Department for Environment Food & Rural Affairs

www.gov.uk/defra

Invitation to Tender

(Open Procedure – PCR2015)

Tender for GB field trials of CattleBCG Vaccine and companion DIVA (DST-F) testing

Tender Reference:24389

Important Notice

All references in this ITT to the Authority include, where appropriate and unless the context otherwise requires, references to the Authority's predecessors and successor(s).

The Information has been prepared to assist interested parties in deciding whether or not to submit a Response in relation to the procurement. It does not purport to be all-inclusive or to contain all of the information that a Tenderer may require. Any descriptions of existing and proposed contractual arrangements are of a general nature only. Where the Information describes any contractual arrangements which are not yet in force, those arrangements are subject to change. Any reference to a contract or other document is qualified in full by reference to the entire terms of the contract or document to which reference is made.

The issue of this ITT in no way commits the Authority to award the contract to any person or party. The Authority reserves the right to terminate the competition, to award a contract without prior notice, to change the basis, the procedures and the timescales set out or referred to in this ITT, or to reject any or all Responses and to terminate discussions with any or all Tenderers at any time. Nothing in this ITT should be interpreted as a commitment by the Authority to award a Contract to a Tenderer.

The Authority does not make any representation or warranty (express or implied) as to the accuracy, reasonableness or completeness of the Information. All such persons or entities expressly disclaim any and all liability (other than in respect of fraudulent misrepresentation) based on or relating to any such information or representations or warranties (express or implied) contained in, or errors or omissions from, this document or based on or relating to the recipient's use, or the use by any of its subsidiaries or the respective representatives of any of them, in the course of its or their evaluation of the service or any other decision. In the absence of express written warranties or representations as referred to below, the Information shall not form the basis of any agreements or arrangements entered into in connection with this procurement.

The Information has been provided in good faith and all reasonable endeavours have been made, and will be made, to inform you of the requirements of the Authority. However, the Information does not purport to be comprehensive or to have been independently verified. You should form your own conclusions about the methods and resources needed to meet these requirements. In particular, neither the Authority nor any of its advisers accept responsibility for representations, writings, negotiations or understandings in connection with this procurement made by the Authority (whether directly or by its agents or representatives), except in respect of any fraudulent misrepresentation made by it. Tenderers are expected to carry out their own checks for verification.

The only information which will have any legal effect and / or upon which any person may rely will be such information (if any) as has been specifically and expressly represented and / or warranted in the Contract or other relevant agreements entered into at the same time as the Contract is entered into or becomes unconditional.

Subject always to the provisions of the preceding paragraph, Tenderers considering entering a contractual relationship with the Authority should make their own investigations and enquiries as to the Authority's requirements beforehand. The subject matter of this ITT shall only have any contractual effect when it is incorporated into the expressed terms of an executed contract.

The issue of this ITT is not to be construed as a commitment by the Authority to enter into a contract as a result of this procurement process. Any expenditure, work or effort undertaken prior to the execution of a Contract is accordingly a matter solely for the commercial judgement of the Tenderer. The Authority reserves the right to withdraw from the procurement at any time or to re-invite Responses on the same or any alternative basis.

Nothing in this ITT shall constitute legal, financial or tax advice. This ITT is not a recommendation by the Authority, nor any other person, to bid for, enter into or agree to enter into any contract in connection with this procurement, nor to acquire shares in the capital of any company that is to carry out any part of the service or in any parent company of that company. In considering any investment in the shares of any company or in bidding for the award of the service, each Tenderer, potential contractor, funder and investor should make its own independent assessment and seek its own professional financial, taxation, insurance and legal advice and conduct its own investigations into the opportunity of being awarded a contract in relation to this procurement and of the legal, financial, taxation and other consequences of entering into contractual arrangements in connection with this the procurement.

This ITT and the Information is confidential.

This ITT is subject to copyright. Neither this ITT, nor the Information, nor any other information supplied in connection with it, may, except with the prior written consent of the Authority, be published, reproduced, copied, distributed or disclosed to any person, nor used for any purpose other than consideration by each Tenderer of whether or not to submit a Response.

The Authority reserves the right at any time to issue further supplementary instructions and updates and amendments to the instructions and Information contained in this ITT as it shall in its absolute discretion think fit.

The Authority will not be responsible for the costs or expenses of any Tenderer in relation to any matter referred to in this ITT howsoever incurred, including the evaluation of the service opportunity, the award, or any proposal for the award of the contract or negotiation of the associated contractual agreements.

Each Tenderer's acceptance of delivery of this ITT constitutes its agreement to and acceptance of the terms set out in this Important Notice.

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SECTION 1: RESPONSE PARTICULARS

GLOSSARY

Unless the context otherwise requires, the following words and expressions used within this Invitation to Tender (except Appendix B: Authority's Conditions of Contract) shall have the following meanings (to be interpreted in the singular or plural as the context requires):

TERM	MEANING
"Authority"	means the Department for Environment, Food and Rural Affairs acting as part of the Crown.
"Bravo"	means the e-Tendering system used by the Authority for conducting this procurement, which can be found at http://defra.bravosolution.co.uk
"CRO"	means Contract Research Organisation
"Contract"	means the contract (set out in Appendix B) to be entered into by the Authority and the successful Tenderer.
"EIR"	means the Environmental Information Regulations 2004 (as amended) together with any guidance and/or codes of practice issued by the Information Commissioner or any Government Department in relation to those Regulations.
"FOIA"	means the Freedom of Information Act 2000 (as amended) and any subordinate legislation made under that Act together with any guidance and/or codes of practice issued by the Information Commissioner or any Government Department in relation to that legislation.
"Information"	means the information contained in the ITT or sent with it, and any information which has been made available to the Tenderer by the Authority, its employees, agents or advisers in connection with the GB field trials of CattleBCG Vaccine and companion DIVA (DST-F) testing procurement.
"the ITT"	means this invitation to tender document and all related documents published by the Authority and made available to Tenderers.
"Pricing Schedule"	means the form accessed via Bravo in which Tenderers are required to submit their pricing information as part of a Tender.
"Regulations"	means the Public Contracts Regulations 2015.
"Response"	means the information submitted in response to the ITT via the online response forms on Bravo including the Tenderer's formal Tender.
"Specification of Requirements"	means the Authority's requirements set out in Section 3 of the ITT.
"Tender"	means the formal offer to provide the goods or services described in section 1.1 of Part 1 of the ITT and comprising the responses to the questions in Bravo and the Pricing Schedule.
"Tenderer"	means anyone responding to the ITT and, where the context requires, includes a potential tenderer.
"Timetable"	means the procurement timetable set out in Part 2 of Section 1 of the ITT.

References to a "Section" and to an "Appendix" are references to a section and to an appendix in the ITT.

Reference to a statute or statutory provision is a reference to such statute or statutory provision as amended or re-enacted. A reference to a statute or statutory provision includes any subordinate legislation made under that statute or statutory provision, as amended or re-enacted.

PART 1: GENERAL

1.1 The Authority wishes to appoint a supplier to act as a Contract Research Organisation (CRO) to run GB field trials of CattleBCG Vaccine and companion DIVA (DST-F) testing. The CRO will be required to recruit herds, run field trials and report outcomes of the final protocol agreed with APHA. The field trials must comply with GCP(vet) therefore CRO will be expected to have their own internal QA/auditing systems in place and will also be subject to regular audit by APHA quality services and an external auditor.

1.2 This procurement is being carried out in accordance with the open procedure as set out in the Regulations.

1.3 The Authority is using Bravo for this procurement which means the ITT and the forms for submitting a Response are only available in electronic form. It can be accessed via your web browser http://defra.bravosolution.co.uk.

1.4 Tenderers are required to submit their Response in accordance with the instructions set out in Bravo and the ITT.

1.5 The information contained in the ITT is designed to ensure that all Responses are given equal and fair consideration. It is important that Tenderers provide all the information asked for in the format and order specified so that the Authority can make an informed decision.

1.6 Tenderers should read the ITT carefully before submitting a Response. It sets out:

- the Timetable and process for the procurement;
- sufficient information to allow Tenderers to submit a compliant Response;
- information regarding the award criteria and evaluation criteria which will be used to assess Responses; and
- the administrative arrangements for the receipt of Responses.

1.7 Tenderers are responsible for ensuring that they understand the requirements for this procurement. If any information is unclear or if a Tenderer considers that insufficient information has been provided, it should raise a query via the clarification process described in clause 3.14.

1.8 Tenderers are responsible for ensuring that they have submitted a complete and accurate Response and that prices quoted are arithmetically correct for the units stated.

1.9 Failure to comply with the instructions set out in the ITT or the provision of false, inaccurate or misleading information, may result in the Tenderer's exclusion from this procurement.

1.10 If there is any conflict between the information set out in the ITT and the information displayed in Bravo, the information set out in the ITT shall take precedence over the information displayed in Bravo.

1.11 The copyright in the ITT is vested in the Crown and may not be reproduced, copied or stored in any medium without the prior written consent of the Authority. The ITT, and any document issued as a supplement to it, are and shall remain the property of the Crown and must be returned upon demand.

