



Department  
for Environment  
Food & Rural Affairs

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## **Contract for the Provision of Research and Development**

**Contract Ref No. project\_24130**

**Bridging the preclinical/clinical gap for optimisation of efficacy and avoidance of resistance for fluoroquinolones, application to canine pyoderma**

**January 2019**

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# SECTION 1

## FORM OF CONTRACT

### PARTIES:

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

### AND

- (2) THE ROYAL VETERINARY COLLEGE, Hawkshead Lane, North Mymms, Hatfield AL9 7TA (the “Contractor”)

(each a “Party” and together the “Parties”)

### WHEREAS

- a) Following the receipt of your proposal the Authority wishes to appoint the Contractor to provide the certain services and the Contractor agrees to provide those services in accordance with these terms and conditions.

### NOW IT IS HEREBY AGREED as follows:

#### 1. TERMS OF CONTRACT

- 1.1 The “Contract” comprises the following:

Section 1:	Form of Contract
Section 2:	Terms and Conditions
Schedule 1:	Specification
Annex A:	Contractor’s Tender response
Schedule 2:	Pricing
Schedule 3:	Change Control
Schedule 4:	Key Performance Indicators
Schedule 5:	Processing, Personal Data and Data Subjects

- 1.2 Execution of the Contract is carried out in accordance with EU Directive 99/93 (Community framework for electronic signatures) and the Electronic Communications Act 2000. The Contract is formed on the date on which both Parties communicate acceptance of its terms on the Authority’s electronic contract management system (“Bravo”).
- 1.3 The Contract starts on 1<sup>st</sup> February 2019 (the “Commencement Date”) and ends on the 1<sup>st</sup> March 2022 (the “End Date”) unless it is terminated early or extended in accordance with the Contract.

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# A GENERAL PROVISIONS

## A1 Definitions and Interpretation

Unless the context otherwise requires the following terms shall have the meanings given to them below:

“**Affected Party**” means the Party seeking to claim relief in respect of a Force Majeure Event.

“**Affiliate**” means in relation to a body corporate, any other entity which directly or indirectly Controls is Controlled by, or is under direct or indirect common Control with, that body corporate from time to time.

“**Approval**” and “**Approved**” means the prior written consent of the Authority.

“**Authorised Representative**” means the Authority representative named in the CCN as authorised to approve agreed Variations.

“**Authority Data**” means

- (a) the data, text, drawings, diagrams, images or sounds (together with any database made up of any of these) which are embodied in any electronic, magnetic, optical or tangible media, and which are: (i) supplied to the Contractor by or on behalf of the Authority; or (ii) which the Contractor is required to generate, process, store or transmit pursuant to the Contract; or
- (b) any Personal Data for which the Authority is the Controller.

“**Authority Premises**” means any premises owned, occupied or controlled by the Authority or any other Crown Body which are made available for use by the Contractor or its Sub-Contractors for provision of the Services.

“**Authority Software**” means software which is owned by or licensed to the Authority (other than under or pursuant to the Contract) and which is or will be used by the Contractor for the purposes of providing the Services.

“**Authority System**” means the Authority’s computing environment (consisting of hardware, software and/or telecommunications networks or equipment) used by the Authority or the Contractor in connection with the Contract which is owned by or licensed to the Authority by a third party and which interfaces with the Contractor System or which is necessary for the Authority to receive the Services.

“**Biological Materials**” means any material (including, without limitation, plants, animals, microbes or viruses) of biological origin which contains genetic information capable of reproduction and/or material derived from the same that is collected or produced through the Contract.

“**BPSS**” means the HMG Baseline Personnel Security Standard for Government employees.

“**Bravo**” has the meaning given in paragraph 1.2 of the Form of Contract.

“**CCN**” means a change control notice in the form set out in Schedule 3.

“**Commencement Date**” means the date set out in paragraph 1.3 of the Form of Contract.

“**Commercially Sensitive Information**” means the information listed in Schedule 4 comprising the information of a commercially sensitive nature relating to:

- (a) the Price;
- (b) details of the Contractor's Intellectual Property Rights; and
- (c) the Contractor's business and investment plans

which the Contractor has indicated to the Authority that, if disclosed by the Authority, would cause the Contractor significant commercial disadvantage or material financial loss.

**"Confidential Information"** means any information which has been designated as confidential by either Party in writing or that ought to be considered as confidential (however it is conveyed or on whatever media it is stored) including information the disclosure of which would, or would be likely to, prejudice the commercial interests of any person or trade secrets or Intellectual Property Rights of either Party and all Personal Data. Confidential Information shall not include information which:

- (a) was public knowledge at the time of disclosure otherwise than by breach of clause E4;
- (b) was in the possession of the receiving Party, without restriction as to its disclosure, before receiving it from the disclosing Party;
- (c) is received from a third party (who lawfully acquired it) without restriction as to its disclosure; or
- (d) is independently developed without access to the Confidential Information.

**"Contract"** has the meaning given in paragraph 1.1 of the Form of Contract.

**"Contract Period"** means the period from the Commencement Date to:

- (a) the End Date; or
- (b) following an Extension the end date of the Extension

or such earlier date of termination or partial termination of the Contract in accordance with the Law or the Contract.

**"Contracting Authority"** means any contracting authority (other than the Authority) as defined in regulation 3 of the Regulations.

**"Contractor Software"** means software which is proprietary to the Contractor, including software which is or will be used by the Contractor for the purposes of providing the Services and which is set out in Schedule 7.

**"Contractor System"** means the information and communications technology system used by the Contractor in performing the Services including the Software, the Contractor Equipment and related cabling (but excluding the Authority System).

**"Control"** means that a person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the other person (whether through the ownership of voting shares, by contract or otherwise) and "Controls" and "Controlled" shall be interpreted accordingly.

**"Conventions"** means any and all of: i) the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture, including any Protocols and other additions or amendments from time to time; ii) any guidelines adopted by the parties to the same (including, without limitation, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization); and iii) any national legal or regulatory requirements made in pursuance of the provisions of the same in any territory.

**“Controller”** has the meaning given in the GDPR.

**“Copyright”** means as it is defined in s.1 of Part 1 Chapter 1 of the Copyright, Designs and Patents Act 1988.

**“Crown”** means the government of the United Kingdom (including the Northern Ireland Executive Committee and Northern Ireland Departments, the Scottish Executive and the National Assembly for Wales), including, but not limited to, government ministers, government departments, government offices and government agencies and “Crown Body” is an emanation of the foregoing.

**“Data Loss Event”** means any event that results, or may result, in unauthorised access to Personal Data held by the Contractor under this Contract, and/or actual or potential loss and/or destruction of Personal Data in breach of this Contract, including any Personal Data Breach.

**“Data Protection Impact Assessment”** means an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data.

**“Data Protection Legislation”** means (i) the GDPR, the LED and any applicable national implementing Laws as amended from time to time (ii) the DPA 2018 (subject to Royal Assent) to the extent that it relates to processing of personal data and privacy; (iii) all applicable Law about the processing of personal data and privacy;

**“Data Protection Officer”** has the meaning given in the GDPR.

**“Data Subject”** has the meaning given in the GDPR.

**“Data Subject Access Request”** means a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data.

**“Database Rights”** means as rights in databases are defined in s.3A of Part 1 Chapter 1 of the Copyright, Designs and Patents Act 1988.

**“Default”** means any breach of the obligations of the relevant Party (including abandonment of the Contract in breach of its terms, repudiatory breach or breach of a fundamental term) or any other default, act, omission, negligence or statement of the relevant Party or the Staff in connection with the subject-matter of the Contract and in respect of which such Party is liable to the other.

**“DOTAS”** means the Disclosure of Tax Avoidance Schemes rules which require a promotor of tax schemes to tell HMRC of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to NICs by the National Insurance (Application of Part 7 of the Finance Act 2004) regulations 2012, SI 2012/1868 made under section 132A of the Social Security Administration Act 1992.

**“DPA 2018”** means the Data Protection Act 2018.

**“EIR”** means the Environmental Information Regulations 2004 (SI 2004/3391) and any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such regulations.

**“End Date”** means the date set out in paragraph 1.3 of the Form of Contract.

**“Equipment”** means the Contractor’s equipment, consumables, plant, materials and such other items supplied and used by the Contractor in the delivery of the Services.

**“Extension”** has the meaning given in paragraph 1.4 of the Form of Contract.

**“FOIA”** means the Freedom of Information Act 2000 and any subordinate legislation made under that Act from time to time together with any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such legislation.

**“Force Majeure Event”** means any event outside the reasonable control of either Party affecting its performance of its obligations under the Contract arising from acts, events, omissions, happenings or non-happenings beyond its reasonable control and which are not attributable to any wilful act, neglect or failure to take reasonable preventative action by that Party, including acts of God, riots, war or armed conflict, acts of terrorism, acts of government, local government or regulatory bodies, for flood, storm or earthquake, or disaster but excluding any industrial dispute relating to the Contractor or the Staff or any other failure in the Contractor’s supply chain.

**“Form of Contract”** means Section 1 of the Contract.

**“GDPR”** means the General Data Protection Regulation (Regulation (EU) 2016/679).

**“General Anti-Abuse Rule”** means:

- (a) the legislation in Part 5 of the Finance Act 2013; and
- (b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid NICs;

**“Good Industry Practice”** means standards, practices, methods and procedures conforming to the Law and the degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged in a similar type of undertaking under the same or similar circumstances.

**“Goods”** means any goods supplied by the Contractor (or by a Sub-Contractor) under the Contract as specified in Schedule 1 including any modified or alternative goods.

**“Halifax Abuse Principle”** means the principle explained in the CJEU Case C-255/02 Halifax and others.

**“HMRC”** means HM Revenue & Customs.

**“ICT Environment”** means the Authority System and the Contractor System.

**“Income”** means 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, arising from the use or exploitation of the Results or any part of the Results.

**“Information”** has the meaning given under section 84 of the FOIA.

**“Initial Contract Period”** means the period from the Commencement Date to the End Date.

**“Intellectual Property Rights”** means patents, utility models, inventions, trademarks, service marks, logos, design rights (whether registrable or otherwise), applications for any of the foregoing, copyright, database rights, domain names, plant variety rights, Know-How, trade or business names, moral rights and other similar rights or obligations whether registrable or not in any country (including but not limited to the United Kingdom) and the right to sue for passing off.

**“ITEPA”** means the Income Tax (Earnings and Pensions) Act 2003.

**“Key Biological Materials”** means Biological Materials held by or on behalf of the Contractor that are agreed by the Contractor, the Authority and (if relevant) the appropriate independent scientific advisory body (in each case acting reasonably) to be of national or international importance.

**“Key Personnel”** mean those persons named in the Specification as key personnel.

**“Know-How”** means all information not in the public domain held in any form (including without limitation that comprised in or derived from 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).

**“Law”** means any law, statute, subordinate legislation within the meaning of section 21(1) of the Interpretation Act 1978, bye-law, enforceable right within the meaning of section 2 of the European Communities Act 1972, regulation, order, regulatory policy, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements of any Regulatory Body with which the Contractor is bound to comply.

**“LED”** means Law Enforcement Directive (Directive (EU) 2016/680).

**“Malicious Software”** means any software program or code intended to destroy, interfere with, corrupt, or cause undesired effects on program files, data or other information, executable code or application software macros, whether or not its operation is immediate or delayed, and whether the malicious software is introduced wilfully, negligently or without knowledge of its existence.

**“Material Breach”** means a breach (including an anticipatory breach) that is serious in the widest sense of having a serious effect on the benefit which the Authority would otherwise derive from:

- (a) a substantial portion of the Contract; or
- (b) any of the obligations set out in clauses A6, B16, D1, E1, E2, E3, E4, E7, E8 or E11.

**“Month”** means calendar month.

**“NICs”** means National Insurance Contributions.

**“Occasion of Tax Non-Compliance”** means:

- (a) any tax return of the Contractor submitted to a Relevant Tax Authority on or after 1 October 2012 which is found on or after 1 April 2013 to be incorrect as a result of:
  - i. a Relevant Tax Authority successfully challenging the Contractor under the General Anti-Abuse Rule or the Halifax Abuse principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle;
  - ii. the failure of an avoidance scheme which the Contractor was involved in, and which was, or should have been, notified to the Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or
- (b) any tax return of the Contractor submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise on or after 1 April 2013 to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Commencement Date or to a civil penalty for fraud or evasion.

**“Personal Data”** has the meaning given in the GDPR.

**“Personal Data Breach”** has the meaning given in the GDPR.

**“Premises”** means the location where the Services are to be supplied as set out in the Specification.

**“Price”** means the price (excluding any applicable VAT) payable to the Contractor by the Authority under the Contract, as set out in Schedule 2 for the full and proper performance by the Contractor of its obligations under the Contract.

**“Processor”** has the meaning given in the GDPR.

**“Prohibited Act”** means:

- (a) to directly or indirectly offer, promise or give any person working for or engaged by the Authority a financial or other advantage to:
  - i. induce that person to perform improperly a relevant function or activity; or
  - ii. reward that person for improper performance of a relevant function or activity;
- (b) to directly or indirectly request, agree to receive or accept any financial or other advantage as an inducement or a reward for improper performance of a relevant function or activity in connection with the Contract;
- (c) an offence:
  - i. under the Bribery Act 2010 (or any legislation repealed or revoked by such Act);
  - ii. under legislation or common law concerning fraudulent acts; or
  - iii. the defrauding, attempting to defraud or conspiring to defraud the Authority;
- (d) any activity, practice or conduct which would constitute one of the offences listed under (c) above if such activity, practice or conduct has been carried out in the UK.

**“Project Year”** means each period of 12 months during the Contract Period beginning with the Commencement Date.

**“Protective Measures”** means appropriate technical and organisational measures which may include: pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of the such measures adopted by it.

**“Property”** means the property, other than real property, issued or made available to the Contractor by the Authority in connection with the Contract.

**“Purchase Order”** means the document in which the Authority specifies the Services which are to be supplied by the Contractor under the Contract.

**“Quality Standards”** means the quality standards published by BSI British Standards, the National Standards Body of the United Kingdom, the International Organisation for Standardization or other reputable or equivalent body (and their successor bodies) that a skilled and experienced operator in the same type of industry or business sector as the Contractor would reasonably and ordinarily be expected to comply with, and as may be further detailed in Schedule 1.

**“Receipt”** means the physical or electronic arrival of the invoice at the address specified in clause A4.4 or at any other address given by the Authority to the Contractor for the submission of invoices from time to time.

**“Regulations”** means the Public Contract Regulations 2015 (SI 2015/102).

**“Regulatory Body”** means a government department and regulatory, statutory and other entities, committees, ombudsmen and bodies which, whether under statute, rules, regulations, codes of practice or otherwise, are entitled to regulate, investigate, or influence the matters dealt with in the Contract or any other affairs of the Authority.

**“Relevant Conviction”** means a conviction that is relevant to the nature of the Services or as listed by the Authority and/or relevant to the work of the Authority.

**“Relevant Requirements”** means all applicable Law relating to bribery, corruption and fraud, including the Bribery Act 2010 and any guidance issued by the Secretary of State for Justice pursuant to section 9 of the Bribery Act 2010.

**“Relevant Tax Authority”** means HMRC or, if applicable, a tax authority in the jurisdiction in which the Contractor is established.

**“Replacement Contractor”** means any third party supplier appointed by the Authority to supply any goods and/or services which are substantially similar to any of the Services in substitution for any of the Services following the expiry, termination or partial termination of the Contract.

**“Request for Information”** means a request for information under the FOIA or the EIR.

**“Results”** means any guidance, specifications, reports, studies, instructions, toolkits, plans, data, drawings, databases, patents, patterns, models, designs or other material which is:

- a) prepared by or for the Contractor for use in relation to the performance of its obligations under the Contract; or
- b) the result of any work done by the Contractor, the Staff or any Sub-Contractor in relation to the provision of the Services.

**“Returning Employees”** means those persons agreed by the Parties to be employed by the Contractor (and/or any Sub-Contractor) wholly or mainly in the supply of the Services immediately before the end of the Contract Period.

**“Security Policy Framework”** means the HMG Security Policy Framework (available from the Cabinet Office’s Government Security Secretariat) as updated from time to time.

**“Services”** means the services set out in Schedule 1 (including any modified or alternative services) and, if the context so requires, includes Goods.

**“Specification”** means the description of the Services to be supplied under the Contract as set out in Schedule 1 including, where appropriate, the Key Personnel, the Premises and the Quality Standards.

**“SSCBA”** means the Social Security Contributions and Benefits Act 1992.

**“Staff”** means all persons employed by the Contractor to perform its obligations under the Contract together with the Contractor’s servants, agents, students, suppliers and Sub-Contractors used in the performance of its obligations under the Contract.

**“Sub-Contract”** means a contract between 2 or more suppliers, at any stage of remoteness from the Authority in a sub-contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of the Contract and **“Sub-Contractor”** shall be construed accordingly.

**“Sub-processor”** means any third party appointed to process Personal Data on behalf of the Contractor related to this Contract.

**“Tender”** means the document submitted by the Contractor to the Authority in response to the Authority’s invitation to suppliers for formal offers to supply the Services.

**“TFEU”** means the Treaty on the Functioning of the European Union.

**“Third Party IP Claim”** has the meaning given to it in clause E8.7 (Intellectual Property Rights).

**“Third Party Software”** means software which is proprietary to any third party which is or will be used by the Contractor to provide the Services including the software and which is specified as such in Schedule 7.

**“Treaties”** means the Treaty on European Union and the TFEU.

**“TUPE”** means the Transfer of Undertakings (Protection of Employment) Regulations 2006.

**“TUPE Information”** means the information set out in clause B17.1.

**“Valid Invoice”** means an invoice containing the information set out in clause C2.5.

**“Variation”** means a variation to the Specification, the Price or any of the terms or conditions of the Contract.

**“VAT”** means value added tax charged or regulated in accordance with the provisions of the Value Added Tax Act 1994.

**“Working Day”** means a day (other than a Saturday or Sunday) on which banks are open for general business in the City of London.

In the Contract, unless the context implies otherwise:

- (a) the singular includes the plural and vice versa;
- (b) words importing the masculine include the feminine and the neuter;
- (c) reference to a clause is a reference to the whole of that clause unless stated otherwise;
- (d) references to a person include an individual, company, body corporate, corporation, unincorporated association, firm, partnership or other legal entity or central Government body;
- (e) the words “other”, “in particular”, “for example”, “including” and similar words shall not limit the generality of the preceding words and shall be construed as if they were immediately followed by the words “without limitation”;
- (f) headings are included for ease of reference only and shall not affect the interpretation or construction of the Contract;
- (g) a reference to any Law includes a reference to that Law as amended, extended, consolidated or re-enacted from time to time;

- (h) references to the Contract are references to the Contract as amended from time to time; and
- (i) if there are no Co-funders, references to the Co-funders shall have no meaning or effect.

## **A2 The Authority's Obligations**

A2.1 Save as otherwise expressly provided, the obligations of the Authority under the Contract are obligations of the Authority in its capacity as a contracting counterparty and nothing in the Contract shall operate as an obligation upon, or in any other way fetter or constrain the Authority in any other capacity, and the exercise by the Authority of its duties and powers in any other capacity shall not lead to any liability (howsoever arising) on the part of the Authority to the Contractor.

## **A3 Contractor's Status**

A3.1 The Contractor shall be an independent contractor and nothing in the Contract shall create a contract of employment, a relationship of agency or partnership or a joint venture between the Parties and accordingly neither Party shall be authorised to act in the name of, or on behalf of, or otherwise bind the other Party save as expressly permitted by the terms of the Contract.

A3.2 The Contractor shall not (and shall ensure that any other person engaged in relation to the Contract 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.

## **A4 Notices and Communications**

A4.1 Subject to clause A4.3, where the Contract states that a notice or communication between the Parties must be "written" or "in writing" it is not valid unless it is made by letter (sent by hand, first class post, recorded delivery or special delivery) or by email or by communication via Bravo.

