NHS TERMS AND CONDITIONS FOR THE PROVISION OF SERVICES (CONTRACT VERSION)

The Authority	**NHS Commissioning Board**
The Supplier	**IQVIA Ltd**
Date	**June 2021**
Type of Services	**Professional**

This Contract is made on the date set out above subject to the terms set out in the schedules listed below ("**Schedules**"). The Authority and the Supplier undertake to comply with the provisions of the Schedules in the performance of this Contract.

The Supplier shall supply to the Authority, and the Authority shall receive and pay for, the Services on the terms of this Contract.

The Definitions in Schedule 4 apply to the use of all capitalised terms in this Contract.

Schedules

Schedule 1	Key Provisions
Schedule 2	General Terms and Conditions
Schedule 3	Information and Data Provisions
Schedule 4	Definitions and Interpretations
Schedule 5	Specification and Tender Response Document
Schedule 6	Commercial Schedule
Schedule 7	Staff Transfer
Schedule 8	Expert Determination
Schedule 9	Mobilisation Plan
Schedule 10	NHS England's Supplier Code of Conduct

Signed by the authorised representative of THE AUTHORITY By e-signature

[redacted]

Full Name: [redacted]
Job Title/Role: [redacted]
Date: 14/6/21

Signed by the authorised representative of THE SUPPLIER By e-signature

[redacted]

Full Name: [redacted]
Job Title/Role: [redacted]
Date: 13 June 2021

Schedule 1

Key Provisions

Guidance: These Key Provisions enable the Authority to complete project specific details and to add any optional and/or extra provisions applicable to the relevant project.

Standard Key Provisions

1 Application of the Key Provisions

1.1 The standard Key Provisions at Clauses 1 to 7 of this Schedule 1 shall apply to this Contract.

1.2 The optional Key Provisions at Clauses 8 to 24 of this Schedule 1 shall only apply to this Contract where they have been checked and information completed as applicable.

1.3 Extra Key Provisions shall only apply to this Contract where such provisions are set out at the end of this Schedule 1.

2 Term

2.1 This Contract shall commence on the 14th **June 2021** and the Term of this Contract shall expire on **30th November 2022** 18 months from the Actual Services Commencement Date. The Term may be extended in accordance with Clause 15.2 of Schedule 2 provided that the duration of this Contract shall be no longer than 22 months in total.

3 Contract Managers

3.1 The Contract Managers at the commencement of this Contract are:

3.1.1 for the Authority:

[redacted] – NHS Cancer Programme

3.1.2 for the Supplier:
[redacted], IQVIA Ltd

4 Names and addresses for notices

4.1 Notices served under this Contract are to be delivered to:

4.1.1 for the Authority:
[redacted] – NHS Cancer Programme
NHS England
Skipton House, London, SE1 6RH

4.1.2 for the Supplier:
[redacted], IQVIA Ltd

IQVIA Ltd, 3 Forbury Place, 23 Forbury Road, Reading RG1 3JH.

5 Management levels for escalation and dispute resolution

5.1 The management levels at which a Dispute may be dealt with as referred to as part of the Dispute Resolution Procedure are as follows:

Level	Authority representative	Supplier representative
1	[redacted] – NHS Cancer Programme	[redacted]
2	[redacted] – NHS Cancer Programme	[redacted] Director
3	[redacted] Cancer Programme	[redacted] UK&I Healthcare IQVIA

6 Order of precedence

6.1 Subject always to Clause 1.10 of Schedule 4, should there be a conflict between any other parts of this Contract the order of priority for construction purposes shall be:

6.1.1 the provisions on the front page of this NHS Contract for the Provision of Services (Contract Version);

6.1.2 Schedule 1: Key Provisions;

6.1.3 Schedule 5: Specification and Tender Response Document (but only in respect of the Authority's requirements);

6.1.4 Schedule 2: General Terms and Conditions;

6.1.5 Schedule 6: Commercial Schedule;

6.1.6 Schedule 3: Information Governance Provisions;

6.1.7 Schedule 7: Staff Transfer;

6.1.8 Schedule 4: Definitions and Interpretations;

6.1.9 the order in which all subsequent schedules, if any, appear; and

6.1.10 any other documentation forming part of the Contract in the date order in which such documentation was created with the more recent documentation taking precedence over older documentation to the extent only of any conflict.

6.2 For the avoidance of doubt, the Specification and Tender Response Document shall include, without limitation, the Authority's requirements in the form of its specification and other statements and requirements, the Supplier's responses, proposals and/or

method statements to meet those requirements, and any clarifications to the Supplier's responses, proposals and/or method statements as included as part of Schedule 5. Should there be a conflict between these parts of the Specification and Tender Response Document, the order of priority for construction purposes shall be (1) the Authority's requirements; (2) any clarification to the Supplier's responses, proposals and/or method statements, and (3) the Supplier's responses, proposals and/or method statements.

7 Application of TUPE at the commencement of the provision of Services

7.1 The Parties agree that at the commencement of the provision of Services by the Supplier, TUPE and the Cabinet Office Statement shall not apply so as to transfer the employment of any employees of the Authority or a Third Party to the Supplier and the provisions of Schedule 7 shall apply.

Optional Key Provisions

8 Implementation phase ☐ (only applicable to the Contract if this box is checked and the Schedule inserted)

8.1 Prior to commencement of delivery of the Services, there is an implementation phase and therefore all references in Schedule 2 to the Implementation Plan shall apply and the Implementation Plan is set out in Schedule **9**.

9 Services Commencement Date (where the Services are to start at a date after the Commencement Date) ☐ (only applicable to the Contract if this box is checked and the dates are inserted in Clause 9.1 of this Schedule 1)

9.1 The Services Commencement Date shall be **[*insert date*]** and the Long Stop Date referred to in Clause 15.5.1 of Schedule 2 shall be **[*insert date*]**.

10 Induction training ☐ (only applicable to the Contract if this box is checked)

10.1 The Supplier shall ensure that all Staff complete the Authority's induction training. All Staff shall complete the training prior to the Actual Services Commencement Date (or immediately following the Services Commencement Date where this date is the date of this Contract) and all new Staff appointed throughout the Term shall also complete the training. The Supplier shall further ensure that all Staff complete any extra training that the Authority makes available to its own staff and notifies the Supplier in writing that it is appropriate for the Staff.

11 Quality assurance standards ☒ (only applicable to the Contract if this box is checked and the standards are listed)

11.1 The following quality assurance standards shall apply, as appropriate, to the provision of the Services: as defined in the Statement of Requirements, Appendix 1

12 Different levels and/or types of insurance ☐ (only applicable to the Contract if this box is checked and the table sets out the requirements)

12.1 The Supplier shall put in place and maintain in force the following insurances with the following minimum cover per claim:

Type of insurance required	Minimum cover
Employer's Liability	£5,000,000
Public Liability	£5,000,000
Professional Indemnity	£5,000,000

13 Further Authority obligations ☐ (only applicable to the Contract if this box is checked and the Schedule inserted)

13.1 The Authority's Obligations are set out in Schedule **5**.

14 Assignment of Intellectual Property Rights in deliverables, materials and outputs ☒ (only applicable to the Contract if this box is checked)

14.1 The Supplier confirms and agrees that all Intellectual Property Rights in and to the deliverables, material and any other output developed by the Supplier as part of the Services in accordance with the Specification and Tender Response Document, shall be owned by the Authority. The Supplier hereby assigns with full title guarantee by way of present and future assignment all Intellectual Property Rights in and to such deliverables, material and other outputs. The Supplier shall ensure that all Staff assign any Intellectual Property Rights they may have in and to such deliverables, material and other outputs to the Supplier to give effect to Clause 14 of this Schedule 1 and that such Staff absolutely and irrevocably waive their moral rights in relation to such deliverables, material and other outputs. Clause 14 of this Schedule 1 shall continue notwithstanding the expiry or earlier termination of this Contract.

15 Inclusion of a Change Control Process ☐ (only applicable to the Contract if this box is checked and the Schedule inserted)

15.1 Any changes to this Contract, including to the Services, may only be agreed in accordance with the Change Control Process set out in Schedule **[]**.

16 Authority step-in rights ☐ (only applicable to the Contract if this box is checked and the Schedule inserted)

16.1 If the Supplier is unable to provide the Services then the Authority shall be entitled to exercise Step In Rights set out in Schedule **[]**.

17 Grant of lease or licence ☐ (only applicable to the Contract if this box is checked)

17.1 Promptly following execution of this Contract, the Supplier shall enter into the **[]**. Failure to comply with this Key Provision shall be an irremediable breach of this Contract.

18 Guarantee ☐ (only applicable to the Contract if this box is checked)

18.1 Promptly following the execution of this Contract, the Supplier shall, if it has not already delivered an executed deed of guarantee to the Authority, deliver the executed deed of guarantee to the Authority as required by the procurement process followed by the Authority. Failure to comply with this Key Provision shall be an irremediable breach of this Contract.

19 Supplier as Data Processor ☒ (only applicable to the Contract if this box is checked)

19.1 The Parties acknowledge that the Authority is the Controller and the Supplier is the Processor in respect of Personal Data Processed under this Contract and that paragraph 2.2 of Schedule 3 and the provisions of the Data Protection Protocol must be complied with by the Parties as a term of this Contract.

20 Purchase Orders ☒ (only applicable to the Contract if this box is checked)

20.1 The Authority shall issue a Purchase Order to the Supplier in respect of any Services to be supplied to the Authority under this Contract. The Supplier shall comply with the terms of such Purchase Order as a term of this Contract. For the avoidance of doubt, any actions or work undertaken by the Supplier under this Contract prior to the receipt of a Purchase Order covering the relevant Services shall be undertaken at the Supplier's risk and expense and the Supplier shall only be entitled to invoice for Services covered by a valid Purchase Order.

21 Monthly payment profile ☐ (only applicable to the Contract if this box is checked)

21.1 The payment profile for this Contract shall be monthly in arrears.

22 Termination for convenience ☒ (only applicable to the Contract if this box is checked and Clause 22.1 of this Schedule 1 is completed)

22.1 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier at any time on ***three (3)* months'** written notice.

23 Right to terminate following a specified number of material breaches ☐ (only applicable to the Contract if this box is checked and Clause 23.1 of this Schedule 1 is completed)

23.1 Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of this Contract in circumstances where it is served with a valid Breach Notice having already been served with at least [two (2)] previous valid Breach Notices within the last twelve (12) calendar month rolling period as a result of any previous material breaches of this Contract which are

capable of remedy (whether or not the Party in breach has remedied the breach in accordance with a Remedial Proposal). The twelve (12) month rolling period is the twelve (12) months immediately preceding the date of the [third] Breach Notice.

24 Expert Determination ☐ (only applicable to the Contract if this box is checked)

24.1 Any Dispute between the Authority and the Supplier shall be dealt in accordance with the expert determination process as specified at Schedule 8.

24.2 For the avoidance of doubt, where this Clause 24 of this Schedule 1 is checked, all Disputes shall be dealt in accordance with Clause 24.1 of this Schedule 1 above and the entirety of Clause 22 of Schedule 2 shall be deemed not to apply and deleted in its entirety from this Contract.

Schedule 2

General Terms and Conditions

Contents

1 Provision of Services

1.1 The Authority appoints the Supplier and the Supplier agrees to provide the Services:

1.1.1 promptly and in any event within any time limits as may be set out in this Contract;

1.1.2 in accordance with all other provisions of this Contract;

1.1.3 with reasonable skill and care and in accordance with any quality assurance standards as set out in the Key Provisions and/or the Specification and Tender Response Document;

1.1.4 in accordance with the Law and with Guidance;

1.1.5 in accordance with Good Industry Practice;

1.1.6 in accordance with the Policies; and

1.1.7 in a professional and courteous manner.

In complying with its obligations under this Contract, the Supplier shall, and shall procure that all Staff shall, act in accordance with the NHS values as set out in the NHS Constitution from time to time.

1.2 The Supplier shall comply with the Implementation Requirements (if any) in accordance with any timescales as may be set out in the Specification and Tender Response Document., Without limitation to the foregoing provisions of this Clause 1.2 of this Schedule 2, the Supplier shall, if specified in the Key Provisions, implement the Services fully in accordance with the Implementation Plan. If the Implementation Plan is an outline plan, the Supplier shall, as part of implementation, develop the outline plan into a full plan and agree this with the Authority. Once this is agreed, the Supplier shall comply with the full Implementation Plan.

1.3 The Supplier shall commence delivery of the Services on the Services Commencement Date.

1.4 The Supplier shall comply fully with its obligations set out in the Specification and Tender Response Document, including without limitation the KPIs.

1.5 The Supplier shall ensure that all relevant consents, authorisations, licences and accreditations required to provide the Services are in place at the Actual Services Commencement Date and are maintained throughout the Term.

1.6 If the Services, or any part of them, are regulated by any regulatory body, the Supplier shall ensure that at the Actual Services Commencement Date it has in place all relevant registrations and shall maintain such registrations during the Term. The Supplier shall notify the Authority forthwith in writing of any changes to such registration or any other matter relating to its registration that would affect the delivery or the quality of Services.

1.7 The Supplier shall notify the Authority forthwith in writing:

1.7.1 of any pending inspection of the Services, or any part of them, by a regulatory body immediately upon the Supplier becoming aware of such inspection; and

1.7.2 of any failure of the Services, or any part of them, to meet the quality standards required by a regulatory body, promptly and in any event within two (2) Business Days of the Supplier becoming aware of any such failure. This shall include without limitation any informal feedback received during or following an inspection raising concerns of any nature regarding the provision of the Services.

1.8 Following any inspection of the Services, or any part of them, by a regulatory body, the Supplier shall provide the Authority with a copy of any report or other communication published or provided by the relevant regulatory body in relation to the provision of the Services.

1.9 Upon receipt of notice pursuant to Clause 1.7 of this Schedule 2 or any report or communication pursuant to Clause 1.8 of this Schedule 2, the Authority shall be entitled to request further information from the Supplier and/or a meeting with the Supplier, and the Supplier shall cooperate fully with any such request.

1.10 Where applicable, the Supplier shall implement and comply with the Policies on reporting and responding to all incidents and accidents, including serious incidents requiring investigation, shall complete the Authority's incident and accident forms in accordance with the Policies and provide reasonable support and information as requested by the Authority to help the Authority deal with any incident or accident relevant to the Services. The Supplier shall ensure that its Contract Manager informs the Authority's Contract Manager in writing forthwith upon (a) becoming aware that any serious incidents requiring investigation and/or notifiable accidents have occurred; or (b) the Supplier's Contract Manager having reasonable cause to believe any serious incidents and/or notifiable accidents requiring investigation have occurred. The Supplier shall ensure that its Contract Manager informs the Authority's Contract Manager in writing within forty eight (48) hours of all other incidents and/or accidents that have or may have an impact on the Services.

1.11 Should the Authority be of the view, acting reasonably, that the Supplier can no longer provide the Services, then without prejudice to the Authority's rights and remedies under this Contract, the Authority shall be entitled to exercise its Step In Rights if the Key Provisions refer to the Authority having such rights under this Contract.

1.12 The Supplier shall be relieved from its obligations under this Contract to the extent that it is prevented from complying with any such obligations due to any acts, omissions or defaults of the Authority. To qualify for such relief, the Supplier must notify the Authority promptly (and in any event within five (5) Business Days) in writing of the occurrence of such act, omission, or default of the Authority together with the potential impact on the Supplier's obligations.

2 Premises, locations and access

2.1 The Services shall be provided at such Authority premises and at such locations within those premises, as may be set out in the Specification and Tender Response Document or as otherwise agreed by the Parties in writing ("**Premises and Locations**").

2.2 Subject to the Supplier and its Staff complying with all relevant Policies applicable to such Premises and Locations, the Authority shall grant reasonable access to the Supplier and its Staff to such Premises and Locations to enable the Supplier to provide the Services.

2.3 Subject to Clause 2.4 of this Schedule 2, any access granted to the Supplier and its Staff under Clause 2.2 of this Schedule 2 shall be non-exclusive and revocable. Such access shall not be deemed to create any greater rights or interest than so granted (to include, without limitation, any relationship of landlord and tenant) in the Premises and Locations. The Supplier warrants that it shall carry out all such reasonable further acts to give effect to this Clause 2.3 of this Schedule 2.

2.4 Where, in order to provide the Services, the Supplier requires any greater rights to use or occupy any specific Premises and Locations over and above such reasonable access rights granted in accordance with Clause 2.2 and Clause 2.3 of this Schedule 2, such further rights shall be limited to any rights granted to the Supplier by the Authority in accordance with any licence and/or lease entered into by the Supplier in accordance with the Key Provisions.

2.5 Where it is provided for by a specific mechanism set out in the Specification and Tender Response Document, the Authority may increase, reduce or otherwise vary the Premises and Locations in accordance with such mechanism subject to the provisions of any licence or lease entered into by the Parties as referred to at Clause 2.4 of this Schedule 2. Where there is no such specific mechanism set out in the Specification and Tender Response Document, any variations to the Premises and Locations where the Services are to be provided shall be agreed by the Parties in accordance with Clause 21 of this Schedule 2. If agreement cannot be reached the matter shall be referred to, and resolved in accordance with, the Dispute Resolution Procedure.

3 Cooperation with third parties

3.1 The Supplier shall, as reasonably required by the Authority, cooperate with any other service providers to the Authority and/or any other third parties as may be relevant in the provision of the Services.

4 Use of Authority equipment

4.1 Unless otherwise set out in the Specification and Tender Response Document or otherwise agreed by the Parties in writing, any equipment or other items provided by the Authority for use by the Supplier:

4.1.1 shall be provided at the Authority's sole discretion;

4.1.2 shall be inspected by the Supplier in order that the Supplier can confirm to its reasonable satisfaction that such equipment and/or item is fit for its intended use and shall not be used by the Supplier until it has satisfied itself of this;

4.1.3 must be returned to the Authority within any agreed timescales for such return or otherwise upon the request of the Authority; and

4.1.4 shall be used by the Supplier at the Supplier's risk and the Supplier shall upon written request by the Authority reimburse the Authority for any loss or damage relating to such equipment or other items caused by the Supplier (fair wear and tear exempted).

5 Staff and Lifescience Industry Accredited Credentialing Register

5.1 Subject to the requirements of this Contract and any Law, the Supplier shall be entirely responsible for the employment and conditions of service of Staff. The Supplier shall

ensure that such conditions of employment are consistent with its obligations under this Contract.

5.2 The Supplier will employ sufficient Staff to ensure that it complies with its obligations under this Contract. This will include, but not be limited to, the Supplier providing a sufficient reserve of trained and competent Staff to provide the Services during Staff holidays or absence.

5.3 The Supplier shall use reasonable endeavours to ensure the continuity of all Staff in the provision of the Services and, where any member of Staff is designated as key to the provision of the Services as set out in the Specification and Tender Response Document or as otherwise agreed between the Parties in writing, any redeployment and/or replacement of such member of Staff by the Supplier shall be subject to the prior written approval of the Authority, such approval not to be unreasonably withheld or delayed.

5.4 The Supplier shall ensure that all Staff are aware of, and at all times comply with, the Policies.

5.5 The Supplier shall:

5.5.1 employ only those Staff who are careful, skilled and experienced in the duties required of them;

5.5.2 ensure that every member of Staff is properly and sufficiently trained and instructed;

5.5.3 ensure all Staff have the qualifications to carry out their duties;

5.5.4 maintain throughout the Term all appropriate licences and registrations with any relevant bodies (at the Supplier's expense) in respect of the Staff; and

5.5.5 ensure all Staff comply with such registration, continuing professional development and training requirements or recommendations appropriate to their role including those from time to time issued by the Department of Health or any relevant regulatory body or any industry body in relation to such Staff.

5.6 The Supplier shall not deploy in the provision of the Services any person who has suffered from, has signs of, is under treatment for, or who is suffering from any medical condition which is known to, or does potentially, place the health and safety of the Authority's staff, patients, service users or visitors at risk unless otherwise agreed in writing with the Authority.

5.7 The Supplier shall ensure that all potential Staff or persons performing any of the Services during the Term who may reasonably be expected in the course of performing any of the Services under this Contract to have access to or come into contact with children or other vulnerable persons and/or have access to or come into contact with persons receiving health care services:

5.7.1 are questioned concerning their Convictions; and

5.7.2 obtain appropriate disclosures from the Disclosure and Barring Service (or other appropriate body) as required by Law and/or the Policies before the

Supplier engages the potential staff or persons in the provision of the Services.

5.8 The Supplier shall take all necessary steps to ensure that such potential staff or persons obtain standard and enhanced disclosures from the Disclosure and Barring Service (or other appropriate body) and shall ensure all such disclosures are kept up to date. The obtaining of such disclosures shall be at the Supplier's cost and expense.

5.9 The Supplier shall ensure that no person is employed or otherwise engaged in the provision of the Services without the Authority's prior written consent if:

5.9.1 the person has disclosed any Convictions upon being questioned about their Convictions in accordance with Clause 5.7.1 of this Schedule 2;

5.9.2 the person is found to have any Convictions following receipt of standard and/or enhanced disclosures from the Disclosure and Barring Service (or other appropriate body) in accordance with Clause 5.7.2 of this Schedule 2; or

5.9.3 the person fails to obtain standard and/or enhanced disclosures from the Disclosure and Barring Service (or other appropriate body) upon request by the Supplier in accordance with Clause 5.7.2 of this Schedule 2.

5.10 In addition to the requirements of Clause 5.7 to Clause 5.9 of this Schedule 2, where the Services are or include regulated activities as defined by the Safeguarding Vulnerable Groups Act 2006 the Supplier:

5.10.1 warrants that it shall comply with all requirements placed on it by the Safeguarding Vulnerable Groups Act 2006;

5.10.2 warrants that at all times it has and will have no reason to believe that any member of Staff is barred in accordance with the Safeguarding Vulnerable Groups Act 2006; and

5.10.3 shall ensure that no person is employed or otherwise engaged in the provision of the Services if that person is barred from carrying out, or whose previous conduct or records indicate that they would not be suitable to carry out, any regulated activities as defined by the Safeguarding Vulnerable Groups Act 2006 or may present a risk to patients, service users or any other person.

5.11 The Supplier shall ensure that the Authority is kept advised at all times of any member of Staff who, subsequent to their commencement of employment as a member of Staff receives a Conviction or whose previous Convictions become known to the Supplier or whose conduct or records indicate that they are not suitable to carry out any regulated activities as defined by the Safeguarding Vulnerable Groups Act 2006 or may present a risk to patients, service users or any other person. The Supplier shall only be entitled to continue to engage or employ such member of Staff with the Authority's written consent and with such safeguards being put in place as the Authority may reasonably request. Should the Authority withhold consent the Supplier shall remove such member of Staff from the provision of the Services forthwith.

5.12 The Supplier shall immediately provide to the Authority any information that the Authority reasonably requests to enable the Authority to satisfy itself that the obligations set out in Clause 5.7 to Clause 5.11 of this Schedule 2 have been met.

5.13 The Authority may at any time request that the Supplier remove and replace any member of Staff from the provision of the Services, provided always that the Authority will act reasonably in making such a request. Prior to making any such request the Authority shall raise with the Supplier the Authority's concerns regarding the member of Staff in question with the aim of seeking a mutually agreeable resolution. The Authority shall be under no obligation to have such prior discussion should the Authority have concerns regarding patient or service user safety.

5.14 Unless otherwise confirmed by the Authority in writing, the Supplier shall ensure full compliance (to include with any implementation timelines) with any Guidance issued by the Department of Health and Social Care and/or any requirements and/or Policies issued by the Authority (to include as may be set out as part of any procurement documents leading to the award of this Contract) in relation to the adoption of, and compliance with, any scheme or schemes to verify the credentials of Supplier representatives that visit NHS premises (to include use of the Lifescience Industry Accredited Credentialing Register). Once compliance with any notified implementation timelines has been achieved by the Supplier, the Supplier shall, during the Term, maintain the required level of compliance in accordance with any such Guidance, requirements and Polices.

