Award Form

FS301058
The third study of Infectious Intestinal Disease in the UK (IID3 study)

This Award Form creates the Contract. It summarises the main features of the procurement and includes the Buyer and the Supplier's contact details.

1.	**Buyer**	Food Standards Agency (the Buyer) Its offices are on: Clive House 70 Petty France London, SW1H 9EX
2.	**Supplier**	Name: **Newcastle University** Address: [redacted]
3.	**Contract**	This Contract between the Buyer and the Supplier is for the supply of Deliverables.
4.	**Contract Reference**	**FS301058**
5.	**Deliverables**	See Schedule 2 (Specification) for further details.
6.	**Start Date**	1st October 2021
7.	**End Date**	30th September 2025
8.	**Extension Period**	Up to 6 months
9.	**Incorporated Terms** (together these documents form the 'the Contract')	The following documents are incorporated into the Contract. Where numbers are missing we are not using these Schedules. If the documents conflict, the following order of precedence applies: 1. This Award Form 2. Any Special Terms (see **Section 10 Special Terms** in this Award Form) 3. Core Terms (version 1.0) 4. Schedule 1 (Definitions) 5. Schedule 20 (Processing Data) 6. The following Schedules (in equal order of precedence): ● Schedule 2 (Specification) ● Schedule 3 (Charges)

		• Schedule 4 (Tender) • Schedule 13 (Contract Management) • Schedule 16 (Security) • Schedule 20 (Processing Data) • Schedule 21 (Variation Form) • Schedule 22 (Insurance Requirements)
10.	**Special Terms**	Not Used
11.	**Social Value Commitment**	Not Applicable
12.	**Commercially Sensitive Information**	Not Used
13.	**Charges**	Details in Schedule 3 (Charges)
14.	**Reimbursable expenses**	Recoverable as set out in Schedule 3 (Charges)
15.	**Payment Method**	All invoices must be sent, quoting a valid purchase order number (PO Number), to: [redacted] Within 10 Working Days of receipt of your countersigned copy of this letter, we will send you a unique PO Number. You must be in receipt of a valid PO Number before submitting an invoice. To avoid delay in payment it is important that the invoice is compliant and that it includes a valid PO Number, PO Number item number (if applicable) and the details (name and telephone number) of your Buyer contact (i.e. Contract Manager). Non-compliant invoices will be sent back to you, which may lead to a delay in payment.
16.	**Insurance**	Details in Annex of Schedule 22 (Insurance Requirements).
17.	**Liability**	In accordance with Clause 11.1 of the Core Terms each Party's total aggregate liability in each Contract Year under the Contract (whether in tort, contract or otherwise) is no more than the greater of £**5 million** or **150**% of the Estimated Yearly Charges.
18.	**Supplier Contract Manager**	[redacted]

19.	**Key Subcontractors**	Details in Schedule 4 (Technical Proposal)
20.	**Buyer Authorised Representative**	[redacted]

Signed for and on behalf of the **Supplier**	Signed for and on behalf of the **Buyer**
[redacted]	

Core Terms – Mid-tier

1. Definitions used in the contract

1.1 Interpret this Contract using Schedule 1 (Definitions).

2. How the contract works

2.1 If the Buyer decides to buy Deliverables under the Contract it must state its requirements using the Award Form). If allowed by the Regulations, the Buyer can:

- make changes to Award Form
- create new Schedules
- exclude optional template Schedules
- use Special Terms in the Award Form to add or change terms

2.2 The Contract:

- is between the Supplier and the Buyer
- includes Core Terms, Schedules and any other changes or items in the completed Award Form

2.3 The Supplier acknowledges it has all the information required to perform its obligations under the Contract before entering into it. When information is provided by the Buyer no warranty of its accuracy is given to the Supplier.

2.4 The Supplier won't be excused from any obligation, or be entitled to additional Costs or Charges because it failed to either:

- verify the accuracy of the Due Diligence Information
- properly perform its own adequate checks

2.5 The Buyer will not be liable for errors, omissions or misrepresentation of any information.

2.6 The Supplier warrants and represents that all statements made and documents submitted as part of the procurement of Deliverables are and remain true and accurate.

3. What needs to be delivered

3.1 All deliverables

3.1.1 The Supplier must provide Deliverables:

- that comply with the Specification, the Tender Response and the Contract
- using professional academic standards
- using its own policies, processes and internal quality control measures as long as they don't conflict with the Contract
- on the dates agreed
- that comply with Law

3.1.2 In the event that a level of warranty is not specified in the Award Form, the Supplier must provide Deliverables with a warranty of at least 90 days from Delivery against all obvious defects.

3.2 Goods clauses

3.2.1 All Goods delivered must be new, or as new if recycled, unused and of recent origin.

3.2.2 All manufacturer warranties covering the Goods must be assignable to the Buyer on request and for free.

3.2.3 The Supplier transfers ownership of the Goods on Delivery or payment for those Goods, whichever is earlier.

3.2.4 Risk in the Goods transfers to the Buyer on Delivery of the Goods, but remains with the Supplier if the Buyer notices damage following Delivery and lets the Supplier know within 3 Working Days of Delivery.

3.2.5 The Supplier warrants that it has full and unrestricted ownership of the Goods at the time of transfer of ownership.

3.2.6 The Supplier must deliver the Goods on the date and to the specified location during the Buyer's working hours.

3.2.7 The Supplier must provide sufficient packaging for the Goods to reach the point of Delivery safely and undamaged.

3.2.8 All deliveries must have a delivery note attached that specifies the order number, type and quantity of Goods.

3.2.9 The Supplier must provide all tools, information and instructions the Buyer needs to make use of the Goods.
3.2.10 The Supplier must indemnify the Buyer against the costs of any Recall of the Goods and give notice of actual or anticipated action about the Recall of the Goods.

3.2.11 The Buyer can cancel any order or part order of Goods which has not been Delivered. If the Buyer gives less than 14 days notice then it will pay the Supplier's reasonable and proven costs already incurred on the cancelled order as long as the Supplier takes all reasonable steps to minimise these costs.

3.2.12 The Supplier must at its own cost repair, replace, refund or substitute (at the Buyer's option and request) any Goods that the Buyer rejects because they don't conform with Clause 3. If the Supplier doesn't do this it will pay the Buyer's costs including repair or re-supply by a third party.

3.3 Services clauses

3.3.1 Late Delivery of the Services will be a Default of the Contract.

3.3.2 The Supplier must co-operate with the Buyer and third party suppliers on all aspects connected with the Delivery of the Services and ensure that Supplier Staff comply with any reasonable instructions of the Buyer or third party suppliers.

3.3.3 The Supplier must at its own risk and expense provide all Supplier Equipment required to Deliver the Services.

3.3.4 The Supplier must allocate sufficient resources and appropriate expertise to the Contract.

3.3.5 The Supplier must take all reasonable care to ensure performance does not disrupt the Buyer's operations, employees or other contractors.

3.3.6 The Supplier must ensure all Services, and anything used to Deliver the Services, are of a quality acceptable to the Buyer.

3.3.7 The Buyer is entitled to withhold payment for partially or undelivered Services but doing so does not stop it from using its other rights under the Contract.

4 Pricing and payments

4.1 In exchange for the Deliverables, the Supplier must invoice the Buyer for the Charges in the Award Form.

4.2 All Charges:

- exclude VAT, which is payable on provision of a valid VAT invoice

- include all costs connected with the Supply of Deliverables

4.3 The Buyer must pay the Supplier the Charges within 30 days of receipt by the Buyer of a valid, undisputed invoice, in cleared funds using the payment method and details stated in the Award Form.

4.4 A Supplier invoice is only valid if it:

- includes all appropriate references including the Contract reference number and other details reasonably requested by the Buyer
- includes a detailed breakdown of Delivered Deliverables and Milestone(s) (if any)

4.5 The Buyer may retain or set-off payment of any amount owed to it by the Supplier if notice and reasons are provided.

4.6 The Supplier must ensure that all Subcontractors are paid, in full, within 30 days of receipt of a valid, undisputed invoice. If this does not happen, the Buyer can publish the details of the late payment or non-payment.

4.7 If the Buyer can get more favourable commercial terms for the supply at cost of any materials, goods or services used by the Supplier to provide the Deliverables and that cost is reimbursable by the Buyer, then the Buyer may either:

- require the Supplier to replace its existing commercial terms with the more favourable terms offered for the relevant items; or
- enter into a direct agreement with the Subcontractor or third party for the relevant item

4.8 If the Buyer uses Clause 4.7 then the Charges must be reduced by an agreed amount by using the Variation Procedure.

4.9 The Buyer's right to enter into a direct agreement for the supply of the relevant items is subject to both:

- the relevant item being made available to the Supplier if required to provide the Deliverables
- any reduction in the Charges excludes any unavoidable costs that must be paid by the Supplier for the substituted item, including any licence fees or early termination charges

4.10 The Supplier has no right of set-off, counterclaim, discount or abatement unless they’re ordered to do so by a court.

5. The buyer's obligations to the supplier

5.1 If Supplier Non-Performance arises from a Buyer Cause:

- the Buyer cannot terminate the Contract under Clause 10.4.1
- the Supplier is entitled to reasonable and proven additional expenses and to relief from Delay Payments, liability and Deduction under this Contract
- the Supplier is entitled to additional time needed to make the Delivery
- the Supplier cannot suspend the ongoing supply of Deliverables

5.2 Clause 5.1 only applies if the Supplier:

- gives notice to the Buyer of the Buyer Cause within 10 Working Days of becoming aware
- demonstrates that the Supplier Non-Performance only happened because of the Buyer Cause
- mitigated the impact of the Buyer Cause

6. Record keeping and reporting

6.1 The Supplier must attend Progress Meetings with the Buyer and provide Progress Reports when specified in the Award Form.

6.2 The Supplier must keep and maintain full and accurate records and accounts in respect of the Contract for 7 years after the End Date and in accordance with the GDPR.

6.3 The Supplier must allow any Auditor access to their premises to verify all contract accounts and records of everything to do with the Contract and provide copies for an Audit.

6.4 The Supplier must provide information to the Auditor and reasonable co-operation at their request.

6.5 If the Supplier is not providing any of the Deliverables, or is unable to provide them, it must immediately:

- tell the Buyer and give reasons
- propose corrective action
- provide a deadline for completing the corrective action

7. Supplier staff

7.1 The Supplier Staff involved in the performance of the Contract must:

- be appropriately trained and qualified
- be vetted using professional academic standards and the Security Policy
- comply with all conduct requirements when on the Buyer's Premises

7.2 Where the Buyer decides one of the Supplier's Staff is not suitable to work on the Contract, the Supplier must replace them with a suitably qualified alternative.

7.3 If requested, the Supplier must replace any person whose acts or omissions have caused the Supplier to breach Clause 27.

7.4 The Supplier must provide a list of Supplier Staff needing to access the Buyer's Premises and say why access is required.

7.5 The Supplier indemnifies the Buyer against all claims brought by any person employed by the Supplier caused by an act or omission of the Supplier or any Supplier Staff.

8. Rights and protection

8.1 The Supplier warrants and represents that:

- it has full capacity and authority to enter into and to perform the Contract
- the Contract is executed by its authorised representative
- it is a legally valid and existing organisation incorporated in the place it was formed
- there are no known legal or regulatory actions or investigations before any court, administrative body or arbitration tribunal pending or threatened against it or its Affiliates that might affect its ability to perform the Contract
- it maintains all necessary rights, authorisations, licences and consents to perform its obligations under the Contract
- it doesn't have any contractual obligations which are likely to have a material adverse effect on its ability to perform the Contract
- it is not impacted by an Insolvency Event

8.2 The warranties and representations in Clauses 2.6 and 8.1 are repeated each time the Supplier provides Deliverables under the Contract.

8.3 The Supplier indemnifies the Buyer against each of the following:

- wilful misconduct of the Supplier, Subcontractor and Supplier Staff that impacts the Contract
- non-payment by the Supplier of any tax or National Insurance

8.4 All claims indemnified under this Contract must use Clause 26.

8.5 The Buyer can terminate the Contract for breach of any warranty or indemnity where they are entitled to do so.

8.6 If the Supplier becomes aware of a representation or warranty that becomes untrue or misleading, it must immediately notify the Buyer.

8.7 All third party warranties and indemnities covering the Deliverables must be assigned for the Buyer's benefit by the Supplier.

9. Intellectual Property Rights (IPRs)

9.1 Each Party keeps ownership of its own Existing IPRs. The Supplier gives the Buyer a non-exclusive, perpetual, royalty-free, irrevocable, transferable worldwide licence to use, change and sub-license the Supplier's Existing IPR to enable it to both:

- receive and use the Deliverables
- make use of the deliverables provided by a Replacement Supplier

9.2 Any New IPR created under the Contract is owned by the Buyer. The Buyer gives the Supplier a licence to use any Existing IPRs and New IPRs for the purpose of fulfilling its obligations during the Contract Period. The Buyer grants the Supplier a royalty-free, sub-licensable, irrevocable, perpetual licence to use the IPR generated during the Agreement for academic, research and publication purposes. Any publication involving New IPR shall only be issued after inspection by the Buyer and with the Buyers explicit consent.

9.3 Where a Party acquires ownership of IPRs incorrectly under this Contract it must do everything reasonably necessary to complete a transfer assigning them in writing to the other Party on request and at its own cost.

9.4 Neither Party has the right to use the other Party's IPRs, including any use of the other Party's names, logos or trademarks, except as provided in Clause 9 or otherwise agreed in writing.

9.5 If there is an IPR Claim, the Supplier indemnifies the Buyer against all losses, damages, costs or expenses (including professional fees and fines) incurred as a result.

9.6 If an IPR Claim is made or anticipated the Supplier must at its own expense and the Buyer's sole option, either:

- obtain for the Buyer the rights in Clause 9.1 and 9.2 without infringing any third party IPR
- replace or modify the relevant item with substitutes that don't infringe IPR without adversely affecting the functionality or performance of the Deliverables

10. Ending the contract

10.1 The Contract takes effect on the Start Date and ends on the End Date or earlier if required by Law.

10.2 The Buyer can extend the Contract for the Extension Period by giving the Supplier no less than 3 Months' written notice before the Contract expires.

10.3 Ending the contract without a reason

10.3.1 The Buyer has the right to terminate the Contract at any time without reason or liability by giving the Supplier at least 90 days' notice and if it's terminated Clause 10.5.2 to 10.5.7 applies.

10.4 When the Buyer can end the Contract

10.4.1 If any of the following events happen, the Buyer has the right to immediately terminate the Contract by issuing a Termination Notice to the Supplier:

- there's a Supplier Insolvency Event
- there's a Default that is not corrected in line with an accepted Rectification Plan
- the Buyer rejects a Rectification Plan or the Supplier does not provide it within 10 days of the request
- there's any material Default of the Contract
- there's any material Default of any Joint Controller Agreement relating to the Contract
- there's a Default of Clauses 2.6, 9, 14, 15, 27, 32 or Schedule 19 (Cyber Essentials) (where applicable) relating to the Contract

- there's a consistent repeated failure to meet the Service Levels in Schedule 10 (Service Levels)
- there's a Change of Control of the Supplier which isn't pre-approved by the Buyer in writing
- there's a Variation to the Contract which cannot be agreed using Clause 24 (Changing the contract) or resolved using Clause 34 (Resolving disputes)
- The Buyer discovers that the Supplier was in one of the situations in 57 (1) or 57(2) of the Regulations at the time the Contract was awarded
- the Court of Justice of the European Union uses Article 258 of the Treaty on the Functioning of the European Union (TFEU) to declare that the Contract should not have been awarded to the Supplier because of a serious breach of the TFEU or the Regulations
- the Supplier or its Affiliates embarrass or bring the Buyer into disrepute or diminish the public trust in them

10.4.2 If there is a Default, the Buyer can, without limiting its other rights, request that the Supplier provide a Rectification Plan.

10.4.3 When the Buyer receives a requested Rectification Plan it can either:

- reject the Rectification Plan or revised Rectification Plan, giving reasons
- accept the Rectification Plan or revised Rectification Plan (without limiting its rights) and the Supplier must immediately start work on the actions in the Rectification Plan at its own cost, unless agreed otherwise by the Parties

10.4.4 Where the Rectification Plan or revised Rectification Plan is rejected, the Buyer:

- must give reasonable grounds for its decision
- may request that the Supplier provides a revised Rectification Plan within 5 Working Days

10.4.5 If any of the events in 73 (1) (a) to (c) of the Regulations happen, the Buyer has the right to immediately terminate the Contract and Clause 10.5.2 to 10.5.7 applies.

10.5 What happens if the contract ends

Where the Buyer terminates the Contract under Clause 10.4.1 all of the following apply:

10.5.1 The Supplier is responsible for the Buyer's reasonable costs of procuring Replacement Deliverables for the rest of the Contract Period.

10.5.2 The Buyer's payment obligations under the terminated Contract stop immediately.

10.5.3 Accumulated rights of the Parties are not affected.

10.5.4 The Supplier must promptly delete or return the Government Data except where required to retain copies by law.

10.5.5 The Supplier must promptly return any of the Buyer's property provided under the terminated Contract.

10.5.6 The Supplier must, at no cost to the Buyer, co-operate fully in the handover and re-procurement (including to a Replacement Supplier).

10.5.7 The following Clauses survive the termination of the Contract: 3.2.10, 6, 7.2, 9, 11, 14, 15, 16, 17, 18, 34, 35 and any Clauses and Schedules which are expressly or by implication intended to continue.

10.6 When the supplier can end the contract

10.6.1 The Supplier can issue a Reminder Notice if the Buyer does not pay an undisputed invoice on time. The Supplier can terminate the Contract if the Buyer fails to pay an undisputed invoiced sum due and worth over 10% of the total Contract Value within 30 days of the date of the Reminder Notice.

10.6.2 If a Supplier terminates the Contract under Clause 10.6.1:

- the Buyer must promptly pay all outstanding Charges incurred to the Supplier
- the Buyer must pay the Supplier reasonable committed and unavoidable Losses as long as the Supplier provides a fully itemised and costed schedule with evidence - the maximum value of this payment is limited to the total sum payable to the Supplier if the Contract had not been terminated
- Clauses 10.5.4 to 10.5.7 apply

10.7 When subcontracts can be ended

At the Buyer's request, the Supplier must terminate any Subcontracts in any of the following events:

- there is a Change of Control of a Subcontractor which isn't pre-approved by the Buyer in writing

- the acts or omissions of the Subcontractor have caused or materially contributed to a right of termination under Clause 10.4
- a Subcontractor or its Affiliates embarrasses or brings into disrepute or diminishes the public trust in the Buyer

10.8 Partially ending and suspending the contract

10.8.1 Where the Buyer has the right to terminate the Contract it can terminate or suspend (for any period), all or part of it. If the Buyer suspends the Contract it can provide the Deliverables itself or buy them from a third party.

10.8.2 The Buyer can only partially terminate or suspend the Contract if the remaining parts of that Contract can still be used to effectively deliver the intended purpose.

10.8.3 The Parties must agree any necessary Variation required by Clause 10.8 using the Variation Procedure, but the Supplier may not either:

- reject the Variation
- increase the Charges, except where the right to partial termination is under Clause 10.3

10.8.4 The Buyer can still use other rights available, or subsequently available to it if it acts on its rights under Clause 10.8.

11. How much you can be held responsible for

11.1 Each Party's total aggregate liability in each Contract Year under the Contract (whether in tort, contract or otherwise) is no more than the greater of £5 million or 150% of the Estimated Yearly Charges unless specified in the Award Form.

11.2 No Party is liable to the other for:

- any indirect Losses
- Loss of profits, turnover, savings, business opportunities or damage to goodwill (in each case whether direct or indirect)

11.3 In spite of Clause 11.1, neither Party limits or excludes any of the following:

- its liability for death or personal injury caused by its negligence, or that of its employees, agents or Subcontractors
- its liability for bribery or fraud or fraudulent misrepresentation by it or its employees
- any liability that cannot be excluded or limited by Law

11.4 In spite of Clause 11.1, the Supplier does not limit or exclude its liability for any indemnity given under Clauses 7.5, 8.3, 9.5, 12.2 or 14.8 or Schedule 7 (Staff Transfer) of the Contract.

11.5 Each Party must use all reasonable endeavours to mitigate any Loss or damage which it suffers under or in connection with the Contract, including any indemnities.

11.6 When calculating the Supplier's liability under Clause 11.1 the following items will not be taken into consideration:

- Deductions
- any items specified in Clause 11.4

11.7 If more than one Supplier is party to the Contract, each Supplier Party is fully responsible for both their own liabilities and the liabilities of the other Suppliers.

12. Obeying the law

12.1 The Supplier must use reasonable endeavours to comply with the provisions of Schedule 26 (Corporate Social Responsibility).

12.2 The Supplier indemnifies the Buyer against any costs resulting from any Default by the Supplier relating to any applicable Law.

12.3 The Supplier must appoint a Compliance Officer who must be responsible for ensuring that the Supplier complies with Law, Clause 12.1 and Clauses 27 to 32.

13. Insurance

The Supplier must, at its own cost, obtain and maintain the Required Insurances in Schedule 22 (Insurance Requirements).

14. Data protection

14.1 The Supplier must process Personal Data and ensure that Supplier Staff process Personal Data only in accordance with Schedule 20 (Processing Data).

14.2 The Supplier must not remove any ownership or security notices in or relating to the Government Data.

14.3 The Supplier must make accessible back-ups of all Government Data, stored in an agreed off-site location and send the Buyer copies every 6 Months.

14.4 The Supplier must ensure that any Supplier system holding any Government Data, including back-up data, is a secure system that complies with the Security Policy and any applicable Security Management Plan.

14.5 If at any time the Supplier suspects or has reason to believe that the Government Data provided under the Contract is corrupted, lost or sufficiently degraded, then the Supplier must notify the Buyer and immediately suggest remedial action.

14.6 If the Government Data is corrupted, lost or sufficiently degraded so as to be unusable the Buyer may either or both:

- tell the Supplier to restore or get restored Government Data as soon as practical but no later than 5 Working Days from the date that the Buyer receives notice, or the Supplier finds out about the issue, whichever is earlier
- restore the Government Data itself or using a third party

14.7 The Supplier must pay each Party's reasonable costs of complying with Clause 14.6 unless the Buyer is at fault.

14.8 The Supplier:

- must provide the Buyer with all Government Data in an agreed open format within 10 Working Days of a written request
- must have documented processes to guarantee prompt availability of Government Data if the Supplier stops trading
- must securely destroy all Storage Media that has held Government Data at the end of life of that media using Good Industry Practice
- securely erase all Government Data and any copies it holds when asked to do so by the Buyer unless required by Law to retain it
- indemnifies the Buyer against any and all Losses incurred if the Supplier breaches Clause 14 and any Data Protection Legislation.

15. What you must keep confidential

15.1 Each Party must:

- keep all Confidential Information it receives confidential and secure
- not disclose, use or exploit the Disclosing Party's Confidential Information without the Disclosing Party's prior written consent, except for the purposes anticipated under the Contract

- immediately notify the Disclosing Party if it suspects unauthorised access, copying, use or disclosure of the Confidential Information

15.2 In spite of Clause 15.1, a Party may disclose Confidential Information which it receives from the Disclosing Party in any of the following instances:

- where disclosure is required by applicable Law or by a court with the relevant jurisdiction if the Recipient Party notifies the Disclosing Party of the full circumstances, the affected Confidential Information and extent of the disclosure
- if the Recipient Party already had the information without obligation of confidentiality before it was disclosed by the Disclosing Party
- if the information was given to it by a third party without obligation of confidentiality
- if the information was in the public domain at the time of the disclosure
- if the information was independently developed without access to the Disclosing Party's Confidential Information
- to its auditors or for the purposes of regulatory requirements
- on a confidential basis, to its professional advisers on a need-to-know basis
- to the Serious Fraud Office where the Recipient Party has reasonable grounds to believe that the Disclosing Party is involved in activity that may be a criminal offence under the Bribery Act 2010

15.3 The Supplier may disclose Confidential Information on a confidential basis to Supplier Staff on a need-to-know basis to allow the Supplier to meet its obligations under the Contract. The Supplier Staff must enter into a direct confidentiality agreement with the Buyer at its request.

15.4 The Buyer may disclose Confidential Information in any of the following cases:

- on a confidential basis to the employees, agents, consultants and contractors of the Buyer
- on a confidential basis to any other Central Government Body, any successor body to a Central Government Body or any company that the Buyer transfers or proposes to transfer all or any part of its business to
- if the Buyer (acting reasonably) considers disclosure necessary or appropriate to carry out its public functions

- where requested by Parliament
- under Clauses 4.7 and 16

15.5 For the purposes of Clauses 15.2 to 15.4 references to disclosure on a confidential basis means disclosure under a confidentiality agreement or arrangement including terms as strict as those required in Clause 15.

15.6 Transparency Information and any Information which is exempt from disclosure by Clause 16 is not Confidential Information.

15.7 The Supplier must not make any press announcement or publicise the Contracts or any part of them in any way, without the prior written consent of the Buyer and must take all reasonable steps to ensure that Supplier Staff do not either.

16. When you can share information

16.1 The Supplier must tell the Buyer within 48 hours if it receives a Request For Information.

16.2 Within the required timescales the Supplier must give the Buyer full co-operation and information needed so the Buyer can:

- publish the Transparency Information
- comply with any Freedom of Information Act (FOIA) request
- comply with any Environmental Information Regulations (EIR) request

16.3 The Buyer may talk to the Supplier to help it decide whether to publish information under Clause 16. However, the extent, content and format of the disclosure is the Buyer's decision, which does not need to be reasonable.

17. Invalid parts of the contract

If any part of the Contract is prohibited by Law or judged by a court to be unlawful, void or unenforceable, it must be read as if it was removed from that Contract as much as required and rendered ineffective as far as possible without affecting the rest of the Contract, whether it's valid or enforceable.

18. No other terms apply

The provisions incorporated into the Contract are the entire agreement between the Parties. The Contract replaces all previous statements and agreements whether written

or oral. No other provisions apply.

19. Other people's rights in the Contract

No third parties may use the Contracts (Rights of Third Parties) Act (CRTPA) to enforce any term of the Contract unless stated (referring to CRTPA) in the Contract. This does not affect third party rights and remedies that exist independently from CRTPA.

20. Circumstances beyond your control

20.1 Any Party affected by a Force Majeure Event is excused from performing its obligations under the Contract while the inability to perform continues, if it both:

- provides a Force Majeure Notice to the other Party
- uses all reasonable measures practical to reduce the impact of the Force Majeure Event

20.2 Either party can partially or fully terminate the affected Contract if the provision of the Deliverables is materially affected by a Force Majeure Event which lasts for 90 days continuously.

20.3 Where a Party terminates under Clause 20.2:

- each party must cover its own Losses
- Clause 10.5.2 to 10.5.7 applies

21. Relationships created by the contract

The Contract does not create a partnership, joint venture or employment relationship. The Supplier must represent themselves accordingly and ensure others do so.

22. Giving up contract rights

A partial or full waiver or relaxation of the terms of the Contract is only valid if it is stated to be a waiver in writing to the other Party.

23. Transferring responsibilities

23.1 The Supplier cannot assign the Contract without the Buyer's written consent.

23.2 The Buyer can assign, novate or transfer its Contract or any part of it to any Crown Body, public or private sector body which performs the functions of the Buyer.

23.3 When the Buyer uses its rights under Clause 23.2 the Supplier must enter into a novation agreement in the form that the Buyer specifies.

23.4 The Supplier can terminate the Contract novated under Clause 23.2 to a private sector body that is experiencing an Insolvency Event.

23.5 The Supplier remains responsible for all acts and omissions of the Supplier Staff as if they were its own.

23.6 If the Buyer asks the Supplier for details about Subcontractors, the Supplier must provide details of Subcontractors at all levels of the supply chain including:

- their name
- the scope of their appointment
- the duration of their appointment

24. Changing the contract

24.1 Either Party can request a Variation to the Contract which is only effective if agreed in writing and signed by both Parties

24.2 The Supplier must provide an Impact Assessment either:

- with the Variation Form, where the Supplier requests the Variation
- within the time limits included in a Variation Form requested by the Buyer

24.3 If the Variation to the Contract cannot be agreed or resolved by the Parties, the Buyer can either:

- agree that the Contract continues without the Variation
- terminate the affected Contract, unless the Supplier has already provided part or all of the provision of the Deliverables, or where the Supplier can show evidence of substantial work being carried out to provide them
- refer the Dispute to be resolved using Clause 34 (Resolving Disputes)

24.4 The Buyer is not required to accept a Variation request made by the Supplier.

24.5 If there is a General Change in Law, the Supplier must bear the risk of the change and is not entitled to ask for an increase to the Charges.

24.6 If there is a Specific Change in Law or one is likely to happen during the Contract Period the Supplier must give the Buyer notice of the likely effects of the changes as soon as reasonably practical. They must also say if they think any Variation is needed either to the Deliverables, the Charges or the Contract and provide evidence:

- that the Supplier has kept costs as low as possible, including in Subcontractor costs
- of how it has affected the Supplier's costs

24.7 Any change in the Charges or relief from the Supplier's obligations because of a Specific Change in Law must be implemented using Clauses 24.1 to 24.4.

25. How to communicate about the contract

25.1 All notices under the Contract must be in writing and are considered effective on the Working Day of delivery as long as they're delivered before 5:00pm on a Working Day. Otherwise the notice is effective on the next Working Day. An email is effective when sent unless an error message is received.

25.2 Notices to the Buyer must be sent to the Buyer Authorised Representative's address or email address in the Award Form.

25.3 This Clause does not apply to the service of legal proceedings or any documents in any legal action, arbitration or dispute resolution.

26. Dealing with claims

26.1 If a Beneficiary is notified of a Claim then it must notify the Indemnifier as soon as reasonably practical and no later than 10 Working Days.

26.2 At the Indemnifier's cost the Beneficiary must both:

- allow the Indemnifier to conduct all negotiations and proceedings to do with a Claim
- give the Indemnifier reasonable assistance with the claim if requested

26.3 The Beneficiary must not make admissions about the Claim without the prior written consent of the Indemnifier which cannot be unreasonably withheld or delayed.

26.4 The Indemnifier must consider and defend the Claim diligently using competent legal advisors and in a way that doesn't damage the Beneficiary's reputation.

26.5 The Indemnifier must not settle or compromise any Claim without the Beneficiary's prior written consent which it must not unreasonably withhold or delay.

26.6 Each Beneficiary must take all reasonable steps to minimise and mitigate any losses that it suffers because of the Claim.

26.7 If the Indemnifier pays the Beneficiary money under an indemnity and the Beneficiary later recovers money which is directly related to the Claim, the Beneficiary must immediately repay the Indemnifier the lesser of either:

- the sum recovered minus any legitimate amount spent by the Beneficiary when recovering this money
- the amount the Indemnifier paid the Beneficiary for the Claim

27. Preventing fraud, bribery and corruption

27.1 The Supplier must not during any Contract Period:

- commit a Prohibited Act or any other criminal offence in the Regulations 57(1) and 57(2)
- do or allow anything which would cause the Buyer, including any of their employees, consultants, contractors, Subcontractors or agents to breach any of the Relevant Requirements or incur any liability under them

27.2 The Supplier must during the Contract Period:

- create, maintain and enforce adequate policies and procedures to ensure it complies with the Relevant Requirements to prevent a Prohibited Act and require its Subcontractors to do the same
- keep full records to show it has complied with its obligations under Clause 27 and give copies to the Buyer on request
- if required by the Buyer, within 20 Working Days of the Start Date of the Contract, and then annually, certify in writing to the Buyer, that they have complied with Clause 27, including compliance of Supplier Staff, and provide reasonable supporting evidence of this on request, including its policies and procedures

27.3 The Supplier must immediately notify the Buyer if it becomes aware of any breach of Clauses 27.1 or 27.2 or has any reason to think that it, or any of the Supplier Staff, has either:

- been investigated or prosecuted for an alleged Prohibited Act
- been debarred, suspended, proposed for suspension or debarment, or is otherwise ineligible to take part in procurement programmes or contracts because of a Prohibited Act by any government department or agency

- received a request or demand for any undue financial or other advantage of any kind related to the Contract
- suspected that any person or Party directly or indirectly related to the Contract has committed or attempted to commit a Prohibited Act

27.4 If the Supplier notifies the Buyer as required by Clause 27.3, the Supplier must respond promptly to their further enquiries, co-operate with any investigation and allow the Audit of any books, records and relevant documentation.

27.5 In any notice the Supplier gives under Clause 27.4 it must specify the:

- Prohibited Act
- identity of the Party who it thinks has committed the Prohibited Act
- action it has decided to take

28. Equality, diversity and human rights

28.1 The Supplier must follow all applicable equality Law when they perform their obligations under the Contract, including:

- protections against discrimination on the grounds of race, sex, gender reassignment, religion or belief, disability, sexual orientation, pregnancy, maternity, age or otherwise
- any other requirements and instructions which the Buyer reasonably imposes related to equality Law

28.2 The Supplier must take all necessary steps, and inform the Buyer of the steps taken, to prevent anything that is considered to be unlawful discrimination by any court or tribunal, or the Equality and Human Rights Commission (or any successor organisation) when working on the Contract.

29. Health and safety

29.1 The Supplier must perform its obligations meeting the requirements of:

- all applicable Law regarding health and safety
- the Buyer's current health and safety policy while at the Buyer's Premises, as provided to the Supplier

29.2 The Supplier must as soon as possible notify the other of any health and safety incidents or material hazards they're aware of at the Buyer Premises that relate to the performance of the Contract.

30. Environment

30.1 When working on Site the Supplier must perform its obligations under the Buyer's current Environmental Policy, which the Buyer must provide.

30.2 The Supplier must ensure that Supplier Staff are aware of the Buyer's Environmental Policy.

31. Tax

31.1 The Supplier must not breach any tax or social security obligations and must enter into a binding agreement to pay any late contributions due, including where applicable, any interest or any fines. The Buyer cannot terminate the Contract where the Supplier has not paid a minor tax or social security contribution.

31.2 Where the Charges payable under the Contract are or are likely to exceed £5 million at any point during the relevant Contract Period, and an Occasion of Tax Non-Compliance occurs, the Supplier must notify the Buyer of it within 5 Working Days including:

- the steps that the Supplier is taking to address the Occasion of Tax Non-Compliance and any mitigating factors that it considers relevant
- other information relating to the Occasion of Tax Non-Compliance that the Buyer may reasonably need

31.3 Where the Supplier or any Supplier Staff are liable to be taxed or to pay National Insurance contributions in the UK relating to payment received under the Contract, the Supplier must both:

- comply with the Income Tax (Earnings and Pensions) Act 2003 and all other statutes and regulations relating to income tax, the Social Security Contributions and Benefits Act 1992 (including IR35) and National Insurance contributions
- indemnify the Buyer against any Income Tax, National Insurance and social security contributions and any other liability, deduction, contribution, assessment or claim arising from or made during or after the Contract Period in connection with the provision of the Deliverables by the Supplier or any of the Supplier Staff

31.4 If any of the Supplier Staff are Workers who receive payment relating to the Deliverables, then the Supplier must ensure that its contract with the Worker contains the following requirements:

- the Buyer may, at any time during the Contract Period, request that the Worker provides information which demonstrates they comply with Clause 31.3, or why those requirements do not apply, the Buyer can specify the information the Worker must provide and the deadline for responding
- the Worker's contract may be terminated at the Buyer's request if the Worker fails to provide the information requested by the Buyer within the time specified by the Buyer
- the Worker's contract may be terminated at the Buyer's request if the Worker provides information which the Buyer considers isn't good enough to demonstrate how it complies with Clause 31.3 or confirms that the Worker is not complying with those requirements
- the Buyer may supply any information they receive from the Worker to HMRC for revenue collection and management

32. Conflict of interest

32.1 The Supplier must take action to ensure that neither the Supplier nor the Supplier Staff are placed in the position of an actual or potential Conflict of Interest.

32.2 The Supplier must promptly notify and provide details to the Buyer if a Conflict of Interest happens or is expected to happen.

32.3 The Buyer can terminate its Contract immediately by giving notice in writing to the Supplier or take any steps it thinks are necessary where there is or may be an actual or potential Conflict of Interest.

33. Reporting a breach of the contract

33.1 As soon as it is aware of it the Supplier and Supplier Staff must report to the Buyer any actual or suspected breach of:

- Law
- Clause 12.1
- Clauses 27 to 32

33.2 The Supplier must not retaliate against any of the Supplier Staff who in good faith reports a breach listed in Clause 33.1 to the Buyer or a Prescribed Person.

34. Resolving disputes

34.1 If there is a Dispute, the senior representatives of the Parties who have authority to settle the Dispute will, within 28 days of a written request from the other Party, meet in good faith to resolve the Dispute.

34.2 If the Dispute is not resolved at that meeting, the Parties can attempt to settle it by mediation using the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure current at the time of the Dispute. If the Parties cannot agree on a mediator, the mediator will be nominated by CEDR. If either Party does not wish to use, or continue to use mediation, or mediation does not resolve the Dispute, the Dispute must be resolved using Clauses 34.3 to 34.5.

34.3 Unless the Buyer refers the Dispute to arbitration using Clause 34.4, the Parties irrevocably agree that the courts of England and Wales have the exclusive jurisdiction to:

- determine the Dispute
- grant interim remedies
- grant any other provisional or protective relief

34.4 The Supplier agrees that the Buyer has the exclusive right to refer any Dispute to be finally resolved by arbitration under the London Court of International Arbitration Rules current at the time of the Dispute. There will be only one arbitrator. The seat or legal place of the arbitration will be London and the proceedings will be in English.

34.5 The Buyer has the right to refer a Dispute to arbitration even if the Supplier has started or has attempted to start court proceedings under Clause 34.3, unless the Buyer has agreed to the court proceedings or participated in them. Even if court proceedings have started, the Parties must do everything necessary to ensure that the court proceedings are stayed in favour of any arbitration proceedings if they are started under Clause 34.4.

34.6 The Supplier cannot suspend the performance of the Contract during any Dispute.

35. Which law applies

This Contract and any issues arising out of, or connected to it, are governed by English law.

Schedule 1 (Definitions)

1.1 In the Contract, unless the context otherwise requires, capitalised expressions shall have the meanings set out in this Schedule 1 (Definitions) or the relevant Schedule in which that capitalised expression appears.

1.2 If a capitalised expression does not have an interpretation in this Schedule or any other Schedule, it shall, in the first instance, be interpreted in accordance with the common interpretation within the relevant market sector/industry where appropriate. Otherwise, it shall be interpreted in accordance with the dictionary meaning.

1.3 In the Contract, unless the context otherwise requires:

1.3.1 the singular includes the plural and vice versa;

1.3.2 reference to a gender includes the other gender and the neuter;

1.3.3 references to a person include an individual, company, body corporate, corporation, unincorporated association, firm, partnership or other legal entity or Crown Body;

1.3.4 a reference to any Law includes a reference to that Law as amended, extended, consolidated or re-enacted from time to time;

1.3.5 the words "including", "other", "in particular", "for example" 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";

1.3.6 references to "writing" include typing, printing, lithography, photography, display on a screen, electronic and facsimile transmission and other modes of representing or reproducing words in a visible form, and expressions referring to writing shall be construed accordingly;

1.3.7 references to "representations" shall be construed as references to present facts, to "warranties" as references to present and future facts and to "undertakings" as references to obligations under the Contract;

1.3.8 references to "Clauses" and "Schedules" are, unless otherwise provided, references to the clauses and schedules of the Core Terms and references in any Schedule to parts, paragraphs, annexes and tables are, unless otherwise provided, references to the parts, paragraphs, annexes and tables of the Schedule in which these references appear;

1.3.9 references to "Paragraphs" are, unless otherwise provided, references to the paragraph of the appropriate Schedules unless otherwise provided; and

1.3.10 references to a series of Clauses or Paragraphs shall be inclusive of the clause numbers specified.

