Department for Environment Food & Rural Affairs

www.gov.uk/defra

R&D Contract for a project: Improved tools for the diagnosis of foot-and-mouth disease (SE1130)

Contract Ref. Project 29701

November 2020

This document/publication is also available on our website at:
www.gov.uk/government/organisations/department-for-environment-food-rural-affairs
procurement@defra.gsi.gov.uk

SECTION 1

FORM OF CONTRACT

This agreement is made on December 2020

PARTIES:

(1) **THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS** of Nobel House, 17 Smith Square, London, SW1P 3JR (the "**Authority**");

AND

[redacted]

(each a "**Party**" and together the "**Parties**")

NOW IT IS HEREBY AGREED:

1. The Contractor and the Authority agree to observe and comply with the Defra Terms and Conditions for Research and Development Projects which are incorporated into this agreement.

2. Annex A shall list the Project awarded non-competitively. The agreement shall not include grants made under the Government's LINK scheme, or projects that are joint funded or where the Contractor is acting jointly with another contractor.

3. The Contractor will carry out the Project in accordance with the objectives, approaches and research plan, and milestones contained in the appropriate Application. Annex A will give the Project Code, the agreed price, and the Start Date and Completion Date of the Project.

4. The Authority will pay to the Contractor the Costs properly incurred in carrying out the Project.

5. This agreement supersedes and replaces any and all previous contracts, agreements and statements relating to the Project, and consists of:

    - this Form of Contract;
    - Defra Terms and Conditions for Research and Development Projects;
    - the Schedules (Intellectual Property Schedule A; Contacts Schedule);
    - the objectives, approaches and research plans, and milestones contained in the Application(s);
    - Annex A Pricing Schedule & Scope of Works.

    (together referred to as "**the Agreement**").

6. In the Defra Terms and Conditions for Research and Development Projects, conditions 7.1.3, 13 (to the extent that it relates to the warranty in 7.1.3), 16, 23.1 and 34.2, shall not apply as between the Authority and a Contractor who is part of the Crown or a Research Council. Further, where the Contractor enters a contract with a subcontractor who is

part of the Crown or a Research Council, the Contractor will not require the sub-contractor to comply with provisions comparable to the said Conditions.

7. To the extent that a Party is part of the Crown this Agreement is not intended to and does not create any legally binding relationship between the Authority and that Party.

8. For the purposes of condition 17 of the Defra Terms and Conditions for Research and Development Projects (conflict or inconsistency), the documents shall take precedence in the order in which they appear in clause 5 of this Form of Contract.

9. Execution of the Agreement is carried out in accordance with the 1999 EU Directive 99/93 (Community framework for electronic signatures) and the UK Electronic Communications Act 2000. The Agreement is formed on the date on which both the Authority and the Contractor have communicated acceptance of its terms on the Authority's electronic contract management system ('Bravo').

10. The Contract duration is 01/04/2020 to 31/03/2023.

SECTION 2

DEFRA TERMS AND CONDITIONS FOR RESEARCH AND DEVELOPMENT PROJECTS

1. DEFINITIONS

1.1 In these terms and conditions, the following words and expressions shall have the meanings given to them below, unless the context otherwise requires:

"Agreement"	The agreement between the Authority and the Contractor incorporating the Form of Contract and documents referred to therein.
"Application"	The application submitted by the Contractor containing his proposal for a Project, which is subsequently agreed for funding by the Authority, amended if necessary.
"Authority"	THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS and any persons authorised to act on the Secretary of State's behalf.
"Authority's Property"	Anything issued or otherwise provided in connection with the Agreement by or on behalf of the Authority or any person authorised to act on its behalf.
"Authority's Representative"	The person named in paragraph 1 of the Contacts Schedule, subject to the provisions of condition 5.
"Contractor"	The organisation named on the Form of Contract as the Contractor.
"Contractor's Representative"	The person named in paragraph 2 of the Contacts Schedule, subject to the provisions of condition 5.
"Completion Date"	The date set out in Annex A unless the Authority has not received a final report as set out in paragraph 3 of the Reports Schedule, in which case the Completion Date shall be the date on which the Authority receives such a report.
"Costs"	Costs incurred by the Contractor for the purposes of the carrying out of the Project, limited to those costs identified in the 'Financial Guidelines for Project Cost Estimates' section of the Application.
"Equipment"	All equipment, materials, consumables and plant, other than the Authority's Property, to be used by the Contractor in carrying out the Project.

"Form of Contract"	The contract document signed by the parties.
"GDPR"	means the General Data Protection Regulation (Regulation (EU) 2016/679).
"Income"	Any revenues received by the Contractor (including without limitation the sale or disposal of products or services, royalties, payments for licences or options and stage payments) irrespective of whether such payment is in money or other consideration,
"Intellectual Property"	Any patent, copyright, design right, registered design, trademark or service mark, trade name, Know-how, patentable invention for the purposes of the Patents Act 1977, database right for the purposes of the Copyright and Rights in Databases Regulations 1997, domain name, technical information or know how and any application for any of the foregoing and any similar rights in any jurisdiction.
"Key Personnel"	Any member of the Contractor's personnel identified by name or job title as key personnel in the Contacts Schedule.
"Know-how"	All information not in the public domain held in any form (including, without limitation, that comprised in or derived from oral and written instructions, diagrams, drawings, data formulae, patterns, specifications, notes, samples, chemical compounds, biological materials, computer software, component lists, instructions, manuals, brochures, catalogues and process descriptions and scientific approaches and methods) used in connection with or arising as a result of the Project.
"Parties"	The Authority and the Contractor.
"Period for the Project"	The period for the carrying out of the Project, being the period between the Start Date and the Completion Date.
"Project"	A research project of which are set out in the Application and Annex A.
"Project Manager"	A person authorised by the Authority to manage a Project.
"Project Year"	Each period of 12 months during the Period of the Project calculated from the Start Date.

"Results"	Any Intellectual Property created by agents, employees, students or sub-contractors of the Contractor as a result of the Project.
"Schedule"	Any of the schedules annexed to the Agreement.
"Start Date"	The date set out in Annex A.
"Terms and Conditions"	The Defra Terms and Conditions for Research and Development Projects.

1.2 Unless the context otherwise requires, references in these Terms and Conditions

1.2.1 to the Contractor or to the Authority shall, where appropriate, be references to any lawful successor, assignee or transferee;

1.2.2 to the Contractor shall, where appropriate, be references to each individual person constituting the Contractor;

1.2.3 to conditions are references to the conditions of these Terms and Conditions

1.2.4 to "person" or "third party" include any individual, company, corporation, firm, partnership, joint venture, association, organisation, institution, trust or agency, whether having a separate legal personality;

1.2.5 to one gender include all genders, and references to the singular include the plural and vice versa;

1.2.6 to any statute, statutory provision or regulation, are references to that statute, statutory provision or regulation, as from time to time amended, extended or re-enacted.

1.3 The headings in this document are for convenience only and shall be ignored in construing these Terms and Conditions.

2. DURATION

2.1 The Contractor shall commence work on the Project no later than the Start Date.

2.2 The Contractor shall complete the Project sufficiently in advance of the Completion Date to enable it to submit a final report as set out in paragraph 3 of the Reports Schedule.

2.3 Subject to the Authority's right of termination, the Agreement shall remain in force for the Project from the Start Date until the Completion Date, unless the Parties agree to extend the duration of the Project.

3. FINANCIAL ARRANGEMENTS

3.1 The Contractor shall calculate Project costs in accordance with the "Financial Guidelines for Project Cost Estimates" contained in the Application.

3.2 The Authority shall pay all sums due to the Contractor within 30 days of Receipt of a Valid Invoice. Valid Invoices should be submitted for payment to the following address: ssd.apdefra@defra.gsi.gov.uk (the Authority's preferred option); or SSCL AP, Defra, PO Box 790, Newport Gwent, NP10 8FZ. The Authority agrees to pay the Contractor the price for the Project quoted in Annex A and, subject to any variation of the Agreement, these shall individually remain fixed for the period of the Project.

3.3 If the Agreement is varied, the prices shown in Annex A shall be adjusted by such reasonable sum as may be agreed, in writing, between the Authority and the Contractor.

3.4 Subject to the Contractor performing its obligations in accordance with the Agreement, the Authority shall pay the values set out in Annex A to the Contractor monthly.

3.5 Where the Contractor is not VAT exempt, and is required to charge VAT to the Authority at the current rate, the Contractor shall submit a VAT invoice at the beginning of each financial year (April- March) covering all payments to be made during that year. No payment will be made by the Authority to such Contractor unless and until this invoice is received by the Authority. The Contractor must exercise care not to charge VAT on expenses which are n o t chargeable to VAT.

3.6 Any overpayment to the Contractor made by the Authority, whether of Project price or VAT, shall be a sum of money recoverable by the Authority from the Contractor.

3.7 Failure to comply with the requirements of paragraphs 3.1 or 3.5 may result in payments being withheld or the Agreement being terminated in accordance with the provisions of condition 23.

4. PAYMENT OF SUB-CONTRACTORS

4.1 Where the Contractor enters into a sub-contract for the provision of services as part of a Project, the Contractor shall ensure that a term is included in the sub-contract which requires the Contractor to pay all sums due to the sub-contractor within a specified period not exceeding 30 days after the Contractor has verified the relevant invoice.

4.2 The Contractor shall use all reasonable endeavours to verify the invoices promptly.

4.3 Where the Contractor becomes liable to pay interest payments to a sub-contractor under the provisions of the Late Payments of Commercial Debts (Interest) Act 1998, the Authority will not reimburse those costs unless they are incurred due to the negligence or default of the Authority.

5. NOMINATED OFFICERS

5.1 The Authority's Representative shall be the person named in paragraph 1.1 of the Contacts Schedule, or such other person that the Authority may nominate having given 14 days' notice to the Contractor.

5.2 The Contractor's Representative shall be the person named in paragraph 2.1 of The Contacts Schedule, or such other person that the Contractor may nominate having given 14 days' notice to the Authority.

6. CONTRACTOR'S STATUS

6.1 In carrying out the Projects, the Contractor shall be acting as principal and not as agent or employee of the Authority. Accordingly:

6.2 The Contractor shall not (and shall ensure that any other person engaged in relation to the Agreement shall not) say or do anything that might lead any other person to believe that the Contractor is acting as the agent or employee of the Authority, and

6.3 Nothing in the Agreement shall impose any liability of the Authority in respect of any liability incurred by the Contractor to any other person but this shall not be taken to exclude or limit any liability of the Authority to the Contractor that may arise by virtue of either a breach of the Agreement or any negligence on the part of the Authority its staff or agents.

7. WARRANTIES

7.1 The Contractor warrants to the Authority that:

7.1.1 the Contractor shall carry out and shall ensure that his employees, agents and sub-contractors also carry out the Projects with all reasonable skill, care and due diligence, in accordance with best professional, technical and scientific knowledge and practice, and any legislative requirements;

7.1.2 any materials or processes used in connection with the carrying out of the Projects shall be in accordance with standards set out in the Agreement;

7.1.3 the proper use by the Authority or any Crown body of any documentation, materials or results delivered by the Contractor pursuant to the Agreement, shall not to the best of the Contractor's knowledge and belief, constitute an infringement of the Intellectual Property rights of any third party. The Contractor warrants to the Authority to undertake appropriate patent, registered design right, trademark, and/or literature searches to identify any actual or potential third-party Intellectual Property rights;

7.1.4 the Contractor has understood the nature and extent of the Projects to be carried out and satisfied himself in relation to all matters connected with the Projects including the supply of and conditions affecting labour, the suitability of the premises where the projects are to be carried out and any Equipment necessary for the carrying out of the Projects subject to all such matters being reasonably discoverable by the Contractor.

7.2 Nothing in this Agreement shall be taken as limiting or excluding the Authority's rights or the Contractor's obligations pursuant to any statute, statutory instrument or the common law.

8. MEETINGS

The Contractor shall, subject to reasonable notice, attend all meetings specified in the Agreement or otherwise arranged by the Authority, for the discussion of matters concerned with the Projects.

9. LIMITATION OF LIABILITY

9.1 In the event that either party breaches this Agreement, subject to Condition 9.3, neither party shall be liable to the other for the following:

9.1.1 loss of profit, business, revenue, goodwill or anticipated savings;

9.1.2 indirect or consequential loss or damage.

9.2 Subject to Condition 9.3 in respect of any Project, the aggregate liability of either party to the other arising out of any breach or breaches of this Agreement shall be limited to the sum identified against it in Annex A.

9.3 Nothing in this Agreement limits or excludes either party's liability for:

9.3.1 personal injury or death arising from its negligence;

9.3.2 fraud; or

9.3.3 any other liability that cannot be excluded by law.

10. INDEMNITY AND INSURANCE

10.1 The Contractor shall ensure that any sub-contractor shall indemnify the Authority, the Crown, its employees, agents and contractors, on demand from and against all liability for:

10.1.1 death or personal injury;

10.1.2 loss of or damage to property (including property belonging to the Crown or the Authority, or for which it is responsible "Authority Property");

10.1.3 breach of statutory duty; and

10.1.4 actions, claims, demands, costs, charges and expenses (including legal expenses on an indemnity basis)

which arises out of or in connection with the sub contractor's provision of a Project.

10.2 The indemnity contained in Condition 10.1 shall not apply to the extent that:

10.2.1 any loss, damage injury, cost and expense is caused by the negligent or willful act or omission of the Authority, its employees, agents or contractors, or by the breach by the Authority, of its obligations under the Agreement; or

10.2.2 the sub-contractor is able to demonstrate that the loss, damage or injury arose as a direct result of the sub-contractor acting on the instructions of the Authority.

