In connection with the questions received to the following request for quotation:

28/2020–SACRO

Professional advisory services in the field of registration and regulatory matters related to the clinical development of a drug candidate (OATD-01) and preparation of documents required by the Polish, German, Dutch and French regulatory authorities,

we provide answers to questions that have arisen up to 15/09/2020 15:00 (CET).

Questions concerning the object of the tender:

1. Could you please elaborate on what is expected in the Gap analysis of the data package? Would you expect us to do a completeness check of the available documents in order to move forward with the phase 2a clinical programme? Or should it also include creating a regulatory strategy to fill the possible gaps and provide insights on the activities needed?

   As this is a phase 2a trial, we expect that your package is already in such a complete state that only a completeness check is needed. This will significantly lower the costs compared to our earlier ballpark quotation. Please confirm if this assumption is correct, or if we should include strategy activities as well

   Answer: We will provide you with a data package and we want you to check its completeness and make a critical assessment of our regulatory strategy, we will want to know if our strategy is acceptable in your opinion (without building a regulatory strategy) - we will be open to your suggestions.

2. Is the Gap analysis of the data package related to the scientific advice or to the CTA submission.

   Answer: We do not want the GAP analysis to delay the SA meeting, therefore it is not necessary before the SA, but will be obligatory before the CTA

3. What would the data package, you are planning to provide contain?

   Answer: Animal models, results from preclinical toxicology studies, results from eCiphrCardio Assay, DDI results, results from previous completed clinical studies (basically everything that will be in the investigator's brochure) and results from pharmacometric modelling

4. We assume, that for protocol writing, you will provide a comprehensive synopsis, so you do not need statistical input (e. g. study size calculation) nor extensive medical review?

   Answer: At your request, the synopsis has been given to you, please estimate the cost of creating the protocol on its basis, it is important that it should be the price for a full document that will comply with the guidelines.

5. We would need to clarify whether you expect the statistical work (sample size calculation, etc.) required for the clinical protocol to be done by us.

We ourselves do not take care of the statistical work required for clinical protocols, however, we have trusted partners that we can engage to cover this part. Frequently, our clients own CROs offer support for this part.

In our response to your RfP we could amend the task in the following way, clarifying that the statistical work is excluded:

- Regulatory compliant clinical trial protocol design EXCLUDING STATISTICAL SECTIONS (sample size calculations, etc.)

Note: the statistical sections can either be provided by OncoArendi's own CRO or by our trusted partner

Alternatively, we can ask our partner for a quotation and include this in the task.

Answer: It is important for us to receive a full document (protocol) that complies with the guidelines, the statistical part is its important element. You as a potential contractor have the right to use subcontractors. Please provide us with the amount for the complete document.