Request for Proposals (RFP)

for
A Contract Research Organization (CRO) to provide clinical trial services for Cardiflo, a cardiovascular screening device for use in primary health care to the CSIR

RFP No. 3351.1/01/06/2021

Date of Issue	Wednesday, 26 May 2021
Last date for queries/concerns	Friday, 28 May 2021
Closing Date	Tuesday, 01 June 2021 at 16h30
Place of tender submission	Electronic submission: tender@csir.co.za Mail size is 30MB, if exceeded, multiple emails can be sent
Enquiries	Strategic Procurement Unit E-mail: tender@csir.co.za
CSIR business hours	08h00 – 16h30
Category	Professional

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SECTION A – TECHNICAL INFORMATION

1 INTRODUCTION

The Council for Scientific and Industrial Research (CSIR) is one of the leading scientific research and technology development organisations in Africa. In partnership with national and international research and technology institutions, CSIR undertakes directed and multidisciplinary research and technology innovation that contributes to the improvement of the quality of life of South Africans. The CSIR's main site is in Pretoria, while it is represented in other provinces of South Africa through regional offices.

2 BACKGROUND

Cardiovascular disease (CVD) is the leading cause of death and disability in the world. In Africa, non-communicable diseases (NCD) are rising rapidly and are projected to exceed communicable, maternal, perinatal and nutritional diseases as the most common causes of death by 2020. In South Africa (SA), approximately 130 heart attacks and 240 strokes occur daily; these are the most common diseases associated with CVD. Although a large proportion of CVD are preventable, they continue to rise mainly because preventive measures are inadequate.

Therefore, there is a need for a testing method and/or screening device for the early detection of CVDs, to reduce the societal burden of these diseases. Early detection of these conditions could lead to treatment and advice on lifestyle changes that offer the potential to reduce the incidence of fatal and nonfatal myocardial infarction (MI) and cerebrovascular events (stroke/Transient Ischaemic Attack), as well as to improve the quality of life.

The CSIR has developed Cardiflo; a mobile portable hand held point of care device. Cardiflo is a continuous wave Doppler ultrasound-screening device that is adapted to screen patients at risk of cardiovascular events. This is done by performing Doppler flow measurements on the carotid arteries using the Cardiflo device, together with customised software on a computer. The intended aim of Cardiflo is its use in the primary healthcare domain to enable point of care screening with the outcome being to encourage people to adopt healthy lifestyles, seek appropriate care and encourage prevention.

The Cardiflo is meant to detect individuals with asymptomatic carotid artery stenosis with the following aims:

- To identify individuals at risk of having a cardiovascular event, particularly in the cerebrovascular and coronary circulations.
- To select individuals who need significant risk factor modification.
- To potentially intervene, at higher levels of care, with carotid endarterectomy or carotid stenting to prevent a cardiovascular event.

It is envisaged that the solution will impact the current value chain and cost structure of the healthcare systems significantly by eliminating the cost of avoidable patient referral to a higher level of care. Furthermore, the Cardiflo device will improve the administrative efficiency and quality control through the mobile connected feature of the Cardiflo device, therefore reducing the overall health care cost.

3 INVITATION FOR PROPOSAL

Proposals are hereby invited for a Contract Research Organization (CRO) to provide clinical trial services for Cardiflo, a cardiovascular screening device for use in primary health care to the CSIR. It is envisaged, that the clinical trial will consist of three phases. The **proposed** patient numbers are: 100-200 patients for phase 1, 100-200 patients for phase 2 and 400-800 patients for phase 3. The feasibility of these proposed patient numbers for each phase should be discussed in the proposal.

During Phase 1 of the trial, initial carotid Doppler ultrasound data and patient health statuses will be gathered, and a proposed CVD analysis method will be evaluated on a sample group. The sample group must show the range of CVD conditions considered as representative of the general South African population and must include a high percentage of individuals with known pre-existing cardiovascular condition/s, for comparison purposes (between normal and abnormal patients).