6 Business continuity

6.1 The Supplier shall use reasonable endeavours to ensure its Business Continuity Plan operates effectively alongside the Authority's business continuity plan where relevant to the provision of the Services. The Supplier shall also ensure that its Business Continuity Plan complies on an ongoing basis with any specific business continuity requirements, as may be set out in the Specification and Tender Response Document.

6.2 Throughout the Term, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees such Business Continuity Plan details and will continue to detail robust arrangements that are reasonable and proportionate to:

6.2.1 the criticality of this Contract to the Authority; and

6.2.2 the size and scope of the Supplier's business operations,

regarding continuity of the provision of the Services during and following a Business Continuity Event.

6.3 The Supplier shall test its Business Continuity Plan at reasonable intervals, and in any event no less than once every twelve (12) months or such other period as may be agreed between the Parties taking into account the criticality of this Contract to the Authority and the size and scope of the Supplier's business operations. The Supplier shall promptly provide to the Authority, at the Authority's written request, copies of its Business Continuity Plan, reasonable and proportionate documentary evidence that the Supplier tests its Business Continuity Plan in accordance with the requirements of this Clause 6.3 of this Schedule 2 and reasonable and proportionate information regarding the outcome of such tests. The Supplier shall provide to the Authority a copy of any updated or revised Business Continuity Plan within fourteen (14) Business Days of any material update or revision to the Business Continuity Plan.

6.4 The Authority may suggest reasonable and proportionate amendments to the Supplier regarding the Business Continuity Plan at any time. Where the Supplier, acting

reasonably, deems such suggestions made by the Authority to be relevant and appropriate, the Supplier will incorporate into the Business Continuity Plan all such suggestions made by the Authority in respect of such Business Continuity Plan. Should the Supplier not incorporate any suggestion made by the Authority into such Business Continuity Plan it will explain the reasons for not doing so to the Authority.

6.5 Should a Business Continuity Event occur at any time, the Supplier shall implement and comply with its Business Continuity Plan and provide regular written reports to the Authority on such implementation.

6.6 During and following a Business Continuity Event, the Supplier shall use reasonable endeavours to continue to provide the Services in accordance with this Contract.

7 The Authority's obligations

7.1 Subject to the Supplier providing the Services in accordance with this Contract, the Authority will pay the Supplier for the Services in accordance with Clause 9 of this Schedule 2.

7.2 The Authority shall, as appropriate, provide copies of or give the Supplier access to such of the Policies that are relevant to the provision of the Services.

7.3 The Authority shall comply with the Authority's Obligations, as may be referred to in the Key Provisions.

7.4 The Authority shall provide the Supplier with any reasonable and proportionate cooperation necessary to enable the Supplier to comply with its obligations under this Contract. The Supplier shall at all times provide reasonable advance written notification to the Authority of any such cooperation necessary in circumstances where such cooperation will require the Authority to plan for and/or allocate specific resources in order to provide such cooperation.

8 Contract management

8.1 Each Party shall appoint and retain a Contract Manager who shall be the primary point of contact for the other Party in relation to matters arising from this Contract. Should the Contract Manager be replaced, the Party replacing the Contract Manager shall promptly inform the other Party in writing of the name and contact details for the new Contract Manager. Any Contract Manager appointed shall be of sufficient seniority and experience to be able to make decisions on the day to day operation of the Contract. The Supplier confirms and agrees that it will be expected to work closely and cooperate fully with the Authority's Contract Manager.

8.2 Each Party shall ensure that its representatives (to include, without limitation, its Contract Manager) shall attend review meetings on a regular basis to review the performance of the Supplier under this Contract and to discuss matters arising generally under this Contract. Each Party shall ensure that those attending such meetings have the authority to make decisions regarding the day to day operation of the Contract. Review meetings shall take place at the frequency specified in the Specification and Tender Response Document. Should the Specification and Tender Response Document not state the frequency, then the first such meeting shall take place on a date to be agreed on or around the end of the first month after the Commencement Date. Subsequent meetings shall take place at monthly intervals or as may otherwise be agreed in writing between the Parties.

8.3 Two weeks prior to each review meeting (or at such time and frequency as may be specified in the Specification and Tender Response Document) the Supplier shall provide a written contract management report to the Authority regarding the provision of the Services and the operation of this Contract. Unless otherwise agreed by the Parties in writing, such contract management report shall contain:

8.3.1 details of the performance of the Supplier when assessed in accordance with the KPIs since the last such performance report;

8.3.2 details of any complaints from or on behalf of patients or other service users, their nature and the way in which the Supplier has responded to such complaints since the last review meeting written report;

8.3.3 the information specified in the Specification and Tender Response Document;

8.3.4 a status report in relation to the implementation of any current Remedial Proposals by either Party; and

8.3.5 such other information as reasonably required by the Authority.

8.4 Unless specified otherwise in the Specification and Tender Response Document, the Authority shall take minutes of each review meeting and shall circulate draft minutes to the Supplier within a reasonable time following such review meeting. The Supplier shall inform the Authority in writing of any suggested amendments to the minutes within five (5) Business Days of receipt of the draft minutes. If the Supplier does not respond to the Authority within such five (5) Business Days the minutes will be deemed to be approved. Where there are any differences in interpretation of the minutes, the Parties will use their reasonable endeavours to reach agreement. If agreement cannot be reached the matter shall be referred to, and resolved in accordance with, the Dispute Resolution Procedure.

8.5 The Supplier shall provide such management information as the Authority may request from time to time within seven (7) Business Days of the date of the request. The Supplier shall supply the management information to the Authority in such form as may be specified by the Authority and, where requested to do so, the Supplier shall also provide such management information to another Contracting Authority, whose role it is to analyse such management information in accordance with UK government policy (to include, without limitation, for the purposes of analysing public sector expenditure and planning future procurement activities) ("**Third Party Body"**). The Supplier confirms and agrees that the Authority may itself provide the Third Party Body with management information relating to the Services purchased, any payments made under this Contract, and any other information relevant to the operation of this Contract.

8.6 Upon receipt of management information supplied by the Supplier to the Authority and/or the Third Party Body, or by the Authority to the Third Party Body, the Parties hereby consent to the Third Party Body and the Authority:

8.6.1 storing and analysing the management information and producing statistics; and

8.6.2 sharing the management information or any statistics produced using the management information with any other Contracting Authority.

8.7 If the Third Party Body and/or the Authority shares the management information or any other information provided under Clause 8.6 of this Schedule 2, any Contracting Authority receiving the management information shall, where such management information is subject to obligations of confidence under this Contract and such management information is provided direct by the Authority to such Contracting Authority, be informed of the confidential nature of that information by the Authority and shall be requested by the Authority not to disclose it to any body that is not a Contracting Authority (unless required to do so by Law).

8.8 The Authority may make changes to the type of management information which the Supplier is required to supply and shall give the Supplier at least one (1) month's written notice of any changes.

9 Price and payment

9.1 The Contract Price shall be calculated as set out in the Commercial Schedule.

9.2 Unless otherwise stated in the Commercial Schedule the Contract Price:

9.2.1 shall be payable from the Actual Services Commencement Date;

9.2.2 shall remain fixed during the Term; and

9.2.3 is the entire price payable by the Authority to the Supplier in respect of the Services and includes, without limitation, any royalties, licence fees, supplies and all consumables used by the Supplier, travel costs, accommodation expenses, the cost of Staff and all appropriate taxes (excluding VAT), duties and tariffs and any expenses arising from import and export administration.

9.3 Unless stated otherwise in the Commercial Schedule:

9.3.1 where the Key Provisions confirm that the payment profile for this Contract is monthly in arrears, the Supplier shall invoice the Authority, within fourteen (14) days of the end of each calendar month, the Contract Price in respect of the Services provided in compliance with this Contract in the preceding calendar month; or

9.3.2 where Clause 9.3.1 of this Schedule 2 does not apply, the Supplier shall invoice the Authority for Services at any time following completion of the provision of the Services in compliance with this Contract.

Each invoice shall contain such information and be addressed to such individual as the Authority may inform the Supplier from time to time.

9.4 The Contract Price is exclusive of VAT, which, if properly chargeable, the Authority shall pay at the prevailing rate subject to receipt from the Supplier of a valid and accurate VAT invoice. Such VAT invoices shall show the VAT calculations as a separate line item.

9.5 The Authority shall verify and pay each valid and undisputed invoice received in accordance with Clause 9.3 of this Schedule 2 within thirty (30) days of receipt of such invoice at the latest. However, the Authority shall use its reasonable endeavours to pay such undisputed invoices sooner in accordance with any applicable government prompt payment targets. If there is undue delay in verifying the invoice in accordance

with this Clause 9.5 of this Schedule 2, the invoice shall be regarded as valid and undisputed for the purposes this Clause 9.5 after a reasonable time has passed.

9.6 Where the Authority raises a query with respect to an invoice the Parties shall liaise with each other and agree a resolution to such query within thirty (30) days of the query being raised. If the Parties are unable to agree a resolution within thirty (30) days the query shall be referred to dispute resolution in accordance with the Dispute Resolution Procedure. For the avoidance of doubt, the Authority shall not be in breach of any of any of its payment obligations under this Contract in relation to any queried or disputed invoice sums unless the process referred to in this Clause 9.6 of this Schedule 2 has been followed and it has been determined that the queried or disputed invoice amount is properly due to the Supplier and the Authority has then failed to pay such sum within a reasonable period following such determination.

9.7 The Supplier shall pay to the Authority any service credits and/or other sums and/or deductions (to include, without limitation, deductions relating to a reduction in the Contract Price) that may become due in accordance with the provisions of the Specification and Tender Response Document. For the avoidance of doubt, the Authority may invoice the Supplier for such sums or deductions at any time in the event that they have not automatically been credited to the Authority in accordance with the provisions of the Specification and Tender Response Document. Such invoice shall be paid by the Supplier within 30 days of the date of such invoice.

9.8 The Authority reserves the right to set-off:

9.8.1 any monies due to the Supplier from the Authority as against any monies due to the Authority from the Supplier under this Contract; and

9.8.2 any monies due to the Authority from the Supplier as against any monies due to the Supplier from the Authority under this Contract.

9.9 Where the Authority is entitled to receive any sums (including, without limitation, any costs, charges or expenses) from the Supplier under this Contract, the Authority may invoice the Supplier for such sums. Such invoices shall be paid by the Supplier within 30 days of the date of such invoice.

9.10 If a Party fails to pay any undisputed sum properly due to the other Party under this Contract, the Party due such sum shall have the right to charge interest on the overdue amount at the applicable rate under the Late Payment of Commercial Debts (Interest) Act 1998, accruing on a daily basis from the due date up to the date of actual payment, whether before or after judgment.

10 Warranties

10.1 The Supplier warrants and undertakes that:

10.1.1 it has, and shall ensure its Staff shall have, and shall maintain throughout the Term, all appropriate licences and registrations with the relevant bodies to fulfil its obligations under this Contract;

10.1.2 it has all rights, consents, authorisations, licences and accreditations required to provide the Services and shall maintain such consents, authorisations, licences and accreditations throughout the Term;

10.1.3 it has and shall maintain a properly documented system of quality controls and processes covering all aspects of its obligations under this Contract and/or under Law and/or Guidance and shall at all times comply with such quality controls and processes;

10.1.4 it shall not make any significant changes to its system of quality controls and processes in relation to the Services without notifying the Authority in writing at least twenty one (21) days in advance of such change (such notice to include the details of the consequences which follow such change being implemented);

10.1.5 where any act of the Supplier requires the notification to and/or approval by any regulatory or other competent body in accordance with any Law and Guidance, the Supplier shall comply fully with such notification and/or approval requirements;

10.1.6 receipt of the Services by or on behalf of the Authority and use of the deliverables or of any other item or information supplied or made available to the Authority as part of the Services will not infringe any third party rights, to include without limitation any Intellectual Property Rights;

10.1.7 it will comply with all Law, Guidance, Policies and the Supplier Code of Conduct in so far as is relevant to the provision of the Services;

10.1.8 it will provide the Services using reasonable skill and care and in accordance with Good Industry Practice and shall fulfil all requirements of this Contract using appropriately skilled, trained and experienced staff;

10.1.9 unless otherwise set out in the Specification and Tender Response Document and/or as otherwise agreed in writing by the Parties, it has and/or shall procure all resources, equipment, consumables and other items and facilities required to provide the Services;

10.1.10 without limitation to the generality of Clause 10.1.7 of this Schedule 2, it shall comply with all health and safety processes, requirements safeguards, controls, and training obligations in accordance with its own operational procedures, Law, Guidance, Policies, Good Industry Practice, the requirements of the Specification and Tender Response Document and any notices or instructions given to the Supplier by the Authority and/or any competent body, as relevant to the provision of the Services and the Supplier's access to the Premises and Locations in accordance with this Contract;

10.1.11 without prejudice to any specific notification requirements set out in this Contract, it will promptly notify the Authority of any health and safety hazard which has arisen, or the Supplier is aware may arise, in connection with the performance of the Services and take such steps as are reasonably necessary to ensure the health and safety of persons likely to be affected by such hazards;

10.1.12 any equipment it uses in the provision of the Services shall comply with all relevant Law and Guidance, be fit for its intended purpose and maintained fully in accordance with the manufacturer's specification and shall remain the Supplier's risk and responsibility at all times;

10.1.13 unless otherwise confirmed by the Authority in writing (to include, without limitation, as part of the Specification and Tender Response Document), it will ensure that any products purchased by the Supplier partially or wholly for the purposes of providing the Services will comply with requirements five (5) to eight (8), as set out in Annex 1 of the Cabinet Office Procurement Policy Note - Implementing Article 6 of the Energy Efficiency Directive (Action Note 07/14 3rd June 2014), to the extent such requirements apply to the relevant products being purchased;

10.1.14 it shall use Good Industry Practice to ensure that any information and communications technology systems and/or related hardware and/or software it uses are free from corrupt data, viruses, worms and any other computer programs or code which might cause harm or disruption to the Authority's information and communications technology systems;

10.1.15 it shall: (i) comply with all relevant Law and Guidance and shall use Good Industry Practice to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify the Authority immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;

10.1.16 it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier's compliance with this Clause 10.1.16 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy;

10.1.17 it will fully and promptly respond to all requests for information and/or requests for answers to questions regarding this Contract, the provision of the Services, any complaints and any Disputes at the frequency, in the timeframes and in the format as requested by the Authority from time to time (acting reasonably);

10.1.18 all information included within the Supplier's responses to any documents issued by the Authority as part of the procurement relating to the award of this Contract (to include, without limitation, as referred to in the Specification and Tender Response Document and Commercial Schedule) and all accompanying materials is accurate;

10.1.19 it has the right and authority to enter into this Contract and that it has the capability and capacity to fulfil its obligations under this Contract;

10.1.20 it is a properly constituted entity and it is fully empowered by the terms of its constitutional documents to enter into and to carry out its obligations under this Contract and the documents referred to in this Contract;

10.1.21 all necessary actions to authorise the execution of and performance of its obligations under this Contract have been taken before such execution;

10.1.22 there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Supplier;

10.1.23 there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into or complying with this Contract;

10.1.24 it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Contract; and

10.1.25 it has satisfied itself as to the nature and extent of the risks assumed by it under this Contract and has gathered all information necessary to perform its obligations under this Contract and all other obligations assumed by it.

10.2 The Supplier warrants that all information, data and other records and documents required by the Authority as set out in the Specification and Tender Response Document shall be submitted to the Authority in the format and in accordance with any timescales set out in the Specification and Tender Response Document.

10.3 Without prejudice to the generality of Clause 10.2 of this Schedule 2, the Supplier acknowledges that a failure by the Supplier following the Actual Services Commencement Date to submit accurate invoices and other information on time to the Authority may result in the commissioner of health services, or other entity responsible for reimbursing costs to the Authority, delaying or failing to make relevant payments to the Authority. Accordingly, the Supplier warrants that, from the Actual Services Commencement Date, it shall submit accurate invoices and other information on time to the Authority.

10.4 The Supplier warrants and undertakes to the Authority that it shall comply with any eProcurement Guidance as it may apply to the Supplier and shall carry out all reasonable acts required of the Supplier to enable the Authority to comply with such eProcurement Guidance.

10.5 The Supplier warrants and undertakes to the Authority that, as at the Commencement Date, it has notified the Authority in writing of any Occasions of Tax Non-Compliance or any litigation that it is involved in that is in connection with any Occasions of Tax Non-Compliance. If, at any point during the Term, an Occasion of Tax Non-Compliance occurs, the Supplier shall:

10.5.1 notify the Authority in writing of such fact within five (5) Business Days of its occurrence; and

10.5.2 promptly provide to the Authority:

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

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

10.6 The Supplier further warrants and undertakes to the Authority that it will inform the Authority in writing immediately upon becoming aware that any of the warranties set out in Clause 10 of this Schedule 2 have been breached or there is a risk that any warranties may be breached.

10.7 Any warranties provided under this Contract are both independent and cumulative and may be enforced independently or collectively at the sole discretion of the enforcing Party.

11 Intellectual property

11.1 The Supplier warrants and undertakes to the Authority that either it owns or is entitled to use and will continue to own or be entitled to use all Intellectual Property Rights used in the development and provision of the Services and/or necessary to give effect to the Services and/or to use any deliverables, matter or any other output supplied to the Authority as part of the Services.

11.2 Unless specified otherwise in the Key Provisions and/or in the Specification and Tender Response Document, the Supplier hereby grants to the Authority, for the life of the use by the Authority of any deliverables, material or any other output supplied to the Authority in any format as part of the Services, an irrevocable, royalty-free, non-exclusive licence to use, modify, adapt or enhance such items in the course of the Authority's normal business operations. For the avoidance of doubt, unless specified otherwise in the Key Provisions and/or in the Specification and Tender Response Document, the Authority shall have no rights to commercially exploit (e.g. by selling to third parties) any deliverables, matter or any other output supplied to the Authority in any format as part of the Services.

12 Indemnity

12.1 The Supplier shall be liable to the Authority for, and shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings in respect of:

12.1.1 any injury or allegation of injury to any person, including injury resulting in death;

12.1.2 any loss of or damage to property (whether real or personal);

12.1.3 any breach of Clause 10.1.6 and/or Clause 11 of this Schedule 2; and/or

12.1.4 any failure by the Supplier to commence the delivery of the Services by the Services Commencement Date;

that arise or result from the Supplier's negligent acts or omissions or breach of contract in connection with the performance of this Contract including the provision of the Services, except to the extent that such loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings have been caused by any act or omission by, or on behalf of, or in accordance with the instructions of, the Authority.

12.2 Liability under Clauses 12.1.1, 12.1.3 and 17.13 of this Schedule 2 and Clause 2.6 of Schedule 3 shall be unlimited. Liability under Clauses 12.1.2 and 12.1.4 of this Schedule 2 shall be subject to the limitation of liability set out in Clause 13 of this Schedule 2.

12.3 In relation to all third party claims against the Authority, which are the subject of any indemnity given by the Supplier under this Contract, the Authority shall use its reasonable endeavours, upon a written request from the Supplier, to transfer the

conduct of such claims to the Supplier unless restricted from doing so. Such restrictions may include, without limitation, any restrictions:

12.3.1 relating to any legal, regulatory, governance, information governance, or confidentiality obligations on the Authority; and/or

12.3.2 relating to the Authority's membership of any indemnity and/or risk pooling arrangements.

Such transfer shall be subject to the Parties agreeing appropriate terms for such conduct of the third party claim by the Supplier (to include, without limitation, the right of the Authority to be informed and consulted on the ongoing conduct of the claim following such transfer and any reasonable cooperation required by the Supplier from the Authority).

13 Limitation of liability

13.1 Nothing in this Contract shall exclude or restrict the liability of either Party:

13.1.1 for death or personal injury resulting from its negligence;

13.1.2 for fraud or fraudulent misrepresentation; or

13.1.3 in any other circumstances where liability may not be limited or excluded under any applicable law.

13.2 Subject to Clauses 12.2, 13.1, 13.3 and 13.5 of this Schedule 2, the total liability of each Party to the other under or in connection with this Contract whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall be limited in aggregate to the greater of: (a) five million GBP (£5,000,000); or (b) one hundred and twenty five percent (125%) of the total Contract Price paid or payable by the Authority to the Supplier for the Services.

13.3 There shall be no right to claim losses, damages and/or other costs and expenses under or in connection with this Contract whether arising in contract (to include, without limitation, under any relevant indemnity), tort, negligence, breach of statutory duty or otherwise to the extent that any losses, damages and/or other costs and expenses claimed are in respect of loss of production, loss of business opportunity or are in respect of indirect loss of any nature suffered or alleged. For the avoidance of doubt, without limitation, the Parties agree that for the purposes of this Contract the following costs, expenses and/or loss of income shall be direct recoverable losses (to include under any relevant indemnity) provided such costs, expenses and/or loss of income are properly evidenced by the claiming Party:

13.3.1 extra costs incurred purchasing replacement or alternative services;

13.3.2 costs associated with advising, screening, testing, treating, retreating or otherwise providing healthcare to patients;

13.3.3 the costs of extra management time; and/or

13.3.4 loss of income due to an inability to provide health care services,

in each case to the extent to which such costs, expenses and/or loss of income arise or result from the other Party's breach of contract, negligent act or omission, breach of statutory duty, and/or other liability under or in connection with this Contract.

13.4 Each Party shall at all times take all reasonable steps to minimise and mitigate any loss for which that Party is entitled to bring a claim against the other pursuant to this Contract.

13.5 If the total Contract Price paid or payable by the Authority to the Supplier over the Term:

13.5.1 is less than or equal to one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 shall be replaced with one million pounds (£1,000,000);

13.5.2 is less than or equal to three million pounds (£3,000,000) but greater than one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 shall be replaced with three million pounds (£3,000,000);

13.5.3 is equal to, exceeds or will exceed ten million pounds (£10,000,000), but is less than fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 shall be replaced with ten million pounds (£10,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 13.2 of this Schedule 2 shall be deemed to have been deleted and replaced with one hundred and fifteen percent (115%); and

13.5.4 is equal to, exceeds or will exceed fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 shall be replaced with fifty million pounds (£50,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 13.2 of this Schedule 2 shall be deemed to have been deleted and replaced with one hundred and five percent (105%).

13.6 Clause 13 of this Schedule 2 shall survive the expiry of or earlier termination of this Contract for any reason.

14 Insurance

14.1 Subject to Clauses 14.2 and 14.3 of this Schedule 2 and unless otherwise confirmed in writing by the Authority, as a minimum level of protection, the Supplier shall put in place and/or maintain in force at its own cost with a reputable commercial insurer, insurance arrangements in respect of employer's liability, public liability and professional indemnity in accordance with Good Industry Practice with the minimum cover per claim of the greater of five million pounds (£5,000,000) or any sum as required by Law unless otherwise agreed with the Authority in writing. These requirements shall not apply to the extent that the Supplier is a member and maintains membership of each of the indemnity schemes run by the NHS Litigation Authority.

14.2 Without limitation to any insurance arrangements as required by Law, the Supplier shall put in place and/or maintain the different types and/or levels of indemnity arrangements explicitly required by the Authority, if specified in the Key Provisions.

14.3 Provided that the Supplier maintains all indemnity arrangements required by Law, the Supplier may self insure in order to meet other relevant requirements referred to at Clauses 14.1 and 14.2 of this Schedule 2 on condition that such self insurance arrangements offer the appropriate levels of protection and are approved by the Authority in writing prior to the Commencement Date.

14.4 The amount of any indemnity cover and/or self insurance arrangements shall not relieve the Supplier of any liabilities under this Contract. It shall be the responsibility of the Supplier to determine the amount of indemnity and/or self insurance cover that will be adequate to enable it to satisfy its potential liabilities under this Contract. Accordingly, the Supplier shall be liable to make good any deficiency if the proceeds of any indemnity cover and/or self insurance arrangement is insufficient to cover the settlement of any claim.