10.3 The Contractor shall require any sub-contractor to take out and maintain insurance with a reputable insurance company, including (but not limited) to employer's liability, public liability and professional indemnity insurance, covering at least all matters which are the subject of indemnities or compensation obligations under these Conditions in such sum as may be specified by the Authority in writing, or, if no such sum is specified, the sum of not less than £5,000,000 for any one incident and unlimited in total.

10.4 The policy or policies of insurance referred to in paragraph 10.3 shall be shown to the Authority's Representative whenever he requests, together with satisfactory evidence of payment of premiums.

10.5 The Contractor shall ensure that no sub-contractor shall take any action or fail to take any reasonable action, or (to the extent that it is reasonably within its power) permit anything to occur in relation to it, which would entitle any insurer to refuse to pay any claim under any insurance policy in which that sub-contractor is an insured, a co-insured or additional insured person.

10.6 The provisions of these conditions do not apply where the sub-contractor is part of the Crown or a Research Council.

11. MONITORING OF PROGRESS AND ACCESS TO DOCUMENTS

11.1 In order to monitor the Contractor's performance of the Projects, the Authority or its representative (which for these purposes may include the Controller and Auditor General and any of his representatives) or his servants or agents, may enter into and inspect at all reasonable times and, save where the Authority has good reason not to give any notice, on reasonable notice, all facilities (whether at the Contractor's premises or elsewhere) used by the Contractor in its performance of its obligations under the Agreement.

11.2 The Contractor agrees that the Authority shall be entitled to audit the Contractor's performance of the Projects and inspect at all reasonable times and, save where the Authority have good reason not to give any notice, on reasonable notice, any and all records of the Contractor connected with its activities under the Agreement.

11.3 The Contractor agrees to make available to the Authority, free of charge, whenever requested, copies of audit reports obtained by the Contractor in relation to the Projects.

11.4 The Contractor shall retain or ensure that it has access to all records which relate to the Projects. On completion of the Projects, or in the event that the Agreement is terminated pursuant to condition 23 or otherwise, the Contractor shall at the direction of the Authority either retain or transfer to the Authority those records required by the Authority, or, where such records are in the possession of any third party, procure that the same is done. If the Authority requires the Contractor to transfer the records to it or to any third party, the Contractor shall be entitled to retain a copy of them.

11.5 For a period not less than 3 years after the completion of the Project or, where relevant, its termination, the Contractor shall retain in its possession all records and documentation relating to the Project unless they have been transferred to the Authority or a third party in accordance with condition 11.4 above.

11.6 The Contractor shall permit duly authorised agents of the Authority and/or the National Audit Office or European Court of Auditors to examine the Contractor's records and documents relating to the Agreement and to provide such copies and oral or written explanations as may reasonably be required.

11.7 This condition does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Contractor under section 6(3) and 6(5) of the National Audit Act 1983.

12. CONTRACTOR'S PERFORMANCE AND PERSONNEL

12.1 The Contract will be monitored throughout the year, specifically at bi-monthly and annual contract review meetings. The Contractor shall properly manage and monitor the Projects and immediately inform the Authority if any aspect of the Agreement is not being or is unable to be performed.

Any performance issues highlighted at the bi-monthly contract review meetings will be

addressed by the Contractor, who will be required to provide an improvement plan to address all issues highlighted within a week of the meeting. Performance management and KPI performance will be a key feature of the Contract Review meetings.

12.2 The Contractor shall provide all the necessary facilities and Equipment necessary to complete the Projects.

12.3 The Contractor shall deploy sufficient personnel of appropriate qualifications, competence and experience to complete the Projects to time and shall ensure that those personnel are properly managed and supervised.

12.4 The Contractor shall give the Authority, if so requested, such particulars as the Authority may reasonably require of all persons who are or may be at any time employed on the Projects.

12.5 If, after due consultation with the Contractor, the Authority gives the Contractor notice that any person or Equipment is to be removed from involvement in a Project, the Contractor shall take immediate steps to comply with such notice and such decision of the Authority shall be final and conclusive.

12.6 The Contractor shall take all reasonable steps to avoid any changes of Key Personnel, but where the Contractor considers it necessary to do so, he will give the Authority not less than one month's notice of any intention to change any Key Personnel and the reasons for such change.

13. UNSATISFACTORY PERFORMANCE

13.1 Where in the reasonable opinion of the Authority the Contractor has failed to:

13.1.1 comply with any of the warranties in Condition 7;

13.1.2 fulfil his obligations under the Reports and Intellectual Property Schedules; or

13.1.3 progress the Project in accordance with the objectives, approaches and research plan, and milestones agreed for the Project.

the Authority may give the Contractor a notice specifying the way in which his performance falls short of the requirements of the Contract or is otherwise unsatisfactory.

13.2 Where the Contractor has been notified of a failure in accordance with Condition 13.1 the Authority may:

13.2.1 direct the Contractor, to remedy the failure at his own expense within such

time as may be specified by the Authority; and/or

12.2.2 withhold or reduce payments to the Contractor, in such amount as the

Authority reasonably deems appropriate in each particular case.

13.3 If, having been notified of any failure, the Contractor fails to remedy it in accordance with Condition 13.2, the Authority may treat the continuing failure as a material breach of the Agreement.

14. UNLAWFUL DISCRIMINATION

14.1 The Contractor shall perform its obligations under this Agreement in accordance with:

14.1.1 all applicable equality law (whether in relation to race, sex, gender reassignment, age, disability, sexual orientation, religion or belief, pregnancy maternity or otherwise), including but not limited to the obligations under the Equality Act 2010;

14.1.2 the Authority's equality and diversity policy as given to the Contractor from time to time;

14.1.3 any other requirements and instructions which the Authority reasonably imposes in connection with any equality obligations imposed on the Authority at any time under applicable equality law; and

14.1.4 the taking of all necessary steps and to inform the Authority of the steps taken to prevent unlawful discrimination designated as such by any court or tribunal, or the Equality and Human Rights Commission (or any successor organisation).

15. HEALTH AND SAFETY

In carrying out the Projects, the Contractor shall comply with best practice and all relevant provisions, whether statutory or otherwise, relating to health and safety at work and shall ensure that any person engaged in relation to the Agreement also so complies, and shall produce evidence of such compliance, if asked by the Authority to do so.

16. PREVENTION OF FRAUD AND BRIBERY

16.1 The Contractor shall comply with all applicable laws, statutes and regulations relating to anti-bribery and anti-corruption including but not limited to the Bribery Act 2010 (the "**Relevant Requirements"**).

16.2 The Contractor shall have and maintain in place throughout the term of this agreement its own policies and procedures, including adequate procedures under the Bribery Act 2010, to ensure compliance with the Relevant Requirements and will enforce them where appropriate. The meaning of adequate procedures shall be determined in accordance with section 7(2) of the Bribery Act 2010 (and any guidance issued under section 9 of that Act).

16.3 The Contractor will promptly report to the Authority any request or demand for any undue financial or other advantage of any kind received by the Contractor in connection with the performance of this Agreement.

17. CONFLICT OF INTEREST

17.1 The Contractor shall ensure that there is no conflict of interest as to be likely to prejudice his impartiality and objectivity in performing the Projects and undertakes that upon becoming aware of any such conflict of interest during the performance of the Projects (whether the conflict existed before the award of the Agreement or arises during the performance of the Projects) he shall immediately notify the Authority in writing of the same, giving particulars of its nature and the circumstances in which it exists or arises and shall furnish such further information as the Authority may reasonably require.

17.2 Where the Authority is of the opinion that the conflict of interest notified to it under Condition 17.1 is capable of being avoided or removed, the Authority may require the Contractor to take such steps as are necessary to avoid or remove the conflict at the Contractor's expense.

17.3 If the Contractor fails to avoid or remove the conflict the Authority may terminate the Agreement and recover from the Contractor, the amount of any loss resulting from such termination.

17.4 Where the Authority is of the opinion that the conflict of interest which existed at the time of

the award of the Agreement could have been discovered with the application by the Contractor of due diligence and ought to have been disclosed, the Authority may terminate the Agreement immediately for breach of a fundamental condition and, without prejudice to any other rights, recover from the Contractor the amount of any loss resulting from such termination.

18. PUBLICATION AND DISCLOSURE

18.1 Subject to the provisions of conditions 18.3, 18.4 and 18.6, the Contractor shall endeavour to make information about, and results from the Projects generally available, and may do so provided he acknowledges in any public statement the financial support of the Authority.

18.2 Subject to the requirements of the Reports Schedule, the Authority shall have the right to disclose, copy or otherwise distribute to the public or use in any way any information arising out of the Projects or comprised in any work relating to the Projects, as it sees fit.

18.3 Where any Project, or any matter related to it, has been identified as being sensitive by:

18.3.1 the Contractor, or

18.3.2 the Authority, as notified in writing to the Contractor,

the Contractor shall give written notice to be received by the Authority at least 10 working days before any planned public statement or other disclosure relating to the Project, providing details of the information proposed to be disclosed, the reason, and the medium of disclosure.

18.4 The Contractor shall notify the Authority immediately if approached by the media about any Project. The Contractor shall notify the Authority immediately if approached by anyone about a matter related to any Project which is considered sensitive by the Contractor, or by the Authority as notified to the Contractor in accordance with condition 18.3.2.

18.5 For the avoidance of doubt, the notifications required by conditions 18.3 and 18.4 are for the purposes of informing the Authority or the Contractor (as the case may be) and are not designed to interfere with the issue of any public statement.

18.6 Where the carrying out of any Project results in, or materially contributes to, the creation of Intellectual Property which the Contractor or the Authority considers may be suitable for commercial exploitation no disclosure of information may be made by the Contractor which would jeopardise such exploitation.

18.7 The Parties acknowledge that, in order to be compliant with the Freedom of Information Act 2000, the Environmental Information Regulations 2004, or any other applicable legislation governing access to information (the "FOI Legislation"), the Parties may be obliged to provide information, on request, to third parties that relates to this Agreement.

18.8 In the event that either Party receives a request for information relating to the Agreement falling within the scope of the FOI Legislation, the Party shall be entitled to disclose such information as necessary in order to ensure its compliance with the FOI Legislation. Where the Party reasonably considers that information is exempt from disclosure, it shall use reasonable endeavours to consult with the other Party.

18.9 In the event that either Party requires the other Party's assistance in supplying any information falling within the scope of the FOI legislation that is held or controlled by the other Party or any other person engaged in relation to the Agreement, the disclosing Party will provide such assistance, at its own cost within ten (10) days of receiving the request.

18.10 A Party shall not be liable for any loss, damage, harm or other detriment suffered by the

other Party arising from the disclosure of any information falling within the scope of the FOI Legislation.

19. DATA PROTECTION

19.1 The Parties acknowledge that for the purposes of the Data Protection Legislation, the Authority is the Controller and the Contractor is the Process or unless otherwise specified in Schedule D. The only processing that the Contractor is authorised to do is listed in Schedule D by the Authority and may not be determined by the Contractor.

19.2 The Contractor shall notify the Authority immediately if it considers that any of the Authority's instructions infringe the Data Protection Legislation.

19.3 The Contractor shall provide all reasonable assistance to the Authority in the preparation of any Data Protection Impact Assessment prior to commencing any processing. Such assistance may, at the discretion of the Authority, include:

(a) a systematic description of the envisaged processing operations and the purpose of the processing;

(b) an assessment of the necessity and proportionality of the processing operations in relation to the Services;

(c) an assessment of the risks to the rights and freedoms of Data Subjects; and

(d) the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.

19.4 The Contractor shall, in relation to any Personal Data processed in connection with its obligations under this Contract:

(a) process that Personal Data only in accordance with Schedule D unless the Contractor is required to do otherwise by Law. If it is so required, the Contractor shall promptly notify the Authority before processing the Personal Data unless prohibited by Law;

(b) ensure that it has in place Protective Measures which are appropriate to protect against a Data Loss Event, which the Authority may reasonably reject (but failure to reject shall not amount to approval by the Authority of the adequacy of the Protective Measures), having taken account of the:

nature of the data to be protected;

harm that might result from a Data Loss Event;

state of technological development; and

cost of implementing any measures;

(c) ensure that:

the Staff do not process Personal Data except in accordance with this Contract (and Schedule D);

it takes all reasonable steps to ensure the reliability and integrity of any Staff who have access to the Personal Data and ensure that they:

are aware of and comply with the Contractor's duties under this clause;

are subject to appropriate confidentiality undertakings with the Contractor or any Sub-processor;

are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third party unless directed in writing to do so by the Authority or as otherwise permitted by this Contract; and

have undergone adequate training in the use, care, protection and handling of Personal Data; and

not transfer Personal Data outside of the European Union unless the prior written consent of the Authority has been obtained and the following conditions are fulfilled:

the Authority or the Contractor has provided appropriate safeguards in relation to the transfer (whether in accordance with the GDPR Article 46 or LED Article 37) as determined by the Authority;

the Data Subject has enforceable rights and effective legal remedies;

the Contractor complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Authority in meeting its obligations); and

the Contractor complies with any reasonable instructions notified to it in advance by the Authority with respect to the processing of the Personal Data;

at the written direction of the Authority, delete or return Personal Data (and any copies of it) to the Authority on termination of the Contract unless the Contractor is required by Law to retain the Personal Data.

19.5 Subject to clause 19.6 the Contractor shall notify the Authority immediately if, in relation to any Personal Data processed in connection with its obligations under this Contract, it:

(a) receives a Data Subject Request (or purported Data Subject Request);

(b) receives a request to rectify, block or erase any Personal Data;

(c) receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;

(d) receives any communication from the Information Commissioner or any other regulatory authority;

(e) receives a request from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law; or

(f) becomes aware of a Data Loss Event.

