Commercial Procurement Services

NHS
Countess of Chester Hospital
NHS Foundation Trust

SCHEDULE A

FRAMEWORK AGREEMENT SPECIFICATION

PROVISION OF CAPSULE ENDOSCOPY MANAGED SERVICES

F067/CEMS/22/PJ

SCHEDULE A. FRAMEWORK AGREEMENT SPECIFICATION

PROVISION OF CAPSULE ENDOSCOPY MANAGED SERVICES ("the Services")

1. Overview

1.1 Suppliers appointed to the Framework agreement will:

1.1.1 Deliver capsule endoscopy Service, reading and reporting services to Patients as referred by NHS Organisations.

1.1.2 Provide high quality support to NHS Organisations that can be called upon at relatively short notice.

1.1.3 Provide medical, nursing or other staff as a part of the Services to perform delivery, reading and reporting services.

1.1.4 Have an excellent record of safe performance.

1.1.5 Have an excellent record of effectiveness in the delivery of capsule endoscopy services.

1.1.6 Establish a positive working relationship between NHS Organisations who use the Framework Agreement and the Supplier to facilitate and maximise service delivery, the emphasis being on timely, quality, cost effective, evidence-based care, with appropriate clinical protocols and audit where possible.

1.2 The Services can be Fully/Part managed by the Supplier and will follow a structured approach.

1.3 The Services will include any or all of the following components:

- Informing the Patient, setting the appointment and managing consent. N.B. Responsibility for obtaining patient consent for the use of capsule endoscopy will be retained at all times by the contracting NHS Organisation.
- Assessing the Patient's ability to be well prepared.
- Patient preparation including providing the Patient with preparation medication and guidelines.
- Meeting the patient in their community (home, primary care centre, other health service centre).
- Re-assessing the ability to conduct a successful procedure
- Supporting the patient in the correct placement of monitoring equipment.
- Supporting the Patient with capsule ingestion and dealing with potential adverse events.

- Assisting the Patient remotely when needed during the procedure.
- Collecting returned monitoring equipment from the Patient and managing reusable equipment.
- Timely, secure and efficient uploading of Patient images in DICOM format.
- Analysis of de-identified Patient images.
- Validation of findings.
- Creation of a comprehensive report of the findings to be transmitted electronically in a timely, secure, and efficient manner to the referring consultant.
- Transmitting data directly to NHS PACS and/or Electronic Patient Record systems in a timely secure and efficient manner
- Secure IT systems that enable the Services to seamlessly refer a patient to a video capsule endoscopy and receive the report the same way as any other endoscopy report. This will include scheduling of follow-ups as well as integration into patient records and other elements of NHS IT infrastructure

1.4 The Supplier must be able to deliver the entirety of the Services as an end-to-end managed service. Contracts called off from the Framework Agreement may include some or all of the components identified above.

2. Service Delivery

2.1 The Supplier will provide, for each instance where they are contracted to provide the Services:

2.1.1 a detailed service implementation and mobilisation plan in collaboration with the Contracting Authority which will include interfaces and transfer points to ensure a seamless Patient experience. The Supplier's service implementation must follow a defined and documented project methodology (for example PRINCE2). Details of this project methodology will be made available to NHS Organisations on request;

2.1.2 Fully qualified and trained Nursing Practitioners capable of informing, assessing, assisting and supporting Patients.

2.1.2.1 Any Nursing Practitioners involved in in person pre-reading activities must:

- be registered with the Nursing and Midwifery Council
- hold a current re-validation certificate
- be appropriately trained in the provision of capsule endoscopy
- be appropriately trained in Patient confidentiality requirements prior to employment and must exercise Patient confidentiality requirements at all times.

Evidence of Nursing Practitioner relevant qualifications and experience will be provided on request to NHS Organisations.

2.1.3 Fully qualified and trained Medical Practitioners, capable of reading and reporting capsule endoscopy. Potential Suppliers must be able to demonstrate experience and capability of sourcing and contracting qualified and trained Medical and Nursing

Practitioners, as above, to deliver large scale services for public or private health bodies.

