



Project funded under H2020-FTIPilot-2016

BreathSpec®

A rapid, non-invasive, cost-effective, analytical device for bacterial or viral infection diagnosis through ultra-high sensitivity breath analysis.



IMSPEX Diagnostics Ltd

Tender Ref: BSP001

August 2017

Invitation to Tender

Part One - Introductory Information for Suppliers

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1. Introductory Information

IMSPEX Diagnostics Ltd (IMSPEX) has a requirement to subcontract services for the delivery of a multi-centered trial consisting of 6 NHS locations. In total, 2,000 patients must be recruited for the diagnosis of bacterial or viral infection through breath analysis.

1.1 Procurement Procedure

As the consortium lead of the BreathSpec project under H2020-FTIPilot-2016, IMSPEX is undertaking this subcontracting call from Grant Agreement Number: 755667, IMSPEX advises all interested parties that it is not currently a contracting authority for the purposes of the Public Contracts Regulations 2015 and is conducting this subcontracting call outside of the Public Contracts Regulations (as amended). Any contract arising from this procurement exercise will itself not be subject to the Public Contracts Regulations 2015 and IMSPEX advises all interested parties that it will not be applying the requirements under the Remedies Directive, as incorporated into the Public Contracts Regulations 2015.

Suppliers are invited to submit their bids based upon the information contained within the complete Invitation to Tender document set.

For the purposes of this document “Supplier” means any potential provider of goods, services or works, submitting a response to this procurement procedure or actual supplier contracted by IMSPEX as a result of this procedure.

1.2 Clarifications and Questions

This tender notice is being published on <http://globaltenders.com/>. Should Suppliers experience difficulties at any time in accessing or using the site they are invited to contact the Tender Manager (details below).

Any correspondence from Suppliers relating to the Tender, whether relating to technical, commercial or other issues must be communicated using the information@imspe.com email address. Failure to do so may result in the queries being excluded from the tender procedure.

Any additional information deemed relevant by IMSPEX or answers to queries that would be of interest to all participating parties, will be communicated equally to all registered suppliers via the email by means a tracked Question and Answer document.

The Tender Manager for this tender is:

Lisa Davies, Finance Manager
IMSPEX Diagnostics Ltd
Ty Menter, Abercynon, CF45 4SN Tel: 01443 740217

1.3 Time table

The key timescales for the project are outlined below (may be subject to change):

Process Stage	Timescale
Issue invitation to Tender	4 th September 2017
Deadline for Tender Submissions	Noon 14 th September 2017
Tender Evaluation	19 th September 2017
Contract Award	24 th September 2017

2. Tender Submissions

IMSPEX requests that interested Suppliers provide and submit a full proposal for the provision of the Goods and/or Services as specified in the attached Invitation to Tender (ITT) documentation. The ITT consists of the following documentation:

- Part One - This Introductory Information document
- Part Two - The Goods and Services Requirement document
- Part Three - The Terms and Conditions– will form part of the contract to be signed at tender award and will be uploaded through the tendering process

Should Suppliers be unable to access any of the above documents, or if Suppliers are unclear as to what the documents refer to, Suppliers are invited to contact the Tender Manager.

All interested Suppliers must provide their submissions to IMSPEX.

The closing date for this Invitation to Tender is 14th September 2017. Your responses must be received electronically by IMSPEX no later than noon 12:00 hrs GMT on this date.

Your response shall include:

- Responses to Goods and Services Requirement:
 - Tender Response (Part 2, section 8)
 - Technical Non-Compliance Statement, if required (Part 2, section 10)

You must submit:

- one electronic copy of the entire tender response via the information@impsex.com email address (please clearly label the title of all electronic files uploaded).

3. Important Information for Suppliers

3.1 Amendments to Submitted Tenders

If the Supplier finds it necessary to make any amendments subsequent to the submission of their tender response, the amendment should be submitted in the same quantities and formats as detailed above for the tender submission, by using the information@imspex.com email address.

Amendments may only be submitted prior to the closing date of the tender procedure.

3.2 Acceptance of Submissions

Bids against the ITT will only be accepted from suppliers who have requested and fully completed the ITT as laid down in the Part Two - Goods and/or Services Requirement document.

The acknowledgement of receipt of any submitted tender shall not constitute any actual or implied agreement between IMSPEX and the Supplier. Nor does IMSPEX undertake to accept the lowest, or part, or all, of any Tender. IMSPEX, at its sole discretion, reserves the right to accept any tender(s), or any part, or all of any tender(s) unless expressly stipulated otherwise in the tender offer.

IMSPEX reserves the right to seek clarification from suppliers if required, upon receipt of tender submissions.

IMSPEX reserves the right to reject or disqualify a Bidder:

- Where the Tender is submitted late, is completed incorrectly, or is incomplete.
- Who has failed to meet mandatory evaluation criteria or on grounds relating to exclusion criteria.
- Who is guilty of serious misrepresentation in relation to its application and/or the process or where there is a change in identity, control, financial standing or other factor impacting on the selection and/or evaluation process affecting the Bidder.