14.5 The Supplier warrants that it shall not take any action or fail to take any reasonable action or (in so far as it is reasonable and within its power) permit or allow others to take or fail to take any action, as a result of which its insurance cover may be rendered void, voidable, unenforceable, or be suspended or impaired in whole or in part, or which may otherwise render any sum paid out under such insurances repayable in whole or in part.

14.6 The Supplier shall from time to time and in any event within five (5) Business Days of written demand provide documentary evidence to the Authority that insurance arrangements taken out by the Supplier pursuant to Clause 14 of this Schedule 2 and the Key Provisions are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.

14.7 Upon the expiry or earlier termination of this Contract, the Supplier shall ensure that any ongoing liability it has or may have arising out of this Contract shall continue to be the subject of appropriate indemnity arrangements for the period of twenty one (21) years from termination or expiry of this Contract or until such earlier date as that liability may reasonably be considered to have ceased to exist.

15 Term and termination

15.1 This Contract shall commence on the Commencement Date and, unless terminated earlier in accordance with the terms of this Contract or the general law, shall continue until the end of the Term.

15.2 The Authority shall be entitled to extend the Term on one or more occasions by giving the Supplier written notice no less than three (3) months prior to the date on which this Contract would otherwise have expired, provided that the duration of this Contract shall be no longer than the total term specified in the Key Provisions.

15.3 In the case of a breach of any of the terms of this Contract by either Party that is capable of remedy (including, without limitation any breach of any KPI and, subject to Clause 9.6 of this Schedule 2, any breach of any payment obligations under this Contract), the non-breaching Party may, without prejudice to its other rights and remedies under this Contract, issue a Breach Notice and shall allow the Party in breach the opportunity to remedy such breach in the first instance via a remedial proposal put forward by the Party in breach ("**Remedial Proposal**") before exercising any right to terminate this Contract in accordance with Clause 15.4(ii) of this Schedule 2. Such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Party in breach in accordance with the timescales referred to in the agreed Remedial Proposal.

Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Party in breach to:

15.3.1 put forward and agree a Remedial Proposal with the non-breaching Party in relation to the relevant default or breach within a period of ten (10) Business Days (or such other period as the non-breaching Party may agree in writing) from written notification of the relevant default or breach from the non-breaching Party;

15.3.2 comply with such Remedial Proposal (including, without limitation, as to its timescales for implementation, which shall be thirty (30) days unless otherwise agreed between the Parties); and/or

15.3.3 remedy the default or breach notwithstanding the implementation of such Remedial Proposal in accordance with the agreed timescales for implementation,

shall be deemed, for the purposes of Clause 15.4(ii) of this Schedule 2, a material breach of this Contract by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

15.4 Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of any of the terms of this Contract which is:

(i) not capable of remedy; or

(ii) in the case of a breach capable of remedy, which is not remedied in accordance with a Remedial Proposal.

15.5 The Authority may terminate this Contract forthwith by issuing a Termination Notice to the Supplier if:

15.5.1 the Supplier does not commence delivery of the Services by any Long Stop Date;

15.5.2 the Supplier, or any third party guaranteeing the obligations of the Supplier under this Contract, ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;

15.5.3 the Supplier undergoes a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (other than for an intra-group change of control) without the prior written consent of the Authority and the

Authority shall be entitled to withhold such consent if, in the reasonable opinion of the Authority, the proposed change of control will have a material impact on the performance of this Contract or the reputation of the Authority;

15.5.4 the Supplier purports to assign, Sub-contract, novate, create a trust in or otherwise transfer or dispose of this Contract in breach of Clause 28.1 of this Schedule 2;

15.5.5 the NHS Business Services Authority has notified the Authority that the Supplier or any Sub-contractor of the Supplier has, in the opinion of the NHS Business Services Authority, failed in any material respect to comply with its obligations in relation to the NHS Pension Scheme (including those under any Direction Letter) as assumed pursuant to the provisions of Part D of Schedule 7;

15.5.6 pursuant to and in accordance with the Key Provisions and Clauses 15.6, 23.8; 25.2; 25.4 and 29.2 of this Schedule 2; or

15.5.7 the warranty given by the Supplier pursuant to Clause 10.5 of this Schedule 2 is materially untrue, the Supplier commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause 10.5 of this Schedule 2, or the Supplier fails to provide details of proposed mitigating factors as required by Clause 10.5 of this Schedule 2 that in the reasonable opinion of the Authority are acceptable.

15.6 If the Authority, acting reasonably, has good cause to believe that there has been a material deterioration in the financial circumstances of the Supplier and/or any third party guaranteeing the obligations of the Supplier under this Contract and/or any material Sub-contractor of the Supplier when compared to any information provided to and/or assessed by the Authority as part of any procurement process or other due diligence leading to the award of this Contract to the Supplier or the entering into a Sub-contract by the Supplier, the following process shall apply:

15.6.1 the Authority may (but shall not be obliged to) give notice to the Supplier requesting adequate financial or other security and/or assurances for due performance of its material obligations under this Contract on such reasonable and proportionate terms as the Authority may require within a reasonable time period as specified in such notice;

15.6.2 a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with Clause 15.6 of this Schedule 2 in accordance with any reasonable timescales specified in any such notice issued by the Authority shall be deemed a breach of this Contract by the Supplier and shall be referred to and resolved in accordance with the Dispute Resolution Procedure; and

15.6.3 a failure to resolve such breach in accordance with such Dispute Resolution Procedure by the end of the escalation stage of such process shall entitle, but shall not compel, the Authority to terminate this Contract in accordance with Clause 15.4(i) of this Schedule 2.

In order that the Authority may act reasonably in exercising its discretion in accordance with Clause 15.6 of this Schedule 2, the Supplier shall provide the Authority with such reasonable and proportionate up-to-date financial or other information relating to the Supplier or any relevant third party entity upon request.

15.7 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier where:

15.7.1 the Contract has been substantially amended to the extent that the Public Contracts Regulations 2015 require a new procurement procedure;

15.7.2 the Authority has become aware that the Supplier should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations 2015 from the procurement procedure leading to the award of this Contract;

15.7.3 the Contract should not have been awarded to the Supplier in view of a serious infringement of obligations under European law declared by the Court of Justice of the European Union under Article 258 of the Treaty on the Functioning of the EU; or

15.7.4 there has been a failure by the Supplier and/or one its Sub-contractors to comply with legal obligations in the fields of environmental, social or labour Law. Where the failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by one of the Supplier's Sub-contractors, the Authority may request the replacement of such Sub-contractor and the Supplier shall comply with such request as an alternative to the Authority terminating this Contract under this Clause 15.7.4.

15.8 If the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the rights of the Authority to terminate this Contract in accordance with Clause 15.5.2 to Clause 15.5.4 of this Schedule 2 shall be deemed mutual termination rights and the Supplier may terminate this Contract by issuing a Termination Notice to the entity assuming the position of the Authority if any of the circumstances referred to in such Clauses apply to the entity assuming the position of the Authority.

15.9 Within three (3) months of the Commencement Date the Supplier shall develop and agree an exit plan with the Authority consistent with the Exit Requirements, which shall ensure continuity of the Services on expiry or earlier termination of this Contract. The Supplier shall provide the Authority with the first draft of an exit plan within one (1) month of the Commencement Date. The Parties shall review and, as appropriate, update the exit plan on each anniversary of the Commencement Date of this Contract.

If the Parties cannot agree an exit plan in accordance with the timescales set out in this Clause 15.9 of this Schedule 2 (such agreement not to be unreasonably withheld or delayed), such failure to agree shall be deemed a Dispute, which shall be referred to and resolved in accordance with the Dispute Resolution Procedure.

16 Consequences of expiry or early termination of this Contract

16.1 Upon expiry or earlier termination of this Contract, the Authority agrees to pay the Supplier for the Services which have been completed by the Supplier in accordance with this Contract prior to expiry or earlier termination of this Contract.

16.2 Immediately following expiry or earlier termination of this Contract and/or in accordance with any timescales as set out in the agreed exit plan:

16.2.1 the Supplier shall comply with its obligations under any agreed exit plan;

16.2.2 all data, excluding Personal Data, documents and records (whether stored electronically or otherwise) relating in whole or in part to the Services,

including without limitation relating to patients or other service users, and all other items provided on loan or otherwise to the Supplier by the Authority shall be delivered by the Supplier to the Authority provided that the Supplier shall be entitled to keep copies to the extent that: (a) the content does not relate solely to the Services; (b) the Supplier is required by Law and/or Guidance to keep copies; or (c) the Supplier was in possession of such data, documents and records prior to the Commencement Date; and

16.2.3 any Personal Data Processed by the Supplier on behalf of the Authority shall be returned to the Authority or destroyed in accordance with the relevant provisions of the Data Protection Protocol.

16.3 The Supplier shall retain all data relating to the provision of the Services that are not transferred or destroyed pursuant to Clause 16.2 of this Schedule 2 for the period set out in Clause 24.1 of this Schedule 2.

16.4 The Supplier shall cooperate fully with the Authority or, as the case may be, any replacement supplier during any re-procurement and handover period prior to and following the expiry or earlier termination of this Contract. This cooperation shall extend to providing access to all information relevant to the operation of this Contract, as reasonably required by the Authority to achieve a fair and transparent re-procurement and/or an effective transition without disruption to routine operational requirements.

16.5 Immediately upon expiry or earlier termination of this Contract any licence or lease entered into in accordance with the Key Provisions shall automatically terminate.

16.6 The expiry or earlier termination of this Contract for whatever reason shall not affect any rights or obligations of either Party which accrued prior to such expiry or earlier termination.

16.7 The expiry or earlier termination of this Contract shall not affect any obligations which expressly or by implication are intended to come into or continue in force on or after such expiry or earlier termination.

17 Staff information and the application of TUPE at the end of the Contract

17.1 Upon the day which is no greater than nine (9) months before the expiry of this Contract or as soon as the Supplier is aware of the proposed termination of the Contract, the Supplier shall, within twenty eight (28) days of receiving a written request from the Authority and to the extent permitted by Law, supply to the Authority and keep updated all information required by the Authority as to the terms and conditions of employment and employment history of any Supplier Personnel (including all employee liability information identified in regulation 11 of TUPE) and the Supplier shall warrant such information is full, complete and accurate.

17.2 No later than twenty eight (28) days prior to the Subsequent Transfer Date, the Supplier shall or shall procure that any Sub-contractor shall provide a final list to the Successor and/or the Authority, as appropriate, containing the names of all the Subsequent Transferring Employees whom the Supplier or Sub-contractor expects will transfer to the Successor or the Authority and all employee liability information identified in regulation 11 of TUPE in relation to the Subsequent Transferring Employees.

17.3 If the Supplier shall, in the reasonable opinion of the Authority, deliberately not comply with its obligations under Clauses 17.1 and 17.2 of this Schedule 2, the Authority may withhold payment under Clause 9 of this Schedule 2.

17.4 The Supplier shall be liable to the Authority for, and shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings that arise or result from any deficiency or inaccuracy in the information which the Supplier is required to provide under Clauses 17.1 and 17.2 of this Schedule 2.

17.5 Subject to Clauses 17.6 and 17.7 of this Schedule 2, during the period of nine (9) months preceding the expiry of this Contract or after notice of termination of this Contract has been served by either Party, the Supplier shall not, and shall procure that any Sub-contractor shall not, without the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed:

17.5.1 make, propose or permit any material changes to the terms and conditions of employment or other arrangements of any of the Supplier Personnel;

17.5.2 increase or seek to increase the emoluments (excluding cost of living increases awarded in the ordinary course of business) payable to any of the Supplier Personnel;

17.5.3 replace any of the Supplier Personnel or increase the total number of employees providing the Services;

17.5.4 deploy any person other than the Supplier Personnel to perform the Services;

17.5.5 terminate or give notice to terminate the employment or arrangements of any of the Supplier Personnel;

17.5.6 increase the proportion of working time spent on the Services by any of the Supplier Personnel; or

17.5.7 introduce any new contractual term or customary practice concerning the making of any lump sum payment on the termination of employment of any of the Supplier Personnel.

17.6 Clause 17.5 of this Schedule 2 shall not prevent the Supplier or any Sub-contractor from taking any of the steps prohibited in that Clause in circumstances where the Supplier or Sub-contractor is required to take such a step pursuant to any changes in legislation or pursuant to a collective agreement in force at that time.

17.7 Where the obligations on the Supplier under Clause 17 of this Schedule 2 are subject to the Data Protection Legislation, the Supplier will, and shall procure that any Sub-contractor will, use its best endeavours to seek the consent of the Supplier Personnel to disclose any information covered under the Data Protection Legislation and utilise any other exemption or provision within the Data Protection Legislation which would allow such disclosure.

17.8 Having as appropriate gained permission from any Sub-contractor, the Supplier hereby permits the Authority to disclose information about the Supplier Personnel to any Interested Party provided that the Authority informs the Interested Party in writing of the confidential nature of the information.

17.9 The Parties agree that where a Successor or the Authority provides the Services or services which are fundamentally the same as the Services in the immediate or subsequent succession to the Supplier or Sub-contractor (in whole or in part) on expiry or early termination of this Contract (howsoever arising) TUPE, the Cabinet Office Statement and Fair Deal for Staff Pensions may apply in respect of the subsequent provision of the Services or services which are fundamentally the same as the Services. If TUPE, the Cabinet Office Statement and Fair Deal for Staff Pensions apply then Clause 17.11 to Clause 17.14 of this Schedule 2 and (where relevant) the provisions of Clause 1.15 of Part D of Schedule 7 shall apply.

17.10 If on the termination or at the end of the Contract TUPE does not apply, then all Employment Liabilities and any other liabilities in relation to the Supplier Personnel shall remain with the Supplier or Sub-contractor as appropriate. The Supplier will, and shall procure that any Sub-contractor shall, indemnify and keep indemnified the Authority in relation to any Employment Liabilities arising out of or in connection with any allegation or claim raised by any Supplier Personnel.

17.11 In accordance with TUPE, and any other policy or arrangement applicable, the Supplier shall, and will procure that any Sub-contractor shall, comply with its obligations to inform and consult with the appropriate representatives of any of its employees affected by the subsequent transfer of the Services or services which are fundamentally the same as the Services.

17.12 The Supplier will and shall procure that any Sub-contractor will on or before any Subsequent Transfer Date:

17.12.1 pay all wages, salaries and other benefits of the Subsequent Transferring Employees and discharge all other financial obligations (including reimbursement of any expenses and any contributions to retirement benefit schemes) in respect of the period between the Transfer Date and the Subsequent Transfer Date;

17.12.2 account to the proper authority for all PAYE, tax deductions and national insurance contributions payable in respect of the Subsequent Transferring Employees in the period between the Transfer Date and the Subsequent Transfer Date;

17.12.3 pay any Successor or the Authority, as appropriate, the amount which would be payable to each of the Subsequent Transferring Employees in lieu of accrued but untaken holiday entitlement as at the Subsequent Transfer Date;

17.12.4 pay any Successor or the Authority, as appropriate, the amount which fairly reflects the progress of each of the Subsequent Transferring Employees towards achieving any commission, bonus, profit share or other incentive payment payable after the Subsequent Transfer Date wholly or partly in respect of a period prior to the Subsequent Transfer Date; and

17.12.5 subject to any legal requirement, provide to the Successor or the Authority, as appropriate, all personnel records relating to the Subsequent Transferring Employees including, without prejudice to the generality of the foregoing, all records relating to national insurance, PAYE and income tax. The Supplier shall for itself and any Sub-contractor warrant that such records are accurate and up to date.

17.13 The Supplier will and shall procure that any Sub-contractor will indemnify and keep indemnified the Authority and/or a Successor in relation to any Employment Liabilities arising out of or in connection with any claim arising from:

17.13.1 the Supplier's or Sub-contractor's failure to perform and discharge its obligations under Clause 17.12 of this Schedule 2;

17.13.2 any act or omission by the Supplier or Sub-contractor in respect of the Subsequent Transferring Employees occurring on or before the Subsequent Transfer Date;

17.13.3 any allegation or claim by any person who is not a Subsequent Transferring Employee but who alleges that their employment should transfer or has transferred to the Successor or the Authority, as appropriate;

17.13.4 any emoluments payable to a person employed or engaged by the Supplier or Sub-contractor (including without limitation all wages, accrued holiday pay, bonuses, commissions, PAYE, national insurance contributions, pension contributions and other contributions) payable in respect of any period on or before the Subsequent Transfer Date;

17.13.5 any allegation or claim by any of the Subsequent Transferring Employees on the grounds that the Successor or Authority, as appropriate, has failed to continue a benefit provided by the Supplier or Sub-contractor as a term of such Subsequent Transferring Employee's contract as at the Subsequent Transfer Date where it was not reasonably practicable for the Successor or Authority, as appropriate, to provide an identical benefit but where the Successor or Authority, as appropriate, has provided (or offered to provide where such benefit is not accepted by the Subsequent Transferring Employee) an alternative benefit which, taken as a whole, is no less favourable to such Subsequent Transferring Employee; and

17.13.6 any act or omission of the Supplier or any Sub-contractor in relation to its obligations under regulation 13 of TUPE, or in respect of an award of compensation under regulation 15 of TUPE except to the extent that the liability arises from the Successor's or Authority's failure to comply with regulation 13(4) of TUPE.

17.14 The Supplier will, or shall procure that any Sub-contractor will, on request by the Authority provide a written and legally binding indemnity in the same terms as set out in Clause 17.13 of this Schedule 2 to any Successor in relation to any Employment Liabilities arising up to and including the Subsequent Transfer Date.

17.15 The Supplier will indemnify and keep indemnified the Authority and/or any Successor in respect of any Employment Liabilities arising from any act or omission of the Supplier or Sub-contractor in relation to any other Supplier Personnel who is not a Subsequent Transferring Employee arising during any period whether before, on or after the Subsequent Transfer Date.

17.16 If any person who is not a Subsequent Transferring Employee claims or it is determined that their contract of employment has been transferred from the Supplier or any Sub-contractor to the Authority or Successor pursuant to TUPE or claims that their employment would have so transferred had they not resigned, then:

17.16.1 the Authority will, or shall procure that the Successor will, within seven (7) days of becoming aware of that fact, give notice in writing to the Supplier;

17.16.2 the Supplier may offer (or may procure that a Sub-contractor may offer) employment to such person within twenty eight (28) days of the notification by the Authority or Successor;

17.16.3 if such offer of employment is accepted, the Authority will, or shall procure that the Successor will, immediately release the person from their employment; and

17.16.4 if after the period in Clause 17.16.2 of this Schedule 2 has elapsed, no such offer of employment has been made or such offer has been made but not accepted, the Authority will, or shall procure that the Successor will (whichever is the provider of the Services or services of the same or similar nature to the Services), employ that person in accordance with its obligations and duties under TUPE and shall be responsible for all liabilities arising in respect of any such person after the Subsequent Transfer Date.

18 Complaints

18.1 To the extent relevant to the Services, the Supplier shall have in place and operate a complaints procedure which complies with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009.

18.2 Each Party shall inform the other of all complaints from or on behalf of patients or other service users arising out of or in connection with the provision of the Services within twenty four (24) hours of receipt of each complaint and shall keep the other Party updated on the manner of resolution of any such complaints.

19 Sustainable development

19.1 The Supplier shall comply in all material respects with applicable environmental and social and labour Law requirements in force from time to time in relation to the Services. Where the provisions of any such Law are implemented by the use of voluntary agreements, the Supplier shall comply with such agreements as if they were incorporated into English law subject to those voluntary agreements being cited in the Specification and Tender Response Document. Without prejudice to the generality of the foregoing, the Supplier shall:

19.1.1 comply with all Policies and/or procedures and requirements set out in the Specification and Tender Response Document in relation to any stated environmental and social and labour requirements, characteristics and impacts of the Services and the Supplier's supply chain;

19.1.2 maintain relevant policy statements documenting the Supplier's significant labour, social and environmental aspects as relevant to the Services being provided and as proportionate to the nature and scale of the Supplier's business operations; and

19.1.3 maintain plans and procedures that support the commitments made as part of the Supplier's significant labour, social and environmental policies, as referred to at Clause 19.1.2 of this Schedule 2.

19.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 19 of this Schedule 2.

20 Electronic services information

20.1 Where requested by the Authority, the Supplier shall provide the Authority the Services Information in such manner and upon such media as agreed between the Supplier and the Authority from time to time for the sole use by the Authority.

20.2 The Supplier warrants that the Services Information is complete and accurate as at the date upon which it is delivered to the Authority and that the Services Information shall not contain any data or statement which gives rise to any liability on the part of the Authority following publication of the same in accordance with Clause 20 of this Schedule 2.

20.3 If the Services Information ceases to be complete and accurate, the Supplier shall promptly notify the Authority in writing of any modification or addition to or any inaccuracy or omission in the Services Information.

20.4 The Supplier grants the Authority a perpetual, non-exclusive, royalty free licence to use and exploit the Services Information and any Intellectual Property Rights in the Services Information for the purpose of illustrating the range of goods and services (including, without limitation, the Services) available pursuant to the Authority's contracts from time to time. Subject to Clause 20.5 of this Schedule 2, no obligation to illustrate or advertise the Services Information is imposed on the Authority, as a consequence of the licence conferred by this Clause 20.4 of this Schedule 2.

20.5 The Authority may reproduce for its sole use the Services Information provided by the Supplier in the Authority's services catalogue from time to time which may be made available on any NHS communications networks in electronic format and/or made available on the Authority's external website and/or made available on other digital media from time to time.

20.6 Before any publication of the Services Information (electronic or otherwise) is made by the Authority, the Authority will submit a copy of the relevant sections of the Authority's services catalogue to the Supplier for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Supplier shall have no right to compel the Authority to exhibit the Services Information in any services catalogue as a result of the approval given by it pursuant to this Clause 20.6 of this Schedule 2 or otherwise under the terms of this Contract.

20.7 If requested in writing by the Authority, and to the extent not already agreed as part of the Specification and Tender Response Document, the Supplier and the Authority shall discuss and seek to agree in good faith arrangements to use any Electronic Trading System.

21 Change management

21.1 The Supplier acknowledges to the Authority that the Authority's requirements for the Services may change during the Term and the Supplier shall not unreasonably withhold or delay its consent to any reasonable variation or addition to the Specification and Tender Response Document, as may be requested by the Authority from time to time.

21.2 Subject to Clause 21.3 of this Schedule 2, any change to the Services or other variation to this Contract shall only be binding once it has been agreed either: (a) in accordance with the Change Control Process if the Key Provisions specify that changes are subject to a formal change control process; or (b) if the Key Provisions make no such reference, in writing and signed by an authorised representative of both Parties.

21.3 Any change to the Data Protection Protocol shall be made in accordance with the relevant provisions of that protocol.

22 Dispute resolution

22.1 During any Dispute, including a Dispute as to the validity of this Contract, it is agreed that the Supplier shall continue its performance of the provisions of the Contract (unless the Authority requests in writing that the Supplier does not do so).

22.2 In the case of a Dispute arising out of or in connection with this Contract the Supplier and the Authority shall make every reasonable effort to communicate and cooperate with each other with a view to resolving the Dispute and follow the procedure set out in Clause 22.3 of this Schedule 2 as the first stage in the Dispute Resolution Procedure.

22.3 If any Dispute arises out of the Contract either Party may serve a notice on the other Party to commence formal resolution of the Dispute. The Parties shall first seek to resolve the Dispute by escalation in accordance with the management levels as set out in Clause 5 of the Key Provisions. Respective representatives at each level, as set out in Clause 5 of the Key Provisions, shall have five (5) Business Days at each level during which they will use their reasonable endeavours to resolve the Dispute before escalating the matter to the next levels until all level have been exhausted. Level 1 will commence on the date of service of the Dispute Notice. The final level of the escalation process shall be deemed exhausted on the expiry of five (5) Business Days following escalation to that level unless otherwise agreed by the Parties in writing.