2.1.3.1 Any Medical Practitioners reading capsule endoscopy images must

- be GMC registered,
- hold a Certificate of Completion of Specialist Training (CCST) in general medicine or general surgery,
- take part in regular medical appraisal,
- have appropriate training in reading and reporting capsule endoscopy
- be appropriately trained in Patient confidentiality requirements prior to employment and must exercise Patient confidentiality requirements at all times.

Evidence of Medical Practitioner qualifications and experience will be provided on request to NHS Organisations.

2.1.3.2 Any reading or element of a reading process undertaken using non-human methods (e.g. using artificial intelligence or machine learning systems) must follow all appropriate and current guidelines pertaining in the relevant jurisdiction and may only be undertaken to the extent explicitly agreed by a Contracting Authority.

2.1.4 A complete capsule endoscopy system including endoscopy capsule, sensors and data recorder.

2.1.4.1 If supplied by the Supplier, all equipment used for capsule endoscopy must be maintained to the standards determined by the manufacturer of the equipment.

2.1.4.2 If supplied by the Supplier, all equipment used for capsule endoscopy must be running the latest version of any software released by the manufacturer. The Supplier is responsible for ensuring that software updates are implemented promptly on release by the manufacturer.

2.1.4.3 If supplied by the Supplier, all capsules used for capsule endoscopy must be single-use and matched to the sensors and data recorder.

2.1.5 If supplied by the Supplier any other equipment or consumables required for the Services, including but not limited to patency testing capsules.

Any products supplied by the Supplier and used for the delivery of the Services under the Framework Agreement must be CE/UKCA certified under the relevant directive

2.1.6 a detailed exit plan in collaboration with the Contracting Authority for the end of each Contract called off from the Framework Agreement.

2.2 Before treating any cohort of Patients, the Supplier must verify with the Contracting Authority that the Supplier has a list of all patients that are to be treated. The list should contain, patient name, Hospital ID, treatment time slot, treatment area on patient and any other relevant information agreed between the Contracting Authority and the Supplier for the performance of the Service.

2.3 For each instance where they are contracted to provide the Services the Supplier must:

- engage effectively with patients, recognising that the patient profile will include a broad spectrum of ages, digital competence and also concern on the treatment that is to be undergone, tailoring the approach to maximise patient engagement;
- prepare and support the broad spectrum of patients in a way that will ensure optimum results from the treatment;
- ensure that each patient is verified on arrival against a checklist provided by the Participating Authority. As a minimum the Patient name, date of birth and address will be verified;
- follow its Patient Identification Policy at all times;
- uphold Patient confidentiality;
- undertake further verifications before proceeding with any examination/treatments (including administration of any preparation medicines or imaging capsules) This should include as a minimum;
    - revalidation of key verification details: Name, Address; Date of Birth
    - verification correct examination is being performed
    - correct area is being scanned
    - any other validation process as deemed necessary prior to the examination / treatment

  The Supplier must have a policy for verification prior to treatment of a minor who is unable to confirm ID details

- have a process to ensure immediate reporting of capsule retention to the appropriate person within the Contracting Authority;
- if an error has been made, inform the patient and the Contracting Authority, and establish (if treatment has already taken place) any consequences and corrective actions that may be needed, carrying out any actions ordered by the Contracting Authority

- collect all sensors and data recorders from Patients after treatment.
- ensure the safe and effective decontamination of all reusable items of capsule endoscopy equipment before its next use.
- ensure all images produced from the procedures are interpreted correctly with a high assurance of accuracy and verified through rigorous process controls;
- provide comprehensive validated reports to the Patient's responsible clinician (usually a Consultant) within the timescale specified by the Contracting Authority;
- resolve any reporting discrepancies (where the report does not agree with local clinical assessment of the images) within the timescale specified by the Contracting Authority
- participate with the Contracting Authority in audits and feedback on reporting data;
- work closely with the Contracting Authority and integrate in an adaptive and responsive way with the Contracting Authority's clinical and management teams.

