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

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Background: KNCV Tuberculosis Foundation
KNCV Tuberculosis Foundation (KNCV) is an international non-profit organization dedicated to the fight against tuberculosis (TB), still the second most deadly infectious disease in the world. KNCV is an international center of expertise for TB control that promotes effective, efficient, innovative and sustainable TB control strategies in a national and international context. We are an organization of passionate TB professionals, including doctors, researchers, training experts, nurses and epidemiologists. We aim to stop the spread of the worldwide epidemic of TB and to prevent the further spread of drug-resistant TB.

Background: The Unite4TB project
The UNITE4TB project, that started in 2021, aims to set a new standard for anti-TB regimen development. It will upgrade current clinical trial methodology and enhance the efficiency with which new regimens are delivered. This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101007873. Throughout the trials that will be performed in the UNITE4TB project, a digital adherence technology (DAT) will be provided to participants to measure and ensure maximal adherence.

The first participant enrollment is expected in the first quarter of 2023. The trials will be conducted in 25 different trial sites across four regions; Europe, Africa, Asia, and South America. Around 2000 participants will enroll in the trial.

Objective of RFQ

To identify a supplier that can provide a digital adherence technology solution linked to a cloud-based platform to store and analyze adherence data, accepted in a regulatory trial environment (CE-IVD approved), for 2000 participants for use across 25 different trial sites.

Timeline

First contractual period will be from 1st of December 2022 to 31st of December 2024 with the possibility to extent. The total project duration will be until December 2027. The candidate should be capable to start activities within one (1) month after contract signing.

Submission

Proposals should be submitted to natalia.andreeva@kncvtbc.org and received by 11:59 CET on **Sunday 16th of October 2022**. Proposals received after this date and time shall be invalid and will be blocked from review. Proposals should be submitted in English and each interested party shall submit only one quotation. The quotation needs to include the following documents:

1. Completed Requirements document
2. Completed Budget

Selection

Selection of the candidate(s) will be based upon independent assessment of the proposals by a review committee. All quotations will be reviewed based on the following criteria:

1. **Overall suitability**: proposed solutions must meet the scope and be presented in a clear and organized manner.
2. **Organizational experience**: Organizations will be evaluated on their experience related to the scope of this RFQ.
3. **Value and cost**: Organizations will be evaluated on the cost of their solution(s) based on the work to be performed in accordance with the scope of this project.

Questions and contact

KNCV reserves the right to request further information during the RFQ process. Questions regarding requirements described in this RFQ must be directed in writing via email to natalia.andreeva@kncvtbc.org before **Friday 7th of October 2022**.

Responses to questions and/or clarifications originating from such questions that improve the quality of the RFQ will be published on the same website. Issuance of a quotation does not in any way constitute a commitment on the part of KNCV nor does it commit to pay for costs incurred in the preparation and submission of proposal.

Background

Throughout the trials that will be performed in the UNITE4TB project, a digital adherence technology (DAT) that transmits daily dosing events (date/time) to a cloud-based platform will be provided to participants to measure and ensure maximal adherence. Dosing events will be stored, analyzed and visualized for trial staff on the secured cloud data platform to monitor participant' adherence and intervene as early as possible were required.

Trial staff can access the dosing histories on the platform via an Android tablet that is provided to the trial sites and/or by using a web dashboard on existing computer infrastructure. Such platform enables triaging participants based on adherence and to perform risk stratification of participants by rule-based prioritization. This allows trial staff to perform standardized interventions such as sending SMS reminders, phone call follow-ups or conducting home visits to sustain high levels of adherence for trial participants.

A DAT such as smart medication packaging that is capable to store and transmit daily dosing events is preferred to intervene as early as possible when adherence is failing. Each trial site should also have access to a real time dashboard display of vital DAT data to monitor their participants proactively and take appropriate actions to support their participants optimally.

Key facts

- The clinical trials will focus on anti-tuberculosis treatment for duration of at least 24 weeks
- The clinical trials will be conducted in 25 different trials sites across four WHO regions (Europe, Africa, Asia and South America
- The first participant is planned to be enrolled in the trial in Q1 2023
- A total of 2000 trial participants is expected over multiple years spread across trial sites in the following countries:
    - Europe: Georgia, Latvia, United Kingdom, Lithuania, Spain, France
    - Asia: Vietnam, Philippines
    - Africa: South Africa, Tanzania, Uganda
    - South America: Brazil

Requirements

In this section, technical-, organizational- and budget requirements of the RFQ are described. The technical characteristics (and requirements) for the digital adherence technology and cloud-based platform will be used during the assessment to evaluate the overall suitability of proposed solution from each candidate.

Technical (Digital Adherence Technology)

The key technical characteristics and requirements for the digital adherence technology are listed in the table below.