1.3.11 the headings in the Contract are for ease of reference only and shall not affect the interpretation or construction of the Contract; and

1.3.12 where the Buyer is a Crown Body it shall be treated as contracting with the Crown as a whole.

1.4 In the Contract, unless the context otherwise requires, the following words shall have the following meanings:

"Achieve"	in respect of a Test, to successfully pass such Test without any Test Issues and in respect of a Milestone, the issue of a Satisfaction Certificate in respect of that Milestone and "**Achieved**", "**Achieving**" and "**Achievement**" shall be construed accordingly;
"Affected Party"	the party seeking to claim relief in respect of a Force Majeure Event;
"Affiliates"	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 of that body corporate from time to time;
"Annex"	extra information which supports a Schedule;
"Approval"	the prior written consent of the Buyer and "**Approve**" and "**Approved**" shall be construed accordingly;
"Audit"	the Buyer's right to: a) verify the accuracy of the Charges and any other amounts payable by the Buyer under a Contract (including proposed or actual variations to them in accordance with the Contract); b) verify the costs of the Supplier (including the costs of all Subcontractors and any third party suppliers) in connection with the provision of the Services; c) verify the Open Book Data; d) verify the Supplier's and each Subcontractor's compliance with the applicable Law;

	e) identify or investigate actual or suspected breach of Clauses 27 to 33 and/or Schedule 26 (Corporate Social Responsibility), impropriety or accounting mistakes or any breach or threatened breach of security and in these circumstances the Buyer shall have no obligation to inform the Supplier of the purpose or objective of its investigations; f) identify or investigate any circumstances which may impact upon the financial stability of the Supplier, any Guarantor, and/or any Subcontractors or their ability to provide the Deliverables; g) obtain such information as is necessary to fulfil the Buyer's obligations to supply information for parliamentary, ministerial, judicial or administrative purposes including the supply of information to the Comptroller and Auditor General; h) review any books of account and the internal contract management accounts kept by the Supplier in connection with the Contract; i) carry out the Buyer's internal and statutory audits and to prepare, examine and/or certify the Buyer's annual and interim reports and accounts; j) enable the National Audit Office to carry out an examination pursuant to Section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Buyer has used its resources. a)
"Auditor"	a) the Buyer's internal and external auditors; b) the Buyer's statutory or regulatory auditors; c) the Comptroller and Auditor General, their staff and/or any appointed representatives of the National Audit Office; d) HM Treasury or the Cabinet Office; e) any party formally appointed by the Buyer to carry out audit or similar review functions; and f) successors or assigns of any of the above;
"Buyer Cause"	any breach of the obligations of the Buyer or any other default, act, omission, negligence or statement of the Buyer, of its employees, servants, agents in connection with or in relation to the subject-matter of the Contract and in respect of which the Buyer is liable to the Supplier;
"BACS"	the Bankers' Automated Clearing Services, which is a scheme for the electronic processing of financial transactions within the United Kingdom;
"Beneficiary"	a Party having (or claiming to have) the benefit of an indemnity under this Contract;

"Buyer Assets"	the Buyer's infrastructure, data, software, materials, assets, equipment or other property owned by and/or licensed or leased to the Buyer and which is or may be used in connection with the provision of the Deliverables which remain the property of the Buyer throughout the term of the Contract;
"Buyer Authorised Representative"	the representative appointed by the Buyer from time to time in relation to the Contract initially identified in the Award Form;
"Buyer Premises"	premises owned, controlled or occupied by the Buyer which are made available for use by the Supplier or its Subcontractors for the provision of the Deliverables (or any of them);
"Contract"	the contract between the Buyer and the Supplier, which consists of the terms set out and referred to in the Award Form;
"Contract Period"	the Contract Period in respect of the Contract;
"Central Government Body"	a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics: a) Government Department; b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal); c) Non-Ministerial Department; or d) Executive Agency;
"Change in Law"	any change in Law which impacts on the supply of the Deliverables and performance of the Contract which comes into force after the Start Date;
"Change of Control"	a change of control within the meaning of Section 450 of the Corporation Tax Act 2010;
"Charges"	b) the prices (exclusive of any applicable VAT), payable to the Supplier by the Buyer under the Contract, as set out in the Award Form, for the full and proper performance by the Supplier of its obligations under the Contract less any Deductions;
"Claim"	any claim which it appears that a Beneficiary is, or may become, entitled to indemnification under this Contract;
"Commercially Sensitive Information"	the Confidential Information listed in the Award Form (if any) comprising of commercially sensitive information relating to the Supplier, its IPR or its business or which the Supplier has indicated to the Buyer that, if disclosed by the Buyer, would cause the Supplier significant commercial disadvantage or material financial loss;
"Comparable Supply"	the supply of Deliverables to another Buyer of the Supplier that are the same or similar to the Deliverables;

"Compliance Officer"	the person(s) appointed by the Supplier who is responsible for ensuring that the Supplier complies with its legal obligations;
"Confidential Information"	means any information, however it is conveyed, that relates to the business, affairs, developments, trade secrets, Know-How, personnel and suppliers of the Buyer or the Supplier, including IPRs, together with information derived from the above, and any other information clearly designated as being confidential (whether or not it is marked as **"confidential"**) or which ought reasonably to be considered to be confidential;
"Conflict of Interest"	a conflict between the financial or personal duties of the Supplier or the Supplier Staff and the duties owed to the Buyer under the Contract, in the reasonable opinion of the Buyer;
"Contract"	c) the contract to be entered into between the Buyer and the Supplier for the provision of the Deliverables;
"Contracts Finder"	the Government's publishing portal for public sector procurement opportunities and contract data;
"Contract Period"	the term of the Contract from the earlier of the: a) applicable Start Date; or b) the Effective Date until the applicable End Date;
"Contract Value"	the higher of the actual or expected total Charges paid or payable under the Contract where all obligations are met by the Supplier;
"Contract Year"	a consecutive period of twelve (12) Months commencing on the Start Date or each anniversary thereof;
"Control"	control in either of the senses defined in sections 450 and 1124 of the Corporation Tax Act 2010 and "**Controlled**" shall be construed accordingly;
"Controller"	has the meaning given to it in the GDPR;
"Core Terms"	d) the Buyer's standard terms and conditions for common goods and services which comprise one part of the Contract the full title of which is Core Terms – Mid-tier version 1.0;
"Costs"	the following costs (without double recovery) to the extent that they are reasonably and properly incurred by the Supplier in providing the Deliverables: a) the cost to the Supplier or the Key Subcontractor (as the context requires), calculated per Work Day, of engaging the Supplier Staff, including: i) base salary paid to the Supplier Staff; ii) employer's National Insurance contributions; iii) pension contributions;

	iv) car allowances; v) any other contractual employment benefits; vi) staff training; vii) work place accommodation; viii) work place IT equipment and tools reasonably necessary to provide the Deliverables (but not including items included within limb (b) below); and ix) reasonable recruitment costs, as agreed with the Buyer; b) costs incurred in respect of Supplier Assets which would be treated as capital costs according to generally accepted accounting principles within the UK, which shall include the cost to be charged in respect of Supplier Assets by the Supplier to the Buyer or (to the extent that risk and title in any Supplier Asset is not held by the Supplier) any cost actually incurred by the Supplier in respect of those Supplier Assets; c) operational costs which are not included within (a) or (b) above, to the extent that such costs are necessary and properly incurred by the Supplier in the provision of the Deliverables; and d) Reimbursable Expenses to the extent these have been specified as allowable in the Award Form and are incurred in delivering any Deliverables; but excluding: a) Overhead; b) financing or similar costs; c) maintenance and support costs to the extent that these relate to maintenance and/or support Deliverables provided beyond the Contract Period whether in relation to Supplier Assets or otherwise; d) taxation; e) fines and penalties; f) amounts payable under Schedule 12 (Benchmarking) where such Schedule is used; and g) non-cash items (including depreciation, amortisation, impairments and movements in provisions);
"Crown Body"	the government of the United Kingdom (including the Northern Ireland Assembly and Executive Committee, the Scottish Government and the National Assembly for Wales), including, but not limited to, government ministers and government departments and particular bodies, persons, commissions or agencies from time to time carrying out functions on its behalf;

"CRTPA"	the Contract Rights of Third Parties Act 1999;
“Data Protection Impact Assessment	an assessment by the Controller of the impact of the envisaged Processing on the protection of Personal Data;
"Data Protection Legislation"	(i) the GDPR, the LED and any applicable national implementing Laws as amended from time to time (ii) the DPA 2018 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 to it in the GDPR;
"Data Subject"	has the meaning given to it in the GDPR
"Data Subject Access Request"	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;
"Deductions"	all Service Credits, Delay Payments (if applicable), or any other deduction which the Buyer is paid or is payable to the Buyer under the Contract;
"Default"	any breach of the obligations of the Supplier (including abandonment of the Contract in breach of its terms) or any other default (including material default), act, omission, negligence or statement of the Supplier, of its Subcontractors or any Supplier Staff howsoever arising in connection with or in relation to the subject-matter of the Contract and in respect of which the Supplier is liable to the Buyer;
"Delay Payments"	the amounts (if any) payable by the Supplier to the Buyer in respect of a delay in respect of a Milestone as specified in the Implementation Plan;
"Deliverables"	Goods and/or Services that may be ordered under the Contract including the Documentation;
"Delivery"	delivery of the relevant Deliverable or Milestone in accordance with the terms of the Contract as confirmed and accepted by the Buyer by the either (a) confirmation in writing to the Supplier; or (b) where Schedule 8 (Implementation Plan and Testing) is used issue by the Buyer of a Satisfaction Certificate. "**Deliver**" and "**Delivered**" shall be construed accordingly;
"Disaster"	the occurrence of one or more events which, either separately or cumulatively, mean that the Deliverables, or a material part thereof will be unavailable (or could reasonably be anticipated to be unavailable) for the period specified in the Award Form (for the purposes of this definition the **"Disaster Period**");
"Disclosing Party"	the Party directly or indirectly providing Confidential Information to the other Party in accordance with Clause 15 (What you must keep confidential);

"Dispute"	any claim, dispute or difference arises out of or in connection with the Contract or in connection with the negotiation, existence, legal validity, enforceability or termination of the Contract, whether the alleged liability shall arise under English law or under the law of some other country and regardless of whether a particular cause of action may successfully be brought in the English courts;
"Dispute Resolution Procedure"	the dispute resolution procedure set out in Clause 34 (Resolving disputes);
"Documentation"	descriptions of the Services and Service Levels, technical specifications, user manuals, training manuals, operating manuals, process definitions and procedures, system environment descriptions and all such other documentation (whether in hardcopy or electronic form) is required to be supplied by the Supplier to the Buyer under the Contract as: a) would reasonably be required by a competent third party capable of Good Industry Practice contracted by the Buyer to develop, configure, build, deploy, run, maintain, upgrade and test the individual systems that provide the Deliverables b) is required by the Supplier in order to provide the Deliverables; and/or c) has been or shall be generated for the purpose of providing the Deliverables;
"DOTAS"	the Disclosure of Tax Avoidance Schemes rules which require a promoter 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 National Insurance Contributions;
"Due Diligence Information"	any information supplied to the Supplier by or on behalf of the Buyer prior to the Start Date;
"Effective Date"	the date on which the final Party has signed the Contract;
"EIR"	the Environmental Information Regulations 2004;
"Employment Regulations"	the Transfer of Undertakings (Protection of Employment) Regulations 2006 (SI 2006/246) as amended or replaced or any other Regulations implementing the European Council Directive 77/187/EEC;
"End Date"	the earlier of: a) the Expiry Date (as extended by any Extension Period exercised by the Buyer under Clause 10.2); or

	b) if the Contract is terminated before the date specified in (a) above, the date of termination of the Contract;
"Environmental Policy"	to conserve energy, water, wood, paper and other resources, reduce waste and phase out the use of ozone depleting substances and minimise the release of greenhouse gases, volatile organic compounds and other substances damaging to health and the environment, including any written environmental policy of the Buyer;
"Estimated Year 1 Charges	the anticipated total Charges payable by the Buyer in the first Contract Year specified in the Award Form;
"Estimated Yearly Charges"	means for the purposes of calculating each Party's annual liability under clause 11.2 : i) in the first Contract Year, the Estimated Year 1 Charges; or ii) in any subsequent Contract Years, the Charges paid or payable in the previous Contract Year; or e) f) iii) after the end of the Contract, the Charges paid or payable in the last Contract Year during the Contract Period; g)
"Equality and Human Rights Commission"	the UK Government body named as such as may be renamed or replaced by an equivalent body from time to time;
"Existing IPR"	any and all IPR that are owned by or licensed to either Party and which are or have been developed independently of the Contract (whether prior to the Start Date or otherwise);
"Expiry Date"	the date of the end of the Contract as stated in the Award Form;
"Extension Period"	such period or periods beyond which the Initial Period may be extended up to a maximum of the number of years in total specified in the Award Form;
"FOIA"	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"	any event, circumstance, matter or cause affecting the performance by either the Buyer or the Supplier of its obligations arising from: h) acts, events, omissions, happenings or non-happenings beyond the reasonable control of the Affected Party which prevent or

	materially delay the Affected Party from performing its obligations under a Contract; a) riots, civil commotion, war or armed conflict, acts of terrorism, nuclear, biological or chemical warfare; b) acts of a Crown Body, local government or regulatory bodies; c) fire, flood or any disaster; or d) an industrial dispute affecting a third party for which a substitute third party is not reasonably available but excluding: i) any industrial dispute relating to the Supplier, the Supplier Staff (including any subsets of them) or any other failure in the Supplier or the Subcontractor's supply chain; ii) any event, occurrence, circumstance, matter or cause which is attributable to the wilful act, neglect or failure to take reasonable precautions against it by the Party concerned; and iii) any failure of delay caused by a lack of funds;
"Force Majeure Notice"	a written notice served by the Affected Party on the other Party stating that the Affected Party believes that there is a Force Majeure Event;
"Award Form"	the document outlining the Incorporated Terms and crucial information required for the Contract, to be executed by the Supplier and the Buyer;
" Incorporated Terms"	the contractual terms applicable to the Contract specified in the Award Form;
" Special Terms"	any additional terms and conditions specified in the Award Form incorporated into the Contract;
" Tender Response"	the tender submitted by the Supplier to the Buyer and annexed to or referred to in Schedule 4 (Tender);
"GDPR"	the General Data Protection Regulation (Regulation (EU) 2016/679)
"General Anti-Abuse Rule"	a) the legislation in Part 5 of the Finance Act 2013 and; and b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid National Insurance contributions;
"General Change in Law"	a Change in Law where the change is of a general legislative nature (including taxation or duties of any sort affecting the Supplier) or which affects or relates to a Comparable Supply;
"Goods"	goods made available by the Supplier as specified in Schedule 2 (Specification) and in relation to a Contract as specified in the Award Form;
"Good Industry Practice"	standards, practices, methods and procedures conforming to the Law and the exercise of 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 within the relevant industry or business sector;
"Government"	the government of the United Kingdom (including the Northern Ireland Assembly and Executive Committee, the Scottish Government and the National Assembly for Wales), including government ministers and government departments and other bodies, persons, commissions or agencies from time to time carrying out functions on its behalf;
"Government Data"	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, including any of the Buyer's Confidential Information, and which: i) are supplied to the Supplier by or on behalf of the Buyer; or ii) the Supplier is required to generate, process, store or transmit pursuant to the Contract;
"Government Procurement Card"	the Government's preferred method of purchasing and payment for low value goods or services [redacted]
"Guarantor"	the person (if any) who has entered into a guarantee in the form set out in Schedule 23 (Guarantee) in relation to this Contract;
"Halifax Abuse Principle"	the principle explained in the CJEU Case C-255/02 Halifax and others;
"HMRC"	Her Majesty's Revenue and Customs;
"ICT Policy"	the Buyer's policy in respect of information and communications technology, referred to in the Award Form, which is in force as at the Start Date (a copy of which has been supplied to the Supplier), as updated from time to time in accordance with the Variation Procedure;
"Impact Assessment"	an assessment of the impact of a Variation request by the Buyer completed in good faith, including: a) details of the impact of the proposed Variation on the Deliverables and the Supplier's ability to meet its other obligations under the Contract; b) details of the cost of implementing the proposed Variation; c) details of the ongoing costs required by the proposed Variation when implemented, including any increase or decrease in the Charges (as applicable), any alteration in the resources and/or expenditure required by either Party and any alteration to the working practices of either Party;

	d) a timetable for the implementation, together with any proposals for the testing of the Variation; and e) such other information as the Buyer may reasonably request in (or in response to) the Variation request;
"Implementation Plan"	the plan for provision of the Deliverables set out in Schedule 8 (Implementation Plan and Testing) where that Schedule is used or otherwise as agreed between the Supplier and the Buyer;
"Indemnifier"	a Party from whom an indemnity is sought under this Contract;
"Independent Control"	where a Controller has provided Personal Data to another Party which is not a Processor or a Joint Controller because the recipient itself determines the purposes and means of Processing but does so separately from the Controller providing it with Personal Data and "**Independent Controller**" shall be construed accordingly;
"Indexation"	the adjustment of an amount or sum in accordance with the Award Form;
"Information"	has the meaning given under section 84 of the Freedom of Information Act 2000;
"Information Commissioner"	the UK's independent authority which deals with ensuring information relating to rights in the public interest and data privacy for individuals is met, whilst promoting openness by public bodies;
"Initial Period"	the initial term of the Contract specified in the Award Form;
"Insolvency Event"	a) in respect of a person: b) 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; or c) 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); or d) a petition is presented for its winding up (which is not dismissed within fourteen (14) Working 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; or e) a receiver, administrative receiver or similar officer is appointed over the whole or any part of its business or assets; or f) 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; or

	g) it is or becomes insolvent within the meaning of section 123 of the Insolvency Act 1986; or h) being a "small company" within the meaning of section 382(3) of the Companies Act 2006, a moratorium comes into force pursuant to Schedule A1 of the Insolvency Act 1986; or i) where the person is an individual or partnership, any event analogous to those listed in limbs (a) to (g) (inclusive) occurs in relation to that individual or partnership; or j) any event analogous to those listed in limbs (a) to (h) (inclusive) occurs under the law of any other jurisdiction;
"Installation Works"	all works which the Supplier is to carry out at the beginning of the Contract Period to install the Goods in accordance with the Contract;
"Intellectual Property Rights" or "IPR"	a) copyright, rights related to or affording protection similar to copyright, rights in databases, patents and rights in inventions, semi-conductor topography rights, trade marks, rights in internet domain names and website addresses and other rights in trade or business names, goodwill, designs, Know-How, trade secrets and other rights in Confidential Information; b) applications for registration, and the right to apply for registration, for any of the rights listed at (a) that are capable of being registered in any country or jurisdiction; and c) all other rights having equivalent or similar effect in any country or jurisdiction;
"Invoicing Address"	the address to which the Supplier shall Invoice the Buyer as specified in the Award Form;
"IPR Claim"	any claim of infringement or alleged infringement (including the defence of such infringement or alleged infringement) of any IPR, used to provide the Deliverables or otherwise provided and/or licensed by the Supplier (or to which the Supplier has provided access) to the Buyer in the fulfilment of its obligations under the Contract;
"IR35"	the off-payroll rules requiring individuals who work through their company pay the same tax and National Insurance contributions as an employee which can be found online at: [redacted]
"Joint Controller Agreement"	the agreement (if any) entered into between the Buyer and the Supplier substantially in the form set out in Annex 2 of Schedule 20 (*Processing Data*);
"Joint Controllers"	where two or more Controllers jointly determine the purposes and means of Processing;
"Key Personnel"	the individuals (if any) identified as such in the Award Form;

"Key Sub-Contract"	each Sub-Contract with a Key Subcontractor;
"Key Subcontractor"	any Subcontractor: a) which is relied upon to deliver any work package within the Deliverables in their entirety; and/or b) which, in the opinion of the Buyer performs (or would perform if appointed) a critical role in the provision of all or any part of the Deliverables; and/or c) with a Sub-Contract with the Contract value which at the time of appointment exceeds (or would exceed if appointed) 10% of the aggregate Charges forecast to be payable under the Contract, and the Supplier shall list all such Key Subcontractors in section 29 of the Award Form;
"Know-How"	all ideas, concepts, schemes, information, knowledge, techniques, methodology, and anything else in the nature of know-how relating to the Deliverables but excluding know-how already in the other Party's possession before the applicable Start Date;
"Law"	any law, 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 with which the Supplier is bound to comply;
"LED"	i) Law Enforcement Directive (Directive (EU) 2016/680)
"Losses"	all losses, liabilities, damages, costs, expenses (including legal fees), disbursements, costs of investigation, litigation, settlement, judgment, interest and penalties whether arising in contract, tort (including negligence), breach of statutory duty, misrepresentation or otherwise and "**Loss**" shall be interpreted accordingly;
"Lots"	the number of lots specified in Schedule 2 (Specification), if applicable;
"Marketing Contact"	shall be the person identified in the Award Form;
"Milestone"	an event or task described in the Implementation Plan;
"Milestone Date"	the target date set out against the relevant Milestone in the Implementation Plan by which the Milestone must be Achieved;
"Month"	a calendar month and "**Monthly**" shall be interpreted accordingly;
"National Insurance"	contributions required by the National Insurance Contributions Regulations 2012 (SI 2012/1868) made under section 132A of the Social Security Administration Act 1992;

"New IPR"	a) IPR in items created by the Supplier (or by a third party on behalf of the Supplier) specifically for the purposes of the Contract and updates and amendments of these items including (but not limited to) database schema; and/or b) IPR in or arising as a result of the performance of the Supplier's obligations under the Contract and all updates and amendments to the same; but shall not include the Supplier's Existing IPR;
"Occasion of Tax Non – Compliance"	where: a) any tax return of the Supplier 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 Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation in any jurisdiction 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 Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime in any jurisdiction; and/or b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 which 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 Start Date or to a civil penalty for fraud or evasion;
"Open Book Data"	complete and accurate financial and non-financial information which is sufficient to enable the Buyer to verify the Charges already paid or payable and Charges forecast to be paid during the remainder of the Contract, including details and all assumptions relating to: a) the Supplier's Costs broken down against each Good and/or Service and/or Deliverable, including actual capital expenditure (including capital replacement costs) and the unit cost and total actual costs of all Deliverables; b) operating expenditure relating to the provision of the Deliverables including an analysis showing: i) the unit costs and quantity of Goods and any other consumables and bought-in Deliverables; ii) manpower resources broken down into the number and grade/role of all Supplier Staff (free of any contingency) together with a list of agreed rates against each manpower grade;

	iii) a list of Costs underpinning those rates for each manpower grade, being the agreed rate less the Supplier Profit Margin; and iv) Reimbursable Expenses, if allowed under the Award Form; c) Overheads; d) all interest, expenses and any other third party financing costs incurred in relation to the provision of the Deliverables; e) the Supplier Profit achieved over the Contract Period and on an annual basis; f) confirmation that all methods of Cost apportionment and Overhead allocation are consistent with and not more onerous than such methods applied generally by the Supplier; g) an explanation of the type and value of risk and contingencies associated with the provision of the Deliverables, including the amount of money attributed to each risk and/or contingency; and h) the actual Costs profile for each Service Period;
"Overhead"	those amounts which are intended to recover a proportion of the Supplier's or the Key Subcontractor's (as the context requires) indirect corporate costs (including financing, marketing, advertising, research and development and insurance costs and any fines or penalties) but excluding allowable indirect costs apportioned to facilities and administration in the provision of Supplier Staff and accordingly included within limb (a) of the definition of "Costs";
"Parliament"	takes its natural meaning as interpreted within by Law;
"Party"	the Buyer or the Supplier and "**Parties**" shall mean both of them where the context permits;
"Personal Data"	has the meaning given to it in the GDPR;
"Personal Data Breach"	has the meaning given to it in the GDPR;
"Prescribed Person"	a legal adviser, an MP or an appropriate body which a whistle-blower may make a disclosure to as detailed in 'Whistleblowing: list of prescribed people and bodies', 24 November 2016, available online at: [redacted]
"Progress Meeting"	a meeting between the Buyer Authorised Representative and the Supplier Authorised Representative;
"Progress Meeting Frequency"	the frequency at which the Supplier shall conduct a Progress Meeting in accordance with Clause 6.1 as specified in the Award Form;

"Progress Report"	a report provided by the Supplier indicating the steps taken to achieve Milestones or delivery dates;
"Progress Report Frequency"	the frequency at which the Supplier shall deliver Progress Reports in accordance with Clause 6.1 as specified in the Award Form;
"Prohibited Acts"	a) to directly or indirectly offer, promise or give any person working for or engaged by the Buyer or any other public body 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; or c) committing any offence: i) under the Bribery Act 2010 (or any legislation repealed or revoked by such Act); or ii) under legislation or common law concerning fraudulent acts; or iii) defrauding, attempting to defraud or conspiring to defraud the Buyer or other public body; or d) any activity, practice or conduct which would constitute one of the offences listed under (c) above if such activity, practice or conduct had been carried out in the UK;
"Protective Measures"	technical and organisational measures which must take account of: j) a) the nature of the data to be protected k) b)harm that might result from Data Loss Event; l) c) state of technological development m) d) the cost of implementing any measures including but not limited to 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;
"Recall"	a request by the Supplier to return Goods to the Supplier or the manufacturer after the discovery of safety issues or defects (including defects in the IPR rights) that might endanger health or hinder performance;

"Recipient Party"	the Party which receives or obtains directly or indirectly Confidential Information;
"Rectification Plan"	the Supplier's plan (or revised plan) to rectify it's breach using the template in Schedule 25 (Rectification Plan Template) which shall include: a) full details of the Default that has occurred, including a root cause analysis; b) the actual or anticipated effect of the Default; and c) the steps which the Supplier proposes to take to rectify the Default (if applicable) and to prevent such Default from recurring, including timescales for such steps and for the rectification of the Default (where applicable);
"Rectification Plan Process"	the process set out in Clause 10.4.2 to 10.4.4 (Rectification Plan Process);
"Regulations"	the Public Contracts Regulations 2015 and/or the Public Contracts (Scotland) Regulations 2015 (as the context requires);
"Reimbursable Expenses"	the reasonable out of pocket travel and subsistence (for example, hotel and food) expenses, properly and necessarily incurred in the performance of the Services, calculated at the rates and in accordance with the Buyer's expenses policy current from time to time, but not including: a) travel expenses incurred as a result of Supplier Staff travelling to and from their usual place of work, or to and from the premises at which the Services are principally to be performed, unless the Buyer otherwise agrees in advance in writing; and b) subsistence expenses incurred by Supplier Staff whilst performing the Services at their usual place of work, or to and from the premises at which the Services are principally to be performed;
"the Buyer's Confidential Information"	c) all Personal Data and any information, however it is conveyed, that relates to the business, affairs, developments, property rights, trade secrets, Know-How and IPR of the Buyer (including all Buyer Existing IPR and New IPR); d) any other information clearly designated as being confidential (whether or not it is marked "confidential") or which ought reasonably be considered confidential which comes (or has come) to the Buyer's attention or into the Buyer's possession in connection with the Contract; and information derived from any of the above;
"Relevant Requirements"	all applicable Law relating to bribery, corruption and fraud, including the Bribery Act 2010 and any guidance issued by the Secretary of State pursuant to section 9 of the Bribery Act 2010;

"Relevant Tax Authority"	HMRC, or, if applicable, the tax authority in the jurisdiction in which the Supplier is established;
"Reminder Notice"	a notice sent in accordance with Clause 10.6 given by the Supplier to the Buyer providing notification that payment has not been received on time;
"Replacement Deliverables"	any deliverables which are substantially similar to any of the Deliverables and which the Buyer receives in substitution for any of the Deliverables , whether those goods are provided by the Buyer internally and/or by any third party;
"Replacement Subcontractor"	a Subcontractor of the Replacement Supplier to whom Transferring Supplier Employees will transfer on a Service Transfer Date (or any Subcontractor of any such Subcontractor);
"Replacement Supplier"	any third party provider of Replacement Deliverables appointed by or at the direction of the Buyer from time to time or where the Buyer is providing Replacement Deliverables for its own account, shall also include the Buyer;
"Request For Information"	a request for information or an apparent request relating to the Contract for the provision of the Deliverables or an apparent request for such information under the FOIA or the EIRs;
"Required Insurances"	the insurances required by Schedule 22 (Insurance Requirements);
"Satisfaction Certificate"	the certificate (materially in the form of the document contained in Annex 2 of Part B of Schedule 8 (Implementation Plan and Testing) or as agreed by the Parties where Schedule 8 is not used in this Contract) granted by the Buyer when the Supplier has Achieved a Milestone or a Test;
"Schedules"	any attachment to the Contract which contains important information specific to each aspect of buying and selling;
"Security Management Plan"	the Supplier's security management plan prepared pursuant to Schedule 16 (Security) (if applicable);
"Security Policy"	the Buyer's security policy, referred to in the Award Form, in force as at the Start Date (a copy of which has been supplied to the Supplier), as updated from time to time and notified to the Supplier;
"Serious Fraud Office"	the UK Government body named as such as may be renamed or replaced by an equivalent body from time to time;
"Service Levels"	any service levels applicable to the provision of the Deliverables under the Contract (which, where Schedule 10 (Service Levels) is used in this Contract, are specified in the Annex to Part A of such Schedule);
"Service Period"	has the meaning given to it in the Award Form;

"Services"	services made available by the Supplier as specified in Schedule 2 (Specification) and in relation to a Contract as specified in the Award Form;
"Service Transfer"	any transfer of the Deliverables (or any part of the Deliverables), for whatever reason, from the Supplier or any Subcontractor to a Replacement Supplier or a Replacement Subcontractor;
"Service Transfer Date"	the date of a Service Transfer;
"Sites"	any premises (including the Buyer Premises, the Supplier's premises or third party premises) from, to or at which: a) the Deliverables are (or are to be) provided; or b) the Supplier manages, organises or otherwise directs the provision or the use of the Deliverables; c) those premises at which any Supplier Equipment or any part of the Supplier System is located (where ICT Services are being provided)
"SME"	an enterprise falling within the category of micro, small and medium sized enterprises defined by the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium enterprises;
"Special Terms"	any additional Clauses set out in the Award Form which shall form part of the respective Contract;
"Specific Change in Law"	a Change in Law that relates specifically to the business of the Buyer and which would not affect a Comparable Supply where the effect of that Specific Change in Law on the Deliverables is not reasonably foreseeable at the Start Date;
"Specification"	the specification set out in Schedule 2 (Specification), as may, in relation to the Contract, be supplemented by the Award Form;
"Standards"	any: a) standards published by BSI British Standards, the National Standards Body of the United Kingdom, the International Organisation for Standardisation or other reputable or equivalent bodies (and their successor bodies) that a skilled and experienced operator in the same type of industry or business sector as the Supplier would reasonably and ordinarily be expected to comply with; b) standards detailed in the specification in Schedule 2 (Specification); c) standards detailed by the Buyer in the Award Form or agreed between the Parties from time to time;

	d) relevant Government codes of practice and guidance applicable from time to time;
"Start Date"	the date specified on the Award Form;
"Storage Media"	the part of any device that is capable of storing and retrieving data;
"Sub-Contract"	any contract or agreement (or proposed contract or agreement), other than a Contract, pursuant to which a third party: a) provides the Deliverables (or any part of them); b) provides facilities or services necessary for the provision of the Deliverables (or any part of them); and/or c) is responsible for the management, direction or control of the provision of the Deliverables (or any part of them);
"Subcontractor"	any person other than the Supplier, who is a party to a Sub-Contract and the servants or agents of that person;
"Subprocessor"	any third Party appointed to process Personal Data on behalf of the Supplier related to the Contract;
"Supplier"	the person, firm or company identified in the Award Form;
"Supplier Assets"	all assets and rights used by the Supplier to provide the Deliverables in accordance with the Contract but excluding the Buyer Assets;
"Supplier Authorised Representative"	the representative appointed by the Supplier named in the Award Form, or later defined in a Contract;
"Supplier's Confidential Information"	a) any information, however it is conveyed, that relates to the business, affairs, developments, IPR of the Supplier (including the Supplier Existing IPR) trade secrets, Know-How, and/or personnel of the Supplier; b) any other information clearly designated as being confidential (whether or not it is marked as "confidential") or which ought reasonably to be considered to be confidential and which comes (or has come) to the Supplier's attention or into the Supplier's possession in connection with the Contract; c) Information derived from any of (a) and (b) above;
"Supplier's Contract Manager	the person identified in the Award Form appointed by the Supplier to oversee the operation of the Contract and any alternative person whom the Supplier intends to appoint to the role, provided that the Supplier informs the Buyer prior to the appointment;
"Supplier Equipment"	the Supplier's hardware, computer and telecoms devices, equipment, plant, materials and such other items supplied and used by the Supplier (but not hired, leased or loaned from the Buyer) in the performance of its obligations under this Contract;

"Supplier Non-Performance"	where the Supplier has failed to: a) Achieve a Milestone by its Milestone Date; b) provide the Goods and/or Services in accordance with the Service Levels ; and/or c) comply with an obligation under the Contract;
"Supplier Profit"	in relation to a period, the difference between the total Charges (in nominal cash flow terms but excluding any Deductions and total Costs (in nominal cash flow terms) in respect of the Contract for the relevant period;
"Supplier Profit Margin"	in relation to a period or a Milestone (as the context requires), the Supplier Profit for the relevant period or in relation to the relevant Milestone divided by the total Charges over the same period or in relation to the relevant Milestone and expressed as a percentage;
"Supplier Staff"	all directors, officers, employees, agents, consultants and contractors of the Supplier and/or of any Subcontractor engaged in the performance of the Supplier's obligations under the Contract;
"Supply Chain Information Report Template"	the document at Annex 1 of Schedule 18 Supply Chain Visibility;
"Supporting Documentation"	sufficient information in writing to enable the Buyer to reasonably assess whether the Charges, Reimbursable Expenses and other sums due from the Buyer under the Contract detailed in the information are properly payable;
"Termination Notice"	a written notice of termination given by one Party to the other, notifying the Party receiving the notice of the intention of the Party giving the notice to terminate the Contract on a specified date and setting out the grounds for termination;
"Test Issue"	any variance or non-conformity of the Deliverables or Deliverables from their requirements as set out in the Contract;
"Test Plan"	a plan: a) for the Testing of the Deliverables; and b) setting out other agreed criteria related to the achievement of Milestones;
"Tests and Testing"	any tests required to be carried out pursuant to the Contract as set out in the Test Plan or elsewhere in the Contract and "**Tested**" shall be construed accordingly;
"Third Party IPR"	Intellectual Property Rights owned by a third party which is or will be used by the Supplier for the purpose of providing the Deliverables;
"Transferring Supplier Employees"	those employees of the Supplier and/or the Supplier's Subcontractors to whom the Employment Regulations will apply on the Service Transfer Date;

"Transparency Information"	the Transparency Reports and the content of the Contract, including any changes to this Contract agreed from time to time, except for – n) (i) any information which is exempt from disclosure in accordance with the provisions of the FOIA, which shall be determined by the Buyer; and (ii) Commercially Sensitive Information;
"Transparency Reports"	the information relating to the Deliverables and performance pursuant to the Contract which the Supplier is required to provide to the Buyer in accordance with the reporting requirements in Schedule 6 (Transparency Reports);
"Variation"	has the meaning given to it in Clause 24 (Changing the contract);
"Variation Form"	the form set out in Schedule 21 (Variation Form);
"Variation Procedure"	the procedure set out in Clause 24 (Changing the contract);
"VAT"	value added tax in accordance with the provisions of the Value Added Tax Act 1994;
"VCSE"	a non-governmental organisation that is value-driven and which principally reinvests its surpluses to further social, environmental or cultural objectives;
"Worker"	any one of the Supplier Staff which the Buyer, in its reasonable opinion, considers is an individual to which Procurement Policy Note 08/15 (Tax Arrangements of Public Appointees) ([redacted])
"Working Day"	any day other than a Saturday or Sunday or public holiday in England and Wales unless specified otherwise by the Parties in the Award Form.
"Work Day"	7.5 Work Hours, whether or not such hours are worked consecutively and whether or not they are worked on the same day;
"Work Hours"	the hours spent by the Supplier Staff properly working on the provision of the Deliverables including time spent travelling (other than to and from the Supplier's offices, or to and from the Sites) but excluding lunch breaks;

Schedule 2 (Specification)

This Schedule sets out what the Buyer wants.

For all Deliverables, the Supplier must help the Buyer comply with any specific applicable Standards of the Buyer.

GENERAL INTRODUCTION

The Food Standards Agency is an independent Government department working across England, Wales and Northern Ireland to protect public health and consumers wider interest in food. We make sure food is safe and what it says it is.

One of the objectives of the FSA's foodborne disease research programme is to provide scientifically robust information on the extent, distribution, causes, risks and cost of foodborne disease to inform our strategic decision-making. Estimation of the extent of foodborne disease is critical for the FSA and will build on two previous studies of the same nature. The third study will allow a re-assessment of the nature and burden of foodborne disease affecting the UK public, in comparison to data collected over a decade ago. This will assess the impact of changes in the food system over the past decade as well as inform the future direction of the FSA's work. The data produced will be used by the FSA as a baseline to monitor progress in reducing foodborne disease in the UK and help to prioritise activities towards the key foodborne pathogens. It will also provide data on the prevalence of AMR genes found in the intestinal microbiome of the UK population, a key input to the UK 5-year action plan (NAP) for antimicrobial resistance 2019 to 2024.

THE SPECIFICATION

Background

Infectious intestinal disease (IID) often presents as diarrhoea and/or vomiting. IID in the UK is predominantly self-limiting, but has a high cost associated with morbidity and can lead to mortality. IID is caused by a range of microorganisms, including bacteria (e.g. *Salmonella*, *Campylobacter* and Shiga toxin-producing *Escherichia coli*), viruses (e.g. norovirus and rotavirus) and parasites (e.g. *Giardia* or *Cryptosporidium*). Transmission of IID can occur through a variety of pathways, for example via foods and person-to-person transmission; the proportion of cases of these pathogens that occur via foodborne transmission is often challenging to estimate. Both previous IID studies indicated that the number of cases of IID in the UK is significantly underreported and cases are often not assigned to a pathogen, with underreporting due to numerous factors, including the individual not seeking medical care, samples not being taken at

point of contact with primary healthcare, and negative test results despite meeting the criteria for an IID diagnosis.

In 1993-1996, the Study of Infectious Intestinal Disease (IID) in England (IID1 study) was carried out to investigate the number of cases of IID, both those occurring in the community and those presenting to GPs, to determine their microbial aetiology and to determine the degree of underreporting through routine laboratory surveillance. In addition, information was collected on long term sequelae, risk factors and the socio-economic costs of illness. Although the study was not designed to determine the proportion of cases of IID that were foodborne, it provided useful data to help interpret information from routine surveillance systems and provided a firm foundation for calculating the level of under-ascertainment.

In 2007-2009, the Second Study of Infectious Intestinal Disease in the community (IID2 study) was carried out, which aimed to determine if the incidence and level of underreporting of IID had changed since the IID1 study was carried out in the mid-1990s and to collect up to date evidence on the data loss at each stage of the reporting pyramid, allowing more accurate estimates of the burden of IID. The scope of the study was expanded to all four countries of the United Kingdom and it trialled a telephone survey as a potential replacement for cohort and GP presentation studies in future monitoring. IID2 also introduced PCR testing and focused on a reduced list of target microorganisms. A follow-on computational study was also completed to estimate the burden of foodborne disease specifically.