3 Data Management

3.1 The Supplier must be registered with the Information Commissioner's Office as a Data Processer and maintain registration throughout the life of the Framework Agreement and the period of all Contracts called off from the Framework Agreement. Details of this registration will be made available to NHS Organisations on request. Registration as a Data Controller may be required for individual contracts. The status of the Supplier as Data Processer or Data Controller will be determined for each Call Off Contract and described in the Call Off Contract.

3.2 The Supplier must be able to demonstrate at any time to the satisfaction of the Contracting Authority experience of handling sensitive patient data and compliance to all relevant regulations.

3.2 Patient records will remain the responsibility of the NHS Organisation. The Supplier shall obtain no proprietary interest in any Patient data and shall ensure the return of any material detailing or recording such Patient data to the NHS Organisation on demand.

3.3 The Supplier must maintain the DPST "Standards Met" or "Standards exceeded" level for the appropriate organisation type by completing the Data Security and Protection Toolkit assessment.

3.4 Where required for the delivery of a call off contract, the supplier must hold and maintain a current HSCN Connection Agreement

3.5 Data transmission must comply with all applicable HL7 Standards

3.6 As part of each call off the supplier will support each organisation to develop a Data Protection Impact Assessment,

3.7 Any data processing carried out by the supplier including the use of participating authority data for training purposes must be strictly in accordance with the participating authority's Data Sharing protocol. For the avoidance of doubt training includes the use of images to train Artificial Intelligence and/or Machine learning systems

3.8 Where the Supplier needs physical access to Patient case notes to perform its duties under the terms of the Service, the Supplier will ensure that all such notes are transferred to the Supplier in a secure manner securely and kept securely at the Supplier premises.

3.9 The Supplier must operate a defined and documented software quality accreditation process to a level at least equivalent to that of IS EN ISO 9001:2008 (or an equivalent recognised standard). Details of this software quality accreditation process will be made available to NHS Organisations on request.

3.10 The Supplier must operate a defined and documented information system security management system to a level at least equivalent to that of IS EN ISO 27001:2013 (or an equivalent recognised standard). Details of this information system security management system will be made available to NHS Organisations on request.

3.11 The Supplier must hold (or commit to obtain, prior to commencement of the Framework Agreement if awarded) Cyber Security Essentials accreditation. Details of this accreditation will be made available to NHS Organisations on request.

4 Clinical Governance

4.1 The Supplier shall take all reasonable care to engage or employ in and about the provision of the Services only such Medical and Nursing Practitioners as are carefully skilled and experienced in their profession and calling. The Supplier will be responsible for ensuring that all Medical and Nursing Practitioners are competent to perform all duties that are required of their role.

4.12 The Supplier will be responsible for ensuring that all of their Medical and Nursing Practitioners are fully trained on any equipment supplied to perform the Services. The Supplier will provide evidence of training on request to NHS Organisations.

4.3 The Supplier will be responsible for ensuring access to relevant training and Continuous Professional Development (CPD) for their Medical and Nursing Practitioners.

4.4 The Supplier will ensure that all Medical and Nursing Practitioners engaged to undertake any of the Services in-person fulfil all statutory requirements of employment including but not limited to the right to work in the UK.

4.5 The Supplier will commit to notifying the NHS Organisation of any relevant staff changes as soon as they become aware of this.

4.6 All persons employed by or subcontracted by the Supplier who may come into contact with Patients during the course of their duties must hold a current enhanced Disclosure and Barring Service (DBS) certificate or Disclosure Scotland Protection of Vulnerable Groups (PVG) certificate, as appropriate, valid for the work that is the subject of any Call Off Contract.