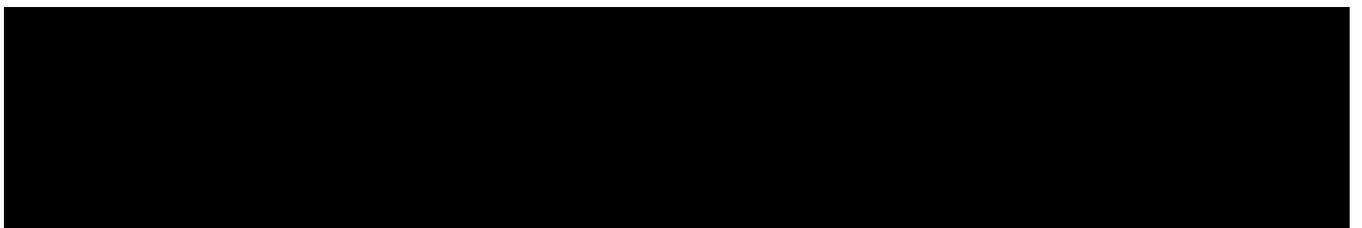
A4.2 If it is not returned as undelivered a notice served:

- (a) in a letter is deemed to have been received 2 Working Days after the day it was sent; and
- (b) in an email is deemed to have been received 4 hours after the time it was sent provided it was sent on a Working Day

or when the other Party acknowledges receipt, whichever is the earlier.

A4.3 Notices pursuant to clauses G3 (Force Majeure), I2 (Dispute Resolution) or to terminate the Contract or any part of the Services are valid only if served in a letter by hand, recorded delivery or special delivery.

A4.4 Notices shall be sent to the addresses set out below or at such other address as the relevant Party may give notice to the other Party for the purpose of service of notices under the Contract:





## **A5 Mistakes in Information**

A5.1 The Contractor is responsible for the accuracy of all drawings, documentation and information supplied to the Authority by the Contractor in connection with the Services and shall pay the Authority any extra costs occasioned by any discrepancies, errors or omissions therein.

## **A6 Conflicts of Interest**

A6.1 The Contractor shall take appropriate steps to ensure that neither the Contractor nor any Staff is placed in a position where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Contractor and the duties owed to the Authority under the provisions of the Contract. The Contractor will notify the Authority without delay giving full particulars of any such conflict of interest which may arise.

A6.2 The Authority may terminate the Contract immediately by notice and/or take or require the Contractor to take such other steps it deems necessary if, in the Authority's reasonable opinion, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Contractor and the duties owed to the Authority under the provisions of the Contract. The actions of the Authority pursuant to this clause A6 shall not prejudice or affect any right of action or remedy which shall have accrued or shall thereafter accrue to the Authority.

# **B. THE SERVICES**

## **B1 Specification**

B1.1 In consideration of the Contractor supplying the Services the Contractor shall be paid the Price as set out in Schedule 2.

## **B2 Samples**

B2.1 If requested by the Authority, the Contractor shall provide the Authority with samples of Goods for evaluation and Approval, at the Contractor's cost and expense.

B2.2 The Contractor shall ensure that the Goods are fully compatible with any equipment, to the extent specified in the Specification.

B2.3 The Contractor acknowledges that the Authority relies on the skill and judgment of the Contractor in the supply of the Goods and the performance of the Contractor's obligations under the Contract.

## **B3 Delivery**

B3.1 Unless otherwise stated in the Specification, where the Goods are delivered by the Contractor, the point of delivery shall be when the Goods are removed from the transporting vehicle at the Premises. If the Goods are collected by the Authority, the point of delivery shall be when the Goods are loaded on the Authority's vehicle.

- B3.2 Except where otherwise provided in the Contract, delivery shall include the unloading, stacking or installation of the Goods by the Staff or the Contractor's suppliers or carriers at such place as the Authority or duly authorised person shall reasonably direct.
- B3.3 Any access to the Premises and any labour and equipment that may be provided by the Authority in connection with delivery shall be provided without acceptance by the Authority of any liability whatsoever to the extent permitted by law.
- B3.4 Where access to the Premises is necessary in connection with delivery or installation of the Goods, the Contractor and its Sub-Contractors shall at all times comply with the security requirements of the Authority.
- B3.5 The Authority shall be under no obligation to accept or pay for any Goods supplied earlier than the date for delivery stated in the Specification.
- B3.6 The Authority is under no obligation to accept or pay for any Goods delivered in excess of the quantity ordered. If the Authority elects not to accept such over-delivered Goods it shall give notice to the Contractor to remove them within 5 Working Days and to refund to the Authority any expenses incurred by it as a result of such over-delivery (including but not limited to the costs of moving and storing the Goods), failing which the Authority may dispose of such Goods and charge the Contractor for the costs of such disposal. The risk in any over-delivered Goods shall remain with the Contractor unless they are accepted by the Authority.
- B3.7 Unless expressly agreed to the contrary, the Authority shall not accept delivery by instalments. If, however, the Authority does specify or agree to delivery by instalments, delivery of any instalment later than the date specified or agreed for its delivery shall, without prejudice to any other rights or remedies of the Authority, entitle the Authority to terminate the whole of any unfulfilled part of the Contract without further liability to the Authority.
- B3.8 The Authority may inspect and examine the manner in which the Contractor supplies the Services at the Premises during normal business hours on reasonable notice. The Contractor shall provide free of charge all such facilities as the Authority may reasonably require for such inspection and examination. In this clause B3, Services include planning or preliminary work in connection with the supply of the Services.
- B3.9 If reasonably requested to do so by the Authority, the Contractor shall co-ordinate its activities in supplying the Services with those of the Authority and other contractors engaged by the Authority.
- B3.10 Timely supply of the Services is of the essence of the Contract, including in relation to commencing the supply of the Services within the time agreed or on a specified date. If the Contractor fails materially to deliver the Services within the time promised or specified in the Specification, the Authority is released from any obligation to accept and pay for the Services and may terminate the Contract, in either case without prejudice to any other rights and remedies of the Authority.

#### **B4 Risk and Ownership**

- B4.1 Subject to clauses B3.5 and B3.6, risk in the Goods shall, without prejudice to any other rights or remedies of the Authority (including the Authority's rights and remedies under clause F1 (Failure to meet Requirements)), pass to the Authority at the time of delivery.
- B4.2 Ownership in the Goods shall, without prejudice to any other rights or remedies of the Authority (including the Authority's rights and remedies under clause F1), pass to the Authority at the time of delivery (or payment, if earlier).

## **B5 Non-Delivery**

- B5.1 On dispatch of any consignment of the Goods the Contractor shall send the Authority an advice note specifying the means of transport, the place and date of dispatch, the number of packages and their weight and volume.
- B5.2 If the Authority has been informed in writing of the despatch of the Goods and, having been placed in transit, the Goods are not delivered to the Authority on the due date for delivery, the Authority shall, within 10 Working Days of the notified date of delivery, give notice to the Contractor that the Goods have not been delivered and may request the Contractor to deliver substitute Goods free of charge within the timescales specified by the Authority or terminate the Contract in accordance with clause B3.10.

## **B6 Labelling and Packaging**

- B6.1 The Contractor shall ensure that the Goods are labelled and packaged in accordance with the Contract.
- B6.2 The Contractor shall comply with the Packaging & Packaging Waste Directive (94/62/EC), implemented in the UK by the Packaging (Essential Requirements) Regulations 2003. The container in which the Goods are held shall be labelled with the Contractor's name, the net, gross and tare weights, and contain a description of its contents. All containers of hazardous Goods (and all documents relating thereto) shall bear prominent and adequate warnings.
- B6.3 The Contractor is responsible for the removal and disposal of all packaging materials from the Premises within the period specified by the Authority and at no cost to the Authority.
- B6.4 If no period for collection and disposal is specified by the Authority, the Contractor shall collect the packaging from the Premises no later than 10 Working Days from the date of delivery of the Goods. The Authority shall be entitled to dispose of any packaging materials which have not been collected by the Contractor within those 10 Working Days or such other period specified by the Authority for collection. The Contractor shall be responsible for the payment of any costs incurred by the Authority in connection with its collection and disposal of that packaging material.
- B6.5 The Contractor shall:
- (a) use packaging capable of easy recovery for further use or recycling. Packaging materials shall be easily separable by hand into recyclable parts consisting of one material (e.g. cardboard, paper, plastic, textile);
  - (b) reuse the packaging and, where reuse is not practicable, recycle the materials in the manufacture of crates, pallets, boxes, cartons, cushioning and other forms of packaging, where these fulfil other packaging specifications;
  - (c) make maximum use of materials taken from renewable sources, if recycled materials are not suitable or not readily available;
  - (d) if using wooden pallets or timber derived products for the packaging and supply of Goods comply with the Authority's timber procurement policy;
  - (e) review packaging specifications periodically to ensure that no unnecessary limitations on the use of recycled materials exist; and
  - (f) if requested to do so, provide the Authority with a description of the product packaging and evidence to satisfy the Authority that it is reusing, recycling and

reviewing its use of packaging. The evidence should provide proof of compliance with BS EN 13430 on recyclability or BS EN 13429 on reusability, or equivalent.

## **B7 Training**

- B7.1 If included in the Specification, the Price includes the cost of instruction of the Authority's personnel in the use and maintenance of the Goods and such instruction shall be in accordance with the requirements detailed in the Specification.

## **B8 Provision and Removal of Equipment**

- B8.1 The Contractor shall provide all the Equipment and resource necessary for the supply of the Services.
- B8.2 The Contractor shall not deliver any Equipment to or begin any work on the Premises without obtaining Approval.
- B8.3 All Equipment brought onto the Premises is at the Contractor's own risk and the Authority has no liability for any loss of or damage to any Equipment unless the Contractor is able to demonstrate that such loss or damage was caused or contributed to by the Authority's Default. The Contractor shall provide for the haulage or carriage thereof to the Premises and the removal of Equipment when no longer required at its sole cost.
- B8.4 Unless otherwise agreed, Equipment brought onto the Premises remains the property of the Contractor.
- B8.5 If the cost of any Equipment is reimbursed to the Contractor such Equipment is the property of the Authority and shall on request be delivered to the Authority as directed by the Authority. The Contractor will keep a full and accurate inventory of such Equipment and will deliver that inventory to the Authority on request and on completion of the Services.
- B8.6 The Contractor shall maintain all Equipment in a safe, serviceable and clean condition.
- B8.7 The Contractor shall, at the Authority's written request, at its own expense and as soon as reasonably practicable:
- (a) remove immediately from the Premises Equipment which is, in the Authority's opinion, hazardous, noxious or not supplied in accordance with the Contract; and
  - (b) replace such item with a suitable substitute item of Equipment.
- B8.8 Within 20 Working Days of the end of the Contract Period, the Contractor shall remove the Equipment together with any other materials used by the Contractor to supply the Services and shall leave the Premises in a clean, safe and tidy condition. The Contractor shall make good any damage to those Premises and any fixtures and fitting in the Premises which is caused by the Contractor or Staff.

## **B9 Goods Delivery**

- B9.1 The Contractor shall perform its obligations under the Contract:
- (a) with appropriately experienced, qualified and trained personnel with all due skill, care and diligence;
  - (b) in accordance with Good Industry Practice; and

(c) in compliance with all applicable Laws.

B9.2 The Contractor shall ensure the Goods:

- (a) conform in all respects with the Specification and, where applicable, with any sample approved by the Authority;
- (b) operate in accordance with the relevant technical specifications and correspond with the requirements of the Specification;
- (c) conform in all respects with all applicable Laws; and
- (d) are free from defects in design, materials and workmanship and are fit and sufficient for all the purposes for which such goods are ordinarily used and for any particular purpose made known to the Contractor by the Authority.

## **B10 Service Delivery**

B10.1 The Contractor shall at all times comply with the Quality Standards and, where applicable, shall maintain accreditation with the relevant Quality Standards authorisation body. To the extent that the standard of the Service has not been specified in the Contract, the Contractor shall agree the relevant standard of the Services with the Authority prior to the supply of the Services and, in any event, the Contractor shall perform its obligations under the Contract in accordance with the Law and Good Industry Practice.

B10.2 The Contractor shall ensure that all Staff supplying the Services do so with all due skill, care and diligence and shall possess such qualifications, skills and experience as are necessary for the proper supply of the Services. The Contractor shall ensure that those Staff are properly managed and supervised.

B10.3 If the Specification includes installation of equipment the Contractor shall notify the Authority in writing when it has completed installation. Following receipt of such notice, the Authority shall inspect the installation and shall, by giving notice to the Contractor:

- (a) accept the installation; or
- (b) reject the installation and inform the Contractor why, in the Authority's reasonable opinion, the installation does not satisfy the Specification.

B10.4 If the Authority rejects the installation pursuant to clause B10.3(b), the Contractor shall immediately rectify or remedy any defects and if, in the Authority's reasonable opinion, the installation does not, within 2 Working Days or such other period agreed by the Parties, satisfy the Specification, the Authority may terminate the Contract with immediate effect by notice.

B10.5 The installation shall be complete when the Contractor receives a notice issued by the Authority in accordance with clause B10.3(a). Notwithstanding acceptance of any installation in accordance with clause B10.3(a), the Contractor shall remain solely responsible for ensuring that the Services and the installation conform to the Specification. No rights of estoppel or waiver shall arise as a result of the acceptance by the Authority of the installation.

B10.6 During the Contract Period, the Contractor shall:

- (a) at all times have all licences, approvals and consents necessary to enable the Contractor and Staff to carry out the installation;

- (b) provide all tools and equipment (or procure the provision of all tools and equipment) necessary for completion of the installation; and
- (c) not, in delivering the Services, in any manner endanger the safety or convenience of the public.

## **B11 Key Personnel**

- B11.1 The Contractor acknowledges that the Key Personnel are essential to the proper provision of the Services.
- B11.2 The Key Personnel shall not be released from supplying the Services without the agreement of the Authority, except by reason of long-term sickness, maternity leave, paternity leave or termination of employment or other similar extenuating circumstances.
- B11.3 Any replacements to the Key Personnel shall be subject to Approval. Such replacements shall be of at least equal status, experience and skills to the Key Personnel being replaced and be suitable for the responsibilities of that person in relation to the Services.
- B11.4 The Authority shall not unreasonably withhold its agreement under clauses B11.2 or B11.3. Such agreement shall be conditional on appropriate arrangements being made by the Contractor to minimise any adverse effect on the Services which could be caused by a change in Key Personnel.
- B11.5 The Authority may, by notice to the Contractor, ask it to remove any Staff whose presence is, in the Authority's reasonable opinion, undesirable. The Contractor shall comply with any such request immediately.

## **B12 Contractor's Staff**

- B12.1 The Authority may, by notice to the Contractor, refuse to admit onto, or withdraw permission to remain on, the Authority's Premises:
  - (a) any member of the Staff; or
  - (b) any person employed or engaged by any member of the Staffwhose admission or continued presence would, in the Authority's reasonable opinion, be undesirable.
- B12.2 At the Authority's written request, the Contractor shall provide a list of the names and addresses of all persons who may require admission in to the Authority's Premises, specifying the capacities in which they are concerned with the Contract and giving such other particulars as the Authority may reasonably request.
- B12.3 The decision of the Authority as to whether any person is to be refused access to the Authority's Premises and as to whether the Contractor has failed to comply with clause B12.2 shall be final.
- B12.4 The Contractor shall ensure that all Staff who have access to the Authority's Premises, the Authority System or the Authority Data have been cleared in accordance with the BPSS.

### **B13 Inspection of Premises**

B13.1 Save as the Authority may otherwise direct, the Contractor is deemed to have inspected the Premises before submitting its Tender and to have complete due diligence in relation to all matters connected with the performance of its obligations under the Contract.

### **B14 Licence to Occupy Premises**

B14.1 Any land or Premises made available from time to time to the Contractor by the Authority in connection with the Contract shall be on a non-exclusive licence basis free of charge and shall be used by the Contractor solely for the purpose of performing its obligations under the Contract. The Contractor shall have the use of such land or Premises as licensee and shall vacate the same on termination of the Contract.

B14.2 The Contractor shall limit access to the land or Premises to such Staff as is necessary for it to perform its obligations under the Contract and the Contractor shall co-operate (and ensure that its Staff co-operate) with such other persons working concurrently on such land or Premises as the Authority may reasonably request.

B14.3 Should the Contractor require modifications to the Authority's Premises, such modifications shall be subject to Approval and shall be carried out by the Authority at the Contractor's expense. The Authority shall undertake approved modification work without undue delay.

B14.4 The Contractor shall (and shall ensure that any Staff on the Authority's Premises shall) observe and comply with such rules, regulations and requirements (including those relating to security arrangements) as may be in force from time to time for the conduct of personnel when on the Authority's Premises as determined by the Authority.

B14.5 The Contract does not create a tenancy of any nature whatsoever in favour of the Contractor or its Staff and no such tenancy has or shall come into being and, notwithstanding any rights granted pursuant to the Contract, the Authority retains the right at any time to use the Premises owned or occupied by it in any manner it sees fit.

### **B15 Property**

B15.1 All Property is and shall remain the property of the Authority and the Contractor irrevocably licenses the Authority and its agents to enter any Premises of the Contractor during normal business hours on reasonable notice to recover any such Property. The Contractor shall not in any circumstances have a lien or any other interest on the Property and the Contractor shall at all times possess the Property as fiduciary agent and bailee of the Authority. The Contractor shall take all reasonable steps to ensure that the title of the Authority to the Property and the exclusion of any such lien or other interest are brought to the notice of all Sub-Contractors and other appropriate persons and shall, at the Authority's request, store the Property separately and ensure that it is clearly identifiable as belonging to the Authority.

B15.2 The Property shall be deemed to be in good condition when received by or on behalf of the Contractor unless the Contractor notifies the Authority otherwise within 5 Working Days of receipt.

B15.3 The Contractor shall maintain the Property in good order and condition (excluding fair wear and tear), and shall use the Property solely in connection with the Contract and for no other purpose without Approval.

B15.4 The Contractor shall ensure the security of all the Property whilst in its possession, either on the Premises or elsewhere during the supply of the Services, in accordance with the Authority's reasonable security requirements as required from time to time.

B15.5 The Contractor shall be liable for all loss of or damage to the Property, unless such loss or damage was caused by the Authority's negligence. The Contractor shall inform the Authority immediately of becoming aware of any defects appearing in, or losses or damage occurring to, the Property.

## **B16 Biological Materials**

B16.1 The Contractor shall ensure that any Biological Materials collected by or on behalf of the Contractor in the course of performance of the Services are:

- (a) collected and used in accordance with the Conventions, where relevant;
- (b) made available to the Authority (or such other person as the Authority may specify) whenever and wherever and in whatever format the Authority may reasonably require for any purpose (including, without limitation, handover on termination of the Services); and
- (c) stored for whatever period is reasonably required by the Authority (or, in the absence of any such requirement, an appropriate period in all the circumstances taking into account the nature of the relevant Biological Materials) following termination of the Contract.

B16.2 The Contractor recognises and acknowledges for the purposes of clause B16.1 (c) that Key Biological Materials in its possession are likely to require long term maintenance and shall put in place appropriate procedures for ensuring that relevant samples are selected for this purpose where applicable.

B16.3 The Contractor shall identify any requirements of the Conventions (including, without limitation, benefit-sharing requirements arising from use of Biological Materials) which may apply in connection with the Services. The Contractor shall comply with any such requirements and inform the Authority of the same. This clause B16.3 shall be without prejudice to the generality of clause B10.1.

B16.4 Failure to comply with any obligation in clause B16 shall amount to a Material Breach for the purpose of clause H2 (Termination on Default). For the avoidance of doubt, where no Biological Materials are, or are to be, collected by or on behalf of the Contractor in the course of performance of the Contract all references to Biological Materials in this clause B16 or elsewhere in the Contract shall have no effect.

## **B17 Offers of Employment**

B17.1 Except in respect of any transfer of Staff under TUPE, for the Contract Period and for 12 Months thereafter the Contractor shall not employ or offer employment to any of the Authority's staff who have been associated with the Services and/or the Contract without Approval.

## **B18 Employment Provisions**

B18.1 Not later than 12 Months prior to the end of the Contract Period, the Contractor shall fully and accurately disclose to the Authority all information that the Authority may reasonably request in relation to the Staff including the following:

- (a) the total number of Staff whose employment/engagement shall terminate at the end of the Contract Period, save for any operation of Law;
- (b) the age, gender, salary or other remuneration, future pay settlements and redundancy and pensions entitlement of the Staff referred to in clause B18.1(a);
- (c) the terms and conditions of employment/engagement of the Staff referred to in clause B18.1(a), their job titles and qualifications;
- (d) details of any current disciplinary or grievance proceedings ongoing or circumstances likely to give rise to such proceedings and details of any claims current or threatened; and
- (e) details of all collective agreements with a brief summary of the current state of negotiations with any such bodies and with details of any current industrial disputes and claims for recognition by any trade union.