22.4 If the procedure set out in Clause 22.3 of this Schedule 2 above has been exhausted and fails to resolve such Dispute, as part of the Dispute Resolution Procedure, the Parties will attempt to settle it by mediation. The Parties, shall acting reasonably, attempt to agree upon a mediator. In the event that the Parties fail to agree a mediator within five (5) Business Days following the exhaustion of all levels of the escalation procedure at Clause 22.3 of this Schedule 2, the mediator shall be nominated and confirmed by the Centre for Effective Dispute Resolution, London.

22.5 The mediation shall commence within twenty eight (28) days of the confirmation of the mediator in accordance with Clause 22.4 of this Schedule 2 or at such other time as may be agreed by the Parties in writing. Neither Party will terminate such mediation process until each Party has made its opening presentation and the mediator has met each Party separately for at least one hour or one Party has failed to participate in the mediation process. After this time, either Party may terminate the mediation process by notification to the other Party (such notification may be verbal provided that it is followed up by written confirmation). The Authority and the Supplier will cooperate with any person appointed as mediator providing them with such information and other assistance as they shall require and will pay their costs, as they shall determine or in the absence of such determination such costs will be shared equally.

22.6 Nothing in this Contract shall prevent:

22.6.1 the Authority taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with the provision of the Services; or

22.6.2 either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party or that relates to the safety of patients and other service users or the security of Confidential Information, pending resolution of the relevant Dispute in accordance with the Dispute Resolution Procedure.

22.7 Clause 22 of this Schedule 2 shall survive the expiry of or earlier termination of this Contract for any reason.

23 Force majeure

23.1 Subject to Clause 23.2 of this Schedule 2 neither Party shall be liable to the other for any failure to perform all or any of its obligations under this Contract nor liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent only that such performance is rendered impossible by a Force Majeure Event.

23.2 The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in Clause 23 of this Schedule 2 and will not be considered to be in default or liable for breach of any obligations under this Contract if:

23.2.1 the Supplier has fulfilled its obligations pursuant to Clause 6 of this Schedule 2;

23.2.2 the Force Majeure Event does not arise directly or indirectly as a result of any wilful or negligent act or default of the Supplier; and

23.2.3 the Supplier has complied with the procedural requirements set out in Clause 23 of this Schedule 2.

23.3 Where a Party is (or claims to be) affected by a Force Majeure Event it shall use reasonable endeavours to mitigate the consequences of such a Force Majeure Event upon the performance of its obligations under this Contract, and to resume the performance of its obligations affected by the Force Majeure Event as soon as practicable.

23.4 Where the Force Majeure Event affects the Supplier's ability to perform part of its obligations under the Contract the Supplier shall fulfil all such contractual obligations that are not so affected and shall not be relieved from its liability to do so.

23.5 If either Party is prevented or delayed in the performance of its obligations under this Contract by a Force Majeure Event, that Party shall as soon as reasonably practicable serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to its failure to perform or any anticipated delay in performance of its obligations.

23.6 Subject to service of such notice, the Party affected by such circumstances shall have no liability for its failure to perform or for any delay in performance of its obligations affected by the Force Majeure Event only for so long as such circumstances continue and for such time after they cease as is necessary for that Party, using its best

endeavours, to recommence its affected operations in order for it to perform its obligations.

23.7 The Party claiming relief shall notify the other in writing as soon as the consequences of the Force Majeure Event have ceased and of when performance of its affected obligations can be resumed.

23.8 If the Supplier is prevented from performance of its obligations as a result of a Force Majeure Event, the Authority may at any time, if the Force Majeure Event subsists for thirty (30) days or more, terminate this Contract by issuing a Termination Notice to the Supplier.

23.9 Following such termination in accordance with Clause 23.8 of this Schedule 2 and subject to Clause 23.10 of this Schedule 2, neither Party shall have any liability to the other.

23.10 Any rights and liabilities of either Party which have accrued prior to such termination in accordance with Clause 23.8 of this Schedule 2 shall continue in full force and effect unless otherwise specified in this Contract.

24 Records retention and right of audit

24.1 Subject to any statutory requirement and Clause 24.2 of this Schedule 2, the Supplier shall keep secure and maintain for the Term and six (6) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Contract.

24.2 Where any records could be relevant to a claim for personal injury such records shall be kept secure and maintained for a period of twenty one (21) years from the date of expiry or earlier termination of this Contract.

24.3 The Authority shall have the right to audit the Supplier's compliance with this Contract. The Supplier shall permit or procure permission for the Authority or its authorised representative during normal business hours having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records reasonably required to audit the Supplier's compliance with its obligations under this Contract.

24.4 Should the Supplier Sub-contract any of its obligations under this Contract, the Authority shall have the right to audit and inspect such third party. The Supplier shall procure permission for the Authority or its authorised representative during normal business hours no more than once in any twelve (12) months, having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Contract that are Sub-contracted to such third party. The Supplier shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if requested.

24.5 The Supplier shall grant to the Authority or its authorised representative, such access to those records as they may reasonably require in order to check the Supplier's compliance with this Contract for the purposes of:

24.5.1 the examination and certification of the Authority's accounts; or

24.5.2 any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which the Authority has used its resources.

24.6 The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of the Supplier and may require the Supplier to provide such oral and/or written explanations as they consider necessary. Clause 24 of this Schedule 2 does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under sections 6(3)(d) and 6(5) of the National Audit Act 1983.

24.7 The Supplier shall provide reasonable cooperation to the Authority, its representatives and any regulatory body in relation to any audit, review, investigation or enquiry carried out in relation to the subject matter of this Contract.

24.8 The Supplier shall provide all reasonable information as may be reasonably requested by the Authority to evidence the Supplier's compliance with the requirements of this Contract.

25 Conflicts of interest and the prevention of fraud

25.1 The Supplier shall take appropriate steps to ensure that neither the Supplier nor any Staff are placed in a position where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Contract. The Supplier will disclose to the Authority full particulars of any such conflict of interest which may arise.

25.2 The Authority reserves the right to terminate this Contract immediately by notice in writing and/or to take such other steps it deems necessary where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Contract. The actions of the Authority pursuant to this Clause 25.2 of this Schedule 2 shall not prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to the Authority.

25.3 The Supplier shall take all reasonable steps to prevent Fraud by Staff and the Supplier (including its owners, members and directors). The Supplier shall notify the Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.

25.4 If the Supplier or its Staff commits Fraud the Authority may terminate this Contract and recover from the Supplier the amount of any direct loss suffered by the Authority resulting from the termination.

26 Equality and human rights

26.1 The Supplier shall:

26.1.1 ensure that (a) it does not, whether as employer or as provider of the Services, engage in any act or omission that would contravene the Equality Legislation, and (b) it complies with all its obligations as an employer or provider of the Services as set out in the Equality Legislation and take reasonable endeavours to ensure its Staff do not unlawfully discriminate within the meaning of the Equality Legislation;

26.1.2 in the management of its affairs and the development of its equality and diversity policies, cooperate with the Authority in light of the Authority's obligations to comply with its statutory equality duties whether under the Equality Act 2010 or otherwise. The Supplier shall take such reasonable and proportionate steps as the Authority considers appropriate to promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age; and

26.1.3 the Supplier shall impose on all its Sub-contractors and suppliers, obligations substantially similar to those imposed on the Supplier by Clause 26 of this Schedule 2.

26.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 26 of this Schedule 2.

27 Notice

27.1 Subject to Clause 22.5 of Schedule 2, any notice required to be given by either Party under this Contract shall be in writing quoting the date of the Contract and shall be delivered by hand or sent by prepaid first class recorded delivery or by email to the person referred to in the Key Provisions or such other person as one Party may inform the other Party in writing from time to time.

27.2 A notice shall be treated as having been received:

27.2.1 if delivered by hand within normal business hours when so delivered or, if delivered by hand outside normal business hours, at the next start of normal business hours; or

27.2.2 if sent by first class recorded delivery mail on a normal Business Day, at 9.00 am on the second Business Day subsequent to the day of posting, or, if the notice was not posted on a Business Day, at 9.00 am on the third Business Day subsequent to the day of posting; or

27.2.3 if sent by email, if sent within normal business hours when so sent or, if sent outside normal business hours, at the next start of normal business hours provided the sender has either received an electronic confirmation of delivery or has telephoned the recipient to inform the recipient that the email has been sent.

28 Assignment, novation and Sub-contracting

28.1 The Supplier shall not, except where Clause 28.2 of this Schedule 2 applies, assign, Sub-contract, novate, create a trust in, or in any other way dispose of the whole or any part of this Contract without the prior consent in writing of the Authority such consent not to be unreasonably withheld or delayed. If the Supplier Sub-contracts any of its obligations under this Contract, every act or omission of the Sub-contractor shall for the purposes of this Contract be deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Authority as if such act or omission had been committed or omitted by the Supplier itself.

28.2 Notwithstanding Clause 28.1 of this Schedule 2, the Supplier may assign to a third party ("**Assignee**") the right to receive payment of any sums due and owing to the

Supplier under this Contract for which an invoice has been issued. Any assignment under this Clause 28.2 of this Schedule 2 shall be subject to:

28.2.1 the deduction of any sums in respect of which the Authority exercises its right of recovery under Clause 9.8 of this Schedule 2;

28.2.2 all related rights of the Authority in relation to the recovery of sums due but unpaid;

28.2.3 the Authority receiving notification of the assignment and the date upon which the assignment becomes effective together with the Assignee's contact information and bank account details to which the Authority shall make payment;

28.2.4 the provisions of Clause 9 of this Schedule 2 continuing to apply in all other respects after the assignment which shall not be amended without the prior written approval of the Authority; and

28.2.5 payment to the Assignee being full and complete satisfaction of the Authority's obligation to pay the relevant sums in accordance with this Contract.

28.3 Any authority given by the Authority for the Supplier to Sub-contract any of its obligations under this Contract shall not impose any duty on the Authority to enquire as to the competency of any authorised Sub-contractor. The Supplier shall ensure that any authorised Sub-contractor has the appropriate capability and capacity to perform the relevant obligations and that the obligations carried out by such Sub-contractor are fully in accordance with this Contract.

28.4 Where the Supplier enters into a Sub-contract in respect of any of its obligations under this Contract relating to the provision of the Services, the Supplier shall include provisions in each such Sub-contract, unless otherwise agreed with the Authority in writing, which:

28.4.1 contain at least equivalent obligations as set out in this Contract in relation to the performance of the Services to the extent relevant to such Sub-contracting;

28.4.2 contain at least equivalent obligations as set out in this Contract in respect of confidentiality, information security, data protection, Intellectual Property Rights, compliance with Law and Guidance and record keeping;

28.4.3 contain a prohibition on the Sub-contractor Sub-contracting, assigning or novating any of its rights or obligations under such Sub-contract without the prior written approval of the Authority (such approval not to be unreasonably withheld or delayed);

28.4.4 contain a right for the Authority to take an assignment or novation of the Sub-contract (or part of it) upon expiry or earlier termination of this Contract;

28.4.5 requires the Supplier or other party receiving services under the contract to consider and verify invoices under that contract in a timely fashion;

28.4.6 provides that if the Supplier or other party fails to consider and verify an invoice in accordance with Clause 28.4.5 of this Schedule 2, the invoice shall

be regarded as valid and undisputed for the purpose of Clause 28.4.7 after a reasonable time has passed;

28.4.7 requires the Supplier or other party to pay any undisputed sums which are due from it to the Sub-contractor within a specified period not exceeding thirty (30) days of verifying that the invoice is valid and undisputed;

28.4.8 permitting the Supplier to terminate, or procure the termination of, the relevant Sub-contract in the event the Sub-contractor fails to comply in the performance of its Sub-contract with legal obligations in the fields of environmental, social or labour Law where the Supplier is required to replace such Sub-contractor in accordance with Clause 15.7.4 of this Schedule 2;

28.4.9 permitting the Supplier to terminate, or to procure the termination of, the relevant Sub-contract where the Supplier is required to replace such Sub-contractor in accordance with Clause 28.5 of this Schedule 2; and

28.4.10 requires the Sub-contractor to include a clause to the same effect as this Clause 28.4 of this Schedule 2 in any Sub-contract which it awards.

28.5 Where the Authority considers that the grounds for exclusion under Regulation 57 of the Public Contracts Regulations 2015 apply to any Sub-contractor, then:

28.5.1 if the Authority finds there are compulsory grounds for exclusion, the Supplier shall ensure, or shall procure, that such Sub-contractor is replaced or not appointed; or

28.5.2 if the Authority finds there are non-compulsory grounds for exclusion, the Authority may require the Supplier to ensure, or to procure, that such Sub-contractor is replaced or not appointed and the Supplier shall comply with such a requirement.

28.6 The Supplier shall pay any undisputed sums which are due from it to a Sub-contractor within thirty (30) days of verifying that the invoice is valid and undisputed. Where the Authority pays the Supplier's valid and undisputed invoices earlier than thirty (30) days from verification in accordance with any applicable government prompt payment targets, the Supplier shall use its reasonable endeavours to pay its relevant Sub-contractors within a comparable timeframe from verifying that an invoice is valid and undisputed.

28.7 The Authority shall upon written request have the right to review any Sub-contract entered into by the Supplier in respect of the provision of the Services and the Supplier shall provide a certified copy of any Sub-contract within five (5) Business Days of the date of a written request from the Authority. For the avoidance of doubt, the Supplier shall have the right to redact any confidential pricing information in relation to such copies of Sub-contracts.

28.8 The Authority may at any time transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract and the Supplier warrants that it will carry out all such reasonable further acts required to effect such transfer, assignment, novation, sub-contracting or disposal. If the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the party assuming the position of the Authority shall not further transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations

under this Contract or any part of this Contract without the prior written consent of the Supplier, such consent not to be unreasonably withheld or delayed by the Supplier.

29 Prohibited Acts

29.1 The Supplier warrants and represents that:

29.1.1 it has not committed any offence under the Bribery Act 2010 or done any of the following ("**Prohibited Acts**"):

(i) offered, given or agreed to give any officer or employee of the Authority any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with the Authority or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the Authority; or

(ii) in connection with this Contract paid or agreed to pay any commission other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the Authority; and

29.1.2 it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010.

29.2 If the Supplier or its Staff (or anyone acting on its or their behalf) has done or does any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 with or without the knowledge of the Supplier in relation to this or any other agreement with the Authority:

29.2.1 the Authority shall be entitled:

(i) to terminate this Contract and recover from the Supplier the amount of any loss resulting from the termination;

(ii) to recover from the Supplier the amount or value of any gift, consideration or commission concerned; and

(iii) to recover from the Supplier any other loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence under the Bribery Act 2010;

29.2.2 any termination under Clause 29.2.1 of this Schedule 2 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority; and

29.2.3 notwithstanding the Dispute Resolution Procedure, any Dispute relating to:

(i) the interpretation of Clause 29 of this Schedule 2; or

(ii) the amount or value of any gift, consideration or commission,

shall be determined by the Authority, acting reasonably, and the decision shall be final and conclusive.

30 General

30.1 Each of the Parties is independent of the other and nothing contained in this Contract shall be construed to imply that there is any relationship between the Parties of partnership or of principal/agent or of employer/employee nor are the Parties hereby engaging in a joint venture and accordingly neither of the Parties shall have any right or authority to act on behalf of the other nor to bind the other by agreement or otherwise, unless expressly permitted by the terms of this Contract.

30.2 Failure or delay by either Party to exercise an option or right conferred by this Contract shall not of itself constitute a waiver of such option or right.

30.3 The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of this Contract or to exercise any right or remedy consequent upon such breach shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.

30.4 Any provision of this Contract which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions of this Contract and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.

30.5 Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of this Contract and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation, undertaking or warranty relied upon is set out in this Contract or unless such representation, undertaking or warranty was made fraudulently.

30.6 Each Party shall bear its own expenses in relation to the preparation and execution of this Contract including all costs, legal fees and other expenses so incurred.

30.7 The rights and remedies provided in this Contract are independent, cumulative and not exclusive of any rights or remedies provided by general law, any rights or remedies provided elsewhere under this Contract or by any other contract or document. In this Clause 30.7 of this Schedule 2, right includes any power, privilege, remedy, or proprietary or security interest.

30.8 Unless otherwise expressly stated in this Contract, a person who is not a party to this Contract shall have no right to enforce any terms of it which confer a benefit on such person except that a Successor and/or a Third Party may directly enforce any indemnities or other rights provided to it under this Contract. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of this Contract.

30.9 This Contract, any variation in writing signed by an authorised representative of each Party and any document referred to (explicitly or by implication) in this Contract or any variation to this Contract, contain the entire understanding between the Supplier and the Authority relating to the Services to the exclusion of all previous agreements, confirmations and understandings and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in this Contract. Nothing in this Contract seeks to exclude either Party's liability for Fraud. Any tender conditions and/or disclaimers set out in the Authority's

procurement documentation leading to the award of this Contract shall form part of this Contract.

30.10 This Contract, and any Dispute or claim arising out of or in connection with it or its subject matter (including any non-contractual claims), shall be governed by, and construed in accordance with, the laws of England and Wales.

30.11 Subject to Clause 22 of this Schedule 2, the Parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any Dispute or claim that arises out of or in connection with this Contract or its subject matter.

30.12 All written and oral communications and all written material referred to under this Contract shall be in English.

Schedule 3

Information and Data Provisions

1 Confidentiality

1.1 In respect of any Confidential Information it may receive directly or indirectly from the other Party ("**Discloser**") and subject always to the remainder of Clause 1 of this Schedule 3, each Party ("**Recipient**") undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser's prior written consent provided that:

1.1.1 the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the Commencement Date;

1.1.2 the provisions of Clause 1 of this Schedule 3 shall not apply to any Confidential Information:

(i) which is in or enters the public domain other than by breach of this Contract or other act or omissions of the Recipient;

(ii) which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality;

(iii) which is authorised for disclosure by the prior written consent of the Discloser;

(iv) which the Recipient can demonstrate was in its possession without any obligation of confidentiality prior to receipt of the Confidential Information from the Discloser; or

(v) which the Recipient is required to disclose purely to the extent to comply with the requirements of any relevant stock exchange.

1.2 Nothing in Clause 1 of this Schedule 3 shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable Law, including the Freedom of Information Act 2000 ("**FOIA**"), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities' Functions or on the Management of Records ("**Codes of Practice**") or the Environmental Information Regulations 2004 ("**Environmental Regulations**").

1.3 The Authority may disclose the Supplier's Confidential Information:

1.3.1 on a confidential basis, to any Contracting Authority (the Parties agree that all Contracting Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any Contracting Authority);

1.3.2 on a confidential basis, to any consultant, contractor or other person engaged by the Authority and/or the Contracting Authority receiving such information;

1.3.3 to any relevant party for the purpose of the examination and certification of the Authority's accounts;

1.3.4 to any relevant party for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources;

1.3.5 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements; or

1.3.6 on a confidential basis to a proposed successor body in connection with any proposed or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Contract;

and for the purposes of this Contract, references to disclosure "on a confidential basis" shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law or this Clause 1.3 of this Schedule 3.

1.4 The Supplier may only disclose the Authority's Confidential Information, and any other information provided to the Supplier by the Authority in relation this Contract, to the Supplier's Staff or professional advisors who are directly involved in the performance of or advising on the Supplier's obligations under this Contract. The Supplier shall ensure that such Staff or professional advisors are aware of and shall comply with the obligations in Clause 1 of this Schedule 3 as to confidentiality and that all information, including Confidential Information, is held securely, protected against unauthorised use or loss and, at the Authority's written discretion, destroyed securely or returned to the Authority when it is no longer required. The Supplier shall not, and shall ensure that the Staff do not, use any of the Authority's Confidential Information received otherwise than for the purposes of performing the Supplier's obligations in this Contract.

1.5 For the avoidance of doubt, save as required by Law or as otherwise set out in this Schedule 3, the Supplier shall not, without the prior written consent of the Authority (such consent not to be unreasonably withheld or delayed), announce that it has entered into this Contract and/or that it has been appointed as a Supplier to the Authority and/or make any other announcements about this Contract.

1.6 Clause 1 of this Schedule 3 shall remain in force:

1.6.1 without limit in time in respect of Confidential Information which comprises Personal Data or which relates to national security; and

1.6.2 for all other Confidential Information for a period of three (3) years after the expiry or earlier termination of this Contract unless otherwise agreed in writing by the Parties.

2 Data protection

2.1 The Parties acknowledge their respective duties under Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties. For the avoidance of doubt, the Supplier shall take reasonable steps to ensure it is familiar with the Data Protection Legislation and any obligations it may have under such Data Protection Legislation and shall comply with such obligations.

2.2 Where the Supplier is Processing Personal Data under or in connection with this Contract, the Parties shall comply with the Data Protection Protocol. Controllers and processors roles may be reviewed as necessary in line with data protection legislation.

2.3 The Supplier and the Authority shall ensure that Personal Data is safeguarded at all times in accordance with the Law, and this obligation will include (if transferred electronically) only transferring Personal Data (a) if essential, having regard to the purpose for which the transfer is conducted; and (b) that is encrypted in accordance with any international data encryption standards for healthcare, and as otherwise required by those standards applicable to the Authority under any Law and Guidance (this includes, data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).

2.4 Where, as a requirement of this Contract, the Supplier is Processing Personal Data relating to patients and/or service users as part of the Services, the Supplier shall:

2.4.1 complete and publish an annual information governance assessment using the NHS information governance toolkit;

2.4.2 achieve a minimum level 2 performance against all requirements in the relevant NHS information governance toolkit;

2.4.3 nominate an information governance lead able to communicate with the Supplier's board of directors or equivalent governance body, who will be responsible for information governance and from whom the Supplier's board of directors or equivalent governance body will receive regular reports on information governance matters including, but not limited to, details of all incidents of data loss and breach of confidence;

2.4.4 report all incidents of data loss and breach of confidence in accordance with Department of Health and/or the NHS England and/or Health and Social Care Information Centre guidelines;

2.4.5 put in place and maintain policies that describe individual personal responsibilities for handling Personal Data and apply those policies vigorously;

2.4.6 put in place and maintain a policy that supports its obligations under the NHS Care Records Guarantee (being the rules which govern information held in the NHS Care Records Service, which is the electronic patient/service user record management service providing authorised healthcare professionals access to a patient's integrated electronic care record);

2.4.7 put in place and maintain agreed protocols for the lawful sharing of Personal Data with other NHS organisations and (as appropriate) with non-NHS organisations in circumstances in which sharing of that data is required under this Contract;

2.4.8 where appropriate, have a system in place and a policy for the recording of any telephone calls in relation to the Services, including the retention and disposal of those recordings;

2.4.9 at all times comply with any information governance requirements and/or processes as may be set out in the Specification and Tender Response Document; and

2.4.10 comply with any new and/or updated requirements, Guidance and/or Policies notified to the Supplier by the Authority from time to time (acting reasonably) relating to the Processing and/or protection of Personal Data.

2.5 Where any Personal Data is Processed by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in Clause 2 of this Schedule 3, as if such Sub-contractor were the Supplier.

2.6 The Supplier shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings whatsoever or howsoever arising from the Supplier's unlawful or unauthorised Processing, destruction and/or damage to Personal Data in connection with this Contract.

3 Freedom of Information and Transparency

3.1 The Parties acknowledge the duties of Contracting Authorities under the FOIA, Codes of Practice and Environmental Regulations and shall give each other all reasonable assistance as appropriate or necessary to enable compliance with those duties.