PART 2: PROPOSED TIMETABLE AND ADMINISTRATIVE ARRANGEMENTS

2.1 The Timetable below is subject to change by the Authority and Tenderers will be informed accordingly.

Issue Notice in the Official Journal of the European Union and ITT		11/09/2020
Deadline for clarification questions from Tenderers	Date	06/10/2020
	Time	17:00
Deadline for Responses	Date	13/10/2020
	Time	17:00
Evaluation of Responses	Start	14/10/2020
	End	30/10/2020
Contract award notification		6/11/2020
Mandatory standstill period	Start	06/11/2020
	End	16/11/2020
Contract award		17/11/2020
Contract start date		07/12/2020
Service commencement date		01/01/2021
Duration of Contract		3 years 3 months
Extension Period		For a further 12 months

PART 3: COMPLETION OF RESPONSE

3.1 By submitting a Response, Tenderers agree:

- to be bound by the terms of the ITT; and
- that if the Authority accepts the Tender in writing, the Tenderer will execute the Contract in the form set out in Appendix B or in such amended form as may be agreed in writing by the Authority.

3.2 The Authority may terminate or amend the procurement or the ITT at any time. Any such termination or amendment will be notified in writing to all Tenderers. In order to give Tenderers reasonable time in which to take an amendment into account in preparing their Responses, the Authority may, at its discretion, extend the deadline for the submission of Responses and/or any other stages of the procurement.

3.3 Unless otherwise stated in the ITT or in writing by the Authority, all communications from Tenderers (including Tenderers' sub-contractors, consortium members, consultants and advisers) during the procurement must be made using Bravo. The Authority will not respond to communications made by other means and

Tenderers should not rely on communications from the Authority unless they are made through Bravo.

Submission of Responses

3.4 Tenderers must complete all parts of the response form in Bravo in accordance with the instructions therein.

3.5 Tenderers should print off the Form of Tender which must be signed by an authorised signatory. The signed Form of Tender must be uploaded and submitted via Bravo as part of a Response in accordance with the instructions in Bravo.

3.6 The Response and any documents accompanying it must be in English.

3.7 Prices must be submitted in £ Sterling, exclusive of VAT.

3.8 Responses will be checked for completeness and compliance with the requirements of the ITT and only compliant Responses will be evaluated.

3.9 Tenderers must be explicit and comprehensive in their Response as this will be the single source of information used to score and rank Responses. The Authority will take into account only information which is specifically asked for in the ITT.

3.10 Where a length of response is stipulated, for example, a word count limit, only the information within the set limit will be evaluated.

3.11 Failure to provide the information required or supply documents referred to in the Response within the deadline for Responses may result in rejection of the Response.

3.12 Tenderers should avoid reference to general marketing or promotional information/material (except where this is specifically required by the relevant question). General marketing or promotional brochures may not be accepted where these are not deemed to be specifically relevant to the question.

3.13 Different persons may be responsible for evaluating different responses to questions in a Response. Therefore, Tenderers should not cross-refer to answers given elsewhere in a Response but should answer each question so that it acts as a stand-alone response. This may mean Tenderers need to repeat certain information in responses to different questions if this is required by those questions.

Clarifications sought by Tenderers

3.14 Any request for clarification regarding the ITT should be submitted at the earliest opportunity via Bravo and in any event no later than the deadline for clarifications set out in the Timetable. The Authority shall be under no obligation to respond to queries raised after the clarification deadline.

3.15 The Authority will respond to all reasonable clarifications as soon as possible but cannot guarantee a minimum response time. The Authority will publish all clarifications and its responses to all Tenderers on Bravo other than in exceptional circumstances.

3.16 If a Tenderer believes that a request for clarification is commercially sensitive or that publishing the same together with the Authority's response as set out above would reveal confidential information, disclosure of which would be detrimental to the Tenderer, it

should clearly state this when submitting the clarification request. However, if the Authority considers either that:

- the clarification and response is not commercially sensitive; and/or
- all Tenderers may benefit from its disclosure

the Authority will notify the Tenderer of this (via Bravo), and the Tenderer will have an opportunity to withdraw the request for clarification. If the request for clarification is not withdrawn within 48 hours of the Authority's notification, Authority may publish the clarification request and its response to all Tenderers and the Authority shall not be liable to the Tenderer for any consequences of such publication.

3.17 The Authority may not respond to a request for clarification or publish such a request where the Authority considers that the response may prejudice the Authority's commercial interests. In such circumstances, the Authority will inform the Tenderer of its view.

Changes to Responses

3.18 Tenderers may modify their Responses prior to the deadline for Responses. No Responses may be modified after the deadline for Responses.

3.19 Tenderers may withdraw their Responses at any time by submitting a notice via Bravo. Unless withdrawn, Tenders shall remain valid and open to acceptance by the Authority for 120 days from the deadline for Responses.

Receipt of Responses

3.20 Responses must be uploaded onto Bravo no later than the time and date set out in the Timetable as the deadline for Responses. The Authority will not consider Responses received after the deadline. The Authority may, however, at its own discretion, extend the deadline and in such circumstances the Authority will notify all Tenderers of the change.

3.21 If a Tenderer experiences problems when uploading its Response, it should contact the Bravo helpdesk for assistance and also inform the Authority.

Acceptance of Tenders

3.22 By issuing the ITT, communicating with a Tenderer or a Tenderer's representative or agents or any other communication in respect of this procurement, the Authority shall not be bound to accept any Tender or award the Contract.

Costs of Responding

3.23 Tenderers shall bear all their own costs and expenses incurred in the preparation and submission of their Responses, site visits and presentations and the Authority will in no case be responsible or liable for those costs, regardless of the outcome of the procurement in relation to individual Responses, even if the procurement is terminated or amended by the Authority.

Clarifications sought by the Authority

3.24 The Authority reserves the right (but is not obliged) to seek clarification of any aspect of a Response and/or provide additional information during the evaluation phase in order to

carry out a fair evaluation. Failure to respond in a timely manner and/or to provide an adequate response to such a request may result in the Response being rejected.

3.25 Tenderers must give the names of two people in their organisation who can answer the Authority's clarification questions. The Authority will not contact any other persons. Tenderers must notify the Authority promptly of any changes.

Confidentiality of the ITT and related documents

3.26 The contents of the ITT and of any other documents or information published or provided by the Authority in respect of this procurement are provided on condition that they remain the property of the Authority, are kept confidential (save in so far as they are already in the public domain) and that the Tenderer shall take all necessary precautions to ensure that they remain confidential and are not disclosed, save as described below.

3.27 Tenderers may disclose information relating to the procurement to their advisers and sub-contractors if:

- disclosure is for the purpose of enabling a Response to be submitted and the recipient of the information undertakes in writing to keep it confidential on the same terms as the Tenderer;
- the Authority gives prior consent in writing to the disclosure;
- the disclosure is made for the purpose of obtaining legal advice in relation to the procurement; or
- the Tenderer is legally required to disclose the information.

3.28 Tenderers shall not undertake any publicity activities in relation to the ITT without the prior written agreement of the Authority, including agreement on the format and content of any publicity. For example, no statements may be made to the media regarding the nature of any Response, its contents or any proposals relating to it without the prior written consent of the Authority.

3.29 All Central Government Departments, their Executive Agencies and Non Departmental Public Bodies are subject to control and reporting within Government. In particular, they report to the Cabinet Office and HM Treasury for all expenditure. Further the Cabinet Office has a cross-Government role delivering overall Government policy on public procurement, including ensuring value for money and related aspects of good procurement practice.

3.30 For these purposes, the Authority may disclose within Government any of the Tenderer's documents and information (including any that the Tenderer considers to be confidential and/or commercially sensitive) provided in its Response. The information will not be disclosed outside Government during the procurement. Tenderers consent to these terms as part of the procurement.

Confidentiality: References and third party evaluators:

3.31 When providing details of contracts as part of a Response, Tenderers agree to waive any contractual or other confidentiality rights and obligations associated with these contracts.

3.32 The Authority reserves the right to contact any named customer contact given as a reference or otherwise referred to as part of a Response. The named customer contact does not owe the Authority any duty of care or have any legal liability, except for any deceitful or maliciously false statements of fact.

3.33 Subject to clauses 3.34, 3.35 to 3.39 below, the Authority will keep confidential and will not disclose to any third parties any information obtained from a named customer contact, other than to the Cabinet Office and/or contracting authorities defined by the Regulations.

3.34 The Authority may use third parties in the course of its evaluation of Responses. The Authority may disclose information contained therein to such third parties for the purposes of the Authority's evaluation of Responses in accordance with the ITT. Tenderers acknowledge that this right shall be in addition to the provisions of clauses 3.29, 3.30 and 3.35 to 3.39.

Freedom of Information and Environmental Information Regulations

3.35 In accordance with the obligations placed on public authorities by the FOIA and the EIR, which provide a public right of access to information held by public bodies, the Authority may be required to disclose information submitted to it by a Tenderer.