3.3 Alterations

None of the documents contained in the Invitation to Tender Document Set may be altered by the Supplier. Any modification considered necessary by the Supplier should be detailed in a separate letter accompanying the tender response.

3.4 Incomplete Tender

Tender submissions may not be considered if the complete information called for is not given at the time of tendering.

3.5 Validity of tender submissions

Tenders shall be valid for a minimum of 6 (six) calendar months from the closing date for the submission of tenders.

3.6 Contract Term

The contract shall be for an initial period of x2 year with an option to extend for up to a further 1 years.

3.7 Sub-contractors

The names and addresses of any sub-contractors the Supplier proposes to employ must be provided with the tender. The Supplier should also give details of the services to be

delivered by the sub-contractor who must comply in totality with the contract between IMSPEX and the Supplier.

3.8 Submission of Multiple Options

If the Supplier wishes to offer more than one solution to the goods or services requirement, this should be contained within the response to Part Two – Goods and / or Services Requirement document, with the options clearly marked. All requested information should be detailed clearly for each option offered.

3.9 Confidentiality

The Supplier (whether their submission is accepted or not) and all other recipients of the ITT document set (whether they submit a tender or not) should treat the details of the specification and the documents attached hereto as private and confidential.

Tender submissions and subsequent clarifications which take part throughout the tender procedure will be treated as confidential by IMSPEX and will not be disclosed to third parties except on a need-to-know basis or as may be required by statutory obligation. Further, it is understood by both parties that submitted responses become the property of IMSPEX and that the Supplier will be bound by the information disclosed in their response for 6 months after the submission date.

3.10 Tender Cancellation

IMSPEX reserves the right to cancel the tender process at any point. IMSPEX is not liable for any costs resulting from any cancellation of this tender process nor for any other costs incurred by those tendering for this Contract.

3.11 Liability

All information contained within this document has been submitted to allow all Suppliers to construct, without bias, their tender response. It shall be the responsibility of the Supplier to ascertain the accuracy of the details as IMSPEX provides all details in good faith and will take no responsibility for variations to the descriptions given.

It is the Supplier's sole responsibility to ascertain the accuracy of the published information from the tendering authority

Suppliers will **not** be entitled to claim from IMSPEX any costs or expenses incurred in responding to this invitation to tender. Prospective Suppliers may be required to demonstrate their submitted tender proposal. Suppliers will be expected to bear their own costs of such demonstrations.

Suppliers must ensure that they have all the information required for the preparation of their tenders and satisfy themselves of the correct interpretation of terminology used in these documents. Suppliers must also ensure that they are fully conversant with the nature and extent of the obligations to be accepted by them if their tender is accepted.

3.12 Language

English shall be the official language for all means of communications between Suppliers and IMSPEX on all matters relating to this ITT.

4. Background Information

4.1 IMSPEX Diagnostics Ltd

IMSPEX Diagnostics Ltd was founded in 2011 as a spinoff of the University of Glamorgan, in South Wales, with the aim to develop markets and applications for Ion Mobility Spectrometry Technology in clinical research, clinical diagnostics, food and environmental analysis.

Through its acquisition of GAS GmbH in January 2013, IMSPEX secured access to World leading IMS technology and to a range of equipment which is market ready for customer applications. Over 2013 the group formed by IMSPEX and GAS has established relationships and provided instruments to a range of blue chip companies, research hospitals and research centres and universities.

4.2 BreathSpec Project Summary

The world faces a growing epidemic of antimicrobial resistance (AMR); however, only two new classes of antibiotics have been brought to the market in the last 30 years. The discovery and development of new antibiotics is essential to maintain medical advances but poses significant scientific, clinical, and financial challenges, particularly for antibiotics active against Gram-negative bacteria (such as E. coli).

Such bacteria have effective barriers against drugs, making treatment difficult, resistance likely and development costs and risks high. In addition, any new antibiotics brought to the market would likely be used cautiously to delay the development of resistance, adding an additional financial challenge in recouping the development costs. The O'Neill Report on AMR identifies diagnostics as critical to the battle against antibiotic resistance.

This project, BreathSpec, proposes a viable solution to the global problem of AMR through the final developmental stages of an existing diagnostic device, which will allow a rapid, binary decision to be made on the need for antibiotic treatment, and which with suitable optimisation will allow further differentiation and stratification to take place. The project includes technical developments to optimise its function, data acquisition for the development of the decision making analytical function and clinical validation.

It addresses these issues by producing reliable identification and quantification of key signature volatiles present in exhaled breath. It provides a non-invasive method for monitoring the volatile organic compounds present in an individual's exhaled breath and has long been recognised as having significant utility as a clinical test that can be used for early disease detection and monitoring, and potentially to diagnose specific bacterial infections for better, more targeted use of existing antibiotics.