Since the original IID study was undertaken in the mid-1990s, national surveillance, the structure of the National Health Service and recommendations to the public of when to approach a GP have changed. These changes may have altered the degree of reporting of IID and the perceived burden of IID in the community. Therefore, updated information on the reporting pyramid is required.

Given that more than ten years have passed since the IID2 study was carried out, the FSA is commissioning a third study of Infectious Intestinal Disease in the community (IID3 study). This study will follow similar strategies as the previous IID studies, aiming to provide data that allows comparisons across the three IID studies. It is envisioned that the development of next generation sequencing technologies since the previous study will allow a greater depth of knowledge to be obtained, for example, through the use of metagenomics to identify previously unidentified causes of IID. It is also expected that the data collected will allow comparisons to the previous work, including the IID, IID2 and IID2 extension studies, concerning the burden of UK-acquired foodborne disease and quantification of the contribution of various food commodities to total foodborne disease burden. In addition, given the growing awareness of the risks of antimicrobial resistance (AMR) and the commitment by HM Government to activities to

“identify and assess the sources, pathways, and exposure risks” of AMR outlined in the NAP, the IID3 study will assess the burden of AMR within the context of IID in the UK.

The Specification

Tenders are invited to carry out a study, comparable to the IID and IID2 studies, to assess the incidence of Infectious Intestinal Disease (IID) in the community and allowing the re-estimation of parameters measured during previous IID studies conducted in the UK.

Overview

We would like to commission a study that will allow an assessment of the incidence of IID in the community. Results must be obtained in a way that allows them to be compared to the previous IID studies and allow international comparisons where possible.

The key questions the IID3 study seeks to answer are as follows:

- What is the overall incidence of IID in the UK in terms of both cases and GP presentations?
- Of the total cases of IID, what number is attributed to domestically acquired (i.e. acquired in the UK, including mixed sources such as imported foods) and non-domestically acquired (i.e. acquired outside the UK) sources?
- What is the aetiology of IID in the UK? Key pathogens of interest will be agreed with the FSA but are likely to be broadly similar to those considered in IID2.
- What is the proportion of IID which is foodborne in the UK, both by pathogen and in total (the latter including estimates for cases of unknown aetiology)?
- What are the ascertainment ratios to adjust for under-reporting related to each IID-causing organism?
- What proportion of the population have within their gut microbiome genes associated with resistance to each of the WHO critically important antimicrobials?
- How do the results of the IID3 study compare to previous studies?
- What are the modelled number of cases in the community, GP reported cases, hospitalisations and deaths due to IID and foodborne disease in the UK?
- What are the modelled number of cases in the community, GP reported cases and hospitalisations by food commodity by pathogen?

In addition, contractors must collect data to allow the FSA to calculate the economic burden of IID in the UK, for example data related to medical and healthcare costs and details on the short and long-term (sequalae) illnesses, with particular emphasis on the

latter. Tenders are invited to propose the level of granularity and stratification of the data that they deem feasible while maintaining the quality of the results. Proposed valuation instruments and other related deliverables will need to be agreed at the beginning with the project officer.

Technical Details

Proposals submitted **must** include the following aspects of project governance:

- Ethical approval
    - Proposals must include consideration of the ethical approval that will be needed to carry out this study and the process for doing so.
- Demonstration of the relevant expertise within the proposal team
    - This project will require a wide array of technical expertise, including microbiology, epidemiology, modelling, metagenomics, data handling, as well as project management and coordination.
    - Proposals must demonstrate proven expertise in all required areas.
- Risk register and mitigation
    - Proposals must include a realistic assessment of the potential risks that may occur during the lifetime of the project and appropriate mitigations.
    - Proposals should also identify break points at which the progress of the project can be assessed to ensure that it is delivering as expected.

Proposals submitted **must** include the following key elements:

- Case definition
    - It is important to establish the case definition for IID to allow comparison to previous IID studies conducted in the UK and internationally. In IID2 the case definition was as follows:

      'loose stools or clinically significant vomiting lasting less than two weeks, in the absence of a known non-infectious cause, preceded by a symptom-free period of three weeks. Vomiting was considered clinically significant if it occurred more than once in a 24-hour period and if it incapacitated the case or was accompanied by other symptoms such as cramps or fever'
    - There has since been a standard case definition proposed (Majowicz et al., 2008) and adopted in many countries:

      'a case of gastroenteritis is defined as an individual with 3 or more loose stools, or any vomiting, in 24 h' which is *'unrelated to*

existing health conditions, medication use, or other non-infectious causes'

- Contractors should outline a case definition that allows for the comparison of data collected in IID3 with the IID2 study and similar international studies. Proposals must include data collection that would satisfy and separate the case definitions above or determine what effect a changing case definition may have on the data collected.
    - A pilot study may be included to show that a change in case definition will not affect the results when compared to the IID2 case definition

- Cohort study
    - In keeping with previous studies, it would be expected that proposals would include a population-based cohort study, which would follow a cohort recruited across the UK, who will be monitored for IID and asked to submit samples for a period of at least one year.
    - The study should include collation of symptoms and other health data including costs associated with the economic burden of disease (including those outlined below and in table on p13), as well as faecal samples for subsequent analysis.
        - List of costs may include data on:
            - GP surgery visit
            - GP home visit
            - Nurse home visit
            - GP phone call: NHS
            - GP phone call: patient
            - NHS direct
            - Out-of-hours clinic
            - A&E visit
            - In-patient: infectious disease
            - Intensive therapy
            - Isolation ward
            - Ambulance (to the hospital)

        - Prescribed medicine

    - The sample size of the study should be sufficient to deliver appropriate precision for the total rate of IID in the UK. Specifically:

        - We would expect that its 95% confidence bounds will be within ±10% of the estimated rate in the community per 1000 person-years.

        - In addition, the study should also be able to detect a 20% difference in the IID community rate from previous studies with 80% power.

        - The rate of those presenting to GPs should also have 95% confidence bounds within ±20% of the estimated rate per 1000 person-years.

        - Given the proposed study design, please state the likely precision of the IID incident rate for each pathogen, and for the "all IID" rate for various age groups.

    - The study should include a representative sample of the UK population, inclusive of participants from England, Scotland, Wales and NI, although a study design allowing robust estimates for each region separately is not required. The sample should include children (under 16s), adults and older adults (over 65s).

    - The proposal should outline how participants will be recruited and how sample collection will be achieved.

- Primary care presentation

    - The proposed work should include a study to estimate the incidence and aetiology (cause) of IID in those presenting to primary care as a complement to the cohort study. In previous studies this has involved all patients at specified clinics reporting IID being invited to provide samples, however the FSA is open to other suggestions for collecting these data.

- PCR and microbiological techniques

    - To allow comparison to previous studies it is expected that IID associated faecal samples collected would be subject to standard microbiological identification and PCR based methods to identify key pathogens of interest. This will facilitate determination of the aetiology of IID.

    - Samples should be typed to strain or genogroup level where appropriate, for example where different strains or genogroups may be associated with differing clinical severity, different food groups, etc. This may be done using traditional microbiological or molecular methods, such as PCR or whole genome sequencing (WGS).

- Additional testing should be undertaken on a subset of samples to assess antimicrobial resistance genes or phenotypes as appropriate to allow comparison to metagenomics data outputs.

- Metagenomics
    - It is expected that proposals will include plans to metagenomically sequence a proportion of faecal samples, both positive for IID and without IID, with appropriate stringency to provide insights on the microbiota including identification of potential IID causing organisms (including non-culturable organisms) and the AMR profile of the samples.
    - The aims of the metagenomics study will be:
        1. Identify whether there are significant differences in the frequency and type of antimicrobial resistance genes (conferring resistance to antimicrobials on the list of WHO critically important antimicrobials) in the UK population between those with and without IID in the UK.
        2. Identify microorganisms within the gut microflora which are significantly associated with the presentation of IID, both in cases where an aetiology has been identified, and those where no target organism is found.
    - It is expected that the study will include a control element to allow for the comparison of participants with IID to those without. Proposals should suggest methods to allow for this comparison.
    - Proposals should include methods and approaches for analysis of metagenomics data, quality assurance of data and storage of metagenomics data and metadata.

- Economic burden
    - The FSA has built a Cost of Illness (COI) model to identify and measure all the costs of a particular food related IID. A bottom-up approach has been used to calculate and estimate the cost of foodborne illness based on the number of cases, severity category (presenting to a GP, hospitalisation, not presenting to a GP) and relevant unit prices (medical costs, wages etc). When aggregated, an estimate of the total cost of the burden of foodborne disease in the UK is obtained. As part of this project we anticipate the collection of data needed for the FSA to use as part of this model. Some examples of data needed to assess the economic burden are found in the table on page 12. The FSA recognises the difficulty to capture all the included costs, tenders are expected to discuss how to best cover them, along with the limitations and risks.

- Food attribution model

- Proposals should include the development of quantitative models with associated parameter estimates to attribute the proportion of IID acquired in the UK that originates from food. Inputs would include data from previous IID studies, other studies/data on attribution of IID, public health data and information from the literature. The structure of the models produced previously following the IID2 study could be considered as a starting point, if additional modifications are made. A model is also available for assessing the cases occurring in the UK via specific food types, while FSA estimates for deaths and foodborne cases of unknown aetiology can be found at Holland et al. 2020 and in the FSA published foodborne disease estimates for 2018 respectively. Expert elicitation may be used for addressing gaps in data and/or the literature.

- Storage of samples
    - Proposals must include consideration of the long-term (>5 years) storage of faecal samples, bacterial isolates and nucleic acid extracts to allow for the possibility of further analysis in the future.

Proposals should include methods and approaches for collecting data to allow the FSA to improve and enhance estimates of the economic burden of food related IIDs pertaining to short and long-term (sequelae) illnesses. This should include (but is not limited to) data on:

1. Long-term Sequelae (e.g. IBS, GBS, HUS)	1.1. Proportion of cases that go on to develop a sequelae 1.2. Age profile. 1.3. Health care resource usage: o Tests to diagnose the sequelae as a result of the foodborne disease o Number of GP/ specialist/ hospital visits due to the sequelae on an annual basis o Prescription costs and over the counter medication 1.4. Absence from work (frequency and length) 1.5. Other related costs: dietary restrictions/ avoidance of restaurants/ transport costs
2. Short-term Illness	2.1 Explore differences in the decision to seek health care based on population profile: o Length of the disease/ illness o Age profile o Income profile/ socio-economic status/ethnicity o Employment status (full-time, part-time, self-employed etc.) o Work absence (number of days and proportion of the cases) o % needing carer assistance 2.2 Information/ data from sample of individuals that seek health care (presenting to a GP): o % of patients that are prescribed drugs o % of patients that are advised to over-the-counter treatments o % of patients prescribed a test (population profile dependent) 2.3 Information from the sample of individuals not seeking health care (not presenting to GP). o % of cases that use over-the-counter treatments. 2.4 Other expenditure (individual expenses) o Special food/drink o Cleaning material/ products o Opportunity costs of prepaid bus passes/ leisure activities/ etc. o Childcare costs as a result of children being excluding from normal childcare setting or school or parents taking leave to care for children o Other relevant expenses

The inclusion of the following element is **desirable** and should be separately costed:

- Other survey methods, for example, online surveys, social media mining. The aim of these additional methods will be:

    1. To provide a lower-cost alternative method of assessing IID in the UK
    2. Producing data comparable to that collected in the cohort study
    3. Allow for potential comparison with international studies on IID
    4. Allow for greater profiling of high-risk groups and seasonality of IID in the UK

The approach should be outlined, describing how it fulfils the FSA aims, what additional value it would add to the project, potential inclusion of break points, and what the case definition will be.

Personnel Details

The requirements for this project are extensive, therefore collaborative applications with an appropriate management framework are encouraged to promote well-balanced, innovative proposals that offer value for money and make use of the best available research and analytical approaches. **Essential expertise** required to fulfil the research requirements include but are not limited to:

- Project management of large multi-institutional research projects
- Epidemiology
- Microbiology, in both the public health and food settings
- Molecular methods including PCR and metagenomics
- Bioinformatics
- Statistics
- Survey design
- Modelling, with desirable experience in modelling food associated disease

Additional thought must be given to ethics and GDPR and highlighted at an organisational level, and how any collaboration between partners will be achieved. In addition, details of measures to mitigate the risk from major events such as COVID-19 and EU-exit must be given as part of the tender application.

Applicants must outline how each of these key areas are covered by staff in the proposed team and additionally highlight other areas of expertise required in this project and how these are fulfilled.

Outcomes

It is anticipated that the following will be delivered to the FSA as part of this work:

- A model comparable to those produced in IID2, including all values associated with underreporting of key human pathogens, must be developed in accordance with all relevant quality assurance documents, outlined in the QA section of this specification. An initial version of the model structure should be provided at an early stage for FSA approval. Any major changes to the design must be agreed separately. An implementation of the model with its documentation should be handed over to the FSA in a workshop at least two months before the submission of the draft final report. This will allow the FSA to use and review the model prior to submission of the final report. We would strongly prefer the model to be built in @Risk, in line with our other risk assessment models. However, it could be implemented in R or Python if demonstrated in the proposal that this is necessary. The calculations and/or code underlying the implemented model must be fully inspectable to allow for peer review and later modification. To permit

straight-forward updates of the model, all its data should be sourced from external files.

- A full technical report addressing the relevant areas of the study which is suitable for publication on the FSA website. The report (template available in appendix) should include a lay summary, an executive summary, introduction (including the background and aims/objectives of the review), methodology, findings, discussion, conclusions, list of evidence gaps, recommendations for further work, references and an appendices section. The final reports structure and format should be drafted in accordance with guidelines from the FSA inclusive of accessibility requirements (Appendix 1). Please note that the final report should be submitted to the FSA **three months before the end of the project** and will undergo an extensive peer-review process before it can be accepted by the FSA. A draft report should be submitted at least 8 weeks before the final report is due to allow FSA officials sufficient time to comment. This may include several rounds of comments from the FSA to the contractor.

- The FSA is committed to championing transparency through Open Data. It is therefore expected that, where possible, data generated during this project will be published openly and in an accessible format.

- Publication of findings from this study in open access peer reviewed journals and presentations at scientific conferences are encouraged by the FSA. Such material will need to be approved by the FSA prior to being submitted to the journal. It is important that the researcher(s) notify the FSA of the publication date for any papers arising from this study at the earliest opportunity especially if the findings are contentious and therefore likely to generate media interest.

References

Study of Infectious Intestinal Disease (IID) in England

Second Study of Infectious Intestinal Disease in the community

Extension to the IID2 study: identifying the proportion of foodborne disease in the UK

The Burden of Foodborne Disease in the UK 2018

Norovirus Attribution Study

Foodborne disease estimates 2018

Holland D, Thomson L, Mahmoudzadeh N, et al. “Estimating deaths from foodborne disease in the UK for 11 key pathogens” *BMJ Open Gastroenterology* (2020); 7:e000377. doi: 10.1136/bmjgast-2020-000377

Majowicz, Shannon E., et al. "A common, symptom-based case definition for gastroenteritis." *Epidemiology & Infection* 136.7 (2008): 886-894.

FSA's openness and transparency values

The Agency is committed to openness, transparency and equality of treatment to all suppliers. In line with these principles, final reports for projects we fund will be published on the Food Standards Agency website (www.food.gov.uk). We also encourage contractors to publish their work in open access peer reviewed scientific publications wherever possible. In line with the Government's Transparency Agenda which aims to encourage more open access to data held by government, the Agency is developing a formal policy on the release of underpinning data from all of its science- and evidence-gathering projects. In the meantime, data should be made freely available in an accessible format, as fully and as promptly as possible. Consideration should be given to data management as new contracts are being negotiated, and resource implications for this should be taken into account. The mechanism for publishing underpinning data should allow the widest opportunity to enable its re-use. Where possible, underpinning data should be included in the final project report. Where data are included in the final report in pdf format, they should also be published separately in a format that can be used for further analysis. Large data sets can be provided separately in an annex to the report, and published, where possible, alongside the final report online. Where it is more appropriate to publish underpinning data in an existing database, archive, repository or other community resource, or for data to be saved in a specialist proprietary format, information will be provided on how the data can be accessed. There will be some circumstances where release of data may need to be restricted or anonymised for reasons of commercial and/or personal sensitivities.

Please note that the FSA has values and specific policy on being open and transparent, which extends to publishing the full dataset of its research and surveillance studies. Both the lead contractor and their sub-contractors must agree to this openness policy. Any potential issues with this should be highlighted within the proposals.

Model Quality Assurance

All modelling must be quality assured and documented. Contractors should include a quality assurance (QA) plan that they will apply to all research tasks and modelling. This QA plan should include the following elements.

The QA plan should document the specification identifying the question to be answered and the scope and context of the model. An outline of the model design should also be included. At the start of the project, the requirements and the preferred approach will be documented and finalised after sign-off by the FSA.

The QA plan should also include a detailed testing plan which should include:

- Tests to compare the model to its original specification.

- Measures of the quality of the model assumptions
- An assessment of the input data quality.
- Checks of the code and its logic.
- Checks of the accuracy of the outputs and measures of the uncertainty associated with key estimates.
- Any sensitivity testing to support the testing mentioned above.
- Usability testing of the model in its final form.

The testing plan should state who will do the testing. Testing should be conducted independently by someone outside the main modelling team.

The QA plan should include the proposed approach to audit model development. A data log should describe all inputs into the model, their origin, appropriateness and limitations. During modelling, all assumptions of the model should be clearly logged, validated and agreed with the FSA. All decisions should also be recorded during modelling. The QA plan should explain how the testing and its results will be recorded, along with any issues encounters resulting changes and re-testing.

The final model (including any new data sets created to produce inputs) should be handed over to the FSA in a usable and well-documented state. User and technical guides should be provided, including a model map. The FSA will then arrange for a peer-review of the model and the reports before publication. Further guidance requirements of QA for government analysis can be found at: https://www.gov.uk/government/publications/the-aqua-book-guidance-on-producing-quality-analysis-for-government

Cost

The onus is on the applicant(s) to provide the costings they believe that is reasonable to meet the evidence gap as outlined in this research specification and provide the justification of this within their research proposal. The applicant(s) should be aware that one of the key criteria that all research proposals are evaluated against is 'value for money' which is delivering the research asked for in the research requirement (including the anticipated outputs and benefits) at a competitive price.

General Data Protection Regulation (GDPR)

General Data Protection Regulation (GDPR) was introduced in the UK from 25th May 2018 and requirements relating to areas including, but not limited to, Privacy by Design, transparency, children's' rights, data pseudonymisation, consent mechanisms and Controllers/Processor relationships are particularly relevant to research. The FSA has set out some of its key GDPR considerations below and would be interested in feedback as part of the submission on any challenges that the Tenderer may anticipate in the context of its research approach and how it would address them:

- the FSA expects that it will be a Data Controller as the Research is necessary to inform and assist the FSA in carrying out its Public Task in accordance with the Food Standards Act 1999.

- the FSA expects that the Lead Contractor appointed to carry out this research on its behalf is recognised as a Joint Data Controller.

- the FSA expects the Lead Contractor to coordinate consortium Sub-processors (any sub-contractors) giving due regard, in accordance with GDPR, as to whether those Sub-processors are also Joint Controllers, Data Controllers or Data Processors when assigning subcontracts.

- the FSA expects that the Lead Contractor will only appoint Sub-processors (any sub-contractors) with the FSA's prior specific or general written authorisation, and impose the same minimum terms imposed on it, on the Sub-processor; and the Lead Contractor will remain liable to the FSA for the Sub-processor's compliance. The Sub-processor must provide sufficient guarantees to implement appropriate technical and organisational measures to demonstrate compliance. In the case of general written authorisation, sub-processors must inform the Lead Contractor who in turn will notify the FSA of intended changes in their Sub-processor arrangements.

- the FSA recognises that parties involved in the project can be both Data Controllers and Data Processors in respect of different elements of data collection and use within the project. The FSA expects that the Lead Contractor will ensure that relationships are clearly defined, not least to facilitate clear communication to Participants in the Research Project about how data is to be collected and used, who is responsible and that clear mechanisms are created for Participants to exercise their rights throughout the research project, and until identifiable data is deleted, by applying very high standards of project coordination and governance.

- the FSA does not expect that any party would conduct aspects of the research project outside or beyond the scope determined by the FSA, but should the Lead Contractor or other parties express an interest in defining further objectives which take the processing of data outside or beyond the scope of the research objectives laid down by the FSA, then the Lead Contractor would be responsible for ensuring the FSA is notified of those objectives and that the necessary contractual terms and governance are in place to ringfence any liabilities arising from GDPR non-compliance in respect of this processing and protect the FSA.

- The FSA expects the Lead Contractor to coordinate the necessary Governance measures across the consortium as appropriate, to ensure that the project is carried out in a way that is compliant with the highest ethical standards including JCOPR, HRA and MRC guidance and GDPR.

- The FSA expects the Lead Contractor comply with security obligations equivalent to those imposed on the FSA and coordinate the necessary technical measures across the consortium to ensure that the project is carried out in a way that is

compliant with GDPR. Technical measures that are required by the FSA are in the "ANNEX A - FSA SECURITY AND DATA REQUIREMENTS – RESEARCH" to this document.

- The FSA expects in addition to technical requirements outlined that the Lead Controller will coordinate application of high standards of Anonymisation and Pseudonymisation including, where applicable, use of encryption protocols on identifiers as appropriate and access restrictions to those encryption codes/keys within the project. Identifiable data collected and shared in the project should be minimised.

- The FSA expects the Lead Contractor to coordinate the preparation of the Data Protection Impact Assessment (DPIA) through to sign off, implement mitigations across the Consortium and make the DPIA available to the FSA on request.

- The FSA expects the Lead Contractors to maintain a Data Management Plan for the Consortium throughout the data lifecycle alongside the DPIA, and make it available on request.

- The FSA expects the Lead Contractor to have reference projects which demonstrate and ability to coordinate and deliver multi-party research projects particularly where the involve the management of highly sensitive clinical data.

- The FSA expects the Lead Contractor to include in its submission details of any audits by an impartial and competent third party against an appropriate internationally recognised standards to assure us of the quality of their research processes as set out in JCOPR.

- The FSA expects that the Lead Contractor considers and mitigates the risk to Data Subject rights and freedoms as part of the DPIA where proposals include obtaining data using techniques that may have higher privacy risks such as, social media mining, web scraping, artificial Intelligence or any situation where a consortium member may not have a Data Subjects explicit consent.

- The FSA expects the Lead Contractor to ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality and have undertaken the necessary Data Protection training;

- the FSA requires to be made available all information necessary to demonstrate compliance with the obligations laid down in Article 28 GDPR and allow for and contribute to audits, including inspections, conducted by the FSA or another auditor mandated by the FSA - and the Processor shall immediately inform the Lead Contractor and the FSA if, in its opinion, an instruction infringes GDPR or other EU or member state data protection provisions;

- the FSA expects that the consortium is able to carry out its obligations with regard to requests by data subjects to exercise their rights under chapter III of

the GDPR, noting different rights may apply depending on the specific legal basis for the processing activity (and notices are put in place to clarify these up-front);

- the Lead Contractor must ensure mechanisms are in place to notify the FSA without undue delay after becoming aware of a personal data breach.

Schedule 3 (Charges)

1. **How Charges are calculated**

1.1 The Charges:

1.1.1 shall be calculated in accordance with the terms of this Schedule;

1.1.2 cannot be increased except as specifically permitted by this Schedule and in particular shall only be subject to Indexation where specifically stated in the Award Form; and]

1.2 Any variation to the Charges payable under a Contract must be agreed between the Supplier and the Buyer and implemented using the procedure set out.

2. **The pricing mechanisms**

2.1 The pricing mechanisms and prices set out in Annex 1 shall be available for use in calculation of Charges in the Contract.

3. **Are costs and expenses included in the Charges**

3.1 Except as expressly set out in Paragraph 4 below, or otherwise stated in the Award Form the Charges shall include all costs and expenses relating to the provision of Deliverables. No further amounts shall be payable in respect of matters such as:

3.1.1 incidental expenses such as travel, subsistence and lodging, document or report reproduction, shipping, desktop or office equipment costs, network or data interchange costs or other telecommunications charges; or

3.1.2 costs incurred prior to the commencement of the Contract.

3.1.3 used to carry out an indexation calculation is updated (for example due to it being provisional) then the indexation calculation shall also be updated unless the Buyer and the Supplier agree otherwise;

3.1.4 is no longer published, the Buyer and the Supplier shall agree a fair and reasonable replacement that will have substantially the same effect.]

4. When you will be reimbursed for travel and subsistence

4.1 Expenses shall only be recoverable where:

4.1.1 the Time and Materials pricing mechanism is used; and

4.1.2 the Award Form states that recovery is permitted; and

4.1.3 they are Reimbursable Expenses and are supported by Supporting Documentation.

4.2 The Buyers expenses policy is as set out in the table below:

Expenses	Reimbursement
Rail travel	Standard class
Mileage	£0.45 per mile for the first 10,000 miles in a financial year £0.25 per mile for any mileage in excess of 10,000 miles in a financial year
Overnight hotel accommodation	Up to £85 per night outside London Up to £130 per night in London
Subsistence	Up to a maximum of £21 for a 24-hour period

Annex 1: Rates and Prices

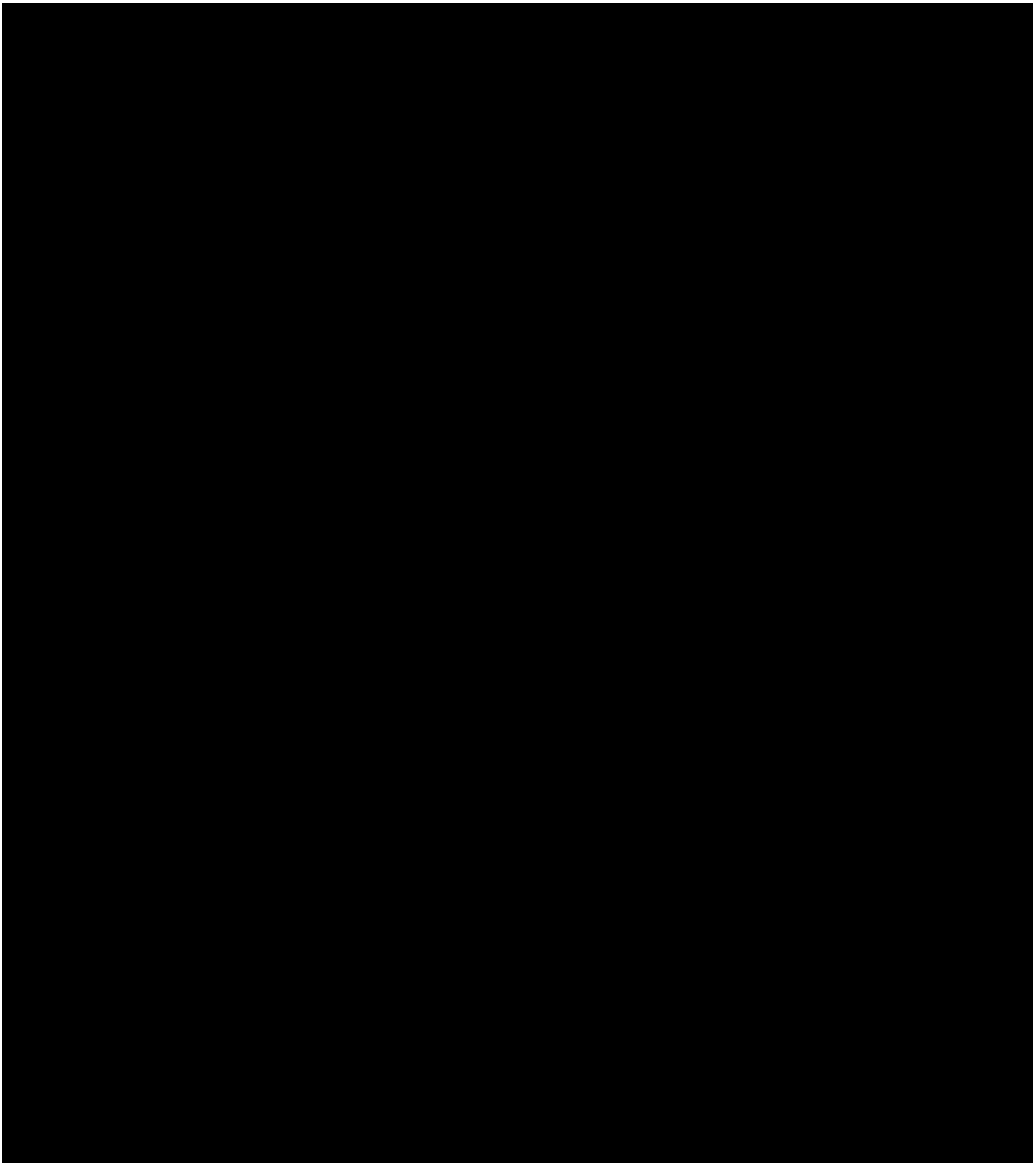
Total Project Costs (excluding VAT) **	**£ 6,786,297.95**

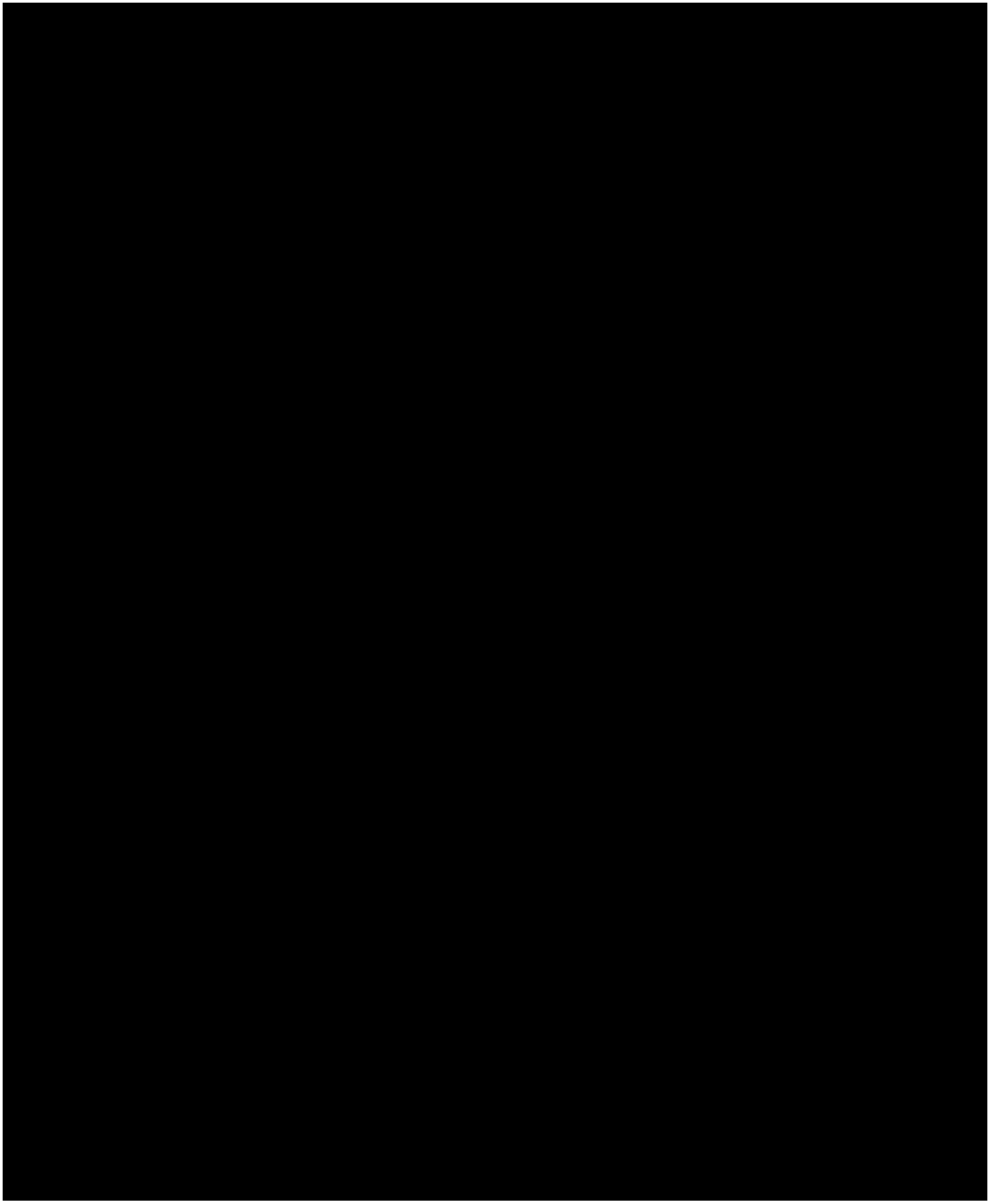
* Please indicate zero, exempt or standard rate. VAT charges not identified above will not be paid by the FSA
** The total cost figure should be the same as the total cost shown in table 4

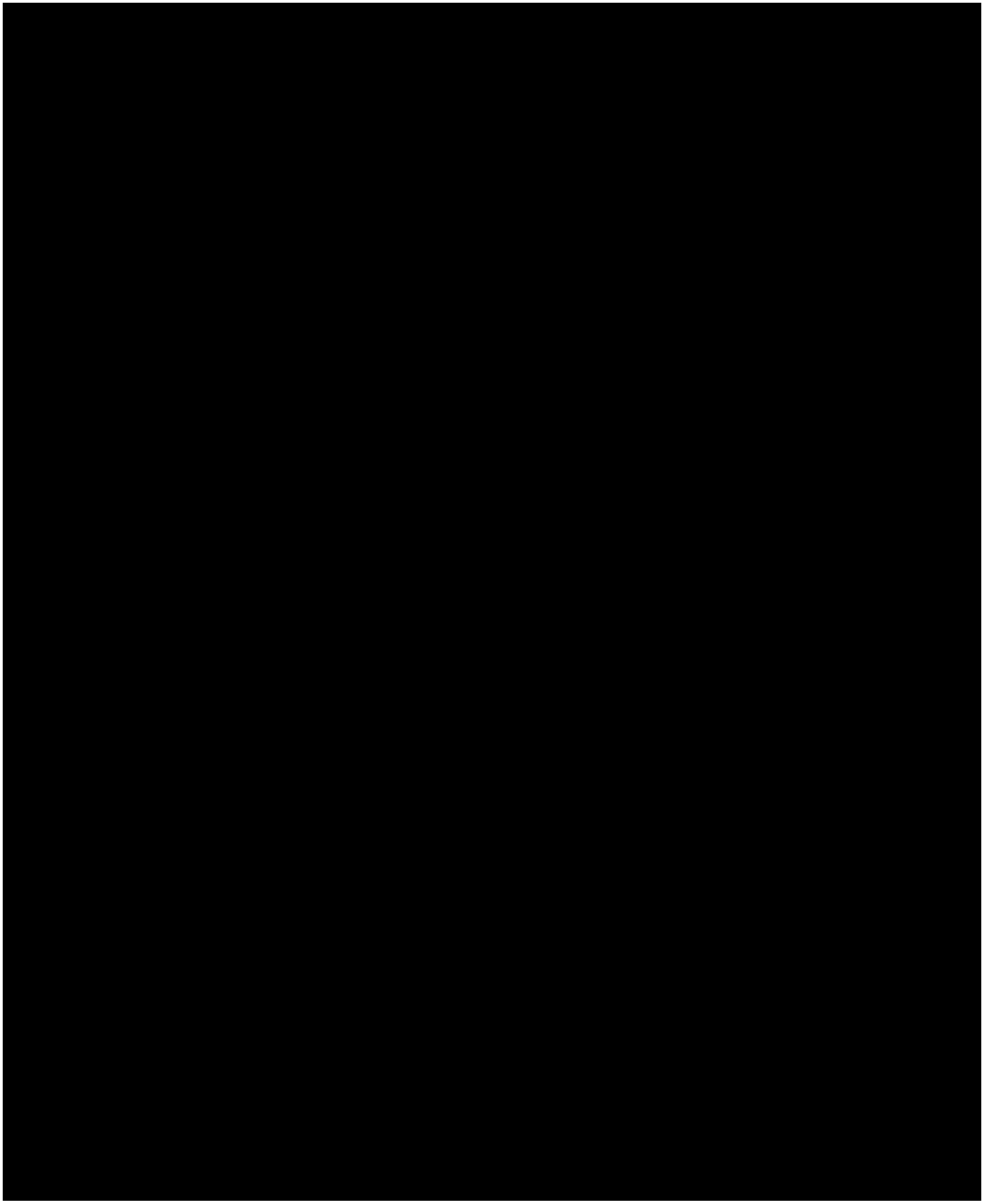
Project Costs Summary

Total Project Costs	**£ 6,786,297.95**

Staff Costs Table

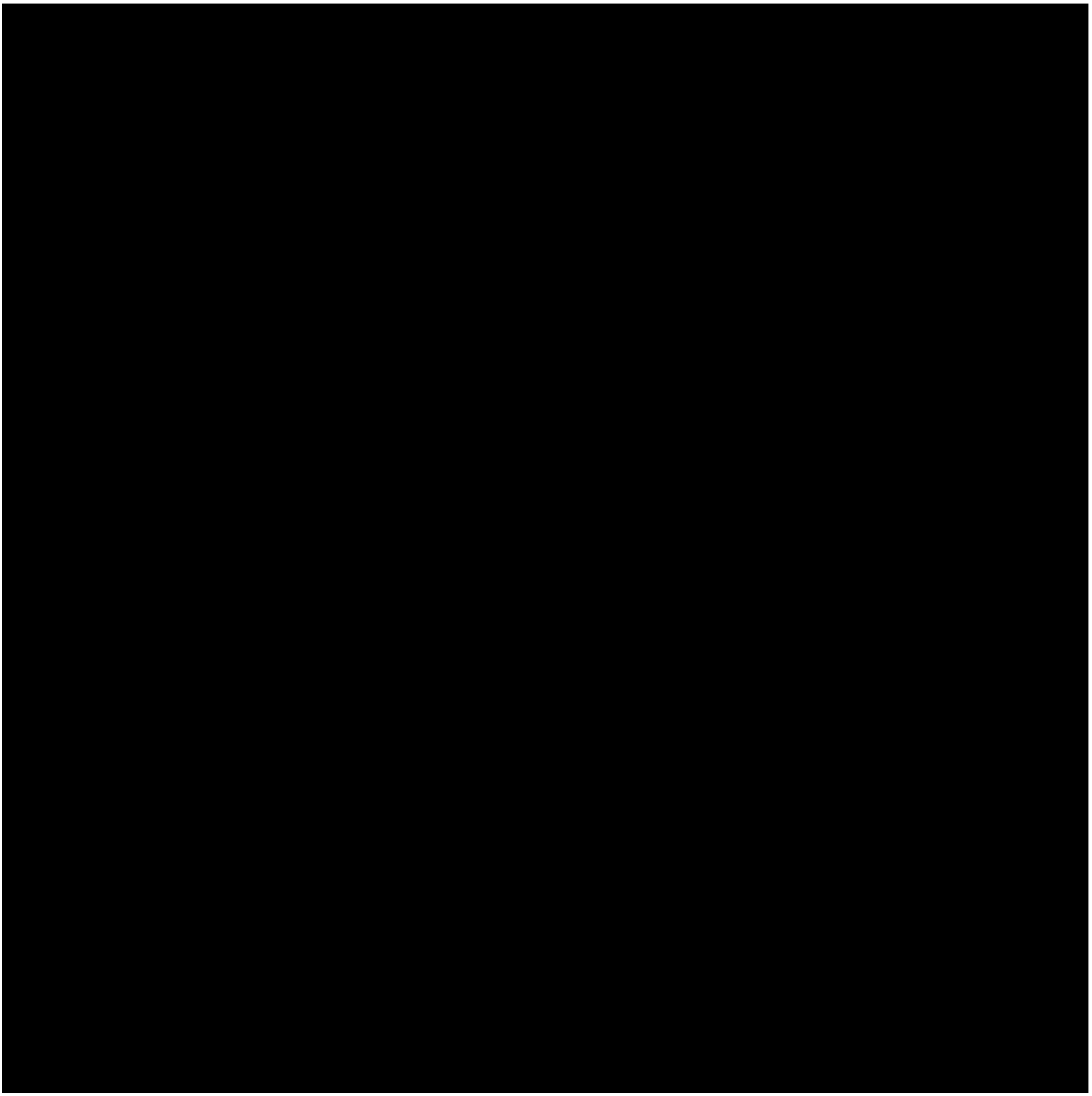


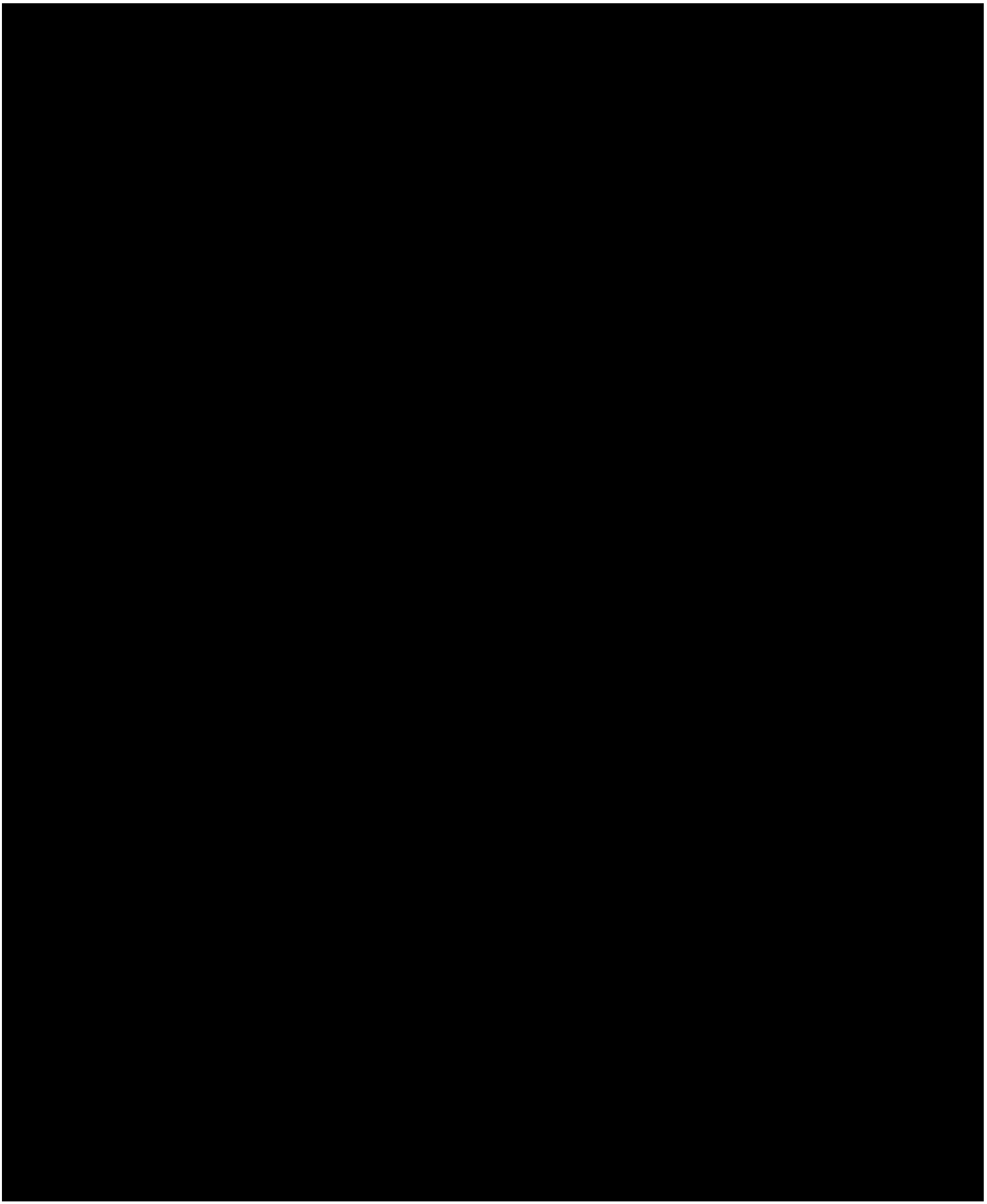




Consumable/Equipment Costs

Please provide a breakdown of the consumables/equipment items you expect to consume during the project