B18.2 At intervals determined by the Authority (which shall not be more frequent than once every 30 days) the Contractor shall give the Authority updated TUPE Information.

B18.3 Each time the Contractor supplies TUPE Information to the Authority it shall warrant its completeness and accuracy and the Authority may assign the benefit of this warranty to any Replacement Contractor.

B18.4 The Authority may use TUPE Information it receives from the Contractor for the purposes of TUPE and/or any retendering process in order to ensure an effective handover of all work in progress at the end of the Contract Period. The Contractor shall provide the Replacement Contractor with such assistance as it shall reasonably request.

B18.5 If TUPE applies to the transfer of the Services on termination of the Contract, the Contractor shall indemnify and keep indemnified the Authority, the Crown and any Replacement Contractor against all actions, suits, claims, demands, losses, charges, damages, costs and expenses and other liabilities which the Authority or the Crown or any Replacement Contractor may suffer or incur as a result of or in connection with:

- (a) the provision of TUPE Information;
- (b) any claim or demand by any Returning Employee (whether in contract, tort, under statute, pursuant to EU Law or otherwise) in each case arising directly or indirectly from any act, fault or omission of the Contractor or any Sub-Contractor in respect of any Returning Employee on or before the end of the Contract Period;
- (c) any failure by the Contractor or any Sub-Contractor to comply with its obligations under regulations 13 or 14 of TUPE or any award of compensation under regulation 15 of TUPE save where such failure arises from the failure of the Authority or a Replacement Contractor to comply with its duties under regulation 13 of TUPE;
- (d) any claim (including any individual employee entitlement under or consequent on such a claim) by any trade union or other body or person representing any Returning Employees arising from or connected with any failure by the Contractor or any Sub-Contractor to comply with any legal obligation to such trade union, body or person; and

- (e) any claim by any person who is transferred by the Contractor to the Authority and/or a Replacement Contractor whose name is not included in the list of Returning Employees.

B18.6 If the Contractor becomes aware that TUPE Information it provided has become inaccurate or misleading, it shall notify the Authority and provide the Authority with up to date TUPE Information.

B18.7 This clause B18 applies during the Contract Period and indefinitely thereafter.

B18.8 The Contractor undertakes to the Authority that, during the 12 Months prior to the end of the Contract Period the Contractor shall not (and shall procure that any Sub-Contractor shall not) without Approval (such Approval not to be unreasonably withheld or delayed):

- (a) amend or vary (or purport to amend or vary) the terms and conditions of employment or engagement (including, for the avoidance of doubt, pay) of any Staff (other than where such amendment or variation has previously been agreed between the Contractor and the Staff in the normal course of business and where any such amendment or variation is not in any way related to the transfer of the Services);
- (b) terminate or give notice to terminate the employment or engagement of any Staff (other than in circumstances in which the termination is for reasons of misconduct or lack of capability);
- (c) transfer away, remove, reduce or vary the involvement of any other Staff from or in the provision of the Services (other than where such transfer or removal: (i) was planned as part of the individual's career development; (ii) takes place in the normal course of business; and (iii) will not have any adverse impact upon the delivery of the Services by the Contractor, (provided that any such transfer, removal, reduction or variation is not in any way related to the transfer of the Services); or
- (d) recruit or bring in any new or additional individuals to provide the Services who were not already involved in providing the Services prior to the relevant period.

## **C PAYMENT**

### **C1 Price**

C1.1 In consideration of the Contractor's performance of its obligations under the Contract, the Authority shall pay the Price in accordance with clause C2 as set out at Schedule 2.

### **C2 Payment and VAT**

C2.1 The Contractor shall submit invoices to the Authority on the dates set out in Schedule 2.

C2.2 The Authority shall, in addition to the Price and following Receipt of a Valid Invoice, pay the Contractor a sum equal to the VAT chargeable on the value of the Services supplied in accordance with the Contract.

C2.3 The Contractor shall add VAT to the Price at the prevailing rate as applicable and shall show the amount of VAT payable separately on all invoices as an extra charge. If the Contractor fails to show VAT on an invoice, the Authority will not, at any later date, be liable to pay the Contractor any additional VAT.

- C2.4 All Contractor invoices shall be expressed in sterling or such other currency as shall be permitted by the Authority in writing.
- C2.5 Valid Invoices shall include:
- (a) the Contractor's full name, address and title of the Contract;
  - (b) (if Goods are included in the Specification) the name and quantity of the Goods delivered including batch numbers;
  - (c) the Purchase Order number
- and, if requested by the Authority:
- (d) timesheets for Staff engaged in providing the Services signed and dated by the Authority's representative on the Premises on the day;
  - (e) the name of the individuals to whom the timesheet relates and hourly rates for each;
  - (f) identification of which individuals are Contractor's staff and which are Sub-Contractors;
  - (g) the address of the Premises and the date on which work was undertaken;
  - (h) the time spent working on the Premises by the individuals concerned;
  - (i) details of the type of work undertaken by the individuals concerned;
  - (j) details of plant or materials operated and on standby;
  - (k) separate identification of time spent travelling and/or meal or rest breaks; and
  - (l) where appropriate, details of journeys made and distances travelled.
- C2.6 The Authority shall not pay Contractor time spent on meal or rest breaks and the Contractor shall ensure that all workers take adequate meal or rest breaks.
- C2.7 The Authority shall not pay for plant which is not in use during a meal or rest break.
- C2.8 Meal and rest breaks will include breaks both in or outside an individual's workplace along with any time taken in travelling to or from the break location and/or any facilities for cleaning/changing/washing in preparation for or return from a meal or rest break.
- C2.9 Timesheets must include a minimum of 30 minutes break for each shift of 8 hours, a minimum of 45 minutes break in a shift of between 8 and 12 hours and a minimum of one hour break will be taken within a shift in excess of 12 hours and the Contractor's rates and Contract Price must include such breaks.
- C2.10 The Authority shall not pay the Contractor's overhead costs unless specifically agreed in writing by the Authority and overhead costs shall include, without limitation; facilities, utilities, insurance, tax, head office overheads, indirect staff costs and other costs not specifically and directly ascribable solely to the provision of the Services.
- C2.11 If Schedule 2 expressly provides that the Authority may be charged for plant which is on standby then in circumstances where plant was waiting to be transferred between Premises or where the Authority has instructed that the plant is retained on the Premises

then a standby charge of 60% of agreed rates may be made in respect of such relevant periods if supported by timesheets.

- C2.12 The Authority shall pay only for the time spent by Staff working on the Premises.
- C2.13 The Authority shall not pay a stand-by rate if plant is on standby because no work was being carried out on the Premises at that time or no operator or other relevant staff were available (unless the standby is because the Contractor is awaiting licensing of the Premises on the Authority's instructions).
- C2.14 The Authority shall not pay for plant or equipment which is stood down during any notice period pursuant to clauses H1, H2 and/or H3 and the Contractor shall mitigate such costs as far as is reasonably possible, for example, by reutilising Staff, plant, materials and services on other contracts.
- C2.15 The Contractor may claim expenses only if they are clearly identified, supported by original receipts and Approved.
- C2.16 If the Authority pays the Contractor prior to the submission of a Valid Invoice this payment shall be on account of and deductible from the next payment to be made.
- C2.17 If any overpayment has been made or the payment or any part is not supported by a Valid Invoice the Authority may recover this payment against future invoices raised or directly from the Contractor. All payments made by the Authority to the Contractor shall be on an interim basis pending final resolution of an account with the Contractor in accordance with the terms of this clause C2.
- C2.18 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:
- 
- C2.19 If a payment of an undisputed amount is not made by the Authority by the due date, then the Authority shall pay the Contractor interest at the interest rate specified in the Late Payment of Commercial Debts (Interest) Act 1998.
- C2.20 The Contractor shall ensure that a provision is included in all Sub-Contracts which requires payment to be made of all sums due to Sub-Contractors within 30 days from the receipt of a valid invoice.
- C2.21 The Contractor shall indemnify the Authority on a continuing basis against any liability, including any interest, penalties or costs incurred, which is levied, demanded or assessed on the Authority at any time in respect of the Contractor's failure to account for or to pay any VAT relating to payments made to the Contractor under the Contract. Any amounts due under this clause C2.21 shall be paid by the Contractor to the Authority not less than 5 Working Days before the date upon which the tax or other liability is payable by the Authority.
- C2.22 The Contractor shall not suspend the Services unless the Contractor is entitled to terminate the Contract under clause H2.3 for failure to pay undisputed sums of money.
- C2.23 The Authority shall not pay an invoice which is not Valid Invoice.

### **C3 Recovery of Sums Due**

- C3.1 If under the Contract any sum of money is recoverable from or payable by the Contractor to the Authority (including any sum which the Contractor is liable to pay to the Authority in respect of any breach of the Contract), the Authority may unilaterally deduct that sum from any sum then due, or which at any later time may become due to the Contractor from the Authority under the Contract or under any other agreement with the Authority or the Crown.
- C3.2 Any overpayment by either Party, whether of the Price or of VAT or otherwise, shall be a sum of money recoverable by the Party who made the overpayment from the Party in receipt of the overpayment.
- C3.3 The Contractor shall make all payments due to the Authority without any deduction whether by way of set-off, counterclaim, discount, abatement or otherwise unless the Contractor has a valid court order requiring an amount equal to such deduction to be paid by the Authority to the Contractor.
- C3.4 All payments due shall be made within a reasonable time unless otherwise specified in the Contract, in cleared funds, to such bank or building society account as the recipient Party may from time to time direct.

## **D. STATUTORY OBLIGATIONS**

### **D1 Prevention of Fraud and Bribery**

- D1.1 The Contractor represents and warrants that neither it, nor to the best of its knowledge any Staff, have at any time prior to the Commencement Date:
- (a) committed a Prohibited Act or been formally notified that it is subject to an investigation or prosecution which relates to an alleged Prohibited Act; and/or
  - (b) been listed by any government department or agency as being debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for participation in government procurement programmes or contracts on the grounds of a Prohibited Act.
- D1.2 The Contractor shall not during the Contract Period:
- (a) commit a Prohibited Act; and/or
  - (b) do or suffer anything to be done which would cause the Authority or any of its employees, consultants, contractors, sub-contractors or agents to contravene any of the Relevant Requirements or otherwise incur any liability in relation to the Relevant Requirements.
- D1.3 The Contractor shall, during the Contract Period:
- (a) establish, maintain and enforce, and require that its Sub-Contractors establish, maintain and enforce, policies and procedures which are adequate to ensure compliance with the Relevant Requirements and prevent the occurrence of a Prohibited Act; and
  - (b) keep appropriate records of its compliance with its obligations under clause D1.3(a) and make such records available to the Authority on request.

- D1.4 The Contractor shall immediately notify the Authority in writing if it becomes aware of any breach of clauses D1.1 and/or D1.2, or has reason to believe that it has or any of the Staff have:
- (a) been subject to an investigation or prosecution which relates to an alleged Prohibited Act;
  - (b) been listed by any government department or agency as being debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for participation in government procurement programmes or contracts on the grounds of a Prohibited Act; and/or
  - (c) received a request or demand for any undue financial or other advantage of any kind in connection with the performance of the Contract or otherwise suspects that any person directly or indirectly connected with the Contract has committed or attempted to commit a Prohibited Act.
- D1.5 If the Contractor notifies the Authority pursuant to clause D1.4, the Contractor shall respond promptly to the Authority's enquiries, co-operate with any investigation, and allow the Authority to audit any books, records and/or any other relevant documentation.
- D1.6 If the Contractor is in Default under clauses D1.1 and/or D1.2, the Authority may by notice:
- (a) require the Contractor to remove from performance of the Contract any Staff whose acts or omissions have caused the Default; or
  - (b) immediately terminate the Contract.
- D1.7 Any notice served by the Authority under clause D1.6 shall specify the nature of the Prohibited Act, the identity of the party who the Authority believes has committed the Prohibited Act and the action that the Authority has taken (including, where relevant, the date on which the Contract shall terminate).

## **D2 Discrimination**

- D2.1 The Contractor shall:
- (a) perform its obligations under the Contract in accordance with:
    - i) all applicable equality Law (whether in relation to race, sex, gender reassignment, age, disability, sexual orientation, religion or belief, pregnancy maternity or otherwise);
    - ii) the Authority's equality and diversity policy as given to the Contractor from time to time;
    - iii) 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
  - (b) take all necessary steps and 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).

### **D3 Rights of Third Parties**

- D3.1 The provisions of clause B18.5 and E8.3 confer benefits on persons named in such provisions (together “**Third Party Provisions**”) other than the Parties (each person a “**Third Party Beneficiary**”) and are intended to be enforceable by Third Party Beneficiaries by virtue of the Contracts (Rights of Third Parties) Act 1999 (“**CRTPA**”).
- D3.2 Subject to clause D3.1, a person who is not a Party has no right under the CRTPA to enforce any provisions of the Contract but this does not affect any right or remedy of any person which exists or is available otherwise than pursuant to the CRTPA and does not apply to the Crown.
- D3.3 No Third Party Beneficiary may enforce or take steps to enforce any Third Party Provision without Approval.
- D3.4 Any amendments to the Contract may be made by the Parties without the consent of any Third Party Beneficiary.

### **D4 Health and Safety**

- D4.1 The Contractor shall perform its obligations under the Contract in accordance with:
- (a) all applicable Law regarding health and safety; and
  - (b) the Authority’s health and safety policy while at the Authority’s Premises.
- D4.2 Each Party shall notify the other as soon as practicable of any health and safety incidents or material health and safety hazards at the Authority’s Premises of which it becomes aware and which relate to or arise in connection with the performance of the Contract. The Contractor shall instruct Staff to adopt any necessary associated safety measures in order to manage any such material health and safety hazards.

### **D5 Environmental Requirements**

- D5.1 The Contractor shall in the performance of the Contract have due regard to the Authority’s environmental, sustainable and ethical procurement policies (“**Environmental Policies**”) which require the Authority through its procurement and management of suppliers to:
- (a) conserve energy, water, wood, paper and other resources and reduce waste;
  - (b) phase out the use of ozone depleting substances;
  - (c) minimise the release of greenhouse gases, volatile organic compounds and other substances damaging to health and the environment;
  - (d) minimise the use of products harmful to health and the environment such as hazardous substances and solvents, replacing them with more benign substances where feasible and, where such substances are necessary, to ensure that they are stored in properly labelled containers, used and disposed of in compliance with legal and regulatory requirements and any instructions from the Authority;
  - (e) reduce fuel emissions wherever possible;
  - (f) maximise the use of recovered materials and, if recycled materials are not suitable or not readily available, to maximise the use of materials taken from renewable sources; and

- (g) promote the design of products that are capable of reuse or remanufacture or easily separable into recyclable parts consisting of one material (e.g. steel, plastic, textile).

D5.2 The Contractor shall ensure that any equipment and materials used in the provision of the Services do not contain:

- (a) ozone depleting substances such as hydrochlorofluorocarbons (HCFCs), halons, carbon tetrachloride, 111 trichloroethane, bromochloromethane or any other damaging substances; and/or
- (b) HFCs and other gaseous and non-gaseous substances with a high global warming potential;

unless given written permission by the Authority to do so.

D5.3 The Contractor shall conserve energy and water; reduce carbon emissions and other greenhouse gases; minimise the use of substances damaging or hazardous to health and the environment and reduce waste by, for example, using resources more efficiently and reusing, recycling and composting and respecting biodiversity.

D5.4 If required by the Authority the Contractor shall provide the Authority with information about its compliance with its obligations under clause D5.3.

D5.5 The Contractor shall ensure that its Staff are aware of the Authority's Environmental Policies.

D5.6 The Contractor shall comply with the minimum environmental mandatory standards in the "Government Buying Standards" and in addition where required by the Authority, comply with any relevant "Best Practice" and "Class Leader" standards in relation to any goods on that list which are supplied to the Authority by or on behalf of the Contractor under the Contract.

D5.7 The Contractor shall:

- (a) identify any risks from climate change and variable weather such as higher temperatures, droughts, flooding, sea and river level rises, coastal and riparian erosion, water scarcity, and loss of water quality which may disrupt and/or affect the supply of the Services; and
- (b) if such risks have been identified, enhance the resilience of its organisation to enable it to adapt and deal with the effects of such extreme events, including by having the necessary awareness-raising, evaluation, preventive, preparatory, recovery measures and support systems in place in order to minimise any disruption to the supply of the Services.

## **E PROTECTION OF INFORMATION**

### **E1 Authority Data**

E1.1 The Contractor shall not delete or remove any proprietary notices contained within or relating to the Authority Data.

- E1.2 The Contractor shall not store, copy, disclose, or use the Authority Data except as necessary for the performance by the Contractor of its obligations under this Contract or as otherwise expressly authorised in writing by the Authority.
- E1.3 To the extent that Authority Data is held and/or processed by the Contractor, the Contractor shall supply Authority Data to the Authority as requested by the Authority in the format specified in the Specification.
- E1.4 The Contractor shall preserve the integrity of Authority Data and prevent the corruption or loss of Authority Data.
- E1.5 The Contractor shall perform secure back-ups of all Authority Data and shall ensure that up-to-date back-ups are stored securely off-site. The Contractor shall ensure that such back-ups are made available to the Authority immediately upon request.
- E1.6 The Contractor shall ensure that any system on which the Contractor holds any Authority Data, including back-up data, is a secure system that complies with the Security Policy Framework.
- E1.7 If Authority Data is corrupted, lost or sufficiently degraded as a result of the Contractor's Default so as to be unusable, the Authority may:
- (a) require the Contractor (at the Contractor's expense) to restore or procure the restoration of Authority Data and the Contractor shall do so promptly; and/or
  - (b) itself restore or procure the restoration of Authority Data, and shall be repaid by the Contractor any reasonable expenses incurred in doing so.
- E1.8 If at any time the Contractor suspects or has reason to believe that Authority Data has or may become corrupted, lost or sufficiently degraded in any way for any reason, then the Contractor shall notify the Authority immediately and inform the Authority of the remedial action the Contractor proposes to take.

## **E2 Data Protection**

- E2.1 The Parties acknowledge that for the purposes of the Data Protection Legislation, the Authority is the Controller and the Contractor is the Processor. The only processing that the Contractor is authorised to do is listed in Schedule 4 by the Authority and may not be determined by the Contractor.
- E2.2 The Contractor shall notify the Authority immediately if it considers that any of the Authority's instructions infringe the Data Protection Legislation.
- E2.3 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.

- E2.4 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 5 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 have been reviewed and approved by the Authority as appropriate to protect against a Data Loss Event having taken account of the:
    - (i) nature of the data to be protected;
    - (ii) harm that might result from a Data Loss Event;
    - (iii) state of technological development; and
    - (iv) cost of implementing any measures;
  - (c) ensure that :
    - (i) the Staff do not process Personal Data except in accordance with this Contract (and in particular Schedule 5);
    - (ii) 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:
      - (A) are aware of and comply with the Contractor's duties under this clause;
      - (B) are subject to appropriate confidentiality undertakings with the Contractor or any Sub-processor;
      - (C) 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
      - (D) have undergone adequate training in the use, care, protection and handling of Personal Data; and
  - (d) 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:
    - (i) 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;
    - (ii) the Data Subject has enforceable rights and effective legal remedies;
    - (iii) 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
    - (iv) the Contractor complies with any reasonable instructions notified to it in advance by the Authority with respect to the processing of the Personal Data;
  - (e) 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.
- E2.5 Subject to clause E2.6 the Contractor shall notify the Authority immediately if it:
- (a) receives a Data Subject Access Request (or purported Data Subject Access 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 in connection with Personal Data processed under this Contract;
  - (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.
- E2.6 The Contractor's obligation to notify under clause E2.5 shall include the provision of further information to the Authority in phases, as details become available.
- E2.7 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 and any complaint, communication or request made under Clause E2.5 (and insofar as possible within the timescales reasonably required by the Authority) including by promptly providing:
  - (a) the Authority with full details and copies of the complaint, communication or request;
  - (b) such assistance as is reasonably requested by the Authority to enable the Authority to comply with a Data Subject Access Request within the relevant timescales set out in the Data Protection Legislation;
  - (c) the Authority, at its request, with any Personal Data it holds in relation to a Data Subject;
  - (d) assistance as requested by the Authority following any Data Loss Event;
  - (e) 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.
- E2.8 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:
  - (a) the Authority determines that the processing is not occasional;
  - (b) 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
  - (c) the Authority determines that the processing is likely to result in a risk to the rights and freedoms of Data Subjects.
- E2.9 The Contractor shall allow for audits of its Personal Data processing activity by the Authority or the Authority's designated auditor.
- E2.10 The Contractor shall designate a Data Protection Officer if required by the Data Protection Legislation.
- E2.11 Before allowing any Sub-processor to process any Personal Data related to this Contract, the Contractor must:
  - (a) notify the Authority in writing of the intended Sub-processor and processing;
  - (b) obtain the written consent of the Authority; and
  - (c) enter into a written agreement with the Sub-processor which give effect to the terms set out in this clause E2 such that they apply to the Sub-processor; and.
  - (d) provide the Authority with such information regarding the Sub-processor as the Authority may reasonably require.

