Terms of References (ToR)

for the purchase of diagnosis equipment & providing expertise in the implementation of New-born Hearing Screening (NHS) projects in Nigeria

Contracting body:	MED-EL Elektromedizinische Geräte GmbH
Title of project:	Empowering the Hearing Healthcare Sector in Developing and Emerging Countries
Contact:	Stephanie Unterrieder, MA (Project Manager Business Development Africa and Regional Manager) Stephanie.unterrieder@medel.com +43 664 607051575

1. BACKGROUND

MED-EL will implement a comprehensive Public-Private-Partnership (PPP) programme in the hearing healthcare sector in ten Sub-Saharan African and four South-Asian countries, co-financed by the Austrian Development Agency (ADA). The MED-EL project team based in Innsbruck (Austria) seeks support in implementing universal and quality-controlled new-born hearing screening pilot programmes from screening to early diagnosis in countries with limited medical infrastructure. Therefore, an external equipment provider and know-how partner, with proven experience in the management and coordination of new-born hearing screening projects is sought. The partner must follow a holistic and compatible approach in the implementation of the screening programme by offering a comprehensive "all-in-one" package.

2. CONTEXT

MED-EL Medical Electronics, based in Innsbruck (Austria), is a family-owned and globally active medical device company and one of the leading manufacturers of hearing systems. While the production is entirely located in Austria, the company is active in over 120 countries with more than 30 subsidiaries and branches worldwide. MED-EL accompanies patients throughout their hearing journey, starting from assessments and surgery to fitting of the processors and after sales measures such as rehabilitation. The central mission of the company is to overcome hearing loss as a barrier to communication and quality of life. As a family-owned company, MED-EL has a long-term perspective and wants to contribute to the local socio-economic development in countries of the global south.

As part of the Strategic Partnership "Empowering the Hearing Healthcare Sector in Developing and Emerging Countries", which is co-financed by the Austrian Development Agency (ADA), and which is referred to as "Hearing Healthcare Alliance", MED-EL aims at sustainably strengthening the hearing-healthcare sector in selected developing and emerging countries. The overall goal is to significantly improve the diagnosis and rehabilitation of people with hearing impairment by establishing sustainable local structures in the hearing healthcare sector in 14 partner countries: Benin, Ghana, Côte d'Ivoire, Mali, Senegal; Ethiopia, Kenya, Nigeria, Tanzania, Uganda; Bangladesh, Bhutan, Nepal; Pakistan. The emphasis will be put on education, infrastructure, and workforce development. As a result, the care of people with hearing impairment will be significantly enhanced.

Due to different project schedules in the respective countries regarding the implementation of new-born hearing screening programmes, the ToRs are issued in country-related instalments.

3. DETAILS OF THE CONTRACT TO BE AWARDED & TASKS TO BE PERFORMED

Pillar A: Project development & procurement

Concept introduction to MED-EL and local partners

- Online Introduction Sessions

Support in the development of project documents:

- Cooperation contract between equipment provider/know-how partner and MED-EL
- NDA – Non-disclosure Agreement between equipment provider/know-how partner, MED-EL and the responsible partner in the project country

- MoU (project agreement) between equipment provider/know-how partner, MED-EL and responsible partner in the project country

Project preparation:

- Ensure necessary IT infrastructure
- Development of NHS implementation protocol in the project country
- Training materials & information booklet/handout for screeners
- Overview of participating centres & responsible field personnel
- Awareness & information materials for the general population (e.g., info flyers, posters)
- Educational materials adapted to the local context (e.g., comprehensive training presentation, step-by-step poster, video learning material, certificates)
- Agreements/contracts with participating hospitals/follow-up sites about tasks and duties)

Provision of equipment:

No.	Description	Quantity
1	Audiology Diagnostic Devices Incl. hardware & software for diagnostic licences + accessories + tracking software	1

Pillar B: Project implementation & management

No.	Description	Quantity (in days)
1	Kick-off and training event I (on-site or online)	1
2	Practical training II (on-site) - Intensive practical training - Visit participating clinics/hospitals	2
3	Online support - Regular monitoring and quality control	7

Pillar C: Reporting

- Regular update meetings with the MED-EL project team
- Written report incl. quarterly statistics to be sent to MED-EL (Mrs. Stephanie Unterrieder) every 6 months
- Support creation of monthly statistics, birth numbers, extracts from the tracking database as well as monthly letters for the screening staff
- Support creation of scientific studies and papers with local partners

4. TECHNICAL CRITERIA FOR EQUIPMENT PURCHASE

The products must be universally applicable and technically capable of covering the diagnosis functions. The devices and the tracking functions must be a compatible technical ecosystem that allows for a functioning follow-up system. The tracking software must enable comprehensive management of screening patients for the identification and administration of their statuses.