3.36 If a Tenderer considers any information which it supplies to the Authority to be commercially sensitive or of a confidential nature, it should complete the schedule of Commercially Sensitive Information set out in Bravo and:

- clearly identify any information provided as confidential or commercially sensitive;
- explain the potential implications of disclosure of such information; and
- provide an estimate of the period of time during which the Tenderer believes that such information will remain confidential or commercially sensitive.

3.37 If a Tenderer identifies information as being confidential and/or commercially sensitive, the Authority will endeavour to maintain the confidentiality of that information, and will, where practicable, consult with the Tenderer before information relating to that Tenderer is disclosed pursuant to a request for information under FOIA and/or EIR to establish whether an exemption from disclosure may apply.

3.38 However, even where information is identified by a Tenderer as being confidential or commercially sensitive, Tenderers acknowledge that there may be circumstances in which the Authority may be required to disclose such information in accordance with the FOIA or the EIR (in addition to any other transparency obligations as set out in clauses 3.29 and 3.30). In particular, the Authority is required to form an independent judgment concerning whether the information is exempt from disclosure under the FOIA or the EIR including whether the public interest favours disclosure or not. Accordingly, the Authority does not guarantee that any information marked "confidential" or "commercially sensitive" will not be disclosed and accepts no liability for any loss or prejudice caused by the disclosure of information.

3.39 If a Tenderer receives a request for information relating to this procurement under the FOIA or the EIR during the procurement, this should be immediately passed on to the Authority and the Tenderer should not respond to the request without first consulting the Authority.

Disclaimers

3.40 Whilst the information in the ITT and any supporting information referred to herein or provided to Tenderers by the Authority have been prepared in good faith the Authority does not warrant that this information is comprehensive or that it has been independently verified.

3.41 Neither the Authority nor its respective advisors, directors, officers, members, partners, employees, other staff or agents:

- makes any representation or warranty (express or implied) as to the accuracy, reasonableness or completeness of the ITT or of any other written or oral communication transmitted (or otherwise made available) to any Tenderer;

- accepts any liability for the information contained in the ITT or in any other written or oral communication (including any communications via Bravo) transmitted (or otherwise made available) to any Tenderer, or for the fairness, accuracy or completeness of that information; or

- shall be liable for any loss or damage (other than in respect of fraudulent misrepresentation or any other liability which cannot lawfully be excluded) arising as a result of reliance on such information or any subsequent communication.

Any party considering entering into contractual relationships with the Authority following receipt of the ITT should make its own investigations and independent assessment of the Authority and its requirements for the goods and/or services and should seek its own professional financial and legal advice.

3.42 Neither the issue of the ITT nor any of the information presented in it should be regarded as a commitment or representation on the part of the Authority to enter into a contractual arrangement. Nothing in the ITT or in any other communication made between the Authority and any other party should be interpreted as constituting a contract, agreement or representation between the Authority and any other party (save for a formal award of contract made in writing) or as constituting a contract, agreement or representation that a contract shall be offered.

Canvassing

3.43 Any Tenderer which directly or indirectly canvasses any officer, member, employee, or agent of the Authority or its members or any other relevant body or any of its officers or members concerning the Contract or this procurement or which directly or indirectly obtains or attempts to obtain information from any such officer, member, employee or agent concerning any other Tenderer or Response will be excluded from this procurement and its Response rejected.

3.44 The Tenderer shall not make contact with any employee, agent or consultant of the Authority which is in any way connected with this procurement during this procurement, unless instructed otherwise by the Authority.

Conflicts of Interest

3.45 The concept of a conflict of interest includes any situation where relevant staff members of the Authority, involved in this procurement have, directly or indirectly, a financial, economic or other personal interest which might be perceived to compromise their impartiality and independence in the context of the procurement procedure and/or affect the integrity of the contract award.

3.46 Where the Tenderer is aware of any circumstances giving rise to a conflict of interest or has any indication that a conflict of interest exists or may arise you should inform the Authority of this as soon as possible (whether before or after they have submitted a Response). Tenderers should remain alert to the possibility of conflicts of interest arising at all stages of the procurement and should update the Authority if any new circumstances

or information arises, or there are any changes to information already provided to the Authority. Failure to do so, and/or to properly manage any conflicts of interest may result in a Response being rejected.

3.47 Provided that it has been carried out in a transparent manner, routine pre-market engagement carried out by the Authority should not represent a conflict of interest for the Tenderer.

Changes to a Tenderer's Circumstances

3.48 The Authority may:

- reject a Response if there is a subsequent change of identity, control, financial standing or other factor which may affect the Authority's evaluation of the Response;
- revisit information contained in a Response at any time to take account of subsequent changes to a Tenderer's circumstances; or
- at any point during the procurement require a Tenderer to certify there has been no material change to information submitted in its Response and in the absence of such certificate, reject the Response.

Sub-Contracting

3.49 Where the Tenderer proposes to use one or more sub-contractors to deliver some or all of the contract requirements, all information requested in the Response should be given in respect of the prime contractor and a separate Appendix should be used to provide details of the proposed bidding model that includes:

- members of the supply chain;
- the percentage of work being delivered by each sub-contractor; and
- the key contract deliverables each sub-contractor will be responsible for.

3.50 The Authority recognises that arrangements in relation to sub-contracting may be subject to future change, and may not be finalised until a later date. However, Tenderers should be aware that where information provided to the Authority indicates that sub-contractors are to play a significant role in delivering key contract requirements, any changes to those sub-contracting arrangements may affect the ability of the Tenderer to proceed with the procurement process or to provide the supplies and/or services required. If the proposed supply chain changes at any time after submission of its Response, the Tenderer should inform the Authority immediately via Bravo. The Authority reserves the right to deselect the Tenderer prior to any award of contract, based on an assessment of the updated information.

Consortia

3.51 If the Tenderer completing the Response is doing so as part of a proposed consortium, the following information must be provided;

- names of all consortium members;

- the lead member of the consortium who will be contractually responsible for delivery of the contract (if a separate legal entity is not being created); and

- if the consortium is not proposing to form a legal entity, full details of proposed arrangements within a separate Appendix.

3.52 Please note that the Authority may require the consortium to assume a specific legal form if awarded the contract, to the extent that a specific legal form is deemed by the authority as being necessary for the satisfactory performance of the contract.

3.53 All members of the consortium will be required to provide the information required in the Response as part of a single composite response to the Authority i.e. each member of the consortium is required to complete the form.

3.54 If the Tenderer proposes to create a separate legal entity the Tenderer should provide details of the actual or proposed percentage shareholding of the constituent members within the new legal entity in a separate appendix. If the Tenderer does not propose to create a separate corporate entity it should set out in a separate annexe full details of its alternative arrangements.

3.55 Tenderers should note, however, that the Authority may require a successful consortium to form a separate corporate entity in accordance with regulation 19(6) of the Regulations.

3.56 The Authority recognises that arrangements in relation to a consortium bid may be subject to future change. Tenderers should therefore respond on the basis of the arrangements as currently envisaged. Tenderers are reminded that the Authority must be immediately notified via Bravo of any changes, or proposed changes, in relation to the bidding model so that a further assessment can be carried out by applying the selection criteria to the new information provided. The Authority may deselect the Tenderer prior to any award of contract, based on an assessment of the updated information.

Pricing

3.57 As stated above, prices must be submitted in £ Sterling, exclusive of VAT.

3.58 The Contract is to be awarded as a fixed price, which will be paid according to the deliverables stated in the Specification of Requirements set out in Section 3.

3.59 The Pricing Schedule sets out the minimum level of pricing information required for the Tender. The Authority may request a detailed breakdown of any pricing submitted as part of a Tender.

Notification of Award and Standstill

3.60 The Authority will notify successful and unsuccessful Tenderers in accordance with the Regulations. A ten day standstill period will take effect in accordance with regulation 87 of the Regulations before the Authority enters into the Contract.

3.61 Following a decision to award the Contract, the Authority will provide reasons for its decision in an award notification letter to all unsuccessful Tenderers.

Lots

3.62 This procurement is not divided into lots because of the specific areas identified to carry out the testing

3.63 Tenderers must make clear which Lots are bidding for. Each Lot will be evaluated separately in accordance with the details set out in the evaluation model (Section 2).

3.64 The Authority intends to award a Contract to the most economically advantageous tender (in accordance with the evaluation model) for each Lot

PART 4: GOVERNMENT POLICY IN RELATION TO TRANSPARENCY

4.1 Tenderers should be aware that the Government has set out the need for greater transparency in public sector procurement and that if they are awarded a Contract, the tender documents and Contract will be published on the Contracts Finder website: www.gov.uk/contracts-finder.

In some circumstances, limited redactions may be made to some contracts before they are published.

PART 5: ARMED FORCES COVENANT

5.1 The Armed Forces Covenant is a public sector pledge from Government, businesses, charities and organisations to demonstrate their support for the armed forces community. The Covenant was brought in under the Armed Forces Act 2011 to recognise that the whole nation has a moral obligation to redress the disadvantages the armed forces community face in comparison to other citizens, and recognise sacrifices made.