- E2.12 The Contractor shall remain fully liable for all acts or omissions of any Sub-processor.
- E2.13 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).
- E2.14 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.
- E2.15 This clause E2 shall apply during the Contract Period and indefinitely after its expiry.

### **E3 Official Secrets Acts and Finance Act 1989**

- E3.1 The Contractor shall comply with the provisions of:
- (a) the Official Secrets Acts 1911 to 1989; and
  - (b) section 182 of the Finance Act 1989.

### **E4 Confidential Information**

- E4.1 Except to the extent set out in this clause E4 or if disclosure or publication is expressly permitted elsewhere in the Contract each Party shall treat all Confidential Information belonging to the other Party as confidential and shall not disclose any Confidential Information belonging to the other Party to any other person without the other party's consent, except to such persons and to such extent as may be necessary for the performance of the Party's obligations under the Contract.
- E4.2 The Contractor hereby gives its consent for the Authority to publish the whole Contract (but with any information which is Confidential Information belonging to the Authority redacted) including from time to time agreed changes to the Contract, to the general public.
- E4.3 If required by the Authority, the Contractor shall ensure that Staff, professional advisors and consultants sign a non-disclosure agreement prior to commencing any work in connection with the Contract in substantially the form attached in Schedule 5. The Contractor shall maintain a list of the non-disclosure agreements completed in accordance with this clause E4.3.
- E4.4 If requested by the Authority, the Contractor shall give the Authority a copy of the list and, subsequently upon request by the Authority, copies of such of the listed non-disclosure agreements as required by the Authority. The Contractor shall ensure that its Staff, professional advisors and consultants are aware of the Contractor's confidentiality obligations under the Contract.
- E4.5 The Contractor may only disclose the Authority's Confidential Information to the Staff who are directly involved in the provision of the Services and who need to know the information, and shall ensure that such Staff are aware of and shall comply with these obligations as to confidentiality.
- E4.6 The Contractor shall not, and shall procure that the Staff do not, use any of the Authority's Confidential Information received otherwise than for the purposes of this Contract.
- E4.7 Clause E4.1 shall not apply to the extent that:

- (a) such disclosure is a requirement of Law placed upon the Party making the disclosure, including any requirements for disclosure under the FOIA or the EIR;
- (b) such information was in the possession of the Party making the disclosure without obligation of confidentiality prior to its disclosure by the information owner;
- (c) such information was obtained from a third party without obligation of confidentiality;
- (d) such information was already in the public domain at the time of disclosure otherwise than by a breach of the Contract; or
- (e) it is independently developed without access to the other Party's Confidential Information.

E4.8 Nothing in clause E4.1 shall prevent the Authority disclosing any Confidential Information obtained from the Contractor:

- (a) for the purpose of the examination and certification of the Authority's accounts;
- (b) for the purpose of any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources;
- (c) to any Crown Body or any Contracting Authority and the Contractor hereby acknowledges that all government departments or Contracting Authorities receiving such Confidential Information may further disclose the Confidential Information to other government departments or other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any government department or any Contracting Authority;
- (d) to any consultant, contractor or other person engaged by the Authority

provided that in disclosing information under clauses E4.8 (c) and (d) the Authority discloses only the information which is necessary for the purpose concerned and requests that the information is treated in confidence and that a confidentiality undertaking is given where appropriate.

E4.9 Nothing in clauses E4.1 to E4.6 shall prevent either Party from using any techniques, ideas or Know-How gained during the performance of its obligations under the Contract in the course of its normal business, to the extent that this does not result in a disclosure of the other Party's Confidential Information or an infringement of the other Party's Intellectual Property Rights.

E4.10 The Authority shall use all reasonable endeavours to ensure that any government department, Contracting Authority, employee, third party or Sub-Contractor to whom the Contractor's Confidential Information is disclosed pursuant to clause E4.6 is made aware of the Authority's obligations of confidentiality.

E4.11 If the Contractor does not comply with clauses E4.1 to E4.6 the Authority may terminate the Contract immediately on notice to the Contractor.

E4.12 In order to ensure that no unauthorised person gains access to any Confidential Information or any data obtained in the supply of the Services, the Contractor shall

maintain adequate security arrangements that meet the requirements of professional standards and best practice.

- E4.13 The Contractor will immediately notify the Authority of any breach of security in relation to Confidential Information and all data obtained in the supply of the Services and will keep a record of such breaches. The Contractor will use its best endeavours to recover such Confidential Information or data however it may be recorded. The Contractor will co-operate with the Authority in any investigation as a result of any breach of security in relation to Confidential Information or data.
- E4.14 The Contractor shall, at its own expense, alter any security systems at any time during the Contract Period at the Authority's request if the Authority reasonably believes the Contractor has failed to comply with clause E4.12.

## **E5 Freedom of Information**

- E5.1 The Contractor acknowledges that the Authority is subject to the requirements of the FOIA and the EIR.
- E5.2 The Contractor shall transfer to the Authority all Requests for Information that it receives as soon as practicable and in any event within 2 Working Days of receipt:
- (a) give the Authority a copy of all Information in its possession or control in the form that the Authority requires within 5 Working Days (or such other period as the Authority may specify) of the Authority's request;
  - (b) provide all necessary assistance as reasonably requested by the Authority to enable the Authority to comply with its obligations under the FOIA and EIR; and
  - (c) not respond to directly to a Request for Information unless authorised to do so in writing by the Authority.
- E5.3 The Authority shall determine in its absolute discretion and notwithstanding any other provision in the Contract or any other agreement whether the Commercially Sensitive Information and any other Information is exempt from disclosure in accordance with the provisions of the FOIA and/or the EIR.

## **E6 Publicity, Media and Official Enquiries**

- E6.1 Without prejudice to the Authority's obligations under the FOIA, the EIR or any obligations under the Regulations, or any policy requirements as to transparency, neither Party shall make any press announcement or publicise the Contract or any part thereof in any way, except with the written consent of the other Party.
- E6.2 The Contractor shall use its best endeavours to ensure that its Staff, professional advisors and consultants comply with clause E6.1.
- E6.3 Notwithstanding clause E6.1 but subject to clause E4 (Confidential Information) and Schedule 4, the Contractor shall endeavour to make the Results generally available (including in scientific journals where reasonably appropriate) and shall acknowledge in any public statement the financial support of the Authority and the Co-funders. The Contractor shall send details of any proposed publication to the Authority at least 2 weeks prior to the proposed publication and shall notify the Authority immediately if approached by the media about the Services.

E6.4 Subject to clause E4 (Confidential Information) and Schedule 4 the Authority may disclose, copy and otherwise distribute to the public or use in any way any information arising out of the Services or comprised in any work relating to the Services.

E6.5 Nothing in the Contract shall permit or require the Contractor or the Co-funders to make any disclosure of information which would jeopardise any commercial exploitation of the Results.

## **E7 Security**

E7.1 The Authority shall be responsible for maintaining the security of the Authority's Premises in accordance with its standard security requirements. The Contractor shall comply with all security requirements of the Authority while on the Authority's Premises, and shall ensure that all Staff comply with such requirements.

E7.2 The Authority shall give the Contractor upon request copies of its written security procedures.

E7.3 The Contractor shall, as an enduring obligation during the Contract Period, use the latest versions of anti-virus definitions available from an industry accepted anti-virus software vendor to check for and delete Malicious Software from the ICT Environment.

E7.4 Notwithstanding clause E7.3, if Malicious Software is found, the Parties shall co-operate to reduce the effect of the Malicious Software and, particularly if Malicious Software causes loss of operational efficiency or loss or corruption of the Authority Data, assist each other to mitigate any losses and to restore the provision of Services to their desired operating efficiency.

E7.5 Any cost arising out of the actions of the Parties taken in compliance with clause E7.4 shall be borne by the Parties as follows:

(a) by the Contractor where the Malicious Software originates from the Contractor Software, the Third Party Software or the Authority Data (whilst the Authority Data was under the control of the Contractor); and

(b) by the Authority if the Malicious Software originates from the Authority Software or Authority Data (whilst the Authority Data was under the control of the Authority).

## **E8 Intellectual Property Rights**

E8.1 All Intellectual Property Rights in:

(a) the Results; or

(b) any guidance, specifications, reports, studies, instructions, toolkits, plans, data, drawings, databases, patents, patterns, models, designs or other material which has not been provided by a third party or exists prior to or generated independently of the Services which is furnished to or made available to the Contractor by or on behalf of the Authority (together with the Results, the "**IP Materials**")

shall vest in the Authority (save for Copyright and Database Rights which shall vest in Her Majesty the Queen) and the Contractor shall not, and shall ensure that the Staff shall not, use or disclose any IP Materials without Approval save to the extent necessary for performance by the Contractor of its obligations under the Contract.

E8.2 The Contractor hereby assigns:

- (a) to the Authority, with full title guarantee, all Intellectual Property Rights (save for Copyright and Database Rights) which may subsist in the IP Materials. This assignment shall take effect on the date of the Contract or (in the case of rights arising after the date of the Contract) as a present assignment of future rights that will take effect immediately on the coming into existence of the Intellectual Property Rights produced by the Contractor;
- (b) to Her Majesty the Queen, with full title guarantee, all Copyright and Database Rights which may subsist in the IP Materials prepared in accordance with clauses E8.1 (a) and (b),

and shall execute all documents and do all acts as are necessary to execute these assignments.

E8.3 The Contractor shall:

- (a) ensure that the third party owner of any Intellectual Property Rights that are or which may be used to perform the Services grants to the Authority a non-exclusive licence or, if itself a licensee of those rights, shall grant to the Authority an authorised sub-licence, to use, reproduce, modify, develop and maintain the Intellectual Property Rights in the same. Such licence or sub-licence shall be non-exclusive, perpetual, royalty-free, worldwide and irrevocable and shall include the right for the Authority to sub-license, transfer, novate or assign to other Contracting Authorities, the Crown, the Replacement Contractor or to any other third party supplying goods and/or services to the Authority ("**Indemnified Persons**");
- (b) not infringe any Intellectual Property Rights of any third party in supplying the Services; and
- (c) during and after the Contract Period, indemnify and keep indemnified the Authority and the Indemnified Persons from and against all actions, suits, claims, demands, losses, charges, damages, costs and expenses and other liabilities which the Authority or the Indemnified Persons may suffer or incur as a result of or in connection with any breach of this clause E8.3, except to the extent that any such claim results directly from:
  - i) items or materials based upon designs supplied by the Authority; or
  - ii) the use of data supplied by the Authority which is not required to be verified by the Contractor under any provision of the Contract.

E8.4 The Authority shall notify the Contractor in writing of any claim or demand brought against the Authority for infringement or alleged infringement of any Intellectual Property Right in materials supplied and/or licensed by the Contractor to the Authority.

E8.5 The Contractor shall at its own expense conduct all negotiations and any litigation arising in connection with any claim, demand or action by any third party for infringement or alleged infringement of any third party Intellectual Property Rights (whether by the Authority, the Contractor or an Indemnified Person) arising from the performance of the Contractor's obligations under the Contract ("**Third Party IP Claim**"), provided that the Contractor shall at all times:

- (a) consult the Authority on all material issues which arise during the conduct of such litigation and negotiations;
- (b) take due and proper account of the interests of the Authority; and

(c) not settle or compromise any claim without Approval (not to be unreasonably withheld or delayed).

E8.6 The Authority shall at the request of the Contractor afford to the Contractor all reasonable assistance for the purpose of contesting any Third Party IP Claim and the Contractor shall indemnify the Authority for all costs and expenses (including, but not limited to, legal costs and disbursements) incurred in doing so. The Contractor shall not be required to indemnify the Authority under this clause E8.6 in relation to any costs and expenses to the extent that such arise directly from the matters referred to in clauses E8.3 (c) i) and ii).

E8.7 The Authority shall not, without the Contractor's consent, make any admissions which may be prejudicial to the defence or settlement of any Third Party IP Claim.

E8.8 If any Third Party IP Claim is made or in the reasonable opinion of the Contractor is likely to be made, the Contractor shall notify the Authority and, at its own expense and subject to Approval (not to be unreasonably withheld or delayed), shall (without prejudice to the rights of the Authority under clauses E8.3 and G2.1(g)) use its best endeavours to:

(a) modify any or all of the Services without reducing the performance or functionality of the same, or substitute alternative services of equivalent performance and functionality, so as to avoid the infringement or the alleged infringement; or

(b) procure a licence to use the Intellectual Property Rights and supply the Services which are the subject of the alleged infringement, on terms which are acceptable to the Authority

and if the Contractor is unable to comply with clauses E8.8(a) or (b) within 20 Working Days of receipt by the Authority of the Contractor's notification the Authority may terminate the Contract immediately by notice to the Contractor.

E8.9 The Contractor grants to the Authority and, if requested by the Authority, any Replacement Contractor, a royalty-free, irrevocable, worldwide, non-exclusive licence (with a right to sub-license) to use any Intellectual Property Rights that the Contractor owned or developed prior to the Commencement Date and which the Authority (or the Replacement Contractor) reasonably requires in order for the Authority to exercise its rights under, and receive the benefit of, the Contract (including, without limitation, the Services).

## **E9 Commercial Exploitation**

E9.1 The Contractor shall:

(a) ensure that its staff, students and sub-contractors are and will be engaged in relation to the Contract and the Services on terms which do not entitle any of them to any rights in the Results; and

(b) ensure that it is and remains entitled to transfer free from any encumbrances any title and/or rights necessary to effect the vesting of Intellectual Property Rights required by the Contract.

E9.2 Subject to clauses E9.3 and E9.4 the Contractor will use reasonable endeavours to exploit the Results commercially for its benefit and the benefit of the Authority and the Co-funders.

E9.3 The Contractor shall identify and inform the Authority of any Results which it considers suitable for commercial exploitation. If the Contractor has identified an opportunity for the commercial exploitation of the Results then it shall either apply to the Authority for a

licence (with a right to sub-license as required) as may be necessary, or provide such assistance as is required by the Authority to facilitate a licence being granted by the Authority to a third party.

- E9.4 The Contractor shall identify and inform the Authority of any Results which may be suitable for registration as a patent, copyright, registered design, trade mark or other legal protection and shall use its reasonable endeavours to apply for such protection throughout or in any part of the world in the name of the Authority, and shall maintain such protection in such part of the world as it considers suitable at its own expense.
- E9.5 Subject to clause E9.6 the Income from the commercial exploitation of the Results shall, after deduction of allowable costs as described below, be apportioned between the Parties as follows:
- (a) the Authority and Co-Funders: 10%, to be divided in the proportion of the actual payments made to the Contractor under the Contract by the Authority and Co-Funders respectively; and
  - (b) the Contractor: 90%.
- E9.6 The Income referred to in clause E9.5 shall be payable for the longer of:
- (a) the term of any patent arising from or incorporating any of the Results; and
  - (b) 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.
- E9.7 The allowable costs for the purposes of clause E9.5 shall be limited to:
- (a) the registration fees for the registering of any rights in relation to such Results;
  - (b) any legal 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;
  - (c) any other reasonable cost or expenditure which may be agreed from time to time by the Authority and the Contractor; and
  - (d) subject to Approval, 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.
- E9.8 The Contractor shall have sole responsibility for making any payments due to Staff 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 clause E9.5. Any payments in respect of a share of Income to be made to the Authority and/or the Co-funders by the Contractor shall be made promptly, in such format as the Authority may direct and accompanied by sufficient information to enable the Authority to identify: i) the contract to which such payments relate; and ii) the means (including a full breakdown of allowable costs) by which such payments have been calculated.
- E9.9 If the Contractor does not intend to protect or exploit any Results then the Authority shall be entitled to obtain protection at its own cost and (if clause E8.1 has been amended or varied so that ownership of the Results vests in the Contractor) to have assigned to it at no charge all rights in the relevant Results. The Contractor will not be entitled to any share

of the Income generated as the result of the protection or exploitation of the relevant Results obtained by the Authority.

E9.10 For the avoidance of doubt, clauses E9.5 to E9.9 do not apply to and do not affect any Intellectual Property Rights in existence before the commencement of the Services.

## **E10 Audit**

E10.1 The Contractor shall keep and maintain until 6 years after the end of the Contract Period, or as long a period as may be agreed between the Parties, full and accurate records of the Contract including the Services supplied under it, all expenditure reimbursed by the Authority, and all payments made by the Authority. The Contractor shall on request afford the Authority or the Authority's representatives such access to those records and processes as may be requested by the Authority in connection with the Contract.

E10.2 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 Services.

E10.3 The Contractor shall permit duly authorised representatives of the Authority and/or the National Audit Office to examine the Contractor's records and documents relating to the Contract and to provide such copies and oral or written explanations as may reasonably be required.

E10.4 The Contractor (and its agents) shall permit the Comptroller and Auditor General (and his appointed representatives) access free of charge during normal business hours on reasonable notice to all such documents (including computerised documents and data) and other information as the Comptroller and Auditor General may reasonably require for the purposes of his financial audit of the Authority and for carrying out examinations into the economy, efficiency and effectiveness with which the Authority has used its resources. The Contractor shall provide such explanations as are reasonably required for these purposes.

## **E11 Tax Compliance**

E11.1 If, during the Contract Period, an Occasion of Tax Non-Compliance occurs, the Contractor shall:

(a) notify the Authority in writing of such fact within 5 Working Days of its occurrence; and

(c) promptly give the Authority:

i) details of the steps it is taking to address the Occasion of Tax Non-Compliance and to prevent the same from recurring, together with any mitigating factors it considers relevant; and

ii) such other information in relation to the Occasion of Tax Non-Compliance as the Authority may reasonably require.

E11.2 If the Contractor or any Staff are liable to be taxed in the UK or to pay NICs in respect of consideration received under the Contract, the Contractor shall:

(a) at all times comply with ITEPA and all other statutes and regulations relating to income tax, and SSCBA and all other statutes and regulations relating to NICs, in respect of that consideration; and

- (b) indemnify the Authority against any income tax, NICs and social security contributions and any other liability, deduction, contribution, assessment or claim arising from or made in connection with the provision of the Services by the Contractor or any Staff.