19.6 The Contractor's obligation to notify under clause 19.5 shall include the provision of further information to the Authority in phases, as details become available.

19.7 Taking into account the nature of the processing, the Contractor shall provide the Authority with full assistance in relation to either Party's obligations under Data Protection Legislation in relation to any Personal Data processed in connection with its obligations under this Contract

and any complaint, communication or request made under Clause 19.5 (and insofar as possible within the timescales reasonably required by the Authority) including by promptly providing:

(g) the Authority with full details and copies of the complaint, communication or request;

(h) such assistance as is reasonably requested by the Authority to enable the Authority to comply with a Data Subject Request within the relevant timescales set out in the Data Protection Legislation;

(i) the Authority, at its request, with any Personal Data it holds in relation to a Data Subject;

(j) assistance as requested by the Authority following any Data Loss Event;

(k) assistance as requested by the Authority with respect to any request from the Information Commissioner's Office, or any consultation by the Authority with the Information Commissioner's Office.

19.8 The Contractor shall maintain complete and accurate records and information to demonstrate its compliance with this clause. This requirement does not apply where the Contractor employs fewer than 250 staff, unless:

(l) the Authority determines that the processing is not occasional;

(m) the Authority determines the processing includes special categories of data as referred to in Article 9(1) of the GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the GDPR; or

(n) the Authority determines that the processing is likely to result in a risk to the rights and freedoms of Data Subjects.

19.9 The Contractor shall allow for audits of its Personal Data processing activity by the Authority or the Authority's designated auditor.

19.10 Each Party shall designate its own Data Protection Officer if required by the Data Protection Legislation.

19.11 Before allowing any Sub-processor to process any Personal Data related to this Contract, the Contractor must:

(o) notify the Authority in writing of the intended Sub-processor and processing;

(p) obtain the written consent of the Authority;

(q) enter into a written agreement with the Sub-processor which give effect to the terms set out in this clause 19 such that they apply to the Sub-processor; and

(r) provide the Authority with such information regarding the Sub-processor as the Authority may reasonably require.

19.12 The Contractor shall remain fully liable for all acts or omissions of any of its Sub-processors.

19.13 The Authority may, at any time on not less than 30 Working Days' notice, revise this clause by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to this Contract).

19.14 The Parties agree to take account of any non-mandatory guidance issued by the Information Commissioner's Office. The Authority may on not less than 30 Working Days' notice to the Contractor amend this Contract to ensure that it complies with any guidance issued by the Information Commissioner's Officer.

19.15 This clause 19 shall apply during the Contract Period and indefinitely after its expiry.

20. AUTHORITY'S PROPERTY

20.1 The Authority's Property shall include any property owned by the Authority including any item of equipment costing in excess of £2,000 which will yield continuous service for at least one year, for which the Authority has reimbursed the Contractor.

20.2 The Authority's Property shall remain the property of the Authority and shall be used in the performance of the Agreement and for no other purpose without prior approval of the Authority.

20.3 The Contractor shall ensure that the title in the Authority's Property is brought to the attention of any third party dealing with the Authority's Property.

20.4 On receipt of the Authority's Property, the Contractor shall subject it to a visual inspection and such additional inspection and testing as may be necessary to check that it is not defective. If the Contractor discovers any defect, he shall notify the Authority within 14 days of receipt of the Property, or such other period as may be agreed with the Authority. The Authority shall, within 14 days of receiving such notification, inform the Contractor of the action to be taken

20.5 The Authority shall be responsible for the repair or replacement of its Property unless the need for repair or replacement is caused by the Contractor's failure to comply with Condition 20.4, or by the negligence or default of the Contractor.

20.6 The Contractor shall maintain all items of the Authority's Property in good and serviceable condition (fair wear and tear excepted), and in accordance with the manufacturer's recommendations.

20.7 The Contractor shall be liable for any loss of or damage to any of the Authority's Property unless the Contractor is able to demonstrate that such loss or damage was caused or contributed to by the negligence or default of the Authority.

20.8 The Authority shall have the right to require the Contractor either to pass the Authority's Property into the Authority's possession or to dispose of it. In the latter event, the Contractor shall pass to the Authority any monies realised by the disposal.

21. EQUIPMENT

21.1 All Equipment purchased by the Contractor for use on the Projects shall, where reasonably practicable, be acquired by competitive tender.

21.2 Unless otherwise agreed in writing with the Authority, the Contractor shall provide the Equipment necessary for the provision of the Projects.

21.3 The Contractor shall maintain all items of Equipment in good and serviceable condition.

21.4 All Equipment shall be at the risk of the Contractor and the Authority shall have no liability for any loss of or damage to any Equipment except to the extent that the Contractor is able to demonstrate that such loss or damage was caused or contributed to by the negligence or default of the Authority.

22. INTELLECTUAL PROPERTY

22.1 Each Party shall comply with Intellectual Property Schedule A.

22.2 Each Party shall inform the other Party promptly if it becomes aware of any infringement or potential infringement of any of the Intellectual Property rights, and the Parties shall consult with each other to decide the best way to respond to such infringement.

22.3 If any warning letter or other notice of infringement is received by a party, or legal suit or other action is brought against a party, alleging infringement of third party rights in the manufacture, use or sale of any licensed product or use of any patents or Intellectual Property rights, that party shall promptly provide full details to the other party, and the parties shall discuss the best way to respond.

22.4 The Contractor shall indemnify the Authority and keep the Authority fully and effectively indemnified against all claims, damages or losses arising from or incurred by reason of any infringement or alleged infringement (including but not limited to the defence of such alleged infringement in the United Kingdom) of any Intellectual Property rights in connection with the use, exercise or commercial exploitation of the Results (other than where any such claim arises as a result of the Authority's negligence or willful default).

23. TERMINATION

23.1 The Contractor shall notify the Authority in writing immediately upon the occurrence of any of the following events:

23.1.1 being an individual: -

a) is the subject of a bankruptcy order; or

b) has made a composition or arrangement with his creditors;

23.1.2 being a company: -

a) goes into compulsory winding up; or
b) passes a resolution for voluntary winding up; or
c) suffers an administrator, administrative receiver or receiver and manager to be appointed or to take possession over the whole or any part of its assets
d) has entered a voluntary arrangement with its creditors under Part I of the Insolvency Act 1986, or has proposed or entered any scheme of arrangement or composition with its; or
e) has been dissolved;

23.1.3 being a partnership or unregistered company: -

a) goes into compulsory winding up; or
b) is dissolved; or (in the case of a partnership only)
c) suffers an administrator or receiver and manager to be appointed over the whole or any part of its assets; or
d) has entered a composition or voluntary arrangement with its creditors; or
e) any individual member of the partnership falls within Condition 23.1.1 above;

23.1.4 Or is in any case affected by any similar occurrence to any of the above in any jurisdiction.

On the occurrence of any of the events described in this condition 23.1 or, if the Contractor shall have committed a material breach of the Agreement and (if such breach is capable of remedy) shall have failed to remedy such breach within thirty days of being required by the Authority in writing to do so, the Authority shall be entitled to terminate this Agreement by notice to the Contractor with immediate effect and without compensation to the Contractor.

23.2 The Authority may terminate the Contract at any time by giving 30 days' notice to the Contractor.

23.3 Without prejudice to the provisions of this condition, the Contractor may submit a request to the Authority to withdraw from the Agreement. The Agreement may be terminated by written agreement between the Contractor and the Authority at any time.

23.4 Without prejudice to the provisions of this condition, either Party may submit a request to the other Party to withdraw from the Agreement. The Agreement may be terminated by written agreement between the Contractor and the Authority at any time.

23.5 Except as expressly provided in this Agreement, termination of the Agreement shall not affect:

23.5.1 any obligation or liability of any Party which has accrued at the date of termination;

23.5.2 any of the provisions of this Agreement which are intended to continue to have effect after the Agreement has been terminated including without limitation the obligations contained in the Intellectual Property Schedule.

23.6 The initial Contract period will be for three (3) years and there is a break clause included at every 6 months of the contract. This break clause may be implemented by the Authority only.

24. PAYMENT ON TERMINATION

24.1 Without prejudice to any other rights or remedies of the Authority, in the event of the Agreement being terminated:

24.1.1 by the Authority in accordance with condition 23 by reason of the default of the Contractor; or

24.1.2 otherwise by reason of the Contractor's breach of the Agreement;

the Authority shall be under no obligation to make any payment to the Contractor for such period as is reasonable for the Authority to assess the loss and/or damage suffered as a result of the termination.

24.2 After such period, the Authority may set off against any sums otherwise due to the Contractor, or recover as a debt, the amount of loss and/or damage the Authority has reasonably assessed as resulting from the termination of the Agreement.

24.3 Any overpayment by the Authority to the Contractor, whether of the agreed price or Value Added Tax, shall be a sum of money recoverable by the Authority from the Contractor.

25. MERGER, TAKEOVER OR CHANGE OF CONTROL

The Contractor shall forthwith inform the Authority in writing of any proposal or negotiations which will or may result in a merger, take-over, change of control, change of name or status, including, where the Contractor is a company as defined in the Companies Act 2006, any change in "control" as defined in Section 1124 of the Corporation Taxes Act 2010.

26. TRANSFER OF RIGHTS AND OBLIGATIONS

26.1 The Contractor shall not sub-contract, transfer, assign, charge, or otherwise dispose of the Agreement or any part of it without the prior written consent of the Authority.

26.2 The Contractor shall ensure, if so, requested by the Authority, that an assignee enters into a novation agreement with the Authority to perform the Agreement as if the assignee were a party to the Agreement in lieu of the Contractor.

26.3 The Contractor shall ensure that any sub-contractor complies with the terms and Conditions of the Agreement, so far as they are applicable and shall provide to the Authority, at its request copies of any sub-contracts. Any sub-contract shall not relieve the Contractor of his obligations under the Agreement.

26.3 The Authority may at any time, on written notice to the Contractor, transfer or assign all or any rights and/or obligations under the Agreement.

27. RIGHTS OF THIRD PARTIES

For the purposes of the Contracts (Rights of Third Parties) Act 1999, this Agreement is not intended to, and does not give any person who is not a party to it any right to enforce any of its provisions.

28. WAIVER AND VARIATION

28.1 The failure of the Authority or the Contractor to exercise any right or remedy shall not constitute a waiver of that right or remedy.

28.2 A waiver of any right or remedy arising from a breach of the Agreement shall not constitute a waiver of any right or remedy arising from any other breach of the Agreement.

28.3 No waiver shall be effective unless it is communicated to either the Authority or the Contractor in writing.

28.4 Any variation of any provision of this Agreement must be effected in writing and issued by the Authority. No purported variation by any other means shall bind the Authority.

29. SEVERANCE

If any condition, clause or provision of the Agreement which is not of a fundamental nature is held to be invalid, illegal or unenforceable for any reason by any court of competent jurisdiction in any proceedings relating to the Agreement, such provision shall be severed and the validity or enforceability of the remainder of the Agreement shall not be affected thereby.

30. NOTICES

30.1 Any notice required to be given under, or any communication between the parties with the respect to any of the provisions of the Agreement shall be in writing in English and shall be deemed duly given if signed by or on behalf of a duly authorised officer of the party giving the notice and if left at, or sent by pre-paid registered or recorded delivery post, or by facsimile transmission or other means of electronic telecommunication in permanent written form to the address of the receiving party as specified in the Agreement (as or amended from time to time by due notice in writing to other party).

30.2 Any such notice or other communication shall be deemed to have been given and received by the addressee:-

30.2.1 at the same time as it is left at the address of or handed to a representative of the party to be served;

30.2.2 by post on the day (not being a Sunday or public holiday two days following the date of posting);

30.2.3 in the case of a facsimile or email or other type of electronic telecommunication on the day following dispatch.

30.3 In proving the giving of a notice it shall be sufficient to prove that the notice was left, or that the envelope containing the notice was correctly addressed and was posted, or that the facsimile or e-mail or other form of electronic communication was correctly addressed and was dispatched and dispatch of the transmission was confirmed and (in the case of a facsimile) confirmed as having been sent to the number above with all pages successfully transmitted.

31. SPECIAL PROVISIONS

Subject to paragraph 8 of the Form of Contract, in the case of any conflict or inconsistency between these Terms and Conditions and any conditions contained within the Form of Contract or the Schedules, the latter conditions shall prevail.

32. ENTIRE AGREEMENT

The Agreement and any variation made in accordance with condition 28 sets out the entire agreement between the Parties and supersedes any prior agreement whether formal or informal and whether legally within the Agreement.

33. LEGAL RELATIONSHIP

Nothing in this Agreement shall be construed so as to create a partnership or joint venture between the Parties or have the effect of making any employee of any one party a servant of the other party. Neither party shall act or describe itself as the agent of the other nor shall it make or represent that it has authority to make any commitments on the other's behalf.

34. DISPUTE RESOLUTION

34.1 The Parties shall in good faith attempt to negotiate a settlement to any dispute between them arising out of or in connection with the Agreement.

34.2 If any such dispute cannot be resolved in accordance with condition 34.1, the relevant Parties shall consider referring the matter to mediation in accordance with condition 34.3.