5.2 The Covenant's 2 principles are that:

- the armed forces community should not face disadvantages when compared to other citizens in the provision of public and commercial services; and
- special consideration is appropriate in some cases, especially for those who have given most such as the injured and the bereaved.

The Authority encourages all Tenderers, and their suppliers, to sign the Corporate Covenant, declaring their support for the Armed Forces community by displaying the values and behaviours set out therein.

5.3 Guidance on the various ways you can demonstrate your support through the Armed Forces Corporate Covenant is provided in Appendix E.

5.4 If you wish to register your support you can provide a point of contact for your company on this issue to the Armed Forces Covenant Team at the address below, so that the MOD can alert you to any events or initiatives in which you may wish to participate. The Covenant Team can also provide any information you require in addition to that included on the website.

Email address: covenant-mailbox@mod.uk
Address: Armed Forces Covenant Team
Zone D, 6th Floor, Ministry of Defence,
Main Building, Whitehall, London, SW1A 2HB

5.5 Paragraphs 5.1 – 5.4 above are not a condition of working with the Authority now or in the future, nor will this issue form any part of the tender evaluation, contract award procedure

or any resulting contract. However, the Authority very much hopes you will want to provide your support.

SECTION 2: EVALUATION:

Evaluation of Responses will comprise the stages set out in the table below. More information on the specific evaluation criteria for specific sections of a Response are detailed in the relevant question as set out on Bravo.

Stage	Section Reference	Evaluation Criteria	Question Scoring/ Weighting (%)
Stage 1	Form of Tender	This stage is not scored but if you do not upload a complete, signed and dated Form of Tender in accordance with the instructions in Bravo, your Response will be rejected as non-compliant.	Pass/Fail
Stage 2	Selection Stage:	This stage is designed to select those Tenderers who are suitable to deliver the Authority's requirements and will be evaluated in accordance with the criteria set out in Sections 1 to 7 of the response form in Bravo and Part 1 of this Section 2 below (in respect of economic and financial standing and technical and professional ability). Failure to meet the stated selection criteria will result in a Response being rejected at this stage and no further assessment of the remainder of the Response (including the Tender) pursuant to the remaining stages below will be undertaken by the Authority.	Pass/Fail E01- Health and Safety E02- Biosecurity Policy E03- Sustainability E04- Equality & Diversity E05- Brief description of previous clinical trial experience and expertise
Stage 3	Tender: Quality Requirements	This stage consists of an evaluation of Tenders in in accordance with the criteria set out for each question in the response form in Bravo.	Technical score is worth up to 80% of the overall score available Scored E06 - Methodology to meet Project objectives of Phase 1 and Phase 2 (35% of the technical score available) E07 – Relevant Experience and Expertise

			(35% of the technical score available) E08 Quality Assurance, Quality control & Data (Reporting) (30% of the technical score available)
Stage 4	Pricing Schedule	Prices will be evaluated in accordance with criteria set out in the Pricing Schedule in Bravo.	Commercial score is worth up to 20% of the total score available
Stage 5	Award	A response which passes the selection stages 1, and 2 will proceed to evaluation of Tenders in accordance with stages 3 to 4 The final score is calculated as follows: 80% is made up of the total of Stage 3 20% is made up from Stage 4 The most economically advantageous tender will be the Response with the highest final score	Stage 5

PART 1: SELECTION STAGE (STAGE 2)

1.1 The selection stage has been designed to assess the suitability of a Tenderer to deliver the Authority's contract requirement(s). Tenderers who are unsuccessful at this stage of the procurement process will not have the remaining sections of their Response evaluated pursuant to the award stage of the process outline in Part 2.

Financial standing (pass/fail)

1.2 The Authority will review the economic information provided in Section 5 of the response form to evaluate a Tenderer's economic and financial standing. The Authority's evaluation will be based on all the information reviewed and will not be determined by a single indicator.

1.3 If, based on its assessment of the information provided in a Response, the Authority decides that a Tenderer does not meet the Authority's required level of economic standing, the Authority may:

- ask for additional information, including information relating to your parent company, if applicable; and/or
- require a parent company guarantee or a performance bond.

1.4 The Authority may reject a Tenderer which is unable to offer a commitment to provide a parent company guarantee or performance bond.

1.5 In addition to the information provided in a Response, the Authority may, at its discretion, consult Dun & Bradstreet reports and other credit rating or equivalent reports depending on where a Tenderer is located.

1.6 The Authority's assessment of economic and financial standing will consider financial strength and risk of business failure.

1.7 **Financial strength** is based on tangible net worth and is rated on a scale of 5A (strongest) to H (weakest) obtained from Dun & Bradstreet. There are also classifications for negative net worth and net worth undetermined (insufficient information). Financial strength will be assessed relative to the estimated annual contract value.

1.8 The Authority will also consider annual turnover. For this procurement, the Authority expects the contractor to have an annual turnover for **each** of its last two financial years of at least £4m GBP.

1.9 In the case of a joint venture or a consortium bid, the annual turnover is calculated by combining the turnover of the relevant organisations in each of the last two financial years. In addition, the annual turnover of at least one of those organisations is expected to be £3m GBP.

1.10 **Risk of Business Failure** is rated on a scale of 1 (minimal) to 4 (significant) obtained from Dun & Bradstreet. There is also a classification of insufficient information. The Authority regards a score of 4 as indicating inadequate economic and financial standing for this procurement.

1.11 The Authority will also calculate and evaluate your:

- **operating performance:** growth or reductions in sales, gross profit, operating profit, profit before tax and earnings before interest, tax, depreciation, amortisation, exceptional items and profit/loss on sale of businesses;

- **liquidity**: net current assets, movements in cash flow from operations, working capital and quick ratios, and average collection and payments periods; and

- **financial structure**: gearing ratios and interest cover.

PART 2: TENDER EVALUATION: AWARD STAGE (STAGES 2 TO 5)

1.1 Tenders will be evaluated on quality and price using the evaluation criteria set out in Bravo to determine which Tender is the most economically advantageous. The Authority will award the Contract to the Tenderer which submits the most economically advantageous tender which will be the highest scoring Response after the weightings in paragraph 1.3 are applied.

1.2 Each question will be scored separately and no reference will be made between the questions.

1.3 To ensure that the relative importance of both sets of criteria is correctly reflected in the overall score, a weighting system will be applied to the evaluation:

- the total quality scores (Stage 3) awarded will form 80% of the final score;
- The score awarded for price (Stage 4) will form 20% of the final score.

1.4 Each scoring question in the quality evaluation is given a weighting to indicate the relative importance of that question in the overall quality score. Weightings for quality scores are provided with the evaluation criteria and are detailed on Bravo for each question in the response form. The evaluation criteria for price are set out in the Pricing Schedule.

1.5 Evaluation of Responses will be undertaken by a panel appointed by the Authority. Each panel member will first undertake an independent evaluation of the Responses applying the relevant evaluation criteria for each question. Then, a moderation meeting will be held at which the evaluation panel will reach a consensus on the marking of each question.

EVALUATION QUESTIONS

Mandatory Requirements

If the Tenderer scores a Fail in E01 to E05 then it will be eliminated from the procurement.

E01 Health & Safety

Weighting: Pass/Fail - Tenderers who do not provide a suitable response to the Evaluation Criteria will be scored as a fail.

Please describe:

- Your organisations commitment to a legally compliant health and safety policy and confirm how you will continually improve its performance in maintaining the highest levels of health and safety during the project. Tenderers should explain how such commitment is reflected in the day to day activities of your (i) senior management team, (ii) workforce, (iii) on-farm activities and (iv) supply chain;

- How you will ensure health and safety commitments are adhered to during delivery of the Service;

- How the health and safety policy will be cascaded to sub-contractors (-if required).

- The escalation process in the event of any health and safety breach relating to the project.

Evaluation Criteria:

- Demonstrates that the Tendering organisation has a current health and safety policy (please attach), how it will be applied, and that it is relevant to the project.

- Please provide an example of any relevant on-farm research SOPs previously used

Please upload your response with filename “Your Company Name_E01”. Your response must be no more than 4 sides of A4, minimum font size 10. Your Health & Safety Policy will be accepted in addition to this limit.

E02 Biosecurity

Weighting: Pass/Fail - Tenderers who do not provide a suitable response to the Evaluation Criteria will be scored as a fail.

Please describe:

- How your (i) senior management team, (ii) workforce and (iii) Supply chain will comply with the standards for personal Cleansing & Disinfecting and other biosecurity measures when visiting livestock holdings. These standards must be equivalent to Defra Standards. Your Biosecurity policy/procedures will be accepted in addition to this limit.
- Provide details of your policies/procedures with regards to biosecurity and delivery of this project.
- The escalation process in the event of any biosecurity breach relating to the project.