The results and feedback obtained from Phase 1 of the study will be used to refine the algorithm and processes for CVD detection. These modifications will be verified on a sample set - Phase 2 of the clinical trial.

During Phase 3 of the clinical trial, a broader larger sample set of individuals will be assessed to determine the effectiveness of the device as a screening tool for CVD.
All phases of the studies must include a case-by-case comparison to a commercial imaging ultrasound machine. The commercial ultrasound machine should be used to identify areas of stenosis, record a comparative Doppler waveform, characterise plaques, and take measurements including the intima media thickness, relevant vessel diameters and blood flow velocities (peak systolic and end diastolic velocities). It is proposed that measurements be taken for each of the 3 arteries (common, internal and external carotid artery), on both the left and right side on a patient (6 measurements per patient). The secondary aims of the trial include gaining feedback regarding the usability of the device and software.

CSIR is seeking a CRO that will:

- Plan the clinical trial
- Finalise the clinical trial protocol(s) and related documentation, including:
  - Study methodology
  - Duration/timeframes
  - Eligibility and exclusion criteria
  - Informed consent and management of withdrawals
- Conduct a feasibility study to select the most suitable site(s), taking into account the recruitment potential, sample size and the types of candidates required. Be responsible for the required regulatory and Ethics submissions, and Study Start up activities to

ensure efficient site activation management and perform site coordination, site initiation, on-site monitoring, site contracting and payment management.

- Be responsible for data management, ensuring data quality, integrity and security.
- Provide the CSIR with full access to the data during and after the trial.
- Write the Clinical Study report, including statistical analysis of the results.

4 PROPOSAL SPECIFICATION

It is requested that all activities listed in the *Invitation for Proposal* be addressed in your proposal (including any services that you do not provide). Further items, which CSIR ask to be addressed in the proposal, are:

- Overview of your organisation
- An overview of your project management approach in general and how it would be applied to this study
- Quality management systems used by your organisation
- Gantt Chart
- Budget
- Project team CVs including the principal investigator, lead data manager, lead clinician, etc.
- Summary of the team's experience in running similar clinical trials

5 FUNCTIONAL EVALUATION CRITERIA

5.1 The evaluation of the detail of the proposal will be based on the following criteria:

No.	Criteria	Weighting
1	Experience of team members in the diagnosis and treatment of CVD (i.e. specialisation and demonstrated track record in the CVD field)	30%
2	Experience of team members specifically in the use of ultrasound for CVD examination	20%
3	Experience and demonstrated track record in the design and execution of clinical trials in the CVD field	25%
4	Ability of the team to recruit sufficient patient numbers within the project timescales	25%

5.2 Proposals with points of less than the pre-determined minimum overall percentage of 70% will be eliminated from further evaluation.

5.3 Refer to Annexure A for the scoring sheet that will be used to evaluate functionality**.**

6 ELIMINATION CRITERIA

Proposals will be eliminated under the following conditions:

- Submission after the deadline
- Proposals submitted at incorrect location or email address

7 NATIONAL TREASURY CENTRAL SUPPLIER DATABASE REGISTRATION

Before any negotiations will start with the winning bidder, it will be required from the winning bidder to:

- Be registered on National Treasury's Central Supplier Database (CSD). Registrations can be completed online at: www.csd.gov.za;
- Provide the CSIR of their CSD registration number; and
- Provide the CSIR with a certified copy of their B-BBEE certificate. If certificate cannot be provided, no points will be scored during the evaluation process. (RSA suppliers only).

SECTION B – TERMS AND CONDITIONS

8 VENUE FOR PROPOSAL SUBMISSION

All proposals must be submitted at:

- Electronically at the following email address:
- tender@csir.co.za

  Should the tender file size exceed 30 MB, tenderers can submit tender in multiple emails.