34.3 The procedure for mediation shall be as follows:

34.3.1 a neutral person ("the Mediator") shall be chosen by agreement between the relevant Parties, alternatively, any Party may within 14 days from the date of the proposal to appoint a mediator, or within 14 days of notice to any Party that the chosen mediator is unable or unwilling to act, apply to the Centre for Dispute Resolution ("CEDR") to appoint a mediator;

34.3.2 the relevant Parties shall within 14 days of the appointment of the Mediator meet with him or her to agree a timetable for the exchange of all relevant and necessary information and the procedure to be adopted for the mediation. If appropriate, the relevant Parties may at any stage seek from CEDR guidance on a suitable procedure;

34.3.3 unless otherwise agreed, all negotiations and proceedings in the mediation connected with the dispute shall be conducted in strict confidence and shall be without prejudice to the rights of the relevant Parties in any future proceedings;

34.3.4 if the relevant Parties reach agreement on the resolution of the dispute, that agreement shall be put in writing and shall be binding upon the relevant Parties;

34.3.5 failing agreement, any relevant Party may invite the Mediator to provide a non-binding but informative opinion in writing. Such opinion shall be provided on a without prejudice basis and shall not be used in evidence in any proceedings relating to the dispute without the prior written consent of the relevant Parties.

34.4 For a period of sixty days from the date of the appointment of the Mediator, or such other period as the relevant Parties may agree, none of the Parties to the dispute may commence any proceedings in relation to the matters referred to the Mediator.

35. OFFICIAL SECRETS ACT

The Contractor shall take all reasonable steps to ensure that any persons employed by him or by any sub-contractor in connection with the Projects are aware of the Official Secrets Acts 1911 to 1989, and that these Acts apply to them during and after performance of any services under or in connection with the Agreement.

36. RE-TENDERING AND HANDOVER

36.1 Within 21 days of being so requested by the Authority's Representative, the Contractor shall provide, and thereafter keep updated, in a fully indexed and catalogued format, all the information necessary to enable the Authority to issue tender documents for the future provision of any Project.

36.2 Where, in the opinion of the Authority, the Transfer of Undertakings (Protection of Employment) Regulations 2006 are likely to apply on the termination of expiration of any Project or Projects, the information to be provided by the Contractor under Condition 36.1 shall include, as applicable, accurate information relating to the staff who would be transferred under the same terms of employment under those Regulations, including in particular:

36.2.1 the number of staff who would be transferred, but with no obligation on the Contractor to specify their names;

36.2.2 in respect of each of those members of staff their age, sex, salary, length of service, hours of work, overtime hours and rates, any other factors affecting redundancy entitlement and any outstanding claims arising from their employment;

36.2.3 the general terms and conditions applicable to those members of staff, including probationary periods, retirement age, periods of notice, current pay agreements,

working hours, entitlement to annual leave, sick leave, maternity and special leave, terms of mobility, any loan or leasing schemes, any relevant collective agreements, facility time arrangements and additional employment benefits.

36.3 The Authority shall take all necessary precautions to ensure that the information referred to in Conditions 36.2 is given only to service providers who have qualified to tender for the future provision of any Project.

36.4 The Authority shall require that all potential providers treat the information in confidence; that they do not communicate it except to such persons within their organisation and to such extent as may be necessary for the purpose of preparing a response to an invitation to tender issued by the Authority; and that they shall not use it for any other purpose.

36.5 The Contractor shall indemnify the Authority against any claim made against the Authority at any time by any person in respect of any liability incurred by the Authority arising from any deficiency or inaccuracy in information which the Contractor is required to provide under Condition 36.2

36.6 The Contractor shall not –

36.6.1 at any time during the Agreement, including any extension, move any staff into the undertaking or relevant part of the undertaking which provides the Projects, who do not meet the standards of skill and experience, or who are in excess of the number, required for the purposes of the Agreement; or

36.6.2 make any substantial change in the terms and conditions of employment of any staff engaged in providing the Projects, which is inconsistent with the Contractor's established employment and remuneration policies.

36.7 Where, in the opinion of the Authority, any change or proposed change in the staff employed in the undertaking or relevant part of the undertaking, or any change in the terms and conditions of employment of such staff, would be in breach of Condition 36.6 the Authority shall have the right:

36.7.1 to make representations to the Contractor against the change or proposed change;

36.7.2 to give notice to the Contractor requiring him to remedy the breach within 30 days; and

36.7.2 if the Contractor has not remedied the breach to the satisfaction of the Authority by the end of the period of 30 days, to terminate the Agreement by reason of the default of the Contractor, in accordance with Condition 23.2.

36.8 The Contractor shall allow access to his premises, in the presence of the Authority's Representative, to any person representing any potential provider whom the Authority has selected to tender for the future provision of the Project or Projects.

36.9 For the purpose of access to the premises in accordance with Condition 36.8, the Authority shall give the Contractor 7 days' notice of a proposed visit together with a list showing the names of all persons who will be attending those premises. Their attendance shall be subject to compliance with the Contractor's security procedures, subject to such compliance not being in conflict with the objectives of the visit.

36.10 The Contractor shall co-operate fully with the Authority during the handover arising from the completion or earlier termination of any Project. This co-operation, during the setting up operations period of the new Contractor, shall extend to allowing full access to, and providing copies of, all documents, reports, summaries and any other information necessary in order to achieve an effective transition without disruption to routine operational

requirements.

36.11 Within 10 working days of being so requested by the Authority's representative, the Contractor shall transfer to the Authority, or any person designated by the Authority, free of charge, all computerised filing, recording, documentation, planning and drawing held on software and utilised in the provision of the Project or Projects. The transfer shall be made in a fully indexed and catalogued disk format, to operate on a proprietary software package identical to that used by the Authority.

37. OCCUPATION OF GOVERNMENT PREMISES

Any land or premises (including temporary buildings) made available to the Contractor by the Authority in connection with the Agreement shall be made available to the Contractor free of charge and shall be used by the Contractor solely for the purposes of performing the Agreement. The Contractor shall have the use of such land or premises as licensee and shall vacate the same upon completion or determination of the Agreement. Any utilities required by the Contractor shall be subject to such charges as are set out elsewhere in the Agreement.

38. ENVIRONMENTAL REQUIREMENTS

38.1 The Contractor shall perform the Agreement in accordance with the Department's environmental policy, which is to conserve energy, water, wood, paper and other resources, reduce waste and phase out the use of ozone depleting substances and minimise the release of greenhouse gases, volatile organic compounds and other substances damaging to health and the environment.

38.2 The Contractor shall pay due regard to the use of recycled products, so long as they are not detrimental to the provision of the Projects or the Environment, to include the use of all packaging, which should be capable of recovery for re-use or recycling.

38.3 The Contractor shall take all possible precautions to ensure that any equipment and materials use in the provision of the Projects do not contain chlorofluorocarbons, halons or any other damaging substances, unless unavoidable, in which case the Authority shall be notified in advance of their use.

38.4 All written work in connection with the Agreement shall (unless otherwise agreed with the Authority) be produced on recycled paper containing at least 80% post-consumer waste and used on both sides where appropriate.

39. GOVERNING LAW

The Agreement shall be governed by and interpreted in accordance with English law and shall be subject to the jurisdiction of the Courts of England and Wales. The submission to such jurisdiction shall not (and shall not be construed so as to) limit the right of the Authority take proceedings against the Contractor in any other court of competent jurisdiction, nor shall the taking of proceedings in any other court of competent jurisdiction preclude the taking of proceedings in any other jurisdiction whether concurrently or not.

INTELLECTUAL PROPERTY SCHEDULE A - INTELLECTUAL PROPERTY RIGHTS VESTED IN THE CONTRACTOR

Ownership and protection

1. Subject to the Contractor complying with the Agreement, any prior rights and the rights of third parties, all rights in relation to the Results shall be vested in the Contractor. Where the Contractor is a Crown body, any copyright shall vest in the Crown.

2. The Contractor shall:

   2.1 ensure that all its staff, students and sub-contractors are and will be engaged in relation to the Agreement and the Projects on terms which vest all rights in Results in the Contractor;

   2.2 continue to report to the Authority at regular intervals (and in any case at least once in every Project Year for so long as the Results are capable of or are being exploited) on the progress of commercial exploitation of the Results and on any assignment or licence of the Results; and

   2.3 do all things and execute at the Authority's expense any documents reasonably required to give effect to such vesting or assignment/licensing in the Authority as is necessary to give effect to paragraph 12 of Schedule A.

Licence back

3. The Contractor hereby grants to the Authority an irrevocable world-wide non-exclusive licence in perpetuity free of any charge or royalty to use the Results for:

   3.1 the purposes of paragraph 4 of the Reports Schedule;

   3.2 the purposes of Condition 18.2 of the Defra Terms and Conditions for Research and Development Projects in the Agreement;

   3.3 any other Government purposes;

   and to sub-licence and sub-sub-licence the Authority's rights on the same terms as the licence. The Contractor shall ensure that any such licence shall be binding on any successor, transferee or assignee of the Contractor.

4. Where such use of the Results by the Authority or sub-licensees also requires a licence to use any Intellectual Property rights of the Contractor other than the Results, the Contractor shall grant such a licence, subject to existing third party rights, which shall be royalty-free where such use is for non-commercial purposes, but shall be on reasonable terms to be agreed between the Parties in good faith where such use is for commercial or revenue generating purposes.

Commercial exploitation

5. The Contractor will use its reasonable endeavours to exploit the Results commercially for its benefit and the benefit of the Authority.

6. In order to comply with Government policy:

   6.1 the Contractor shall identify and inform the Authority of any Results which he considers suitable for commercial exploitation, and shall use reasonable endeavours to pursue or procure commercial exploitation thereof;

6.2 the Contractor shall provide to the Authority such information as the Authority may reasonably require regarding commercial exploitation of the Results, including details of any licences to third parties granted in respect of the Results/Intellectual Property.

7. Subject to paragraph 12, the Contractor shall:

7.1 identify and inform the Authority of any Results which may be suitable for protection and exploitation;

7.2 secure such protection for the Results in all or any part of the world, and shall maintain such protection as is necessary to promote commercial exploitation of the Results at his own expense; and

7.3 inform the Authority of any such Results so protected, and of any subsequent assignment or licence of such Results.

8. Subject to paragraph 9 and without prejudice to paragraph 12, and irrespective of whether the Contractor has assigned the Results, the Income from the commercial exploitation of the Results shall, after deduction of allowable costs as described in paragraph 10, be apportioned between the Parties as follows:

8.1. The Authority, 10%;

8.2 The Contractor, 90%.

9. The income referred to in paragraph 8 shall be payable for the longer of:

9.1 The term of any patent arising from or incorporating any of the Results; or

9.2 The period in which any Know-How arising from the Results and used in any products or services exploited by the Contractor remains secret and substantial.

10. The allowable costs of the Parties, for the purposes of paragraph 8, shall not include any of the sums referred to in Annex A and shall be limited to:

10.1 the registration fees for the registering or maintaining of any rights and any associated filing and prosecution costs in relation to such Results;

10.2 any legal or other professional fees and costs reasonably incurred in relation to legal proceedings in relation to such Results in any appropriate forum and before any appropriate tribunal in any country and any costs ordered by any such tribunal to be paid by the Parties or any of them;

10.3 any other reasonable cost or expenditure which may be agreed from time to time by the Authority and the Contractor;

10.4 subject to the Authority's prior agreement, any reasonable marketing, packaging and/or distribution costs, and any relevant experimental development costs including costs of field trials and/or demonstration projects incurred at the Contractor's expense.

11. The Contractor shall have sole responsibility for making any payments due to his employees, students or contractors under any rewards or incentive schemes, whether contractual, ex gratia, or statutory, in relation to the Results, and any such payments shall not be a cost or expenditure liable to be subtracted from any Income pursuant to paragraph 8 above.

12. If so requested by the Authority, the Contractor will inform the Authority, in writing, whether or not he intends to protect or exploit any part of the Results in any part of the world. If the Contractor does not intend to protect or exploit the Results but the Authority desires such protection to be obtained or to carry out such exploitation then the Authority shall be entitled to obtain such protection at its own cost and to have assigned at no charge any such part of the Results which the Contractor has given notice that he does not intend to pursue or no longer has interest in pursuing. The Contractor will not be entitled to any share of the income generated as the result of the exploitation of Intellectual Property by the Authority.

13. The Contractor shall keep at its normal place of business detailed accurate and up to date records and accounts showing details of its commercial exploitation of the Results including the sale of products or services which incorporate the Results, Income received, allowable costs deducted and the amount of licensing revenues received by it in respect of the Results in a format sufficient to ascertain that revenue sharing pursuant to this Agreement has been properly accounted for and apportioned in accordance with this Agreement. The Contractor shall make such records and accounts available at its premises in the United Kingdom on reasonable notice for inspection during business hours by the Authority or its representatives for the purpose of the verifying the accuracy of any statement or report given by the Contractor to the Authority and to take copies and shall supply the Authority or its representative with such explanation as it may request.

14. Subject to paragraph 12, the Contractor shall indemnify the Authority and sub-licensees and keep them fully indemnified from and against any claims which they may sustain or incur, or which may be brought or established against any of them, by any person, and which in any case arise directly or indirectly out of or in relation to or by reason of:

    14.1 any instruction or advice given by the contractor on how to apply the Results;

    14.2 the Contractors' or his licensee's or sub licensee's possession, operation, copying or use of the Results; or

    14.3 product liability rights arising out of any product developed from the Results or any work resulting in such a product (save to the extent that such liability arises solely as a result of the acts of omissions of or on behalf of the Authority or sub-licensee).

Miscellaneous

15. If the Contractor is unable to carry out his obligations or satisfy any requirements under the Agreement due to any infringement or alleged infringement of any Intellectual Property right which he cannot rectify within a reasonable period such inability shall be deemed a breach by the Contractor and the Authority may without prejudice to any other rights and remedies exercise the powers and remedies available to it under Condition 22.

16. For the avoidance of doubt, and subject to the provisions of paragraph 4, the provisions of this Schedule do not apply to and do not affect any Intellectual Property in existence before the commencement of the Projects.

