Overview of received questions and answers

RFQ for the provision of digital adherence technology and cloud-based platform for clinical trial participants

https://www.kncvtbc.org/en/request-for-quotation-rfq-for-the-provision-of-digital-adherence-technology-and-cloud-based-platform-for-clinical-trial-participants/

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Study related questions

1. **What is the study design (parallel arms - double blinded - randomized)?**

Randomized open-label trial (parallel design)

2. **Will the trial utilize a phased approach to country/site enrollment?**

A phased approach will be utilized

3. **What is/are the exact dosing regimen(s) that will be tested in the study?**

The regimens will comprise four drugs and will initially contain a single Novel Chemical Entity (NCE) paired with a three-drug backbone. Treatment will be administered daily. All drugs will be given orally.

4. **How will the different treatments be supplied (pills in bottles/bulks, primary blisters)?**

All of the above; repackaging to daily dosing might be required

5. **How many treatment arms will be involved?**

Up to 7 treatment arms

6. **When is the expected first participant enrollment in Q1 of 2023? Could we receive clarification on whether this is the beginning or end of the quarter?**

First participant enrolment is expected at the end of Q1/beginning of Q2 2023.

7. **The RFQ states that at least 2000 devices should be available for worldwide shipping and distribution to trial sites by 31st of December 2022 ". For accurate costing purposes the number of devices is required. What is the minimum number of devices that will be required for the first 2 years of the project, taking into account any reuse of devices?"**

We expect that a minimum of 750 devices are required for the first 2 years of the project (2023-2024)

8. **Out of the 25 different trial sites across 12 countries, can you provide further information regarding anticipated enrollment in each country?**

Not at this moment

Digital adherence technology related questions

9. **There is a requirement for tamper resistance. Does this relate to the technology or the medicine?**

This relates to the technology

10. **Is there a requirement for child-resistant access to the medicine?**

No

11. **The design requires the package to fit a weekly regimen. Will there be multiple weekly supplies provided at once to patients or will there be a weekly visit throughout the study to supply the weekly treatment?**

The first 8 weeks will be weekly visits then until week 24 every 2 weeks

12. **The RFQ mentions CE-IVD approval. Since the solution does not involve IVD, can you confirm that CE-IVD is not required?**

Correct, CE-IVD is not required

Platform related questions

13. **Will any additional customizations be requested as part of this RFP (e.g. secure two-way SMS messaging, pill count data collection, live telehealth initiation, asynchronous video-observed therapy capabilities)?**

Not requested at this stage

14. **Will an integration with the clinical trial system be required? If so, what is the expected timeline for this integration?**

This will be preferred by mid-2023

15. **Can we submit separate offers for the DATs & Cloud based platform?**

Yes, that is possible

Training and support related questions

16. **Will the training be conducted remotely or in-person? What is the structure of the training? How many training sessions will be required?**

It is expected that remote and/or in-person study protocol trainings can be conducted. Please provide preferred training methodology and packages.

17. **Is this RFP requesting any program management associated with DAT implementation/maintenance, aside from technical support?**

Yes that is possible

Budget related questions

18. **In order to estimate the shipping cost, we will need to know the size of each shipment. How many devices will be shipped to each country?**

This is not yet known but you can use 100 devices as a ballpark figure

19. **Does the RFQ require an estimation of import duties for the specific countries?**

This is not a requirement

20. **Is there a preference to what currency should be used to define costs?**

The preferred currency is euro

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