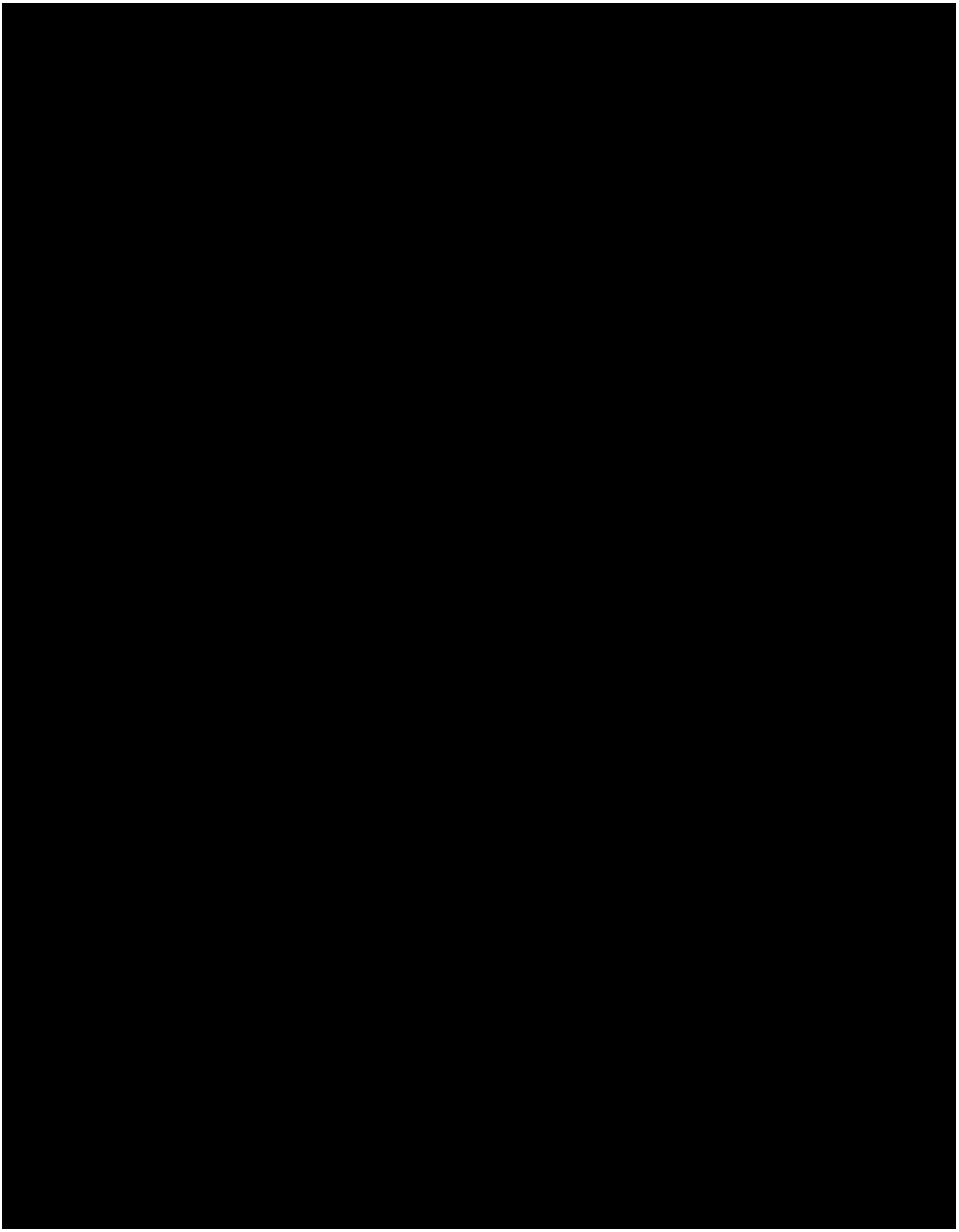


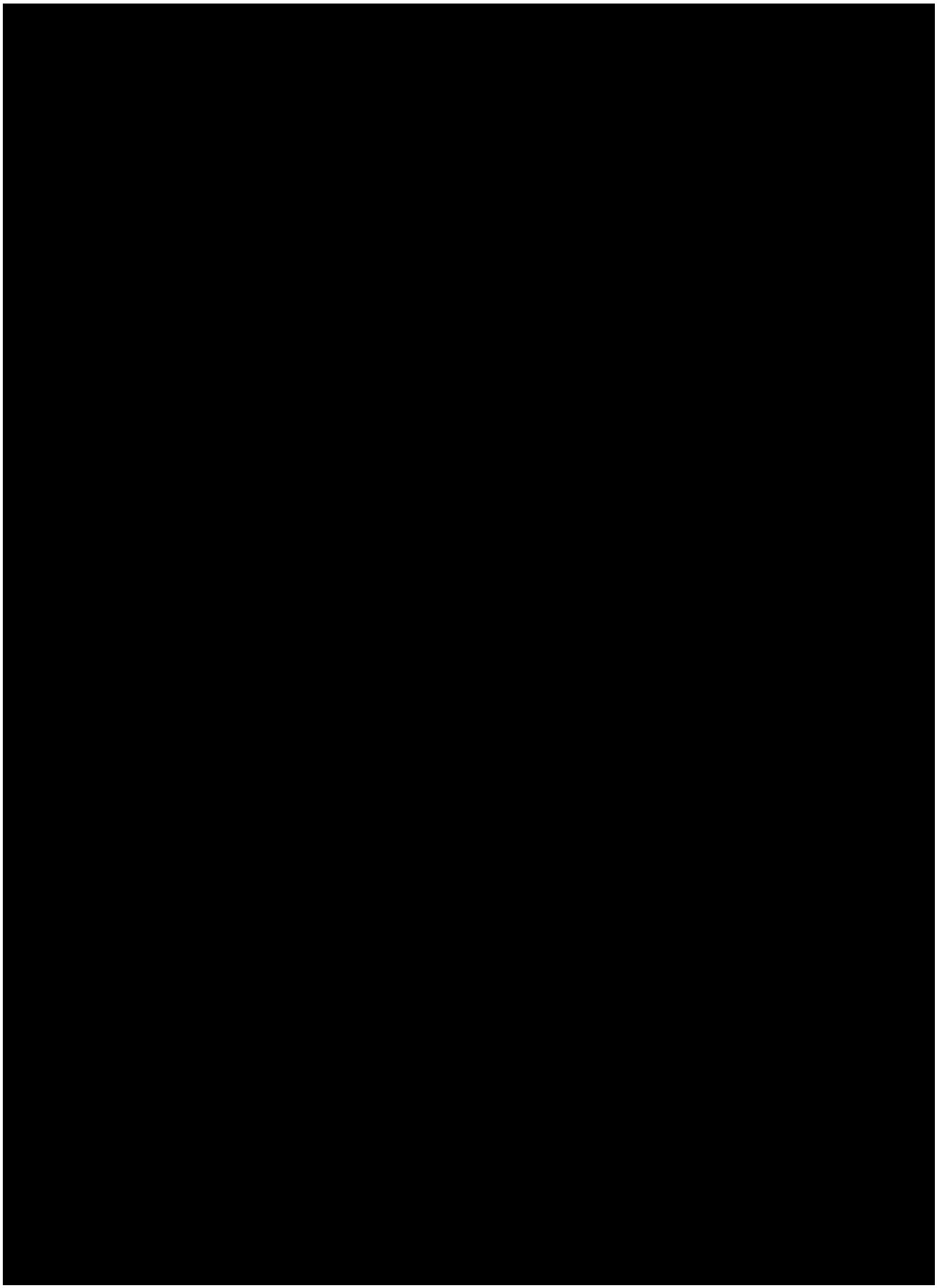


Travel and Subsistence Costs

Please provide a breakdown of the travel and subsistence costs you expect to incur during the project

The Pricing Schedule





[redacted]

Total	**£ 6,786,297.95**

* Please insert the amount to be invoiced net of any VAT for each deliverable
** Please insert the applicable rate of VAT for each deliverable
*** 20% of the total project budget is withheld and will be paid upon acceptance of a satisfactory final report by the agency.
§The number of weeks after project commencement for the deliverable to be completed

Summary of Payments

[redacted]

Schedule 4 (Tender)

LEAD APPLICANT'S DETAILS

TENDER SUMMARY				

This tender builds on the findings of 1993-96 IID1 Study and 2007-2009 IID2 Study. The former investigated the number of cases of IID in the community and presenting to GPs, and assessed microbial aetiology and the degree of underreporting through routine laboratory surveillance. The latter aimed to measure changes in incidence and underreporting of IID since the IID1 Study and to collect up to date evidence on the data loss at each stage of the reporting pyramid, allowing more accurate estimates of the burden of IID. In this IID3 Study tender, we take advantage of modern methods in microbiology to quantify carriage of antimicrobial resistance genes, coupled with improved surveillance, active participation, socio-economic and modelling methods. More accurate surveillance pyramids will be produced, and these will also be recalibrated back to the same standards of IID1 and IID2, given the differences in diagnostic, laboratory, analytical and modelling methods available 15 and 25 years ago. This will allow FSA to understand changes in IID since the original two studies, obtain the most accurate, up to date surveillance pyramids, and assess levels of antimicrobial resistance.

Three prospective studies will be developed: first a population-based prospective cohort, second a GP presentation study that captures all patients that present to their GP with IID, and third a GP enumeration study that monitors current practice. Stool samples from the first two studies will be available for microbial assessment. Socio-demographics, seasonality and geography will be incorporated into analyses as these are known to affect both the incidence and severity of IID.

This tender is split into six Work Packages (WP). The bid is constructed around the ‘surveillance pyramid’ as it is essential that the factors that affect this pyramid from the broad top-most level (total IID in the population) down to the narrowly focussed base level (stool samples sent to National Surveillance) are quantified, errors and biases estimated, and their interactions understood. This proposal splits the surveillance pyramid into 5 levels. The first (top-most) level is to estimate IID in the population. The second level focuses on IID that is seen by doctors in the community, measured through the GP presentation study. The third level moving down the surveillance pyramid is to determine IID in stool samples. Two approaches to this are used: first the GP enumeration study, where current practice is observed, but stool samples are not always requested, and secondly the GP presentation study, with non-selective collection and testing of stool samples. The fourth level of the surveillance pyramid uses modern microbiological techniques to diagnose IID, and detect antimicrobial resistances genes. The fifth and final layer of the pyramid is a calibration study, to relate the stool sample data back to National Surveillance of reportable and notifiable diseases. Finally, the data analysis work package will integrate the data from other work packages, and provide the FSA with a set of robust, validated models capable of predicting IID under a range of plausible scenarios, with error estimates for all parameters.

TENDER TITLE			
The third study of Infectious Intestinal Disease in the UK (IID3 study)			
TENDER REFERENCE	**FS301058**		
PROPOSED START DATE	[01/10/2021]	**PROPOSED END DATE**	[30/09/2025]

Please note that the end date proposed here exceeds that in the tender specification. This is to allow for break points in the contract during which time will accrue whilst a collaboration agreement between all partner organisations is signed, new appointments are made, Health Research Authority approval is sought (this cannot happen before funding is in place), and the FSA reviews the outcome of pilot work prior to the start of the main study proposed in this document. Resource use during the break points is fully accounted for in the proposal.

1. Proposed plan of work, including the scope and approach taken

Please describe how you will meet our specification and summarise how you will deliver your solution. Describe and justify the approach to the proposed work including the methodology and study design, where applicable, that will be used to address the specific requirements outlined above. Where relevant (e.g. for an analytical survey), please also provide details of the sampling plan.

We present below the considerations that have gone into shaping this proposal. We have accounted for the epidemiological and biological features of infectious intestinal disease (IID), lessons learned from the IID2 Study and the practicalities of delivering the FSA's revised requirements. Our consortium combines the complementary strengths of Newcastle University, Public Health England, the University of Liverpool, Liverpool Clinical Laboratories, the University of Oxford, Public Health Wales and Health Protection Scotland. Our collective expertise is summarised in Table 1 below:-

Institution	Expertise
Newcastle University	• Project management of large multi-institutional research projects • Epidemiology • Survey Design • Biological and Statistical Modelling
Public Health England	• Microbiology • Molecular methods including PCR and Whole Genome Sequencing • Bioinformatics • Reference Microbiology • Public Health surveillance of IID
University of Liverpool	• Biobanking in a Good Clinical Laboratory Practice facility • Epidemiology
Liverpool Clinical Laboratories	• Primary diagnostics using molecular methods including PCR, and traditional microbiological methods
University of Oxford	• Primary Care including patient recruitment to large observational studies • Survey design • Collection, collation and linkage of patient data within a Trusted Research Environment
Public Health Wales	• Reference Parasitology • Public Health surveillance of IID
Health Protection Scotland	• Public Health surveillance of IID

In brief, the IID3 study design comprises three population-based studies (a population-based prospective cohort study, two prospective studies in Primary Care), and a microbiology study involving diagnostic and reference microbiology and AMR determination. We plan to deliver the IID3 study

through a series of interlinked, multidisciplinary Work Packages (WPs) involving collective effort across these them. Project management and reporting are coordinated in WP1 (Figure 1). The main study will be delivered through WP2-5 which are interlinked and sequential. Data analysis of WPs 2 to 5 will take place in WP6. The various Work Packages, and their relationships to critical measurements in the surveillance pyramid are shown in Figure 1.

1. Illness in the UK Population (WP2)

To measure the incidence of infectious intestinal disease (IID) in the UK population we will conduct a population-based prospective cohort study (WP2).

In WP2 we will recruit a group of volunteer households (Cohort 1), representative of the UK population, through general practices who are members of the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC), a nationally representative network of over 1,800 general practices. We have an established household key that can link individuals in the same household and so we will be able to track secondary spread in households [1,2,3]. Our work on household incidence has been conducted in collaboration with the principal investigator (SJO'B), who is already familiar with the data.

We will recruit households using three strategies:- (1) Request to volunteer via the patient online access system; (2) Text messaging to patients using the practice text messaging system; (3) Direct recruiting in practice. We will take consent and collect data about any episodes of IID using the online patient access systems provided by the two largest UK primary care computerised medical record (CMR) system suppliers (EMIS [4] and TPP [5,6). These are used by millions of patients to book appointments, to request their prescriptions, view their test results and medical records. We have recently completed data collection for a study through this route about the symptoms of COVID-19, with over 15,000 initial expressions of interest and 2,000 paired responses [7]. Usage is broadly

similar across age groups between 20 and 60 years of age and has risen substantially during the COVID-19 pandemic; EMIS's *Patient Access* platform has now exceeded 10 million users, representing an increase of 10% since March 2020 with more prescription and record viewing by patients online. These platforms allow a parent or carer to register on behalf of another person, so a parent can register on behalf of their children.

We will use the same case definition as that employed in the IID1 and IID2 studies (see point 13 below) to ensure comparability between the three studies. The index case of illness in a household in all three studies is the basis for comparison. Given the sample size required (N = approx. 9,000 person-years of follow-up) we propose a two-year main study period. This will allow for tapering at either end as practice/participant recruitment increases at the beginning and then declines towards the end of the study period. Furthermore, the study will be taking place in the wake of the dual impacts of EU Exit and the COVID-19 pandemic. We already know that the COVID-19 pandemic has had a profound impact on reporting of IID (Figure 2), but it is unclear if this reflects a real reduction in incidence or in health-seeking or reporting behaviour. It is also unclear how long the impact of the COVID-19 pandemic will last.

The design of the IID3 Study will allow us to determine which of these scenarios are in play and account for them in the final analysis. This is because we will capture the incidence of IID at population level regardless of health-seeking behaviour. It is unclear at the time of writing what might be the impact of EU Exit on the incidence of IID but there are almost certainly going to be changes in the food supply chain. These might take longer to play out in terms of IID incidence, which strengthens the case for a two-year period of data collection.

We propose to follow up households so that we can assess secondary spread amongst household members from an index case of IID, thus giving a more complete assessment of the total burden of IID, which is particularly important when assessing the overall economic burden of IID. This recruitment strategy takes account of lessons learned in the design of the IID1 and IID2 Studies (e.g. inability to study adequately seasonality and secondary spread).

2. Illness presenting to Primary Care in the UK (WP3)

To measure the incidence of patients with IID presenting to Primary Care in the UK we will work with a sub-set of General Practices in the RCGP RSC network. Participating practices will recruit

prospectively all patients who present with IID and request a stool sample from them (Cohort 2). We will use the same case definition as that employed in the IID1 and IID2 studies to ensure comparability between the three studies. We will also audit recruitment into Cohort 2 by undertaking a validation study. This will allow us to understand whether we did, indeed, capture every case to estimate under-ascertainment in this element of the study. We will also compare the results from Cohort 2 with those from a second group of practices in the RCGP RSC network in which we simply observe what happens during routine care (Cohort 3). We will extract data from the clinical records about the number of patients who presented with symptoms of IID, the number who were requested to submit a stool sample, the number who did so and what pathogens were found in routine laboratory testing. This will allow us to calculate a second level of under-ascertainment, namely between Cohorts 2 and 3.

Table 1 summarises the main features of the three prospective cohorts.

Table 1: Summary of cohorts, purpose, sample request process, and laboratory

Cohort	Name	Purpose	Sample request process	Laboratory and analyses
Cohort 1	Household	Population / community IID in the UK	Online by participant households + online questionnaire	Liverpool Micr
Cohort 2	Presentation	Aetiology of clinically diagnosed IID in the UK	By GP through their computerised medical record + online or phone questionnaires	Liverpool Micr
Cohort 3	Enumeration	Routine practice in the UK	Routine practice, no additional data	Routine local l

These results will feed into the calibration study in WP5 and analysis in WP6 (see below).

3. Data Collection (WP2, WP3)

In WP2 we will recruit households who have linked to their practice's *Patient Access* system or are willing to do so. *Patient Access* will allow them to complete a screening questionnaire on enrolment and request a stool sample kit online at baseline. They will use *Patient Access* to complete a questionnaire as soon as someone in the household develops symptoms of IID to capture data including clinical symptoms, illness duration, and a history of foreign travel. Follow-up questionnaires will review the time taken through to recovery and include details about sickness absence and resource use. A key reason for using the *Patient Access* app is that we are able to link questionnaire data to individual computerised medical records, capturing other data which may inform about the aetiology of participants' symptoms (e.g. medication change – such as starting metformin or other drugs associated with gastrointestinal side effects; or referral for investigation where a change in bowel habit may be associated with other bowel disease). Participants will receive electronic reminders monthly of their involvement in the study, with an opportunity to report any missed IID episodes.

4. Sample Collection (WP2, WP3)

During the COVID-19 pandemic the RCGP RSC has had to move its virology sampling scheme from sampling in GP surgeries to giving patients a code to allow online requesting of sample containers. We propose to use this mechanism to provide specimen containers and post-paid (biohazard secure) packages that will fit through a letterbox and licensed to send in the post. Samples from symptomatic patients will be returned to the practice and thence to our primary diagnostic laboratory in Liverpool (Liverpool Clinical Laboratories (LCL)) via the National Pathology Exchange system (NPEx) (WP4). We have chosen this system for sample submission because it is what General Practitioners and patients are accustomed to using. This will make it as simple as possible to request and submit samples and for the results to feed straight back into the electronic patient record. It is very important to remember that for these cohorts of patients, primary diagnostic work is being carried out by LCL. Thus, the results are important for clinical management as well as research. In the IID2 Study the submission handling and reporting systems generated a lot of paper records, which had to be

entered manually into the patient record, requiring a lot of extra work in primary care. We can circumvent this by using electronic requesting and reporting. Furthermore, electronic sample requests will feed seamlessly into the Laboratory Information Management System (LIMS) at LCL, reducing the risk of transcription errors and providing a clear audit trail for samples.

5. Microbiology Studies (WP4)

WP4 will yield information about the aetiology of IID in the UK.

5a. Primary Diagnostics

On receipt in Liverpool, stool samples from Cohort 1 and Cohort 2 will be examined for a comprehensive range of bacterial, viral and protozoal pathogens, and include determination of antimicrobial resistance. Microbiological testing for causative agents of IID has developed substantially since the IID2 Study was completed. In particular, this comprises a switch by many laboratories in the primary method used to identify pathogens; traditional diagnostic approaches (including microscopy, culture, and immunoassays) are now being replaced by molecular methods (PCR) to detect the key bacteria, viruses and parasites of interest. Therefore, in contrast to IID2, all specimens from IID3 will be examined by PCR using a combination of commercial and bespoke assays, as a first line investigation for organisms known to be significantly associated with IID.

All faecal samples will undergo PCR testing using the Serosep molecular diagnostics platform (www.serosep.com/entericbio-molecular-diagnostics/panels). This will comprise three panels:

- EntericBio DX (Salmonella, STEC, Shigella, Campylobacter, Cryptosporidium, Giardia, Yersinia, *Entamoeba histolytica*, Vibrio)
- EntericBio Viral Panel 3 (Norovirus GI/GII, Sapovirus, Astrovirus, Adenovirus, Rotavirus)
- EntericBio *C difficile* (in subjects age > 65 years)

Open access functionality on the Panther Fusion analyser (Hologic, Inc.) will be used to test for additional gastrointestinal pathogens not included in the above commercial panels. This PCR panel will comprise up to six laboratory-developed tests (LDTs) adapted from PHE/PHW protocols and will be established prior to the pilot study; the LDTs will target *Clostridium perfringens*, diarrhoeagenic *Escherichia coli* (DEC), *Aeromonas* spp. and *Cyclospora cayetanensis* [Appendix A].

Bacterial culture will be reserved for those faecal specimens that have tested positive by PCR with either the routine or additional panel, to enable subsequent molecular and phenotypic characterization. Bacterial culture, using enrichment culture as required, will be undertaken according to UK Microbiology Standards (https://www.gov.uk/government/publications/smi-b-30-investigation-of-faecal-specimens-for-enteric-pathogens). It is recognised that culture from faecal specimens of some pathogens associated with IID is technically challenging, and thus methods will be established at LCL in close collaboration with Public Health England (PHE) [Appendix A]. This approach will be developed (with appropriate Quality Control and Quality Assurance) prior to the pilot study, with the potential for undertaking part of this work at PHE.

Our approach, using PCR as a primary detection method, will nevertheless support comparison of aetiology with IID2, since in IID2 the presence of many (though not all) pathogens was subsequently investigated in reference laboratories by PCR [Appendix A]. In addition, as in IID2, testing will be largely unselective; i.e. each specimen will be tested for all key pathogens regardless of demographic or clinical information.

Key differences between IID2 and IID3 for individual pathogens include:-

- Not routinely examined in IID2 but proposed to be included in IID3: *E. histolytica*, *Vibrio* spp, and *Aeromonas* spp. In IID2, examination for *E. histolytica* and *Vibrio* spp was restricted to those specimens obtained from subjects with a history of foreign travel; in IID3, all specimens will be tested since these organisms are included in the commercial assay to be employed. Additionally, testing for *Aeromonas* spp. is proposed to be included in IID3 since there is recent evidence of its importance in travel-related gastrointestinal illness [8].

- Routinely examined in IID2 but proposed not to be included in IID3: *Listeria monocytogenes* was identified in 0% of cases in IID2 and therefore will not be included in IID3. This approach is supported by nil report of *L. monocytogenes* by clinical and reference laboratories from faecal specimens of patients with listeriosis.
- A fundamental change in testing methodology for *Shigella* spp. and *Yersinia* spp. (from culture only in IID2 to PCR with culture of PCR positives in IID3) and for *Cyclospora cayetanensis* (from microscopy only in IID2 to PCR only in IID3). This is expected to lead to an increase in the number of these organisms identified in IID3 due to the increased sensitivity of PCR over both microscopy and culture.
- Testing for *C difficile* will be limited to over 65-year olds in IID3. It is noted that less than 1% of samples tested positive for *C difficile* in IID2; this is likely explained by laboratory difficulty to selectively enrich spores and induce germination of this species. Recent studies at PHE have reported more frequent isolation of *C difficile* from samples submitted by GPs or taken at initial screen of elderly patients admitted to emergency services with gastrointestinal symptoms.

Material that will underpin subsequent reference microbiology investigations will include original stool (where available), and bacterial isolates obtained by culture of faecal samples that have tested positive by PCR. Lysate from the Serosep assay will be retained. Appropriate material will be shipped from LCL to the relevant reference laboratory for further investigation. All material will be stored at an appropriate temperature until transferred to the Biobank at University of Liverpool.

5b. Reference Microbiology

Organisms recovered will be sent to the Reference Laboratories at PHE (bacteria), the London School of Hygiene and Tropical Medicine (viruses) and Public Health Wales (protozoa) as required where they will be characterised, typed and antimicrobial resistance determined using a range of methods including whole genome sequencing (WGS). PHE may also undertake specialist diagnostic work for some of the organisms that are challenging to culture (see above). All results will be recorded in the patients' GP records. We will compare the findings from Cohort 2, where we collect samples from every case and test them for a comprehensive range of pathogens, with what is found routinely in clinical and laboratory practice in the RCGP RSC network of General Practices (Cohort 3). This will allow us to estimate under-ascertainment in sampling and testing rates that will feed into the calibration study.

6. Calibration Study (WP5)

We will re-calibrate UK surveillance data (WP5, WP6). Figure 1 shows that the usual route for cases of IID to appear in national surveillance data follows the orange route i.e., Cohort 3. By working out the degree of under-ascertainment using the rates from Cohorts 1, 2 and 3 compared with rates from UK surveillance data, we will be able to estimate multipliers for IID overall and by pathogen.

7. Data Analysis (WP6)

The analysis of all data generated in WP2, WP3, WP4 and WP5 will be conducted in WP6. The plan of analysis is described in detail in Section B below.

8. Comparing the outputs of IID3 with IID2 and other relevant studies (WP2 to WP6)

Finally, using the outputs from WPs 2 to 6 we will compare the results of the IID3 Study will the results of the IID2 and IID1 Studies as well as relevant international studies.

9. Sampling frame for Cohorts 1, 2, and 3

General Practices recruiting patients or households to both WP2 and WP3 will be members of the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) primary care sentinel network. This is one of Europe's oldest sentinel systems. The network was set up in 1957 and has been involved in sentinel surveillance since 1967 [9]. For most of this period it

has had around 100 general practices and over 1 million patients [10] but has rapidly expanded during the COVID-19 pandemic now including over 1,800 practices and 15 million patients [11,12]. Infectious Intestinal Disease (IID) is already included in its range of monitored conditions. The RSC currently has national representation across England and Wales. The RSC also has expressions of interest from Scotland and Northern Ireland and will use these practices to enable UK-wide recruitment.

10. Case definitions for Cohorts 1, 2, and 3

The same case definition as was used for the IID1 and IID2 studies will be used, to ensure direct comparability. Thus, cases are persons with loose stools or clinically significant vomiting lasting less than two weeks, in the absence of a known non-infectious cause, preceded by a symptom-free period of three weeks. Vomiting is considered clinically significant if it occurs more than once in a 24-hour period and if it incapacitates the case or is accompanied by other symptoms such as cramps or fever.

In addition to this we will collect data in such a way as to be able to apply the international case definition developed by Majowicz *et al* [13]. In this definition a case of gastroenteritis is defined as an individual with 3 or more loose stools, or any vomiting, in 24 hours which is unrelated to existing health conditions, medication use, or other non-infectious causes.

It should be noted that the unit of comparison for all three studies will be the index case in a household. This was the basis of generating incidence rates in the IID1 and IID2 studies and the same will apply to the IID3 study.

11. Inclusion and exclusion criteria for Cohorts 1, 2 and 3

Inclusion criteria for Cohort 1: We will include households of any size as we want to sample across the range of household sizes in the UK. We will monitor the distribution of household size to ensure our distribution is across the following groups: single occupancy, 2-3 people, 4 to 6, and 7 or more in a household and broadly in line with the national distribution. Householders must be capable of informed consent and willing to participate in the study for at least 12 months. Recruitment will be on a rolling basis over 24 months in total.

Exclusion criteria for Cohort 1: We will exclude households where a member of the household has inflammatory bowel disease (IBD). The reason for excluding people with IBD is that it difficult to define an onset date.

Inclusion criteria for Cohort 2: We will include all people who fit with the case definition, of all ages and willing to give informed consent to provide details of their illness and recovery. People can opt to have a specimen sent but not complete the questionnaire.

Exclusion criteria for Cohort 2: We will exclude people with IBD.

For Cohort 3, usual practice will determine sampling.

12. Electronic data capture for Cohorts 1 and 2

The RCGP RSC, EMIS, TPP and XLab Systems (the latter is the NPEx provider) will collaborate to:-

- capture informed consent online for WP2 (Cohort 1) and WP3 (Cohort 2),
- link Cohort 1 participants to an online sample request system for their baseline and subsequent questionnaires.
- provide baseline and follow up questionnaires for people who attend their GP who are part of Cohort 2, in WP3, and the same for households, in WP2 (Cohort 1).
- enable consenting participants to describe their symptoms, illness duration and impact online. We will collect the same data from WP2 (Cohort 1) and all primary care presentations element of WP3 Cohort 2).

- provide a pseudonymised extract of participants' data, RSC (including pathology free text arising from microbiological testing), for linkage and curating in the Trusted Research Environment (TRE), with agreed variables added to the FSA database.

13. Sample size considerations for the prospective studies

Power calculations shown below are based on the convention of 80% power, and a 95% probability level, a significance level of α=0.05 for the null-hypothesis tests. If the null hypothesis is rejected when it is true, then a Type I error has occurred, and the level of α is by convention set to 1 in 20 to minimise this risk. If the null hypothesis is accepted when it is false, then a Type II error has occurred; the probability of a Type II error is *β*. The probability of rejecting the null hypothesis when it is false is the power of the analysis, calculated as *1-β*.

Lehr's equation [14] provides a convenient approximation of power analysis for ***continuous data***. This can be derived as:

$$n = \frac{2\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2}{\left(\frac{\mu_1 - \mu_2}{\sigma}\right)^2}$$

with means μ_1 and μ_2, homogenous variances ($\sigma_o^2 = \sigma_1^2 = \sigma^2$), equal sample size ($n_0 = n_1 = n$) and *z* from a normal distribution. Substituting in the typical values above, in standard deviations, for *α* of +/- 1.96, and *β* 0.84 gives:

$$n = \frac{2(1.96 + 0.84)^2}{\Delta^2}$$

where Δ is the standardised mean difference:

$$\Delta = \frac{\mu_o - \mu_1}{\sigma} = \frac{\delta}{\sigma}$$

This approximates to Lehr's equation for calculation of sample size:

$$n = \frac{16}{\Delta^2}$$

However, for the IID3 study we are dealing with ***binomial data (i.e. proportions)***. Hence it is necessary to adapt Lehr's equation [15] such that the average of the proportions can be represented as:

$$\bar{p} = \frac{p_0 + p_1}{2}$$

and hence the estimated sample size with power $\bar{q}$ is:

$$n = \frac{16\bar{p}\bar{q}}{(p_0 - p_1)^2}$$

Note that due to this modification for binomial (proportion) data *z*-values are no longer applicable.

Sample size estimates for community cohort component for a study estimating a single UK-wide pyramid, based on ability to detect a 20% decrease in incidence of severe IID with 80% power and 95% probability are shown below (Table 2).

Table 2: Numbers of patients needed in the UK per GP practice assuming 150 GPs initially recruited, and 50% loss of GP practices.

Organism	Baseline incidence in community cohort	Reduction needed to be detected	Person-years	Number of patients per GP practice N = 150	Number per GP N
All IID	25%[1]	20%	1,116	7	
Severe IID*	6%[2]	20%	5,676	38	
Severe IID	**4%**	**20%**	**8,676**	**58**	
Severe IID	2%[3]	20%	17,676	118	
Campylobacter	0.93%[4]	20%	38,386	256	
Salmonella	0.06%[5]	20%	599,676	3998	7

Notes: *Severe IID = presenting to Primary Care; [1,3,4,5] Based on incidence in IID2 Study (person-years of follow-up = 4,658);
[2] Based on incidence in IID1 Study (person-years of follow-up = 4,026).

We have based our planning assumptions around a baseline incidence of severe IID of 4%. We have chosen 150 practices because we believe that the recruitment target in each practice is achievable. However, our extensive experience of conducting studies of this type means that we know that not all practices that volunteer to take part in the study will recruit participants, and some practices/participants will drop out along the way. Assuming that the incidence of IID in the IID3 study is around 25% then we can expect up to 2,000 stool samples from the cohort, provided that every case submits a sample.

Taking population size into account this means that we plan to recruit 126 practices in England (7,288 person-years of follow-up), 13 in Scotland (752 person-years of follow-up), seven in Wales (405 person-years of follow-up) and four in Northern Ireland (231 person-years of follow-up).

Sample size estimates for GP presentation component for a study estimating a single UK-wide pyramid, based on the ability to detect at least a 20% reduction in incidence with 90% power and 95% probability are shown in Table 3.

Table 3: GP Presentation Study - required number of person-years and GP practices in the UK (assuming an average GP practice size of 9,000 patients).

Organism	Baseline incidence[1]	Reduction to be detected	Person-years	GP practices
Norovirus	0.21%	20%	171,105	19
Campylobacter	0.12%	20%	299,676	33
Salmonella	0.02%	20%	1,799,676	200

[1] Incidence of GP presentation in IID2 study (Person-years of follow-up = 312,232)

Based on samples submitted in the IID2 Study we have assumed that we will receive in the region of 1,000 samples in the GP Presentation Study.

The sample sizes given above in Tables 2 and 3 are for the UK. If measurement of changes in IID incidence for each of the four UK nations separately are needed, then the sample size for each nation would be the same as for the UK. We consider this to be impractical and unaffordable.

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2. Objectives and deliverables, including proposed timescale for delivery and dissemination

Please summarise how you will deliver your solution, including specific objectives and deliverables and the timescale for delivery. This should include potential publication plans.

