

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

17/2021 – ARG

Advisory services and expert advice in the field of clinical oncology in designing a clinical trial and preparing the documentation necessary to start a clinical trial

we provide answers to questions that have arisen up to 26/03/2021 13:00 (CET).

Questions concerning the object of the tender:

1. The only documents you with to receive back is the completed template you sent plus the CV correct?

Correct

2. Regarding preparation of documents for scientific advice and documentation necessary to start a trial, this is a little unclear exactly what you are requesting. Are you just referring to a protocol synopsis?

Regarding preparation of documents for scientific advice: Our external vendor is responsible for the preparation of SA meeting but an expert will be formulating the questions and positions for the briefing book associated with clinical part and in general supporting the process of preparation for the meeting in the area of clinical oncology

Regarding documentation necessary to start a trial: Since our company has been cooperating with the vendors, the majority of the regulatory documents will be prepared externally. An expert will be responsible one time for evaluation and revision of the documents prepared by the vendor and the other time for providing a substantive contribution to the preparation of the documents like protocol, CTA, ICF etc in the field of clinical oncology. At this stage the process of preparation of the synopsis is quite advanced

3. When we were initially thinking about this bid, we thought that perhaps regulatory experts and pre-clinical experts would be required, is my understanding correct that you only want one person included in this? We think that a preclinical gap analysis would be good to do and so perhaps we could include other experts to ensure all bases are covered?

As we have mentioned in the request, we are looking only for one person - the clinicians who is experienced in preparation of the scientific and regulatory documents. The gap analysis is already done.

4. We have spoken internally and we feel that this request would be best placed with a multidisciplinary team approach inclusive of at the very least a drug development expert and regulatory affairs specialist to support scientific meeting prep, pIND meetings etc rather than just one person. We would have a physician overseeing at reg meetings or meetings with investigators and advisors but feel a reg expert is going to be required also to prep the documents. I also wanted to mention that our physicians are not practicing also as that is not practical. As such, I wanted to flag this to you and get your feedback before submitting a

response to your RFP and for you to confirm if we can we submit a proposal for both a drug development expert and a regulatory expert?

We are looking for an expert who is a practicing physician - it is one of the conditions for the acceptance of the offer for evaluation, otherwise the offer will be rejected

Questions concerning the formal issues of the tender:

1. It says to add a gross and NET rate, I know the gross figure, but would it be deducting the started 23% taxation in Poland?

I understand the Contractor that will submit the offer is a VAT payer? If so, gross value = net value+(net value*%VAT)

In reference to VAT matter, I don't know where is your company located (company = bidder) and thus what is the proper rate of VAT applicable on advisory services.

2. What would be company identification number?

It is a tax identification number of a Contractor.

3. The contractor and our company, are both based in the UK, and so we wouldn't need to change VAT as your office is located in Poland. So should I just submit the NET rate instead of a gross one?

If the Contractor (bidder) is based in the UK, then the net value=gross value

4. When I submit/attach the profile of the candidate, should I remove the name, or keep it on the CV?

It's up to you, anonymous CV will be acceptable.