of medical terms in accordance with the MedDRA dictionary, generate queries to obtain completeness of data, send the database to the person designated for statistical analysis, save the data sent by the Manufacturer and reports from the analysis of a secure location (cloud.gumed)

16. Question

Description of the Subject Matter of the Order, item 23 Supervision over the quality of statistical data in the study and the statistical results developed - please clarify what specific tasks and responsibilities of the Contractor the Ordering Party foresees as part of such supervision? What does the Ordering Party understand by the term "Data and statistical results"?

Answer

By the term "Data and statistical results", the Ordering Party understands all data collected and analyzed as part of a clinical trial, which are used for statistical inference and interpretation of the study results. This includes both raw data collected from study participants and the results of statistical analyses conducted on this data in Great Britain.

17. Question

Description of the Subject of the Order, item 24 Preparation of parts of the final report (CSR – Clinical Study Report) in accordance with ICH E3 (EMA) – what specific parts of the report does the Ordering Party have in mind?

Answer

The Ordering Party has in mind the preparation of the final report (CSR), in accordance with the ICH E3 guidelines (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – Efficacy Guidelines) together with all required parts of such a document in Great Britain.

18. Question

The detailed cost estimate includes 76 monitoring visits. Please indicate how this value was calculated. Additionally, due to the differences in costs, please split this item into two - "on-site" and "remote" visits and provide the expected number of individual visits that are the basis for the calculation (in the description provided by the Ordering Party: minimum 15 personal Monitoring Visits <> (this is different from) minimum 2 on-site visits per Site in each of the 5 years of the Study in each of the 3 Sites). What does the assumption of "15 online visits" refer to - the site, year, or the entire study?

Answer

The entire study in Great Britain will last 76 months, during which the following will be carried out in each site: 2 on-site Monitoring Visits and 15 online Monitoring Visits. So far, we have carried out feasibility of one site in Newcastle and this site is confirmed. If additional sites in Great Britain are contracted (maximum 2), the same number is planned in each of them. We will cover costs after visits are completed according to the billing plan.

19. Question

Why is the number 76 months entered in the detailed cost estimate in the quantity column, i.e. the duration of the entire study, while the "'ORDER DESCRIPTION' name" column states "estimated monthly flat-rate for 60 months". Does this mean that there is an error in the table and the "quantity" column should state 60 months instead of 76 months? What do you mean by entering a flat-rate for 60 months?

Answer

76 months should be assumed. The Ordering Party makes appropriate corrections.

Sprawę prowadzi: Marzena Landowska