A. THE OBJECTIVES

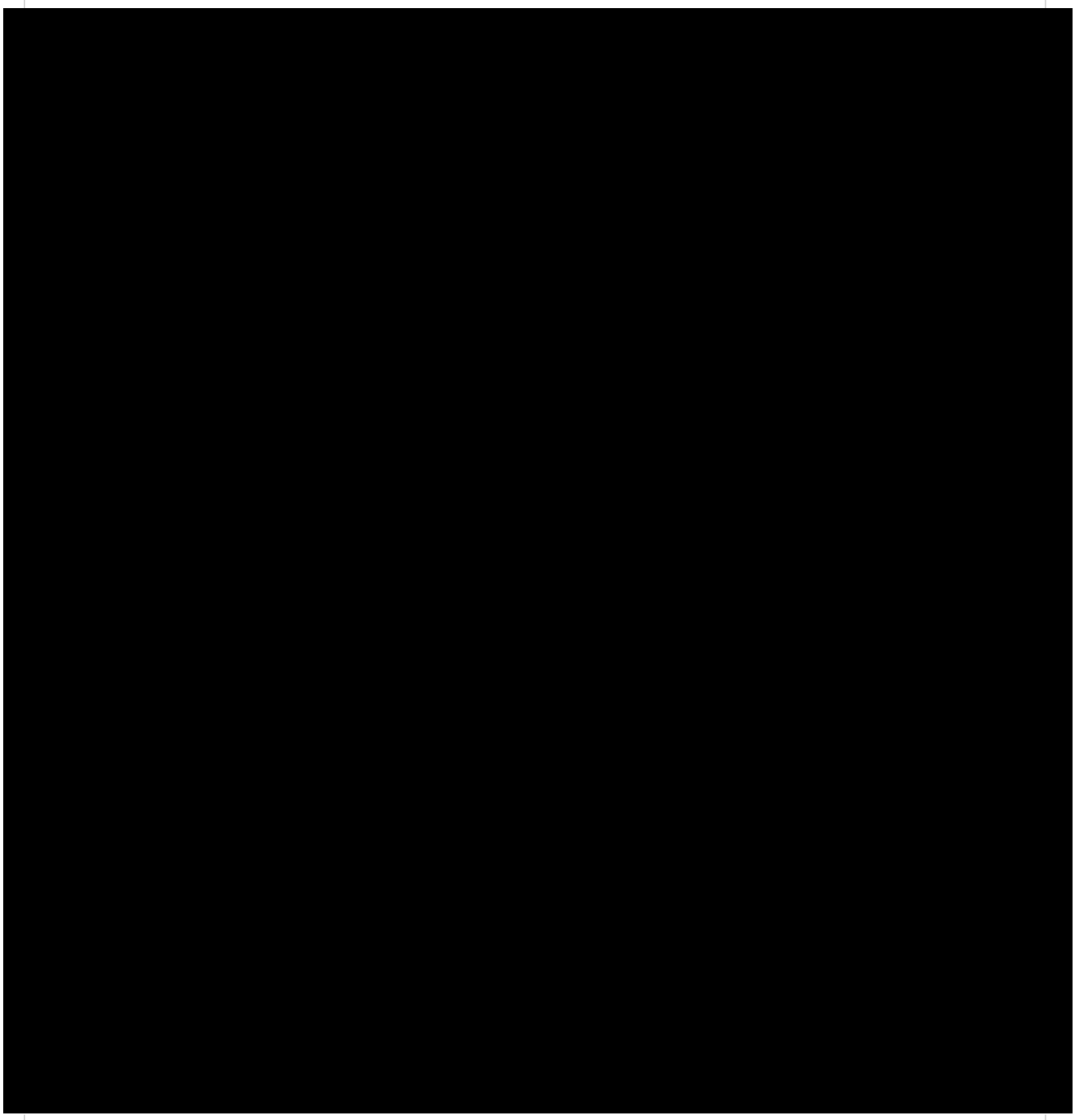
Please detail how your proposed work can assist the agency in meeting it stated objectives and policy needs. Please number the objectives and add a short description. Please add more lines as necessary.

Objective Number	Objective Description
01	Ensure the smooth running of all aspects of the research
02	Determine the overall incidence of IID in the UK population
03	Establish the incidence of IID presenting to primary care (WP3, WP6)
04	Clarify the proportion of IID that is UK-acquired (WP2,
05	Describe the pathogens causing IID in the UK, including levels of antimicrobial resistance (AMR) (WP2, WP3, WP4, WP6)
06	Re-calibrate UK surveillance data for IID overall and by pathogen (WP2, WP3, WP4, WP5, WP6)
07	Determine the number of cases in the community, GP reported cases, hospitalisations and deaths due to IID in the UK (WP2, WP3, WP4, WP5, WP6)
08	Compare results of the IID3 study with previous studies (WPs 2 to 6)

B. THE PLAN

Please provide a detailed project plan including, the tasks and sub-tasks required to realise the objectives (detailed in Part A). The tasks should be numbered in the same way as the objectives and should be clearly linked to each of the objectives. Please also attach a flow chart illustrating the proposed plan. This plan should also include timelines of any anticipated publications or communications (e.g. presentations) to be given as part of the project.

We will deliver the project objectives through nine interconnected work packages. Multiple work packages are essential to address each objective as shown in Figure 3.



WORK PACKAGE 1: PROJECT MANAGEMENT (OBJECTIVE 01)
Leadership of this WP rests with Newcastle University [redacted] In WP1 we will establish systems to ensure the smooth running of all aspects of the research programme (Objective 01). This WP activities should be read in conjunction with Section 5A below. The tasks and sub-tasks are as follows:-

Task WP1/01: Draft and finalise a collaboration agreement between all Participant Organisations
If awarded the contract, we intend to implement a Brunswick-style collaboration agreement between all Participant Organisations once a contract is signed between the Lead Applicant and the Food Standards Agency.

Task WP1/02: Appoint an External Advisory Panel (EAP)
We propose to appoint an EAP to provide independent scientific advice and challenge during the research programme. This is considered good practice on research programmes of this size and scope. We envisage that this group will comprise up to six international experts and at least two lay members.
Sub-task WP1/02/01: Draft terms of reference for the EAP for discussion and approval at the IID3 Study Executive Committee (IID3EC).
Sub-task WP1/02/02: Agree membership of the EAP with the Food Standards Agency.
Sub-task WP1/02/03: Invite proposed panel members to serve on the EAP.

Task WP1/03: Organise Executive Committee (IID3EC) Meetings
Sub-task WP1/03/01: Arrange quarterly meetings of the IID3EC, starting with the project initiation meeting, according to the project timeline.
Sub-task WP1/03/02: Arrange annual conferences commencing June 2022.
Sub-task WP1/03/03: Prepare meeting agendas in collaboration with the Food Standards Agency, prepare papers (where appropriate) and compose accurate minutes of meetings. Finalised documents will be held on the study website (See Task WP1/05).

Task WP1/04: Ensure that new appointments are made
Several Participant Organisations will need to appoint to new posts, described in Section 3B below and in the justification for support on the financial template. This task will include preparation of job descriptions and adverts, holding interview panels, and making appointments.

Task WP1/05: Oversee submission of research protocols and other research materials for ethical review
Sub-task WP1/05/01: Preparation of all research materials in collaboration with WP2, WP3, WP4, WP5, and WP6.
This will involve preparation of all study materials including invitation letters, study information sheets, consent forms, all questionnaires, design of databases and finalisation of microbiological testing algorithms.
Sub-task WP1/05/02: Oversee drafting of the ethics submission to the Health Research Authority (HRA) in collaboration with WP2, WP3, WP4, WP5, and WP6. HRA Approval brings together the assessment of governance and legal compliance, with the independent ethical opinion by a Research Ethics Committee (REC) so that we only need to submit one application. Studies led from England but with sites in Northern Ireland, Scotland or Wales are supported through existing UK-wide compatibility systems where each country accepts relevant centralised assurances from national coordinating functions to avoid duplication. Research governance requirements in Clinical Commissioning Groups (CCGs) will be adhered to and we will seek to register the study on the NIHR portfolio.
Sub-task WP1/05/03: Oversee drafting of ethics submission to Newcastle University in collaboration with WP8.
Sub-task WP1/05/04: Oversee preparation and submission of annual reports for the HRA and the Newcastle University Research Ethics Committee in collaboration with WP2, WP3, WP4, WP5, and WP6.

Task WP1/06: Create and maintain a study website
We will design, build and maintain a secure study website, accessible to all study participants and to the Food Standards Agency's Project Officer via individual passwords. All documents relating to the study (e.g., meeting agendas, meeting minutes, protocols, questionnaires, project reports, publications) will be held on this website, along with study updates and newsletters. Thereafter the website will be maintained for the lifetime of the project.
Sub-task WP1/06/01: Secure a suitable domain name.
Sub-task WP1/06/02: Build a study website that has a public-facing component and a secure, password-protected area for all study investigators and Food Standards Agency personnel.

Task WP1/07: Standard Operating Procedures (SOPs)
Sub-task WP1/07/01: Draft a protocol for document control across all WPs, to be agreed at the IID3EC, and then implement it.
Sub-task WP1/07/02: Collate SOPs across all WPs and maintain only the most recent versions on the study website to avoid old drafts of documents being used inadvertently.

Sub-task WP1/07/03: Draft a publication and dissemination policy across all WPs, to be agreed at the IID3EC, and then implement it.

Task WP1/08: Oversee production of study reports
Sub-task WP1/08/01: Preparation and submission of pilot study report in collaboration with all WPs.
Sub-task WP1/08/02: Preparation and submission of interim study report in collaboration with all WPs.
Sub-task WP1/08/03: Preparation and submission of near-final draft study report in collaboration with all WPs.
Sub-task WP1/08/04: Preparation and submission of final draft study report in collaboration with all WPs.
Sub-task WP1/08/05: Revise and agree final study report with Food Standards Agency in collaboration with all WPs.

Task WP1/09: Quality Control (See also Section 7C below)
Sub-task WP1/09/01: In collaboration with WP6, finalise the draft quality assurance policy to be agreed at the IID3EC and then implemented.
Sub-task WP1/09/02: Develop and implement an internal audit programme to ensure compliance with the Joint Code of Practice on Research.
Sub-task WP1/09/03: Ensure that the project timeline is reviewed at IID3EC meetings.
Sub-task WP1/09/04: Ensure that the risk register is reviewed and update at IID3EC meetings.

Task WP1/10: Archiving of study data at the end of the research programme (See also Section 7C below)
Ensure that all study data and samples are archived in a publicly accessible data archive and a biobank, respectively.

WORK PACKAGE 2: PROSPECTIVE COHORT STUDY (OBJECTIVES 02, 04, 05, 06, 07, 08)
Leadership of this WP rests with the University of Oxford [redacted] In WP2 we will report the incidence, aetiology, and impact of IID in the population, whether or not they attend their general practice. Samples and questionnaire data will be collected direct from patients, though these data will be linkable to their GP and other health data (e.g. hospitalisation). Questionnaires and samples will be collected at baseline (recruitment) and with each episode of IID in the household. There will be questionnaires weekly until symptoms have resolved. This component of the study will be known as Cohort 1.

Task WP2/01: Ethics, Governance and NIHR Portfolio adoption (see also Task WP1/05)
Sub-task WP2/01/01: Study documentation
Draft scientific protocol, all study documentation (invitation letters, patient information sheets, questionnaires etc) in collaboration with WP1, WP3, WP4, and WP6 for inclusion in the Integrated Research Application Service (IRAS) application.
Sub-task WP2/01/02: Ethics
Submit the IRAS application for ethical and Health Research Authority (HRA) approval for pilot and main studies, in collaboration with WP1, WP3, WP4, WP5, and WP6.
Sub-task WP2/01/03: NIHR Portfolio adoption.
Submit application for NIHR Portfolio adoption.

Task WP2/02: Practice recruitment
Once a favourable ethical opinion has been granted, we will start practice recruitment. We will do this in collaboration with NIHR Clinical Research Networks (CRN). The lead CRN will be Thames Valley and South Midlands (TVSM) (see letter of support (Appendix 2)). This is the local Clinical Research Network for our GP hub, which is located in Oxford. Current member practices of the RCGP RSC will be approached for interest and recruited to ensure even distribution across the seven regions of England and the three devolved nations. Practices with large populations, good representation of the BAME population or a strong history of participation in RCGP RSC research studies may be approached directly to recruit them. We will also work with local CRNs to promote the study to practices. We will need to recruit 150 practices to carry out the Cohort 1 study (See Section 1 above for consideration of sample sizes).

Task WP2/03: Practice training
The RSC team in Oxford will be responsible for research practice training. Practices will receive training in the use of the patient access systems for EMIS and TPP, pathology requesting and participant recruitment. Practice training will cover procedures for WP2 and WP3 (see below).

Task WP2/04: Household recruitment and follow-up
We will recruit households using three strategies:- (1) Requests to volunteer via the patient online access system; (2) Text messaging to patients using the practice text messaging; (3) Direct recruiting in practice. We will monitor the distribution of household size to ensure our distribution is across the following groups: single occupancy, 2-3 people, 4 to 6, and 7 or more in a household and broadly in line with the national distribution.

Sub-task WP2/04/02: Informed Consent
We will record participant consent in the patients' computerised medical records.

Sub-task WP2/04/03: Baseline data collection and sample submission
At enrolment we will ask Cohort 1 households to complete a baseline questionnaire.

Subtask WP2/41/04: Household follow-up
We will ask Cohort 1 households to make an online record of any episodes of IID and submit diarrhoeal stool specimens straightaway for microbiological testing in WP4. We will send weekly questionnaires to Cohort 1 households until IID symptoms are over. We will capture data needed for analysis in WP 6 including demographics, IID event data, their sequelae, any associated prescribing, sickness absence, out-of-pocket expenses and a history of foreign travel. We will also send monthly messages to Cohort 1 households to remind them of their participation in the study.

Task WP2/05: Access to the trusted research environment (TRE), and creation of datasets
The Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) has a trusted research environment (TRE) recognised by Health Data Research UK (HDRUK) (for further details see Section 7C below). The RSC will work with Liverpool Clinical Laboratories, Public Health England and other members of WPs 4, 5, and 6 to provide access to the TRE. We will provide linkage of primary care, hospital, death and other data to that collected in WP4. This will be integrated in the TRE. We will provide linked to appropriate sample or catalogue references in WP4 (e.g. to genomic data which may be extensive). Phenotypes and ontologies will be developed to provide data compatible with devolved nations data, in WP5. We will also pilot and then operationalise data feeds/analysis for WP6. Across WP2 (Cohort 1) and WP3 (Cohort 2, only - see below) we will create details of non-responders. We will define, then operationalise the dataset available to FSA, for which they will be Joint Data Controllers. This should be deliverable in near real time. We plan to provide both a themed dataset and dynamic data services.

Task WP2/06: Pilot Study
We will undertake a pilot study to:-

- evaluate the process of recruitment
- field test the questionnaires
- assess questionnaire response rates and the degree of non-participation
- test the sample kit requesting with results returned to practices. This will be facilitated by XLab Systems' NPEx network
- apply for hospital episode statistics (HES), and Office of National Statistics (ONS) death data to link to our primary care data. This is needed for clinical outcomes and cost (WP6).
- provide all study members who require access to the TRE and test access and linkage.
- finalise the protocol and complete the ethics application for the main study.

The time allowed for the pilot study is three months.

Task WP2/07: Main Study
The time allowed for the main study is 24 months to account for tapering at either end of the study period. Practice and participant recruitment are likely to be staggered, based on the experience of the IID2 Study and the INTEGRATE Study.

Task WP2/08: Lock and prepare data for final analysis
Agree and implement lockdown date for the dataset for final analysis.

WORK PACKAGE 3: PRIMARY CARE PRESENTATION STUDY (OBJECTIVES 03, 04, 05, 06, 07, 08)

Leadership of this WP rests with the University of Oxford [redacted] This WP comprises three components, which are a GP Presentation Study (Cohort 2), a GP Enumeration Study (Cohort 3) and a GP Validation Study.

Task WP3/01: GP Presentation Study (Cohort 2)

This will be prospective study of cases consulting their GP with IID together with microbiological sampling of all such cases and the collection of selected demographic and epidemiological data. All stool samples from Cohort 2 will be examined at the laboratory in Liverpool according to a standard algorithm (see WP4).

Sub-task WP3/01/01: Ethics, Governance and NIHR Portfolio adoption

This will be included in Task WP2/01 described above.

Sub-task WP3/01/02: Practice recruitment

150 GP practices will be recruited to Cohort 2 from the RCGP RSC network. Practices will be recruited to ensure national representation is achieved across the seven regions of England and the devolved nations. RCGP RSC member practices will be asked for expressions of interest and local CRNs will support the recruitment of practices. We intend to recruit 150 practices to carry out the Cohort 2 Study.

Sub-task WP3/01/03: Training

See Task WP2/03 described above.

Sub-task WP3/01/04: Patient recruitment, consent and follow-up

Each time a patient presents with symptoms of IID that meet the case definition, we will ask them to provide a stool sample and they will receive a link to complete the follow-up questionnaire via their practice's patient access platform at the time of the sample request as well as 7 days after their consultation. If symptoms persist, they will receive further questionnaires weekly until resolution. The first and follow-up questionnaires will be the same as those for Cohort 1 in WP2. Where a patient cannot use online access to record their questionnaire details, these can be recorded in-practice into the patient's computerised medical record. We will record age-band, gender, ethnicity and socioeconomic status of people who: (1) Have IID and do not provide a sample or questionnaire – retaining their demographic details; (2) Those who provide an initial sample or questionnaire and are then lost to follow up. This will give us important information about the characteristics of non-responders. We will record evidence of informed consent from all participants in the computerised medical record.

Sub-task WP3/01/05: Pilot Study

The methods will be piloted (See Task WP2/06) during the first three months of data collection.

Sub-task WP3/01/06: Main Study

The main study will take place over a 24-month period.

Task WP3/02: GP Enumeration Study (Cohort 3)

In this task we will observe usual practice, i.e. specimens will only be collected where GPs would request them as part of their routine clinical practice. We anticipate a much lower rate of attendance and sampling. This will be a 24-month prospective study of cases presenting to GPs with IID, observing normal clinical practice; information will be collected on clinical severity, stool sample submission and, if so, the microbiology laboratory result. Samples collected as part of routine clinical practice will be sent to the laboratories normally serving the general practice population and examined according to the receiving laboratories' own protocols. Data from the rest of the RSC sentinel network Cohort 3 will be (>1,200 general practices with a combined list size of >12 million providing nationally representative data about usual practice) will form Cohort 3. Should General Practices in Cohorts 1 or 2 not be able to recruit households or patients to target, Cohort 3 will provide a pool of substitute practices. The nature of the RSC extract means that it also includes retrospective data so that we can compare patterns of disease in our observation year with that seen across the pandemic, or previous more typical years. Cohort 3 is thus passive surveillance of IID, with no interventions and so Task WP3/02 provides rates through the orange route on the surveillance pyramid shown in Figure 1.

Task WP3/03: GP Validation Study (Audit of recruitment to Cohort 2)

In the validation study we will audit recruitment to the GP Presentation Study by undertaking an electronic record search in practices taking part in the GP Presentation Study (Cohort 2). In the IID2

Study we identified 7,524 records of consultations for IID-related symptoms through a Read code search during the study period. 4,770 of these consultations met the case definition for IID. This compared with 2,233 eligible patients who were referred to the IID2 GP Presentation Study. Of those patients identified as eligible at consultation 2,203 (99%) were invited to take part in the study, 1,392 (63%) responded positively, 1,264 (57%) attended a baseline recruitment interview, and 1,254 (57%) were recruited. We need to take account of this attrition to estimate under-ascertainment in the GP Presentation Study (Cohort 2). Under-ascertainment is defined as cases of IID who presented to the practices but were not ascertained. The purpose of the validation study is, therefore, to identify the extent of under-ascertainment in the IID3 study and factors associated with it.

Task WP3/04*:* Lock and prepare data for final analysis
Agree and implement lockdown date for the dataset for final analysis.

In summary, Task WP3/01 provides rates through the blue route on the surveillance pyramid shown in Figure 1. Task WP3/02 provides rates through the orange route on the surveillance pyramid shown in Figure 1. WP2 and WP3 will also provide data for WP5 (Calibrating National Surveillance) and WP6 (Analysis).

WORK PACKAGE 4: CLINICAL MICROBIOLOGY (OBJECTIVES 05, 06, 07, 08)
Overall leadership of this WP rests with the University of Liverpool [redacted] in close collaboration with Liverpool Clinical Laboratories [redacted] and the UK Health Security Agency (UKHSA) [redacted] The aim of WP4 is to establish the aetiology of IID using the most appropriate, currently available methods while enabling comparison with IID2 results.

Task WP4/01: Diagnostic Microbiology
The primary responsibility for this task rests with Liverpool Clinical Laboratories (LCL) [redacted]. Liverpool Clinical Laboratories (LCL) is the largest pathology service provider in Cheshire and Merseyside, formed in 2013 from the amalgamation of the pathology clinical services and laboratories of the Aintree University Hospital NHS Foundation Trust and the Royal Liverpool and Broadgreen University Hospitals NHS Trust. As of 1st October 2019, Aintree and The Royal have merged to become Liverpool University Hospitals NHS Foundation Trust. LCL primarily work on the diagnosis of disease and evaluate the effectiveness of treatments and undertake research into the causes and cures of disease, processing over 5 million sample tests each year. LCL provides specialist clinical laboratory services, regionally and nationally, meeting the needs of acute, primary and specialist healthcare providers. Its high-quality clinical laboratories cover the three main disciplines of Blood Sciences, Infection and Immunity and Cellular Pathology. Diagnosis of faecal pathogens is undertaken within the discipline of Infection and Immunity. The department uses molecular and traditional methods for high throughput detection of organisms associated with gastroenteritis. The department is UKAS Accredited and GCP compliant. The diagnostic service is supported by 13 Consultant Microbiologists, 3 Consultant Virologists, 1 Consultant Clinical Scientist in Virology and a Clinical Scientist in Bacteriology as well as specialist Biomedical Scientists in both specialties. LCL has collaborative relationships with the University of Liverpool and has established policies and procedures for sharing clinical specimens for research purposes. LCL has previously participated in studies of gastrointestinal infections with the University of Liverpool and has the appropriate infrastructure and resources to support IID3.
Sub-task WP4/01/01: Specimen handling and reporting
Faecal specimens will be submitted to LCL from participating GP practices through the National Pathology Exchange (NPEx) laboratory service. The samples will be accompanied by a specimen request form that will include patient's surname and forename, address, postcode and date of birth. Clinical details will include date of illness onset, history of foreign travel and presence of underlying disease. The request form will include a section to be signed by the subject for consent to test the specimens, and for agreement to the archiving of material for additional relevant analysis at a future date. All specimens will be screened for routine GI pathogens on the day of receipt at LCL if received within normal working hours; they will otherwise be refrigerated and tested the next working day. Clinical reports will be sent to participating GP practices. Clinically significant findings will be actioned according to routine practise and statutory notification requirements within LCL. The samples will also be tested using a panel of additional pathogen targets; these pathogens lie outside the scope of routine diagnostic practise. A separate research report will be issued to GPs detailing results of these assays.
Sub-taskWP4/01/02: Specimen testing

All faecal samples will undergo PCR testing using the Serosep molecular diagnostics platform (www.serosep.com/entericbio-molecular-diagnostics/panels). This will comprise three panels:

- EntericBio DX (Salmonella, STEC, Shigella, Campylobacter, Cryptosporidium, Giardia, Yersinia, *Entamoeba histolytica*, Vibrio)
- EntericBio Viral Panel 3 (Norovirus GI/GII, Sapovirus, Astrovirus, Adenovirus, Rotavirus)
- EntericBio *C. difficile* (in subjects age > 65 years)

Open access functionality on the Panther Fusion analyser (Hologic, Inc.) will be used to test for additional gastrointestinal pathogens not included in the above commercial panels. This PCR panel will comprise up to six laboratory-developed tests (LDTs) adapted from PHE/PHW protocols and will be established prior to the pilot study; the LDTs will target Clostridium perfringens, diarrhoeagenic *Escherichia coli* (DEC), *Aeromonas* spp. and *Cyclospora cayetanensis* [Appendix A]. Bacterial culture will be reserved for those faecal specimens that have tested positive by PCR with either the routine or additional panel, to enable subsequent molecular and phenotypic characterization. Bacterial culture, utilising enrichment culture as required, will be undertaken according to UK Microbiology Standards (https://www.gov.uk/government/publications/smi-b-30-investigation-of-faecal-specimens-for-enteric-pathogens). It is recognised that culture from faecal specimens of some pathogens associated with IID is technically challenging, and thus methods will be established at LCL in close collaboration with PHE [Appendix A]. This approach will be developed (with appropriate Quality Control and Quality Assurance) prior to the pilot study, with the potential for undertaking part of this work at PHE.

Sub-task WP4/01/03: Development phase

Development work will be undertaken prior to receipt of study specimens. This will include:-

- Development of multiplex PCR assays at LCL for pathogens of interest not included in the Serosep commercial assays: these include *Clostridium perfringens*, diarrhoeagenic *Escherichia coli* (DEC), *Aeromonas* spp. and *Cyclospora cayetanensis*
- Establishment of culture methods at LCL for a range of bacteria, beyond those sought in the routine diagnostic laboratory (e.g. diarrhoeagenic *E. coli*, *Clostridium difficile*, *Aeromonas* spp.)

Material that will underpin subsequent reference microbiology investigations will include original stool (where available), and bacterial isolates obtained by culture of faecal samples that have tested positive by PCR. Lysate from the Serosep assay will be retained. Appropriate material will be shipped from LCL to the relevant reference laboratory for further investigation. All material will be stored at an appropriate temperature until transferred to the Biobank at University of Liverpool. There will be no long-term storage of material at LCL. The laboratory diagnostic workflow is illustrated in Appendix B (Figure1).

Task WP4/02: Reference Microbiology

The primary responsibility for this task rests with the appropriate Reference Laboratory (UKHSA for bacteria and viruses; and PHW for protozoa) [redacted] The aim is to characterise organisms to an appropriate level, and to identify the presence of AMR among bacterial isolates [Appendix C]. Reference laboratory investigations will include:-

(i) Subtyping of organisms where such information is epidemiologically important (e.g. in aiding differentiation of domestic from imported infection; and in outbreak investigation).

(ii) Antimicrobial resistance testing for key bacterial pathogens including *Salmonella* spp., *Shigella* spp., *Campylobacter* spp., *Vibrio* spp., STEC and DEC. The rising prevalence of AMR among enteric pathogens is of major public health concern, and is increasing especially rapidly among certain groups (e.g. imported infections). Data will be compared with metagenomic outputs.

Subtask WP4/02/01: Bacteria

PHE's Gastrointestinal Bacterial Reference Laboratories (GBRU) is responsible for the genomic analysis of over 12,000 gastrointestinal bacterial isolates submitted by hospitals, General Practices and as part of outbreak investigations each year. All strains are analysed against a database of meta and clinical data to predict potential source of transmission/contamination (food source, geographical location, travel and clinical symptoms among other key criteria). This large, internationally recognised dataset is currently composed of over 150,000 genomes/isolate. Recent analytical developments have now incorporated AMR prediction for enteropathogens, which will support understanding of circulating resistance mechanisms in the UK among imported and local infective strains.

Bacterial isolates from IID3 will be examined for antimicrobial resistance, toxin typic, serological analyses and clonal cgMLST. Potential source of infection will be derived from analysis of whole

genome data against the UK Gastrointestinal Data Warehouse and the wider international genome sequence archives and databases. A subset of bacterial isolates will undergo conventional antimicrobial susceptibility testing (determination of minimum inhibitory concentration) for the presence of phenotypic resistance against relevant antibiotics. The laboratory workflow is illustrated in Appendix B (Figure 2).

Sub-task WP4/02/02: Protozoa
Genotyping will be undertaken on PCR positive stools at the national Cryptosporidium Reference Unit (CRU, managed by Public Health Wales) [redacted] The CRU is responsible for the investigation and management of human cryptosporidiosis in England and Wales, including molecular epidemiology. Additionally, *Giardia* spp. genotyping is undertaken for Wales. The CRU handles around 3,000 clinical samples per annum and additionally undertakes research projects involving clinical, food, water and environmental investigations. Facilities include those supporting traditional microscopical investigations, real-time and conventional PCR, fragment sizing, and Sanger sequencing. The core staff of six comprises a consultant Clinical Scientist, two principal Clinical Scientists, a Biomedical Scientist, a Biomedical Support Worker and a research scientist. There is additional medical support from a Consultant Microbiologist. The CRU is located in a clinical diagnostic laboratory and is accredited by UKAS to ISO 15189, thus supported by a Quality Management System including a Laboratory Information Management System for the recording and reporting of clinical samples and results.

For *Cryptosporidium* spp., differentiation to the species-level informs the epidemiology as the human-infective species differ, and so understanding the infecting species can point to different sources (humans, animals). Following DNA extraction, a duplex probe-based real-time PCR targeting the Lib13 gene of C. parvum and the A1325 gene of *C. hominis* will be used, with minor species sought by sequencing amplicons of the 18S rRNA gene. For selected samples, sequencing the gp60 and multi-locus molecular epidemiological tools will be used to investigate relationships between isolates and in outbreaks for source tracking. For *Giardia* spp., wide-scale genotyping studies have not yet been undertaken; the human-infective assemblages A and B will be sought using a duplex probe-based real-time PCR targeting the tpi gene with assemblage-specific primers. For *Cyclospora cayetanensis*, a multiple loci deep sequencing approach will be used. The laboratory workflow is illustrated in Appendix B (Figure 3).

Sub-task WP4/02/03: Viruses
Where viral nucleic acids are detected, further characterisation of the virus will be undertaken by whole genome sequencing.

Task WP4/03: Pilot Study
A pilot study will allow establishment, evaluation and refinement of study procedures relating to diagnostic microbiology, reference microbiology and biobanking. Key components to be addressed will include:-

- Workflows representing all WP4 components (illustrated in Appendix B)
- Efficiency of transport of faecal specimens from participating GP practises to LCL, and reporting of results by LCL to GP practises
- Efficiency of procedures that link study sub-tasks (e.g. shipping from LCL and UoL Biobank to reference laboratories and QI; reporting of results from reference laboratories to LCL)

The pilot study will take place over a period of three months.

Task WP4/04: Main Study
The main study will take place over a period of 24 months.

Task WP4/05: Biobanking
Leadership of this task rests with the University of Liverpool ([redacted] Faecal material and bacterial isolates will be received from Liverpool Clinical Laboratories. The sample repository will be located in the Good Clinical Practise Laboratory Facility (GCPLab) based in the William Henry Duncan Building, University of Liverpool. The GCPLab will design, build and validate a bespoke, study-specific Laboratory Information System (LIMS) workflow to uniquely label and track all samples. This will provide a full audit trail for all sample-related information (reagent/kit batches, equipment used,

RNA/DNA concentrations), ensuring that sample data can be robustly linked to the patient and to clinical information.

All freezers within the GCPLab are alarmed and have an environmental monitoring system that records 24/7, and alerts the team via text and phone call (24/7) if there are temperature excursions.
The GCPLab will provide sample reports and will ship samples as required to partner laboratories for further analysis. All equipment within the GCPLab is serviced and calibrated on a yearly basis.
The GCPLab uses the Q Pulse document management system for version control, for recording and reporting sample quality incidents (QI's) and for corrective and preventive action as required.

A stool aliquot (up to 1gm) will be stored frozen at -80^{O}C in 1mL of PBS. After processing in the diagnostic laboratory, a second aliquot (up to 0.5gm) will be placed in RNA/DNA shield (Zymo) and any remaining stool will be directly frozen. Nucleic acid will be extracted from each specimen. All material will be stored for a minimum of 5 years following study completion, ensuring compliance with Human Tissue Authority (HTA) regulations. The Biobank material will include the following, all stored at -80^{O}C:

- Original faecal material
- 1-2ml of a faecal suspension in PBS
- 1-2ml of faecal material in RNA/DNA shield
- Nucleic acid extract
- Bacterial isolates

After the end of the study, all remaining samples will be adopted by the Liverpool University Biobank (LUB). The LUB is a multi-discipline biobank established to consolidate existing collections held within the University of Liverpool and collaborating institutions. It is licensed by the HTA and has ethical approval for the adoption, collection and storage of biosamples. The LUB offers a wide range of biobanking services including sample storage and processing, provision of samples, and sample collection services to facilitate research projects.
The access arrangements for release and use of the samples, once they have been adopted by LUB, is governed by an Ethical Review Board. The Ethical Review Board will review formal applications for the release and use of the samples, conferring sponsorship and ethical approval if deemed appropriate. A member of the study team (internal or external) will be invited to attend the Ethical Review Board to ensure that the sample requests for future investigations are compatible with the overall project aims.

WORK PACKAGE 5: NATIONAL REPORTING STUDY (OBJECTIVES 06, 07, 08)
Leadership of WP5 rests with Newcastle University [redacted] The aim is to compare pathogen specific-rates calculated from Cohorts 1, 2 and 3 with those recorded in the national surveillance systems of the four UK nations, and to compare IID rates from Cohort 1 with rates recorded by NHS111 in England, Wales and Northern Ireland and rates recorded by NHS24 in Scotland.

Task WP5/01: Collating UK surveillance data of laboratory-confirmed cases of IID
We will extract from the national databases in England, Wales, Scotland and Northern Ireland laboratory reports of confirmed cases of IID for the full range of target organisms.

Task WP5/02: Collating UK data on IID calls handled by NHS111 and NHS24
We will work with PHE's Real-Time Syndromic Surveillance Team in Birmingham to obtain data on calls to NHS111 during the two-year main study period. We will seek anonymised individual records on all calls for which the main complaint is recorded as 'Diarrhoea', 'Vomiting' or 'Food poisoning'. We will collect information on the date of the call, the age and sex of the patient, call type (based on the predominant complaint as assessed by the triage nurse) and call outcome (based on what the caller was advised to do). We will work with Health Protection Scotland to obtain similar data from NHS24.

WORK PACKAGE 6: ANALYSIS OF POPULATION-BASED STUDIES (OBJECTIVES 02, 03, 04, 05, 06, 07, 08)
Leadership of WP6 rests with Newcastle University [redacted] The overall aim of WP6 is to integrate both the findings and data from the other WPs in IID3 to quantify the population level of IID and understand the key causal microbiological, sociological, economic and food drivers that

affect it. In particular, it will produce quantitative comparisons of disease burden with those estimated in the IID1 and IID2 studies and will provide FSA with more accurate and updated measurements of the different components within the surveillance pyramids.

Task WP6/01: Pipeline and methods for analysing RCGP data streams
We will develop a pipeline for data streaming from the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC). This will require development of a download protocol and system for collating relevant meta-data. Preliminary data will be collated on the incidence of IID disease (all cause and specific pathogens) for the three years prior to the initiation of our study period in IID3. We will collate relevant meta data describing demography IMD for the study population of 1800 GP practices. We then used a binomial mixed effect model with social demography, sample time and COVID-19 disease and lock down status (ward level) and season (harmonic covariates) as independent variables for each patient and GP practice as the random effect. We seek to quantify the impacts of season, COVID-19 lockdown status (through multiple phases of lockdown), local disease on the incidence of all cause IID and campylobacteriosis. Other pathogens will be considered where incidence is high enough to model with adequate power. Other error model structures (zero-inflated negative binomial [14]) will be considered when distributional assumptions are not met by the binomial model. We need to analyse the sequence of years and seasonal nature of pathogens in order to align these with the subsequent data collected for cohorts 1, 2 and 3 in WP2 and WP3. We hypothesise that COVID-19 has reduced presentation of IID to primary care and need the pre-, during and post COVID-19 variables to adjust for this in our consideration of IID prevalence to be collated in WP2 and WP3.

Task WP6/02: Methods for assessing representativeness, response bias, compliance and list inflation for the prospective study (Figure 8)
Data collection in WP2 and WP3 for the Household (Cohort 1), GP presentation (Cohort 2) and enumeration (Cohort 3) studies rely on general practices within the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) of 1800 practices. Thus, the GP practice will provide our sampling unit for patients and households and ensures good geographical coverage of the sample populations in each of the UK nations. It also allows quantification of between-practice variation in disease, demography, comorbidities and socio-economic drivers. WP2 and WP3 will provide estimates of IID in their respective study cohorts and anonymised meta data on socio-demographics from EMIS and the TPP System for this WP. Use of mixed effect modelling in data analysis allows us to generalise from our sample population of GPs to the wider population of GP practices, since it provides a formal statistical model for expectations of the wider population of GP practices. Whenever appropriate we will analyse data using mixed-modelling approaches for all-cause IID; we will also use these methods for individual pathogens where datasets have sufficient numbers of disease records.
Sub-task WP6/02/01: Representativeness will be assessed by comparison of characteristics of the study population with routine data from the National Census and general practice statistics. We will quantify inter-GP practice variation in patient characteristics, including socio-demographic features associated with the patient population, using mixed-effect modelling. We will quantify seasonality historically in Cohort 3 using harmonic regression whilst assessing the extent to which seasonal patterns vary across practices. Seasonal variation in the data will be removed through detrending, and factors that drive residual non-seasonal disease variation determined through (generalised) linear mixed-effects models [56,57]. If there is any remaining temporal autocorrelation in the data, this will be adjusted for using autoregression [56].
Sub-task WP6/02/02: Compliance in Cohorts 1 and 2 will be calculated as the proportion of subjects submitting a questionnaire or stool relative to the total subjects who had confirmed participation in the presentation study. Differences in compliance across age, sex or practice groups/area will be assessed using mixed-effect analyses with GP practice as a random effect; Pearson chi-square test and multiple logistic regression.
Sub-task WP6/02/03: Under-ascertainment in Cohorts 1 and 2 will be investigated by comparing frequency of IID diagnosis in the GP presentation study files with that ascertained in the WP8 study. This will also be used to assess the likely contribution of unmeasured GP practice variation on ascertainment. Factors influencing under-ascertainment will be investigated using multiple logistic regression in a mixed effect framework (i.e. generalised linear mixed-effects models with binomial error structure). The inverse of the predicted under-ascertainment from this model will be used as a multiplier

for the number of cases reported in each practice, taking into account the practice characteristics and intra-class correlation from the mixed effects models.
Sub-task WP6/02/04: GP list inflation factors will be calculated for Cohorts 1 and 2 based on ineligible people (died, moved away or living away) in the practice population identified during cohort recruitment.

Task WP6/03: Methods to estimate number and seasonality of cases of IID in the population, contacts with NHS Direct, and presentation to GP, by IID (Figure 9)
We will exploit the hierarchical structure of patients within GP practice as our modelling framework. All analyses of incidence of individual IID pathogens will be based on results from PCR analyses (WP4), positive samples for which will be subject to culturing, to allow comparison with IID1 and IID2.
Sub-task WP6/03/01: ***The incidence rate of IID in the community*** will be calculated from the total number of cases reported in the population (Cohort 1; WP2) and the follow-up time of members of the cohort. We will quantify seasonality using harmonic regression whilst assessing the extent to which seasonal patterns vary across practices. Seasonal variation in the data will be removed through detrending, and factors that drive residual non-seasonal disease variation determined through (generalised) linear mixed-effects models [16,17]. If there is any remaining temporal autocorrelation in the data, this will be adjusted for using autoregression [16].
Sub-task WP6/03/02: The incidence rate of IID presenting to the GP (Cohort 2; WP3) will be calculated from the total number of cases reported in the presentation and enumeration components (Cohort 2 and Cohort 3; WP3) and the follow-up time of all persons registered in the practice populations. Adjustments will be made to the numerator and denominator of the GP presentation rates to adjust for under ascertainment and list inflation. Information on individual patient symptoms will be incorporated into the analyses as appropriate; anonymised data from WP2 and WP3 via the Trusted Research Environment (TRE).

Task WP6/04: Determine role of individual pathogens where number of confirmed cases is sufficient (Figure 10)

Sub-task WP6/04/01: Comparison of incidence from pathogen culture. All stool samples identified from Cohorts 1 and 2 as positive by PCR to any of the pathogens will be cultured (WP4). We will used this to compare frequency of organism by PCR and culture methods and allow direct comparison with the results of IID1 and IID2 (see also Subtask WP6/05/01). For each target organism investigated, the percentage identified will be calculated only from the stools that reached the required stage of testing for that organism. For organisms for which more than one method is used, sensitivity and specificity of new method compared to old method will be estimated for samples tested using both methods and compared through ROC plots and AUC.