CONTACTS SCHEDULE B

1. Authority

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

REPORTS SCHEDULE C

1. Unless otherwise authorised in writing by the Authority, the Contractor shall submit an annual report for the Project to the appropriate Project Manager of the Authority. The Contractor shall provide one hard copy of the report, and one copy on either computer readable disk or by e-mail in the format specified by or agreed with the Authority, no later than 4 weeks after the end of the Project Year, or, for work lasting one year or less, no later than 4 weeks after the end of the first six months. This report shall:

    1.1 list the scientific objectives as set out in the Agreement, indicating where amendments have been agreed;

    1.2 indicate in non-scientific terms the scientific progress achieved since the commencement of the Project or since the last report; how this relates to the policy objectives as set out in the relevant current statement of policy rationale and programme objectives relating to research and development issued by the Authority using the Rationale Objectives Appraisal Monitoring Evaluation. (ROAME) system, plus any findings of particular interest;

    1.3 indicate whether the scientific objectives in the Agreement are appropriate for the remainder of the Project, giving reasons for any changes, together with financial, staff and time implications;

    1.4 list the milestones for the relevant Project Year as set out in the Agreement, indicating which milestones have been met and whether the remaining milestones appear realistic;

    1.5 list any outputs, e.g. published papers or presentations and identify any opportunities for exploiting any Intellectual Property or technology transfer arising out of the Project and any action taken to protect and exploit such Intellectual Property;

    1.6 comment briefly on any new scientific opportunities which may arise from the Project.

2. The Contractor shall also submit an Intellectual Property Report for each financial year (April-March) covering all the project placed under this Agreement. The contractor shall provide one hard copy of the report, and one copy on either computer readable disk or email no later than 31 May of each year.

3. For the Project the Contractor shall submit by the project completion date a final report to the appropriate Project Manager of the Authority consisting of two hard copies, and one electronic copy on either computer readable disk or by e-mail in a format specified by the Authority. The report shall include the following:

    3.1 the Project's code and title as set out in Annex A; the name of the Contractor; the total Defra Project costs; and the Project's Start Date and Completion Date.

    3.2 an executive summary of not more than two sides of A4 written in a style understandable to the intelligent non-scientist. This should include the main objectives of the Project; the methods and findings of the research; and any other significant events and options for new work.

    3.3 a scientific report (which as a guide should be no longer than 20 sides of A4) to include:

3.3.1 the scientific objectives as set out in the Agreement;

3.3.2 the extent to which the objectives set out in the Agreement have been met;

3.3.3 details of methods used, and the Results obtained, including statistical analysis where appropriate;

3.3.4 a discussion of the Results and their reliability;

3.3.5 the main implications of the findings;

3.3.6 possible future work;

3.3.7 any action resulting from the research (eg protection of Intellectual Property, knowledge transfer).

4. Final reports will usually be published on the Authority's website. When submitting the final report to the Authority the Contractor shall indicate any information contained in the report which he considers to be commercially sensitive and the Authority shall not disclose such information without first having consulted the Contractor.

5. The Authority reserves the right to return to the Contractor any annual, final, or Intellectual Property report submitted by the Contractor which is not, in the reasonable opinion of the Authority, satisfactory, either in form or content, having regard to the provisions of this Schedule. In the event that such a report is returned to the Contractor, the Contractor shall remedy any deficiencies identified by the Authority and submit a revised report at no additional cost to the Authority.

6. The Contractor shall supply any additional reports in respect of the Project, including project, Intellectual Property and financial reports, at such time or times, and in such form, as the Authority may reasonably require.

SCHEDULE D - PROCESSING, PERSONAL DATA AND DATA SUBJECTS

1. This Schedule shall be completed by the Authority, who may take account of the view of the Contractor, however the final decision as to the content of this Schedule shall be with the Authority at its absolute discretion.

[redacted]

[redacted]

[redacted]

4. The Contractor shall comply with any further written instructions with respect to processing by the Authority.

5. Any such further instructions shall be incorporated into this Schedule.

Data Processing descriptor	Narrative
Identity of the Controller and Processor	N/A
Subject matter of the processing	N/A
Duration of the processing	N/A
Nature and purposes of the processing	N/A
Type of Personal Data	N/A
Categories of Data Subject	N/A
Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data	N/A

Annex A - Part A: Pricing Schedule & Scope of Works

[redacted]

2. Subject to any variation of the Project, the amount in paragraph 1, above, shall remain firm throughout the duration of the Contract.

3. In the event that the Contract is varied, the amount in paragraph 1 shall be adjusted by such reasonable sum as may be agreed, in writing, between the Authority and the Contractor.

[redacted]

Note the Authority retain the right to suspend payments of installments to the contractor in the event of failure to deliver against 2 or more successive milestones in table 2.3 in Annex A - Scope of works.

Note that the final monthly payment will only be made once all work has been completed to the satisfaction of Defra Project Officer as detailed in the Contracts Schedule. All payments quoted are exclusive of VAT.

5. The Contractor shall provide the Authority with an invoice of the eligible costs properly incurred by the Contractor in carrying out the Research Project during the relevant period, indicate the relevant milestone(s), Purchase Order (to be notified separately) and show separately the costs to be met by the Authority.

6. Within 30 days of receiving an invoice satisfactory to the Authority, the Authority shall pay to the Contractor the amount of the eligible costs which the Authority reasonably consider to have been properly incurred by the Contractor in the carrying out of the Research Project during the relevant period.

7. The Authority is liable to the Contractor only for their respective payments in accordance with The Pricing Schedule. Any overpayment to the Contractor made by the Authority, whether of Research Project price or of VAT, shall be a sum of money recoverable by the Authority from the Contractor.

Annex A – Part B: SCOPE OF WORKS

The Below is The Pirbright Institute (TPI) Evid2 Proposal, (ref. SE1130) with a Start Date of 1 April 2020.

Background

Foot-and-mouth disease (FMD) infects domesticated livestock (cattle, sheep, pigs and goats) and is highly transmissible. Although the UK is free from FMD, circulation of the disease in Asia and Africa poses a continuous threat to the livestock industry in this country via trade and movement of people. The National Reference Laboratory (NRL) for FMD at The Pirbright Institute maintains contingency to rapidly test samples from suspect (report) cases of FMD that might arise in the UK, as well as provide wider support to Defra's control policy during any future FMD outbreaks. Diagnostic approaches need to accommodate a wide range of different sample types to accurately detect and differentiate FMD viruses (FMDV) representing each of the seven different serotypes and rule-out other viral diseases with similar vesicular signs. Serological tests are also required for surveillance purposes to detect animals that have been previously exposed to FMDV, particularly for use after an outbreak to demonstrate disease freedom in the National herd in order to regain FMD-free status for international trade with the OIE/EU. Work at the NRL is supported via an annually renewable Defra "surveillance" contract to cover statutory responsibilities and more focussed research projects that ensure that the tests used remain fit-for-purpose, cost-effective, and that the expertise in newer technologies is kept up to date.

This 3-year project balances immediate and long-term priorities for the virology and serology tests to improve the methods used at the NRL for the diagnosis of FMD. We will develop optimized methods for the recovery of "live" FMDV from samples and implement new immunoassays and molecular tools to rapidly detect and serotype FMDV. We also plan to improve the range of serological tools that are available to detect FMDV-specific antibody responses, evaluate new serological technologies that can complement existing tests and identify novel epitopes that have potential to be used in diagnostic assays. Where appropriate, we will adopt these methods into the routine testing pipeline and seek external accreditation (via UKAS) for these activities. This work covers specific areas that represent key Defra priorities:

(i) Use of validated and accredited tests for rapid detection of FMDV infection in livestock,

(ii) Tests that can be used to accurately identify FMDV strains causing outbreaks,

(iii) Tools for sero-surveillance to provide an evidence-base to demonstrate FMD freedom after outbreaks

The project will ensure that the routine diagnostic systems used within the FMD National Reference Laboratory at Pirbright (and surge capacity at APHA-Weybridge) have resilience to respond rapidly to the threats of FMD incursion into the UK.

In the event of FMD cases in the UK, these improved tests will decrease the time that farms are placed under restrictions, enable more targeted disease control and reduce the slaughter of uninfected animals and as a consequence lower the costs of controlling FMD outbreaks (to industry and government). [redacted]

Background

Foot-and-mouth disease (FMD) is a highly contagious disease of cloven-hoofed livestock

affecting animal production and trade in many parts of the world. It is regarded as one of the most economically important diseases of livestock due to its potential to infect multiple species, affect animal productivity and its ability to rapidly spread within and between geographical regions. The disease is caused by a virus (FMDV; family Picornaviridae, genus Aphthovirus) which has a non-enveloped virion of icosahedral symmetry encapsulating a positive-sense, single-stranded RNA genome of ~8.4 kb. Seven immunologically distinct serotypes of the virus exist: O, A, C, Southern African Territories (SAT) 1, SAT 2, SAT 3 and Asia 1, with serotypes O and A the most widely geographically distributed.

The highly contagious nature of FMDV means that the virus spreads rapidly and sporadic incursions of disease into FMD-free regions are difficult and expensive to control. As an example, the 2001 FMD epidemic is estimated to have cost the UK economy £8 billion (Anon, 2002) and control of the disease required the slaughter of more than 6 million animals (Scudamore and Harris, 2002). Laboratory-based diagnostic tests play a pivotal role in control and eradication programmes by accurately and promptly confirming the FMD status of animals with suspected clinical signs. As part of previous projects funded by Defra, we have developed diagnostic tests that can be used to detect FMD viruses and FMDV-specific antibodies with high confidence (Figure 1).

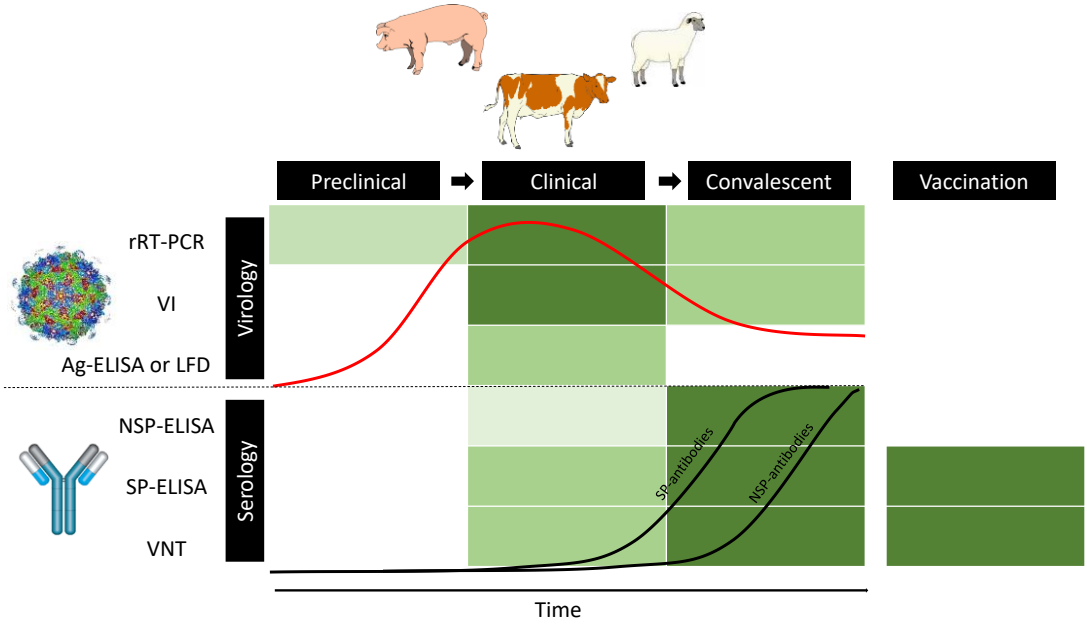


Figure 1: Virological and serological assays that can be used for diagnosis during the different stages of FMDV infection and in vaccinated animals. Boxes (with degree of shading defining the value of individual tests) outline when assays can be used, while traces represent the level of FMD virus replication in susceptible hosts (Red), and the generation of FMDV-specific antibodies (Black) against structural proteins (SP) and non-structural proteins (NSP). Detection of FMDV in preclinical and convalescent phases of infection requires tests with analytical sensitivity, such as rRT-PCR.

Virological assays such as real-time RT-PCR (rRT-PCR) can be employed to test a wide range of different sample types with high sensitivity and specificity, while serological assays have been validated to identify animals (and herds) previously exposed to FMD virus (including infected animals in a vaccinated population) and to monitor immune responses after vaccination. Many of the tests developed by Pirbright are recommended for international trade purposes and are included in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. In addition to improving laboratory-based test methods, work previously funded by Defra has explored novel "field" technologies that may support local clinical diagnosis, where the principal driver is speed and simplicity for use. This work has led to development of FMDV-specific lateral-flow devices (LFD) which were used on-farm during the FMD cases in 2007 and in the laboratory for triage of samples.

A brief review of capability gaps that will be addressed by this project:

Virology tests: Based on our experiences in 2007, it is anticipated that automated rRT-PCR will be the cornerstone of any future laboratory response to FMD outbreaks in the UK (Reid et al., 2009). During this new project, we aim to establish a flexible framework that will allow us to rapidly accredit new rRT-PCR tests that might be required to respond to emerging vial threats (Objective 1) and will also develop new rRT-PCR assays to characterise specific viral lineages in FMDV-positive samples (Objective 4). We will also optimise a new protocol to "rescue" infectious FMDV (Objective 2), and work to develop immunoassays that can accommodate antigenic variants of FMDV (Objective 3). The improvements to laboratory-based tests will be supplemented by studies to assess the performance of new antigen LFDs (Objective 5) and an RT-loop mediated isothermal amplification (RT-LAMP) assay which shows promise for use in "point-of-care" applications (Objective 6).