Characteristic	Requirement
Device – Basic	A digital solution that can electronically detect medication intake with date/time stamp
Device - Design	Solution is designed to require little to no participant engagement Fits a weekly regimen that consist of multiple medication formulations for tuberculosis treatment Supports (daily) organization of different medication formulations Highly intuitive operation (such as opening pill box or pill bottle) Tamper evident features
Device - Dosing regimens	Can work / detect different dosing regimens (multiple doses per day, weekly doses, and infrequent dosing)
Device - Reminders / alerts	Device should provide to participants reminders/alerts at designated times (dosing or clinic visit reminder) and on operational status Audible or visible alerts

	Alerts must be easily programmable, configurable and customizable by trial staff (remotely)
Device – Battery Capacity	Device should have battery that lasts complete trial period (> 24 weeks) without charging A mechanism should be available to show the battery status on the device
Device –Charging	Charging of device should be possible without disassembly of device Device charging via USB-C port preferred
Device - Operating Environment	Large temperature range (5-40C) Broad humidity (to 95% non-condensing) and altitude ranges Direct sun light to low light Dusty conditions Intermittent electrical access
Device - Waterproof	Water resistant
Device - Durability	Device should function entire treatment duration (24 weeks) including transportation to sites at weekly interval
Device - Performance and Accuracy	>99% accuracy in dosing event capture >99% accuracy in dosing event transmission Ability to capture multiple daily dosing events
Device - Data Capture	Records participant medication dosing history by capturing date and time events the device was engaged with using well established technologies A mechanism should exist to eliminate false events (too quick engagements/openings) A mechanism should exist to record that the device is functional and no major malfunction has occurred. This device diagnostic data should be made available together with dosing histories
Device - Data Storage	Internal memory able to store >500 dosing events Non-volatile memory should be used that does not lose data due to loss of power Dosing events, configuration and time integrity should be retained when batteries are removed for short duration <2 minutes)
Device - Data Transfer (mobile)	Dosing events and device diagnostic data should be transmitted automatically via mobile cellular data to back-end system (daily frequency) Data transfer includes dosing events and device diagnostic data Automated data transfer can happen without (smart)phone or WiFi
Device – Mobile Connectivity	Device should have built-in mechanism (eg eSIM card) for mobile data transfer that can work with multiple mobile network operators across countries Device should work with 2/3/4G connectivity Device should be able to roam across different mobile networks (e.g. global eSIM card)
Device – Data Transfer (offline)	Device should have back up mechanism to transfer data to tablet, phone or pc at trial site via USB cable or other in case of failure of mobile data transfer
Device – Service and maintenance	Minimal maintenance required
Device – Regulatory requirements	Device meets regulatory requirements for trial use in all trial countries (a final list can be provided)
Device – Distribution	Devices can be shipped to the trial sites in the countries mentioned in this document
Device – Availability	At least 2000 devices should be available for worldwide shipping and distribution to trial sites by 31st of December 2022

Technical (cloud-based platform)

The key technical characteristics and requirements for the cloud-based platform are listed in the table below.

Characteristic	Requirement
Cloud Data Platform - General	Dosing events from all devices should be stored, analyzed, and displayed on secured cloud data platform that has been used successfully in other clinical trials
Cloud Data Platform – Devices	A variety of devices work with the cloud data platform
Cloud Data Platform - Access	Accessible via web and/or app (Android / iOS)
Cloud Data Platform - Configuration	Devices will be used in >20 different sites. Global administrator should be able to create global configuration that is mostly generic across all sites
Cloud Data Platform - Registration	Easy process to register / link participant with device (Additional) participant fields at registration of device are customizable
Cloud Data Platform – Functionality for trial staff	Ability to access participant dosing history Ability to provide data driven adherence (visuals / calendar) feedback to participants (when they visit trial site) Ability to triage participants based on adherence Prioritization / grouping of participants based on adherence patterns (customizable)
Cloud Data Platform – Users & Permissions	Different user profiles and permission levels exist such as for trial staff at trial sites and overall trial
Cloud Data Platform – Hosting	All dosing events and other data is hosted via industry standard services such as Amazon Web Services, Microsoft Azure or Google Cloud Global data hosting satisfies regulatory requirements Hosting approach has been used successfully in other (global) clinical trials
Cloud Data Platform - Alerts	Ability to send automated SMS alerts Configuration of the device reminders can be set-up remotely
Cloud Data Platform - Customized Data Reports	Customizable reports that include dosing events per each device, participant and period exportable via CSV and/or XLS format (example to be provided)
Cloud Data Platform - Data Exchange (API)	API or other webservice available to exchange data (such as dosing events) with other systems such as clinical trial management systems via webservice
Cloud Data Platform – Support and troubleshooting	Support mechanisms exist for troubleshooting and provision of support utilizing the cloud-based platform
Regulatory Requirements	Meet CE-IVD requirements Meet jurisdictional market requirements Meet HIPAA requirements Meet ISO certification
Cloud Data Platform - Training	Trainings are available for trial staff to learn how to use the device and platform

Organizational

1. Provide proof of the expertise, capacity, and experience in the successful execution of comparable works such as in other clinical trials.
2. Provide proof of the expertise to coordinate shipping and distributing digital technologies to various locations worldwide.

3. Provide proof of the expertise in conducting trainings for trial staff to utilize cloud-based adherence platform.
4. Provide examples of SLA or technical support documents to show ability to provide (remote) technical support to trials sites located in various regions/countries.

Budget

This RFQ is designed to provide a digital adherence technology solution linked to a cloud-based platform to 2000 trial participants including technical support. Each submitted budget must provide details of:

- All costs related to the procurement and shipping of the digital adherence technology product(s) to trail sites
- All costs related to the setup, configuration and maintenance (e.g. hosting) of the cloud-based platform
- All cost related to the provision of trainings to clinical trial staff
- All costs related to the provision of technical support during the project duration

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