Sub-task WP6/04/02: Number of cases by organism. For Cohorts 1 and 2 age and seasonality incidence will be estimated for each target organism using denominators derived from the age/sex registers of the study practices and the sampled population (WP2 and WP3). Organism-specific incidence rates will be calculated from the number of cases with each target organism identified, regardless of whether other organisms were present in the same sample. Under-ascertainment will be assumed to be the same for all organisms. Rates will be adjusted for non-compliance in submitting stool samples, using the overall compliance data (WP2). This assumes that non-compliant cases have the same identification rate for each organism as compliant cases. Calculation of confidence intervals will be adjusted to ensure that there is no increase the apparent precision due to this correction for non-compliance.

Sub-task WP6/04/03: Detection of drivers of disease outbreaks. We anticipate over-dispersion in the datasets from Cohorts 1 and 2 with excess zeroes relative to actual disease events. This will require use of zero-inflated poisson (ZIP) and zero-inflated negative binomial (ZINB) mixed-effect models to investigate potential causative factors that affect disease outbreaks [18]. As before GP practice will be used as a random effect. We will use the models to predict GP presentation rates with the associated variation due to GP random effects. Analysis will be based on episodes rather than

subjects, assuming each episode to be independent unless the ZINB models provide a better model for the presentation of disease. Exceptions might include contagious IID such as norovirus.
Sub-task WP6/04/04: Surveillance pyramids. These will be calculated from the overall incidence rates in the community and presenting to GPs by considering the ratios between these rates and their respective CIs. This will be achieved by spatial micro-simulation. Each stage in the pyramid leads to an estimate of incidence of each pathogen or disease, with associated confidence intervals requiring adjustments for heterogeneous ascertainment. We will use simulation to draw samples from each stage of the pyramid, constrained by the 95% CI and appropriate frequency distribution and project them through to predict population levels of disease estimating CI on the final sets of simulations. The ratio of community rates to nationally reported cases will be calculated by projecting the overall cohort and presentation incidence rates to the population and comparing these to that reported to the laboratory reporting surveillance system over the same period. When more than one laboratory method was used, these will be estimated separately for results from both methods, for comparison with the first IID and as baseline for the future.

Figure 10: Determine the role of individual pathogens

Task WP6/05: Methods to compare aetiology of IID and surveillance pyramids by organism for England using data from the first, second and third IID studies (Figure 11)
Sub-task WP6/05/01: Incidence rates and presentation rates (overall for IID and by target organism) will be compared between IID1, IID2 and the new IID3, based on the incidence in the (current) study estimated using the laboratory methods used in the first study; changes in incidence in the community and presentation to GPs will be estimated, together with their associated 95% CIs.
Sub-task WP6/05/02: Three key components of the surveillance pyramids will be compared between IID1, IID2 and the new IID3: overall incidence rates in the community, presentation to GPs, reported to the laboratory surveillance system. Comparisons will be made on a simple comparison of the ratios between these ratios. Performing the same calculation on the upper and lower confidence intervals for each ratio will derive the upper and lower sensitivity bands.
Sub-task WP6/05/03: Molecular data that were used to derive some of the surveillance pyramids calculated in IID1 and IID2 used different molecular methods to those available for IID3. The surveillance pyramid for IID3 can be re-calculated on the assumption that the molecular methods available in the past using different targets are currently being used. This will allow a more direct comparison with the new IID3 surveillance, with the original ones for IID1 and IID2.

Task WP6/06: Annual rates of IID in the community, presenting to GPs and in the enumeration study (from WP2 and WP3) (Figure 12)

These will be estimated separately, after adjustment for refusals and for seasonality, separately by age, sex and other relevant variables for each of the four countries with 95% confidence intervals. We will estimate annual rates of IID in the community as reported using the "Poo-App" developed in WP8. We will compare incidence data for this and the GP presentation and enumeration studies to assess the extent to which a citizen science approach can be used to collate information on IID. We anticipate that the citizen science community utilising the app will have a different socio-demographic profile to the GP data sets and will use age and gender to assess differences in the reporting mechanism. In addition, we will assess the extent to which this methodology over or under-estimates IID.

Sub-task WP6/06/01: The proportion of cases of IID reporting having presented to GP or contacting NHS111 (Cohort 2 and Cohort 3; WP3) will be estimated separately by age, and sex for each of the four countries.

Sub-task WP6/06/02: The rates of IID in the community and presenting to GP will be estimated for each Northern Ireland, Scotland and Wales by applying the inverse of telescoping factor estimated in England (and assuming this is the same for the other countries) to the estimates of IID from the telephone survey in each of the countries, separately by age and sex.

Task WP6/07: Pilot Study analysis
Analyses will be undertaken at the end of the pilot study.

Task WP6/08: Mid-project analysis
Analyses will be undertaken half-way through the main study period to provide the Food Standards Agency with provisional surveillance pyramids.

Task WP6/09: Final analysis
The primary responsibility for the statistical analyses rests with Newcastle, in collaboration with the RCGP RSC at Oxford, the University of Liverpool and Public Health England (PHE).

References:

16. Brainard, J., Rushton, S.P, Winters, T., Hunter, P.R. (2020) Introduction and spread of COVID-19-like illness in care homes in Norfolk, UK, Journal of Public Health, doi:10.1093/pubmed/fdaa218
17. Rushton SP, Sanderson RA, Diggle PJ, Shirley MDF, Blain AP, Lake I, Maas JA, Reid WDK, Hardstaff J, Williams N, Jones NR, Rigby D, Strachan NJC, Forbes KJ, Hunter PR, Humphrey TJ, O'Brien SJ. Climate, human behaviour or environment: individual-based modelling of Campylobacter seasonality and strategies to reduce disease burden. J Transl Med. 2019 Jan 21;17(1):34. doi: 10.1186/s12967-019-1781-y.
18. Sanderson, RA., Maas, JP, Blain, AP, Gorton, R, Ward, J, O'Brien, SJ, Hunter, PR and Rushton, SP. Spatio-temporal models to determine association between Campylobacter cases and environment. International Journal of epidemiology 47(1), 202-2162

C. DELIVERABLES

Please outline the proposed project milestones and deliverables. Please provide a timetable of key dates or significant events for the project (for example fieldwork dates, dates for provision of research materials, draft and final reporting, deposition of data into a publicly accessible depository). Deliverables must be linked to the objectives.
For larger or more complex projects please insert as many deliverables /milestones as required.
Each deliverable should be:

i. no more 100 characters in length
ii. self-explanatory
iii. cross referenced with objective numbers i.e. deliverables for Objective 1 01/01, 01/02 Objective 2 02/01, 02/02 etc

Please insert additional rows to the table below as required.

A final deliverable pertaining to a retention fee of 20 % of the total value of the proposed work will automatically be calculated on the financial template. This will be paid upon acceptance of the final report and deposition of all relevant datasets to a publicly accessibly repository.		
DELIVERABLE NUMBER OR MILESTONE IN ORDER OF EXPECTED ACHIEVEMENT	**TARGET DATE**	**TITLE OF DELIVERABLE OR MILESTONE**
M 01/01	31/10/21	Project initiation meeting
M 01/02	31/01/22	Ethics submission to Health Research Authority (HRA)
M 01/03	31/01/22	IID3 Study Executive Committee Meeting
D 01/01	**28/02/22**	**Summary report to the FSA on HRA submission**
M 02-05/01	30/04/22	Secure TRE access to relevant IID3 Study consortium members
M 02-05/02	01/05/22	Start of pilot prospective studies
D 01/02	**31/05/22**	**Draft publication and dissemination strategy submitted to FSA**
M 02-05/03	31/07/22	Analyses of pilot prospective studies starts
M01/05	31/07/22	IID3 Study Executive Committee Meeting
D 02-05/01	**31/08/22**	**Pilot studies report to FSA**
		BREAK POINT – ALLOW ONE MONTH
M 01/06	30/09/22	1st Annual IID3 Study Conference
M 02-05/04	01/10/22	Start of main prospective studies
M 01/07	31/10/22	IID3 Study Executive Committee Meeting
D 02-05/02	**30/11/22**	**Summary report on GP practice recruitment**
M 01/08	31/01/23	IID3 Study Executive Committee Meeting
D 02-06/01	**28/02/23**	**Draft analytical strategy for prospective studies submitted to FSA**
M 01/09	30/04/23	IID3 Study Executive Committee Meeting
D 02-05/03	**31/05/23**	**Summary report on GP practice and participant recruitment submitted to FSA**
M 01/10	31/07/23	IID3 Study Executive Committee Meeting
D 02-05/04	**30/09/23**	**Mid-project report on prospective studies to FSA**
M 01/11	30/09/23	2nd Annual IID3 Study Conference
		BREAK POINT – ALLOW ONE MONTH
M 01/12	31/10/23	IID3 Study Executive Committee Meeting
M 02-06/01	01/11/23	Collation of UK surveillance data starts
M 01/13	31/01/24	IID3 Study Executive Committee Meeting
D 02-06/02	**28/02/24**	**Progress report on prospective studies submitted to FSA**
M 01/14	30/04/24	IID3 Study Executive Committee Meeting
D 02-06/03	**31/05/24**	**Progress report on prospective studies submitted to FSA**
M 01/15	31/07/24	IID3 Study Executive Committee Meeting
M 01/16	30/09/24	3rd Annual IID3 Study Conference
M 02-06/02	30/09/24	Main prospective studies completed

M 02-06/03	30/09/24	Collation of UK surveillance dataset up to date and complete
M 02-06/04	31/10/24	Lock prospective study and UK surveillance datasets for final analyses
M 01/17	31/10/24	IID3 Study Executive Committee Meeting
D 02-05/05	**30/11/24**	**Summary report on prospective study recruitment submitted to FSA**
M 01/18	31/01/25	IID3 Study Executive Committee Meeting
M 01/19	30/04/25	IID3 Study Executive Committee Meeting
D 02-08/01	**30/04/25**	**Penultimate draft of IID3 Study report submitted to FSA**
D 02-08/02	**30/06/25**	**Final report draft submitted to FSA**
M 01/20	31/07/25	IID3 Study Executive Committee Meeting
M 01/21	30/09/25	4th Annual IID3 Study Conference
D 02-08/03	**30/09/25**	**IID3 Study data deposited in publicly available archive**
D 02-08/04	**30/09/25**	**IID3 Study samples bio-banked**
D 02-08/05	**30/09/25**	**Validated statistical models with instruction manuals available for FSA use**
D 02-08/06	**30/09/25**	**Final IID3 Study report agreed**

3: ORGANISATIONAL EXPERIENCE, EXPERTISE and STAFF EFFORT

A. PARTICIPATING ORGANISATIONS' PAST PERFORMANCE

Please provide evidence of up to three similar projects that the project lead applicant and/or members of the project team are currently undertaking or have recently completed. Please include:

- The start date (and if applicable) the end date of the project/(s)
- Name of the client who commissioned the project
- Details of any collaborative partners and their contribution
- The value
- A brief description of the work carried out.
- How the example(s) demonstrate the relevant skills and/or expertise.
- What skills the team used to ensure the project (s) were successfully delivered.

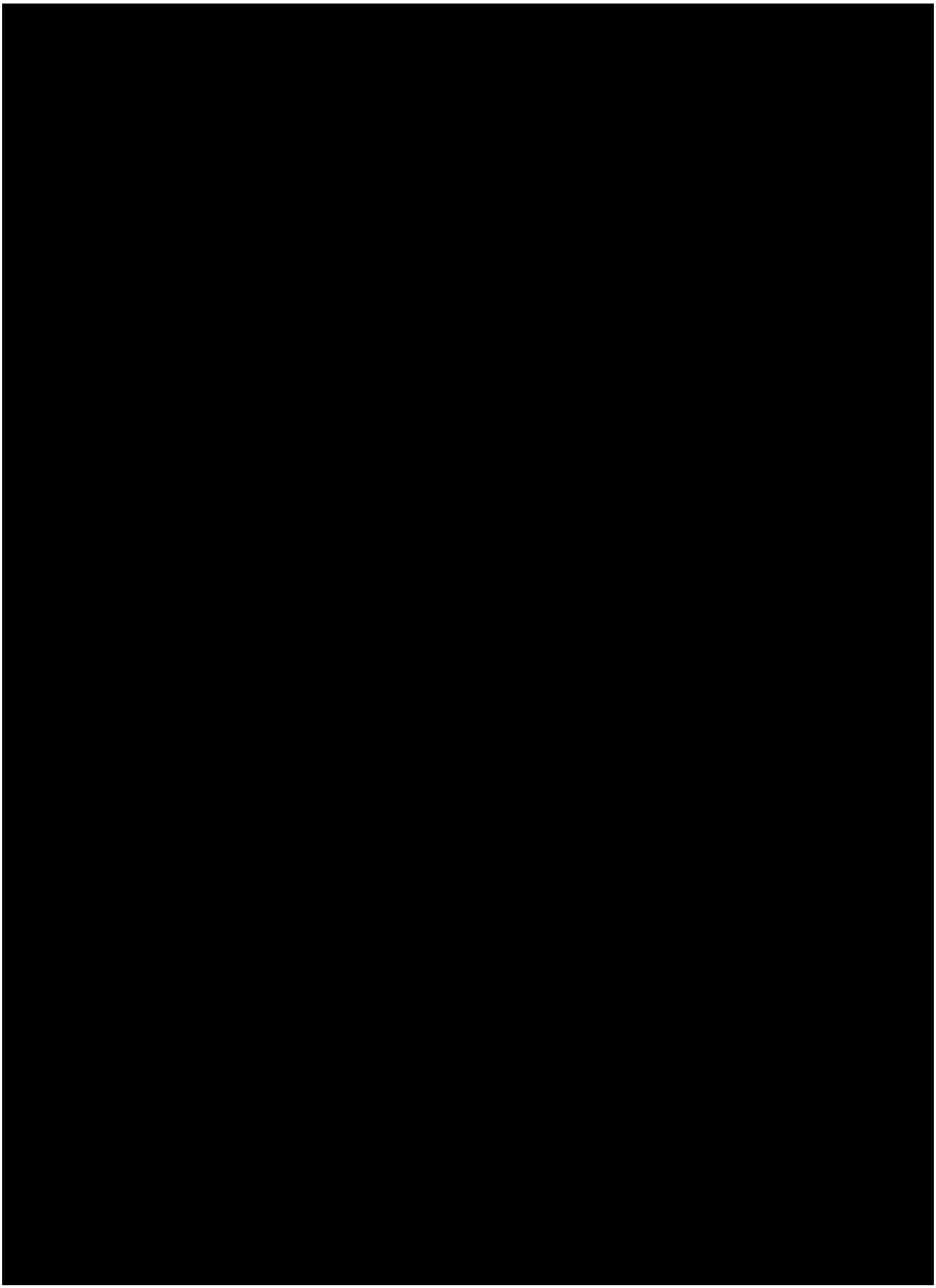
[redacted]

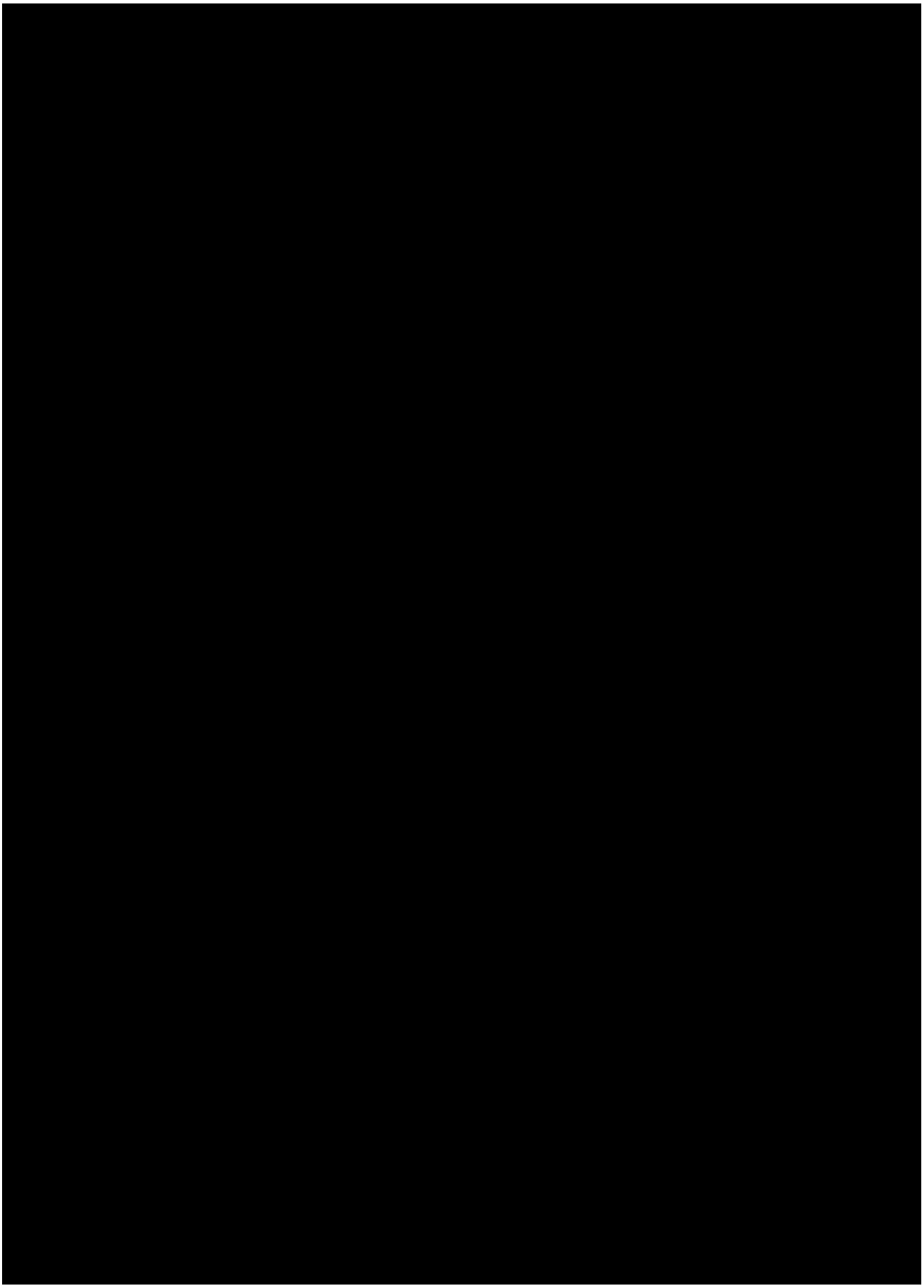
[redacted]

B. NAMED STAFF MEMBERS AND DETAILS OF THEIR SPECIALISM AND EXPERTISE

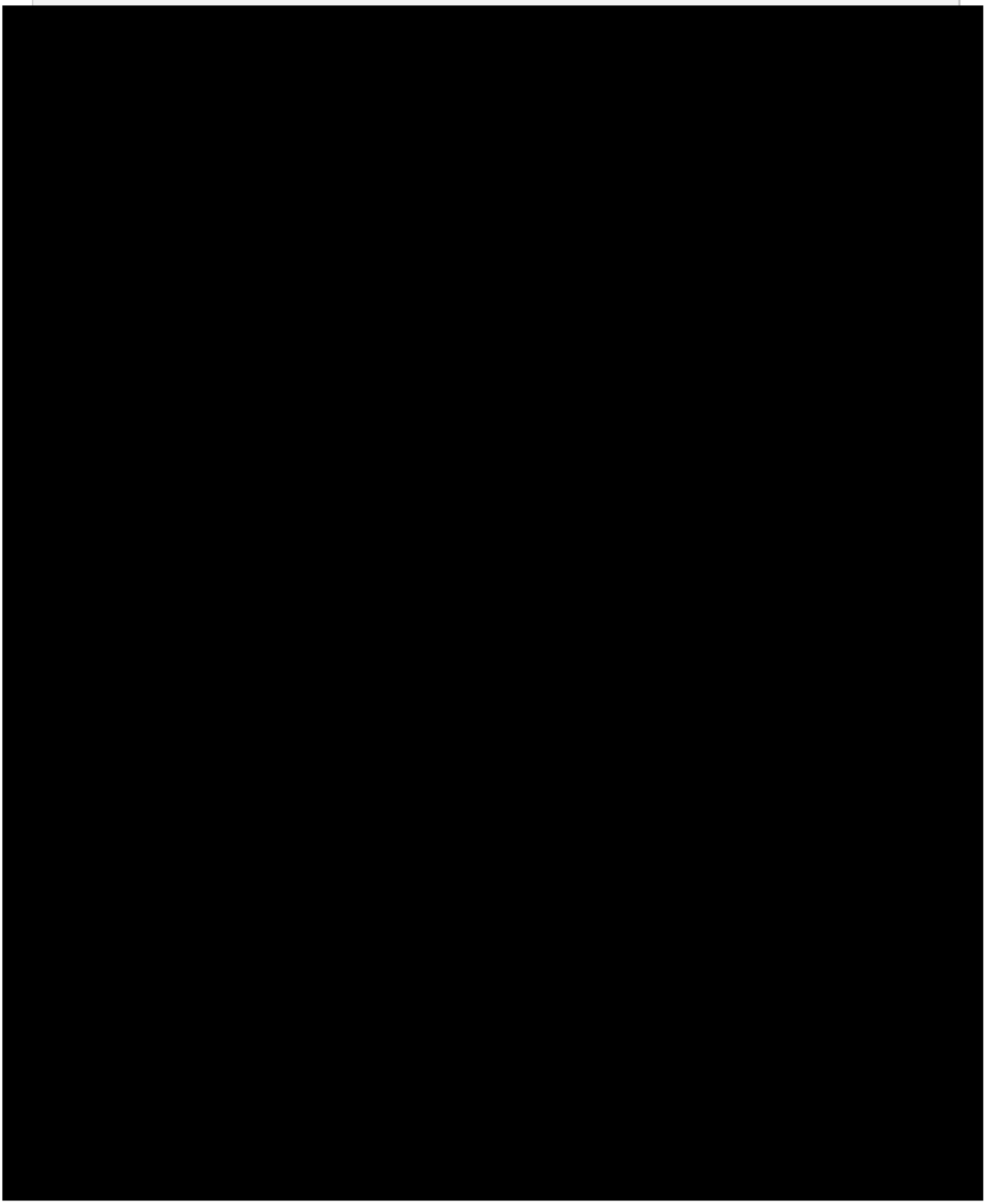
For each participating organisation on the project team please list:- the names and grades of all staff who will work on the project together with details of their specialism and expertise, their role in the project and details of up to 4 of their most recent, relevant published peer reviewed papers (where applicable). If new staff will be hired to deliver the project, please detail their grade, area/(s) of specialism and their role in the project team.

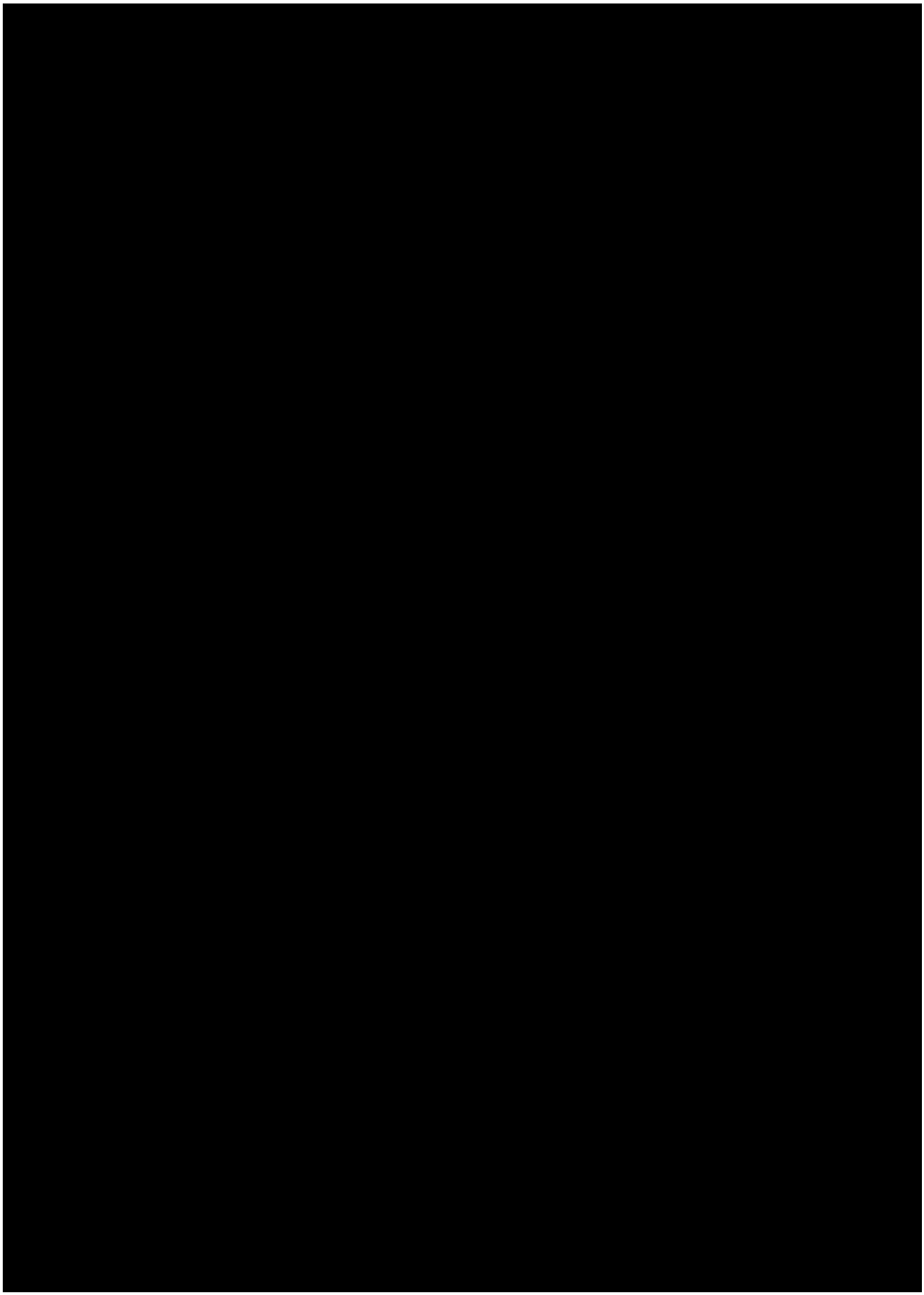
Lead Applicant	Newcastle University





Specialism: Administrative and clerical **Role in project:** Contribution to WP1 assisting Research Programme Manager and PI	
Participant Organisation 1	UK Health Security Agency (Public Health England)





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Participant Organisation 2	University of Oxford

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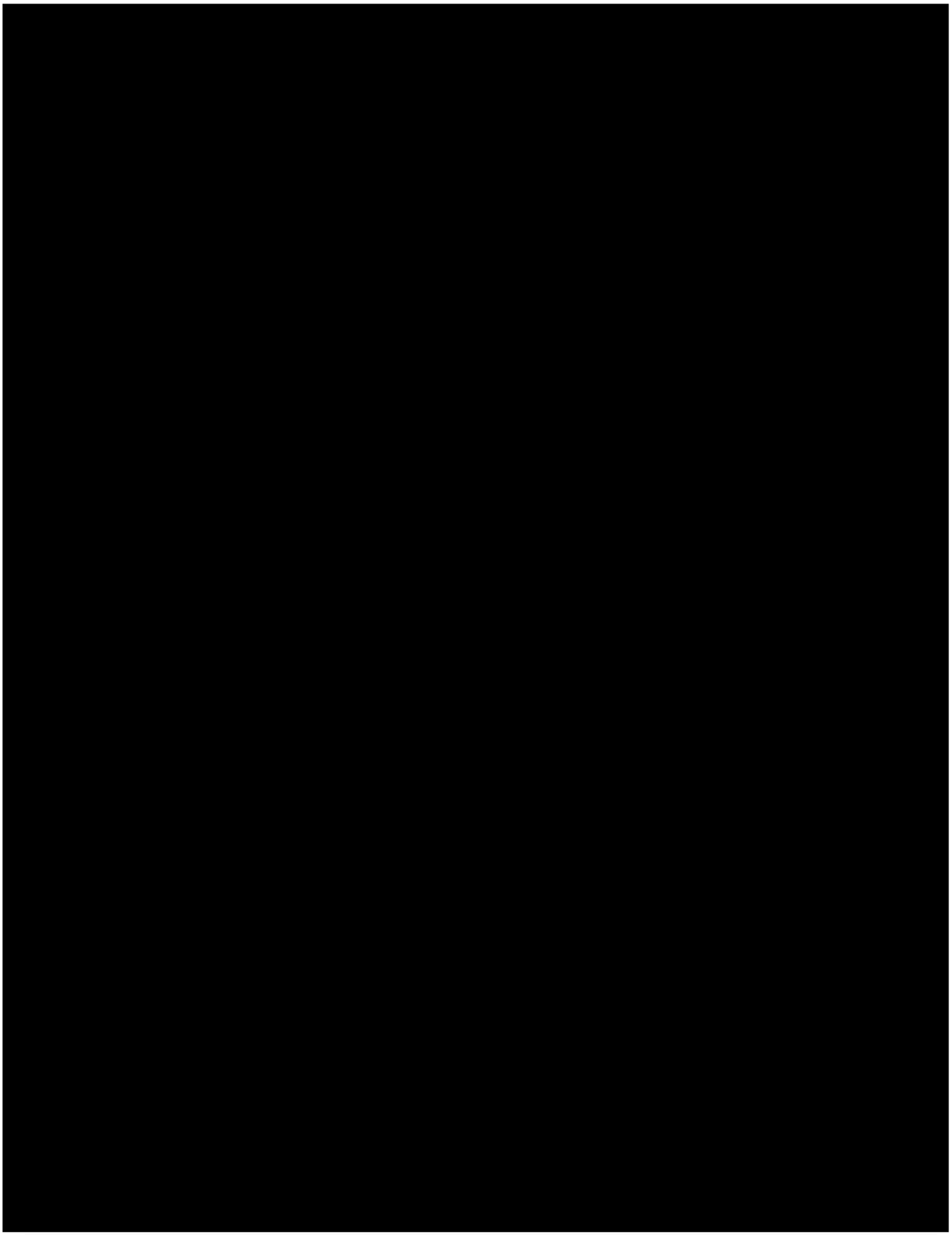
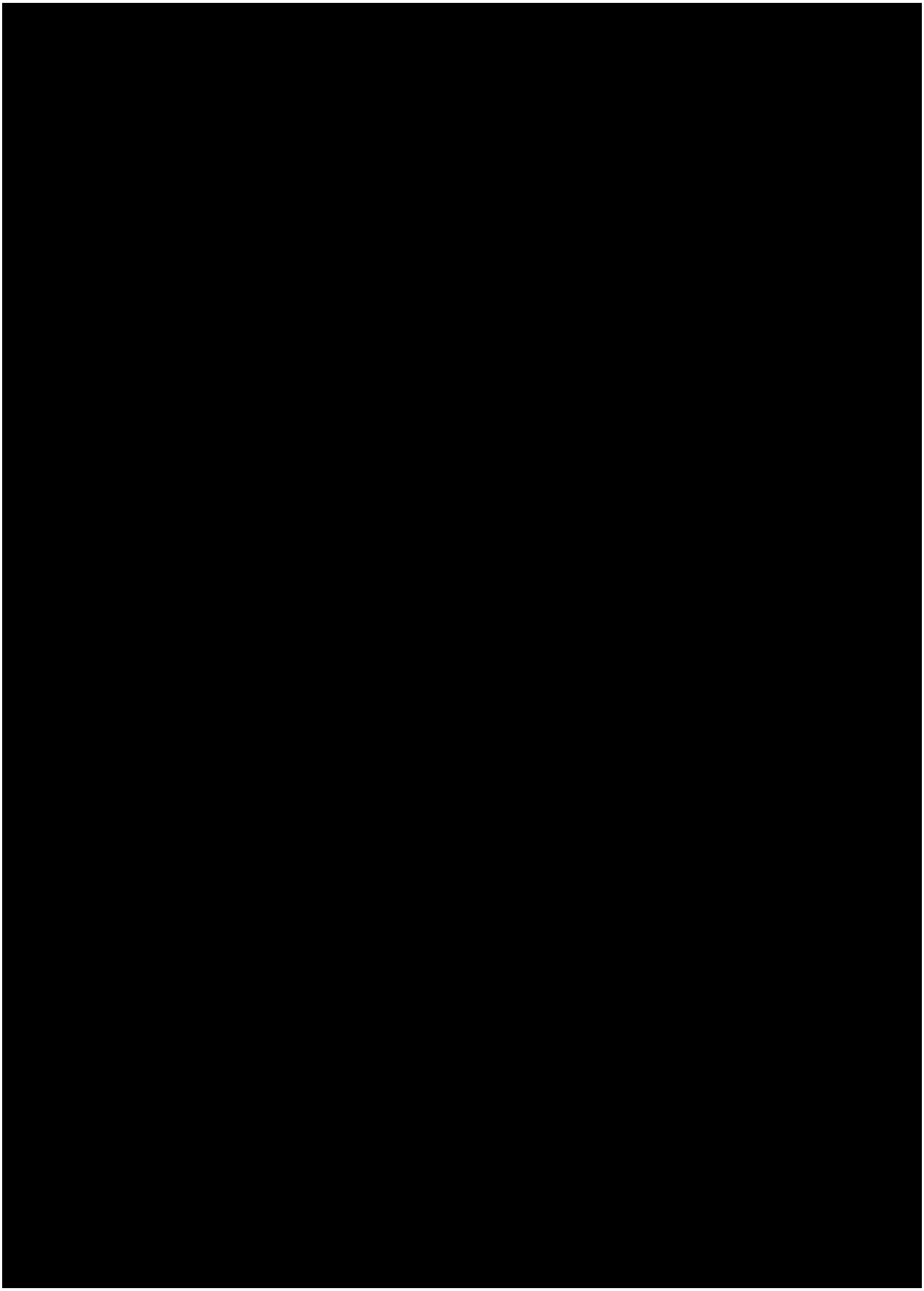


Participant Organisation 3	University of Liverpool
Named staff members, details of specialism and expertise.	



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Participant Organisation 4	Liverpool Clinical Laboratories
Named staff members, details of specialism and expertise	

[redacted]

[redacted]

Participant Organisation 5	Public Health Scotland
Named staff members, details of specialism and expertise.	

[redacted]

Participant Organisation 6	Public Health Wales
Named staff members, details of specialism and expertise.	

[redacted]

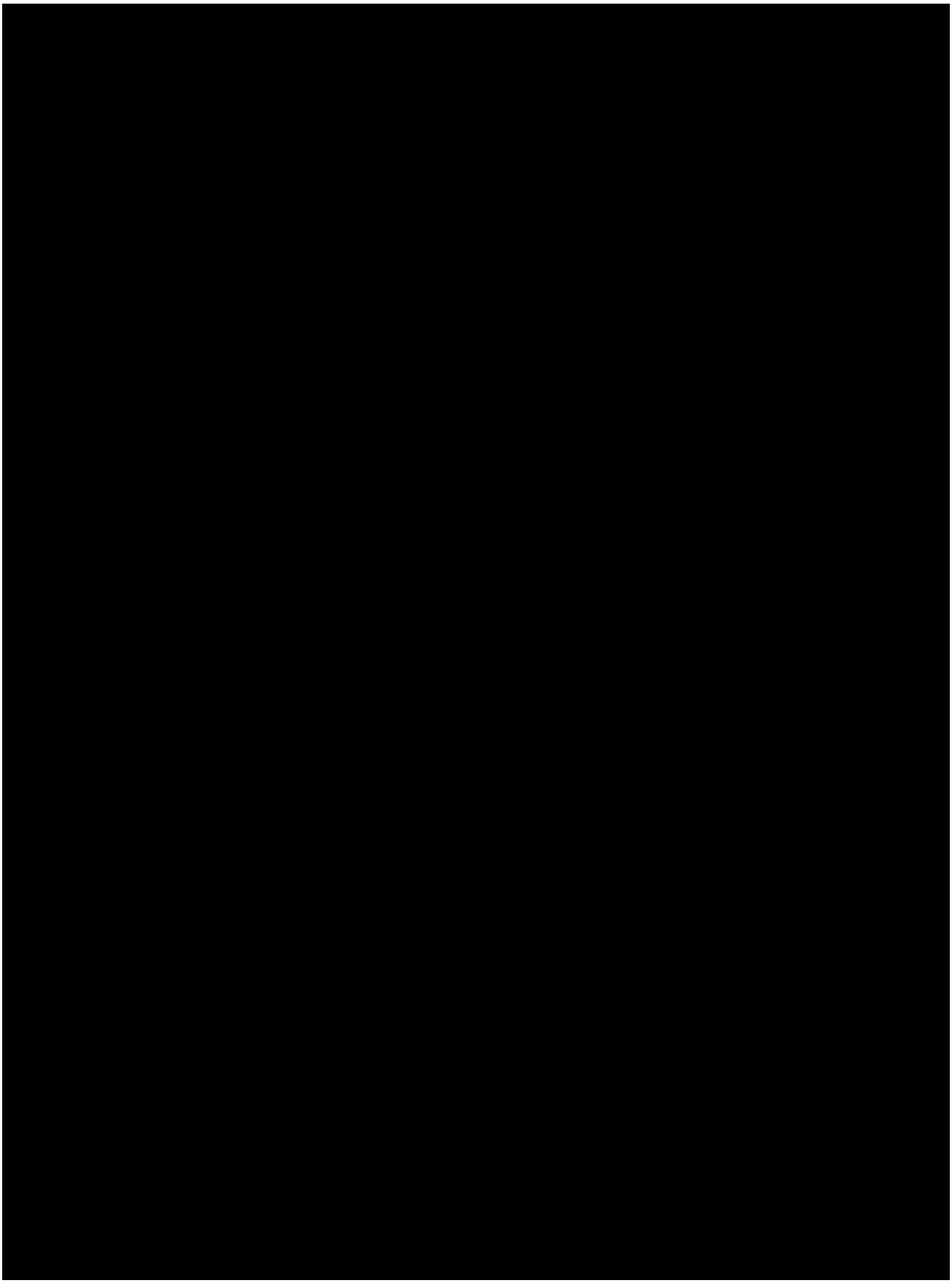
[redacted]

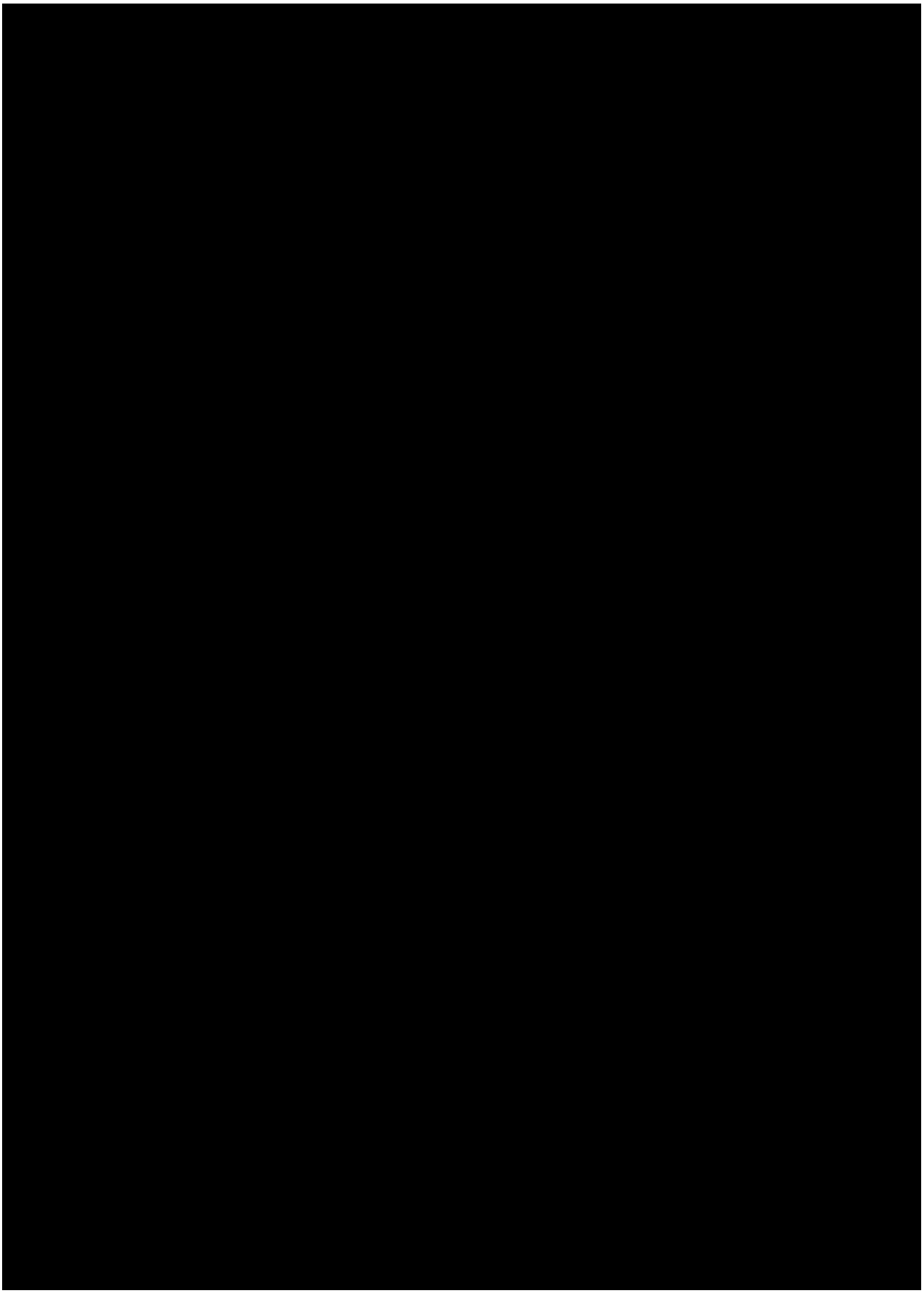
C. STAFF EFFORT

In the table below, please detail the staff time to be spent on the project (for every person named in section above) and their role in delivering the proposal If new staff will be hired in order to deliver the project please include their grade, name and the staff effort required.