9 TENDER PROGRAMME

The tender program, as currently envisaged, incorporates the following key dates:

- Issue of tender documents: Wednesday, 26 May 2021
- Last date for queries/concerns on closing date Friday, 28 May 2021
- Closing / submission Date: Tuesday, 01 June 2021

10 SUBMISSION OF PROPOSALS

10.1 All proposals are to be clearly marked with the RFP number. Proposals must consist of two parts:

PART 1: Technical Proposal: RFP No: 3351.1/01/06/2021

PART 2: Pricing Proposal, B-BBEE and other Mandatory Documentation:
RFP No.: 3351.1/01/06/2021

10.2 Proposals submitted by companies must be signed by a person or persons duly authorised.

10.3 The CSIR will award the contract to qualified tenderer(s)' whose proposal is determined to be the most advantageous to the CSIR, taking into consideration the technical (functional) solution, price and B-BBEE.

11 DEADLINE FOR SUBMISSION

Proposals must be submitted at the address mentioned above no later than the closing date of **Tuesday, 01 June 2021** during CSIR's business hours. The CSIR business hours are between 08h00 and 16h30.

Where a proposal is not received by the CSIR by the due date and stipulated place, it will be regarded as a late tender. Late tenders will not be considered.

12 AWARDING OF TENDERS

12.1 Awarding of tenders will be published on the National Treasury e-tender portal or the CSIR's tender website. No regret letters will be sent out.

13 EVALUATION PROCESS

13.1 **Evaluation of proposals**

An evaluation team will assess and evaluate all proposals for functionality, price and B-BBEE. Based on the results of the evaluation process and upon successful negotiations, the CSIR will approve the awarding of the contract to successful tenderers.

A two-phase evaluation process will be followed;

- The first phase includes evaluation of **elimination** and **functionality criteria**.
- The second phase includes the evaluation of **price** and **B-BBEE** status.

Pricing Proposals will only be considered after functionality phase has been adjudicated and accepted. Only proposals that achieved the specified minimum qualification scores for functionality will be evaluated further using the preference points system.

13.2 **Preference points system**

The 80/20 preference point system will be used where 80 points will be dedicated to price and 20 points to B-BBEE status

14 PRICING PROPOSAL

14.1 Pricing proposal must be cross-referenced to the sections in the Technical Proposal. Any options offered must be clearly labelled. Separate pricing must be provided for each option offered to ensure that pricing comparisons are clear and unambiguous.

14.2 Price needs to be provided in South African Rand (excl. VAT), with details on price elements that are subject to escalation and exchange rate fluctuations clearly indicated.

14.3 Price should include additional cost elements such as freight, insurance until acceptance, duty where applicable.

14.4 Only firm prices* will be accepted during the tender validity period. Non–firm prices** (including prices subject to rates of exchange variations) will not be considered.

**Firm price is the price that is only subject to adjustments in accordance with the actual increase or decrease resulting from the change, imposition, or abolition of customs or excise duty and any other duty, levy, or tax which, in terms of a law or regulation is binding on the contractor and demonstrably has an influence on the price of any supplies, or the rendering costs of any service, for the execution of the contract;*
***Non-firm price is all prices other than "firm" prices.*

14.5 Payment will be according to the CSIR Payment Terms and Conditions.

15 VALIDITY PERIOD OF PROPOSAL

Each **proposal** shall be valid for a minimum period of three (3) months calculated from the closing date.

16 APPOINTMENT OF SERVICE PROVIDER

16.1 The contract will be awarded to the tenderer who scores the highest total number of points during the evaluation process, except where the law permits otherwise.

16.2 Appointment as a successful service provider shall be subject to the parties agreeing to mutually acceptable contractual terms and conditions. In the event of the parties failing to reach such agreement CSIR reserves the right to appoint an alternative supplier.

16.3 Awarding of contracts will be announced on the National Treasury website and no regret letters will be sent to unsuccessful bidders.

17 ENQUIRIES AND CONTACT WITH THE CSIR

Any enquiry regarding this RFP shall be submitted in writing to CSIR at tender@csir.co.za with ***"RFP No 3351.1/01/06/2021 - The provision of a Contract Research Organization (CRO) to provide clinical trial services for Cardiflo, a cardiovascular screening device for use in primary health care to the CSIR"*** as the subject.