3.2 The Supplier shall assist and cooperate with the Authority to enable it to comply with its disclosure obligations under the FOIA, Codes of Practice and Environmental Regulations. The Supplier agrees:

3.2.1 that this Contract and any recorded information held by the Supplier on the Authority's behalf for the purposes of this Contract are subject to the obligations and commitments of the Authority under the FOIA, Codes of Practice and Environmental Regulations;

3.2.2 that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the FOIA, Codes of Practice and Environmental Regulations is a decision solely for the Authority;

3.2.3 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier itself is subject to the FOIA, Codes of Practice and Environmental Regulations it will liaise with the Authority as to the contents of any response before a response to a request is issued and will promptly (and in any event within two (2) Business Days) provide a copy of the request and any response to the Authority;

3.2.4 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier is not itself subject to the FOIA, Codes of Practice and Environmental Regulations, it will not respond to that request (unless directed to do so by the Authority) and will promptly (and in any event within two (2) Business Days) transfer the request to the Authority;

3.2.5 that the Authority, acting in accordance with the Codes of Practice issued and revised from time to time under both section 45 of FOIA, and regulation 16 of the Environmental Regulations, may disclose information concerning the Supplier and this Contract; and

3.2.6 to assist the Authority in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA and the Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of FOIA, and providing copies of all information requested by the Authority within five (5) Business Days of that request and without charge.

3.3 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations, the content of this Contract is not Confidential Information.

3.4 Notwithstanding any other term of this Contract, the Supplier consents to the publication of this Contract in its entirety (including variations), subject only to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations.

3.5 In preparing a copy of this Contract for publication under Clause 3.4 of this Schedule 3, the Authority may consult with the Supplier to inform decision making regarding any redactions but the final decision in relation to the redaction of information will be at the Authority's absolute discretion.

3.6 The Supplier shall assist and cooperate with the Authority to enable the Authority to publish this Contract.

3.7 Where any information is held by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in Clause 3 of this Schedule 3, as if such Sub-contractor were the Supplier.

4 Information Security

4.1 Without limitation to any other information governance requirements set out in this Schedule 3, the Supplier shall:

4.1.1 notify the Authority forthwith of any information security breaches or near misses (including without limitation any potential or actual breaches of confidentiality or actual information security breaches) in line with the Authority's information governance Policies; and

4.1.2 fully cooperate with any audits or investigations relating to information security and any privacy impact assessments undertaken by the Authority and shall provide full information as may be reasonably requested by the Authority in relation to such audits, investigations and assessments.

4.2 Where required in accordance with the Specification and Tender Response Document, the Supplier will ensure that it puts in place and maintains an information security management plan appropriate to this Contract, the type of Services being provided and the obligations placed on the Supplier. The Supplier shall ensure that such plan is consistent with any relevant Policies, Guidance, Good Industry Practice and with any relevant quality standards as may be set out in the Key Provisions and/or the Specification and Tender Response Document.

4.3 Where required in accordance with the Specification and Tender Response Document, the Supplier shall obtain and maintain certification under the HM Government Cyber

Essentials Scheme at the level set out in the Specification and Tender Response Document.

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Schedule 4

Definitions and Interpretations

1 Definitions

1.1 In this Contract the following words shall have the following meanings unless the context requires otherwise:

"Actual Services Commencement Date"	means the date the Supplier actually commences delivery of the Services;
"Actuary"	means a Fellow of the Institute and Faculty of Actuaries;
"Authority"	means the authority named on the form of Contract on the first page;
"Authority's Actuary"	means the Government Actuaries Department;
"Authority's Obligations"	means the Authority's further obligations, if any, referred to in the Key Provisions;
"Breach Notice"	means a written notice of breach given by one Party to the other, notifying the Party receiving the notice of its breach of this Contract;
"Broadly Comparable"	means certified by an Actuary as satisfying the condition that there are no identifiable Eligible Employees who would overall suffer material detriment in terms of their future accrual of Pension Benefits under the scheme compared with the NHS Pension Scheme assessed in accordance with Annex A of Fair Deal for Staff Pensions;
"Business Continuity Event"	means any event or issue that could impact on the operations of the Supplier and its ability to provide the Services including an influenza pandemic and any Force Majeure Event;
"Business Continuity Plan"	means the Supplier's business continuity plan which includes its plans for continuity of the Services during a Business Continuity Event;
"Business Day"	means any day other than Saturday, Sunday, Christmas Day, Good Friday or a statutory bank holiday in England and Wales;
"Cabinet Office Statement"	the Cabinet Office Statement of Practice – Staff Transfers in the Public Sector 2000 (as revised 2013) as may be amended or replaced;
"Change Control Process"	means the change control process, if any, referred to in the Key Provisions;

"Codes of Practice"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
"Commencement Date"	means the date of this Contract;
"Commercial Schedule"	means the document set out at Schedule 6;
"Confidential Information"	means information, data and material of any nature, which either Party may receive or obtain in connection with the conclusion and/or operation of the Contract including any procurement process which is: (a) Personal Data including without limitation which relates to any patient or other service user or his or her treatment or clinical or care history; (b) designated as confidential by either party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or (c) Policies and such other documents which the Supplier may obtain or have access to through the Authority's intranet;
"Contract"	means the form of contract at the front of this document and all schedules attached to the form of contract;
"Contracting Authority"	means any contracting authority as defined in regulation 3 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority;
"Contract Manager"	means for the Authority and for the Supplier the individuals specified in the Key Provisions; or such other person notified by a Party to the other Party from time to time in accordance with Clause 8.1 of Schedule 2;
"Contract Price"	means the price exclusive of VAT that is payable to the Supplier by the Authority under the Contract for the full and proper performance by the Supplier of its obligations under the Contract;
"Controller"	shall have the same meaning as set out in the GDPR;
"Convictions"	means, other than in relation to minor road traffic offences, any previous or pending prosecutions, convictions, cautions and binding-over orders (including any spent convictions as contemplated by section 1(1) of the Rehabilitation of Offenders Act 1974 or any replacement or amendment to that Act);
"Cost Increase"	shall have the meaning given to the term in Clause **1.3.2** of Part D of Schedule 7;

"Cost Saving"	shall have the meaning given to the term in Clause **1.3.4** of Part D of Schedule 7;
"Data Protection Legislation"	means (i) the Data Protection Act 1998 or, from the date it comes into force, the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; (ii) the GDPR, the Law Enforcement Directive (Directive (EU) 2016/680) and any applicable national implementing Law as amended from time to time; and (iii) all applicable Law about the processing of personal data and privacy;
"Data Protection Protocol"	means any document of that name as provided to the Supplier by the Authority (as amended from time to time in accordance with its terms), which shall include, without limitation, any such document appended to Schedule 3 (Information and Data Provisions) of this Contract;
"Direction Letter"	means an NHS Pensions Direction letter issued by the Secretary of State in exercise of the powers conferred by section 7 of the Superannuation (Miscellaneous Provisions) Act 1967 and issued to the Supplier or a Sub-contractor of the Supplier (as appropriate) relating to the terms of participation of the Supplier or Sub-contractor in the NHS Pension Scheme in respect of the Eligible Employees;
"Dispute(s)"	means any dispute, difference or question of interpretation or construction arising out of or in connection with this Contract, including any dispute, difference or question of interpretation relating to the Services, any matters of contractual construction and interpretation relating to the Contract, or any matter where this Contract directs the Parties to resolve an issue by reference to the Dispute Resolution Procedure;
"Dispute Notice"	means a written notice served by one Party to the other stating that the Party serving the notice believes there is a Dispute;
"Dispute Resolution Procedure"	means the process for resolving Disputes as set out in Clause 22 of Schedule 2 or, where Clause 24 of Schedule 1 of the Contract applies, the process for resolving Disputes as set out in Schedule 8. For the avoidance of doubt, the Dispute Resolution Procedure is subject to Clause 29.2.3 of Schedule 2;
"DOTAS"	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs 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 by the National Insurance Contributions (Application of Part 7 of the Finance

	Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992;
"Electronic Trading System(s)"	means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time;
"Eligible Employees"	means each of the Transferred Staff who immediately before the Employee Transfer Date was a member of, or was entitled to become a member of, or but for their compulsory transfer of employment would have been entitled to become a member of, either the NHS Pension Scheme or a Broadly Comparable scheme as a result of their employment or former employment with an NHS Body (or other employer which participates automatically in the NHS Pension Scheme) and being continuously engaged for more than 50% of their employed time with the Authority (in the case of Transferring Employees) or a Third Party (in the case of Third Party Employees) in the delivery of services the same as or similar to the Services. For the avoidance of doubt a member of Staff who is or is entitled to become a member of the NHS Pension Scheme as a result of being engaged in the Services and being covered by an "open" Direction Letter or other NHS Pension Scheme "access" facility but who has never been employed directly by an NHS Body (or other body which participates automatically in the NHS Pension Scheme) is not an Eligible Employee entitled to Fair Deal for Staff Pensions protection under Part D of Schedule 7;
"Employee Transfer Date"	means the Transferred Staff's first day of employment with the Supplier (or its Sub-contractor);
"Employment Liabilities"	means all claims, demands, actions, proceedings, damages, compensation, tribunal awards, fines, costs (including but not limited to reasonable legal costs), expenses and all other liabilities whatsoever;
"Environmental Regulations"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
"eProcurement Guidance"	means the NHS eProcurement Strategy available via: http://www.gov.uk/government/collections/nhs-procurement together with any further Guidance issued by the Department of Health in connection with it;
"Equality Legislation"	means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less

	Favourable Treatment) Regulations 2000 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998;
"Exit Requirements"	means the Authority's exit requirements, as set out in the Specification and Tender Response Document and/or otherwise as part of this Contract, which the Supplier must comply with during the Term and/or in relation to any expiry or early termination of this Contract;
"Fair Deal for Staff Pensions"	means guidance issued by HM Treasury entitled "Fair Deal for staff pensions: staff transfer from central government" issued in October 2013 (as amended, supplemented or replaced);
"FOIA"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
"Force Majeure Event"	means any event beyond the reasonable control of the Party in question to include, without limitation: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Contract; (b) acts of terrorism; (c) flood, storm or other natural disasters; (d) fire; (e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (f) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; (g) compliance with any local law or governmental order, rule, regulation or direction applicable outside of England and Wales that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to provide the Services, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and (i) a failure in the Supplier's and/or Authority's supply chain to the extent that such failure is due to any event suffered

	by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties; but excluding, for the avoidance of doubt, the withdrawal of the United Kingdom from the European Union and any related circumstances, events, changes or requirements;
"Fraud"	means any offence under any law in respect of fraud in relation to this Contract or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority;
GDPR	means the General Data Protection Regulation (Regulation (EU) 2016/679);
"General Anti-Abuse Rule"	means (a) the legislation in Part 5 of the Finance Act 2013; and (b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;
"Good Industry Practice"	means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced service provider engaged in the provision of services similar to the Services under the same or similar circumstances as those applicable to this Contract, including in accordance with any codes of practice published by relevant trade associations;
"Guidance"	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Services, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Department of Health, Monitor, NHS England, the Medicines and Healthcare Products Regulatory Agency, the European Medicine Agency, the European Commission, the Care Quality Commission and/or any other regulator or competent body;
"Halifax Abuse Principle"	means the principle explained in the CJEU Case C-255/02 Halifax and others;
"HM Government Cyber Essentials Scheme"	means the HM Government Cyber Essentials Scheme as further defined in the documents relating to this scheme published at: https://www.gov.uk/government/publications/cyber-essentials-scheme-overview;

"Implementation Plan"	means the implementation plan, if any, referred to in the Key Provisions;
"Implementation Requirements"	means the Authority's implementation and mobilisation requirements (if any), as may be set out in the Specification and Tender Response Document and/or otherwise as part of this Contract, which the Supplier must comply with as part of implementing the Services;
"Intellectual Property Rights"	means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trade marks and registered designs;
"Interested Party"	means any organisation which has a legitimate interest in providing services of the same or similar nature to the Services in immediate or proximate succession to the Supplier or any Sub-contractor and who had confirmed such interest in writing to the Authority;
"Key Provisions"	means the key provisions set out in Schedule 1;
"KPI"	means the key performance indicators as set out in Schedule 5;
"Law"	means any applicable legal requirements including, without limitation,: (a) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales; (b) any applicable European Union obligation, directive, regulation, decision, law or right (including any such obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument); (c) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; (d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; (e) requirements set by any regulatory body as applicable in England and Wales; (f) any relevant code of practice as applicable in England and Wales; and (g) any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above);

"Long Stop Date"	means the date, if any, specified in the Key Provisions;
"Losses"	all damage, loss, liabilities, claims, actions, costs, expenses (including the cost of legal and/or professional services) proceedings, demands and charges whether arising under statute, contract or at common law;
"Measures"	means any measures proposed by the Supplier or any Sub-contractor within the meaning of regulation 13(2)(d) of TUPE;
"NHS"	means the National Health Service;
"NHS Body"	has the meaning given to it in section 275 of the National Health Service Act 2006 as amended by section 138(2)(c) of Schedule 4 to the Health and Social Care Act 2012;
"NHS Pensions"	means NHS Pensions (being a division of the NHS Business Services Authority) acting on behalf of the Secretary of State as the administrators of the NHS Pension Scheme or such other body as may from time to time be responsible for relevant administrative functions of the NHS Pension Scheme, including the Pensions Division of the NHS Business Services Authority;
"NHS Pension Scheme"	means the National Health Service Pension Scheme for England and Wales, established pursuant to the Superannuation Act 1972 and governed by subsequent regulations under that Act including the NHS Pension Scheme Regulations;
"NHS Pension Scheme Arrears"	means any failure on the part of the Supplier or any Sub-contractor to pay employer's contributions or deduct and pay across employee's contributions to the NHS Pension Scheme or meet any other financial obligations under the NHS Pension Scheme or any Direction Letter in respect of the Eligible Employees;
"NHS Pension Scheme Regulations"	means, as appropriate, any or all of the National Health Service Pension Scheme Regulations 1995 (SI 1995/300), the National Health Service Pension Scheme Regulations 2008 (SI 2008/653) and any subsequent regulations made in respect of the NHS Pension Scheme, each as amended from time to time;
"Occasion of Tax Non-Compliance"	means: (a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 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 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; and/or (b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion;
"Party"	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;
"Payment Date"	means twenty (20) Business Days after the last of the conditions in Clause **1.7** of Part D of Schedule 7 has been satisfied;
"Pension Benefits"	any benefits (including but not limited to pensions related allowances and lump sums) relating to old age, invalidity or survivor's benefits provided under an occupational pension scheme;
"Personal Data"	shall have the same meaning as set out in the GDPR;
"Policies"	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
"Premature Retirement Rights"	rights to which any Transferred Staff (had they remained in the employment of an NHS Body or other employer which participates automatically in the NHS Pension Scheme) would have been or is entitled under the NHS Pension Scheme Regulations, the NHS Compensation for Premature Retirement Regulations 2002 (SI 2002/1311), the NHS (Injury Benefits) Regulations 1995 (SI 1995/866) and section 45 of the General Whitley Council conditions of service, or any other legislative or contractual provision which replaces, amends, extends or consolidates the same from time to time;
"Premises and Locations"	has the meaning given under Clause 2.1 of Schedule 2;
"Process"	shall have the same meaning as set out in the GDPR. Processing and Processed shall be construed accordingly;
"Processor"	shall have the same meaning as set out in the GDPR;
"Purchase Order"	means the purchase order required by the Authority's financial systems, if a purchase order is referred to in the Key Provisions;
"Relevant Tax Authority"	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;

"Remedial Proposal"	has the meaning given under Clause 15.3 of Schedule 2;
"Services"	means the services set out in this Contract (including, without limitation, Schedule 5 which sets out the requirements of the Authority as issued to tenderers as part of the procurement process and the Supplier's response to these requirements);
"Services Commencement Date"	means the date delivery of the Services shall commence as specified in the Key Provisions. If no date is specified in the Key Provisions this date shall be the Commencement Date;
"Services Information"	means information concerning the Services as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 20 of Schedule 2 for inclusion in the Authority's services catalogue from time to time;
"Specification and Tender Response Document"	means the document set out in Schedule 5 as amended and/or updated in accordance with this Contract;
"Staff"	means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any Sub-contractors and person employed or engaged by such Sub-contractors;
"Step In Rights"	means the step in rights, if any, referred to in the Key Provisions;
"Sub-contract"	means a contract between two or more suppliers, at any stage of remoteness from the Supplier in a sub-contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Contract;
Sub-contractor	means a party to a Sub-contract other than the Supplier;
"Subsequent Transfer Date"	means the point in time, if any, at which services which are fundamentally the same as the Services (either in whole or in part) are first provided by a Successor or the Authority, as appropriate, giving rise to a relevant transfer under TUPE;
"Subsequent Transferring Employees"	means any employee, agent, consultant and/or contractor who, immediately prior to the Subsequent Transfer Date, is wholly or mainly engaged in the performance of services fundamentally the same as the Services (either in whole or in part) which are to be undertaken by the Successor or Authority, as appropriate;
"Successor"	means any third party who provides services fundamentally the same as the Services (either in whole or in part) in immediate or subsequent succession to the Supplier upon the expiry or earlier termination of this Contract;

"Supplier"	means the supplier named on the form of Contract on the first page;
"Supplier Code of Conduct"	means the code of that name published by the Government Commercial Function originally dated September 2017, as may be amended, restated, updated, re-issued or re-named from time to time;
"Supplier Personnel"	means any employee, agent, consultant and/or contractor of the Supplier or Sub-contractor who is either partially or fully engaged in the performance of the Services;
"Term"	means the term as set out in the Key Provisions;
"Termination Notice"	means 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 this Contract on a specified date and setting out the grounds for termination;
"Third Party"	means any supplier of services fundamentally the same as the Services (either in whole or in part) immediately before the Transfer Date;
"Third Party Body"	has the meaning given under Clause 8.5 of Schedule 2;
"Third Party Employees"	means all those employees, if any, assigned by a Third Party to the provision of a service that is fundamentally the same as the Services immediately before the Transfer Date;
"Transfer Amount"	an amount paid in accordance with Clause **1.7** of Part D of Schedule 7 and calculated in accordance with the assumptions, principles and timing adjustment referred to in Clause **1.6** of Part D of Schedule 7 in relation to those Eligible Employees who have accrued defined benefit rights in the NHS Pension Scheme or a Third Party's Broadly Comparable scheme and elected to transfer them to the Supplier's Broadly Comparable scheme or the NHS Pension Scheme under the Transfer Option;
"Transfer Date"	means the Actual Services Commencement Date;
"Transfer Option"	an option given to each Eligible Employee with either: (a) accrued rights in the NHS Pension Scheme; or (b) accrued rights in a Broadly Comparable scheme, as at the Employee Transfer Date, to transfer those rights to the Supplier's (or its Sub-contractor's) Broadly Comparable scheme or back into the NHS Pension Scheme (as appropriate), to be exercised by the Transfer Option Deadline, to secure year-for-year day-for-day service credits in the relevant scheme (or actuarial equivalent, where there are benefit differences between the two schemes);

"Transfer Option Deadline"	the first Business Day to fall at least three (3) months after the notice detailing the Transfer Option has been sent to each Eligible Employee;
"Transferred Staff"	means those employees (including Transferring Employees and any Third Party Employees) whose employment compulsorily transfers to the Supplier or to a Sub-contractor by operation of TUPE, the Cabinet Office Statement or for any other reasons, as a result of the award of this Contract;
"Transferring Employees"	means all those employees, if any, assigned by the Authority to the provision of a service that is fundamentally the same as the Services immediately before the Transfer Date;
"TUPE"	means the Transfer of Undertakings (Protection of Employment) Regulations 2006 (2006/246) and/or any other regulations or other legislation enacted for the purpose of implementing or transposing the Acquired Rights Directive (77/187/EEC, as amended by Directive 98/50 EC and consolidated in 2001/23/EC) into English law; and
"VAT"	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax.

1.2 References to any Law shall be deemed to include a reference to that Law as amended, extended, consolidated, re-enacted, restated, implemented or transposed from time to time.

1.3 References to any legal entity shall include any body that takes over responsibility for the functions of such entity.

1.4 References in this Contract to a "Schedule", "Appendix", "Paragraph" or to a "Clause" are to schedules, appendices, paragraphs and clauses of this Contract.

1.5 References in this Contract to a day or to the calculation of time frames are references to a calendar day unless expressly specified as a Business Day.

1.6 Unless set out in the Commercial Schedule as a chargeable item and subject to Clause 30.6 of Schedule 2, the Supplier shall bear the cost of complying with its obligations under this Contract.

1.7 The headings are for convenience only and shall not affect the interpretation of this Contract.

1.8 Words denoting the singular shall include the plural and vice versa.

1.9 Where a term of this Contract provides for a list of one or more items following the word "including" or "includes" then such list is not to be interpreted as an exhaustive list. Any such list shall not be treated as excluding any item that might have been included in such list having regard to the context of the contractual term in question.

General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.

1.10 Where there is a conflict between the Supplier's responses to the Authority's requirements (the Supplier's responses being set out in Schedule 5) and any other part of this Contract, such other part of this Contract shall prevail.

1.11 Where a document is required under this Contract, the Parties may agree in writing that this shall be in electronic format only.

1.12 Where there is an obligation on the Authority to procure any course of action from any third party, this shall mean that the Authority shall use its reasonable endeavours to procure such course of action from that third party.

1.13 Any guidance notes in grey text do not form part of this Contract.

1.14 Any Breach Notice issued by a Party in connection with this Contract shall not be invalid due to it containing insufficient information. A Party receiving a Breach Notice ("**Receiving Party**") may ask the Party that issued the Breach Notice ("**Issuing Party**") to provide any further information in relation to the subject matter of the Breach Notice that it may reasonably require to enable it to understand the Breach Notice and/or to remedy the breach. The Issuing Party shall not unreasonably withhold or delay the provision of such further information as referred to above as may be requested by the Receiving Party but no such withholding or delay shall invalidate the Breach Notice.

1.15 Any terms defined as part of a Schedule or other document forming part of this Contract shall have the meaning as defined in such Schedule or document.

Schedule 5

Specification and Tender Response Document

Evaluation – SPECIFICATION OF REQUIREMENTS

Programme Overview

1.1 Policy Background

NHS England and NHS Improvement are looking to award a contract to a national Evaluator (the "Evaluator") to conduct a comprehensive service evaluation for the Cytosponge programme.

Cytosponge is a diagnostic tool which can be used to detect Barrett's Oesophagus (BO), a potential precursor to oesophageal (OG) cancer. The NHS Cancer Programme has prioritised the implementation of Cytosponge within the secondary care diagnostic pathway for patients with low-risk reflux symptoms from the endoscopy waiting list.

This implementation will form a key part of the recovery plan to restore services disrupted as a result of Covid-19 and contribute to NHS Long Term Plan ambitions. The ambitions are to speed up the transition of proven new technologies to business-as-usual in the NHS and to reduce variation in access to innovation across the NHS.

Across England, gastroscopy activity from March to September 2020 averaged 46.5% of its usual levels[1]. Patients in the routine referral cohort, who have been referred to secondary care with reflux symptoms, are likely to be waiting longer than usual for a gastroscopy in secondary care to be available. Cytosponge has been selected by the NHS Cancer Programme because of its potential to prioritise patients and reduce the demand on upper Gastrointestinal Tract (GI) endoscopy services. By offering low-risk eligible patients on the secondary care waiting list a Cytosponge diagnostic test, Cytosponge has the potential to eliminate unnecessary endoscopies and rapidly prioritise patients at risk of BO, maximising the use of scarce resources for endoscopy.

Cytosponge is a capsule that is swallowed whilst holding onto a string. The capsule dissolves in the stomach and a sponge expands. When brought up, the sponge collects cells from the oesophagus that are analysed to detect intestinal metaplasia (TFF3) and dysplasia (atypia and p53) without a full gastroscopy. This device was designed by Professor Rebecca Fitzgerald from the University of Cambridge, who is

(a) _____

[1] NHS England – Statistics, Monthly Diagnostics Waiting Times and Activity (2017 data, released April 2019), https://www.england.nhs.uk/statistics/statistical-work-areas/diagnostics-waiting-times-and-activity/monthly-diagnostics-waiting-times-and-activity/monthly-diagnostics-data-2020-21/, Accessed January 2021.

working with Medtronic to produce the devices and Cyted Ltd to analyse the samples.