Name and Role of Person where known/Role of person to be recruited.	Working hours per staff member on this project Note: This is based on 227 working days per year and an 8-hour working

[redacted]





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5: PROJECT AND RISK MANAGEMENT

A. PROJECT MANAGEMENT

Please fully describe how the project will be managed to ensure that objectives and deliverables will be achieved on time and on budget. Please describe how different organisations/staff will interact to deliver the desired outcomes.
Highlight any in-house or external accreditation for the project management system and how this relates to this project.

The project management plan should be read in conjunction with WP1.

1. Organisations involved

The study will be managed through a formal collaboration agreement between the following organisations:-
Newcastle University [redacted]
Public Health England [redacted]
The University of Oxford/Royal College of General Practitioners Research and Surveillance Centre (RSC) [redacted]
The University of Liverpool [redacted]
Liverpool Clinical Laboratories [redacted]
Health Protection Scotland [redacted]
Public Health Wales [redacted]

Most of the Work Package and/or Site Leaders have worked together successfully over at least two decades delivering complex, multidisciplinary research programmes where the Principal Investigators have been geographically distributed. Examples include the NIHR Health Protection Research Unit in Gastrointestinal Infections, the NIHR Health Protection Research Unit in Genomics and Enabling Data, and the Second Study of Infectious Intestinal Disease in the community (IID2 Study).

2. Oversight of the study

The study will be overseen by an Executive Committee (IID3EC), which will meet quarterly to monitor the progress of all aspects of the study, to advise on strategic and scientific issues and to oversee a risk register, advising on risk management strategies as necessary. Membership will include the Work Package Leaders involved in delivering the study, Site Leaders (where they are not also Work Package Leaders), and representation from the Food Standards Agency. We anticipate that the FSA will wish to send its Project Officer(s), and additional representatives from the Science, Evidence and Research Division (SERD).

Where a WP or Site Leader is unavailable for a planned meeting, they should nominate a deputy to attend on their behalf.

WP Leaders will report progress to the IID3EC on a quarterly basis. Key aspects will include general practice recruitment, recruitment to cohorts 1 and 2, case ascertainment, compliance with questionnaire completion and stool sample submission. It is envisaged that three IID3EC meetings per year will be held virtually with the fourth being a conference of all IID3 Study investigators held over two days (locations to be determined).

An External Advisory Panel will be appointed in consultation with the Food Standards Agency. It is envisaged that the EAP will comprise up to six international experts and two lay members. The EAP will

be invited to the annual conference, as will FSA Project Officer(s), and additional representatives from SERD.

An IID3 Study Monitoring Group will be established and will meet frequently to monitor progress of all elements of the study, including compliance practice by practice and within the laboratories. Meetings will be held via tele-/videoconference. The FSA Project Officer(s) will be invited to attend.

3. Roles and responsibilities of Partner Organisations

The roles and responsibilities of Partner Organisations are summarised in Figure 14 overleaf.

The roles of lead and participating organisations by task are described below. Leadership roles are highlighted in bold.

Lead Applicant – Newcastle University
The objectives for Newcastle University are:-
a) Managing and co-ordinating of all work within the project (**WP1**)
b) Epidemiological study design (WP2, WP3, WP4, **WP5**)
c) Leading the analytical strategy (**WP6**)
d) Leading data analyses and interpretation (**WP6**)

Lead role:-
Tasks WP1/01 to WP1/10
Tasks WP5/01 to WP5/02
Tasks WP6/01 to 09

Collaborative role:-
Task WP2/01 – Sub-tasks WP2/01/01; WP2/01/02
Task WP2/06
Task WP2/07
Task WP2/08
Task WP3/01 – Sub-tasks WP3/01/01; WP3/01/05; WP3/01/06
Task WP3/02
Task WP3/03

Task WP3/04
Task WP4/03
Task WP4/04

Participating Organisation 1 – UK Health Security Agency (Public Health England)
The objectives for the UKHSA are:-
a) Undertaking reference and specialist diagnostic microbiological work (**WP4**)
b) Estimating the proportion of cases reported to national surveillance in England, Northern Ireland and Wales (WP5)
c) Interpretation of data analyses (WP6)

Lead role:-
Task WP4/02 – Sub-tasks WP4/02/01; WP4/02/03
Task WP4/03
Task WP4/04

Collaborative role:-
Task WP1/01
Task WP1/04
Task WP1/05
Task WP1/07
Task WP1/08
Task WP1/09
Task WP1/10
Task WP2/01 to WP2/08
Task WP3/01 to WP3/04
Task WP5/01
Task WP5/02
Task WP6/04 – Sub-tasks WP6/01/01; WP6/04/02; WP6/04/04
Task WP6/05 – Sub-tasks WP6/05/01; WP6/05/02; WP6/05/03
Task WP6/07
Task WP6/08
Task WP6/09

Participating Organisation 2 – University of Oxford
The objectives for the University of Oxford are:-
a) Epidemiological study design (**WP2, WP3**)
b) Conducting the prospective cohort study (**WP2**)
c) Conducting the GP presentation study (**WP3**)
d) Conducting the Enumeration study (**WP3**)
e) Interpretation of data analysis (WP6)

Lead role:-
Task WP2/01 to WP2/08
Task WP3/01 to WP3/04

Collaborative role:-
Task WP1/01
Task WP1/04
Task WP1/05
Task WP1/07
Task WP1/08
Task WP1/09
Task WP1/10
Task WP4/01

Task WP5/01
Task WP5/02
Task WP6/01 to WP6/09

Participating Organisation 3 – University of Liverpool
The objectives for the University of Liverpool are:-
(a) Microbiological study design (**WP4**)
(b) Creating a biobank (**WP4**)
(c) Interpretation of data analyses (WP6)

Lead role:-
Task WP4/01
Task WP4/03
Task WP4/04
Task WP4/05

Collaborative Role:-
Task WP1/01
Task WP1/04
Task WP1/05
Task WP1/07
Task WP1/08
Task WP1/09
Task WP1/10
Task WP2/01 to WP2/08
Task WP3/01 to WP3/04
Task WP6/04 – Sub-tasks WP6/01/01; WP6/04/02; WP6/04/04
Task WP6/05 – Sub-tasks WP6/05/01; WP6/05/02; WP6/05/03
Task WP6/07
Task WP6/08
Task WP6/09

Participating Organisation 4 – Liverpool Clinical Laboratories
The objectives for the Liverpool Clinical Laboratories are:-
(a) Undertaking primary diagnostic microbiology work (**WP4**)
(b) Interpretation of data analysis (WP6)

Lead Role:-
Task WP4/01
Task WP4/03
Task WP4/04

Collaborative role:-
Task WP1/01
Task WP1/04
Task WP1/05
Task WP1/07
Task WP1/08
Task WP1/09
Task WP1/10
Task WP2/01 to WP2/08
Task WP3/01 to WP3/04
Task WP4/02
Task WP4/05

Task WP6/04 – Sub-tasks WP6/01/01; WP6/04/02; WP6/04/04
Task WP6/05 – Sub-tasks WP6/05/01; WP6/05/02; WP6/05/03
Task WP6/07
Task WP6/08
Task WP6/09

Participating Organisation 5 – Public Health Scotland (PHS)
The objectives for PHS are:-
a) Contributing to the national surveillance study (WP5)
b) Interpretation of analysis (WP6)

Collaborative role:-
Task WP1/01
Task WP1/04
Task WP1/05
Task WP1/07
Task WP1/08
Task WP1/09
Task WP1/10
Task WP5/01 to WP5/02
Task WP6/01 to WP6/09

Participating Organisation 6 – Public Health Wales (PHW)
The objectives for PHW are:-
a) Undertaking reference microbiological work (**WP4**)
b) Contributing to the national surveillance study (WP5)
c) Interpretation of analyses (WP6)

Lead role:-
Task WP4/02 – Sub-task WP4/02/02
Task WP4/03
Task WP4/04

Collaborative role:-
Task WP1/01
Task WP1/04
Task WP1/05
Task WP1/07
Task WP1/08
Task WP1/09
Task WP1/10
Task WP5/01 to WP5/02
Task WP6/01 to WP6/09

We anticipate that WP meetings will be held monthly and that the FSA Project Officer(s) will be invited to attend all WP meetings.

4. Competence

The CVs of all personnel associated with the project will be held by the Project Lead Contractor. Training for newly appointed members of staff will be undertaken by senior members of the project team. Training records for all staff will be documented and maintained for the duration of the project.

5. Project Planning

A proposed project timeline containing detailed Gantt Charts is included as Appendix G. It is recognised that this is a large and complex project, and that timing is critical. Break points are proposed to allow a full stock-take at each stage of the project and before proceeding to the next stage.

A risk register will be developed and maintained throughout the lifetime of the project and reviewed both at weekly IID3 study management team meetings. The risk register will be a standing item on the agenda of the quarterly IID3 Study Executive Committee meetings. A password-protected secure study website will be set up and maintained for the duration of the study. Protocols for cohort recruitment will be developed by the University of Oxford/RSC. These documents will be held centrally on the study website as well as locally. Document handling and release procedures will be developed that will detail at what stage study documents might be disclosed, for example in response to a Freedom of Information Act request. The study will meet the requirements of the Data Protection Act, the General Data Protection Regulations and Health Research Authority procedures.

6. Quality Control (See also Section 7C)

6.1 Data Management and Processing
See Section 7C below. Data will be managed through a Trusted Research Environment at the University of Oxford.

6.2 Quality Assurance and Modelling (See also Section 7A)
We have drafted a Quality Assurance policy for the modelling work that will take place during the IID3 project. We will finalise this document at the IID3EC.

6.3 Internal Audit
An internal audit programme will be developed to ensure adherence to study protocols and procedures. The Project Manager will implement the internal audit programme and at least one aspect of the study will be audited once per quarter. Internal audit will be a standing item on the agenda of the IID3 Study Executive Committee.

6.4 Publication Policy (See also WP1 in Section B above)
A publication policy, including an authorisation process, will be developed and approved by the IID3 Study Executive Committee. This will cover material published on the study website, project reports (deliverables), the final project report, conference abstracts and peer-reviewed papers.

7. Health and Safety

The project will comply with existing Health and Safety legislation.

8. Handling of samples and materials

Protocols for sample collection, submission to the Liverpool Clinical Laboratories and submission of isolates/material to Public Health England will be developed. This will include procedures for members of the public collecting samples and laboratory staff receiving samples.

9. Facilities and Equipment

All equipment used during the project will be maintained and calibrated according to existing maintenance schedules and manufacturers' instructions. Maintenance and calibration records will be available for inspection.

10. Documentation of procedures and methods (See also WP1, WP4 in Section B above)

Standard Operating Procedures related to all aspects of recruitment, sample handling, data entry and validation, and publication will be developed and held on the study website.

11. Research/work records (See also WP4 in Section B above)

Checks will be inserted at all phases of data collection and processing. This will include countersignatures in laboratory notebooks and indexing of computer data-files. This will mean that the originator of all study records will be available at every stage of data handling and processing.

B. RISK MANAGEMENT

In the table provided, please identify all relevant risks in delivering this project on time and to budget. Briefly outline what steps will be taken to minimise these risks and how they will be managed by the project team. Please add more lines as required

Identified risk	Likelihood of risk (high, medium, low)	Impact of Risk (high, medium, low)	Risk management strategy
Work Package 1			
Start date delayed	Medium	High	1. Complete contractual paperwork with the FSA promptly
Collaboration Agreement delayed	High	High	1. Check status of collaboration agreement with Newcastle Contracts Office at fortnightly intervals 2. Ensure that Newcastle Contracts Office chases partners at fortnightly intervals 3. Negotiate to extend the breakpoint with the FSA
Pandemic, national or regional outbreak e.g. COVID-19	Medium/High	High	1. Ensure bio-secure workplace, with strict hygiene, 'bubbles' and regular testing 2. Work from home where possible and/or virtual meetings 3. Suspend study for the duration with agreement of FSA
Budget not does not align with proposal	Medium	High	1. Monitor expenditure closely 2. Review budget regularly 3. Agree with FSA to move money between budget lines if necessary 4. Avoid delays to project
Incorrect collaborator invoices submitted	High	Medium	1. All collaborators issued payment schedule 2. Project Manager notify collaborators with deliverable numbers and all invoice details required. 3. Process at Newcastle immediately on arrival. 4. Notify collaborators of any problems asap.
Key appointments not made	Medium	High	1. Finalise job descriptions as soon as contract is signed. 2. Advertise posts nationally to secure the best possible field of candidates. 3. Contingency plans for key appointments in the event of failure to fill posts.
Key appointees leave post early	Medium	High	1. Ensure project report submitted to FSA before end date 2. Contingency plans for key appointments in the event that they leave post early. 3. Documentation on retention and redeployment of staff 4. Ask existing staff to work out-of-hours 5. List of deputies maintained 6. Good HR policy 7. Good internal communications

			8. Ensure that preparation of final report and peer-review publications commence as early as possible.
Key staff on sick leave	Medium	High	1. Maintain list of deputies who are familiar with the study 2. Website regularly updated with information to permit familiarisation with the study 3. All Principal investigators, in consultation with FSA will decide how to proceed.
Breaches of Study Protocol	Medium	High	1. Internal audit programme 2. Detailed study protocols 3. Standard Operating Procedures 4. Compliance with Research Management & Governance 5. Compliance with Ethics 6. Document control system
Failure of data management systems	Low	High	1. Regular backup of database to be created 2. Strict cyber-security protocols implemented plus relevant software updates
Failure to maintain data confidentiality	Low	High	1. Comply with Data Protection Act and General Data Protection Regulations 2. Use Trusted Research Environment at the University of Oxford 3. Follow protocols for protecting patient identifiable information (PII)
Work Package 2 (Cohort 1)			
Failure to recruit sufficient practices	Medium	High	1. Publicise study as soon as ethical approval secured 2. Prepare inviting study information materials 3. Remuneration for practices 4. NIHR Portfolio registration
Failure to recruit sufficient participants	Medium	Medium	1. Invite large initial pool of potential patients to participate 2. Timely follow-up of non-responders 3. Re-recruit if necessary
Response rate to cohort study lower than expected	Medium	High	1. Monitor response rate weekly 2. Build in regular feedback to maintain particpants 3. Provide frequent feedback to participants 4. Consider increasing sample size if necessary 5. Consider second wave of recruitment
High drop-out rate from cohort	Medium	High	1. Monitor participation rate weekly 2. Re-recruit if necessary
Time delay in samples reaching LCL	Low	High	1. Weekly monitoring to assess any delays
Uneven demographic spread of participants			1. Ensure good distribution of practices 2. Weight results if necessary
Work Package 3 (Cohort 2)			
As for Work Package 2 plus			
Failure to recruit sufficient participants	Medium	High	1. NIHR Portfolio adoption 2. Increase number of GP practices 3. Increase the number of people invited
Stool samples refused	Medium	High	1. Clear study material

Work Package 4 (Microbiology)			
Assay failures	Low	High	1. Use of commercial, fully validated assays 2. High level of expertise available 3. Inclusion of controls at all levels 4. Audit
Kit manufacturer goes out of business, stops or changes kits	Low	High	1. Go back to 10% suspensions and re-test all samples using new kits 2. Use kits in general use from reputable company. 3. Batch purchase 4. Internal Quality Control 5. Documentation and traceability in lab
Problem or breakdown of Containment Level 3 facilities	Low	Low	1. Transfer most work to Containment Level 2
Equipment failure including loss of archive	Low	High	1. Freezer alarmed 2. Freezer monitored each working day 3. Back-up available 4. Service continuity planning 5. Duplicate equipment available 6. Maintenance contracts on all equipment
LCL closes due to problems	Low	High	1. Contingency arrangements to move work to another laboratory
Serious laboratory incident	Low	High	1. Adequate level of safety and quality of infrastructure 2. Compliance with JCoPR
Laboratory acquired infection	Low	High	1. Staff training 2. PPE available, hygiene measures 3. Containment Level 3 facilities available 4. Relevant immunisations given
Work Package 5 (Calibration Study)			
Data provided late for analysis	Low	High	1. Agree in detail with the national surveillance teams the timing and format of the data needed 2. Develop data specifications/protocols with preliminary tests. 3. Maintain regular contact with the national surveillance teams.
Work Package 6 (Analysis)			
Failure to access patient RCSP RSC data for Cohort 3	Low	Low	1. Develop protocol and interact directly with RCGP RSC at early stage of project
Failure to access patient meta- data (cohorts 1,2,3)	Low	High	1. Re-evaluate and data collation protocol 2. Regular testing of data processing pipeline including pilot studies
Failure to detect IID in cohorts 1 and 2	Low/Medium	High	1. Increase recruitment after pilot study
Failure to link microbiological data with cohort data	Low	High	1. Re-evaluate protocol for data flow
Failure to identify appropriate error models for analyses in WP6	Low	Medium	1. Develop alternative error models and use Bayesian approaches
Data provided late for analysis – Pilot Study	Low	High	1. Analyse according to schedule for Pilot Study. 2. Validation and Enumeration studies – analyse early

Data provided late for analysis – Main Study	Medium	High	1. Weekly monitoring of data 2. Regular contact with National Surveillance Leads
Mis-match between different potential analytical methods	Low	Medium	1. Draft and sign-off analysis plan agreed by all

7. QUALITY MANAGEMENT

A. QUALITY MANAGEMENT

Please provide details of the measures that will be taken to manage and assure the quality of work. You should upload your Quality Assurance policy in the supporting documents section of your application.

This should include information on the quality assurance (QA) systems, which have been implemented or are planned, and should be appropriate to the work concerned. All QA systems and procedures should be clear and auditable, and may include compliance with internationally accepted quality standards specified in the ITT e.g. ISO 9001 and ISO17025. It must include details on the quality assurance and version control methods of any models created as part of the project.

Specific to science projects and where relevant, applicants must indicate whether they would comply with the Joint Code of Practice for Research (JCoPR). If applicants do not already fully comply with the JCoPR please provide a statement to this effect to provide an explanation of how these requirements will be met. The FSA reserves the right to audit projects against the code and other quality standards

The lead principal investigator is responsible for all work carried out in the project; (including work supplied by sub-contractors) and should therefore ensure that the project is carried out in accordance with the Joint Code of Practice

Liverpool Clinical Laboratories, and the laboratories at PHE and PHW hold **UKAS** accreditation. The Biobank at the University of Liverpool is a **Good Clinical Laboratory Practice (GCLP)** recognised facility. Good Clinical Laboratory Practice (GCLP) is a quality standard for the analysis of clinical trial samples which incorporates the legal requirements of Good Clinical Practice (GCP). In the GCLP facility all work is carried out using Standard Operating Procedures (SOPs) produced before work can begin, they are version controlled and dated and signed by the authors and by a Quality Assurance (QA) Manager. All staff allowed to work in the GCLP facility have to provide evidence of regular training in GCP as it applies to the laboratory Equipment used in the GCLP facility is all quality controlled on installation (IQ) and in use for the purpose specified, the latter requiring an independent Operational Quality (OQ) certification and Performance Quality (PQ) control. Records of the quality control and maintenance of equipment are stored and can be cross-referenced with laboratory books. All this means that any experiment can be inspected with the confidence that a commitment to use a given protocol was made before the experimental data was obtained and that all data was stored including data on failed experiments. Samples are stored in compliance with the Human Tissue Act.

We have enclosed a draft quality assurance plan for the modelling work to be undertaken in the IID3 Study.

We described in Section 5A above we will develop and implement an internal audit programme that will address all aspects of the IID3 study.

We will comply with the Joint Code of Practice on Research.

B. ETHICS

Please identify the key ethical issues for this project and how these will be managed. Please respond to any issues raised in the Specification document.
Please describe the ethical issues of any involvement of people, human samples, animal research or personal data in this part. In addition, please describe the ethical review and governance arrangements that would

apply to the work done. Please outline what ethical approvals will need to be gained as part of this project and the expected timelines of these.

Applicants are reminded that, where appropriate, the need to obtain clearance for the proposed project from their local ethics committee. This is the responsibility of the project Lead Applicant. However, if a sub-contractor requires such clearance the project Lead Applicant should ensure that all relevant procedures have been followed. If there are no ethical issues please state this.

We consider that the main ethical issues raised by this study are:-

1. Collection of personal data: This will be resolved by evidencing informed consent to participate in the population-based studies.
2. Data storage and compliance with GDPR: Study data will be held in a Trusted Research Environment at the University of Oxford, recognised by Health Data Research UK (See section 7C below for further details).
3. Retention of stool samples for future research: This will be resolved by seeking written, informed consent from participants.
4. Inclusion of children in the population-based studies: We will prepare information that is "child friendly" so that younger children will understand what is being asked of them. Without the agreement of a parent or guardian as well as the child they will not be enrolled into the study.
5. Asking individuals to participate in more than one part of the study: There is a possibility that families who agree to take part in the population-based cohort study in WP2 may also present to Primary Care in WP3. The first time that we contact potential participants to invite them to take part in the study we will provide an information sheet explaining all the different parts of the study. Since we will be seeking informed consent for entry into WP2 and WP3 they will have the choice to opt out of either or both studies.

The IID3 Study involves participant recruitment through the National Health Service (WP2 and WP3) and so an application for ethical approval through the Health Research Authority's (HRA) Integrated Research Application System (IRAS) is mandatory. This is a single system for applying for the permissions and approvals for health and social care/community care research in the UK. The review process takes a minimum of 60 days, provided that no changes need to be made to the application or accompanying documentation, in which case the application would have to be re-reviewed.

As noted above, informed consent must be evidenced from participants on enrolment to the study, and participants must also provide separate written consent for archiving of their samples in the University of Liverpool's Biobank. In the case of a child these consents must be provided by a parent or guardian.

The process of gaining HRA approval through IRAS will be led by the University of Oxford, overseen by Newcastle University as the Lead Applicant.

C. DATA MANAGEMENT

This section should include details on data protection, data dissemination and how data will be shared between the lead organisation and any contractors as needed.

Please identify any specific data protection issues for this project and how these will be managed. Please respond to any specific issues raised in the Specification document.
Please note that the successful Applicant will be expected to comply with the Data Protection Act (DPA) 1998 and ensure that any information collected, processed and transferred on behalf of the FSA, will be held and transferred securely.

In this part please provide details of the practices and systems which are in place for handling data securely including transmission between the field and head office and then to the FSA. Plans for how data will be deposited (i.e., within a community or institutional database/archive) and/or procedures for the destruction of physical and system data should also be included in this part (this is particularly relevant for survey data and personal data collected from clinical research trials). The project Lead Applicant will be responsible for ensuring that they and any sub-contractor who processes or handles information on behalf of the FSA are conducted securely.

1. Trusted Research Environment (TRE) for IID3 data controllership and information governance:

1a. Trusted Research Environment:
The Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) has a trusted research environment (TRE) recognised by Health Data Research UK (HDRUK) – this is called "ORCHID."[1],[2] ORCHID is also approved as meeting NHS Digitals Data Security and Protection (DSP) toolkit requirements.[3] ORCHID is a clinical informatics digital hub, with platforms to support surveillance, interventional studies (including near patient testing) and trials.[4] Data within ORCHID is pseudonymised, using an NHS Digital approved approach which enables linkage to other datasets.

1b. Linked datasets from NHS Digital:
We will link the RSC data to hospital data (Hospital Episode Statistics (HES))[5], and death certificate data (Office of National Statistics (ONS)).[6] SdeL is an ONS approved researcher and permitted access to these data.[7] As soon as we have ethical approval for this study we will make an application to NHS Digital's Data Access Request Service (DARS) for three releases of HES and ONS data at the start, and after the completion of the first and second year of the main study (allowing 3 months for HES being released in arrears.

1c. Linked datasets within the IID3 consortium:
We will also link RSC data to questionnaire results from WP3, the results data from WP4, and any national data collections from WP5. Where feasible this will be the complete result. We will use pseudonymised NHS number as the unique key for data linkage.[8] We will train all the participants in WP4 and WP5, who wish to store data, how to pseudonymise data for linkage within the TRE. Where data are extensive (e.g. some genome sequence data) we will hold an indexing link to the source data. We will encrypt files, then use the Oxfile system for transfer of encrypted, pseudonymised data between consortium members.[9]

1d. Providing data access – Data sharing agreement (DSA) within the consortium:
Within ORCHID we will curate clinical variables within an IID3 consortium themed dataset. The primary indexing tool of the ORCHID platform is the systematised nomenclature of medicine (SNOMED) clinical terms (CT).[10] All our historic data, Read coded etc., are now mapped to SNOMED CT. The variables (but not the data) included in our themed datasets are available online.[11]

It will be possible for approved researchers from across the consortium to work on the IID3 consortium themed dataset remotely. The ORCHID TRE has all the commonly used statistical and data processing packages; these include R, SAS, STATA, SQL and Python. Others can be added. We will create a data sharing agreement (DSA) within the IID3 consortium to achieve this.

We will conduct a data protection and impact assessment (DPIA) at project set-up and annually to ensure we achieve privacy/data protection by design.

1e. Data feeds to facilitate local analyses:
We will provide feeds of data at an agreed interval to support other WPs research. This will include WP4, WP5 and WP6. These will be pseudonymised.

1f. FSA IID3 themed dataset and Data Controllership:
A requirement of the tender is that: "the FSA expects that it will be a Data Controller as the Research is necessary to inform and assist the FSA in carrying out its Public Task in accordance with the Food Standards Act 1999." We plan to achieve this by agreeing a specification for a themed dataset that will meet the FSA's requirements. Each study participant, and consortium member will give consent within our DSA that in principle they will do this and agree to flag those data items that can be shared with FSA. This process will require its own specific DSA and DPIA and be included in our applications to DARS. We can provide the FSA a regular data-feed, plus dynamic data provision to populate a dashboard. It would be possible to also consider a responsive service if a natural catastrophe (e.g. flooding) or biosecurity hazard within the food chain. This may

form part of a sustainability plan. Given appropriate consents this could be modelled on the surveillance ORCHID provides to Public Health England, including observatories and weekly reports.

2. Destruction of Physical and System Data:
We will agree with the FSA for how long they expect us to retain raw data supporting outputs after the end of the project. We will follow the University of Oxford's policy on the "Management and Protection of Data Collected for Research Purposes" available at https://researchsupport.admin.ox.ac.uk/files/bpg09datacollectionandmanagementpdf. Any paper records will be shredded. Records stored on a computer hard drive or USB drive will be erased using commercial software applications designed to remove all data from the storage device. For any data recorded on CDs, or DVDs or other portable media, the storage devices will be physically destroyed or made un-readable. Local IT support staff periodically hold hard drive destruction 'events', and researchers can take advantage of these events. We will keep records stating what records were destroyed, and when and how we did so.

3. Data archiving:
We envisage that fully anonymised data from the IID3 Study will be archived UK National Data Archive held at the University of Essex. The IID1 Study and IID2 Study datasets are held in that collection. The IID3 Study archive will include all study documentation (e.g. protocol, study handbooks, clinical algorithms), all questionnaire data, and microbiological data.

4. Biobanking:
All material will be stored for a minimum of 5 years following study completion, ensuring compliance with Human Tissue Authority (HTA) regulations.

References:
[1] Health Data Research UK (HDRUK). Trusted Research Environments. ORCHID. URL: https://www.healthdatagateway.org/collectioncategories/trusted-research-environment
[2] Health Data Research UK (HDRUK). Oxford-Royal College of GPs Clinical Informatics Digital Hub (ORCHID). URL: https://web.www.healthdatagateway.org/collection/5626663352808625
[3] NHS Digital. Data Security and Protection Toolkit. University of Oxford - Medical Sciences Division – Nuffield Department of Primary Care Health Sciences. URL: https://www.dsptoolkit.nhs.uk/OrganisationSearch/EE133863-MSD-NDPCHS
[4] de Lusignan S, Jones N, Dorward J, Byford R, Liyanage H, Briggs J, Ferreira F, Akinyemi O, Amirthalingam G, Bates C, Lopez Bernal J, Dabrera G, Eavis A, Elliot AJ, Feher M, Krajenbrink E, Hoang U, Howsam G, Leach J, Okusi C, Nicholson B, Nieri P, Sherlock J, Smith G, Thomas M, Thomas N, Tripathy M, Victor W, Williams J, Wood I, Zambon M, Parry J, O'Hanlon S, Joy M, Butler C, Marshall M, Hobbs FDR. The Oxford Royal College of General Practitioners Clinical Informatics Digital Hub: Protocol to Develop Extended COVID-19 Surveillance and Trial Platforms. JMIR Public Health Surveill. 2020 Jul 2;6(3):e19773. doi: 10.2196/19773.
[5] NHS Digital. Hospital Episode Statistics (HES). URL: https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics
[6] NHS Digital. ONS Mortality Data. URL: https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/linked-hes-ons-mortality-data
[7] Office for National Statistics (ONS). Accessing secure research data as an accredited researcher. URL: https://www.ons.gov.uk/aboutus/whatwedo/statistics/requestingstatistics/approvedresearcherscheme
[8] de Lusignan S. Effective pseudonymisation and explicit statements of public interest to ensure the benefits of sharing health data for research, quality improvement and health service management outweigh the risks. Inform Prim Care. 2014;21(2):61-3. doi: 10.14236/jhi.v21i2.68.
[9] University of Oxford IT. Overview: OxFile - Large File Exchange Service URL: https://help.it.ox.ac.uk/oxfile-large-file-exchange-service
[10] de Lusignan S. Codes, classifications, terminologies and nomenclatures: definition, development and application in practice. Inform Prim Care. 2005;13(1):65-70. doi: 10.14236/jhi.v13i1.580.
[11] University of Oxford. ORCHID - Using Oxford-RCGP RSC for observational studies. URL: https://orchid.phc.ox.ac.uk/index.php/orchid-data/

D. SUSTAINABILITY

The Food Standards Agency is committed to improving sustainability in the management of operations. Procurement looks to its suppliers to help achieve this goal. You will need to demonstrate your approach to sustainability, in particular how you will apply it to this project taking into account economic, environmental and

social aspects. This will be considered as part of our selection process and you must upload your organisation's sustainability policies into the eligibility criteria in Bravo.
Please state what (if any) environmental certification you hold or briefly describe your current Environmental Management System (EMS)

One unforeseen benefit of the COVID-19 pandemic has been the realisation that productive remote working is possible, and we do not always have to meet in person to be effective. Preparation of this proposal has been a case in point. We have used Microsoft Teams to share documents and Zoom meetings to discuss the scope and content of our application. We are all conscious of the fact that we tend to travel distances a lot and that was certainly the case in the IID2 Study when there were frequent meetings in London, with the associated costs and carbon-related consequences of travel. If successful with this tender we propose to hold one annual conference to which all investigators will be invited, and to meet remotely during the rest of the year using Teams or Zoom. We will make use of the annual conference to meet with the proposed External Advisory Panel.

Newcastle University's Environmental Management System (EMS) is certified to ISO 14001. Our accompanying Energy Management System (EnMS) is certified to ISO 50001. The Environment and Sustainability Committee reviews both policies every year.

E. DISSEMINATION AND EXPLOITATION (Science Projects Only)

Where applicable please indicate how you intend to disseminate the results of this project, including written and verbal communication routes if appropriate. Applicants are advised to think carefully about how their research aligns with the FSA strategy, what is the impact that their research has on public health/ consumers and decide how the results can best be communicated to the relevant and appropriate people and organisations in as cost-effective manner as possible. Please provide as much detail as possible on what will be delivered. Any costs associated with this must be documented in the Financial Template.

The applicant should describe plans for the dissemination of the results for the project team as a whole and for individual participants. Details should include anticipated numbers of publications in refereed journals, articles in trade journals etc., presentations or demonstrations to the scientific community, trade organisations and internal reports or publications. Plans to make any information and/or reports available on the internet with the FSA's permission are also useful, however, this does not remove the requirement for Tenderers to think how best to target the output to relevant groups.
If a final report is part of the requirement, please make sure, as part of the executive summary, that aims and results are clear to the general audience and that the impact of the research on public health/consumers and its alignment to FSA priorities is clearly stated.

Please note that permission to publish or to present findings from work supported by the FSA must be sought in advance from the relevant FSA Project Officer. The financial support of the FSA must also be acknowledged.

Please indicate whether any Intellectual Property (IP) may be generated by this project and how this could be exploited. Please be aware the FSA retains all rights to the intellectual property generated by any contract and where appropriate may exploit the IP generated for the benefit of public health.

In this part Applicants should demonstrate the credibility of the partnership for exploitation of the results and explain the partnership's policy in respect of securing patents or granting licenses for the technology (if applicable). It should deal with any possible agreements between the partners to extend their co-operation in the exploitation phase and with relevant agreements with companies, in particular users, external to the partnership.

Regular progress reports during the lifetime of the project:
These will be prepared monthly by each Study Team and posted to the study website. They will be available to all study participants, including General Practitioners recruiting patients for the prospective cohort studies. The format of the routine progress report, and its circulation, will be agreed as part of the publication and dissemination policy referred to in WP1. The Food Standards Agency's Project Manager(s) will also be included in this reporting mechanism as a matter of routine.

Access to raw, pseudonymised data:
The raw, pseudonymised data will be available for inspection by the Food Standards Agency at regular intervals. A representative from the Food Standards Agency will be invited to become involved with preparing the analytical strategy for the study and will be able to make site visits to

Oxford University/ Royal College of General Practitioners Research and Surveillance Centre, which is leading recruitment, and Newcastle University, which is leading the analyses. We will always comply with the Data Protection Act and the General Data Protection Regulations – only pseudonymised or anonymised data will be available for analysis.

Archiving of stool specimens:
This will be organised by the University of Liverpool. Samples from participants who have provided consent for sample archiving will be stored in the University of Liverpool Biobank (see WP4).

Archiving of organisms:
This will be organised by Public Health England.

Archiving of study data:
This will be organised by Newcastle University, the University of Manchester, the Danish Technical University and the University of Oxford. The archive will include all study documentation (e.g. protocol, study handbooks, clinical algorithms), all questionnaire data, and all microbiological data.

Interim results:
A mechanism for publicising interim results will be agreed as part of the publication and dissemination policy (see WP1). It is suggested that a small group including Sarah O'Brien and the FSA's Project Officer take final responsibility for agreeing what interim results, if any, can be published. Recourse to a third party (an internationally recognised external expert) might be needed in the event of any disagreement.

Final report:
The results of the study will be presented to the Food Standards Agency in a final report, which will give the Agency the opportunity to communicate findings of interest to the general public. A Drafting Committee for the report will be established as part of the publication policy. The report will be presented to the Food Standards Agency in January 2026, to give time for amendments to be made before the end of the study. All the organisations involved in this consortium encourage the communication of research findings to the general public in an easily accessible manner and, where appropriate and by agreement with the Agency, results will be disseminated through the public relations officers of these organisations.

Conference proceedings and peer-reviewed publications:
A mechanism for drafting and presenting scientific outputs from the study will be agreed as part of the publication strategy (see Work Package 1). This will include peer-reviewed publications on the aetiology and epidemiology of infectious intestinal disease, including self-reported disease, as well as the surveillance and economic implications of the study findings.

Intellectual Property (IP):
The proposed research is unlikely to lead to commercially exploitable results. However, if any IP results from the IID3 Study this will belong to the Food Standards Agency.

Schedule 5 (Commercially Sensitive Information)

Not Used

Schedule 6 (Transparency Reports)

1.1 The Supplier recognises that the Buyer is subject to PPN 01/17 (Updates to transparency principles v1.1 (https://www.gov.uk/government/publications/procurement-policy-note-0117-update-to-transparency-principles). The Supplier shall comply with the provisions of this Schedule in order to assist the Buyer with its compliance with its obligations under that PPN.

Schedule 13 (Contract Management)

1. Definitions

1.1 In this Schedule, the following words shall have the following meanings and they shall supplement Schedule 1 (Definitions):

"Project Manager"	the manager appointed in accordance with paragraph 2.1 of this Schedule;

2. Project Management

2.1 The Supplier and the Buyer shall each appoint a Project Manager for the purposes of this Contract through whom the provision of the Services and the Deliverables shall be managed day-to-day.

2.2 The Parties shall ensure that appropriate resource is made available on a regular basis such that the aims, objectives and specific provisions of this Contract can be fully realised.

3. Role of the Supplier Project Manager

3.1 The Supplier Project Manager shall be:

3.1.1 the primary point of contact to receive communication from the Buyer and will also be the person primarily responsible for providing information to the Buyer;

3.1.2 able to delegate his position to another person at the Supplier but must inform the Buyer before proceeding with the delegation and it will be delegated person's responsibility to fulfil the Project Manager's responsibilities and obligations;

3.1.3 able to cancel any delegation and recommence the position himself; and

3.1.4 replaced only after the Buyer has received notification of the proposed change.

3.2 The Buyer may provide revised instructions to the Supplier's Project Manager in regards to the Contract and it will be the Supplier Project Manager's responsibility to ensure the information is provided to the Supplier and the actions implemented.