Any other contact with CSIR personnel involved in this tender is not permitted during the RFP process other than as required through existing service arrangements or as requested by the CSIR as part of the RFP process.

18 MEDIUM OF COMMUNICATION

All documentation submitted in response to this RFP must be in English.

19 COST OF PROPOSAL

Tenderers are expected to fully acquaint themselves with the conditions, requirements and specifications of this RFP before submitting proposals. Each tenderer assumes all risks for resource commitment and expenses, direct or indirect, of proposal preparation and participation throughout the RFP process. The CSIR is not responsible directly or indirectly for any costs incurred by tenderers.

20 CORRECTNESS OF RESPONSES

20.1 The tenderer must confirm satisfaction regarding the correctness and validity of their proposal and that all prices and rates quoted cover all the work/items specified in the RFP. The prices and rates quoted must cover all obligations under any resulting contract.

20.2 The tenderer accepts that any mistakes regarding prices and calculations will be at their own risk.

21 VERIFICATION OF DOCUMENTS

21.1 Tenderers should check the numbers of the pages to satisfy themselves that none are missing or duplicated. No liability will be accepted by the CSIR in regard to anything arising from the fact that pages are missing or duplicated.

21.2 *Electronic copy* of each proposal must be submitted.

21.3 Pricing schedule and B-BBEE credentials should be submitted with the proposal, but as a separate document and no such information should be available in the technical proposal.

22 SUB-CONTRACTING

22.1 A tenderer will not be awarded points for B-BBEE status level if it is indicated in the tender documents that such a tenderer intends sub-contracting more than **25%** of the value of the contract to any other enterprise that does not qualify for at least the points that such a

tenderer qualifies for. Unless the intended sub-contractor is an exempted micro enterprise that has the capability and ability to execute the sub-contract.

22.2 A tenderer awarded a contract may not sub-contract more than **25%** of the value of the contract to any other enterprise that does not have an equal or higher B-BBEE status level than the person concerned, unless the contract is sub-contracted to an exempted micro enterprise that has the capability and ability to execute the sub-contract.

23 ENGAGEMENT OF CONSULTANTS

The consultants will only be remunerated at the rates:

23.1 Determined in the "Guideline for fees", issued by the South African Institute of Chartered Accountants (SAICA); or

23.2 Set out in the "Guide on Hourly Fee Rates for Consultants", by the Department of Public Service and Administration (DPSA); or

23.3 Prescribed by the body - regulating the profession of the consultant.

24 TRAVEL EXPENSES

24.1 All travel expenses for the CSIR's account, be it directly via the CSIR's travel agent or indirectly via re-imbursements, must be in line with the CSIR's travel policy. The following will apply:

24.1.1 Only economy class tickets will be used.

24.1.2 A maximum of R1400 per night for accommodation, dinner, breakfast and parking will be allowed.

24.1.3 No car rentals of more than a Group B will be accommodated.

25 ADDITIONAL TERMS AND CONDITIONS

25.1 A tenderer shall not assume that information and/or documents supplied to CSIR, at any time prior to this request, are still available to CSIR, and shall consequently not make any reference to such information document in its response to this request.

25.2 Copies of any affiliations, memberships and/or accreditations that support your submission must be included in the tender.

25.3 In case of proposal from a joint venture, the following must be submitted together with the proposal:

- Joint venture Agreement including split of work signed by both parties;
- The original or certified copy of the B-BBEE certificate of the joint venture;
- The Tax Clearance Certificate of each joint venture member;
- Proof of ownership/shareholder certificates/copies; and
- Company registration certificates.

25.4 An omission to disclose material information, a factual inaccuracy, and/or a misrepresentation of fact may result in the disqualification of a tender, or cancellation of any subsequent contract.