Please upload your response with filename "Your Company Name_E02". Your response must be no more than 2 sides of A4, minimum font size 10. Your Biosecurity policies/procedures will be accepted in addition to this limit.

E03 Sustainability Policy

Weighting: Pass/Fail - Tenderers who do not provide a suitable response to the Evaluation Criteria will be scored as a fail.

The Authority's policies are to achieve best value for money and continual improvements in the sustainable management of its estate, operations, and procurement. These support the Government's green commitments. The policies are included in the Authority's sustainable procurement policy statement published at:
www.gov.uk/government/publications/defra-s-sustainable-procurement-policy-statement
In the context of the sustainable procurement policy statement, please explain how you intend to help the Authority improve its sustainable performance in delivering this Contract, describing the methods to be employed and drawing on the aspects of sustainability listed below; how what needs to be done would be communicated to those engaged on the contract; how you would demonstrate, measure and monitor progress; and any innovative sustainable approaches such as use of improved tools, techniques and technologies.

Evaluation Criteria:

- Yes/No the supplier has a Sustainability Policy in line with the above requirements
- Evidence of current sustainability policy provided as an attachment.

Please upload your response with filename "E03_Your organisation name"._ Your response must be no more than 4 sides of A4, minimum font size 10. Your sustainability policies/procedures will be accepted in addition to this limit

E04 Equality & Diversity

Weighting: Pass/Fail - Tenderers who do not provide a suitable response to the Evaluation Criteria will be scored as a fail.

The Authority is committed to promoting equality and diversity within its operations and service delivery. Please describe your organisation's commitment to equality and diversity and how you ensure that compliance with relevant legislation is achieved and maintained and how you promote

equality and diversity. The response should be tailored to this contract where possible. In addition, please also provide a copy of your equality and diversity policy or an equivalent document.

Evaluation Criteria:

- Yes/No the supplier has an Equality and Diversity Policy in line with the above requirements

- Include a copy of the Tenderers equality and diversity policy or an equivalent document which shows their organisation's commitment to equality and diversity and confirms their compliance with relevant legislation

Please upload your response with filename "E04_Your organisation name". Your response must be no more than 4 sides of A4, minimum font size 10. Your Equality & Diversity policy will be in addition to this page limit.

Mandatory Technical Requirements

E05 Brief description of previous clinical trial experience and expertise

Weighting: Pass/Fail - Tenderers who do not provide a suitable response to the Evaluation Criteria will be scored as a fail.

Please provide a summary of expertise available and previous clinical field trials conducted under GCP vet standard, providing relevant examples of successful delivery for farm animal products in particular, and the use of trial reports in applications for Marketing Authorisations.
Your response must be a maximum of 1000 words. Links to other documents will be considered as part of your response, e.g. links to published documents online.

Evaluation Criteria

- The supplier must provide evidence of previous successful GCP clinical trials it has been involved with

Your response must be a maximum of 750 words. Your response must be no more than 2 sides of A4, minimum font size 10. Any responses exceeding 750 words will not be evaluated beyond the 750th word. Links to other documents will not be considered as part of your response, e.g., links to published documents online. Please upload a document with the filename: "E05_Your Company Name".

If the Tenderer scores a No or Fail in E05 and then it will be eliminated from the procurement.

Technical Questions

Evaluations of questions E06 – E08 will be based on responses to specific questions covering key criteria which are outlined below. Scores will be based on the following scoring:

- **For a score of 100: Excellent** – Response is completely relevant and excellent overall. The response is comprehensive, unambiguous and demonstrates a best-in-class thorough understanding of the requirement and provides details of how the requirement will be met in full
- **For a score of 70: Good** – Response is relevant and good. The response demonstrates a good understanding and provides details on how the requirements will be fulfilled

- **For a score of 50: Acceptable** – Response is relevant and acceptable. The response provides sufficient evidence to fulfil basic requirements
- **For a score of 20: Poor** – Response is partially relevant and/or poor. The response addresses some elements of the requirements but contains insufficient / limited detail or explanation to demonstrate how the requirement will be fulfilled
- **For a score of 0**: Unacceptable – Nil or inadequate response. Fails to demonstrate an ability to meet the requirement

If you score 20 or less in respect of questions E06 – E08 then you may be eliminated from the procurement.

The weighted scores below for questions E06 – E08 are a percentage available of the total technical score of 80%.

Please note tenderers should not include commercial values in their technical responses. All price information should be submitted in the commercial section (Stage 5) only.

E06 – Methodology to meet Project objectives of Phase 1 and Phase 2 (Weighting 35%)
Please provide details of your project management and delivery methodology, stating clearly how this meets the aims, objectives, and deliverables detailed in the specification and draft protocols

Your response must include:

- A detailed plan of recruitment of herds to ensure participation, incentive package to ensure participant enrolment, endurance, and compliance throughout both phases of the trial

- Please identify the individual(s) who will have overall responsibility for the contract and a representative available for day-to-day contact with APHA's project manager. How continuity will be ensured should key staff be absent, or leave the team, during the term of the contract

- Please provide details of the proposed project management arrangements including timelines and communication with APHA. If relevant, include details of any subcontracting arrangements and how this will be managed.

- A robust approach to project management with a description of how it will be implemented, including in relation to change management, issues escalation, and quality control.

- A clear and achievable project plan, which sets out the key milestones, including timelines, and inter-dependencies#

Please upload your response with filename "E06_ Your Organisation Name". Your response must be no more than 8 sides of A4, minimum font size 10.

E07– Relevant Experience and Expertise (Weighting 35%)

Please provide details of the structure of the project team, including subcontractors if relevant, and the key personnel who will be involved in delivering the project, outlining their roles and responsibilities along with demonstrable evidence as to their relevant skills, expertise and experience in delivery of GCPvet trials, specifically farm based. CVs for key individuals who will be involved in delivering the project can be attached as an annex (maximum of two sides of A4 per CV).

- Please provide details of your organisation's experience and expertise in undertaking on farm trial including any multi-centre trial research to GCP(vet) guidance standards, providing relevant examples of these being completed according to protocols on time and to budget and report where these have been used.

- Please provide details of your organisations experience of dealing with deviations to protocols, and your ability to communicate and analyse results effectively.

Please upload a document entitled "E07_Your organisation name". Your response must be no more than 6 sides of A4, minimum font size 10.

E08 Quality Assurance, Quality Control, & Data (Reporting 30%)
Please provide details of how you intend to quality assure work undertaken as part of this contract and outputs so that deliverables are provided efficiently, to GCPvet standards and on time. Please identify Quality Assurance and Control methodology to be used, highlighting any key risks associated with this contract and provide details of risk mitigation.

Your response must include:

- Provide details of the strategies, policies, or systems you will use to ensure the delivery of the project and the data produced meet quality requirements, including work delivered by sub-contractors.

- Identify risks, including any technical, personnel, stakeholder, timetable, and commercial risks, and provide details of risk mitigation and redress including in the event that outputs do not meet the specification.

- Provide details on technical and organisational measures to ensure the security of the Personal Data of herd owners and testing outcomes in particular

- Provide details on how reporting requirements described in 6.1 and 9.5 will be met

- Provide a protocol that will be followed to immediately alert APHA's named lead scientist of any adverse effects to reagents used or clinical observations as describe (draft SPCs) during the trial

Please upload your response with filename "E08_ Your organisation name". Your response must be no more than 6 sides of A4, minimum font size 10. Any Quality Control accreditation can be in addition to the 4 sides of A4. A one page Risk Log should be supplied in addition to the 6 sides of A4.

Commercial Envelope

1. Tenderers must insert their pricing proposal, in the Commercial Workbook. The total project cost submitted shall be for the whole contract period and this will be the price evaluated.

2. Prices must be submitted in £ Sterling (GBP), excluding VAT.

3. Tenderers are required to complete all sections of the commercial workbook in the commercial envelope. The sections are for information purposes only and will not be scored. The information will be used by the Authority to understand how the submitted price is calculated. The information provided may be used to form the Pricing Schedule of the Contract.

4. The Contractor may be required to recruit and test additional cattle in either phase. Please provide costs for additional cattle within the workbook. These costs will not be evaluated form the Pricing Schedule of the Contract.

5. Note that the cost for travel and subsistence must be included within these costs and be in line with the Authority's Travel and Subsistence Policy, detailed in the travel and subsistence policy (10) below

6. Tenderers must insert their pricing proposal in the Commercial Questionnaire on Bravo

7. Tenderers must provide a breakdown of their price in Appendix C (attached below as an example) and indicate how payments should be made against the milestones table. The breakdown of price and milestone payments will not be scored.

8. The price evaluation will be scored as follows:

   The maximum marks available for this part of the Tender will be 20% and will focus on the cost-breakdown for delivering the full scope of requirements detailed in protocols attached to this ITT.

   The total price submitted by Tenderers as part of the Commercial Questionnaire will be used for this evaluation.