3.3 Receipt of communication from the Supplier Project Manager by the Buyer does not absolve the Supplier from its responsibilities, obligations or liabilities under the Contract.

4. Role of The Operational Board

4.1 Not Used

5. Contract Risk Management

5.1 Both Parties shall pro-actively manage risks attributed to them under the terms of this Contract.

5.2 The Supplier shall develop, operate, maintain and amend, as agreed with the Buyer, processes for:

5.2.1 the identification and management of risks;

5.2.2 the identification and management of issues; and

5.2.3 monitoring and controlling project plans.

5.3 The Supplier allows the Buyer to inspect at any time within working hours the accounts and records which the Supplier is required to keep.

5.4 The Supplier will maintain a risk register of the risks relating to the Contract which the Buyer and the Supplier have identified.

Schedule 16 (Security)

Part A: Short Form Security Requirements

1. Definitions

1.1 In this Schedule, the following words shall have the following meanings and they shall supplement Schedule 1 (Definitions):

"Breach of Security"	the occurrence of: a) any unauthorised access to or use of the Deliverables, the Sites and/or any Information and Communication Technology ("ICT"), information or data (including the Confidential Information and the Government Data) used by the Buyer and/or the Supplier in connection with this Contract; and/or b) the loss and/or unauthorised disclosure of any information or data (including the Confidential Information and the Government Data), including any copies of such information or data, used by the Buyer and/or the Supplier in connection with this Contract, in either case as more particularly set out in the Security Policy where the Buyer has required compliance therewith in accordance with paragraph 2.2;
"Security Management Plan"	the Supplier's security management plan prepared pursuant to this Schedule, a draft of which has been provided by the Supplier to the Buyer and as updated from time to time.

2. Complying with security requirements and updates to them

2.1 The Supplier shall comply with the requirements in this Schedule in respect of the Security Management Plan. Where specified by a Buyer it shall also comply with the Security Policy and shall ensure that the Security Management Plan produced by the Supplier fully complies with the Security Policy.

2.2 Where the Security Policy applies the Buyer shall notify the Supplier of any changes or proposed changes to the Security Policy.

2.3 If the Supplier believes that a change or proposed change to the Security Policy will have a material and unavoidable cost implication to the provision of the Deliverables it may propose a Variation to the Buyer. In doing so, the Supplier must support its request by providing evidence of the cause of any increased costs and the steps that it has taken to mitigate those costs. Any change to the Charges shall be subject to the Variation Procedure.

2.4 Until and/or unless a change to the Charges is agreed by the Buyer pursuant to the Variation Procedure the Supplier shall continue to provide the Deliverables in accordance with its existing obligations.

3. Security Standards

3.1 The Supplier acknowledges that the Buyer places great emphasis on the reliability of the performance of the Deliverables, confidentiality, integrity and availability of information and consequently on security.

3.2 The Supplier shall be responsible for the effective performance of its security obligations and shall at all times provide a level of security which:

3.2.1 is in accordance with the Law and this Contract;

3.2.2 as a minimum demonstrates Good Industry Practice;

3.2.3 meets any specific security threats of immediate relevance to the Deliverables and/or the Government Data; and

3.2.4 where specified by the Buyer in accordance with paragraph 2.2 complies with the Security Policy and the ICT Policy.

3.3 The references to standards, guidance and policies contained or set out in Paragraph 3.2 shall be deemed to be references to such items as developed and updated and to any successor to or replacement for such standards, guidance and policies, as notified to the Supplier from time to time.

3.4 In the event of any inconsistency in the provisions of the above standards, guidance and policies, the Supplier should notify the Buyer's Representative of such inconsistency immediately upon becoming aware of the same, and the Buyer's Representative shall, as soon as practicable, advise the Supplier which provision the Supplier shall be required to comply with.

4. Security Management Plan

4.1 Introduction

4.1.1 The Supplier shall develop and maintain a Security Management Plan in accordance with this Schedule. The Supplier shall thereafter comply with its obligations set out in the Security Management Plan.

4.2 Content of the Security Management Plan

4.2.1 The Security Management Plan shall:

(a) comply with the principles of security set out in Paragraph 3 and any other provisions of this Contract relevant to security;

(b) identify the necessary delegated organisational roles for those responsible for ensuring it is complied with by the Supplier;

(c) detail the process for managing any security risks from Subcontractors and third parties authorised by the Buyer with access to the Deliverables, processes associated with the provision of the Deliverables, the Buyer Premises, the Sites and any ICT, Information and data (including the Buyer's Confidential Information

and the Government Data) and any system that could directly or indirectly have an impact on that Information, data and/or the Deliverables;

(d) be developed to protect all aspects of the Deliverables and all processes associated with the provision of the Deliverables, including the Buyer Premises, the Sites, and any ICT, Information and data (including the Buyer's Confidential Information and the Government Data) to the extent used by the Buyer or the Supplier in connection with this Contract or in connection with any system that could directly or indirectly have an impact on that Information, data and/or the Deliverables;

(e) set out the security measures to be implemented and maintained by the Supplier in relation to all aspects of the Deliverables and all processes associated with the provision of the Goods and/or Services and shall at all times comply with and specify security measures and procedures which are sufficient to ensure that the Deliverables comply with the provisions of this Contract;

(f) set out the plans for transitioning all security arrangements and responsibilities for the Supplier to meet the full obligations of the security requirements set out in this Contract and, where necessary in accordance with paragraph 2.2 the Security Policy; and

(g) be written in plain English in language which is readily comprehensible to the staff of the Supplier and the Buyer engaged in the provision of the Deliverables and shall only reference documents which are in the possession of the Parties or whose location is otherwise specified in this Schedule.

4.3 Development of the Security Management Plan

4.3.1 Within twenty (20) Working Days after the Start Date and in accordance with Paragraph 4.4, the Supplier shall prepare and deliver to the Buyer for Approval a fully complete and up to date Security Management Plan which will be based on the draft Security Management Plan.

4.3.2 If the Security Management Plan submitted to the Buyer in accordance with Paragraph 4.3.1, or any subsequent revision to it in accordance with Paragraph 4.4, is Approved it will be adopted immediately and will replace the previous version of the Security Management Plan and thereafter operated and maintained in accordance with this Schedule. If the Security Management Plan is not Approved, the Supplier shall amend it within ten (10) Working Days of a notice of non-approval from the Buyer and re-submit to the Buyer for Approval. The Parties will use all reasonable endeavours to ensure that the approval process takes as little time as possible and in any event no longer than fifteen (15) Working Days from the date of its first submission to the Buyer. If the Buyer does not approve the Security Management Plan following its resubmission, the matter will be resolved in accordance with the Dispute Resolution Procedure.

4.3.3 The Buyer shall not unreasonably withhold or delay its decision to Approve or not the Security Management Plan pursuant to Paragraph 4.3.2. However a refusal by the Buyer to Approve the Security Management Plan on the grounds that it does not comply with the requirements set out in Paragraph 4.2 shall be deemed to be reasonable.

4.3.4 Approval by the Buyer of the Security Management Plan pursuant to Paragraph 4.3.2 or of any change to the Security Management Plan in accordance with Paragraph 4.4 shall not relieve the Supplier of its obligations under this Schedule.

4.4 **Amendment of the Security Management Plan**

4.4.1 The Security Management Plan shall be fully reviewed and updated by the Supplier at least annually to reflect:

(a) emerging changes in Good Industry Practice;

(b) any change or proposed change to the Deliverables and/or associated processes;

(c) where necessary in accordance with paragraph 2.2, any change to the Security Policy;

(d) any new perceived or changed security threats; and

(e) any reasonable change in requirements requested by the Buyer.

4.4.2 The Supplier shall provide the Buyer with the results of such reviews as soon as reasonably practicable after their completion and amendment of the Security Management Plan at no additional cost to the Buyer. The results of the review shall include, without limitation:

(a) suggested improvements to the effectiveness of the Security Management Plan;

(b) updates to the risk assessments; and

(c) suggested improvements in measuring the effectiveness of controls.

4.4.3 Subject to Paragraph 4.4.4, any change or amendment which the Supplier proposes to make to the Security Management Plan (as a result of a review carried out in accordance with Paragraph 4.4.1, a request by the Buyer or otherwise) shall be subject to the Variation Procedure.

4.4.4 The Buyer may, acting reasonably, Approve and require changes or amendments to the Security Management Plan to be implemented on timescales faster than set out in the Variation Procedure but, without prejudice to their effectiveness, all such changes and amendments shall thereafter be subject to the Variation Procedure for the purposes of formalising and documenting the relevant change or amendment.

5. Security breach

5.1 Either Party shall notify the other in accordance with the agreed security incident management process (as detailed in the Security Management Plan) upon becoming aware of any Breach of Security or any potential or attempted Breach of Security.

5.2 Without prejudice to the security incident management process, upon becoming aware of any of the circumstances referred to in Paragraph 5.1, the Supplier shall:

5.2.1 immediately take all reasonable steps (which shall include any action or changes reasonably required by the Buyer) necessary to:

(a) minimise the extent of actual or potential harm caused by any Breach of Security;

(b) remedy such Breach of Security to the extent possible and protect the integrity of the Buyer and the provision of the Goods and/or Services to the extent within its control against any such Breach of Security or attempted Breach of Security;

(c) prevent an equivalent breach in the future exploiting the same cause failure; and

(d) as soon as reasonably practicable provide to the Buyer, where the Buyer so requests, full details (using the reporting mechanism defined by the Security Management Plan) of the Breach of Security or attempted Breach of Security, including a cause analysis where required by the Buyer.

5.3 In the event that any action is taken in response to a Breach of Security or potential or attempted Breach of Security that demonstrates non-compliance of the Security Management Plan with the Security Policy (where relevant in accordance with paragraph 2.2) or the requirements of this Schedule, then any required change to the Security Management Plan shall be at no cost to the Buyer.

Schedule 20 (Processing Data)

Status of the Controller

1. The Parties acknowledge that for the purposes of the Data Protection Legislation, the nature of the activity carried out by each of them in relation to their respective obligations under a Contract dictates the status of each party under the DPA. A Party may act as:

(a) "Controller" in respect of the other Party who is "Processor";

(b) "Processor" in respect of the other Party who is "Controller";

(c) "Joint Controller" with the other Party;

(d) "Independent Controller" of the Personal Data where the other Party is also "Controller",

in respect of certain Personal Data under a Contract and shall specify in Annex 1 *(Processing Personal Data)* which scenario they think shall apply in each situation.

Where one Party is Controller and the other Party its Processor

2. Where a Party is a Processor, the only Processing that it is authorised to do is listed in Annex 1 *(Processing Personal Data*) by the Controller.

3. The Processor shall notify the Controller immediately if it considers that any of the Controller's instructions infringe the Data Protection Legislation.

4. The Processor shall provide all reasonable assistance to the Controller in the preparation of any Data Protection Impact Assessment prior to commencing any Processing. Such assistance may, at the discretion of the Controller, include:

(a) a systematic description of the envisaged Processing and the purpose of the Processing;

(b) an assessment of the necessity and proportionality of the Processing 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.

5. The Processor shall, in relation to any Personal Data Processed in connection with its obligations under the Contract:

(a) Process that Personal Data only in accordance with Annex 1 *(Processing Personal Data*), unless the Processor is required to do otherwise by Law. If it is

so required the Processor shall notify the Controller before Processing the Personal Data unless prohibited by Law;

(b) ensure that it has in place Protective Measures, including in the case of the Supplier the measures set out in Clause 14.3 of the Core Terms*,* which the Controller may reasonably reject (but failure to reject shall not amount to approval by the Controller of the adequacy of the Protective Measures) having taken account of the:

(i) nature of the data to be protected;

(ii) harm that might result from a Personal Data Breach;

(iii) state of technological development; and

(iv) cost of implementing any measures;

(c) ensure that :

(i) the Processor Personnel do not Process Personal Data except in accordance with the Contract (and in particular Annex 1 *(Processing Personal Data*));

(ii) it takes all reasonable steps to ensure the reliability and integrity of any Processor Personnel who have access to the Personal Data and ensure that they:

(A) are aware of and comply with the Processor's duties under this Schedule 20, Clauses 14 (*Data protection*), 15 (*What you must keep confidential*) and 16 (*When you can share information*);

(B) are subject to appropriate confidentiality undertakings with the Processor or any Subprocessor;

(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 Controller or as otherwise permitted by the Contract; and

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

(d) not transfer Personal Data outside of the EU unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:

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

(ii) the Data Subject has enforceable rights and effective legal remedies;

(iii) the Processor 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 Controller in meeting its obligations); and

(iv) the Processor complies with any reasonable instructions notified to it in advance by the Controller with respect to the Processing of the Personal Data; and

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

6. Subject to paragraph 7 of this Schedule 20, the Processor shall notify the Controller immediately if in relation to it Processing Personal Data under or in connection with the Contract 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 the 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 Personal Data Breach.

7. The Processor's obligation to notify under paragraph 6 of this Schedule 20 shall include the provision of further information to the Controller, as details become available.

8. Taking into account the nature of the Processing, the Processor shall provide the Controller with assistance in relation to either Party's obligations under Data Protection Legislation and any complaint, communication or request made under paragraph 6 of this Schedule 20 (and insofar as possible within the timescales reasonably required by the Controller) including by immediately providing:

(a) the Controller with full details and copies of the complaint, communication or request;

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

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

(d) assistance as requested by the Controller following any Personal Data Breach; and/or

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

9. The Processor shall maintain complete and accurate records and information to demonstrate its compliance with this Schedule 20. This requirement does not apply where the Processor employs fewer than 250 staff, unless:

(a) the Controller determines that the Processing is not occasional;

(b) the Controller 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 Controller determines that the Processing is likely to result in a risk to the rights and freedoms of Data Subjects.

10. The Processor shall allow for audits of its Data Processing activity by the Controller or the Controller's designated auditor.

11. The Parties shall designate a Data Protection Officer if required by the Data Protection Legislation.

12. Before allowing any Subprocessor to Process any Personal Data related to the Contract, the Processor must:

(a) notify the Controller in writing of the intended Subprocessor and Processing;

(b) obtain the written consent of the Controller;

(c) enter into a written agreement with the Subprocessor which give effect to the terms set out in this Schedule 20 such that they apply to the Subprocessor; and

(d) provide the Controller with such information regarding the Subprocessor as the Controller may reasonably require.

13. The Processor shall remain fully liable for all acts or omissions of any of its Subprocessors.

14. The Buyer may, at any time on not less than 30 Working Days' notice, revise this Schedule 20 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 the Contract).

15. The Parties agree to take account of any guidance issued by the Information Commissioner's Office. The Buyer may on not less than 30 Working Days' notice to the Supplier amend the Contract to ensure that it complies with any guidance issued by the Information Commissioner's Office.

Where the Parties are Joint Controllers of Personal Data

16. In the event that the Parties are Joint Controllers in respect of Personal Data under the Contract, the Parties shall implement paragraphs that are necessary to comply with GDPR Article 26 based on the terms set out in Annex 2 to this Schedule 20 (*Processing Data*).

Independent Controllers of Personal Data

17. With respect to Personal Data provided by one Party to another Party for which each Party acts as Controller but which is not under the Joint Control of the Parties, each Party undertakes to comply with the applicable Data Protection Legislation in respect of their Processing of such Personal Data as Controller.

18. Each Party shall Process the Personal Data in compliance with its obligations under the Data Protection Legislation and not do anything to cause the other Party to be in breach of it.

19. Where a Party has provided Personal Data to the other Party in accordance with paragraph 7 of this Schedule 20 above, the recipient of the Personal Data will provide all such relevant documents and information relating to its data protection policies and procedures as the other Party may reasonably require.

20. The Parties shall be responsible for their own compliance with Articles 13 and 14 GDPR in respect of the Processing of Personal Data for the purposes of the Contract.

21. The Parties shall only provide Personal Data to each other:

(a) to the extent necessary to perform their respective obligations under the Contract;

(b) in compliance with the Data Protection Legislation (including by ensuring all required data privacy information has been given to affected Data Subjects to meet the requirements of Articles 13 and 14 of the GDPR); and

(c) where it has recorded it in Annex 1 *(Processing Personal Data).*

22. Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of Processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, each Party shall, with respect to its Processing of Personal Data as Independent Controller, implement and maintain appropriate technical and organisational measures to ensure a level of security appropriate to that risk, including, as appropriate, the measures referred to in Article 32(1)(a), (b), (c) and (d) of the GDPR, and the measures shall, at a minimum, comply with the requirements of the Data Protection Legislation, including Article 32 of the GDPR.

23. A Party Processing Personal Data for the purposes of the Contract shall maintain a record of its Processing activities in accordance with Article 30 GDPR and shall make the record available to the other Party upon reasonable request.

24. Where a Party receives a request by any Data Subject to exercise any of their rights under the Data Protection Legislation in relation to the Personal Data provided to it by the other Party pursuant to the Contract **("Request Recipient")**:

(a) the other Party shall provide any information and/or assistance as reasonably requested by the Request Recipient to help it respond to the request or correspondence, at the cost of the Request Recipient; or

(b) where the request or correspondence is directed to the other Party and/or relates to that other Party's Processing of the Personal Data, the Request Recipient will:

(i) promptly, and in any event within five (5) Working Days of receipt of the request or correspondence, inform the other Party that it has received the same and shall forward such request or correspondence to the other Party; and

(ii) provide any information and/or assistance as reasonably requested by the other Party to help it respond to the request or correspondence in the timeframes specified by Data Protection Legislation.

25. Each Party shall promptly notify the other Party upon it becoming aware of any Personal Data Breach relating to Personal Data provided by the other Party pursuant to the Contract and shall:

(a) do all such things as reasonably necessary to assist the other Party in mitigating the effects of the Personal Data Breach;

(b) implement any measures necessary to restore the security of any compromised Personal Data;

(c) work with the other Party to make any required notifications to the Information Commissioner's Office and affected Data Subjects in accordance with the Data Protection Legislation (including the timeframes set out therein); and

(d) not do anything which may damage the reputation of the other Party or that Party's relationship with the relevant Data Subjects, save as required by Law.

26. Personal Data provided by one Party to the other Party may be used exclusively to exercise rights and obligations under the Contract as specified in Annex 1 *(Processing Personal Data).*

27. Personal Data shall not be retained or processed for longer than is necessary to perform each Party's respective obligations under the Contract which is specified in Annex 1 *(Processing Personal Data)*.

28. Notwithstanding the general application of paragraphs 2 to 15 of this Schedule 20 to Personal Data, where the Supplier is required to exercise its regulatory and/or legal obligations in respect of Personal Data, it shall act as an Independent Controller of Personal Data in accordance with paragraphs16 to 27 of this Schedule 20.

Annex 1 - Processing Personal Data

1.1 The contact details of the Buyer's Data Protection Officer are: [redacted]

1.2 The contact details of the Supplier's Data Protection Officer are: [redacted] The Processor shall comply with any further written instructions with respect to Processing by the Controller.

1.3 Any such further instructions shall be incorporated into this Annex.

Description	Details
Identity of Controller for each Category of Personal Data	**The Parties are Joint Controllers** The Parties are Joint Controllers The Parties acknowledge that they are Joint Controllers for the purposes of the Data Protection Legislation in respect of: Personal data collection for the purposes of conducting the IID3 study. The Data Processors are:- The University of Oxford (volunteer and patient recruitment, data linkage, preparation of data for analysis). This will all take place within the Trusted Research Environment at the University of Oxford. No patient-identifiable data will be transferred to Newcastle University or to the Food Standards Agency. Liverpool Clinical Laboratories (diagnostic microbiology) The University of Liverpool (biobanking) UK Health Security Agency (reference microbiology) Public Health Wales (reference microbiology) Health Protection Scotland (reference microbiology)
Duration of the Processing	The duration will be 1st January 2022 to 30th September 2025.

Nature and purposes of the Processing	The nature and purposes of the processing are:- At the University of Oxford – volunteer and patient recruitment, data linkage to microbiology results and past medical history including treatment with antimicrobials. At Liverpool Clinical Laboratories (LCL) – patient sample processing and reporting results to GP and to the University of Oxford. At the University of Liverpool – storage of patient samples and associated metadata for the purposes of future research. No sample/metadata will be stored without informed patient consent. At the UK Health Security Agency – patient sample processing and reporting results to LCL and to the University of Oxford. At Public Health Wales – patient sample processing and reporting results to LCL and to the University of Oxford. At Health Protection Scotland – patient sample processing and reporting results to LCL and to the University of Oxford.
Type of Personal Data	Each of the organisations above that are processing data will process the following personal data:- Full name, address, full postcode, date of birth, telephone number (landline and/or mobile), ethnicity, clinical history, treatment history, diagnostic and reference microbiology results.
Categories of Data Subject	Volunteers Patients
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	Personal data will be kept no longer than the end of the processing period, at which point all personal data will be shredded electronically and a fully anonymised dataset prepared for archiving.

Annex 2 - Joint Controller Agreement

1. Joint Controller Status and Allocation of Responsibilities

1.1 With respect to Personal Data under Joint Control of the Parties, the Parties envisage that they shall each be a Data Controller in respect of that Personal Data in accordance with the terms of this Annex 2 (Joint Controller Agreement) in replacement of paragraphs 2-15 of Schedule 20 (Where one Party is Controller and the other Party is Processor) and paragraphs 7-27 of Schedule 20 (Independent Controllers of Personal Data). Accordingly, the Parties each undertake to comply with the applicable Data Protection Legislation in respect of their Processing of such Personal Data as Data Controllers.

1.2 The Parties agree that the Supplier:

(a) is the exclusive point of contact for Data Subjects and is responsible for all steps necessary to comply with the GDPR regarding the exercise by Data Subjects of their rights under the GDPR;

(b) shall direct Data Subjects to its Data Protection Officer or suitable alternative in connection with the exercise of their rights as Data Subjects and for any enquiries concerning their Personal Data or privacy;

(c) is solely responsible for the Parties' compliance with all duties to provide information to Data Subjects under Articles 13 and 14 of the GDPR;

(d) is responsible for obtaining the informed consent of Data Subjects, in accordance with the GDPR, for Processing in connection with the Services where consent is the relevant legal basis for that Processing; and

(e) shall make available to Data Subjects the essence of this Annex (and notify them of any changes to it) concerning the allocation of responsibilities as Joint Controller and its role as exclusive point of contact, the Parties having used their best endeavours to agree the terms of that essence. This must be outlined in the Supplier's privacy policy (which must be readily available by hyperlink or otherwise on all of its public facing services and marketing).

1.3 Notwithstanding the terms of clause 1.2, the Parties acknowledge that a Data Subject has the right to exercise their legal rights under the Data Protection Legislation as against the relevant Party as Controller.

2. Undertakings of both Parties

2.1 The Supplier and the Buyer each undertake that they shall:

(a) report to the other Party every 6 months on:

(i) the volume of Data Subject Access Request (or purported Data Subject Access Requests) from Data Subjects (or third parties on their behalf);

(ii) the volume of requests from Data Subjects (or third parties on their behalf) to rectify, block or erase any Personal Data;

(iii) any other requests, complaints or communications from Data Subjects (or third parties on their behalf) relating to the other Party's obligations under applicable Data Protection Legislation;

(iv) any communications from the Information Commissioner or any other regulatory authority in connection with Personal Data; and

(v) any requests from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law,

that it has received in relation to the subject matter of the Contract during that period;

(b) notify each other immediately if it receives any request, complaint or communication made as referred to in clauses 2.1(a)(i) to (v);

(c) provide the other Party with full cooperation and assistance in relation to any request, complaint or communication made as referred to in clauses 2.1(a)(iii) to (v) to enable the other Party to comply with the relevant timescales set out in the Data Protection Legislation;

(d) not disclose or transfer the Personal Data to any third party unless necessary for the provision of the Services and, for any disclosure or transfer of Personal Data to any third party, save where such disclosure or transfer is specifically authorised under the Contract or is required by Law). For the avoidance of doubt, the third party to which Personal Data is transferred must be subject to equivalent obligations which are no less onerous than those set out in this Annex;

(e) request from the Data Subject only the minimum information necessary to provide the Services and treat such extracted information as Confidential Information;

(f) ensure that at all times it has in place appropriate Protective Measures to guard against unauthorised or unlawful Processing of the Personal Data and/or accidental loss, destruction or damage to the Personal Data and unauthorised or unlawful disclosure of or access to the Personal Data;

(g) take all reasonable steps to ensure the reliability and integrity of any of its Personnel who have access to the Personal Data and ensure that its Personnel:

(i) are aware of and comply with their duties under this Annex 2 (Joint Controller Agreement) and those in respect of Confidential Information

(ii) are informed of the confidential nature of the Personal Data, are subject to appropriate obligations of confidentiality and do not publish, disclose or divulge any of the Personal Data to any third party where the that Party would not be permitted to do so;

(iii) have undergone adequate training in the use, care, protection and handling of personal data as required by the applicable Data Protection Legislation;

(h) ensure that it has in place Protective Measures as appropriate to protect against a Personal Data Breach having taken account of the:

(i) nature of the data to be protected;

(i) harm that might result from a Personal Data Breach;

(iii) state of technological development; and

(iv) cost of implementing any measures;

(i) ensure that it has the capability (whether technological or otherwise), to the extent required by Data Protection Legislation, to provide or correct or delete at the request of a Data Subject all the Personal Data relating to that Data Subject that the Supplier holds; and

(i) ensure that it notifies the other Party as soon as it becomes aware of a Personal Data Breach.

2.2 Each Joint Controller shall use its reasonable endeavours to assist the other Controller to comply with any obligations under applicable Data Protection Legislation and shall not perform its obligations under this Annex in such a way as to cause the other Joint Controller to breach any of its obligations under applicable Data Protection Legislation to the extent it is aware, or ought reasonably to have been aware, that the same would be a breach of such obligations

3**. Data Protection Breach**

3.1 Without prejudice to Clause 3.2, each Party shall notify the other Party promptly and without undue delay, and in any event within 48 hours, upon becoming aware of any

Personal Data Breach or circumstances that are likely to give rise to a Personal Data Breach, providing the Buyer and its advisors with:

(a) sufficient information and in a timescale which allows the other Party to meet any obligations to report a Personal Data Breach under the Data Protection Legislation;

(b) all reasonable assistance, including:

(i) co-operation with the other Party and the Information Commissioner investigating the Personal Data Breach and its cause, containing and recovering the compromised Personal Data and compliance with the applicable guidance;

(ii) co-operation with the other Party including taking such reasonable steps as are directed by the Buyer to assist in the investigation, mitigation and remediation of a Personal Data Breach;

(iii) co-ordination with the other Party regarding the management of public relations and public statements relating to the Personal Data Breach; and/or

(iv) providing the other Party and to the extent instructed by the other Party to do so, and/or the Information Commissioner investigating the Personal Data Breach, with complete information relating to the Personal Data Breach, including, without limitation, the information set out in clause 3.2.

3.2 Each Party shall take all steps to restore, re-constitute and/or reconstruct any Personal Data where it has lost, damaged, destroyed, altered or corrupted as a result of a Personal Data Breach as it was that Party's own data at its own cost with all possible speed and shall provide the other Party with all reasonable assistance in respect of any such Personal Data Breach, including providing the other Party, as soon as possible and within 48 hours of the Personal Data Breach relating to the Personal Data Breach, in particular:

(a) the nature of the Personal Data Breach;

(b) the nature of Personal Data affected;

(c) the categories and number of Data Subjects concerned;

(d) the name and contact details of the Supplier's Data Protection Officer or other relevant contact from whom more information may be obtained;

(e) measures taken or proposed to be taken to address the Personal Data Breach; and

(f) describe the likely consequences of the Personal Data Breach.

4**. Audit**

4.1 The Supplier shall permit:

(a) the Buyer, or a third-party auditor acting under the Buyer's direction, to conduct, at the Buyer's cost, data privacy and security audits, assessments and inspections concerning the Supplier's data security and privacy procedures relating to Personal Data, its compliance with this Annex 2 and the Data Protection Legislation; and/or

(b) the Buyer, or a third-party auditor acting under the Buyer's direction, access to premises at which the Personal Data is accessible or at which it is able to inspect any relevant records, including the record maintained under Article 30 GDPR by the Supplier so far as relevant to the Contract, and procedures, including premises under the control of any third party appointed by the Supplier to assist in the provision of the Services.

4.2 The Buyer may, in its sole discretion, require the Supplier to provide evidence of the Supplier's compliance with clause 4.1 in lieu of conducting such an audit, assessment or inspection.

5. Impact Assessments

5.1 The Parties shall:

(a) provide all reasonable assistance to each other to prepare any Data Protection Impact Assessment as may be required (including provision of detailed information and assessments in relation to Processing operations, risks and measures); and

(b) maintain full and complete records of all Processing carried out in respect of the Personal Data in connection with the Contract, in accordance with the terms of Article 30 GDPR.

6. ICO Guidance

The Parties agree to take account of any guidance issued by the Information Commissioner and/or any relevant Central Government Body. The Buyer may on not less than thirty (30) Working Days' notice to the Supplier amend the Contract to ensure that it complies with any guidance issued by the Information Commissioner and/or any relevant Central Government Body.

7. Liabilities for Data Protection Breach

7.1 If financial penalties are imposed by the Information Commissioner on either the Buyer or the Supplier for a Personal Data Breach ("**Financial Penalties**") then the following shall occur:

(a) if in the view of the Information Commissioner, the Buyer is responsible for the Personal Data Breach, in that it is caused as a result of the actions or inaction of the Buyer, its employees, agents, contractors (other than the Supplier) or systems and procedures controlled by the Buyer, then the Buyer shall be responsible for the payment of such Financial Penalties. In this case, the Buyer will conduct an internal audit and engage at its reasonable cost when necessary, an independent third party to conduct an audit of any such Personal Data Breach. The Supplier shall provide to the Buyer and its third party investigators and auditors, on request and at the Supplier's reasonable cost, full cooperation and access to conduct a thorough audit of such Personal Data Breach;

(b) if in the view of the Information Commissioner, the Supplier is responsible for the Personal Data Breach, in that it is not a Personal Data Breach that the Buyer is responsible for, then the Supplier shall be responsible for the payment of these Financial Penalties. The Supplier will provide to the Buyer and its auditors, on request and at the Supplier's sole cost, full cooperation and access to conduct a thorough audit of such Personal Data Breach; or

(c) if no view as to responsibility is expressed by the Information Commissioner, then the Buyer and the Supplier shall work together to investigate the relevant Personal Data Breach and allocate responsibility for any Financial Penalties as outlined above, or by agreement to split any financial penalties equally if no responsibility for the Personal Data Breach can be apportioned. In the event that the Parties do not agree such apportionment then such Dispute shall be referred to the Dispute Resolution Procedure set out in Clause 34 of the Core Terms (*Resolving disputes*).

7.2 If either the Buyer or the Supplier is the defendant in a legal claim brought before a court of competent jurisdiction ("**Court**") by a third party in respect of a Personal Data Breach, then unless the Parties otherwise agree, the Party that is determined by the final decision of the court to be responsible for the Personal Data Breach shall be liable for the losses arising from such Personal Data Breach. Where both Parties are liable, the liability will be apportioned between the Parties in accordance with the decision of the Court.

7.3 In respect of any losses, cost claims or expenses incurred by either Party as a result of a Personal Data Breach (the "**Claim Losses**"):

(a) if the Buyer is responsible for the relevant Personal Data Breach, then the Buyer shall be responsible for the Claim Losses;

(b) if the Supplier is responsible for the relevant Personal Data Breach, then the Supplier shall be responsible for the Claim Losses: and

(c) if responsibility for the relevant Personal Data Breach is unclear, then the Buyer and the Supplier shall be responsible for the Claim Losses equally.

7.4 Nothing in either clause 7.2 or clause 7.3 shall preclude the Buyer and the Supplier reaching any other agreement, including by way of compromise with a third party complainant or claimant, as to the apportionment of financial responsibility for any Claim Losses as a result of a Personal Data Breach, having regard to all the circumstances of the Personal Data Breach and the legal and financial obligations of the Buyer.

8. Termination

If the Supplier is in material Default under any of its obligations under this Annex 2 (*Joint Controller Agreement*), the Buyer shall be entitled to terminate the Contract by issuing a Termination Notice to the Supplier in accordance with Clause 10 of the Core Terms (*Ending the contract*).

9. Sub-Processing

10.1 In respect of any Processing of Personal Data performed by a third party on behalf of a Party, that Party shall:

(a) carry out adequate due diligence on such third party to ensure that it is capable of providing the level of protection for the Personal Data as is required by the Contract, and provide evidence of such due diligence to the other Party where reasonably requested; and

(b) ensure that a suitable agreement is in place with the third party as required under applicable Data Protection Legislation.

10. Data Retention

The Parties agree to erase Personal Data from any computers, storage devices and storage media that are to be retained as soon as practicable after it has ceased to be necessary for them to retain such Personal Data under applicable Data Protection Legislation and their privacy policy (save to the extent (and for the limited period) that such information needs to be retained by the Party for statutory compliance purposes or as otherwise required by the Contract), and taking all further actions as may be necessary to ensure its compliance with Data Protection Legislation and its privacy policy.

Schedule 21 (Variation Form)

This form is to be used in order to change a contract in accordance with Clause 24 of the Core Terms (Changing the Contract)

Contract Details		
This variation is between:	**[**Buyer**]** (**"the Buyer"**) And **[insert** name of Supplier**]** (**"the Supplier"**)	
Contract name:	**[insert** name of contract to be changed] **("the Contract")**	
Contract reference number:	**[insert** contract reference number]	
Details of Proposed Variation		
Variation initiated by:	**[delete** as applicable: Buyer/Supplier]	
Variation number:	**[insert** variation number]	
Date variation is raised:	**[insert** date]	
Proposed variation		
Reason for the variation:	**[insert** reason]	
An Impact Assessment shall be provided within:	**[insert** number] days	
Impact of Variation		
Likely impact of the proposed variation:	**[Supplier to insert** assessment of impact]	
Outcome of Variation		
Contract variation:	This Contract detailed above is varied as follows: • **[Buyer to insert** original Clauses or Paragraphs to be varied and the changed clause]	
Financial variation:	Original Contract Value:	£ **[insert** amount]
	Additional cost due to variation:	£ **[insert** amount]
	New Contract value:	£ **[insert** amount]

1. This Variation must be agreed and signed by both Parties to the Contract and shall only be effective from the date it is signed by the Buyer

2. Words and expressions in this Variation shall have the meanings given to them in the Contract.

3. The Contract, including any previous Variations, shall remain effective and unaltered except as amended by this Variation.

Signed by an authorised signatory for and on behalf of the Buyer

Signature	
Date	
Name (in Capitals)	
Address	

Signed by an authorised signatory to sign for and on behalf of the Supplier

Schedule 22 (Insurance Requirements)

1. The insurance you need to have

1.1 The Supplier shall take out and maintain or procure the taking out and maintenance of the insurances as set out in the Annex to this Schedule and any other insurances as may be required by applicable Law (together the "**Insurances**"). The Supplier shall ensure that each of the Insurances is effective no later than

the Start Date in respect of those Insurances set out in the Annex to this Schedule and those required by applicable Law; and

1.2 The Insurances shall be:

1.2.1 maintained in accordance with Good Industry Practice;

1.2.2 (so far as is reasonably practicable) on terms no less favourable than those generally available to a prudent contractor in respect of risks insured in the international insurance market from time to time;

1.2.3 taken out and maintained with insurers of good financial standing and good repute in the international insurance market; and

1.2.4 maintained for at least six (6) years after the End Date.

2. How to manage the insurance

2.1 Without limiting the other provisions of this Contract, the Supplier shall:

2.1.1 take or procure the taking of all reasonable risk management and risk control measures in relation to Deliverables as it would be reasonable to expect of a prudent contractor acting in accordance with Good Industry Practice, including the investigation and reports of relevant claims to insurers;

2.1.2 promptly notify the insurers in writing of any relevant material fact under any Insurances of which the Supplier is or becomes aware; and

2.1.3 hold all policies in respect of the Insurances and cause any insurance broker effecting the Insurances to hold any insurance slips and other evidence of placing cover representing any of the Insurances to which it is a party.

3. What happens if you aren't insured

3.1 The Supplier shall not take any action or fail to take any action or (insofar as is reasonably within its power) permit anything to occur in relation to it which would entitle any insurer to refuse to pay any claim under any of the Insurances.

3.2 Where the Supplier has failed to purchase or maintain any of the Insurances in full force and effect, the Buyer may elect (but shall not be obliged) following

written notice to the Supplier to purchase the relevant Insurances and recover the reasonable premium and other reasonable costs incurred in connection therewith as a debt due from the Supplier.

4. Evidence of insurance you must provide

4.1 The Supplier shall upon the Start Date and within 15 Working Days after the renewal of each of the Insurances, provide evidence, in a form satisfactory to the Buyer, that the Insurances are in force and effect and meet in full the requirements of this Schedule.

5. Making sure you are insured to the required amount

5.1 The Supplier shall ensure that any Insurances which are stated to have a minimum limit "in the aggregate" are maintained at all times for the minimum limit of indemnity specified in this Contract and if any claims are made which do not relate to this Contract then the Supplier shall notify the Buyer and provide details of its proposed solution for maintaining the minimum limit of indemnity.

6. Cancelled Insurance

6.1 The Supplier shall notify the Buyer in writing at least five (5) Working Days prior to the cancellation, suspension, termination or non-renewal of any of the Insurances.

6.2 The Supplier shall ensure that nothing is done which would entitle the relevant insurer to cancel, rescind or suspend any insurance or cover, or to treat any insurance, cover or claim as voided in whole or part. The Supplier shall use all reasonable endeavours to notify the Buyer (subject to third party confidentiality obligations) as soon as practicable when it becomes aware of any relevant fact, circumstance or matter which has caused, or is reasonably likely to provide grounds to, the relevant insurer to give notice to cancel, rescind, suspend or void any insurance, or any cover or claim under any insurance in whole or in part.

7. Insurance claims

7.1 The Supplier shall promptly notify to insurers any matter arising from, or in relation to, the Deliverables, or the Contract for which it may be entitled to claim under any of the Insurances. In the event that the Buyer receives a claim relating to or arising out of the Contract or the Deliverables, the Supplier shall co-operate with the Buyer and assist it in dealing with such claims including without limitation providing information and documentation in a timely manner.

7.2 Except where the Buyer is the claimant party, the Supplier shall give the Buyer notice within twenty (20) Working Days after any insurance claim in excess of 10% of the sum required to be insured pursuant to Paragraph 5.1 relating to or arising out of the provision of the Deliverables or this Contract on any of the Insurances or which, but for the application of the applicable policy excess, would

be made on any of the Insurances and (if required by the Buyer) full details of the incident giving rise to the claim.

7.3 Where any Insurance requires payment of a premium, the Supplier shall be liable for and shall promptly pay such premium.

7.4 Where any Insurance is subject to an excess or deductible below which the indemnity from insurers is excluded, the Supplier shall be liable for such excess or deductible. The Supplier shall not be entitled to recover from the Buyer any sum paid by way of excess or deductible under the Insurances whether under the terms of this Contract or otherwise.

ANNEX: REQUIRED INSURANCES

1. The Supplier shall hold the following insurance cover from the Start Date in accordance with this Schedule:

1.1 professional indemnity insurance with cover (for a single event or a series of related events and in the aggregate) of not less than] ten million pounds (£10,000,000);

1.2 public liability insurance [with cover (for a single event or a series of related events and in the aggregate)] of not less than ten million pounds (£10,000,000); and

1.3 employers' liability insurance [with cover (for a single event or a series of related events and in the aggregate) of not less than] ten million pounds (£10,000,000).

Schedule 27 (Key Subcontractors)

Not Used

Schedule 32 (Background Checks)

Not Used