Serology tests: The NRL maintains a range of serological tests to address diverse FMD surveillance scenarios that cover the different FMDV serotypes. Focussing on FMDV serotypes that pose the greatest risk to the UK, we will continue to validate ELISAs for use to screen large numbers of sera (including the capacity at Weybridge) during FMD outbreaks (Objective 8). We will also undertake studies to understand the basis of poor inter-serotypic specificity of structural protein (SP) ELISAs (Objective 9) and evaluate a highly parallel technology that might be used to dissect serotype-specific responses with high confidence (Objective 10). A phage-display approach will be used to identify novel FMDV-specific epitopes for use in future diagnostic tests (Objective 12). The virus neutralisation test (VNT) is the confirmatory test for FMDV serology: during this project, we plan to adopt an alternative cell line for VNT that can be handled outside of high-containment (Objective 7) and assess a new approach to measure FMDV-specific opsonising antibodies that can be used as an adjunct to VNT (Objective 11).

The Pirbright Institute is the UK's National Reference Laboratory (NRL) for FMD, the FAO's World Reference Laboratory for FMD (WRLFMD) and an OIE Reference Laboratory for FMD. These international reference designations provide access to clinical samples and sera from surveillance programs in countries where FMD is endemic that are suitable for these assay validation studies. Furthermore, participation in the Disease Emergency Response Committee (DERC) to ensure these activities are coordinated with APHA-Weybridge.

References:

- Anonymous, 2002a. The 2001 Outbreak of Foot and Mouth Disease. Report by the controller and Auditor General. National Audit Office HC 939 Session 2001–2002
- Reid S. M., Ebert K., Bachanek-Bankowska K., Batten C., Sanders A., Wright C., Shaw A. E., Ryan E. D. Hutchings G. H., Ferris N. P., Paton D. J. and King D. P. (2009) Performance of real-time RT-PCR for the detection of foot-and-mouth disease virus during field outbreaks in the United Kingdom in 2007. *Journal of Veterinary Diagnostic Investigation* **21** (3): 321-330.
- Scudamore, J.M., Harris, D.M., 2002. Control of foot and mouth disease: Lessons from the experience of the outbreak in Great Britain in 2001. Revue Scientifique et Technique. Office International des Epizootes 21, 699–710

Objectives

The project has the following objectives:

1. Implementation of *flexible*-scope to cover ISO/IEC 17025 accreditation for rRT-PCR tests
2. Establishment of an optimized RNA transfection method to recover "live" FMDV from degraded samples.
3. Development of improved antigen-ELISA systems for rapid serotyping of FMDV
4. Development of a molecular toolbox for the rapid characterisation of FMDV
5. Comparison of lateral-flow tests for FMDV detection
6. Evaluation of a novel RT-LAMP format for FMDV detection
7. Adoption of an alternative cell line for the virus neutralization test
8. Expansion of serological ELISA test portfolio to cover serotypes that threaten the UK
9. Uncovering the basis of inter-serotypic cross-reactivity for SP-ELISAs
10. Development of Luminex SP-assays for serotype discrimination of FMDV-specific antibodies

11. Evaluation of a novel antibody opsonisation assay to complement the VNT

Assess the suitability of PhIP-Seq to recognize and characterize FMDV epitopes

Within each of the objectives, the project will cover the following activities:

1. **Implementation of *flexible-scope* to cover ISO/IEC 17025 accreditation for PCR tests**
   Real-time RT-PCRs (rRT-PCRs) are used to detect viral RNA in clinical samples collected from suspect cases of FMDV. Tests in a generic format have been developed for other viruses causing vesicular disease (such as swine vesicular disease virus [SVDV]) and are used for differential diagnostic purposes. While front-line tests for FMDV and SVDV are accredited to international standards (ISO/IEC 17025), other rRT-PCR assays, such as those for vesicular stomatitis virus (VSV), Seneca Valley virus (SVV), and the tests described in Objective 4, currently have lower priority and have not been accredited for use. Formal accreditation of a new rRT-PCR test is a protracted and time-consuming process, and in order to have the capability to quickly adopt new tests, we propose to transfer our accreditation for rRT-PCRs from *fixed-* to *flexible-scope* format. Establishing this capacity may prove advantageous, particularly in the event of the emerging viral threats (such as SVV) or the evolution of atypical FMDVs with critical mutations in diagnostic targets, such that they are undetectable using an existing rRT-PCR test (for a previous example, see: Ferris et al, 2006). In order to prepare a framework for this change in accreditation, we plan to develop and validate a new rRT-PCR for the detection of VSV to support our work as the NRL for VSV. Our current rRT-PCR test for VSV is based on a published assay (Wilson, 2009), with unpublished modifications encompassing a complex mixture of 16 primers and 4 probes recommended by collaborators at Plum Island (USA). We aim to develop a simpler format of this test, focusing on only one or both of the two major serotypes in the USA (New Jersey which represents the most frequently detected VSV serotype, and Indiana that has caused outbreaks during 2019) The test(s) will be validated using archived VSV isolates available at Pirbright. Documents will be prepared to satisfy UKAS requirements for a transition of rRT-PCR assays to a flexible scope (detailed in Pirbright document QA-SOP-48: *management of flexible scope*). **Adoption of a flexible-scope system will enable new rRT-PCRs to be rapidly accredited, even during an outbreak**.

2. **Establishing an optimized RNA transfection method for "live" FMDV recovery from poor quality samples.**
   FMDV is a relatively fragile virus and modest changes in pH and temperature can destroy the viral capsid and prevent infectivity. These factors necessitate the need for correct storage and transport conditions for samples submitted for diagnostic testing. For example, approximately 20% of samples received to Pirbright (as part of our OIE and FAO International Reference Laboratory activities) do not yield FMD viral isolates, even though FMDV RNA can be detected using rRT-PCR. The inability to generate viral isolates hampers subsequent work to define antigenic profiles of field isolates via vaccine-matching methods. During this objective, we will use transfection methods to introduce viral RNA (full genome comprising positive sense poly-adenylated RNA) into the cytoplasm of susceptible cells to recover "live" FMD virus. We (and other groups) have generated preliminary data to show that chemical transfection methods can be used to successfully rescue "live" FMDV from poor quality samples (e.g., https://www.wrlfmd.org/sites/world/files/quick_media/WRLFMD-2018-00027-SEL-GTR-O-O_001.pdf). We now aim to establish a transfection protocol with optimized conditions to maximize our ability to propagate "live" FMDV from samples. We will evaluate a range of commercially available transfection reagents and compare their efficiency in recovering infectious FMDV. In addition, we plan to assess factors that may impact on transfection efficiency, such as cell confluency, sample matrix type, and sample storage and treatment. We will also investigate the ability of these protocols to recover "live" FMDV using nucleic acid immobilized onto lateral-flow devices, or FTA cards to simulate simple-to-use approaches that might be deployed into the field and provide a more cost-effective way to send samples from endemic countries for laboratory analysis. We will prepare dilution series of samples with known CT values (from rRT-PCR) to transfect, in order to determine the "limit of transfection." This information will then be used to predict which samples may be suitable for transfection/virus recovery. Additionally, we will seek opportunities to collaborate and share

results with other European FMD Reference Laboratories (including ANSES, France), where similar studies are on-going. **This optimized method will enhance our ability to characterize FMDV from samples collected both in FMD-endemic countries and the UK, for which virus could not be otherwise isolated.**

3. **Development of improved antigen-ELISA systems for rapid serotyping of FMDV**
   Currently, the NRL uses antigen-ELISA (Ag-ELISA) to detect/serotype FMDV in clinical samples. ELISA results are generated within ~4 hours, and therefore this test is used during the primary-response for FMD report cases, along with rRT-PCR testing. Different "sandwich" formats of this test rely on pairs of (i) FMDV-serotype specific polyclonal antisera, (ii) FMDV-serotype specific monoclonal antibodies (MAbs) or (iii) MAb with recombinant αVβ6 integrin. Unfortunately, the polyclonal Ag-ELISA exhibits relatively poor diagnostic sensitivity, particularly with recent field viruses from a range of different FMDV topotypes (e.g. O/CATHAY). As such, a second MAb-based Ag-ELISA (using reagents from IZSLER, Italy and validated during SE1129) is being added to our scope of accreditation. More recently (also as part of SE1129), we have developed a new format of the Ag-ELISA that uses HRP-conjugated recombinant αVβ6 integrin as a common detector ligand (i.e., used in place of serotype-specific reagents). Using cell culture FMDV isolates, encouraging results have been generated that demonstrate broad agreement between the typing MAb sandwich and the new MAb-capture and integrin detector formats of the test. During this new project, we aim to complete the validation of this simpler test format using a wide range of clinical isolates (vesicular epithelium suspensions) representative of different FMDV serotypes and lineages. **Improved Ag-ELISA methods will provide more robust tools for rapid serotyping of FMDV positive samples.**

4. **Development of a molecular toolbox for the rapid typing of FMDV**
   The ability to rapidly and accurately type FMDV is an important capability of the NRL, in order to identify the possible origin of a FMD outbreak and support downstream type-specific diagnostic activities, such as sequencing and vaccine matching. We have previously developed a number of rRT-PCR assays for specific FMD viral lineages (Ahmed et al., 2012, Reid *et al.*, 2014, Bachanek-Bankowska *et al.*, 2016, Knowles *et al.*, 2014, Saduakassova *et al.,* 2018). Each of these assays has high analytical sensitivity and target the capsid coding sequences, which is the serotype-specific region of the genome. However, continuous evolution of FMD viruses in the field means that these tests can quickly lose diagnostic sensitivity. During this project, we will design and implement a simple system to regularly review and update the suitability of these primer sets using sequences uploaded to NCBI/GenBank and data generated by SE2944. The outputs from this tool displaying nucleotide mismatches in primer and probe target sequences will be uploaded to our website to complement the technical protocols that are already available (see: https://www.wrlfmd.org/laboratory-protocols/fmdv-rt-pcr#panel-5362) and will include rRT-PCR assays developed at Pirbright as well as published tests developed by other FMD Reference Laboratories. Based on risk to the UK, we will also design new tailored rRT-PCR tests to detect FMDV lineages that are not currently covered, including FMD viruses recently circulating in North Africa (A/AFRICA), Asia (A/ASIA/Sea-97, O/CATHAY, O/SEA/Mya-98) and countries in the Eastern Mediterranean region (sub-lineages of O/ME-SA/PanAsia-2). The diagnostic sensitivity and specificity of these tests will be assessed using the sample archive at Pirbright and their performance (i.e. limit of detection) compared to the pan-serotypic rRT-PCR assays. We will also evaluate the suitability of performing these assays in a multiplex format to cover region-specific risks which would provide greater sample throughput (and reduce costs). **These molecular assays will provide a means to rapidly type FMDV samples and could be deployed for testing in the event of an FMD outbreak in the UK.**

5. **Comparison of lateral-flow tests for FMDV detection**

Lateral-flow devices (LFDs) are designed to rapidly detect FMD antigen and have a similar test performance (in terms of sensitivity and specificity) to the polyclonal Ag-ELISA. However, LFDs can generate a positive result in under 30 minutes, whereas the Ag-ELISA and rRT-PCR assays require ~4 hours after the sample has been processed. Currently, the SVANODIP® FMDV-Ag LFD test (developed in partnership with Pirbright, IZSLER (Italy) and SVANOVA (now part of Boehringer-Ingelheim); Ferris et al., 2009) is included in our ISO/IEC 17025 accreditation scope. Unfortunately, we are experiencing difficulties acquiring these tests from the manufacturer, which highlights our vulnerability of relying on a sole supplier. With no indication as to when the LFDs may be available for purchase in the future, it is critical to evaluate devices manufactured by alternative suppliers and new devices currently in development. Through on-going collaborations with international partners [redacted], we are aware of new devices in development. For example, CFIA (Winnipeg, Canada) has recently approached us to support the development and validation of a novel LFD format that utilizes recombinant αVβ6 integrin (the universal cellular receptor of FMDV) coupled with a pan-serotypic monoclonal antibody. Additionally, we have a long-standing research partnership [redacted] to validate monoclonal antibody reagents for assays, such as LFDs. Using clinical samples (vesicular epithelium) received at Pirbright as part of our OIE/FAO International Reference Laboratory activities, we will (i) assess the suitability of the new αVβ6 integrin/monoclonal antibody LFD for FMDV detection, (ii) validate new type-specific LFDs [redacted], and (iii) assess the diagnostic sensitivity and specificity of commercially available tests (e.g. Princeton BioMeditech and type-specific LFDs available from other sources). **Rapid and accurate diagnosis of new FMD cases is essential: in addition to use at the NRL, LFDs have the potential to be deployed to Animal Health field teams for use to support clinical diagnosis of suspect cases.**