   The calculation used is the following:

   $$\text{Score} = \frac{\text{Lowest Tender Price}}{\text{Tender Price}} \times 20\ \%\ \text{(Maximum available marks)}$$

   For example, if three Tenders are received and Tenderer A has quoted £1,000,000 as their total price, Tenderer B has quoted £1,500,000 and Tenderer C has quoted £2,000,000 then the calculation will be as follows:

   Tenderer A Score = £1,000,000/£1,000,000 x 20 % (Maximum available marks) = 20 %

   Tenderer B Score = £1,000,000/£1,500,000 x 20 % (Maximum available marks) = 12 %

   Tenderer C Score = £1,000,000/£2,000, 000 x 20 % (Maximum available marks) = 10 %

SECTION 3: SPECIFICATION OF REQUIREMENTS

This Section sets out the Authority's requirements.

1. Policy Content

1.1 The Government's top priority in its response to the Godfray review (link) of England's 25-year bovine tuberculosis (BTB) eradication strategy, is to develop a deployable cattle BTB vaccine within the next five years

1.2 Bovine tuberculosis (BTB) is one of the most pressing animal health problems in the UK.

1.3 UK government administrations are committed to eradicating the disease. Current strategies are underpinned by the identification and slaughter of BTB-infected cattle alongside other measures to tackle the spread of infection from wildlife.

1.4 The UK government has invested heavily in research since 1998 to develop a cattle BTB vaccine and DIVA tests that can differentiate infected from vaccinated animals.

1.5 The government's primary BTB research goal is to develop a deployable cattle BTB vaccine within the next five years.

1.6 An authorised vaccine supported by an authorised "Differentiating Infected from Vaccinated Animals" (DIVA) test is expected to be a strong additional tool to help eradicate BTB in those parts of the country where the disease is endemic.

2. Overview of requirements

2.1 The purpose of this project is to conduct Good Clinical Practice (GPC) field trials on cattle in specified TB incident areas to generate sufficient data to deploy a cattle BTB vaccine within the next five years. The primary objective is to secure the necessary marketing authorisations (MAs) for both the vaccine (CattleBCG) and a DIVA skin test (DST-F) to differentiate infected from vaccinated animals.

2.2 APHA have a candidate vaccine (CattleBCG) and DIVA skin test (DST-F) for trial. CattleBCG is the same strain and presentation as the Bacillus Calmette–Guérin (BCG) authorised for use as an injectable in humans and badgers. The candidate DIVA test is a skin test developed by APHA with partners around the world. Together, these are expected to be critical additions to the available tools to help control and eradicate BTB.

2.3 The field trials are primarily designed to assess safety, specificity, and performance of the DST-F reagent and to confirm the safety of CattleBCG in the field in a variety of cattle categories. In addition, the trial will involve blood sampling to measure the response to vaccination.

2.4 Field trial design has been separated into two phases:

- Phase 1: DST-F specificity in unvaccinated TB free animals in the Low Risk Areas (England)/Low incident Area (Wales)
- Phase 2: CattleBCG vaccination and DST-F performance in TB free animals in High Risk and Edge Areas (England)/High and Intermediate incident Areas (Wales).

2.5 In both trial phases the tuberculin skin test (SICCT) using Purified Protein Derivative Avian (PPDA) and Purified Protein Derivative Bovine (PPDB) will be performed in parallel to DST-F to generate comparative data.

2.6 This approach is designed to address UK regulatory requirements for Marketing Authorisations of veterinary medicinal products and is in line with the EFSA opinion on field trials of the vaccine and DIVA test. The Veterinary Medicines Directorate (VMD) is responsible for assessing marketing authorisation applications to ensure the safety, quality, and efficacy of veterinary medicines in the UK.

2.7 During the trial phases all SICCT tests will be conducted in compliance with relevant TB Orders for England and Wales

3. Contractor deliverables (Scope):

3.1 Ensure that the project is conducted and meets the principles of good clinical practice (GCP) as described in VICH GL9 (GCP) guidelines.

3.2 Identify eligible cattle herds for each trial phase in collaboration with APHA.

3.3 Provide and agree with APHA a recruitment and incentive package to ensure participant enrolment, endurance, and compliance throughout the trial.

3.4 Ensure that, where required appropriate relationships are firmly established to ensure the project can be delivered, for example with delivery partners such as official veterinarians

3.5 Ensure that the required number of testing visits are carried out by suitably qualified official veterinarians and that these visits are of consistently high biosecurity and quality in accordance with the requirements described in the Invitation to Tender. (Defra link)

3.6 Ensure specified time-critical samples (blood, milk, and nasal swabs) are packaged according to the sample handling criteria and sent to APHA laboratories for analysis within the time period specified. (Details are in the protocol Appendix 2)

3.7 Will work with APHA to arrange removal of animals with a positive reaction to either of the skin tests and final gamma test in Phase 2 within 10 working days of test result

3.8 Immediately report any unexpected observations/results other than those described in draft Summary of product characteristics (SPCs) (Details attached to protocols)

3.9 Responsible for management and compliance with appropriate regulations and guidance for on-farm activities, licenced and Investigational Veterinary Products.

3.10 Will work in collaboration with APHA and contracted external auditor to finalise the draft protocols for both phases prior to final sign off

3.11 Will be expected to work in collaboration with APHA to begin field trials as soon as possible following contract award

3.12 Be responsible for the project management, co-ordination, and reporting requirements as specified in this Invitation to Tender.

3.13 Participate in regular (frequency to be decided) check point meetings with the APHA project group to update on progress to key deliverables

3.14 Capture data and provide reports and statistical analysis following each phase of the study and where requested as part of the check point meetings with APHA (to be agreed).

4. Key Requirements

4.1 The Contractor will be required to achieve work delivery outcomes against work delivery milestones which are set out in their tendered delivery plan. The delivery milestones submitted in the tender will be included as a schedule to the Contract. The outcome of Phase 1 determines whether Phase 2 can go ahead. However preparations for completion of Phase 2, which should include recruitment of eligible herds; will be required during Phase 1 to ensure that Phase 2 can be started as quickly as possible following completion of Phase 1.

Note: These are the key requirements summarised for the achievable delivery outcomes

4.2 Outcomes – Phase 1

- In collaboration with APHA select appropriate herds for participation
- Recruit and confirm herd participation
- Confirm testing schedules and protocols with APHA
- Report skin testing results to APHA following each completed test
- Monthly reporting of surveillance data
- Complete testing requirements within 12 months to GCP standards
- Final GCP(vet) Phase 1 report and analysis including but not exclusively with regards to calculations from DSF - T specificity

4.3 Outcomes Phase 2

- Plan recruitment during Phase 1 to avoid excessive delays in Phase 2 start
- In collaboration with APHA select appropriate herds for participation
- Recruit and confirm herd participation
- Confirm skin testing, sample collection schedules and protocols with APHA
- Report skin testing results to APHA following each completed test
- Monthly reporting of surveillance data
- Complete testing requirements within 18 months to GCP
- Final GPC(vet) Phase 2 report and appropriate analysis

5. Technical requirements

5.1 Phase 1 Field Study: DST-F in unvaccinated cattle summary

5.1.1 The number of animals tested will depend upon the desired precision and maximum number of false positives.

Category	Number	Location	Duration
Mixed – test for specificity in TB free cattle	300 – 2,500 depending on desired precision	OTF herds in low risk areas	12m[a]

[a]Each animal on study for 14 days, but 12 months allowed for recruitment and completion of maximum number.

5.1.2 The SICCT and DST-F skin tests must be conducted by a suitably qualified Official Veterinarian

5.1.3 Specific surveillance for safety data will be completed on approximately 50 animals from each category as per table below:

		Target number of cattle observed		
Safety assessment	**Frequency**	**50 days to 3 month old calves**	**Dairy cows**	**Beef cows**
DST-F injection site Skin thickness Diameter of reaction Description of reaction	Daily measurement for first 7 days and then twice further up to 14 days or until reaction is resolved	50	50	50
Pain and heat at DST-F injection site	Daily assessment for the first 14 days	50	50	50
Rectal temperature	Measure immediately prior to and daily for 7 days after DST-F injection and then twice further up to 14 days	50	50	50
General health observations	Daily assessment for the first 14 days	All	All	All

5.1.4 Cattle which test DST-F or SICCT positive should be immediately notified to the APHA project manager, recorded appropriately and will be subject to detailed post mortem examination.