## **F. CONTROL OF THE CONTRACT**

### **F1 Failure to meet Requirements**

- F1.1 If the Authority informs the Contractor in writing that the Authority reasonably believes that any part of the Services do not meet the requirements of the Contract or differs in any way from those requirements, and this is not as a result of a default by the Authority, the Contractor shall at its own expense re-schedule and carry out the Services in accordance with the requirements of the Contract within such reasonable time as may be specified by the Authority.
- F1.2 The Authority may by notice to the Contractor reject any of the Goods which fail to conform to the approved sample or fail to meet the Specification. Such notice shall be given within a reasonable time after delivery to the Authority of such Goods. If the Authority rejects any of the Goods pursuant to this clause the Authority may (without prejudice to its other rights and remedies) either:
  - (a) have such Goods promptly, free of charge and in any event within 5 Working Days, either repaired by the Contractor or replaced by the Contractor with Goods which conform in all respects with the approved sample or with the Specification and due delivery shall not be deemed to have taken place until such repair or replacement has occurred; or
  - (b) treat the Contract as discharged by the Contractor's breach and obtain a refund (if payment for the Goods has already been made) from the Contractor in respect of the Goods concerned together with payment of any additional expenditure reasonably incurred by the Authority in obtaining other goods in replacement.
- F1.3 The Authority will be deemed to have accepted the Goods if it expressly states the same in writing or fails to reject the Goods in accordance with clause F1.2.
- F1.4 The issue by the Authority of a receipt note for delivery of the Goods shall not constitute any acknowledgement of the condition, quantity or nature of those Goods, or the Authority's acceptance of them.
- F1.5 The Contractor hereby guarantees the Goods against faulty materials or workmanship for such period as may be specified in the Specification or, if no period is specified, for a period of 18 months from the date of delivery. If the Authority shall within such period or within 25 Working Days thereafter give notice to the Contractor of any defect in any of the Goods as may have arisen during such period under proper and normal use, the Contractor shall (without prejudice to any other rights and remedies which the Authority may have) promptly remedy such defects (whether by repair or replacement as the Authority shall elect) free of charge.
- F1.6 Any Goods rejected or returned by the Authority as described in clause F1.2 shall be returned to the Contractor at the Contractor's risk and expense.

### **F2 Monitoring of Contract Performance**

- F2.1 The Contractor shall immediately inform the Authority if any of the Services are not being or are unable to be performed, the reasons for non-performance, any corrective action and the date by which that action will be completed.

- F2.2 At 6 monthly intervals from the Commencement Date (each being a "Review Date"), the Authority shall carry out a review of the performance of the Contractor ("Checkpoint Review"). Without prejudice to the generality of the foregoing, the Authority may in respect of the period under review consider such items as (but not limited to): the Contractor's delivery of the Services; the Contractor's contribution to innovation in the Authority; whether the Services provide the Authority with best value for money; consideration of any changes which may need to be made to the Services; a review of future requirements in relation to the Services and progress against key milestones.
- F2.3 The Contractor shall provide at its own cost any assistance reasonably required by the Authority to perform such Checkpoint Review including the provision of data and information.
- F2.4 The Authority may produce a report (a "Checkpoint Review Report") of the results of each Checkpoint Review stating any areas of exceptional performance and areas for improvement in the provision of the Services and where there is any shortfall in any aspect of performance reviewed as against the Authority's expectations and the Contractor's obligations under this Contract.
- F2.5 The Authority shall give the Contractor a copy of the Checkpoint Review Report (if applicable). The Authority shall consider any Contractor comments and may produce a revised Checkpoint Review Report.
- F2.6 The Contractor shall, within 10 Working Days of receipt of the Checkpoint Review Report (revised as appropriate) provide the Authority with a plan to address resolution of any shortcomings and implementation of improvements identified by the Checkpoint Review Report.
- F2.7 Actions required to resolve shortcomings and implement improvements (either as a consequence of the Contractor's failure to meet its obligations under this Contract identified by the Checkpoint Review Report, or those which result from the Contractor's failure to meet the Authority's expectations notified to the Contractor or of which the Contractor ought reasonably to have been aware) shall be implemented at no extra charge to the Authority.

### **F3 Reporting**

- F3.4 Unless Approved, the Contractor shall submit by the completion date of the Services a final report (the "Final Report") consisting of 2 hard copies and one electronic copy on either computer readable disk or by e-mail in a format specified by the Authority. The Final Report shall include the following:
- (a) the Services' code and title as set out in the Specification; the name of the Contractor; the total costs; and the Commencement Date and date of completion of the Services;
  - (b) an executive summary of not more than 2 sides of A4 written in a style understandable to the intelligent non-scientist. This should include the main objectives of the Services; the methods and findings of the research; and any other significant events and options for new work; and
  - (c) a scientific report.
- F3.5 The scientific report referred to in clause F3.4(c) above shall contain:
- (a) the scientific objectives as set out in the Specification;

- (b) the extent to which the objectives set out in the Specification have been met;
- (c) details of methods used and the Results obtained, including statistical analysis where appropriate;
- (d) a discussion of the Results and their reliability;
- (e) the main implications of the findings;
- (f) possible future work; and
- (g) any action resulting from the research, for example, protection of Intellectual Property Rights and knowledge transfer.

F3.6 Notwithstanding clause E6 (Publicity, Media and Official Enquiries), the Authority may publish the Final Report on a website. When submitting the Final Report to the Authority the Contractor shall indicate any information contained in the Final Report which it considers to be commercially sensitive or which might otherwise merit non-publication and the Authority shall not disclose such information without first having consulted the Contractor (without prejudice to the Authority's discretion as to whether to publish following such consultation).

F3.7 The Authority reserves the right to reject any Annual Report or Final 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. If an Annual Report or Final Report is rejected by the Authority, the Contractor shall remedy any deficiencies identified by the Authority and submit a revised version at no additional cost to the Authority or the Co-funders.

F3.8 The Contractor shall supply any additional reports, including financial reports, in respect of the Services, at such time or times, and in such form, as the Authority may reasonably require. Without prejudice to the generality of the foregoing, 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 granted to third parties in respect of any Intellectual Property Rights in the same. The Contractor shall further 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 the Contract has been properly accounted for and apportioned in accordance with the Contract.

F3.9 The Contractor shall, subject to reasonable notice, attend all meetings specified in the Contract or otherwise arranged by the Authority for the purpose of discussion of the Services.

#### **F4 Remedies for inadequate performance**

F4.1 If the Authority reasonably believes the Contractor has committed a Material Breach it may, without prejudice to its rights under clause H2 (Termination on Default), do any of the following:

- (a) without terminating the Contract, itself supply or procure the supply of all or part of the Services until such time as the Contractor has demonstrated to the Authority's reasonable satisfaction that the Contractor will be able to supply the Services in accordance with the Specification;

- (b) without terminating the whole of the Contract, terminate the Contract in respect of part of the Services only (whereupon a corresponding reduction in the Price shall be made) and thereafter itself supply or procure a third party to supply such part of the Services;
- (c) withhold or reduce payments to the Contractor in such amount as the Authority reasonably deems appropriate in each particular case; and/or
- (d) terminate the Contract in accordance with clause H2.

F4.2 Without prejudice to its right under clause C3 (Recovery of Sums Due), the Authority may charge the Contractor for any costs reasonably incurred and any reasonable administration costs in respect of the supply of any part of the Services by the Authority or a third party to the extent that such costs exceed the payment which would otherwise have been payable to the Contractor for such part of the Services.

F4.3 If the Authority reasonably believes the Contractor has failed to supply all or any part of the Services in accordance with the Contract, professional or industry practice which could reasonably be expected of a competent and suitably qualified person, or any legislative or regulatory requirement, the Authority may give the Contractor notice specifying the way in which its performance falls short of the requirements of the Contract or is otherwise unsatisfactory.

F4.4 If the Contractor has been notified of a failure in accordance with clause F4.3 the Authority may:

- (a) direct the Contractor to identify and remedy the failure within such time as may be specified by the Authority and to apply all such additional resources as are necessary to remedy that failure at no additional charge to the Authority within the specified timescale; and/or
- (b) withhold or reduce payments to the Contractor in such amount as the Authority deems appropriate in each particular case until such failure has been remedied to the satisfaction of the Authority.

F4.5 If the Contractor has been notified of a failure in accordance with clause F4.3, it shall:

- (a) use all reasonable endeavours to immediately minimise the impact of such failure to the Authority and to prevent such failure from recurring; and
- (b) immediately give the Authority such information as the Authority may request regarding what measures are being taken to comply with the obligations in this clause F4.5 and the progress of those measures until resolved to the satisfaction of the Authority.

F4.6 If, having been notified of any failure, the Contractor fails to remedy it in accordance with clause F4.5 within the time specified by the Authority, the Authority may treat the continuing failure as a Material Breach and may terminate the Contract immediately on notice to the Contractor.

## **F5 Transfer and Sub-Contracting**

F5.1 Except where clauses F5.5 and F5.6 both apply, the Contractor shall not transfer, charge, assign, sub-contract or in any other way dispose of the Contract or any part of it without Approval. All such documents shall be evidenced in writing and shown to the Authority on request. Sub-contracting any part of the Contract shall not relieve the Contractor of any of its obligations or duties under the Contract.

- F5.2 The Contractor is responsible for the acts and/or omissions of its Sub-Contractors as though they are its own. If it is appropriate, the Contractor shall provide each Sub-Contractor with a copy of the Contract and obtain written confirmation from them that they will provide the Services fully in accordance with the Contract.
- F5.3 The Contractor shall ensure that its Sub-Contractors and suppliers retain all records relating to the Services for at least 6 years from the date of their creation and make them available to the Authority on request in accordance with the provisions of clause E10 (Audit). If any Sub-Contractor or supplier does not allow the Authority access to the records then the Authority shall have no obligation to pay any claim or invoice made by the Contractor on the basis of such documents or work carried out by the Sub-Contractor or supplier.
- F5.4 If the Authority has consented to the award of a Sub-Contract the Contractor shall ensure that:
- (a) the Sub-Contract contains a right for the Contractor to terminate the Sub-Contract if the relevant Sub-Contractor does not comply in the performance of its contract with legal obligations in environmental, social or labour law;
  - (b) the Sub-Contract includes a provision having the same effect as set out in clause F5.4 (a) in any Sub-Contract which it awards; and
  - (c) copies of each Sub-Contract shall, at the request of the Authority, be sent by the Contractor to the Authority immediately.
- F5.5 If the Authority believes there are:
- (a) compulsory grounds for excluding a Sub-Contractor pursuant to regulation 57 of the Regulations, the Contractor shall replace or not appoint the Sub-Contractor; or
  - (b) non-compulsory grounds for excluding a Sub-Contractor pursuant to regulation 57 of the Regulations, the Authority may require the Contractor to replace or not appoint the Sub-Contractor and the Contractor shall comply with such requirement.
- F5.6 Notwithstanding clause F5.1, the Contractor may assign to a third party (the “**Assignee**”) the right to receive payment of the Price or any part thereof due to the Contractor (including any interest which the Authority incurs under clause C2 (Payment and VAT)). Any assignment under this clause F5.6 shall be subject to:
- (a) reduction of any sums in respect of which the Authority exercises its right of recovery under clause C3 (Recovery of Sums Due);
  - (b) all related rights of the Authority under the Contract in relation to the recovery of sums due but unpaid; and
  - (c) the Authority receiving notification under both clauses F5.7 and F5.8.
- F5.7 If the Contractor assigns the right to receive the Price under clause F5.6, the Contractor or the Assignee shall notify the Authority in writing of the assignment and the date upon which the assignment becomes effective.
- F5.8 The Contractor shall ensure that the Assignee notifies the Authority of the Assignee’s contact information and bank account details to which the Authority shall make payment.

F5.9 The provisions of clause C2 shall continue to apply in all other respects after the assignment and shall not be amended without Approval.

F5.10 Subject to clause F5.11, the Authority may assign, novate or otherwise dispose of its rights and obligations under the Contract or any part thereof to:

- (a) any Contracting Authority;
- (b) any other body established or authorised by the Crown or under statute in order substantially to perform any of the functions that had previously been performed by the Authority; or
- (c) any private sector body which substantially performs the functions of the Authority

provided that any such assignment, novation or other disposal shall not increase the burden of the Contractor's obligations under the Contract.

F5.11 Any change in the legal status of the Authority such that it ceases to be a Contracting Authority shall not, subject to clause F5.12, affect the validity of the Contract and the Contract shall bind and inure to the benefit of any successor body to the Authority.

F5.12 If the rights and obligations under the Contract are assigned, novated or otherwise disposed of pursuant to clause F5.10 to a body which is not a Contracting Authority or if there is a change in the legal status of the Authority such that it ceases to be a Contracting Authority (in the remainder of this clause F5 both such bodies being referred to as the "Transferee"):

- (a) the rights of termination of the Authority in clauses H1 and H2 shall be available to the Contractor in respect of the Transferee; and
- (b) the Transferee shall only be able to assign, novate or otherwise dispose of its rights and obligations under the Contract or any part thereof with the prior consent in writing of the Contractor.

F5.13 The Authority may disclose to any Transferee any Confidential Information of the Contractor which relates to the performance of the Contractor's obligations under the Contract. In such circumstances the Authority shall authorise the Transferee to use such Confidential Information only for purposes relating to the performance of the Contractor's obligations under the Contract and for no other purpose and shall take all reasonable steps to ensure that the Transferee gives a confidentiality undertaking in relation to such Confidential Information.

F5.14 Each Party shall at its own cost and expense carry out, or use all reasonable endeavours to ensure the carrying out of, whatever further actions (including the execution of further documents) the other Party reasonably requires from time to time for the purpose of giving that other Party the full benefit of the provisions of the Contract.

## **F6 Waiver**

F6.1 The failure of either Party to insist upon strict performance of any provision of the Contract, or the failure of either Party to exercise, or any delay in exercising, any right or remedy shall not constitute a waiver of that right or remedy and shall not cause a diminution of the obligations established by the Contract.

F6.2 No waiver shall be effective unless it is expressly stated to be a waiver and communicated to the other Party in writing in accordance with clause A4.2 (Notices).

F6.3 A waiver of any right or remedy arising from a breach of the Contract shall not constitute a waiver of any right or remedy arising from any other or subsequent breach of the Contract.

## **F7 Variation**

F7.1 If, after the Commencement Date, the Authority's requirements change, the Authority may request a Variation subject to the terms of this clause 7.

F7.2 The Authority may request a Variation by notifying the Contractor in writing of the Variation and giving the Contractor sufficient information to assess the extent of the Variation and consider whether any change to the Price is required in order to implement the Variation within a reasonable time limit specified by the Authority. If the Contractor accepts the Variation it shall confirm it in writing.

F7.3 If the Contractor is unable to accept the Variation or where the Parties are unable to agree a change to the Price, the Authority may:

- (a) allow the Contractor to fulfil its obligations under the Contract without the Variation to the Specification; or
- (b) terminate the Contract immediately except where the Contractor has already delivered all or part of the Services or where the Contractor can show evidence of substantial work being carried out to fulfil the requirements of the Specification; and in such case the Parties shall attempt to agree upon a resolution to the matter. If a resolution cannot be reached, the matter shall be dealt with under the Dispute Resolution procedure detailed in clause I2 (Dispute Resolution).

F7.4 No Variation will take effect unless and until recorded in a validly executed CCN. Execution of a CCN shall be made via electronic signature as described in clause 1.2 of Section 1 of the Contract.

F7.5 A CCN takes effect on the date both Parties communicate acceptance of the CCN via Bravo and, on the date it communicates its acceptance of the CCN in this way, the Contractor is deemed to warrant and represent that the CCN has been executed by a duly authorised representative of the Contractor in addition to the warranties and representations set out in clause G2.

F7.6 The provisions of clauses F7.4 and F7.5 may be varied in an emergency if it is not practicable to obtain the Authorised Representative's approval within the time necessary to make the Variation in order to address the emergency. In an emergency, Variations may be approved by a different representative of the Authority. However, the Authorised Representative shall have the right to review such a Variation and require a CCN to be entered into on a retrospective basis which may itself vary the emergency Variation.

## **F8 Severability**

F8.1 If any provision of the Contract which is not of a fundamental nature is held invalid, illegal or unenforceable for any reason by any court of competent jurisdiction, such provision shall be severed and the remainder of the provisions of the Contract shall continue in full force and effect as if the Contract had been executed with the invalid, illegal or unenforceable provision eliminated.

## **F9 Remedies Cumulative**

F9.1 Except as expressly provided in the Contract all remedies available to either Party for breach of the Contract are cumulative and may be exercised concurrently or separately,

and the exercise of any one remedy shall not be deemed an election of such remedy to the exclusion of other remedies.

## **F10 Entire Agreement**

F10.1 The Contract constitutes the entire agreement between the Parties in respect of the matters dealt with therein. The Contract supersedes all prior negotiations between the Parties and all representations and undertakings made by one Party to the other, whether written or oral, except that this clause shall not exclude liability in respect of any fraudulent misrepresentation.

## **F11 Counterparts**

F11.1 The Contract may be executed in counterparts, each of which when executed and delivered shall constitute an original but all counterparts together shall constitute one and the same instrument.

# **G LIABILITIES**

## **G1 Liability, Indemnity and Insurance**

G1.1 Neither Party limits its liability for:

- (a) death or personal injury caused by its negligence;
- (b) fraud or fraudulent misrepresentation;
- (c) any breach of any obligations implied by section 12 of the Sale of Goods Act 1979 or section 2 of the Supply of Goods and Services Act 1982;
- (d) any breach of clauses D1, E1, E2 or E4 or any breach of Schedule 8; or
- (e) any liability to the extent it cannot be limited or excluded by Law.

G1.2 Subject to clauses G1.3 and G1.4, the Contractor shall indemnify the Authority and keep the Authority indemnified fully against all claims, proceedings, demands, charges, actions, damages, costs, breach of statutory duty, expenses and any other liabilities which may arise out of the supply, or the late or purported supply, of the Services or the performance or non-performance by the Contractor of its obligations under the Contract or the presence of the Contractor or any Staff on the Premises, including in respect of any death or personal injury, loss of or damage to property, financial loss arising from any advice given or omitted to be given by the Contractor, or any other loss which is caused directly by any act or omission of the Contractor.

G1.3 Subject to clause G1.1 the Contractor's aggregate liability in respect of the Contract shall not exceed 200% of the Total Contract Value.

G1.4 The Contractor shall not be responsible for any injury, loss, damage, cost or expense if and to the extent that it is caused by the negligence or wilful misconduct of the Authority or by breach by the Authority of its obligations under the Contract.

G1.5 The Authority may recover from the Contractor the following losses incurred by the Authority to the extent they arise as a result of a Default by the Contractor:

- (a) any additional operational and/or administrative costs and expenses incurred by the Authority, including costs relating to time spent by or on behalf of the Authority in dealing with the consequences of the Default;
- (b) any wasted expenditure or charges;
- (c) the additional costs of procuring a Replacement Contractor for the remainder of the Contract Period and or replacement deliverables which shall include any incremental costs associated with the Replacement Contractor and/or replacement deliverables above those which would have been payable under the Contract;
- (d) any compensation or interest paid to a third party by the Authority; and
- (e) any fine or penalty incurred by the Authority pursuant to Law and any costs incurred by the Authority in defending any proceedings which result in such fine or penalty.

G1.6 Subject to clauses G1.1 and G1.5, neither Party shall be liable to the other for any:

- (a) loss of profits, turnover, business opportunities or damage to goodwill (in each case whether direct or indirect); or
- (b) indirect, special or consequential loss.

G1.7 Unless otherwise specified by the Authority, the Contractor shall, with effect from the Commencement Date for such period as necessary to enable the Contractor to comply with its obligations herein, take out and maintain with a reputable insurance company a policy or policies of insurance providing an adequate level of cover in respect of all risks which may be incurred by the Contractor, arising out of the Contractor's performance of its obligations under the Contract, including death or personal injury, loss of or damage to property or any other loss. Such policies shall include cover in respect of any financial loss arising from any advice given or omitted to be given by the Contractor. Such insurance shall be maintained for the duration of the Contract Period and for a minimum of 6 years following the end of the Contract.

G1.8 The Contractor shall hold employer's liability insurance in respect of Staff and such insurance shall be in accordance with any legal requirement from time to time in force.

G1.9 The Contractor shall give the Authority, on request, copies of all insurance policies referred to in this clause or a broker's verification of insurance to demonstrate that the appropriate cover is in place, together with receipts or other evidence of payment of the latest premiums due under those policies.

G1.10 If the Contractor does not give effect to and maintain the insurances required by the provisions of the Contract, the Authority may make alternative arrangements to protect its interests and may recover the costs of such arrangements from the Contractor.

G1.11 The provisions of any insurance or the amount of cover shall not relieve the Contractor of any liabilities under the Contract.

G1.12 The Contractor shall not 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 the Contractor, which would entitle any insurer to refuse to pay any claim under any insurance policy in which the Contractor is an insured, a co-insured or additional insured person.