The target population for this use of Cytosponge is routine patients referred with reflux symptoms with no alarm systems by general practitioners to secondary care on a diagnostic upper GI endoscopy pathway.

Inclusion criteria for Cytosponge:

- Patients with symptoms of reflux including:
  - Heartburn (burning sensation on chest usually after eating),
  - Regurgitation (an unpleasant sour taste in mouth caused by stomach acid)
  - Waterbrash (excessive salivation)

The goals for the Cytosponge programme are to:

- embed a new diagnostic modality for this cohort of patients, including enhancing patient experience and providing guidance to clinicians for managing their treatment,
- enable the prioritisation of patients who are more at risk of serious pathology for rapid access to an upper GI endoscopy, and;
- reduce the number of unnecessary endoscopies for this cohort of patients.

A programme wide Logic Model presenting the implementation plan for the programme alongside anticipated outcomes and impacts is provided in **Appendix 1**. This provides a preliminary framework against which the outcomes of the Cytosponge programme can be evaluated.

1.2 Approach to implementation

The NHS Cancer Programme will take a rolling two-phased approach to implementation. All Cancer Alliances were invited to put forward an expression of interest to take part in Cytosponge implementation. 19 of 21 Cancer Alliances expressed interest. Phase 1 will deliver an initial 700 devices, and phase 2 will deliver a further 10,000 devices. The number of devices has been allocated to Cancer Alliances based on population size and all devices will need to be used by 31 March 2022.

Phase 1:
Delivery for phase 1 will start in March 2021. Five Cancer Alliances were selected based on readiness to deliver (have a named clinical champion for Cytosponge and

trained band 7 nurses) and will launch the first phase of implementation. Cytosponge clinics will commence once nurse training has been completed. The length of each clinic will vary depending on the number of Cytosponge devices allocated to a site.

The Cancer Alliances identified for phase one are: East of England North, East of England South, Greater Manchester, North East London, and West Yorkshire and Harrogate.

Phase 2:
The remaining 14 Cancer Alliances will be trained between February and April 2021 and will commence delivery of Cytosponge as soon as nurses have been trained and signed-off.

A complete list of Cancer Alliances and participating sites can be found in section 2.6 *(Site locations)*.

1.3 Governance

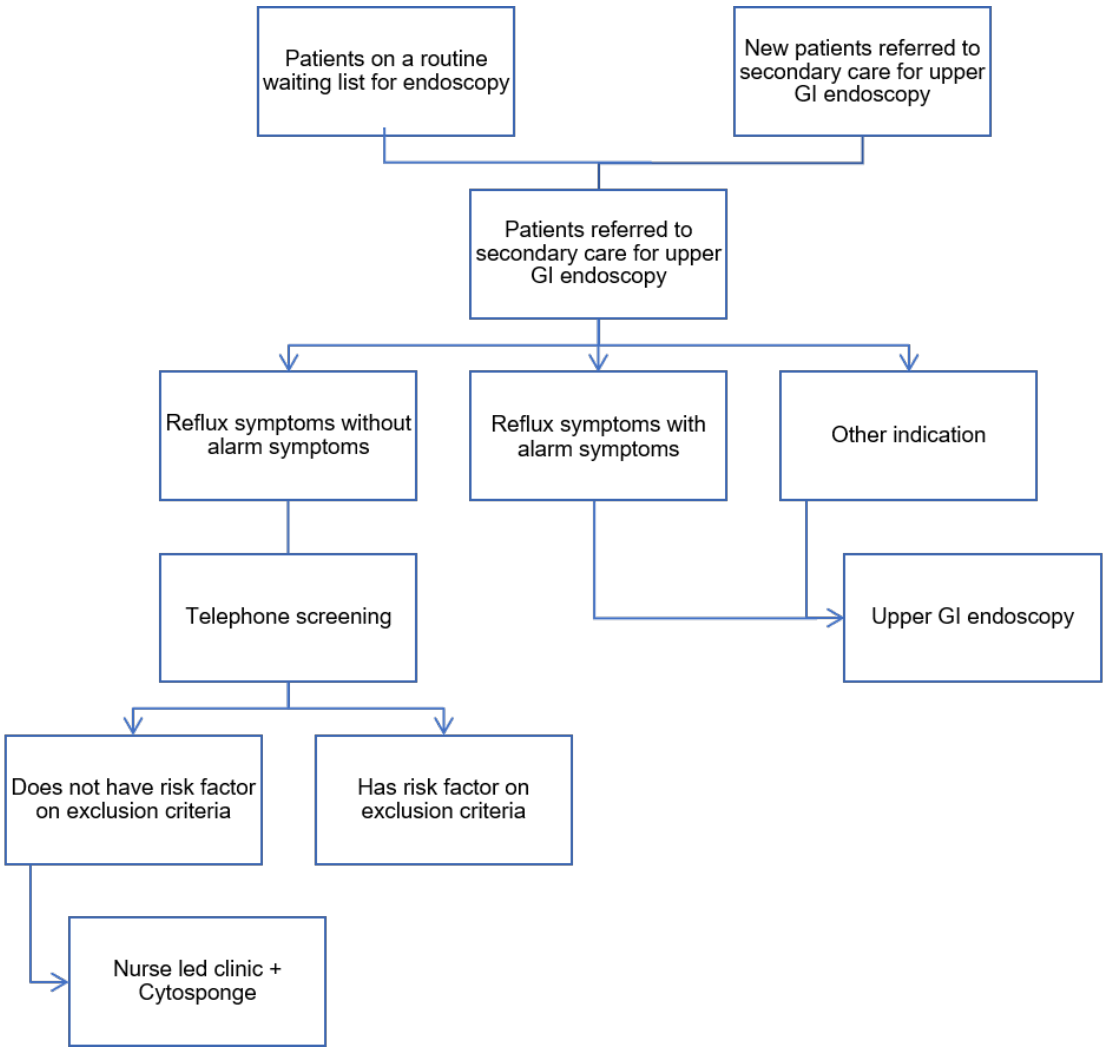
A Cytosponge Working Group has been established to oversee the development of an implementation plan for Cancer Alliances to pilot the roll-out of Cytosponge. The Working Group brings together innovation expertise with Upper GI specialists, Cancer Alliances, patients, legal and procurement, and the companies who developed Cytosponge. The group provides practical advice and recommendations to the NHS Cancer Programme.

An evaluation subgroup was established to focus on the development of the evaluation and support the appointment of the Evaluator. The subgroup identified the aims of the evaluation, the high-level evaluation questions and sub-themes, see 2.4 *(Evaluation high-level themes and subthemes)*. The evaluation subgroup is comprised of health economists, NICE, clinicians, Cancer Alliances, and innovation and policy experts. A complete membership list of the evaluation subgroup can be found in **Appendix 2**.

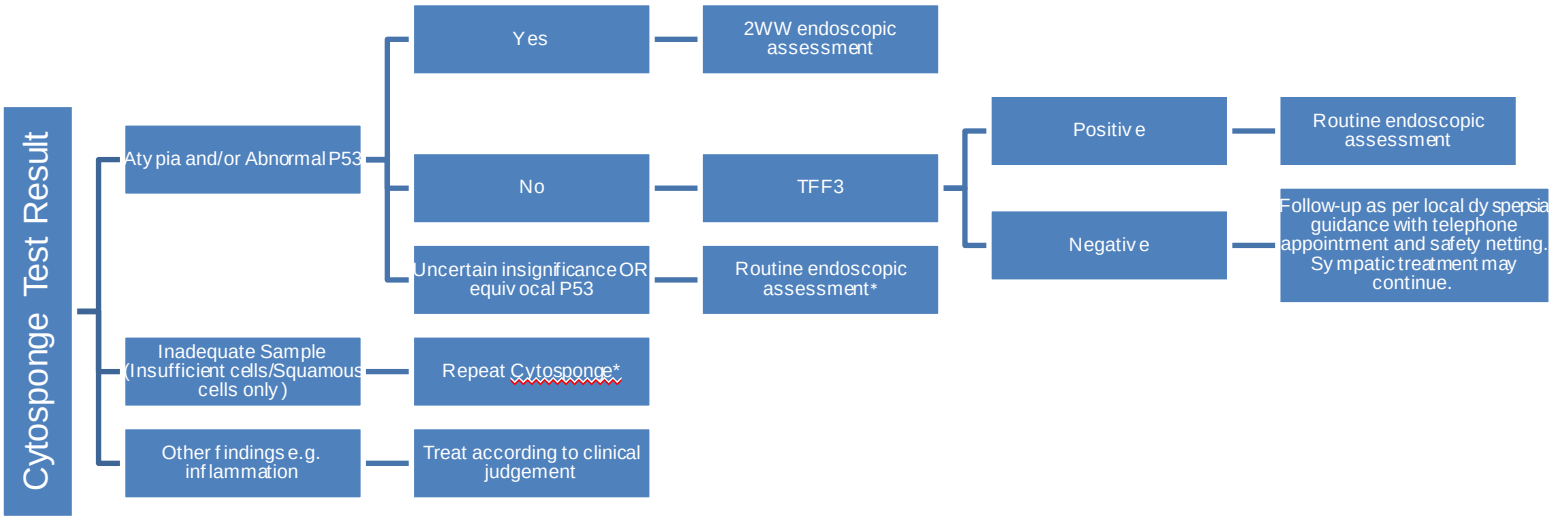
An Oversight Group will be established to monitor the ongoing delivery of the programme. The Evaluator will report into the Oversight Group.

1.4 Cytosponge in upper GI endoscopy pathway

The implementation of Cytosponge testing will change the diagnostic pathway for patients routinely referred to secondary care for an upper GI endoscopy. The proposed new pathway is outlined in the diagram below:



Follow-up actions for patients will depend on the results of the Cytosponge test. This is shown in the diagram below:



2 Scope of procurement

2.1 Background to Evaluation

Evidence from clinical randomised control trials (RCTs) have demonstrated the efficacy of Cytosponge as a potential targeted screening tool for detecting Barrett's Oesophagus (BO) in primary care settings[2]. The purpose of this commissioned evaluation is to test these findings outside of primary care, specifically assessing the impact of implementing Cytosponge as a triaging diagnostic tool for patients referred to secondary care on a routine referral for an endoscopy. Evidence generated and analysed as part of this evaluation will inform a decision on the future national roll-out for implementing Cytosponge in secondary care.

A service evaluation is required to generate evidence to understand how the implementation of Cytosponge impacts service delivery and patient outcomes in secondary care. The full evaluation will include a comprehensive assessment of the implementation processes, patient experience, health and service outcomes, and the economic value of this programme. As part of conducting this evaluation, the appointed Evaluator will be responsible determining the necessary data to collect and a suitable counterfactual to respond to these evaluation requests.

(a) _____

[2] Fitzgerald, R.C., di Pietro, M., O'Donovan, M., Maroni, R., Muldrew, B., Debiram-Beecham, I., Gehrung, M., Offman, J., Tripathi, M., Smith, S.G. and Aigret, B., 2020. Cytosponge-trefoil factor 3 versus usual care to identify Barrett's oesophagus in a primary care setting: a multicentre, pragmatic, randomised controlled trial. The Lancet, 396(10247), pp.333-344.
https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(20)31099-0.pdf

In addition, to speed up the adoption of- and reduce variation in access to-innovative technologies, the NHS Cancer Programme is seeking NICE approval through the Diagnostic Assessment Programme (DAP) for this use case of Cytosponge. It is expected that evidence generated through this evaluation will be presented to NICE as part of the DAP. To satisfy the evidence requirements of the DAP, the appointed Evaluator will need to consider how to gather:

- Evidence that Cytosponge reduces the number of endoscopies when used as a diagnostic triaging tool in secondary care for routine referrals and that this translates into resource use savings: in a real-life setting, compared to current clinical practice.
- Economic evidence for Cytosponge: Is Cytosponge a cost-effective use of NHS resources?

Further information about the DAP can be found in **Appendix 3**.
The scope and evaluation themes are detailed in 2.3 (*Scope overview)* and 2.4 *(Evaluation high-level themes and subthemes)*.

2.1.1 Sensitivity and Specificity

As part of the economic evaluation, an estimation of the sensitivity and specificity of the Cytosponge test result is required.

The appointed Evaluator should establish sensitivity by following the outcomes of patients who receive a negative Cytosponge test result. Specificity can be assessed by following the outcomes of patients who receive a confirmatory endoscopy after receiving a positive Cytosponge result. See 2.2 (Out of scope for this evaluation) for further details on evaluating sensitivity and specificity.

2.2 Out of scope for this evaluation

Alternative use cases for Cytosponge have been proposed, including as a targeted selective triaging tool in primary care, and as a monitoring tool for BO surveillance. For this programme, Cytosponge will only be implemented as a triaging diagnostic tool in secondary care. It is, therefore, not in scope for this evaluation to determine Cytosponge's effectiveness as an alternative tool.

The true sensitivity and specificity rates of Cytosponge in secondary care as a triaging tool will not be assessed in this evaluation. It has been deemed out of scope to conduct concurrent Cytosponge and endoscopy tests for patients.

2.3 Scope overview

NHS England and NHS Improvement is looking to award a contract to a national Evaluator (the "Evaluator") to comprehensively evaluate the Cytosponge programme. The evaluation will be 18 months from date of awarded contract. The requirements of the Evaluator are:

i) to review the proposed evaluation questions for the impact, process and economic evaluations (as set out in 2.4 *Evaluation high-level themes and subthemes*) and determine an agreed methodology to meet the evaluation requirements including the identification of a suitable counterfactual and economic analysis,

ii) to establish processes that enable sites to report data on an agreed dataset to the Evaluator,

iii) to submit monthly management data on programme activity and quarterly and annual progress reports to the NHS Cancer Programme Management team on programme delivery and;

iv) to collate and interpret data to provide a full impact, process, and economic evaluation.

2.4 High-level evaluation questions and sub-themes

The evaluation should address key high-level evaluation questions that have been agreed by the evaluation subgroup. **Table 1** sets out the high-level evaluation questions and corresponding sub-themes, as well as the potential approaches to addressing them.

Table 1: evaluation high-level question to be addressed

Evaluation Type	Evaluation Question / Sub theme	Purpose	Potential approaches
Impact	1. **What impact does Cytosponge (delivered in**	This will demonstrate progress towards	Impact evaluation, using a suitable methodology to

	secondary care as a routine referral triaging tool) have on endoscopy demand (both in the short and long term)? 1.1. Avoidance of unnecessary Endoscopy 1.2. Proportion of confirmatory endoscopies required (as a result of a positive test result) 1.3. Proportion of re-referrals from negative Cytosponge results	any reductions in endoscopy demand and any alleviation of pressure on endoscopy services.	establish a robust counterfactual. Potential methodologies to be determined by the Evaluator must include, but are not limited to, the establishment of comparator sites or construction of synthetic matched control groups. The Evaluator must ensure the inclusion/exclusion criteria for patient matching for the comparator are clearly described. Data to inform impact evaluation will come from agreed minimum data set and secondary data sets.
Impact	2. **What impact does Cytosponge have on patient outcomes?** 2.1. Time to Barrett's Oesophagus and cancer diagnosis 2.2. Time to treatment or discharge 2.3. Stage of diagnosis 2.4. Unintended consequences,	This will demonstrate progress on prioritising more at-risk patients for an endoscopy leading to a faster diagnosis. This will also identify possible unintended outcomes and impacts of the programme.	Impact evaluation, with an appropriate counterfactual, to understand any impact on patient outcomes. Data to inform impact evaluation will come from agreed minimum data set and secondary data sets.

	including other diagnoses.		
Impact	3. **What impact does Cytosponge have on the diagnostic experience of patients?** 3.1. Patient Experience 3.2. Patient Engagement	This information will help NHS England and NHS Improvement to understand participants' perception of the Cytosponge programme, its procedure, and how patients respond to their results. Emerging evidence will allow sites to make changes where participant feedback identifies any issues or barriers to engagement.	The Evaluator must determine the most appropriate/feasible method and timing for collecting this evidence. Methods may include interviews with participants and/or a participant satisfaction questionnaire following the a Cytosponge test. The number patients who decline or do not attend (DNA) a Cytosponge appointment with their reasons will be recorded as part of the agreed minimum data set.
Impact	4. **How does Cytosponge affect patient inequalities, both in access to a diagnosis, and outcomes?** 4.1. Understanding the local issues and inequalities	This will demonstrate whether Cytosponge has a positive impact on addressing inequalities in health outcomes or creating further inequality. The feasibility for delivering Cytosponge in secondary care will also provide	Impact evaluation, with an appropriate counterfactual to understand any impact on local variations in time to diagnosis of BO and cancer and other related health outcomes.

		evidence for feasibility of administering Cytosponge in primary care which may have an impact on access to diagnosis and health inequalities.	
Process	5. **What are the barriers and enablers to the implementation of the Cytosponge in secondary care?** 5.1. Enablers / barriers 5.2. Sustainability 5.3. Scalability	This will help NHS England and NHS Improvement to identify a blueprint of the 'key ingredients' for success to implementing Cytosponge in secondary care and understand the extent to which sites were able to deliver the programme according to the specification. This will also inform future NHS England and NHS Improvement policies on a national Cytosponge programme in secondary and primary care.	Interviews and focus groups with key stakeholders across all sites, and bespoke collection of feedback from participants and staff (clinical and non-clinical). Appraisal of relevant local documentation, including, but not limited to, PIDs, logic models, and risk registers, as developed. Bespoke process and activity data collections, where necessary. Where emerging evidence indicates a lower uptake rate than expected, the evaluation should consider reasons for this using a formative approach.
Economic	6. **What is the short- and long-term**	This information will support	The appointed Evaluator will be

	cost effectiveness of Cytosponge, when used as a diagnostic triage tool in secondary care?	evidence requirements for the NICE Diagnostic Assessment Programme. A cost effectiveness analysis will consider initial investment, impact on patient health outcomes and endoscopy resource.	expected to establish and embed the necessary data and data capture processes required to undertake a full economic analysis to satisfy the NICE Diagnostic Assessment Programme evidence requirements. This will include assessing the sensitivity and specificity rates, determining the number of patients to be tested and the length of time required for follow-up data. The economic analysis should include a quantification of both intended and unintended consequences. All healthcare provider costs should be considered, including, but not limited to costs of training, pathology, devices, staffing and resources.
Economic	**7. What investment would be required for a national roll out of this programme?**	This will help NHS England and NHS Improvement to understand the financial resources and investment that	Within the evaluation period, the appointed Evaluator should seek to compare resource models across each of the site with a view to

		would be required for a national rollout following completion of this pilot programme.	understanding the investments require for a national roll out at the end of this programme.

2.5 Methodological approach

It is expected that a breadth of analytical approaches will be employed to address the proposed evaluation questions and sub-themes, as indicated above. Additional innovative suggestions on alternative methodologies are welcomed from bidders, although any proposed approaches must be proportionate and flexible, balancing robustness with a need to generate timely evidence.

A key part of this service evaluation is for the appointed Evaluator to establish an appropriate counterfactual or control groups. This is necessary to measure the impacts and economics of the Cytosponge programme. Potential methodologies may include, but not be limited to, the establishment of comparator sites or construction of synthetic control groups. Alongside the impact analysis, the appointed Evaluator is also expected to conduct a suitable cost analysis for the economic evaluation serving the evidence requirements for the Diagnostic Assessment Programme as set out by NICE.

More information about the requirements for establishing a counterfactual for the impact and economic aspects of this evaluation can be found in **Appendix 3.** This sets out preliminary analytical scoping on potential approaches and considerations for establishing a counterfactual.

2.6 Site locations

The pilot programme will launch in two phases. Phase 1 is anticipated to begin in February/March 2021. Five Cancer Alliances are participating in phase 1. These are:

- East of England North Cancer Alliance
- East of England South Cancer Alliance
- Greater Manchester Cancer Alliance
- North East London Cancer Alliance
- West Yorkshire and Harrogate Cancer Alliance

Table 2: proposed sites by Cancer Alliance and Trust – Phase 1, 2021/22

Sites	Cancer Alliance	NHS Region
West Suffolk Hospital	East of England North	East of England
Cambridge University Hospital (Addenbrookes)	East of England North	East of England
East and North Herts Trust	East of England South	East of England
Bedfordshire Hospitals Trusts (Bedford site)	East of England South	East of England
Salford Royal	Greater Manchester	North West
Royal Oldham Hospital	Greater Manchester	North West
Manchester Foundation	Greater Manchester	North West
Barking, Havering and Redbridge University Hospitals (BHRUT)	North East London	London
Barts Health Mile End EDC	North East London	London
Leeds Teaching Hospitals NHS Trust	West Yorkshire and Harrogate	North East and Yorkshire
Calderdale and Huddersfield NHS Trust	West Yorkshire and Harrogate	North East and Yorkshire
Harrogate District Foundation NHS Trust	West Yorkshire and Harrogate	North East and Yorkshire

A further 14 Cancer Alliances will participate in phase 2, with a rolling start date of April 2021 onwards. These are:

- Cheshire and Merseyside Cancer Alliance
- East Midlands Cancer Alliance
- Humber, Coast and Vale Cancer Alliance
- Kent and Medway Cancer Alliance
- Lancashire and South Cumbria Cancer Alliance
- Northern Cancer Alliance
- Peninsula Cancer Alliance
- RM Partners (West London) Cancer Alliance
- Somerset, Wiltshire, Avon, and Gloucestershire (SWAG) Cancer Alliance
- South East London Cancer Alliance
- South Yorkshire and Bassetlaw Cancer Alliance
- Thames Valley Cancer Alliance
- Wessex Cancer Alliance
- West Midlands Cancer Alliance

Specific sites participating in phase 2 will be identified in March/April 2021.

2.7 Evaluation dataset

The evaluation dataset sets out the full data requirements to satisfy the evaluation questions of this programme. A proposed evaluation data set (**Appendix 4**) has been developed through mapping data items against the logic model, clinical pathway, and evaluation questions and collaborating with clinicians, statisticians, and Cancer Alliances. This dataset contains both patient level data items submitted by the sites via the minimum data set and data items collated from additional secondary data sources to reduce site burden.

The appointed Evaluator will be expected to work with NHS England and NHS Improvement and Cancer Alliances to finalise this patient level dataset and propose any additional data items that will be required to address the prescribed evaluation questions. Data items will be collected, stored, and used through data sharing agreements.

2.7.1 Minimum Data Set

This data will be a subset of the full evaluation dataset required to meet the evaluation aims. The minimum data set is any new patient level data collected as part of this programme.

2.7.2 Secondary Data

Additional data can be taken from other sources to reduce the burden on projects. Data from other datasets on cancer treatment and patient outcomes, such as the Secondary User Service (SUS) and ONS Mortality dataset, will be sourced from NHS Digital. Data on cancer diagnosis and staging will be sourced from the Cancer Outcomes and Services Dataset (COSD). It is expected that the appointed Evaluator will scope out the secondary data sets available and link data items to the minimum data set at patient level to form the full evaluation data set.

2.8 Data collection

Patient level data will be recorded at source on existing primary and secondary care patient management systems and clinical systems, e.g. EMIS, PACS, PAS, CWT and COSD. Data on each participant will be added to the local clinical system and updated as they progress along a pathway.

The appointed Evaluator is expected to work with NHS England and NHS Improvement, Cancer Alliances, and their constituent organisations to:

- Agree an approach to data collection and processing, and arrangements for data pseudonymisation, in accordance with the Data Protection Act 2018;
- Link locally collected data to nationally available datasets, e.g. Cancer Registry and Hospital Episodes Statistics (HES) to obtain necessary data to respond to evaluation themes and;
- Collect additional data beyond this minimum dataset as necessary to address the prescribed evaluation themes.