5.1.5 Phase 1 is expected to be completed in 12 months

5.1.6 The detailed protocol for phase 1 can been seen in Appendix 1

5.2 Schedule of Events Phase 1

5.2.1 A schedule of events will be prepared for each trial site to include:

- Selection of farms with APHA
- Final agreement of protocol
- External audit of protocol

- Expected start date of the animal phase
- Timing of skin testing (DST-F and SICCT)
- Timing of safety monitoring
- Expected completion date as report submission

5.2.2 Each site specific schedule prepared by the CRO Investigator will be copied to the farmer and the CRO master file for inclusion in the final report. The structure of the schedule will be as outlined in the table below:

5.2.3 Phase 1 – Schedule of events

Day	Activity
Pre trial	Trial site recruitment, informed consent and protocol refinement
0	Safety observations (in subset of animals, Appendix 1 for details)
0	Day 1 of skin test (all animals)
1	Safety observations (in subset of animals, Appendix 1 for details)
2	Safety observations (in subset of animals, Appendix 1 for details)
3	Safety observations (in subset of animals, Appendix 1 for details)
3	Day 2 of skin test (all animals)
4	Notify APHA of any SICCT positive animals so that routine TB control policy can be applied
4	Arrange removal of any skin test (SICCT or DST-F) positive animals to APHA Weybridge for PME
4	Safety observations (in subset of animals, Appendix 1 for details)
5	Safety observations (in subset of animals, Appendix 1 for details)
6	Safety observations (in subset of animals, Appendix 1 for details)
7	Safety observations (in subset of animals, Appendix 1 for details)
8	Safety observations (in subset of animals, Appendix 1 for details)
8	Ensure all SICCT results (positive and negative) are recorded on APHA's SAM system
9	Safety observations (in subset of animals, Appendix 1 for details)
10	Safety observations (in subset of animals, Appendix 1 for details)
11	Safety observations (in subset of animals, Appendix 1 for details)
12	Safety observations (in subset of animals, Appendix 1 for details)
13	Safety observations (in subset of animals, Appendix 1 for details)
14	Safety observations (in subset of animals, Appendix 1 for details)
14+	Continue safety observations until skin reactions at DST-F injection site are resolved

5.3 Phase 2 Field Study: CattleBCG vaccination and DST-F summary

5.3.1 Phase 2 will only commence if the specificity of DST-F is considered acceptable by Defra.

5.3.2 The cattle selection for the trial will be a combination of breeds, sex, age and gestation (if appropriate) from either the High Risk or Edge Areas (in England), High, Intermediate incidence areas (in Wales) or both.

5.3.3 Cattle from unrestricted officially TB-free (OTF) herds will be randomly assigned within herds, half to the vaccine group, and half to the control group. The method of randomisation should be described in the protocol

5.3.4 The number of cattle for this phase will be approximately 2000 (1900 minimum); over 7 separate herds with ~1000 cattle vaccinated and ~1000 cattle used as a control.

5.3.5 Cattle (n) will be recruited from neonatal, up to 3 months of age, (~100), beef (~600), dairy (~1000) and Approved Finishing Units (AFUs) (~200).

Target category	Number of animals and age	Location	Duration
Neonates	100 (3week to 3months), mixed male and female	TBD – dairy or beef herd sites	Up to 18m[a]
Dairy cows	1000, variable ages	High risk area and edge	Up to 18m[a]
Beef cows	600, variable ages	High risk area and edge	Up to 18m[a]
Mixed beef and dairy	200, variable ages	Approved Finishing Units	Up to 18m[a]
Total	1900[b]		

[a]This includes the time for recruiting trial sites and animals, the 12 months for actual field trial, time for post mortem and culture tests and writing of report. The aim would be to carry out as much of the different field trial studies as possible in parallel (and within 18m), but exact timings will need to be resolved once the delivery team is in place. [b]If this looks like it will be exceeded, a variation to the ATC will be needed.

5.3.6 All cattle will be blood sampled for the Interferon gamma release assay prior to vaccine administration, at 6-8 weeks after vaccination and at the end of the trial period for assessment of vaccine response.

5.3.7 At 9-11 weeks after vaccination, a DST-F skin test will be performed on vaccinated animals and DST-F and SICCT skin tests performed on control animals. All skin test positive animals will be removed for detailed post mortem examination at APHA Weybridge.

5.3.8 General health observations will be required for 14 days in all animals vaccinated with BCG or injected with DST-F, a smaller cohort will require specific safety testing as detailed in appendix 2

5.3.9 Specific surveillance will be completed as summarised in table at 5.4.3

5.3.10 On completion of the study, all cattle will be tested with the SICCT, and blood sampled for the Interferon gamma release assay. Any animals that are positive in either the

SICCT or Interferon gamma release assay will be sent to slaughter with the standard FSA inspection for TB carried out.

5.3.11 All animals from herds taking part in the field trials that go to slaughtered during the study period (not just those from AFUs), will be subject to official post-mortem inspection at the abattoir.

5.3.12 Phase 2 is expected to be completed in 18 months.

5.3.13 The detailed protocol for phase 2 can be seen in Appendix 2

5.4 Schedule of Events Phase 2

5.4.1 A schedule of events will be prepared for each trial site to include:

- Selection of farms with APHA
- Protocol finalised
- Protocol subject to external audit
- Expected start date of the animal phase
- Timing of vaccination
- Timing of skin testing (DST-F and SICCT)
- Timing and identity of sample collection
- Timing of safety monitoring
- Expected completion date
- Submission of externally audited report

5.4.2 Each site specific schedule prepared by the CRO Investigator will be copied to the farmer and the CRO master file for inclusion in the final report. The structure of the schedule will be as outlined in the table below.

5.4.3 Phase 2 – Schedules events summary below for full details see protocol in appendix 2

Time	Description	Activity	Sampling
Preparation pre-trial	Trial site recruitment	Informed consent, protocol refinement	
Preparation pre-trial	Routine tuberculin skin test (SICCT)	SICCT	
Day 0*	Randomly allocate 50% vaccinates, 50% controls (all cattle in herd confirmed SICCT negative)	Inclusion/exclusion. Read skin test results Vaccination with CattleBCG	Blood (for IGRA**)
Days 0-14	Safety monitoring. Numbers for each category for each site to be confirmed. Target is 50 per category across a maximum of 7 sites.	Daily monitoring of DST-F and CattleBCG injection sites. Rectal temperature: Measure immediately prior to and daily for 7 days after DST-F injection or vaccination, and then twice further until day 14	
Days 0-14	Cows lactating at time of vaccination	Daily milk samples for bacteriology	Milk
Days 0-45	Safety monitoring – continued skin thickness measurement at CattleBCG	21,28,35, and 45 days post vaccination or until resolved	

	injection site		
Days 0-56	Nasal swabs for bacteriology	Once per week for 7 weeks post vaccination	Nasal Swab
6-8 weeks	Sampling for vaccine response. Tested blinded to treatment		Blood (for IGRA**)
9-11 weeks	Vaccinates: DST-F. Controls: DST-F and SICCT	Skin testing	
+72 hours	Read skin test results		
End of study ~ 12 months	All cattle: SICCT	Skin testing and blood sampling	Blood (for IGRA**)

* Day 0 should follow pre-trial preparation as closely as reasonably practical **IGRA = Interferon-gamma Release Assay using the Bovigam ELISA test (Thermo Fisher)

6. Analysis and Reporting

6.1 The suppler will be required to

6.1.1 Provide appropriate analysis on data collected during both phases of the trials full analysis requirements will be agreed with APHA and tender award.

6.1.2 Reporting of skin test results and any adverse clinical reactions within 24hrs of observations and surveillance data on a monthly basis for both Phases

6.1.3 Final report at the end of Phases to GCP vet standards -

7. Project Management

7.1 The Supplier will identify specific individuals and key staff with experience of GCP trials, specifically farm based. Also appointing a named individual as the main point of contact with the APHA project manager.

7.2 The Supplier will be required to attend an inception meeting with APHA in the first month of contract commencement to agree the details of the methodology, timelines, and general ways of working. This session will provide a thorough overview of the project, its aims and objectives, the approach of the trial, an opportunity for the CRO to expand on how they will deliver and achieve the objectives of the trials and agree the collaborative interactions required with APHA to include but not limited to; sample collection and their scheduling processes, removal of positive animals for PME.

7.3 The supplier will be expected to work in collaboration with APHA to select appropriate herds for participation in the trial and arrange the removal and post mortem of any skin test positive animals for the duration of the trial period

7.4 The supplier will be expected to manage participant enrolment and their compliance throughout the trial to completion.

7.5 Throughout the duration of the Contract, the Supplier will provide appropriate written and/or other progress updates and will agree to meet with APHA project team as and

when required. The frequency of contact will be decided at the start of the contract as part of the inception meeting and will follow a pre-defined schedule of meetings and/or contact required.

7.6 The Supplier will notify APHA without delay if there are any unexpected results and if there is a risk that the project timeline may extend for any reason.

7.7 APHA will inform the Supplier without delay if there is any deficiency in the quality of the services provided under the contract. The Supplier will take steps to ensure any problems are resolved as a matter of urgency.

8. Quality Assurance

8.1 The supplier to ensure that a structured Quality Assurance programme is implemented to provide evidence and assurance the project is conducted in accordance with the principles of good clinical practice (GCP) as described in VICH GL9 (GCP) guidelines. Informing APHA immediately of any significant non-conformances.

8.2 The supplier to permit supplemental quality audits conducted by APHA Quality Assurance and an independent external auditor as detailed in the APHA audit plan.

8.3 The supplier to ensure both skin tests will be carried out by a Suitably Qualified Official Veterinarian and SICCT test are recorded on APHAs SAM system.