4.1 Measuring device

Feature	Description
Test Methods	Instruments must provide diagnostic modules of OAE (TEOAE, DPOAE), AEP (ABR, ASSR), Impedance, PTA (Air (with headphones and insert ear receiver) and Bone conduction), and Free-field aided responses with loudspeakers.
Quality Criteria	Transmission of measurements, not only results including quality indicators such as artifacts, EEG, stimulus stability.
Device Upgrades by license codes	Upgrades must be enabled by entering a new license code on the device, without using further software.
Firmware Updates	Device firmware updates shall be enabled to be rolled out centrally without onsite support. Ease of maintenance is key.
User-Login	Instruments must offer a user-login. Actions on the device must be assignable to individual examiners.
Site/Facility Management	The site and facility management enables the use of the device in various departments and locations.
Profile Management	Various user-profiles for individual permissions must be enabled on the device.
Risk Factor- and Predefined Comment function	Instruments must offer a uniform list of risk factors and predefined comments. Risk factors and predefined comments can be selected, assigned and transmitted from the device to a central server. Free text input for comments must also be enabled.
Interchangeable Transducers	Probes can be interchanged between units without additional calibration. Calibration data must be stored in the transducer.
Patients Status Information on Instrument	The instrument must allow additional status information to be sent to the tracking centre. This includes: • Type of examination • Appointment management for re-screening • Confirmation of participation • Referral to other facilities • Result of the examination • Diagnosis

4.2 Data transfer

Feature	Description
Use of a Radio Wireless Modem	Data must be transmitted via a mobile internet network by using a modem with SIM card. The data transfer must be protected with an SSL certificate or higher security standards.
Installation and Maintenance of the Modem	The radio modem must be independent from any hospital IT network. It must be delivered in a “ready to use” mode. All settings have been made prior to the delivery. The modem shall operate without any local maintenance and service.
Bi-directional Data Transfer	Data transfer must enable two-way transmission (bi-directional). Instruments and tracking software must be able to send and receive data in both directions.
Data Transmission without Sub-Systems	Data must be sent directly from the measuring device, without using sub-systems, such as PC- or Laptop applications. Data must be protected against any manipulation, e.g., deletion/editing of single results on its way from instrument to central server.

4.3 Tracking software

Feature	Description
ID-Management	Transmitted patient ID’s must be checked against their validity before processing.
Monitoring the Reception of Data	With respect to incoming data requests, plausibility checks shall be carried out to check the completeness and integrity of the data packages.
Risk Factor- and Comment Management	List of risk factors and predefined comments can be sent uniformly from a central server to all devices.

Site/Facility Management	The system should provide site/facility management. Clinics, departments, and other institutions must be centrally stored and managed in the tracking software.
Device Management	The system should provide device management. Measuring instruments must be centrally stored and managed in the tracking software.
User Management	The system should provide user management. All certified examiners must be centrally stored with individual login and contact details.
ID Management	The system should provide ID management. Screening ID (Patient ID) including their check-algorithm must be identified and checked by the tracking software.
Field Management	The system should provide field management where uniform demographic entries can be provided on the instruments. Entry fields must be able to be set as mandatory.
Individual Languages	The system shall be able to switch in individual localisations, according to user settings.
Status Management	The system shall enable individual status-calculations, based on incoming test information.
Resubmission-Management	Patients must appear on work lists according to tracking-related criteria.
Data Management	The system should provide tools to search for implausible records and to facilitate corrections.
Statistics	The data records received must be able to be statistically evaluated according to tracking-related criteria.

5. MINIMUM ELIGIBILITY

For the management of this long-term multi-stakeholder programme, an equipment and know-how partner with demonstrated expertise in the implementation of New-born Hearing Screening (NHS) Programmes in challenging conditions in countries of the Global South is being sought. The organization shall have minimum 10 years of experience in providing expertise in the implementation and management of quality-controlled NHS projects. At least one expert should be familiar with managing and running projects in developing and emerging countries.

Proven experience in the following areas is required:

- Min. 10 years' experience in providing expertise in the implementation and management of quality-controlled NHS projects
- Experience in training and education of various stakeholders and professionals (e.g., workshops, 1:1 online and offline sessions, creation of suitable training materials)
- At least 2 reference projects, preferably in Africa and in Asia
- Experienced team capable of offering continued project management
- Linguistic fluency (spoken and written) in German, English and French
- Possess stakeholder management and problem-solving skills in different cultural contexts
- Flexible, demand-driven and able to adopt to the needs of the different project stakeholders

6. PERIOD OF SERVICES

The contract and service period starts on the 10th of April 2023 and is limited to max. two years.

7. REPORTING

The contractor shall report to Mrs. Stephanie Unterrieder, project lead of Public Private Partnerships at MED-EL. The contractor shall submit evidence of services at the end of the contract period in the form of a final report.

8. SUBMISSION OF DOCUMENTS

The offer must contain the following documents:

a. Description of products and technical details
b. Description of services
c. Methodology
d. Time schedule
e. Cost plan/Price offer
f. Name, function and qualification of the staff that will be engaged for this project
g. Reference projects (as specified in grid for assessing eligibility)

If necessary, a live demonstration of products and a concept presentation may be requested by MED-EL.

The documents (technical and price proposal) must be **submitted by 04th of April 2023** via e-mail (PDF only!) to stephanie.unterrieder@medel.com.