## **G2 Warranties and Representations**

G2.1 The Contractor warrants and represents on the Commencement Date and for the Contract Period that:

- (a) it has full capacity and authority and all necessary consents to enter into and perform the Contract and that the Contract is executed by a duly authorised representative of the Contractor;
- (b) in entering the Contract it has not committed any fraud;
- (c) as at the Commencement Date, all information contained in the Tender or other offer made by the Contractor to the Authority remains true, accurate and not misleading, save as may have been specifically disclosed in writing to the Authority prior to execution of the Contract and in addition, that it will advise the Authority of any fact, matter or circumstance of which it may become aware which would render such information to be false or misleading;
- (d) no claim is being asserted and no litigation, arbitration or administrative proceeding is presently in progress or, to the best of its knowledge and belief, pending or threatened against it or any of its assets which will or might have an adverse effect on its ability to perform its obligations under the Contract;
- (e) it is not subject to any contractual obligation, compliance with which is likely to have a material adverse effect on its ability to perform its obligations under the Contract;
- (f) no proceedings or other steps have been taken and not discharged (nor, to the best of its knowledge, are threatened) for the winding up of the Contractor or for its dissolution or for the appointment of a receiver, administrative receiver, liquidator, manager, administrator or similar officer in relation to any of the Contractor's assets or revenue;
- (g) it owns, or has obtained or is able to obtain valid licences for, all Intellectual Property Rights that are necessary for the performance of its obligations under the Contract;
- (h) any person engaged by the Contractor shall be engaged on terms which do not entitle them to any Intellectual Property Right in any IP Materials;
- (i) in the 3 years (or period of existence where the Contractor has not been in existence for 3 years) prior to the date of the Contract:
  - (i) it has conducted all financial accounting and reporting activities in compliance in all material respects with the generally accepted accounting principles that apply to it in any country where it files accounts;
  - (ii) it has been in full compliance with all applicable securities and tax laws and regulations in the jurisdiction in which it is established; and
  - (iii) it has not done or omitted to do anything which could have a material adverse effect on its assets, financial condition or position as an ongoing business concern or its ability to fulfil its obligations under the Contract;

- (j) it has and will continue to hold all necessary (if any) regulatory approvals from the Regulatory Bodies necessary to perform its obligations under the Contract; and
- (k) it has notified the Authority in writing of any Occasions of Tax Non-Compliance and any litigation in which it is involved that is in connection with any Occasion of Tax Non-Compliance.

### **G3 Force Majeure**

- G3.1 Subject to the remaining provisions of this clause G3, a Party may claim relief under this clause G3 from liability for failure to meet its obligations under the Contract for as long as and only to the extent that the performance of those obligations is directly affected by a Force Majeure Event. Any failure or delay by the Contractor in performing its obligations under the Contract which results from a failure or delay by an agent, Sub-Contractor or supplier shall be regarded as due to a Force Majeure Event only if that agent, Sub-Contractor or supplier is itself impeded by a Force Majeure Event from complying with an obligation to the Contractor.
- G3.2 The Affected Party shall as soon as reasonably practicable issue a Force Majeure Notice, which shall include details of the Force Majeure Event, its effect on the obligations of the Affected Party and any action the Affected Party proposes to take to mitigate its effect.
- G3.3 If the Contractor is the Affected Party, it shall not be entitled to claim relief under this clause G3 to the extent that consequences of the relevant Force Majeure Event:
  - (a) are capable of being mitigated by any of the Services, but the Contractor has failed to do so; and/or
  - (b) should have been foreseen and prevented or avoided by a prudent provider of services similar to the Services, operating to the standards required by the Contract.
- G3.4 Subject to clause G3.5, as soon as practicable after the Affected Party issues the Force Majeure Notice, and at regular intervals thereafter, the Parties shall consult in good faith and use reasonable endeavours to agree any steps to be taken and an appropriate timetable in which those steps should be taken, to enable continued provision of the Services affected by the Force Majeure Event.
- G3.5 The Parties shall at all times following the occurrence of a Force Majeure Event and during its subsistence use their respective reasonable endeavours to prevent and mitigate the effects of the Force Majeure Event. Where the Contractor is the Affected Party, it shall take all steps in accordance with Good Industry Practice to overcome or minimise the consequences of the Force Majeure Event.
- G3.6 Where, as a result of a Force Majeure Event:
  - (a) an Affected Party fails to perform its obligations in accordance with the Contract, then during the continuance of the Force Majeure Event:
    - i) the other Party shall not be entitled to exercise its rights to terminate the Contract in whole or in part as a result of such failure pursuant to clause H2.1 or H2.3; and
    - ii) neither Party shall be liable for any Default arising as a result of such failure;

- (b) the Contractor fails to perform its obligations in accordance with the Contract it shall be entitled to receive payment of the Price (or a proportional payment of it) only to the extent that the Services (or part of the Services) continue to be performed in accordance with the terms of the Contract during the occurrence of the Force Majeure Event.

G3.7 The Affected Party shall notify the other Party as soon as practicable after the Force Majeure Event ceases or no longer causes the Affected Party to be unable to comply with its obligations under the Contract.

G3.8 Relief from liability for the Affected Party under this clause G3 shall end as soon as the Force Majeure Event no longer causes the Affected Party to be unable to comply with its obligations under the Contract and shall not be dependent on the serving of notice under clause G3.7.

## **H DEFAULT, DISRUPTION AND TERMINATION**

### **H1 Termination on Insolvency and Change of Control**

H1.1 The Authority may terminate the Contract with immediate effect by notice and without compensation to the Contractor where the Contractor is a company and in respect of the Contractor:

- (a) a proposal is made for a voluntary arrangement within Part I of the Insolvency Act 1986 or of any other composition scheme or arrangement with, or assignment for the benefit of, its creditors;
- (b) a shareholders' meeting is convened for the purpose of considering a resolution that it be wound up or a resolution for its winding-up is passed (other than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation);
- (c) a petition is presented for its winding up (which is not dismissed within 14 days of its service) or an application is made for the appointment of a provisional liquidator or a creditors' meeting is convened pursuant to section 98 of the Insolvency Act 1986;
- (d) a receiver, administrative receiver or similar officer is appointed over the whole or any part of its business or assets;
- (e) an application order is made either for the appointment of an administrator or for an administration order, an administrator is appointed, or notice of intention to appoint an administrator is given;
- (f) it is or becomes insolvent within the meaning of section 123 of the Insolvency Act 1986;
- (g) being a "small company" within the meaning of section 247(3) of the Companies Act 1985, a moratorium comes into force pursuant to Schedule A1 of the Insolvency Act 1986; or
- (h) any event similar to those listed in H1.1(a)-(g) occurs under the law of any other jurisdiction.

- H1.2 The Authority may terminate the Contract with immediate effect by notice and without compensation to the Contractor where the Contractor is an individual and:
- (a) an application for an interim order is made pursuant to sections 252-253 of the Insolvency Act 1986 or a proposal is made for any composition scheme or arrangement with, or assignment for the benefit of, the Contractor's creditors;
  - (b) a petition is presented and not dismissed within 14 days or order made for the Contractor's bankruptcy;
  - (c) a receiver, or similar officer is appointed over the whole or any part of the Contractor's assets or a person becomes entitled to appoint a receiver, or similar officer over the whole or any part of his assets;
  - (d) the Contractor is unable to pay his debts or has no reasonable prospect of doing so, in either case within the meaning of section 268 of the Insolvency Act 1986;
  - (e) a creditor or encumbrancer attaches or takes possession of, or a distress, execution, sequestration or other such process is levied or enforced on or sued against, the whole or any part of the Contractor's assets and such attachment or process is not discharged within 14 days;
  - (f) he dies or is adjudged incapable of managing his affairs within the meaning of Part VII of the Mental Capacity Act 2005;
  - (g) he suspends or ceases, or threatens to suspend or cease, to carry on all or a substantial part of his business; or
  - (h) any event similar to those listed in clauses H1.2(a) to (g) occurs under the law of any other jurisdiction.

H1.3 The Contractor shall notify the Authority immediately 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 undergoes a change of control within the meaning of section 1124 of the Corporation Taxes Act 2010 ("Change of Control"). The Authority may terminate the Contract with immediate effect by notice and without compensation to the Contractor within 6 Months of:

- (a) being notified that a Change of Control has occurred; or
- (b) where no notification has been made, the date that the Authority becomes aware of the Change of Control,

but shall not be permitted to terminate where Approval was granted prior to the Change of Control.

- H1.4 The Authority may terminate the Contract with immediate effect by notice and without compensation to the Contractor where the Contractor is a partnership and:
- (a) a proposal is made for a voluntary arrangement within Article 4 of the Insolvent Partnerships Order 1994 or a proposal is made for any other composition, scheme or arrangement with, or assignment for the benefit of, its creditors; or
  - (b) it is for any reason dissolved; or
  - (c) a petition is presented for its winding up or for the making of any administration order, or an application is made for the appointment of a provisional liquidator; or

- (d) a receiver, or similar officer is appointed over the whole or any part of its assets;  
or
- (e) the partnership is deemed unable to pay its debts within the meaning of section 222 or 223 of the Insolvency Act 1986 as applied and modified by the Insolvent Partnerships Order 1994; or
- (f) any of the following occurs in relation to any of its partners:
  - (i) an application for an interim order is made pursuant to sections 252-253 of the Insolvency Act 1986 or a proposal is made for any composition scheme or arrangement with, or assignment for the benefit of, his creditors;
  - (ii) a petition is presented for his bankruptcy; or
  - (iii) a receiver, or similar officer is appointed over the whole or any part of his assets;
- (g) any event similar to those listed in clauses H1.4(a) to (f) occurs under the law of any other jurisdiction .

H1.5 The Authority may terminate the Contract with immediate effect by notice and without compensation to the Contractor where the Contractor is a limited liability partnership and:

- (a) a proposal is made for a voluntary arrangement within Part I of the Insolvency Act 1986 or a proposal is made for any other composition, scheme or arrangement with, or assignment for the benefit of, its creditors;
- (b) it is for any reason dissolved;
- (c) an application is made either for the appointment of an administrator or for an administration order, an administrator is appointed, or notice of intention to appoint an administrator is given within Part II of the Insolvency Act 1986;
- (d) any step is taken with a view to it being determined that it be wound up (other than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation) within Part IV of the Insolvency Act 1986;
- (e) a petition is presented for its winding up (which is not dismissed within 14 days of its service) or an application is made for the appointment of a provisional liquidator within Part IV of the Insolvency Act 1986;
- (f) a receiver, or similar officer is appointed over the whole or any part of its assets;  
or
- (g) it is or becomes unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986;
- (h) a moratorium comes into force pursuant to Schedule A1 of the Insolvency Act 1986; or
- (i) any event similar to those listed in clauses H1.5 (a) to (h) occurs under the law of any other jurisdiction.

H1.6 References to the Insolvency Act 1986 in clause H1.5(a) shall be construed as being references to that Act as applied under the Limited Liability Partnerships Act 2000 subordinate legislation.

## **H2 Termination on Default**

H2.1 The Authority may terminate the Contract with immediate effect by notice if the Contractor commits a Default and:

- (a) the Contractor has not remedied the Default to the satisfaction of the Authority within 25 Working Days or such other period as may be specified by the Authority, after issue of a notice specifying the Default and requesting it to be remedied;
- (b) the Default is not, in the opinion of the Authority, capable of remedy; or
- (c) the Default is a Material Breach.

H2.2 If, through any Default of the Contractor, data transmitted or processed in connection with the Contract is either lost or sufficiently degraded as to be unusable, the Contractor shall be liable for the cost of reconstitution of that data and shall reimburse the Authority in respect of any charge levied for its transmission and any other costs charged in connection with such Default.

H2.3 If the Authority fails to pay the Contractor undisputed sums of money when due, the Contractor shall give notice to the Authority of its failure to pay. If the Authority fails to pay such undisputed sums within 90 Working Days of the date of such notice, the Contractor may terminate the Contract in writing with immediate effect, save that such right of termination shall not apply where the failure to pay is due to the Authority exercising its rights under clause C3.1 (Recovery of Sums Due) or to a Force Majeure Event.

## **H3 Termination on Notice**

H3.1 The Authority may terminate the Contract at any time by giving 30 days' notice to the Contractor.

## **H4 Other Termination Grounds**

H4.1 The Authority may terminate the Contract on written notice to the Contractor if:

- (a) the Contract has been subject to a substantial modification which requires a new procurement procedure pursuant to regulation 72(9) of the Regulations;
- (b) the Contractor was, at the time the Contract was awarded, in one of the situations specified in regulation 57(1) of the Regulations, including as a result of the application of regulation 57 (2), and should therefore have been excluded from the procurement procedure which resulted in its award of the Contract;
- (c) the Contract should not have been awarded to the Contractor in view of a serious infringement of the obligations under the Treaties and the Regulations that has been declared by the Court of Justice of the European Union in a procedure under Article 258 of the TFEU; or
- (d) the Contractor has not, in performing the Services, complied with its legal obligations in respect of environmental, social or labour law.

## **H5 Consequences of Expiry or Termination**

H5.1 If the Authority terminates the Contract under clauses H2 or H4 and makes other arrangements for the supply of the Services the Authority may recover from the Contractor

the cost reasonably incurred of making those other arrangements and any additional expenditure incurred by the Authority throughout the remainder of the Contract Period.

- H5.2 If Contract is terminated under clauses H2 or H4 the Authority shall make no further payments to the Contractor (for Services supplied by the Contractor prior to termination and in accordance with the Contract but where the payment has yet to be made by the Authority), until the Authority has established the final cost of making the other arrangements envisaged under this clause.
- H5.3 If the Authority terminates the Contract under clause H3 the Authority shall make no further payments to the Contractor except for Services supplied by the Contractor prior to termination and in accordance with the Contract but where the payment has yet to be made by the Authority.
- H5.4 Save as otherwise expressly provided in the Contract:
- (a) termination or expiry of the Contract shall be without prejudice to any rights, remedies or obligations accrued under the Contract prior to termination or expiration and nothing in the Contract shall prejudice the right of either Party to recover any amount outstanding at such termination or expiry; and
  - (b) termination of the Contract shall not affect the continuing rights, remedies or obligations of the Authority or the Contractor under clauses C2 (Payment and VAT), C3 (Recovery of Sums Due), D1 (Prevention of Fraud and Bribery), E2 (Data Protection), E3 (Official Secrets Acts 1911 to 1989, Section 182 of the Finance Act 1989), E4 (Confidential Information), E5 (Freedom of Information), E8 (Intellectual Property Rights), E10 (Audit), F10 (Remedies Cumulative), G1 (Liability, Indemnity and Insurance), H5 (Consequences of Expiry or Termination), H7 (Recovery upon Termination) and I1 (Governing Law and Jurisdiction).

## **H6 Disruption**

- H6.1 The Contractor shall take reasonable care to ensure that in the performance of its obligations under the Contract it does not disrupt the operations of the Authority, its employees or any other contractor employed by the Authority.
- H6.2 The Contractor shall immediately inform the Authority of any actual or potential industrial action, whether such action be by its own employees or others, which affects or might affect its ability at any time to perform its obligations under the Contract.
- H6.3 If there is industrial action by the Staff, the Contractor shall seek Approval to its proposals to continue to perform its obligations under the Contract.
- H6.4 If the Contractor's proposals referred to in clause H6.3 are considered insufficient or unacceptable by the Authority acting reasonably, then the Contract may be terminated with immediate effect by the Authority by notice.
- H6.5 If the Contractor is unable to deliver the Services owing to disruption of the Authority's normal business, the Contractor may request a reasonable allowance of time, and, in addition, the Authority will reimburse any additional expense reasonably incurred by the Contractor as a direct result of such disruption.

## **H7 Recovery upon Termination**

- H7.1 On termination of the Contract for any reason, the Contractor shall at its cost:

- (a) immediately return to the Authority all Confidential Information, Personal Data and IP Materials in its possession or in the possession or under the control of any permitted suppliers or Sub-Contractors, which was obtained or produced in the course of providing the Goods and Services;
- (b) immediately deliver to the Authority all Property (including materials, documents, information and access keys) provided to the Contractor in good working order;
- (c) immediately vacate any Authority Premises occupied by the Contractor;
- (d) assist and co-operate with the Authority to ensure an orderly transition of the provision of the Services to the Replacement Contractor and/or the completion of any work in progress; and
- (e) promptly provide all information concerning the provision of the Services which may reasonably be requested by the Authority for the purposes of adequately understanding the manner in which the Services have been provided and/or for the purpose of allowing the Authority and/or the Replacement Contractor to conduct due diligence.

H7.2 If the Contractor does not comply with clauses H7.1(a) and (b), the Authority may recover possession thereof and the Contractor grants a licence to the Authority or its appointed agents to enter (for the purposes of such recovery) any premises of the Contractor or its permitted suppliers or Sub-Contractors where any such items may be held.

## **H8 Retendering and Handover**

H8.1 Within 21 days of being requested by the Authority, 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 the Services.

H8.2 The Authority shall take all necessary precautions to ensure that the information referred to in clause H8.1 is given only to potential providers who have qualified to tender for the future provision of the Services.

H8.3 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.

H8.4 The Contractor indemnifies 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 clause H8.1.

H8.5 The Contractor shall allow access to the Premises in the presence of the Authorised Representative, to any person representing any potential provider whom the Authority has selected to tender for the future provision of the Services.

H8.6 If access is required to the Contractor's Premises for the purposes of clause H8.5, 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 visiting. 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.

H8.7 The Contractor shall co-operate fully with the Authority during any handover at the end of the Contract. This co-operation shall include 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.

H8.8 Within 10 Working Days of being requested by the Authority, 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 Services. 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.

## **H9 Exit Management**

H9.1 Upon termination the Contractor shall render reasonable assistance to the Authority to the extent necessary to effect an orderly assumption by a Replacement Contractor in accordance with the procedure set out in clause H10.

## **H10 Exit Procedures**

H10.1 Where the Authority requires a continuation of all or any of the Services on expiry or termination of this Contract, either by performing them itself or by engaging a third party to perform them, the Contractor shall co-operate fully with the Authority and any such third party and shall take all reasonable steps to ensure the timely and effective transfer of the Services without disruption to routine operational requirements.

H10.2 The following commercial approach shall apply to the transfer of the Services if the Contractor:

- (a) does not have to use resources in addition to those normally used to deliver the Services prior to termination or expiry, there shall be no change to the Price; or
- (b) reasonably incurs additional costs, the Parties shall agree a Variation to the Price based on the Contractor's rates either set out in Schedule 2 or forming the basis for the Price.

H10.3 When requested to do so by the Authority, the Contractor shall deliver to the Authority details of all licences for software used in the provision of the Services including the software licence agreements.

H10.4 Within one Month of receiving the software licence information described above, the Authority shall notify the Contractor of the licences it wishes to be transferred, and the Contractor shall provide for the approval of the Authority a plan for licence transfer.

## **H11 Knowledge Retention**

H11.1 The Contractor shall co-operate fully with the Authority in order to enable an efficient and detailed knowledge transfer from the Contractor to the Authority on the completion or earlier termination of the Contract and in addition, to minimise any disruption to routine operational requirements. To facilitate this transfer, the Contractor shall provide the Authority free of charge with full access to its Staff, and in addition, copies of all documents, reports, summaries and any other information requested by the Authority. The Contractor shall comply with the Authority's request for information no later than 15 Working Days from the date that that request was made.

# I DISPUTES AND LAW

## I1 Governing Law and Jurisdiction

11.1 Subject to the provisions of clause I2 the Contract, including any matters arising out of or in connection with it, 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 limit the right of the Authority to take proceedings against the Contractor in any other court of competent jurisdiction, and the taking of proceedings in any other court of competent jurisdiction shall not preclude the taking of proceedings in any other jurisdiction whether concurrently or not.

## I2 Dispute Resolution

12.1 The Parties shall attempt in good faith to negotiate a settlement to any dispute between them arising out of or in connection with the Contract within 20 Working Days of either Party notifying the other of the dispute and such efforts shall involve the escalation of the dispute to the finance director of the Contractor and the commercial director of the Authority.

12.2 Nothing in this dispute resolution procedure shall prevent the Parties from seeking from any court of competent jurisdiction an interim order restraining the other Party from doing any act or compelling the other Party to do any act.

12.3 If the dispute cannot be resolved by the Parties pursuant to clause I2.1 either Party may refer it to mediation pursuant to the procedure set out in clause I2.5.