The appointed Evaluator will therefore need to:

- Be experienced in the data management and analysis of nationally collected complex datasets, including clinical information, and;
- Demonstrate expertise in adhering to Information Governance (IG) requirements to collect patient identifiable data from local systems, and to link it with existing national datasets.

2.9 Volume and numbers

This pilot programme will be offering 10,000 Cytosponge tests within a one-year period (1 April 2021 to 31 March 2022). Based on previous research trials, of the 10,000 patients who will receive Cytosponge, 8,500 (85%) are estimated to be discharged back into the community, with 1,500 (15%) getting referred for confirmatory endoscopy.

3 Requirements

3.1 Mandatory standards

In addition to the common law duty of confidentiality, and to process individual's personal data where applicable for the proposed purpose, NHS England and NHS Improvement, with the appointed Evaluator, must satisfy the lawful basis for using confidential information (for common law duty of confidence). Further to this and to satisfy the conditions for processing personal data, NHS England will be using Article 9, 2(h) of the Data Protection Act 2018, via the Health and Social Care Act 2012 Section 17, 13 (1). It is expected that the appointed Evaluator is registered with the

ICO (able to provide a Data Protection Notification number), and compliant with the Data Security and Protection Toolkit.

3.2 Reporting

Reporting will be required for four areas, set out below. Each report will cumulatively build and increase understanding of answers to the evaluation questions.

Specific evaluation themes to be addressed are expected to vary across each reporting period, as set out in 2.4 (*Evaluation high-level themes and subthemes)*. A proposed reporting schedule and minimum requirements for each reporting period is set out in **Table 4**.

Bids should indicate which evaluation themes will be addressed in each reporting period, and the frequency of this. This will then be agreed with the appointed Evaluator during the evaluation scoping phase.

3.2.1 Evaluation Strategy Report

The appointed Evaluator will be expected to produce an evaluation strategy, setting out the overall approach to evaluation and specific methodological approaches to be taken to address each of the evaluation questions. This strategy should guide the operation and development of evaluation activity throughout the duration of the programme.

The Evaluator is expected to submit this report within twelve weeks of contract commencement date.

Delivery will be assessed using Key Performance Indicator 1[see section 4.5 *(Performance and measurement)*].

3.2.2 Monthly management information

The appointed Evaluator should collate monthly management information data from sites and submit aggregated report to NHS England and NHS Improvement summarising the monthly progress of the implementation of the Cytosponge programme. Reports should be presented at Cancer Alliance level.

Each monthly report will need to include the most recent reporting month data, as well as cumulative data from preceding months.

Evidence generated through the management information (MI) reporting and evaluation should be sufficient to:

- Measure progress towards implementation;
- Inform local service improvement, and;
- Inform longer term national policy development.

Management information items should include, but not be limited to:

At Cancer Alliance level

a) number of nurses trained
b) number of Cytosponge sites that are live
c) number of Cytosponge appointments offered
d) number of Cytosponge appointments accepted
e) number of Cytosponge appointments attended
f) number of non-attendances to Cytosponge appointments
g) number of significant adverse events
h) number of inadequate samples
i) number of TFF3 negative with no other cytological or diagnosis results
j) number of participants requiring upper GI endoscopy following Cytosponge results
k) number of re-referrals for upper GI endoscopies for patients receiving a negative Cytosponge result.
l) number of cancers detected.

Delivery will be assessed using Key Performance Indicator 2 [see section 4.5 *(Performance and measurement)*].

3.2.3 Quarterly reports

Quarterly reporting is based on the information collected from sites to address the 'Evaluation high-level questions and subthemes' set out in section 2.44.

Quarterly formative reports are to be submitted to NHS England and NHS Improvement in November 2021, February 2022, May 2022, and August 2022.

Evaluation themes should be addressed at both Cancer Alliance and national levels in all quarterly reports, as necessary. Reports should identify best practice learning points relevant at each level and include a 'lessons learnt' implementation checklist

setting out the key requirements to deliver a Cytosponge triaging diagnostic pathway in secondary care.

Delivery will be assessed using Key Performance Indicator 3 [see section 4.5 *(Performance and measurement)*].

3.2.4 Final Summative report

A final summative evaluation report will be submitted to NHS England and NHS Improvement and should, at a minimum, include:

- A consolidation and summary of all interim reports.,
- A final summative report on key leanings gained, including implications for a future national rollout.
- A final summative assessment of the impact and cost-effectiveness of the Cytosponge programme.

The final summative report is expected to be submitted in November 2022 following the end of the of implementation (31st March 2022), allowing for an additional six month follow up on patient outcomes, and time to consolidate findings.

Delivery will be assessed using Key Performance Indicator 4 [see section 4.5 *(Performance and measurement)*].

3.2.5 Additional Reporting Elements

Any reasonable and agreed requests for additional elements from NHS England and NHS Improvement are to be included in all reporting outputs. Such requests will be communicated in advance of reporting deadline. Additional requests will be mutually agreed by both NHS England and Improvement's contract manager and the appointed representative of the Evaluator.

Throughout the programme the appointed Evaluator should contribute its experience, expertise, and insights.

Table 4: Proposed reporting schedule and minimum requirements

Reporting period	Output	Purpose

June 2021	Evaluator Appointed	Evaluation contract formally commences.
August 2021	Evaluation strategy	Sets out the overall approach to evaluation and specific methodological approaches to be taken to address the prescribed evaluation themes. This strategy should guide the operation and development of evaluation activity throughout the duration of the programme.
November 2021	Quarterly report	Summary reflecting work completed during the previous six months. This report will focus on process and formative findings, including implementation progress to date. It should also provide a comprehensive review of lessons learnt to support rollout across other sites. Initial descriptive report on endoscopy and patient outcomes.
February 2022	Quarterly report	Drawing from information from site and participant experience, identify best practice learning points relevant at national and Cancer Alliance levels. Compared with the previous quarterly report, this report will have a growing focus on descriptive impact outcomes including impact on local endoscopy demand and patient outcomes.
May 2022	Quarterly report	Comprehensive and cumulative summary of work completed during evaluation to date. All evaluation questions that are feasible to respond to at that point in time should be addressed. In line with the end of the implementation time period for the Cytosponge programme, this report should present findings from full process evaluation and ongoing descriptive findings on impact outcomes.
August 2022	Quarterly Report	Comprehensive and cumulative summary of the Cytosponge programme. All evaluation questions should be addressed. This report should present

		the ongoing findings from the follow up of outcomes for the impact evaluation.
November 2022	Final summative evaluation report	Summative assessment of the full programme including the findings from the impact and economic evaluation analyses.

3.3 Publication standards

Annual reports, together with the final summative report, must be produced to publication standard, and should be reflected in project costings as necessary.

3.4 Knowledge dissemination

The appointed Evaluator will be required to work with NHS England and NHS Improvement, Cancer Alliances and their constituent organisations, to implement approaches to ensure learning from the evaluation informs policy development and local service improvement, as appropriate.

4 Contract

4.1 Contract management

The contract will be managed by the NHS England and NHS Improvement's NHS Cancer Programme team with support from NHS England and NHS Improvement's corporate services and the Cancer Alliance Data, Evidence and Analysis Service (CADEAS).

4.2 Evaluation timeframes

The appointed Evaluator will be in place for 18 months. This will allow for the evaluation to run alongside and continue after the implementation of the Cytosponge programme which is due to complete in March 2022. Evaluation arrangements (including Evaluation Strategy and data collection) should be in place by 31 August 2021. To allow for a 6-month follow-up of outcomes from the last patients receiving a Cytosponge test, the final summative report will be due 30th November 2022.

4.3 Location

Though services may be delivered remotely, significant contact with sites will be necessary. Regular meetings with the NHS Cancer Programme team and Cancer Alliance Data, Evidence and Analysis Service (CADEAS) at NHS England and NHS Improvement will be required. These meetings may be held remotely, via Microsoft Teams, or in the London office (Skipton House, 80 London Road, London, SE1 6LH) for which the appointed Evaluator will be expected to travel as and when circumstances allow.

4.4 Roles and Responsibilities

NHS England and NHS Improvement and Public Health England (PHE) responsibilities:

- Nomination of a responsible officer to act as NHS England and NHS Improvement contract manager;
- Comment and sign-off of Evaluation Strategy;
- Comment and sign-off for all draft and final reports (e.g. monthly management reports, quarterly reports);
- Comment and sign-off of all draft and final delivery materials required to conduct evaluation (e.g. survey sampling, participant questionnaires, interview guides);
- Coordinating and organisation of meetings, as required;
- Monitoring progress against agreed milestones and help troubleshooting any arising issues;
- Provide oversight of the work through the Oversight Group, who will meet monthly.

Supplier responsibilities:

- Identification of a contract manager to oversee the work and liaise with /report to NHS England and NHS Improvement contract manager. The supplier will notify NHS England and NHS Improvement in advance of changes in key personnel, at least four weeks prior to changes occurring;
- Attendance at meetings with NHS England and NHS Improvement, as and when required, including monthly meetings with the NHS England and NHS Improvement contract manager, as well as presenting to the Evaluation Oversight Group;
- Provision of clear assurance processes for delivery;
- Lead the production of the evaluation strategy;

- Lead all field work to collect data to satisfy the evidence requirements to respond to the evaluation questions;
- Produce and finalise all agreed reports to respond to the evaluation questions;
- Contribute experience, expertise, and insights throughout the Evaluation.

Ways of working: The appointed Evaluator will be expected to work in a collaborative manner, specifically working with the NHS appointed contract manager to build a joint understanding of how the programme of works is progressing, presenting issues and risks in a timely manner, and striving for continuous improvement at a project and programme level.

4.5 Performance and measurement

Key Performance Indicators (KPIs) and payment conditions are indicated below.

Table 5: Key Performance Indicators (KPIs) and payment conditions.

KPI Ref	KPI	Frequency	Measurement	Payment condition
1	Timeliness of evaluation strategy	Once	Received within 12 weeks of contract start date. Evaluation strategy agreed and signed off as satisfactory by the NHS Cancer Programme within 10 working days of receipt.	Associated payment milestone released to Supplier on receipt of satisfactory report meeting all associated KPIs.
2	Timeliness of reporting – monthly management reports	Monthly	Received by agreed date. Signed off as satisfactory by the NHS Cancer Programme within 5 days of receipt.	Associated payment milestone released to Supplier on receipt of satisfactory report meeting all associated KPIs.
3	Timeliness of reporting – quarterly evaluation reports	Quarterly	Received by agreed date. Signed off as satisfactory by the NHS Cancer Programme within 10 days of receipt.	Associated payment milestone released to Supplier on receipt of satisfactory report meeting all associated KPIs.
4	Timeliness of reporting – final evaluation	Once	Received by 31st November 2022.	Associated payment milestone released to Supplier on receipt of

	summative report.		Signed off as satisfactory by the NHS Cancer Programme within 30 days of receipt.	satisfactory report meeting all associated KPIs.

4.6 Payment schedule

Table 6: Payment milestones

Payment milestone	*KPI Ref.*	*Payment (% contract value)*
Information systems, the ability to collect data and the requisite governance arrangements in place for all sites and signed off as satisfactory by the NHS Cancer Programme.		5% on verification that information governance and data collection arrangements are in place.
Evaluation strategy submitted to the NHS Cancer Programme and signed off as satisfactory by the NHS Cancer Programme.	1	5% paid on acceptance of the finalised evaluation strategy by NHS England and NHS Improvement.
Quarterly reports signed off as satisfactory by the NHS Cancer Programme	3	70% split equally over the period from submission of the first quarterly monthly report to submission of final quarterly report.
Final reports signed off as satisfactory by the NHS Cancer Programme.	4	20% paid on acceptance of the final report by NHS England (expected to be 30 November 2022).

4.7 Financial value

The financial value of the contract is anticipated to be up to £[redacted].

5 Appendices

Appendix 1: Cytosponge programme Logic Model
Appendix 2: Cytosponge evaluation subgroup membership
Appendix 3: Approaches to establishing a counterfactual for impact evaluation
Appendix 4: Evaluation data set

Evaluation – Specification of Requirements Appendix 1

Logic Model

Background

Across England, gastroscopy activity from March to September 2020 averaged 46.5% of its usual levels. Patients in the routine referral cohort are currently at risk of waiting a significantly long time for a gastroscopy in secondary care to be available. Cytosponge has been prioritised as an innovative intervention for use in secondary care for patients on routine referral for acid reflux symptoms. This programme aims to alleviate pressure of upper GI endoscopy services by identifying those most at risk for developing cancer and prioritising them on the waiting list.

Evaluation purpose

There is promising evidence from clinical randomised control trials demonstrating the efficacy of Cytosponge as a diagnostic tool for detecting Barrett's Oesophagus in patients, in primary care settings. This evaluation aims to test these findings in secondary care, specifically assessing the impact of implementing Cytosponge as a triaging tool on patient outcomes and endoscopy services. The full evaluation will include a comprehensive assessment of the processes, impacts and economic value of this programme.

Evaluation Questions

The service evaluation aims to address the following questions:
Impact Evaluation
An assessment of how the programme affects the anticipated outcomes (intended and unintended)

1. What impact does Cytosponge have on endoscopy demand (both in the short and long term)?
2. What impact does Cytosponge have on patient outcomes?
3. What impact does Cytosponge have on the diagnostic experience of patients?
4. How does Cytosponge affect patient inequalities, both in access to a diagnosis, and outcomes?

Economic Evaluation
An assessment aimed to identify the value gained from resources required to implement the programme.

1. What is the short- and long-term cost effectiveness of Cytosponge Testing, when used as a triage tool in secondary care?
2. What investment would be required for a national roll out of this programme?

Process Evaluation
An assessment of whether the programme activities have been implemented as intended and resulted in anticipated outputs.

1. What are the barriers and enablers to the implementation of Cytosponge as a triage tool in secondary care?

THEORY OF CHANGE

The Cytosponge Theory of Change has been developed following evaluation scoping work conducted by the Cytosponge Evaluation sub working group, alongside Programme Managers and CADEAS from the NHS England and NHS Improvement Cancer Programme.

This Theory of Change describes the anticipated benefits/unintended consequences following the implementation of the Cytosponge triaging pathway, and how and why this change is expected to happen.

The Theory of Change is illustrated through the Logic Model presented on the next tab. The Logic Model presents the implementation plan for the programme, alongside anticipated outcomes and impacts.

The purpose of this model is to create a common understanding of what success will look like for the programme. It will also provide a preliminary framework against which the outcomes of the Cytosponge programme can be evaluated. The appointed Evaluator is encouraged to use this model as a starting point for their scoping work.

Situation	Patients who have been referred to secondary care with reflux symptoms are currently at risk of waiting longer than usual for a gastroscopy to be available. Cytosponge has been selected by the NHS Cancer Programme because of its potential to prioritise patients and reduce the demand on upper Gastrointestinal Tract (GI) endoscopy services. By offering low-risk but not no-risk eligible patients on the secondary care waiting list a Cytosponge diagnostic test, Cytosponge has the potential to eliminate unnecessary endoscopies and rapidly prioritise patients at risk of BO, maximising the use of scarce resources for endoscopy.
Aims	• Embed a new diagnostic modality for this cohort of patients, including enhancing patient experience and providing guidance to clinicians for managing their treatment; • Enable the prioritisation of patients who are more at risk of serious pathology for rapid access to an upper GI endoscopy; • Reduce the number of unnecessary endoscopies for this cohort of patients; • Support the recovery and restoration of routine services disrupted as a result of the Covid-19 pandemic, at a local and national level; and • Contribute to the NHS Long Term Plan ambitions, in particular to speed up the transition of proven new technologies to business-as-usual in the NHS and to reduce variation in access to innovation across the NHS.

Inputs	Activities	Outputs	Outcomes		Impact
			Short term	**Intermediate - Long term**	
• Dedicated programme team and support from senior project manager, project managers, clinical lead, CADEAS support. • Investment funding • Staffing resources on local sites: Nurses to triage waiting list, nurses to make triaging phone calls, nurses to conduct appointment, nurses to deliver results, and clinicians to conduct follow up endoscopies and determine treatment regimens. Non-clerical staff to collate, store and disseminate data. • Cytosponge tests / equipment • Cyted Lab resource • Cyted lab staffing appropriate trained to Cytosponge test results. • Governance structures to oversee guidance documents and implementation of the programme and quality assure the process. • IT infrastructure to collate, record and disseminate data back to the NHS Cancer Programme. • Cancer Alliance resource for project management, implementation, monitoring, and data support	**Activities to Facilitate Intervention:** • Nurse training to deliver Cytosponge procedure. • Development of Cytosponge Triaging Diagnostic pathway. • Provision of clinical and strategic framework, including quality assurance documentation, the clinical protocol and programme governance. • Provision of patient resources, including patient information leaflet and Consent form **Intervention Activities:** • Project management to oversee the implementation and delivery of the programme, alongside clinical oversight and local governance. • Engagement of healthcare providers in the local system to ensure agreement on the management of adverse events, incidental findings and monthly information reporting. • Identification of eligible participants from waiting list. • Delivery of Cytosponge tests and appropriate follow up of results and treatment as required in line with clinical guidance. • Participation in the evaluation, including data collection, supporting the evaluator in providing necessary information and evidence, including interview participation and the provision of datasets for evaluative purposes.	• Qualified workforce expanded. • Innovative Cytosponge Triaging Pathway embedded within sites. • Routine low-risk symptom eligible patients offered a Cytosponge test and receive appropriate information about the procedure before attending. •Routine low-risk symptom patients attend Cytosponge appointment and receive Cytosponge test. • Patients with a high risk of having Barrett's Oesophagus and Oesophageal cancer receive urgent endoscopy (2 WW pathway) following Cytosponge test. • Patients with no evidence of Barrett's Oesophagus and Oesophageal cancer discharged from the Upper GI Endoscopy waiting list. • Patients with Barrett's Oesophagus and Oesophageal cancer receive appropriate treatment and management of their symptoms.	• Reduced unnecessary endoscopies • Reduced time to diagnosis for patients with cancer and BO • Reduced time to treatment for patients with cancer and BO • Reduced inequalities in access to diagnostic test, due to more acceptable Cytosponge test • Improved patient experience for diagnostic test, e.g. less invasive than endoscopy • Reduced time to diagnostic test for low risk patients • Reduced healthcare staff and resources required to implement test compared with endoscopy **Unintended Consequences:** • Missed cancers (due to Cytosponge sensitivity rates - false negative Cytosponge test) • Missed other diagnoses, including severe reflux requiring surgery (due to negative Cytosponge test)	**Endoscopy services:** • Reduced cost for endoscopy services (staffing and equipment) • Reduction in demand for endoscopy services • Reduction in unnecessary endoscopies **Patient Outcomes:** • Improved patient quality of life (health related quality of life) • Improved time to diagnosis and treatment for BO and cancer **Other (unintended outcomes):** • Culture shift within primary care - could generate more GP referrals for test	**Impact on Endoscopy services:** • Recovery and restoration of routine services from the pandemic at a local and national level **Impact of Cytosponge patient pathway:** • Improved knowledge of resources, cost, training, staffing, ease of use, patient satisfaction involved in Cytosponge pathway to support implementation of Cytosponge diagnostic testing in other settings and for different use cases e.g. as a screening tool in primary care **Impact on implementation of targeted innovations:** • Created an established pathway to test and evaluate prioritised innovations in a real world setting, supporting the ambition from the NHS Long Term Plan: Speed up the path from innovation to business-as-usual, spreading proven new techniques and technologies and reducing variation.

Rationale	Evidence from clinical randomised control trials (RCTs) have demonstrated the efficacy of Cytosponge as a potential targeted screening tool for detecting Barrett's Oesophagus (BO) in primary care settings . The purpose of this commissioned evaluation is to test these findings outside of primary care, specifically assessing the impact of implementing Cytosponge as a triaging diagnostic tool for patients referred to secondary care on a routine referral for an endoscopy. Evidence generated and analysed as part of this evaluation will inform a decision on the future national roll-out for implementing Cytosponge in secondary care.
Assumptions - **Underpinning the programme's Theory of Change are several assumptions about how the proposed activities will lead to the intended outcomes and impacts – which will be tested as part of the evaluation.**	• There is a population of eligible low-risk symptom patients on the endoscopy waiting list • Of the eligible population, most will not hit exclusion criteria • Patients will accept Cytosponge offer, • A sufficient number of patients will attend Cytosponge appointment (limited do not attend patients) • Overall accuracy for Barrett's Oesophagus from a Cytosponge test, sensitivity 80% Specificity 94% • 10-15% repeat test rate, due to low confidence result • Detachment of device from thread occurs in 1 in 4,000 procedures. • A Cytosponge test is more acceptable for patients than endoscopy • Hospitals have resource to triage waiting list, ring patients to organise Cytosponge Appointments, and deliver Cytosponge appointments. • Sites have capacity available for follow-up diagnostic tests, including endoscopies and biopsies for high-risk patients-risk patients • Sites have capacity available for monitoring symptoms and delivering treatment

Appendix 2: Cytosponge evaluation subgroup membership

Cytosponge

Evaluation –
Subgroup membership Appendix 2

[redacted]

Cytosponge

Evaluation – Specification of Requirements Appendix 3

Approaches to establishing a counterfactual

Section 1

Purpose

This paper presents possible options and considerations for identifying a counterfactual to assess the impact and cost-effectiveness of Cytosponge implemented as a diagnostic triage tool for routine referrals in secondary care, as part of a national evaluation.

This is not an exhaustive list of methodologies and issues. It sets out preliminary analytical scoping and some possible approaches. The appointed Evaluator is expected to consider and expand upon this work to establish a robust approach to identifying a counterfactual for this programme.

Background

Cytosponge has been selected by the NHS Cancer Programme because of its potential to prioritise patients and reduce the demand on upper Gastrointestinal Tract (GI) endoscopy services. By offering low-risk eligible patients on the secondary care waiting list a Cytosponge diagnosis test, Cytosponge has the potential to rapidly prioritise patients who are most at risk of serious pathology, whilst minimising the number of upper GI endoscopy procedures required.

The target population for the use of Cytosponge is routine patients referred with reflux symptoms with no alarm symptoms by general practitioners to secondary care on a diagnostic upper GI endoscopy pathway.

Inclusion criteria is as follows:

- Patients with symptoms of reflux including:
    - heartburn (burning sensation on chest usually after eating),
    - regurgitation (an unpleasant sour taste in mouth caused by stomach acid) and;
    - waterbrash (excessive salivation)

The full exclusion criteria list is listed in **Section 2**.

The implementation of Cytosponge in secondary care as a diagnostic triage tool will be monitored and evaluated with the objective of understanding its contribution to:

- the reduction in the demand on upper GI endoscopy services,
- the prioritisation of most at risk patients for an endoscopy service,
- a more cost-effective use of NHS resources,
- supporting the recovery and restoration of routine services from the pandemic at a local and national level, and;
- creating an established pathway to test and evaluate prioritised innovations in a real-world setting, supporting the Long Term Plan ambition to 'speed up the path from innovation to business-as-usual, spreading proven new techniques and technologies and reducing variation' from the NHS Long Term Plan.

Impact evaluation

An impact evaluation is used to evidence how a defined health problem changes after an intervention.

The goals for the Cytosponge programme are to:

- embed a new diagnostic modality for this cohort of patients, including enhancing participant experience and guidance to clinicians for managing their treatment,
- enable the prioritisation of patients who are more at risk of serious pathology for rapid access to an upper GI endoscopy and;
- reduce the number of unnecessary endoscopies for this cohort of patients.

As a new intervention, a full evaluation is required to demonstrate whether these goals have been achieved and by how much. The results of this evaluation must then be interpreted and presented to decision-makers to inform a decision on national roll-out of this programme.

