Request for Proposals (RFP)

The provision of services for conducting Phase I clinical trials on human participants in South Africa for the CSIR

RFP No. 1047/14/11/2022

Date of Issue	31 October 2022	
Compulsory briefing session	N/A	
Closing Date and Time	14 November 2022 @ 16:30	
Submission of Tenders	tender@csir.co.za	
Enquiries	Strategic Procurement Unit	E-mail: tender@csir.co.za
CSIR business hours	08h00 – 16h30	
Category	Professional Services	

TABLE OF CONTENTS

SECTION A – TECHNICAL INFORMATION

1 INTRODUCTION

The Council for Scientific and Industrial Research (CSIR) is one of the leading scientific research and technology development organizations 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

The CSIR, through its Advanced Agriculture and Food and Next Generation Health Clusters, is implementing a project which seeks to add value to a South African indigenous plant species known as Siphonochilus aethiopicus through Phase I clinical studies to investigate safety on health individuals recruited for this activity. The CSIR has investigated toxicity of the Siphonochilus aethiopicus in vitro and in vivo studies, respectively. In both sets of experiments, the CSIR found that the plant species demonstrated no evidence of toxicity as shown by the data generated.

The CSIR further identified major chemical markers for quality purposes and has developed and optimised the extraction process technology during the research and development phase based on the plant species for the manufacture of safe and quality capsules, which can be implemented into the controlled manufacturing facility for manufacturing purposes. However, the CSIR does not have the clinical research capabilities to fully implement the project to completion. We are therefore requiring your clinical research services in support of the CSIR project.

3 INVITATION FOR PROPOSAL

Proposals are hereby invited for the supply of services to the CSIR, to undertake Phase I clinical studies based on the plant species according to the requirements of South African Health Products Regulatory Authority (SAHPRA) requirements to conduct clinical trials on human participants and according to the South African Good Clinical Practice Guidelines and the CSIR Research Ethics Policy (CSIR-MS-POL-R&D-048 2007), respectively. The service provider must be certified South African Clinical Research Organisation with vast experience in conducting clinical studies for respiratory infections or diseases such as asthma.

The type of services required:

- Protocol Development
- Follow up -Regulatory and Ethics
- Clinical Trial Conduct
- Analytical Lab
- Safety Labs
- Independent Monitor
- Data Management and Statistics
- Clinical Study Report

4 PROPOSAL SPECIFICATION

All proposals are to be submitted in a format specified in this enquiry (if applicable). However, tenderers are welcome to submit additional / alternative proposals over and above the originally specified format.

Proposal format, not limited to the following

- Company background
- Company demonstrated track record in conducting clinical trials in South Africa
- Knowledge and requirements for conducting clinical trails in South Africa
- Knowledge of respiratory infections including asthma
- Designing clinical trials
- Risks and mitigating factors
- Breakdown budget
- Project plan: milestones, deliverables, outcomes
- Partners (if any)

5 FUNCTIONAL EVALUATION CRITERIA

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

Selection criteria	Score
Qualifications for Lead Advisor	10%
At least 10 years of track record, previous experience and past performance in conducting clinical trials for a wide range of respiratory diseases or infections such as asthma	40%
Demonstrated knowledge and understanding of the South African regulatory affairs for conducting clinical trials	30%
Clinical trial design, monitoring and data management Technical expertise in clinical research, e.g., pharmacovigilance, biostatistics, etc	20%

5.2 Proposals with functionality / technical points of less than the pre-determined minimum overall percentage of 70 % and less than 50 % on any of the individual criteria 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; and
- Supplier does not demonstrated experience in conducting clinical trials in South Africa for respiratory infections/diseases such as asthma
- Supplier does not demonstrate the regulatory requirements to conduct clinical trials in South Africa
- Supplier that is going to outsource the clinical trial services from the third party
- Bidders that are listed on the NT database of restricted suppliers will not be considered.
- Bidders that are registered on the NT Register of Tender Defaulters will not be considered.
- Bidders that do not submit a fully completed and signed SBD 1 and SBD 4 Form will

not be considered

7 NATIONAL TREASURY CENTRAL SUPPLIER DATABASE (CSD) 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 no certificate can 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 electronically at tender@csir.co.za

9 TENDER PROGRAMME

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

- Issue of tender documents: 31 October 2022
- Compulsory briefing session / site inspection etc: N/A
- Last date for submission of queries: 09 November 2022
- Closing / submission Date: 14 November 2022
- Estimated contract duration (in months/years) <6 months

10 SUBMISSION OF PROPOSALS

10.1 All proposals are to be sealed. No open proposals will be accepted.

10.2 All proposals are to be clearly marked with the RFP number and the name of the tenderer on the outside of the main package. Proposals must consist of two parts, each of which is submitted in separate mail clearly marked:

PART 1: Technical Proposal: RFP No 1047/14/11/2022

PART 2: Pricing Proposal, B-BBEE and other Mandatory Documentation: RFP No 1047/14/11/2022

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

10.4 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 shall be submitted at the email address mentioned above no later than the closing date of**Monday, 14 November 2022** 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

All proposals will be evaluated by an evaluation team 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. If all tenders received are more than R50m, the proposal will be cancelled and re-issued.

Provide a valid copy of a B-BBEE Certificate or valid sworn affidavit. No B-BBEE status will equal to zero points. B-BBEE certificate must be issued by SANAS accredited agency or a valid sworn affidavit in line with DTI regulations. (RSA suppliers only).

B-BBEE Verification Agency B-BBEE Certificates can be verified on SANAS website on Verification Agency (B-BBEE) under Accredited Facilities (Quick Access Links): https://www.sanas.co.za/Pages/index.aspxto check validity of the B-BBEE Certificate.

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 1047/14/11/2022- The provision of services for conducting Phase I clinical trials in South Africa"** 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 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.

21.3 If a courier service company is being used for delivery of the proposal document, the RFP description must be endorsed on the delivery note/courier packaging to ensure that documents are delivered to the tender box, by the stipulated due date.

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 Give preference to locally manufactured goods;

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

26.6 Award this RFP as a whole or in part;

26.7 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 1047/14/11/2022

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 regards to 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

EVALUATION CRITERIA/SCORING SHEET

NO	CRITERIA	SCORING	WEIGHT
1.	**Qualifications for Lead Principal Investigator** Highest educational qualification obtained in: • Pharmaceutical Sciences • Clinical Sciences • Medical Technology	10 = PHD or higher 5 = Masters or higher 4= Honors degree or higher (NQF8); 4 = Degree (NQF7) 3 = National diploma (NQF6)	10%
2.	Years of experience, track record, previous experience and past performance in conducting clinical trials for a wide range of respiratory diseases or infections such as asthma.	10 = 10 years and more. 7 = more than 8 and up to 9 years 5 = more than 5 and up to 8 years 0 = 0 and up to 4 years	40%
3.	Demonstrated knowledge and understanding of the South African regulatory affairs for conducting clinical trials.	10 = Excellent (demonstrated at leastfour components and above) 7 = Good (demonstrated at least three components) 5 = Average (demonstrated at least two components) 1 = Below Average (demonstrated at least one components)	30%
4.	Years of experience in clinical trial design, monitoring and data management, technical expertise in clinical research, e.g., pharmacovigilance, biostatistics, etc.	10 = 10 years and more. 7= more than 7 and up to 9 years 5 = more than 5 and up to 6 years 0 = 0 and up to 4 years	20%
	Total		100
	Minimum threshold		70%