12.4 The obligations of the Parties under the Contract shall not cease, or be suspended or delayed by the reference of a dispute to mediation (or arbitration) and the Contractor and the Staff shall comply fully with the requirements of the Contract at all times.

12.5 The procedure for mediation and consequential provisions relating to mediation are as follows:

- (a) a neutral adviser or mediator (the "**Mediator**") shall be chosen by agreement between the Parties or, if they are unable to agree upon a Mediator within 10 Working Days after a request by one Party to the other or if the Mediator agreed upon is unable or unwilling to act, either Party shall within 10 Working Days from the date of the proposal to appoint a Mediator or within 10 Working Days of notice to either Party that he is unable or unwilling to act, apply to the Centre for Effective Dispute Resolution to appoint a Mediator;
- (b) the Parties shall within 10 Working Days of the appointment of the Mediator meet with him in order to agree a programme for the exchange of all relevant information and the structure to be adopted for negotiations. If appropriate, the Parties may at any stage seek assistance from the Centre for Effective Dispute Resolution to provide guidance on a suitable procedure;
- (c) unless otherwise agreed, all negotiations connected with the dispute and any settlement agreement relating to it shall be conducted in confidence and without prejudice to the rights of the Parties in any future proceedings;
- (d) if the Parties reach agreement on the resolution of the dispute, the agreement shall be recorded in writing and shall be binding on the Parties once it is signed by their duly authorised representatives;

- (e) failing agreement, either of the Parties may invite the Mediator to provide a non-binding but informative written opinion. Such an opinion shall be provided on a without prejudice basis and shall not be used in evidence in any proceedings relating to the Contract without the prior written consent of both Parties; and
- (f) if the Parties fail to reach agreement within 60 Working Days of the Mediator being appointed, or such longer period as may be agreed by the Parties, then any dispute or difference between them may be referred to the Courts unless the dispute is referred to arbitration pursuant to the procedures set out in clause I2.6.

I2.6 Subject to clause I2.2, the Parties shall not institute court proceedings until the procedures set out in clauses I2.1 and I2.3 have been completed save that:

- (a) The Authority may at any time before court proceedings are commenced, serve a notice on the Contractor requiring the dispute to be referred to and resolved by arbitration in accordance with clause I2.7;
- (b) if the Contractor intends to commence court proceedings, it shall serve notice on the Authority of its intentions and the Authority shall have 21 days following receipt of such notice to serve a reply on the Contractor requiring the dispute to be referred to and resolved by arbitration in accordance with clause I2.7; and
- (c) the Contractor may request by notice to the Authority that any dispute be referred and resolved by arbitration in accordance with clause I2.7, to which the Authority may consent as it sees fit.

I2.7 If any arbitration proceedings are commenced pursuant to clause I2.6,

- (a) the arbitration shall be governed by the provisions of the Arbitration Act 1996 and the Authority shall give a notice of arbitration to the Contractor (the "Arbitration Notice") stating:
  - (i) that the dispute is referred to arbitration; and
  - (ii) providing details of the issues to be resolved;
- (b) the London Court of International Arbitration ("**LCIA**") procedural rules in force at the date that the dispute was referred to arbitration in accordance with I2.7(b) shall be applied and are deemed to be incorporated by reference to the Contract and the decision of the arbitrator shall be binding on the Parties in the absence of any material failure to comply with such rules;
- (c) the tribunal shall consist of a sole arbitrator to be agreed by the Parties;
- (d) if the Parties fail to agree the appointment of the arbitrator within 10 days of the Arbitration Notice being issued by the Authority under clause I2.7(a) or if the person appointed is unable or unwilling to act, the arbitrator shall be appointed by the LCIA;
- (e) the arbitration proceedings shall take place in London and in the English language; and
- (f) the arbitration proceedings shall be governed by, and interpreted in accordance with, English Law.

# SCHEDULE 1 - SPECIFICATION

## SPECIFICATION OF REQUIREMENTS

### BRIDGING THE PRECLINICAL/CLINICAL GAP FOR OPTIMISATION OF EFFICACY AND AVOIDANCE OF RESISTANCE FOR FLUOROQUINOLONES, APPLICATION TO CANINE PYODERMA

#### 1.1 Summary/overview

*Staphylococcus pseudintermedius*, particularly methicillin-resistant *Staphylococcus pseudintermedius* (MRSP), infections continue to provide a major challenge to effective therapy in veterinary practice. *Staphylococcus pseudintermedius* is a common pathogen in dogs and cats, with high incidence rates in cases of canine pyoderma (together with *Escherichia coli*). Although *Staphylococcus pseudintermedius* infections in humans are uncommon, they are of public health concern, in consequence of the zoonotic risk that MRSP poses to pet owners and veterinarians; approximately 5% are carriers. To treat *S. pseudintermedius*-induced pyoderma, many clinicians use fluoroquinolones, which are critically important in human and veterinary medicine. Enrofloxacin, marbofloxacin and pradofloxacin are licensed for deep canine pyoderma. We hypothesise that, due to differences in susceptibility and adaptive resistance between fluoroquinolones, the critical values (clinical breakpoint) for efficacy and avoidance of resistance must be defined on a drug-by-drug basis, using a combination of in vitro and in vivo techniques described below: - First, we will determine the minimum inhibitory concentration (MIC), minimum bactericidal concentration (MBC), and mutant prevention concentration (MPC) of licensed veterinary and human fluoroquinolones against historically banked clinical isolates from cases of canine pyoderma (*S. aureus*, *S. pseudintermedius* and *E. coli*). - Second, we will carry out static in vitro time-kill assays. Isolates *S. aureus*, *S. pseudintermedius*, and *E. coli* will be exposed to 0, 0.25, 0.5, 1, 2, 4 and 8 multiples of MIC of marbofloxacin, enrofloxacin and pradofloxacin. Pharmacokinetic / Pharmacodynamic modelling will be performed to calculate drug efficacy and potency and to determine the optimal drug-exposure value for prediction of efficacy. - Third, real canine plasma concentration-time profiles for marbofloxacin and pradofloxacin will be reproduced in a hollow fiber infection model.

Dose fractionation experiments will confirm whether high concentration or long exposure best predict efficacy and resistance emergence. Marbofloxacin-resistant *S. pseudintermedius* strains will be cultured in the presence of low and high doses of marbofloxacin and pradofloxacin for 5 days and PK-PD modelling carried out. - Fourth, we will conduct a non-interventional study to establishing the temporal dynamic of antimicrobial resistance in dogs receiving fluoroquinolones. We will recruit twenty dogs with pyoderma or skin wounds which, after identification and susceptibility testing, will be treated for up to 8 weeks with either marbofloxacin or pradofloxacin. In vitro time kill assays on isolated pathogens will be conducted in parallel and compared to in vivo outcome (efficacy and resistance). The effect of fluoroquinolones on gastrointestinal and skin bacteria (resistance emergence and susceptibility restoration) will be evaluated before, during treatment and 4 weeks after the final dose. Also monitored will be fluoroquinolone saliva concentration and density per skin surface unit during treatment. - Finally, the pharmacokinetic data and MIC distribution (literature data) together with the relationship between exposure and dynamic of bacterial kill modelled above will be used to propose clinical breakpoints (highest MIC value considered "sensitive") for fluoroquinolones in canine pyoderma. Outcomes from this work will inform clinicians, regulators and drug companies on clinical cut-offs values for efficacy and minimisation resistance of currently approved fluoroquinolones. The findings will also provide insights to regulators on the combined use of static and dynamic studies to support the registration process.

#### 1.2 Timing

The Contract will commence on the 1<sup>st</sup> February 2019 and the expiry date is the 1<sup>st</sup> March 2022.

### 1.3 Background

*Staphylococcus pseudintermedius* particularly methicillin-resistant *Staphylococcus pseudintermedius* (MRSP) infections continue to provide a major challenge to effective therapy in veterinary practice. Multi-drug resistance has led to loss of efficacy of the majority of antimicrobial drugs (AMDs) currently available to veterinarians (Guardabassi, Larsen et al. 2013, Pomba, Rantala et al. 2017). *Staphylococcus pseudintermedius* is a common pathogen in dogs and cats, with high incidence rates in cases of canine pyoderma (together with Enterobacteriaceae such as *Escherichia coli* and *Proteus* species). Although *Staphylococcus pseudintermedius* infections in humans are uncommon, they are of public health concern, in consequence of the zoonotic risk that MRSP poses to pet owners and veterinarians; approximately 5% are carriers (Stegmann, Burnens et al. 2010).

In first opinion veterinary practice, *Staphylococcus pseudintermedius*-induced pyoderma cases are therapeutically challenging, due to; limited penetration of drugs into fibrotic infected skin, the chronicity of the condition and limited susceptibility of the organisms to many drug classes. Consequently, many clinicians use fluoroquinolones, which are licensed for deep canine pyoderma. Fluoroquinolones are critically important in human medicine and their veterinary use may induce co-selection of resistant bacteria of clinical relevance for human patients. Fluoroquinolones currently licensed for canine use include enrofloxacin, marbofloxacin and pradofloxacin, whilst ciprofloxacin (a metabolite of enrofloxacin) and moxifloxacin (from which pradofloxacin is derived) are used in humans. Due to marked differences between Minimum Inhibitory Concentration (MIC) and Mutant Prevention Concentration (MPC) of each fluoroquinolone (for example marbofloxacin and pradofloxacin), the clinical breakpoint for efficacy and avoidance of resistance cannot be defined for the class, but only on a drug-by-drug basis (Wetzstein 2005).

A crucial approach to limiting the emergence and subsequent spread of resistance relies on the computation of the optimal dose for the host species / drug / pathogen. Determination of the dose selected for evaluation in clinical trials and the corresponding clinical cut-off should take into account the following information (Mouton, Dudley et al. 2002):

- (i) bacterial susceptibility, usually defined as MIC, and the distribution of MICs encountered in the field;
- (ii) drug pharmacokinetics (PK) and its variability in the target species;
- (iii) drug pharmacodynamics (PD), that is the relationship between exposure and efficacy and potency (Craig 1998, Toutain and Lees 2004). Antimicrobial drug PD is quantified by the target numerical value of the selected PK/PD index, AUC/MIC ratio, time>MIC or C<sub>max</sub>/MIC ratio that best predicts the clinical and bacteriological outcomes (cure, failure or relapse).

While MIC field distributions (section i above) and population PK (ii above) can be applied using meta-analysis approaches, integration of PK/PD index values has relied on historical literature obtained from neutropenic infected mouse models or clinical data from humans. This approach has limitations, as the optimal PK/PD index value may vary significantly when applied to differing host/pathogen/drug relationships. Hence, there is an urgent need to fill the data gap (section iii) with quality evidence.

Historically, PK/PD indices have been determined using static in vitro methods such as the time-kill curves (TKCs). Time-kill curves establish bacterial growth/kill over 24h, from an initial inoculum of known size, cultured in a matrix spiked with increasing MIC-fold concentrations of the drugs (0, 0.25, 0.5, 1, 2, 4 and 8 times MIC). At RVC, the TKC method has been used for many years (Lees, Pelligand et al. 2015) and now we are able to describe TKCs with complex mathematical models (Nielsen and Friberg 2013). These models yield key data on drug potency, efficacy, mode of action (time- or concentration-dependent killing) and whether resistance is surmountable with high drug concentrations. These properties cannot be defined with experimental MIC determinations alone. However, TKCs have limitations. They cannot be extended over longer periods to reflect duration of clinical treatment, nor do they address the dynamic changes in drug concentration over time, as occurs in vivo. Thus, additional models are required to predict the development of resistance in

vivo from in vitro experiments (Cadwell 2012). Conforming with the principles of the National Centre for 3Rs (NC3Rs), dynamic in vitro models, such as the 2-compartment Hollow-Fibre Infection Model (HFIM) have been used to explore the more complicated antimicrobial/pathogen interactions without resort to animal models. Our research group has gained experience with the hollow-fibre infection model and has validated it as a model for dynamic PK/PD analysis of calf respiratory pathogens/drug combination [REDACTED]

In this project, a combination of static and dynamic methods will be used to predict optimal dosing regimens for fluoroquinolones for canine skin pathogens (*Staphylococcus aureus*, *Staphylococcus pseudintermedius* and *Escherichia coli*) together with a proof of concept clinical study in dogs with pyoderma. This combined approach will ensure identification of the optimal value of the PK/PD index and the mechanistic modelling of the dynamics of selection of resistant bacteria (Firsov, Vostrov et al. 1997, Nielsen and Friberg 2013) for both efficacy and prevention of resistance emergence.

#### **1.4 Project aims and objectives**

It is a priority for veterinary science to ascertain both benefits and limitations of static and dynamic PK/PD systems used to support dose-finding studies for AMDs. These models facilitate reduction of experimental animal studies and enhance drug development programmes. Building on the validation work accomplished with the HFIM [REDACTED] this project will use this dynamic method together with Time Kill Curves (TKCs: static methods) to explore the PD and PK of fluoroquinolones in canine pyoderma, with reference to their effect against *Staphylococcus* spp. and *Escherichia coli*.

The aim of this PhD project is to identify PK/PD relationships and resistance emergence across strains, through modelling of static and dynamic in vitro methods. The data will contribute to optimising treatment efficacy, limiting resistance emergence and reducing experimental animal use.

The specific project objectives are as follows:

An extensive literature review will be conducted during the first 3 months of the project and practical measures put in place for subsequent experimental work.

##### **Objective 1: (4-9 months) basic In vitro phenotyping –**

Determination of minimum inhibitory concentration (MIC), minimum bactericidal concentration (MBC), and mutant prevention concentration (MPC) of veterinary (marbofloxacin, enrofloxacin and pradofloxacin) and human fluoroquinolones (ciprofloxacin and moxifloxacin) against historically banked clinical isolates from cases of canine pyoderma (fluoroquinolone-sensitive and resistant strains of *Staphylococcus aureus*, *Staphylococcus pseudintermedius* and *E. coli*).

##### **Objective 2: (9-15 months) Static PD: time-kill curves –**

Isolates of fluoroquinolone-sensitive and resistant *S. aureus*, *S. pseudintermedius*, and *E. coli* will be exposed to 0, 0.25, 0.5, 1, 2, 4 and 8 or greater multiples of MIC of marbofloxacin, enrofloxacin and pradofloxacin in a static in vitro time-kill assay. PK/PD modelling will be performed from these curves, as described by Nielsen et al. (2013), to calculate the maximum efficacy and potency (EC50) of drugs and determine the optimal AUC/MIC value for prediction of efficacy.

##### **Objective 3: Dynamic PD: Hollow Fibre Infection Model (12-18 months)**

Concentration-time profiles for marbofloxacin and pradofloxacin in dogs will be reproduced in the HFIM to model in vivo drug PK. Dose fractionation will allow confirmation of the nature of the PK/PD index that best predicts efficacy and resistance emergence. Marbofloxacin-resistant *S.*

pseudintermedius strains will be cultured in the HFIM in the presence of low and high doses of marbofloxacin and pradofloxacin for 5 days. PK-PD modelling will be carried out.

#### **Objective 4: Clinical proof-of-concept bridging study (6-28 months recruitment)**

A non-interventional study will be conducted, with the purpose of establishing the trajectory (temporal dynamic) of antimicrobial resistance in dogs with deep pyoderma or soft tissue infections (including wound infections). Twenty dogs will be recruited with deep pyoderma or skin wounds which, after skin pathogen identification and susceptibility testing, will be treated for up to 8 weeks with either marbofloxacin or pradofloxacin. In vitro studies on isolated pathogens (TKC) will be conducted in parallel and compared to in vivo outcome (efficacy and resistance). The effect of fluoroquinolones on gastrointestinal and skin bacteria (resistance emergence and susceptibility restoration after the end of treatment) will be evaluated before, during treatment and 4 weeks after the final dose. Also monitored will be fluoroquinolone saliva concentration and density per skin surface unit during treatment.

#### **Objective 5: Clinical breakpoint determination (28-30 months):**

The PK data (from scientific literature), MIC distribution (scientific literature) and PK/PD indices determined in this programme will be used for PK/PD modeling and Monte Carlo simulations to propose clinical breakpoints for pradofloxacin and marbofloxacin in canine pyoderma.

Outcomes from this work will inform clinicians, regulators and drug companies on numerical values of clinical cut-offs to ensure clinical efficacy and minimise the selection of resistance at the currently approved fluoroquinolone dose rates. The findings will also provide insights to regulators on the use of combined TKC and HFIM modeling in the drug registration process.

#### **Detailed objectives**

##### **Objective 1: (4-9 months) basic In vitro phenotyping**

The minimum inhibitory concentration (MIC), minimum bactericidal concentration (MBC) and mutant prevention concentration (MPC) of fluoroquinolones of veterinary (marbofloxacin, pradofloxacin, enrofloxacin, danofloxacin, difloxacin) and human (ciprofloxacin and moxifloxacin) interest will be measured from historically banked clinical isolates from cases of canine pyoderma. The MPC is defined as the lowest drug concentration that inhibits growth of the least-susceptible single-step mutants in a large bacterial population ( $10^{10}$  CFU/mL). Six fluoroquinolone-sensitive and six fluoroquinolone-resistant strains of *S. aureus*, *S. pseudintermedius* and *E. coli* will be selected from libraries held by collaborators. The resistant strains will ideally include three strains with different chromosomal resistance mechanisms (DNA gyrase mutation, topoisomerase IV mutation and overexpression of efflux pump). MIC determinations will be performed in culture media according to EUCAST methodology, except that five series of overlapping dilutions will be run for more accurate determination of MIC. MPC will be measured according to Blondeau (2009) and used to calculate the Mutant Selection Window (MSW = MPC-MIC) and the Mutant Prevention Index (MPI = MPC/MIC).

##### **Objective 2: (9-15 months) Static PD: time-kill curves**

Isolates of fluoroquinolone-sensitive and resistant *S. aureus*, *S. pseudintermedius*, and *E. coli* (in objective 1) will be exposed to 0, 0.25, 0.5, 1, 2, 4, and 8 or greater fold MIC of marbofloxacin and pradofloxacin in a static in vitro time-kill assay. AUC/MIC values for bacteriostatic and bactericidal levels of kill will be established. The proportion of resistant bacteria will be determined on agar containing a concentration three times MIC and estimation of proportion of persisters will be attempted (Brauner, Fridman et al. 2016). At least two inoculum strengths ( $5 \times 10^5$  and  $5 \times 10^8$  CFU/mL) will be tested to evaluate the effect of inoculum size. To test within-strain repeatability, at least one strain for each species will be evaluated in triplicate for each drug.

The data will be used to model the action of each drug against each organism using full individual curves with non-linear mixed effect modeling (Phoenix NLME), as described by Nielsen et al. (2013). The parameters of the test system (the growth and death rate constants,  $K_{\text{growth}}$  and  $K_{\text{death}}$ , and the maximal count observable  $B_{\text{max}}$ ) and of the drug ( $E_{\text{max}}$  maximal effect, the concentration associated with 50% of this maximal effect  $EC_{50}$  and  $n$ , the slope of the concentration effect relationship) will be estimated. This will allow the determination of optimal AUC/MIC values for efficacy prediction in a robust system, accounting for day-to-day variability, level of kill and inoculum effect. For resistant strains, the influence of the mechanism of resistance on the drug PD parameters, and whether resistance is surmountable with higher doses, will be studied.

### **Objective 3: Dynamic PD: HFIM (12-18 months)**

The HFIM comprises a two-compartment hollow-fibre cartridge, a central reservoir (CR), a diluent reservoir and an elimination reservoir. The two-compartment cartridge is divided into the intra-capillary space (ICS) and the extra-capillary space (ECS): the ICS provides a semi-permeable channel enabling circulation of medium and drug throughout the system, whilst the ECS provides a confined environment in which the bacteria can be cultured. Inflow of diluent medium and outflow of excess medium allow the drug concentration to be controlled over time to simulate the in vivo PK (derived from the literature) and modelled in the simulation. Drug dosing is achieved through bolus, continuous infusion or fractionation of the daily dose by administration to the CR. Drug concentration rapidly equilibrates within the cartridge and across the ICS membrane. Measurement of drug concentration and enumeration of bacterial count will be determined for the duration of each experiment.