6. **Evaluation of a novel RT-LAMP format for FMDV detection**

Loop-mediated isothermal amplification (LAMP) is a rapid nucleic acid amplification technology that uses a strand-displacing polymerase, specific primers and amplification under isothermal conditions. Work to develop LAMP assays for livestock viruses has been pioneered at Pirbright and we have recently taken FMDV-specific RT-LAMP assays into East Africa to demonstrate that these tests are robust and have application for in-field diagnosis of FMD (Howson et al., 2017a; Howson et al. 2017b). Tests in this format are rapid (<30 mins) and have an analytical sensitivity that is broadly equivalent to rRT-PCR. However, current LAMP assays are still largely dependent upon hardware to detect amplified reaction products and maintain a "contained system". These factors limit opportunities to use these assays in the field and in FMD endemic countries. In this project, we will collaborate with the University of Glasgow to use a paper-based assay format (Figure 2) that has the benefits of LAMP, whilst providing a simple lateral flow readout (similar to rapid immunodiagnostic tests) (Reboud et al., 2019), and the ability to detect up to 5 different targets in a single device (Yang et al 2018). This simple-to-use test has three separate modules: (i) sample-preparation based on paper-folding or "origami", (ii) target amplification with an isothermal amplification protocol, and (iii) detection on an easy-to-read paper lateral-flow strip encased in a plastic cassette (similar to a pregnancy test). Additionally, these tests have the capacity to detect multiple targets simultaneously. The team in Glasgow has already expanded the test repertoire from plasmodium to brucella, leptospira, bovine herpesvirus and most importantly for this proposal,

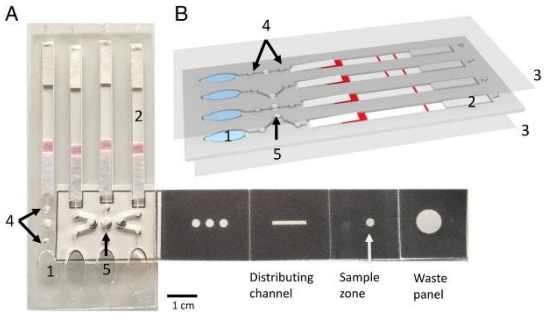


Figure 2. The paper-based sample processing technique is fabricated simply by using hot wax printing onto filter paper, whilst the lateral flow detection unit is made by laser cutting of the cassette and mounting. The device is currently assembled by hand. Adapted from Reboud et al. 2019.

hepatitis C virus (another RNA virus). The paper platform is currently optimised for small sample volumes, including swabs (directly in contact with the paper device). Swabs, whether derived directly from animals or from the environment (e.g. feed troughs) are simpler to collect and process and will thus be evaluated as a preferred sample-type. However, as the RNA concentration may be low, we will also explore the possibility of using tissue suspensions (using homogenisation methods designed for field use; Howson et al., 2017a). FMDV-specific primers that we have previously developed (Dukes et al., 2006) will be loaded onto the paper device and performance of this device will be compared to rRT-PCR. **Rapid molecular field tests have the potential to be used to "negate" farms thereby reducing the time that farms are under restrictions.**

7. **Adoption of an alternative cell line for virus neutralization test**

The virus neutralization test (VNT) is considered to be the "gold standard" method used for FMDV serology. In comparison to ELISA formats, this test has higher levels of inter-serotypic specificity and is widely used as an assay used to monitor humoral immune responses in livestock after infection or vaccination, and for the generation of vaccine matching results (r_1-values). VNT is also used to confirm the status of sera that generate non-negative results after initial ELISA screening. The test measures the ability of sera to inhibit FMDV replication in a permissive cell line. Unfortunately, the IB-RS-2 cell line used for these purposes is persistently infected with classical swine fever virus, which restricts the handling of these cells to high-containment laboratories (classified as SAPO3). As part of SE1129, we have validated a new cell line (LFBK-αVβ6 that expresses the integrin cell receptor for FMDV) as a replacement for IB-RS-2 in VI tests undertaken by the Virology Section of the NRL. Our validation data demonstrate that this cell line has high analytical and diagnostic sensitivity which is maintained over a greater number of cell passages compared to the IB-RS-2 cell line. During this new project, we will assess the performance of the LFBK-αVβ6 cell line for use in the VNT. Studies will encompass parallel testing of serum panels representative of antibodies raised against all FMDV serotypes using the LFBK-αVβ6 and IB-RS-2 cell lines. The virus titres as well as the neutralisation titres (including r_1-values) will be compared between the two cell lines. If the LFBK-αVβ6 cell line demonstrates equivalent performance to the existing system, a QA validation portfolio will be prepared to enable the LFBK-αVβ6 cell line to be incorporated into the ISO/IEC 17025 accredited testing. These validation data will be shared with the wider FMD community (including the OIE/FAO FMD Lab Network) and may improve the harmonization of VNT methods used in different laboratories, since IB-RS-2 cells cannot be easily distributed to all labs due to their infectious status. **Successful completion of this objective will simplify cell culture requirements for the NRL, since the same cell line will be used for routine testing of both virology and serological samples.**

8. **Expansion of serological ELISA test portfolio to cover serotypes that threaten the UK**

The FMD contingency plan includes the use of both structural (SP) and non-structural protein (NSP) ELISAs for post-outbreak sero-surveillance. The strategy adapted during the 2007 FMD outbreak was to use the SP ELISA as the primary screening test and the NSP as an independent secondary confirmatory test. The PrioCHECK FMDV NS has previously been accredited to ISO/IEC 17025, and, as part of SE1129, the ID.Vet NSP kit was accredited to ensure that the required number of kits are available during a medium or large-scale FMD outbreak in the UK. Currently the PrioCHECK FMDV SP ELISA kits for serotype O, A and Asia 1 are the only commercial SP ELISA kits accredited to ISO/IEC 17025. For contingency the ID.Vet SP ELISA kits for serotype O, A and Asia 1 will be validated for possible inclusion in the Pirbright's ISO/IEC 17025 schedule. Experimentally vaccinated and/or infected sera as well as sera from an FMDV negative population will be tested simultaneously on both the ID.VET SP ELISA and the PrioCHECK SP ELISA. The concordance between the two tests will be measured and if appropriate the ID.VET SP ELISA(s) will be added to the ISO/IEC 17025 scope. We will also assist APHA in obtaining similar accreditation. **This work ensures that the serological tests used at Pirbright and APHA-Weybridge cover the range of different FMDV serotypes that might cause outbreaks in the UK.**

9. **Uncovering the basis of inter-serotypic cross-reactivity for SP-ELISAs**

Structural protein (SP)-ELISAs are used to detect FMDV-specific antibodies and are used for sero-surveillance and post-vaccination monitoring purposes. As part of SE1129, we have assessed the inter-serotype specificity of routinely used serological assays from different sources including in-house polyclonal antibody-based liquid phase blocking ELISA (LPBE), in house polyclonal antibody based solid phase competition ELISA (SPCE), monoclonal antibody-based ELISAs from IZSLER and commercially available kits based on SPCE principle from ID.Vet and ThermoFisher. These assays and kits are designed to specifically detect antibodies raised against one of five different FMDV serotypes (O, A, Asia 1 SAT 1 and SAT 2). A selection of 365 monovalent experimental sera, representing all seven serotypes: O (n=116), A (n=120), C (n=18), Asia 1 (n=61), SAT 1 (n=14), SAT 2 (n=30) and SAT 3 (n=6) were assayed and analyzed according to the validated protocol for each ELISA. Although highest reactivity of these tests was evident for sera specific to the serotype of the ELISA, a degree of cross-reactivity was evident for all of these test formats. We hypothesize that this cross-reactivity is due to the presentation of incomplete or degraded FMDV antigens in these assays which expose epitopes present on the internal surface of the viral capsid that are conserved across the FMDV serotypes. In order to test this, we propose to prepare a model system (using serotype O and A); where ELISA antigens in different formats will be used to compare responses of monovalent serotype-homologous and serotype-heterologous sera. Antigens representative of an identical FMDV isolate will include (i) recombinant stabilized viral capsids, (ii) recombinant wild-type viral capsid, (iii) purified wild-type virus and (iv) degraded (heat treated) wild-type virus. **Findings from this objective will define the specificity constraints of SP-ELISAs which will help to understand the limitations of using these tests to monitor antibody responses in animals which may have been exposed to multiple FMDV serotypes (either though vaccination with a multi-valent vaccine or natural infection).**

10. **Development of Luminex SP-assays for improved serotype discrimination of FMDV-specific antibodies**

Sero-surveillance and post-vaccination monitoring often needs to accommodate exposure of animals to different FMDV serotypes (particularly in FMD endemic regions). SP-ELISAs offer an approach to generate data to support these activities; however, our results generated during SE1129 (see objective above) demonstrate that SP-ELISAs suffer from inter-serotypic cross-reactivity which confounds our ability to accurately discriminate antibody responses due to different FMDV serotypes.

Table 1: Preliminary data demonstrating the enhanced serotypic specificity of the Luminex array. Results shown are for cattle sera after vaccination (days post vaccination: dpv) with O1-Manisa. Black boxes denote positive results for the respective tests.

	Luminex assay			Commercial SP-ELISA		
	O-MFI	A22-MFI	Asia1-MFI	O (IDvet)	A (IDvet)	Asia1 (Thermo)
0dpv	1.4	1.2	1.3	118.00	95.58	-2.74
10dpv	8.6	1.4	1.3	9.10	37.58	49.29
35dpc	10.3	1.5	1.5	-0.50	56.58	15.02

During this project, we will evaluate whether multi-serotypic responses can be more accurately measured using a Luminex approach using recombinant FMDV capsids as antigens. Used in previous projects to multiplex NSP-responses, the Luminex array offers parallel capacity to perform tests (up to 100 independent channels and with unique dye-labelled beads). Preliminary data for three FMDV serotypes (O, A and Asia 1) indicate that the Luminex format can more accurately determine the serological status of sera collected from vaccinated animals, in contrast to commercial SP-ELISA kits that suffer from poor inter-serotypic specificity (representative pilot data for cattle vaccinated with serotype O see Table 1). Using recombinant FMDV capsids previously generated during SE1129 (and other on-going projects at the Institute), we will prepare a Luminex array to cover different FMDV

serotypes (O, A, Asia 1, SAT 1 and SAT 2). Previously characterized sera collected from vaccination and/or infection studies in cattle, sheep and pigs will be evaluated alongside parallel testing using SP-ELISAs. **A simple-to-use test to accurately discriminate antibody responses to different FMDV serotypes would be a useful tool for post-vaccination monitoring that could be applied to improve our understanding of the burden and epidemiology of FMD in endemic countries.**

11. Evaluation of a novel opsonisation assay for FMDV-specific antibodies to complement VNT

The amount of anti-FMDV capsid antibody present in the bovine post-vaccinal serum (BVS) correlates well with clinical protection. Despite this, there are frequent reports where vaccinated animals are protected against viral challenge without detectable level of antibodies and vice versa. Serological tests (VNT and ELISA) quantify the ability of BVS to neutralize or bind field strains of FMDV, but this may not accurately reflect all of the components that confer protective responses in the host species. Although the precise mechanism of FMDV *in vivo* protection remains largely unknown, cellular immunity such as antibody-mediated opsonisation and phagocytosis may also play a role. A transformed murine macrophage cell line (RAW264.7) expressing the bovine immunoglobulin G Fc receptor II (Fcγ RII) is available at Pirbright; these cells are not susceptible to FMDV infection unless the virus forms an immune complex in association with an antibody. Successful opsonisation and uptake can be measured in terms of cell death by flow cytometry. Preliminary work shows that this cell line can detect opsonizing antibodies. In previous Defra-funded projects we have generated sera from vaccinated and infected cattle from three cattle potency tests (O, A and Asia). The clinical status and neutralizing antibody status of samples collected from these studies are clearly documented. These sera will be used along with respective viruses to infect the murine macrophage cell line (RAW264.7). The results from the opsonisation test will be compared to the established "gold standard" VNT.

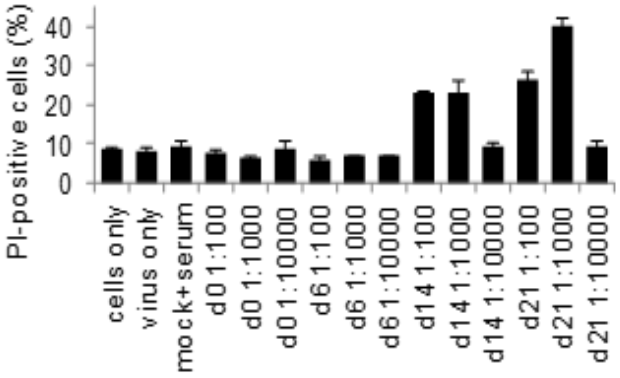


Figure 3: Propidium iodide uptake after incubation of RAW264.7 cells with different concentrations of cattle sera collected after 0, 6, 14 and 21 days post-vaccination. Controls include RAW264.7 cells, virus and mock (negative) serum

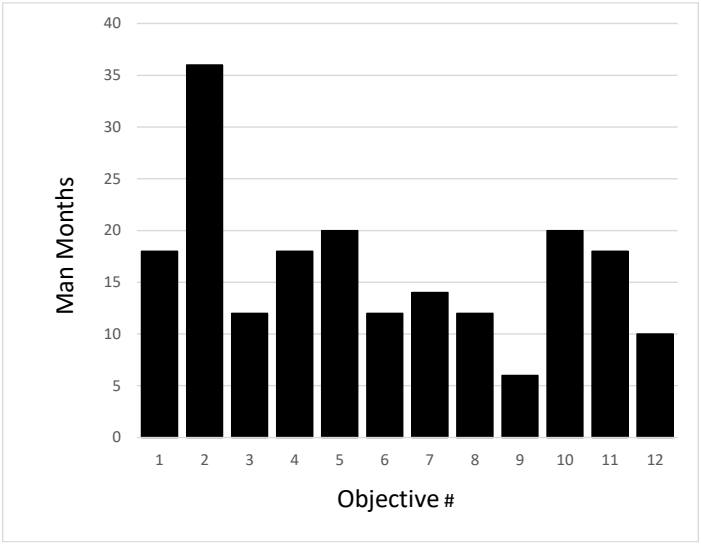
This work will enhance our ability to evaluate protective responses of FMDV vaccines and has the potential to complement data generated using the VNT.