8.4 Blood testing, swab and milk sample collections, and surveillance of study animals should be completed by a sufficiently qualified personnel in line with GCP guidance

9. Deliverables

9.1 A project plan, outlining key milestones, as agreed with APHA following an inception meeting.

9.2 A summary of progress and outcomes for each objective delivered at the end of each Phase of the trial

9.3 Phase 1 testing results to be reported following completion of each test.

9.4 Final presentation and reports of the trial outcomes

10.0 Travel and Subsistence

All Travel and Subsistence should be in line with Defra's Travel and Subsistence Policy. Claims should always be supported by valid receipts for audit purposes and must not exceed any of the stated rates below. Should the stated rated be exceeded, Defra reserve the right to reimburse only up to the stated rate.

Rail Travel

All Journeys – Standard class rail unless a clear business case demonstrating value for money can be presented. This includes international rail journeys by Eurostar and other international and overseas rail operators.

Mileage Allowance

Mileage Allowance	First 10,000 business miles in the tax year	Each business mile over 10,000 in the tax year
Private cars and vans – no public transport rate*	45p	25p
Private cars and vans – public transport rate	25p	25p
Private motor cycles	24p	24p
Passenger supplement	5p	5p
Equipment supplement**	3p	3p
Bicycle	20p	20p

*NB the 'no public transport rate' for car and van travel can only be claimed where the use of a private vehicle for the journey is essential e.g. on grounds of disability or where there is no practical public transport alternative. If the use of the vehicle is not essential the 'public transport rate' should be claimed.

** Under HMRC rules this expense is taxable.

UK Subsistence

Location	Rate
London (Bed and Breakfast)	£130 per night
Rates for specific cities (Bed and Breakfast)	Bristol £100 per night Weybridge £100 per night Warrington £90 per night Reading £85 per night
UK Other (Bed and Breakfast)	£75 per night for all other locations

11.0 Performance Management Framework (including Key Performance Indicators (KPIs)

KPI	Measure	KPI Rating		
		Not Met	Partly Met	Met
KPI 1 – Customer Service	Notification of issues affecting delivery of project plan schedule	Below Expectations <100%	NA	Meets Expectations 100%
KPI 2 – Quality	Conformances to trial protocols	No protocols applied	Some Protocols applied	All Protocols applied
KPI 3 - Reporting of test results	Reporting of all DST-F results to APHA within 24 hrs of test completion and provide monthly updates of tests completed	Below Expectations > 24 hours	N/A	Meets Expectations < 24 hours
KPI 4 – Removal of Positive test animals	Arrangement and removal (in collaboration with APHA) of any skin test positive cattle (SICCT or DST-F) +ve DST reactions for Post Mortem Examination within 10 days of disclosure	Below Expectations > 10 days	N/A	Meets Expectations < 10 days
KPI 5 – Reporting and analysis	Provide analysis and reports following each phase within one month of phase completion	Below Expectations <100%	NA	Meets Expectations 100%
KPI 6 - Reporting of any unexpected adverse reactions(other than those as described in Draft SPCs)	Reporting of detection as soon as practically feasible and within 24hrs of observation	Below Expectations > 24 hours	N/A	Meets Expectations < 24 hours

KPI 7 Reporting of test trial staff accidents and incidents	Reporting of any accidents or incidents involving trial staff in particular in relation to equipment and veterinary products.	Below Expectations > 24 hours	N/A	Meets Expectations < 24 hours
KPI 8 Reporting – Final Report	Produce a draft of the final report for APHAs approval within 3 months of study completion and final report 1 month after APHAs review	Below Expectations <100%	NA	Meets Expectations 100%

11.1 KPIs shall be monitored on a regular basis and shall form part of the Contract performance review

11.2 Key Performance Indicators (KPIs) are essential in order to align Contractor's performance with the requirements of the Authority and to do so in a fair and practical way. KPIs have to be realistic and achievable; they also have to be met. Failing to meet the KPIs would indicate otherwise that the service is failing to deliver. As a result, recourse might be to terminate and seek alternative supply.

11.3 Any performance issues highlighted in the progress reports will be addressed by the Contractor, who may be required at the request of the Authority to provide an improvement plan ("Remediation Plan") to address all issues highlighted within a week of the Authority request

APPENDIX A

FORM OF TENDER

(Print, Sign, Scan and Upload to Bravo)

To be returned by 17:00 (UK time) on 13th October 2020.

Aman Sharma
Category Manager
Department for Environment, Food and Rural Affairs
Network Procurement
Nobel House, London, SW1P 3JR

TENDER FOR THE: GB field trials of CattleBCG Vaccine and companion DIVA (DST-F) testing
Tender Ref: 24389

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1. We have examined the invitation to tender and its appendices set out below (the **ITT**) and hereby offer to provide the goods and/or services specified in the ITT and in accordance with the attached documents to the Authority commencing 07/12/2020 for the period specified in the ITT.

    - Response Particulars (Section 1)
    - Specification of Requirements (Section 3)
    - Form of Tender (Appendix A)
    - Authority's Conditions of Contract (Appendix B)

2. If this Tender is accepted, we will execute the Contract and any other documents required by the Authority within 10 days of being asked to do so.

3. We agree that:

    a. before executing the Contract substantially in the form set out in the ITT, the formal acceptance of this tender in writing by this Authority or such parts as may be specified, together with the documents attached shall comprise a binding contract between the Authority and us;

    b. pursuant to EU Directive 1999/93/EC (Community Framework for Electronic Signatures) and the Electronic Communications Act 2009, the Contract may be executed electronically using the Authority's electronic tendering and contract management system;

    c. we are legally bound to comply with the confidentiality provisions set out in the ITT;

    d. any other terms or conditions or any general reservation which may be provided in any correspondence sent by the Authority in connection with this procurement shall not form part of this tender without the prior written consent of the Authority;

    e. the Tender shall remain valid for 120 days from the closing date for Responses specified in the ITT; and

    f. the Authority may disclose our information and documents (submitted to the Authority during the procurement) more widely within Government for the purpose of

ensuring effective cross-Government procurement processes, including value for money and related purposes.

4. We confirm that:

   a. there are no circumstances affecting our organisation which could give rise to an actual or potential conflict of interest that would affect the integrity of the Authority's decision making in relation to the award of the Contract; or

   b. if there are, or may be such circumstances giving rise to an actual or potential conflict of interest we have disclosed this in full to the Authority.

5. We undertake and it shall be a condition of the Contract that:

   a. the amount of our tender has not been calculated by agreement or arrangement with any person other than the Authority and that the amount of our tender has not been communicated to any person until after the closing date for the submission of tenders and in any event not without the consent of the Authority;

   b. we have not canvassed and will not, before the evaluation process, canvass or solicit any member or officer, employee or agent of the Authority or other contracting authority in connection with the award of the Contract and that no person employed by us has done or will do any such act; and

   c. we have not made arrangements with any other party about whether or not they may submit a tender except for the purposes of forming a joint venture.

6. I warrant that I am authorised to sign this tender and confirm that we have complied with all the requirements of the ITT.

Signed _____

Date _____

In the capacity of _____

Authorised to sign Tender for and on behalf of _____

Postal Address _____

Post Code _____

Telephone No. _____

Email Address _____

APPENDIX B

AUTHORITY'S CONDITIONS OF CONTRACT

The Authorities Conditions of Contract that are applicable to this Invitation to Tender and any subsequent contract are Conditions of Contract for Services

Contract For Services.doc

APPENDIX E

ARMED FORCES CORPORATE COVENANT

Section 1: Principles of the Armed Forces Covenant
We Company XYZ will endeavour in our business dealings to uphold the key principles of the Armed Forces Covenant, which are:

- no member of the Armed Forces Community should face disadvantage in the provision of public and commercial services compared to any other citizen;
- in some circumstances special treatment may be appropriate especially for the injured or bereaved.

Section 2: Demonstrating our Commitment
Company XYZ recognises the value serving personnel, reservists, veterans and military families bring to our business. We (Company XYZ) will seek to uphold the principles of the Armed Forces Covenant, by:

- promoting the fact that we are an armed forces-friendly organisation;
- seeking to support the employment of veterans young and old and working with the Career Transition Partnership (CTP), in order to establish a tailored employment pathway for Service Leavers;
- striving to support the employment of Service spouses and partners;
- endeavouring to offer a degree of flexibility in granting leave for Service spouses and partners before, during and after a partner's deployment;
- seeking to support our employees who choose to be members of the Reserve forces, including by accommodating their training and deployment where possible;
- offering support to our local cadet units, either in our local community or in local schools, where possible;
- aiming to actively participate in Armed Forces Day;
- offering a discount to members of the Armed Forces Community;
- any additional commitments XYZ could make (based on local circumstances).

[You are encouraged to sign up to as many of the above as appropriate to your business. Please amend to provide details of how you intend to meet each commitment.]

We will publicise these commitments through our literature and/or on our website, setting out how we will seek to honour them and inviting feedback from the Service community and our customers on how we are doing. [Amended as appropriate for your business.]