Free drug (non-protein bound) concentration-time profiles for marbofloxacin and pradofloxacin, obtained in dogs after oral administration, will be reproduced in the HFIM (marbofloxacin dosed at 2mg/kg/day, yielding a  $C_{\text{max}}$  of 1.5  $\mu\text{g/mL}$  at 2h, with protein binding < 10%; pradofloxacin dosed at 3mg/kg/day, yielding a  $C_{\text{max}}$  of 1.6  $\mu\text{g/mL}$  at 2h with protein binding of 30%). Initial pilot experiments will identify a hollow fibre cartridge with a satisfactory membrane permeability to both fluoroquinolones. Measurement of drug concentration within the HFIM, (both the ECS and the CR) will be determined to ensure comparability with the in vivo scientific literature values. Determinations will be made using either HPLC with fluorometric detection (Zhang, Li et al. 2013) or liquid chromatography/mass spectrometry (LC/MS).

A dose fractionation experiment will allow confirmation of the PK/PD index that best predicts both efficacy and resistance emergence ((Marcusson, Komp Lindgren et al. 2014)). Four strains will be studied: one strain each of marbofloxacin-susceptible and marbofloxacin-resistant *S. pseudintermedius* and *E. coli*. Each strain will be cultured in the HFIM for 5 days in the presence of: (i) a range of doses from 0.1 (sub-clinical) to 10 times the daily clinical doses of marbofloxacin and pradofloxacin; (ii) pulse dosing to achieve a high  $C_{\text{max}}$  but with rapid clearance; and (iii) with continuous infusions to target the MIC and MPC. The proportion of resistant bacteria will be quantified. Mutants will be tested for co-resistance to methicillin and the mutational mechanism involved. The data will verify (or not) if the current recommendations for AUC/MIC for efficacy (Gram positive > 30h and Gram negative > 125h) and AUC/MPC for prevention of resistance (>25h) are appropriate for veterinary fluoroquinolones.

### **Objective 4: Clinical proof-of-concept bridging study (6-28 months recruitment)**

A non-interventional study will be conducted, with the purpose of establishing the trajectory (temporal dynamic) of antimicrobial resistance in dogs with deep pyoderma or soft tissue infections (including wound infections). In collaboration with the dermatology team of the Queen Mother Hospital for Animals (RVC), cases of canine pyoderma and skin wounds requiring marbofloxacin or pradofloxacin treatment will be recruited for an open label study in a small group of 20 dogs (any breed, age, sex; weight from 3.4 to 80kg). Marbofloxacin and pradofloxacin are licensed for use in dogs for pyoderma therapy; an advantage of fluoroquinolones compared to cephalosporins is their ready penetration into fibrotic tissue. The choice of marbofloxacin or pradofloxacin will be left to the

discretion of the attending clinician. The purpose of this small-scale clinical study is not to differentiate between efficacies of the two drugs, but to acquire pilot data for a future larger scale clinical trial that will relate drug concentrations in blood and skin to therapeutic success and development of resistance (not within the framework of this PhD). This project will enable prediction of the number of subjects (sample size) and the viability of the clinical endpoints for the larger study.

The comparative resistance inducing profile of marbofloxacin and pradofloxacin will be evaluated in vivo and whether it relates to the skin concentration achieved. A second objective will be to identify whether in vitro studies on clinical isolates (TKCs), carried out in parallel with the clinical trial, can provide a therapeutic advantage and accurately predict clinical outcome in term of efficacy and resistance, over and above knowledge of MIC.

Cytology samples and bacteriological samples (conventional swabs +/- skin biopsy) will be collected at the time of first visit for diagnostic identification and culture sensitivity (measured as MIC) using disc diffusion and microdilution methods. Dogs will be allocated to either marbofloxacin or pradofloxacin treatment (Visit 1). They will be monitored at 3 to 4 weeks after therapy commencement (Visit 2) and again at 6 to 8 weeks (for deep pyoderma, Visit 3) and finally one month after completion of the treatment (Final evaluation, Visit 4). Efficacy assessment at visits 2 and 3 will be made employing two end-points, namely: (i) absence of clinical signs associated with pyoderma and (ii) clinical cure rate (disappearance of depression and pruritus). The rate of recurrences at visit 4 will be recorded. Skin bacteriology samples will be taken using a detergent scrub technique with 0.1% Triton X100 (Williamson and Kligman 1965, Bond, Lloyd et al. 1995). Drug skin density (concentration per unit of surface area) will be measured from the scrub fluid recovered or from tape stripping, using a LC/MS method. Drug saliva concentration will also be measured at visits 2 and 3. Faecal samples will be collected at all visits and grown for Enterococci and E. coli. These will be cultured on plates in the absence of the drugs and in the presence of each fluoroquinolone at concentrations of 0.5 and 8.0 µg/mL to evaluate the proportion of resistant bacteria.

In parallel with the in vivo treatment, TKCs will be conducted with the bacteria isolated to establish the in vitro potency of marbofloxacin and pradofloxacin in clinical isolates, as in objective 2.

### **Objective 5: Clinical breakpoint determination (28-30 months):**

In this final phase, plasma concentration-time curves for a large number of individual dogs for both marbofloxacin and pradofloxacin will be obtained from drug companies (both pioneer and generic products). Drug companies will be solicited soon after the start of the PhD for sharing individual pharmacokinetic data. We will carry out PK/PD modelling using the previously reported range of MICs from clinical isolates (Schink, Kadlec et al. 2013) together with AUC/MIC PK/PD cut-off values for *S. aureus*, *S. pseudintermedius* and *E. coli*, calculated as described above, will be used to propose a clinical breakpoint, according to EUCAST / VetCAST methodology (Mouton, Brown et al. 2012).

### **Outputs**

The outputs for this project are:

1. Knowledge acquisition through the use of static and dynamic in vitro methods to identify and quantify MIC, MBC, MPC and PK/PD indices and breakpoints for veterinary fluoroquinolones.
2. Dissemination of clinically relevant information to the veterinary scientific community. The key stakeholders are veterinarians and scientists in industry, academia and licensing bodies, including veterinary practitioners, pharmacometricians, regulators and policy makers.

Knowledge acquisition:

- Determination of MIC, MBC, and MPC for fluoroquinolones will provide new data for PD parameters for veterinary clinical isolates of *S. aureus*, *S. intermedius*, and *E. coli*. These data will be available to the veterinary and scientific communities and to companies to inform drug use and novel developments.
- Static time-kill curves will provide information regarding the speed of onset, time course and magnitude of antimicrobial efficacy; together with appropriate modelling, this will inform the value of the PK/PD indices in dogs for determination of optimal doses.
- Dynamic hollow-fibre infection modelling will further validate the integrated PK/PD approach in veterinary medicine. The data will indicate the capacity of this in vitro system for optimisation of dosage regimens to avoid resistance emergence.
- This comprehensive approach to evaluation of efficacy and resistance potential will create new standards and guidelines for use with veterinary New Compound Entities with antimicrobial activities. This approach will enable drug companies to de-risk the dose finding / confirmation phases of novel product development. It will also support future versions of EMA/CVMP/627/2001-Rev.1 (Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances, revised in 2016).

Dissemination of information:

Information will be disseminated through peer reviewed scientific publications, presentations at international congresses and possibly in training workshops.

- **Publications**

Results from each objective 1 to 4 will be incorporated in publications submitted to peer reviewed journals and will thus make a significant contribution to the scientific literature, with modelling of the data also opening up the possibility of publishing in pharmacometrics journals.

- **Posters**

Data generated will be displayed at multiple conferences with likely target societies being the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID, yearly), the International Conference on Antimicrobial Agents in Veterinary Medicine (AAVM 2018 [Rome] and 2020) and the congresses of the European Association for Veterinary Pharmacology and Toxicology (EAVPT 2018 [Poland]).

- **Presentations**

The findings will be presented both internally at RVC and to the study sponsors through research seminars and conferences across both the Hawkshead and Camden College campuses and to VMD/Defra on study completion.

During the course of the study, periodic progress presentations (six monthly) will take place at the RVC and/or the VMD; these presentations will ensure that the VMD stakeholders are updated on progress and outcomes. An annual report will be submitted to VMD and PhD assessors (yearly appraisal). The thesis will be submitted for the PhD of London University (for February 2018 start, submission is expected from February 2021, but no later

## **1.5 Performance**

In accordance with Clause F2, the contractor shall produce a 6 monthly Performance management report, detailing performance against KPI's set out at Schedule 4.

The Contractor shall maintain their own management reports, including a Risk, Issues and Changes Log.

Any performance issues highlighted in the 6 monthly reports will be addressed by the Contractor, who shall be required to provide an improvement plan ("Remediation Plan") to address all issues highlighted within a week of the Authority request.

The Authority shall hold meetings with the Contractor to discuss and agree the conduct of the Contract.

The Authority shall hold 6 monthly review meetings with the Contractor to review the Contractor's quarterly Performance Management reports and implementation of any improvement plan

### **Service Credits**

Service credits sit within the wider service management approach being pursued by the Contractor and the Authority.

The service credit regime shall be instigated on each occasion where there is a service failure (i.e. where it is recognised by the Authority that the standards have fallen below the minimum).

Failure to achieve the overall performance target of a minimum standard for KPI one (1) and KPI three (3) shall result in the Fixed price not being paid until resolved to the Authority's satisfaction.

Failure to achieve the performance target for KPI two (2) and KPI four (4) will result in the reimbursement of 5% of the total order value to the Authority.

The Authority has full and complete discretion on whether to claim all, part or none of a service credit to which it is due. Any applicable service credits shall be calculated and applied at the end of each complete contract year and at end of the Contract.

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 shall operate from the Contract start date until the end of the Contract.

Should either the Contractor or the Authority decide to terminate the contract in accordance with the contract terms at any point during the agreed period, a final review meeting shall be held.

The Authority will manage the Contracts for R&D resulting from this procurement and will appoint a:

Supplier Liaison Officer (SLO)  
Deputy SLO (DSLO)  
Contract Manager (CM)

The SLO will be the principal point of contact for the Authority.

The Contractor will appoint a corresponding Service Manager (SM) and Deputy Service Manager (DSM).

Monthly meetings will be held with the Contractor, principally to review progress and operational delivery of the Contract, but also including key performance indicators (KPIs), invoicing, risks and issues. A Defra Group Commercial (DGC) representative, with responsibility for procurement on behalf of the Authority, may be present at quarterly and annual review meetings.

The Contractor will submit an exception report to raise any issue requiring authorisation by the Authority when the issue arises.

Issues which cannot be resolved by the SLO and SM (and/or their respective Deputies) through routine contact or in the monthly meetings will be referred to the CM who may either mediate a solution or raise the matter at the next Quarterly and/or Annual Review Meeting as appropriate, involving the Authority as necessary.

Other ad hoc meetings may be held, at the request of the Authority or the Contractor, throughout the life of the contract to discuss specific issues.

The Contractor will be responsible for travel and subsistence costs incurred as a result of attendance at any meeting. Meetings may also be held by teleconference with the agreement of all parties.

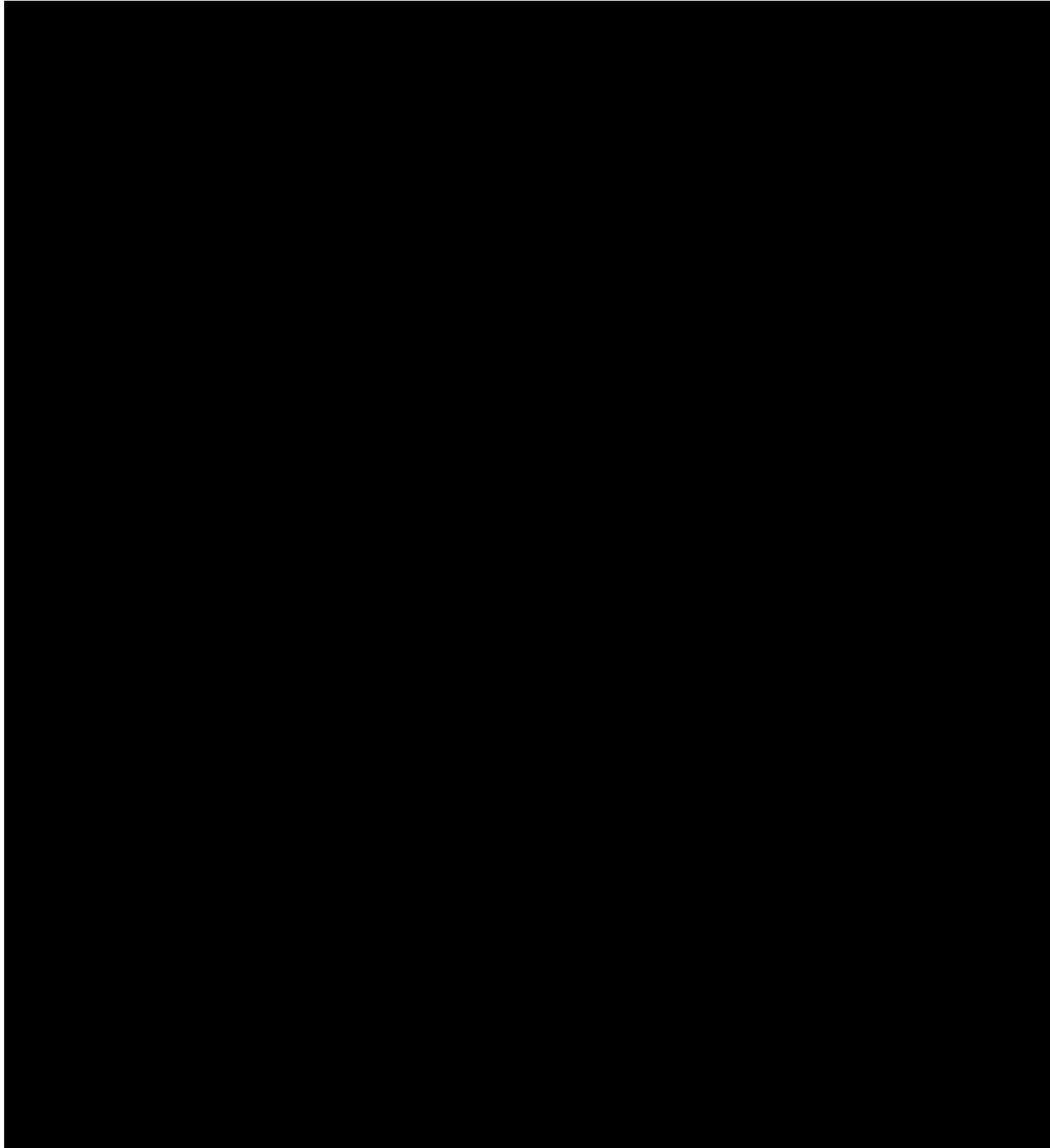
The meetings will be held at the most mutually convenient location, usually face-to-face, but with teleconference facilities available.

Quarterly and Annual meetings will be minuted with secretariat support and actions provided by Defra, with agreed dates for completion. The Contractor will maintain a joint register of risks, issues and actions

The CM should ensure that all meeting minutes, risk registers and any other contract documentation is recorded against the Authority's contract records.

## SCHEDULE 2 - PRICING

1. Subject to all work being completed satisfactory and in accordance with this Contract the Customer will pay to the Contractor **£191,699.00** (excluding VAT), in accordance with the Stage Payment Scheme detailed below;



In addition to this amount, a sum equal to the Value Added Tax chargeable at such rate as may be in force from time to time on the value of the supply of the Work provided in accordance with this Agreement.

# SCHEDULE 3 - CHANGE CONTROL

## Contract Change Note ("CCN")

<b>CCN Number</b>	
<b>Contract Reference Number &amp; Title</b>	
<b>Variation Title</b>	
<b>Number of Pages</b>	

WHEREAS the Contractor and the Authority entered into a Contract for Bridging the preclinical/clinical gap for optimisation of efficacy and avoidance of resistance for fluoroquinolones, application to canine pyoderma , dated January 2019 (the "Original Contract") and now wish to amend the Original Contract

IT IS AGREED as follows

1. The Original Contract shall be amended as set out in this Change Control Notice:

Change Requestor / Originator		
Summary of Change		
Reason for Change		
Revised Contract Price	Original Contract Value	£
	Previous Contract Changes	£
	Contract Change Note [x]	£
	New Contract Value	£
Revised Payment Schedule		
Revised Specification (See Annexe [x] for Details)		
Revised Contract Period		
Change in Contract Manager(s)		
Other Changes		

2. Save as amended all other terms of the Original Contract shall remain effective.
3. This CCN takes effect from the date on which both Parties communicate acceptance of its terms via Bravo.

# SCHEDULE 4 – KEY PERFORMANCE INDICATORS

## Key Performance Indicators

*To be agreed at inception meeting*

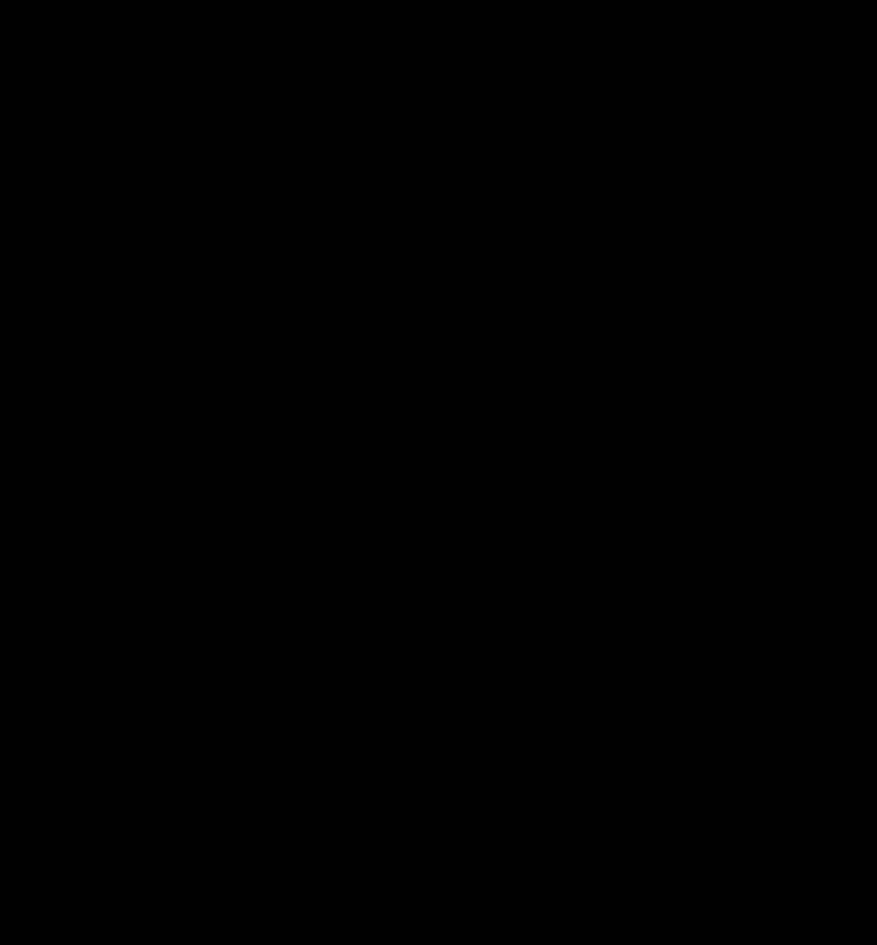
No.	KPI	KPI Description	KPI Rating		
1	Reporting	Timeliness and accuracy of all reports	Below expectations	Meets expectations	Exceeds expectations
2	Project Management	Degree to which milestones and deliverables are completed within agreed upon schedule	Below expectations	Meets expectations	Exceeds expectations
3	Deliverable Quality	Deliverables are completed with a high level of quality, professionalism, and attention to detail	Occasionally meets expected quality	Regularly meets expected quality	Always meets expected quality
4	Innovation	Supplier continually provides innovative ideas (e.g. technology enhancements, process efficiencies, etc.)	Disagree	Neutral	Agree

# SCHEDULE 5 - 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.
2. The contact details of the Authority Data Protection Officer are:  

3. The contact details of the Contractor Data Protection Officer are:  

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	
Subject matter of the processing	
Duration of the processing	
Nature and purposes of the processing	

Type of Personal Data	
Categories of Data Subject	
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	