12. Assess the suitability of PhIP-Seq to recognize and characterize FMDV epitopes

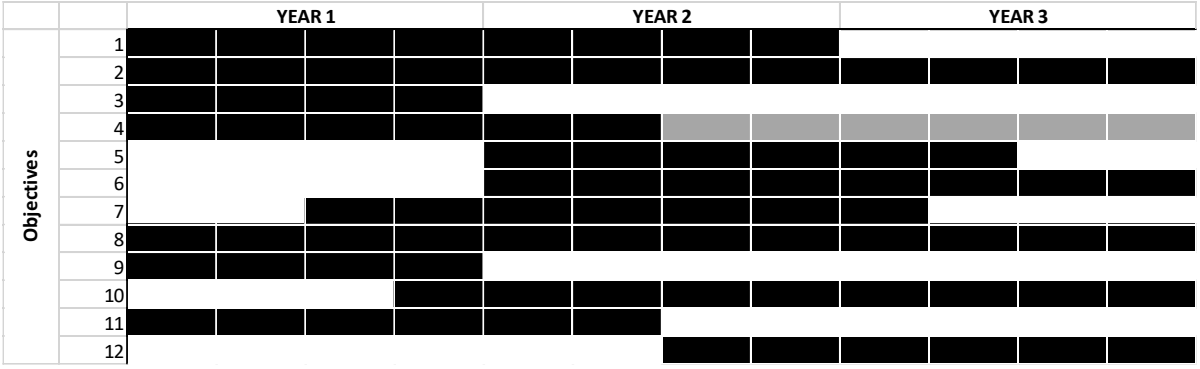
The polyclonal nature of an FMDV-specific antibody response and the relative importance of different epitopes is not well understood. A limitation of VNT or serological ELISAs is that they measure the "global" response to the FMD virus particle (and components) and do not differentiate the contribution from serotype-specific as well as protective epitopes. Phage display approaches (including phage immunoprecipitation followed by sequencing, PhIP-Seq) can be used to dissect these polyclonal responses to provide a serological fingerprint that describes the reactivity of sera. In this project, we aim to use control and FMDV-immune sera to screen phage-display libraries to identify a repertoire of reactive peptides that are reflective of an immune response to infection and/or vaccination with FMDV. A phage library will be exposed to the serum samples and any phage that binds will be immuno-precipitated using protein A/G coated magnetic beads. Sequencing of the precipitated phage will reveal which peptides are recognized by the serum samples. Paired sera (pre- and post-vaccination

and/or infection) from individual animals exposed to different FMDV serotypes will be used to identify FMDV-specific peptides. Initial studies will focus on commercially available random phage libraries which will increase the probability of capturing conformational epitopes, although a limitation of this approach will be that the viral identity of these targets will not be immediately decoded. However, downstream experiments can be used to ultimately identify the location of the relevant epitope on the FMDV particle. Later studies may employ a VirScan approach using a FMDV-specific custom library that displays overlapping peptides tiled across the FMDV polyprotein. This represents a FMDV-centric approach to identifying epitopes, although it will only detect linear epitopes. Unlike the random peptide libraries, a VirScan approach will directly identify the location of a reactive epitope within the virus polyprotein. The existing VirScan library enables the simultaneous detection of 206 human viruses representing >1000 strains in a single assay (Xu et al., 2015). Interestingly, this approach has been successfully used to distinguish between hepatitis C genotypes; therefore, it is conceivable that the method can yield targets that will differentiate between FMDV lineages. **We anticipate that the outputs from this work will improve our understanding of FMDV-specific immune responses and may provide novel ligands that can be incorporated into the development of future immunoassays.**

The figure below outlines the approximate allocation of resources within the project to these different research objectives (not including project management):



Gantt Chart describing the organization of the project objectives:



NB: Tools described for objective 4 will be established by month 18 and will be updated for the remainder of the project

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Risk category table:

Commercial Risks:

Risk Detail	Date Identified	Owner	Remedial Action	Resolution Date
Contract failing to meet objectives.	July 2020	The Authority	The success of the Contract will be Improved tools for the diagnosis of foot-and-mouth disease in the event of an outbreak. Therefore, robust terms and conditions and clearly defined milestones in the Contract is essential. Careful contract management, regular progress meetings and stage payments based on satisfactory completion of milestones	March 2023
Failing to meet timescales	July 2020	The Authority	Robust T&C's and close monitoring of the contract progression is essential. Together with robust Key Performance Indicators (KPI's) and Clauses 'Failure to meet requirements' and 'Monitoring Contract Performance' from the R&D Contract will provide contractual cover.	March 2023

Covid 19 Re-emergence of the Covid-19 pandemic having an impact on the delivery of the project.	October 2020	The Authority	The project timescales will need to be re-visited to understand the impact and whether the project can be completed.	

Sustainability Risks:

Risk Detail	Date Identified	Owner	Remedial Action	Resolution Date
Environmental/Environmental Incidents	Aug 20	The Authority and the Contractor	Work to be undertaken at approved SAPO4 high containment facilities at the Pirbright Institute. SAPO4 facilities are governed by strict protocols associated with a National Reference Laboratory. TPI which is licensed (and audited) by HSE for these activities	March 2023

Environmental/Hazardous Materials and Chemicals	Aug 20	Project Team/TPI	Project will use routine laboratory chemicals/reagents that (where it is appropriate). Will be handled under local risk assessments. All samples collected from FMDV infected animals will be handled according to code of practice under SAPO4 approved methods. H&S requirements to be highlighted in the end of year reports. All notifiable breaches to be communicated to the Authority within one business day.	March 2023
Environmental/Environmental Incidents	Aug 20	TPI	The work undertaken in the project will be performed within the SAPO4 high-containment envelope at The Pirbright Institute which is licensed (and audited) by HSE for these activities. The Contractor shall inform the Authority of any Notifiable breaches of Environmental Law within one business day and will be monitored by the Authority using KPIs.	March 2023

Environmental/Fuel Efficiency	Aug 20	TPI	The Pirbright Institute participates in the Energy Savings Opportunity Scheme (ESOS). Organisations that qualify for this scheme must carry out ESOS assessments every 4 years. A report from TPI on completion of the project confirming TPI have maintained their ESOS accreditation during the performance of this Contract. If accreditation is not maintained this should be reported in the first instance to the Authority within one business day.	March 2023

Environmental/ Waste (Inc. Packaging & Consumables)	Aug 20	TPI	Laboratory waste generated in the project will be treated using strict protocols at the Pirbright Institute (these activities fall under the SAPO licensing of the site). A report from TPI on completion of the project containing % reduction of waste and a % increased use of recyclable and recycled materials.	March 2023
Use of consumables	Aug 20	TPI	Routine laboratory consumables will be used as part of the requirement. Laboratory stockpiles of reagents are managed via a separate contract with Defra	March 2023

Environmental/Carbon Efficiency	Aug 20	TPI	The Pirbright Institute participates in the Energy Savings Opportunity Scheme (ESOS). Organisations which qualify for this scheme must carry out ESOS assessments every 4 years. DGC expect TPI to maintain their ESOS accreditation through the life of the Contract. If accreditation is not maintained. A report from TPI on completion of the project confirming TPI have maintained their ESOS accreditation during the performance of this Contract. If accreditation is not maintained this should be reported in the first instance to the Authority within one business day.	March 2023

Milestones and Deliverables table

All milestones and deliverables must link directly to the objectives, approaches and work plan. Please also denote whether activities stated depend on the availability of high containment by adding 'C' and the level of containment required (e.g., C/SAPO3). Please add further lines as necessary.

	Target date (dd/mm/yyyy)	Project month	Description of milestone including the deliverable. (maximum 120 characters)
1	31/03/2021	12	3-1: Report on the diagnostic sensitivity of the integrin detector Ag-ELISA using clinical samples (C/SAPO4)
2	31/03/2021	12	4-1: Develop at least two new lineage-specific rRT-PCRs (to cover risks to the UK) (C/SAPO4)
3	31/03/2021	12	9-1: Report results from experiments to compare antibody binding to intact and degraded viral capsids (C/SAPO4)
4	30/09/2021	18	1-1: Develop and validate rRT-PCR test for VSV (C/SAPO4)
5	30/09/2021	18	4-2: Implement simple tool to monitor sequence mismatches in lineage-specific rRT-PCRs
6	30/09/2021	18	6-1: Prepare research agreement for LAMP assay work [redacted]
7	30/09/2021	18	5-1: Review availability of LFDs available from commercial and academic sources
8	30/09/2021	18	8-1: Validation of ELISA kits for SP-serology (serotype O) (C/SAPO4)
9	30/09/2021	18	11-1: Report on the performance of oposonisation assay using post-vaccination FMDV sera (C/SAPO4)
10	31/03/2022	24	1-2: Prepare validation dossier to support *flexible-scope* accreditation
11	31/03/2022	24	6-2: Transfer an FMDV-specific RT-LAMP assay onto "origami" format
12	31/03/2022	24	10-1: Prepare recombinant viral capsid for use as antigens on the Luminex system
13	31/03/2022	24	12-1: Prepare reagents required to undertake PhIP-seq for FMDV
14	30/09/2022	30	7-1: Assessment of LFBK-αVβ6 cells for use in VNT (C/SAPO4)
15	31/03/2023	36	2-1: Report on optimised transfection method for FMDV (C/SAPO4)
16	31/03/2023	36	5-2: Report on comparative performance of Ag-LFDs for FMDV detection (and typing) (C/SAPO4)
17	31/03/2023	36	6-3: Report on relative performance of "origami" RT-LAMP for FMDV detection (C/SAPO4)
18	31/03/2023	36	7-2: Preparation of a QA validation dossier for the use of LFBK-αVβ6 cells
19	31/03/2023	36	8-2: Validation of ELISA kits for SP-serology (serotypes A and Asia 1) (C/SAPO4)
20	31/03/2023	36	10-2: Report on the performance of Luminex assays to detect FMDV serotype-specific antibodies (C/SAPO4)
21	31/03/2023	36	12-2: Report outlining the results from PhIP-seq (and VirScan) to identify FMDV-specific epitopes

Appendix 1 - Key Performance Indicators

As part of the Authority's continuous drive to improve the performance of all Contracts, this PMF will be used to monitor, measure and control all aspects of the Contractor's performance of contract responsibilities.

The purpose of the PMF is to set out the obligations on the Contractor, to outline how the Contractor's performance will be evaluated and to detail the sanctions for performance failure. The Contractor is responsible for the performance of any sub-contractors.

KPIs are essential in order to align Contractor performance with the requirements of the Authority and to do so in a fair and practical way. KPIs have to be realistic, measurable and achievable; they also have to be met otherwise indicating that the service is failing to deliver. Without the use of service credits in such a situation, this service failure places strain on the relationship as delivery falls short of agreed levels.

The proactive approach to correcting failures and addressing their cause improves the relationship and enables a partnership rather than a confrontational style of working. Its focus is on managing and improving service.

The Authority shall review performance against KPI's and, if appropriate, instigate meetings and work closely with the Contractor to agree action plans. The Authority expects the Contractor to agree and implement these plans. If this does not happen, only then shall service credit principles be applied.

Service Credit Principles

The use of service credits is governed by the following principles:

Service credits sit within the wide service management approach being pursued by the Contractor and the Authority. Use of service credits does not preclude any other remedy for failure of performance available to the Authority under the terms and conditions of the contract.

The service credit regime shall be instigated on each occasion where there is a service failure. Failure to meet a KPI may also give rise to a remediation plan.

- KPIs with a service credit rating of one (1) will have a service credit of three per cent (3%) of the invoice amount for the monitoring period, applied for each KPI failure.

- KPIs with a service credit rating of two (2) will have a service credit of five per cent (5%) of the invoice amount for the monitoring period, applied for each KPI failure.

- The maximum annual service credit to be applied will be no more than ten per cent (10%) of the total annual contract value per Contractor.

The Authority has full and complete discretion on whether to claim all, part or none of a service credit to which it is due.

Service credits claimed shall be paid to the Authority as a credit note within one (1) month following the date at which the service credits were applied.

The full, agreed service credit regime will operate from the Contract start date until the end of the contract period. The KPIs may be adjusted to ensure that they are appropriate and achievable.

Please Note: Delays related to COVID19 will not be subject to the KPI Service Credit Principles.

Metric	KPI (If any of the deliverables are deemed not to meet the Minimum Standard the over-arching KPI itself will be 'failed)	What is required to make this measurable	KPI Measurement	Minimum Standard (KPI Failure)	Acceptable Standard	Service Credit Rating
Milestones 1 to 3	Project Management	Completion of milestones 1 to 3	The Authority will review the Contractor's progress against specified milestones	**One or more Milestones not completed by 31/3/2021**	**Milestones completed by 31/3/2021**	**1**
Milestones 4 to 9	Project Management	Completion of milestones 4 to 9	The Authority will review the Contractor's progress against specified milestones	**One or more Milestones not completed by 30/9/2021**	**Milestones completed by 30/9/2021**	**1**
Milestones 10 to 13	Project Management	Completion of milestones 10 to 13	The Authority will review the Contractor's progress against specified milestones	**One or more Milestones not completed by 31/3/2022**	**Milestones completed by 31/3/2022**	**1**
Milestone 14	Project Management	Completion of milestone 14	The Authority will review the Contractor's progress against specified milestones	**Milestone not completed by 30/9/2022**	**Milestones completed by 30/9/2022**	**1**
Milestones 15 to 19	Project Management	Completion of milestones 15 to 19	The Authority will review the Contractor's progress against specified milestones	**One or more Milestones not completed by 31/3/2023**	**Milestones completed by 31/3/2023**	**1**