25.5 Failure to comply with any of the terms and conditions as set out in this document will invalidate the Proposal.

26 CSIR RESERVES THE RIGHT TO

26.1 Extend the closing date.

26.2 Verify any information contained in a proposal.

26.3 Request documentary proof regarding any tendering issue.

26.4 Appoint one or more service providers, separately or jointly (whether or not they submitted a joint proposal).

26.5 Award this RFP as a whole or in part.

26.6 Cancel or withdraw this RFP as a whole or in part.

27 DISCLAIMER

This RFP is a request for proposals only and not an offer document. Answers to this RFP must not be construed as acceptance of an offer or imply the existence of a contract between the parties. By submission of its proposal, tenderers shall be deemed to have satisfied themselves with and to have accepted all Terms & Conditions of this RFP. The CSIR makes no representation, warranty, assurance, guarantee or endorsements to tenderer concerning the RFP, whether with regard to its accuracy, completeness or otherwise and the CSIR shall have no liability towards the tenderer or any other party in connection therewith.

DECLARATION BY TENDERER

Only tenderers who completed the declaration below will be considered for evaluation.

RFP No: ……..

I hereby undertake to render services described in the attached tendering documents to CSIR in accordance with the requirements and task directives / proposal specifications stipulated in RFP No.…….. at the price/s quoted. My offer/s remains binding upon me and open for acceptance by the CSIR during the validity period indicated and calculated from the closing date of the proposal.

I confirm that I am satisfied with the correctness and validity of my proposal; that the price(s) and rate(s) quoted cover all the services specified in the proposal documents; that the price(s) and rate(s) cover all my obligations and I accept that any mistakes regarding price(s) and rate(s) and calculations will be at my own risk.

I accept full responsibility for the proper execution and fulfilment of all obligations and conditions devolving on me under this proposal as the principal liable for the due fulfilment of this proposal.

I declare that I have no participation in any collusive practices with any tenderer or any other person regarding this or any other proposal.

I accept that the CSIR may take appropriate actions, deemed necessary, should there be a conflict of interest or if this declaration proves to be false.

I confirm that I am duly authorised to sign this proposal.

NAME (PRINT) …….

CAPACITY ……..

SIGNATURE …….

NAME OF FIRM ……..…..

DATE ……

WITNESSES

1 ……

2 ……

DATE: ……..

28 ANNEXURE A

Criteria	Weighting	0	7	10
Experience and demonstrated track record in the design and execution of clinical trials in the CV field. The organisation must have a proven track record of previous successfully executed clinical trials, within specified timelines. If an organization has been involved in clinically trialing medical devices, similar and/or identical to the Cardiflo device these should be emphasized.	25	No proof of successfully executed clinical trials, within specified timelines provided.	Proof of at least 1-4 successfully executed clinical trials, within specified timelines provided.	Proof of at least 5 or more successfully executed clinical trials, within specified timelines.
Experience of team members in the diagnostic and treatment of CVD (i.e. specialisation and demonstrated track record in the CVD field) Study team includes member/s who are proficient and have experience in cardiovascular physiology, anatomy and pathology.	30	Team members have no experience in the cardiovascular field (CVD).	Proof of team having knowledge and experience in the cardiovascular field, as evidenced by the proposal and CVs.	Proof of team having knowledge and experience in the cardiovascular field, including a member professionally qualified in this field, as evidenced by the proposal and CVs.

Experience of team members specifically in the user of ultrasound for CVD examination. Study team includes member/s who are proficient and/or qualified in diagnostic ultrasound.	20	Team members have no experience in the medical ultrasound field.	Proof of team having knowledge and experience in the medical ultrasound field, as evidenced by the proposal and CVs.	Proof of team having knowledge and experience in the medical ultrasound field, including at least one member professionally qualified in this field, as evidenced by the proposal and CVs.
Ability of the team to recruit sufficient patient numbers within the project timescales. Proposal includes description of activities listed in the Invitation for Proposal section.	25	Proposal addresses none of the activities listed.	Proposal addresses at least 3 of the activities in detail.	Proposal addresses all of the activities in detail.
			- Clinical trial and protocol plan - Preliminary suggestions on clinical sites which may be suitable for this study - Description of data management plan - Regulatory and ethics submission plan - Other (documentation plan, general procedure followed, etc)	