The full impact evaluation for this programme should answer the following high-level impact evaluation questions:

8. What impact does Cytosponge (delivered in secondary care as a routine referral triaging tool) have on endoscopy demand (both in the short and long term)?
9. What impact does Cytosponge have on patient outcomes?
10. What impact does Cytosponge have on the diagnostic experience of patients?
11. How does Cytosponge affect patient inequalities, both in access to a diagnosis, and outcomes?

In response to these questions, the impact evaluation should consider the following themes:

- avoidance of unnecessary endoscopies,
- time to diagnosis for BO and Cancer,
- stage of diagnosis,
- unintended consequences, including missed diagnoses and adverse events,
- patient experience,
- patient engagement,
- adverse effects, and;
- an understanding of the local issues and inequalities

Economic evaluation

An economic evaluation is used to identify and value the cost and health benefits associated with alternative products, to determine how best to allocate resources. As an innovative diagnostic intervention within secondary care, an economic evaluation is required for this programme to:

- evidence whether Cytosponge is a cost-effective use of NHS resources, and
- understand the investment required for a national roll-out.

To speed up the adoption of- and reduce variation in access to- innovative technologies, the NHS Cancer Programme is seeking NICE approval through the Diagnostic Assessment Programme (DAP) for this use case of Cytosponge.

Diagnostic Assessment Programme (DAP)

The NICE DAP evaluates diagnostic technologies, like Cytosponge, that have the potential to improve health outcomes but whose introduction is likely to be associated with an overall increase in cost to the NHS.

Satisfying the evidence requirements of the DAP, the appointed Evaluator is required to conduct a cost-utility analysis to compare the costs and effects of Cytosponge with the 'gold standard' comparator, which is endoscopy.

As recommended by NICE, the cost-utility analysis will take the perspective of the NHS and personal social services.

Considerations

Evaluating the cost-effectiveness of diagnostic interventions is complex. A short summary of key issues that the appointed Evaluator must consider within their application and scoping phase is presented below.

Outcome Uncertainty

The economic assessment of Cytosponge is more complex than assessments of therapeutic interventions, because of uncertainty about the relation between a Cytosponge result and outcomes of care. Outcomes of interest will follow from further tests/measurements and treatments that are either initiated or not initiated based on the Cytosponge result.

This will require a length of study long enough to follow patients receiving a Cytosponge test to their final health outcome. Whilst the evaluation data set aims to collect data on the clinical management of patients, the effects of treatment might not be fully realised during the length of this proposed evaluation.

Test Accuracy

The sensitivity – the proportion of people who have Barrett's Oesophagus (BO) and/or cancer who are correctly diagnosed - and the specificity – the proportion of people who do not have BO and/cancer who are correctly identified as not having the conditions – will also affect the cost-effectiveness of Cytosponge.

The sensitivity and specificity of Cytosponge will not be assessed by comparing Cytosponge results with endoscopy results at the time of testing. It has been deemed out of scope to conduct concurrent Cytosponge and endoscopy tests.

Instead, the appointed Evaluator must consider the feasibility of- and how- assessing sensitivity by following the outcomes of patients who receive a negative Cytosponge test result and assessing specificity by following the outcomes patients who receive a confirmatory endoscopy after receiving a positive Cytosponge result will impact findings.

Missed Diagnoses

The impact of missed diagnosis from other conditions, such as severe reflex, not tested for by Cytosponge must be considered in the model.

Adverse effects

Adverse effects impacting the successful completion of Cytosponge testing much be considered in the economic model. These include:

- the number of follow-up Cytosponge testing following equivocal test results,
- the number of patients who attend a Cytosponge appointment and are unable to swallow, and their follow-up endoscopy testing,
- the number of attempts (sponges) required at each appointment,
- the proportion of patients eligible for testing but who decline a test and;
- the number of adverse events during the test, e.g. sponge detachment from the thread, and follow-up endoscopies required as a result.

Test timing

Disease progression can impact diagnostic testing accuracy. For example, if the disease is more advanced, tests are typically more sensitive. The timing of the diagnosis of a disease can also affect the efficacy of treatment and quality of life.

The target population for this use case of Cytosponge is all patients on the waiting list in secondary care, referred with reflux symptoms with no alarm symptoms. Patients invited for a Cytosponge test across the different sites in this roll-out may have been waiting on the waiting list for different lengths of time. This must be taken into consideration by the appointed Evaluator in the economic evaluation,

Relevant costs

The costs considered in the model should be relevant for the perspective of the economic evaluation: NHS and personal social services (PSS).

It is important that the costs model parallels of the benefits included, so that it includes all costs necessary to obtain the benefits (or harms) resulting from the testing. These include the costs of the test itself (including any retests), and of follow-up testing, treatment, treatment of adverse effects from the test or treatment, and any monitoring needed before or after the treatment.

Requirements

For the Impact and Economic evaluations, the appointed Evaluator will be expected to:

- identify and value the costs and outcomes of interest,
- conceptualise the elements of the health care service relevant for this decision problem,
- determine a suitable counterfactual,
- establish appropriate methods for analysis,
- establish requisite templates and protocols for data collection and analysis for the intervention and comparator sites and;
- report and present findings back to decision-makers.

Proposed methodologies

Definition of the counterfactual

A robust evaluation of the impact outcomes of the Cytosponge programme will require an assessment of what may have occurred in its absence (i.e. a counterfactual). This typically requires the selection of a group of patients or areas that have not benefitted from the intervention to act as a comparator. Specifically, a counterfactual for this programme should reliably evidence what would have happened to this cohort of patients had they not received a Cytosponge testing appointment. To satisfy the evidence requirements for the DAP, the patients in the counterfactual must receive the standard practice alternative, as recommended by NICE, which for this use case would be an endoscopy. Establishing a counterfactual is not straightforward since, by definition, it cannot be observed – it is what would have happened had the Cytosponge programme not been introduced. A strong evaluation is, therefore, one which is successful in isolating the effect of a programme from all other potential influences, thereby producing a good estimate of the counterfactual.

Possible options for establishing a counterfactual are outlined below. The appointed Evaluator may consider these approaches alone, together, or establish a new counterfactual approach. Due to the practical and ethical barriers to conducting a Randomised Controlled Trial, an experimental design (random allocation) has been ruled out by the NHS Cancer Programme.

Quasi- experimental design

Quasi-experimental methods attempt to mimic the conditions of randomisation so that any measured differences can be attributed to the intervention, i.e. the Cytosponge programme. This is typically achieved through statistical matching, i.e. matching groups with similar characteristics and outcomes, or through a comparison of two groups where the outcomes of interest have historically moved in parallel.

Two principal approaches to matching are described below.

Direct patient level matching

What is it?

This approach refers to comparing outcomes at the individual patient level. Participants in the intervention group, i.e. those with the defined symptom profile to be offered a Cytosponge diagnostic test, are matched with similar non-intervention participants to create a counterfactual.

How does it translate in this programme?

This could be achieved in two ways in the Cytosponge programme, by matching patients offered a Cytosponge diagnostic test:

(1) to a group of patients with the same symptom profile who remain on the waiting list at the same hospital site at a concurrent time frame and compare outcomes.
(2) to a group of patients with the same symptom profile at a different hospital site a concurrent time.

What are the considerations?

(1) Same site considerations:

- The size of the Cytosponge pilot will not cover all eligible patients in England to receive a Cytosponge test. Depending on the size of a site's waiting list and the number of Cytosponge tests they have been allocated, some sites may have patients who remain on their waiting list who would be eligible for a Cytosponge test based on the referral criteria but who are not offered a Cytosponge test as part of this programme.
- This method would require the appointed Evaluator to understand the size of the waiting list and eligible patients at each site; and determine an approach to how

sites will offer a Cytosponge to a subgroup of eligible patients, without conducting a Randomised Control Trial.
- Sites have been instructed to triage eligible patients by working backwards on their waiting list, starting with patients waiting longest to receive an endoscopy.

(2) Alternative site considerations:

- Further research should be conducted to determine how many sites to include and how many patients should be part of the counterfactual sample to ensure an adequately statistically powered analysis.
- Further research should be conducted to determine how to match sites, and how to incentivise their participation in collating the required data. One option is to include and provide funding to sites which have expressed interest to participate in the Cytosponge programme but have not been selected to participate in phase 1 or phase 2 of this roll-out. Additional funding from NHS England and NHS Improvement could be made available to support this.
- The outcomes measured in the matched group would be independent of whether those patients would or would not have accepted a Cytosponge has it been offered to them.
- The appointed Evaluator will need to determine the feasibility of collating patient level data to isolate patients with the matched symptom profile to make them eligible for a Cytosponge test in the control sites.

Matched area comparison: Matching project areas compared to comparator areas.

What is it?

Due to challenges in obtaining patient level data from comparator sites, there are a variety of levels of spatial aggregation that could be explored through the evaluation. This approach would require statistical matching to ensure that similar sites are compared.

How does it translate in this programme?

The outcomes in sites with a Cytosponge pathway in place would be compared to outcomes in sites where no Cytosponge pathway exists, with the assumption that any difference in outcomes between sites is due to the Cytosponge programme. The possible site options to be considered for this programme are: Cancer Alliance, CGG, and Trust level.

What are the considerations?

- There are many possible competing factors affecting the endoscopy waiting list across sites. For example, some NHS Hospital Trusts have implemented manual triaging of their waiting lists to prioritise more at-risk patients for an endoscopy. Through aggregation, it would be difficult to isolate any changes to effect as being as a result of this intervention.
- Area level comparisons require that the intervention impacts enough of the area's population to 'impact' area level outcomes. It is not certain that enough sites in each CCG or Cancer Alliance area will be participating to create an impact large enough to be visible at these aggregated levels.
- The appointed Evaluator would be required to undertake power calculations to understand the minimum patient volumes required.

Pre and post design

What is it?

This approach involves taking observations of the outcomes of interest both before and after the implementation of the Cytosponge programme at the same site.

How does it translate in this programme?

This would involve comparing outcomes of interest for patients at the sites before the implementation of Cytosponge and after.

What are the considerations?

- Further research is required to define the 'before' timeframe. Given the impacts of Covid-19 on waiting list size and time to diagnosis over the last year, there is a difficulty in determining pre intervention 'normal' conditions.

Section 2

Exclusion criteria for Cytosponge (absolute contraindications):

- Alarm symptoms:
    - dysphagia
    - dyspepsia and weight loss
    - dyspepsia and anaemia
- Previous cancer of the oesophagus
- Patient with a diagnosis of an oropharyngeal, oesophageal or gastro-oesophageal tumour
- Patient who has had treatment to the oesophagus e.g. photo dynamic therapy, endoscopic mucosal resection, radio frequency ablation, surgery
- Patient known to have oesophageal varices or cirrhosis of the liver
- Patient with a known anomaly of the oesophagus e.g. webbing, pouch, stricture etc.
- Patients who are pregnant (relative contraindication, Cytosponge not harmful but may not be appropriate)
- Patients unable to give consent
- Patients who have had a stroke or any other neurological disorder where their swallowing has been affected
- Patients who have had a myocardial infarction in the last 3 months.

Appendix 4: Evaluation data set

Cytosponge

Evaluation – Specification of Requirements Appendix 4

Evaluation Data Set

Table of Contents

Section 1

Evaluation Data Set

This Evaluation Data Set sets out the full patient level data requirements to satisfy the evaluation questions of this programme. The dataset has been developed through discussions with clinicians, feedback from projects, and through mapping the data items against the logic model, clinical pathway, and evaluation questions. This dataset is made up from items submitted by the projects via the minimum data set and secondary data collated from additional sources to reduce site burden. The appointed Evaluator will be required to review this data set against their own evaluation approach, and work with NHS England and NHS Improvement and Cancer Alliances finalise it. Data items will be collected, stored, and used through data sharing agreements.

This dataset does not include any items pertaining to patient or clinician experience. The appointed Evaluator will be expected to collate this information either through questionnaires and/or interviews in addition.

Minimum Data Set

Monthly collation, monitoring and reporting of data collected by projects. This data will be a subset of the full Evaluation Data Set required to answer the evaluation questions. The minimum data set is patient level data made up from new data collected as part of this programme and data stored within Clinical Systems on sites such as the Radiology Management System.

Secondary Data

Additional data will be taken from other sources to reduce the burden on projects. For example, data from the Secondary User Service (SUS) and ONS Mortality dataset on cancer treatment and patient outcomes can be sourced from NHS Digital. Data on Cancer Diagnosis and staging can be sourced from the Cancer Outcomes and Services Dataset (COSD). It is expected that the appointed Evaluator will identify the Secondary data required and link relevant items with the minimum data set at patient level to form the full Evaluation Data Set.

Identifiers:

Data item	Definition	Format	Response Options From national data source databases dictionaries where appropriate
Participant ID	Pseudonymised NHS Number	Number	
Site ID	Project site code	Text	
Date Consent Obtained		Date (DD/MM/YYYY)	Date
Age	Age at invite	Number	
GP Practice Name	GP Practice at invite	Text	
GP Practice Post code	GP Practice at invite	Text	
Cancer Alliance code*	Cancer Alliance at invite	Text	

**See Section 2*

Patient Demographics:

Data item	Definition	Format	Response Options From national data source databases dictionaries where appropriate
Sex	Sex at birth	Text	Male Female Not Specified Not Known
Ethnicity	The ethnicity of a person, as specified by the person.	Text	White Mixed or multiple ethnic groups Asian or Asian British Black, Black British, Caribbean or African Other Ethnic Groups Prefer not to say

Waiting List Patient Characteristics:

Data item	Definition	Format	Response Options From national data source databases dictionaries where appropriate
Date of referral	Date referred to Secondary Care Endoscopy	Date (DD/MM/YYYY)	Date
Referral type		Text	2 Week Wait (urgent) Routine (non-urgent)

			Direct Access Referral
Symptoms on referral		Text	Dysphagia Weight loss Upper abdominal pain Reflux Upper abdominal mass Haematemesis Treatment-resistant dyspepsia Low haemoglobin levels Raised platelet count Nausea Vomiting Coughing or hoarseness Indigestion or heartburn
Cytosponge eligibility	Does the patient meet Cytosponge Eligibility?	Text	Yes/No
Reasons for exclusion after triaging phone call	Eligible patients may be excluded following triaging phone call because of a change in symptoms, previous endoscopy result, or because of medications they are taking.	Text	Dysphagia Weight Loss Anaemia Unable to swallow tablets Taking excluded Anti-Coagulants Oesophagus webbing Oesophagus pouch Oesophagus stricture Other
Acid Suppressants status	Is the patient taking acid-suppressants?	Text	Yes/No

Invite Outcomes:

Data item	**Definition**	**Format**	**Response Options** From national data source databases dictionaries where appropriate
Phone invite Date		Date (DD/MM/YYYY)	Date
Invitation Outcome		Text	Participant declined invitation Participant accepted invitation
Reasons for decline	Why has the participant declined invitation offer for a Cytosponge appointment?	Text	**Covid-19 related:** • Isolating • Shielding • Concerned about travelling to hospital • Worried about the virus

			• Waiting to be vaccinated **Engagement:** • Not interested in the test / prefer to wait • Does not like the sound of the procedure • Not the gold standard test **Accessibility:** • Did not understand invitation materials • Felt invited by mistake **Other:** • Symptoms resolved • If other, please write in the comment box on the form

Cytosponge Test Procedure:

Data item	**Definition**	**Format**	**Response Options** From national data source databases dictionaries where appropriate
Cytosponge Appointment Date		Date (DD/MM/YYYY)	Date
Cytosponge Appointment Time	The time of day for the procedure	Time (HH:MM)	Time
Cytosponge Test appointment number	Is this a repeat Cytosponge appointment for a patient or their first?	Number	Number
Cytosponge Attendance		Text	Participant attended Cytosponge Participant did not attend Cytosponge Participant attended but did not complete the Cytosponge procedure
Reasons for Non-Attendance	Why was the participant unable to attend Cytosponge appointment?	Text	**Booking:** • Did not know it was booked • Did not know how to cancel

			• Did not receive confirmation **Accessibility:** • Date/time was inconvenient • No support to get to appointment • Too far away • Could not find location • Issues with transport **Engagement:** • No longer interested, would prefer to wait for endoscopy **Covid-19 related:** • Isolating • Shielding • Concerned about travelling to hospital • Worried about the virus • Waiting to be vaccinated **Other:** • Too worried to attend (fear of results) • Other commitments/change of plans/illness • Symptoms resolved • If other, please write in the comment box on the form
Number of attempts of test	Up to 3 attempts to swallow	Number	1 2 3
Adverse events	Significant adverse events which would need to be escalated	Text	Detached sponge Bleeding Inhalation
Nurse band	What pay band is the nurse administering the cytosponge test	Text	Band 6 Band 7 Band 8a Band 8b

Cytosponge Test Results:

Data item	Definition	Format	Response Options From national data source databases dictionaries where appropriate
Date Patient receives Results		Date (DD/MM/YYYY)	Date
Test Result Outcomes	Cytosponge report conclusions		Atypia (definite and including dysplasia) and/or abnormal p53 Atypia of uncertain significance OR Equivocal p53 (but not both) TFF3 inadequate samples. TFF3 negative + normal P53, no atypia TFF3 positive **only** (+normal P53, no atypia) TFF3 Equivocal

Subsequent Outcomes:

Data item	Definition	Format	Response Options From national data source databases dictionaries where appropriate
Repeat Cytosponge Test	Has the patient received a repeat Cytosponge test due to a previous inadequate result?	Text	Yes/No
Repeat Cytosponge appointment date		Date (DD/MM/YYYY)	Date or Not Applicable
Repeat Cytosponge appointment attendance		Text	Participant attended Cytosponge appointment Participant did not attend Cytosponge appointment Participant attended but did not complete the Cytosponge procedure Not applicable (due to no inadequate result found)
Confirmatory Endoscopy	Is a confirmatory Endoscopy required?	Text	Yes/No
Confirmatory Endoscopy Date		Date (DD/MM/YYYY)	Date or Not applicable (due to negative. Cytosponge result)

Confirmatory Endoscopy Attendance		Text	Participant attended Endoscopy. Participant did not attend Endoscopy. Participant attended but did not complete the Endoscopy procedure. Not Applicable (due to negative Cytosponge result).
Re-referral to Secondary care	Was the patient re-referred to secondary care following a negative cytosponge result?	Text	Yes/No or Not Applicable (due to positive Cytosponge result)
Re-referral to Secondary care Date		Date (DD/MM/YYYY)	Date or 9999 for Not Applicable
Date of subsequent Endoscopy	Date of endoscopy after re-referral for patients who received a previous negative cytosponge test result	Date (DD/MM/YYYY)	Date or 9999 for Not Applicable

Diagnostic Outcomes:

Data item	**Definition**	**Format**	**Response Options** From national data source databases dictionaries where appropriate
Abnormality found from subsequent endoscopy	This item captures the false positive rate of the Cytosponge test	Text	Yes/No or Not Applicable
Oesophageal Biopsy	Whether an oesophageal biopsy was taken	Text	Yes/No or Not Applicable
Oesophageal Biopsy date	Date Oesophageal biopsy was completed	Date (DD/MM/YYYY)	Date or 9999 for Not Applicable
Oesophageal Biopsy Result	Oesophageal Biopsy Report (radiology details e.g. includes complications or details of abandoned procedure)	Text	
Stomach Biopsy	Whether a stomach biopsy was taken	Text	Yes/No or Not Applicable

Stomach Biopsy date	Date stomach biopsy was completed	Date (DD/MM/YYYY)	Date or 9999 for Not Applicable
Stomach Biopsy Result	Stomach Biopsy Report, specifically, was Gastric Intestinal Metaplasia present?	Text	
Barrett Oesophagus Diagnosis	Confirmed presence of Barrett's Oesophagus	Text	Yes/No or Not Applicable
Dysplasia	Confirmed presence of dysplasia with Barrett's Oesophagus		Yes/No or Not Applicable
Dysplasia grade		Text	Negative Indefinite for dysplasia Low-grade dysplasia High-grade dysplasia Intramucosal adenocarcinoma
Prague Classification Circumferential length	Measurement	Text	
Prague Classification Maximal Length	Measurement	Text	
Barrett's Oesophagus Diagnosis Date		Date (DD/MM/YYYY)	Date or 9999 for Not Applicable
Gastric Intestinal metaplasia		Text	Yes/No or Not Applicable
Oesophageal cancer Diagnosis	Based on secondary care record - documented final cancer diagnosis (including histopathologic ally confirmed subtype e.g. adenocarcinoma vs squamous cell carcinoma where available/relevant).	Text	Yes/No or Not Applicable
Oesophageal cancer Diagnosis Stage		Text	Stage I Stage II Stage III Stage IV
Oesophageal cancer		Date (DD/MM/YYYY)	Date or 9999 for Not Applicable

Diagnosis Date			
Other Cancer Diagnosis	Other cancer diagnoses made following endoscopy or subsequent investigation (maybe in addition Barrett's Oesophagus)	Text	
Other Cancer Diagnosis Stage		Text	Stage I Stage II Stage III Stage IV
Other Diagnosis	Other non-cancer diagnoses made following endoscopy or subsequent investigation (maybe in addition to cancer or Barrett's Oesophagus)	Text	

Treatment / Monitoring Outcomes:

Data item	**Definition**	**Format**	**Response Options** From national data source databases dictionaries where appropriate
Treatment route		Text	
Treatment Start Date		Date (DD/MM/YYYY)	Date or 9999 for Not Applicable
Death within 30 days of any procedure		Text	Yes/No or Not Applicale
Date of death	From death certificate	Date (DD/MM/YYYY)	Date or 9999 for Not Applicable
Primary Cause of death	From death certificate	Date (DD/MM/YYYY)	Date or 9999 for Not Applicable

Section 2

Cancer Alliance Code	
E56000005	Cheshire and Merseyside
E56000022	East of England – North
E56000023	East of England – South
E56000024	East Midlands
E56000019	Greater Manchester
E56000004	Humber, Coast and Vale
E56000011	Kent and Medway
E56000018	Lancashire and South Cumbria
E56000017	North East and Cumbria (Northern)
E56000028	North East London
E56000021	North West and South West London (RM Partners)
E56000014	Peninsula
E56000015	Somerset, Wiltshire, Avon and Gloucestershire (SWAG)
E56000010	South East London
E56000025	South Yorkshire and Bassetlaw
E56000013	Thames Valley
E56000016	Wessex
E56000007	West Midlands
E56000003	West Yorkshire and Harrogate

Schedule 6

Commercial Schedule

NHS Total Cost

Service	Price: Breakdown of costs (Total per activity)				
	B - People Costs	C - Software and Info Systems	D - Travel and subsistence	E - Sub - Contract	Totals
Mobilisation, and ongoing project management	[redacted]				[redacted]
Evaluation Strategy Report					
Data collection, QA, linkage of patient quantitative level data		[redacted]			
Qualitative research, including survey design and administration, interviews and focus groups					
Process evaluation analysis and QA					
Impact evaluation analysis and QA					
Economic evaluation analysis and QA					
Monthly management information reporting		[redacted]			
Quarterly reporting					
Final summative evaluation report					
Total Cost	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

The total score submitted in red will be used to evaluate the tenders as the total cost of the service.

People Costs

Job Title/Role	(£) Day Rate for this Project	(Days) Number of days working for this Project	(£) Total Cost
Programme Manager	[redacted]	25.0	[redacted]
Project Manager		45.0	
Analyst		48.0	
Consultant		380.0	
Senior Consultant		55.0	
Director		6.0	
Principle		12.0	
[Insert any additional roles]			
[Insert any additional roles]			
[Insert any additional roles]			
[Insert any additional roles]			
[Insert any additional roles]			
[Insert any additional roles]			
Total Cost	[redacted]	**571.00**	[redacted]

Software and information systems

Items covered	(£) Value
Software - Data Collection assumes 40 sites	[redacted]
Software - Dashboard licenses (150)	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
Total Cost	[redacted]

Travel and subsistence

Items covered	(£) Value
Travel	[redacted]
Subsistence	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
[Insert any other additional items]	
Total Cost	£[redacted]