4.7 All DBS or PVG checks undertaken must have been completed to include all information pertaining to children and vulnerable adults and will cover induction, all mandatory training, occupational health checks, and all appropriate General Medical Council (GMC), Health and Care Professions Council (HCPC) and/or Nursing and Midwifery Council (NMC) checks

4.8 The Supplier must ensure that the NHS Organisation is informed directly should convictions be received regarding them or their employees or subcontractors after the date of the DBS or PVG check. Appropriate action will be taken if necessary. In the event that any person in any of the groups referred to previously are substantively employed by the NHS Organisation concerned, that organisation will continue to retain full responsibility for this for those employees. The Awarding Authority will also be informed to allow relevant and permitted information to be passed to other NHS Organisations to promote safeguarding.

4.9 The Supplier must ensure that the NHS Organisation is informed directly of any relevant suspension from service proceedings conducted by the GMC, HCPC and/or NMC or disciplinary matters concerning their employees or subcontractors.

4.10 If the Supplier carries out Regulated Activities as described in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (and as amended) and none of the permitted exemptions apply then the Supplier must hold, and maintain for the duration of the period in which the Regulated Activities are carried out, appropriate registration with the Care Quality Commission (for Regulated Activities in carried out in England), Healthcare Inspectorate Wales (for Regulated Activities in carried out in Wales), Healthcare Improvement Scotland (for Regulated Activities in carried out in Scotland) or The Regulation and Quality Improvement Authority (for Regulated Activities in carried out in Northern Ireland), or with any successor to any of these organisations, as appropriate.

Information about registration with the Care Quality Commission can be found here

Information about registration with Healthcare Inspectorate Wales can be found here https://hiw.org.uk/

Information about registration with Healthcare Improvement Scotland can be found here https://www.healthcareimprovementscotland.org/

Information about registration with The Regulation and Quality Improvement Authority can be found here https://www.rqia.org.uk/

4.11 The Supplier must not through its actions or inactions jeopardise the NHS Organisation's compliance with Care Quality Commission (or equivalent organisations

in Scotland, Wales and Northern Ireland, where applicable) standards, and with those of any future regulatory bodies as appropriate throughout the life of the Framework Agreement and during any Contract whose performance concludes outside the period of the Framework Agreement. The Supplier will use best endeavours to ensure that the actions or inactions of its staff do not jeopardise the compliance referred to in this clause 4.11.

5 Corporate Governance

5.1 The Supplier must have robust, auditable management and corporate governance procedures including clear responsibilities for all staff and appropriate employment policies and procedures, insurances and indemnities and, where relevant, clear written agreements with sub-contractors. The Supplier will provide details of their policies and procedures for corporate governance to any requesting NHS Organisations and will notify the NHS Organisations that have entered into a Call Off Contract of any changes in these.

5.2 The Supplier will be responsible for ensuring that all applicable clinical negligence insurances are in place prior to the performance of any Service under a Contract called off under the Framework Agreement.

5.3 The Supplier must ensure that it retains all appropriate public liability, professional liability and employer liability insurance at all times throughout the life of the Framework Agreement and during any treatments whose performance concludes outside the period of the Framework Agreement.

5.4 The Supplier shall produce to the Awarding Authority or to any NHS Organisation on request documentary evidence that the insurance required is properly maintained.

5.5 Where the Supplier employees or subcontractors deployed under a Call Off Contract are responsible for procuring and maintaining their own professional indemnity insurance cover, the Supplier shall procure that any such employees or subcontractors maintains such cover in an amount adequate to cover potential liabilities for the minimum insurance period specified in a Call Off Contract and exhibits details of the relevant policy with confirmation from the insurers if required that the professional responsibilities performed in connection with the provision of Services are covered by such insurance.

5.6 Any Patient enquiries to the Supplier will be dealt with in an appropriate and timely manner.

5.7 The Supplier will maintain a complaints procedure in line with applicable law and provide as and when necessary details of such a procedure to the Awarding Authority or to any NHS Organisation.

5.8 The Supplier shall inform the Awarding Authority of any complaints made by any NHS Organisation and supply copies of all correspondence to the Awarding Authority which relates to complaints or the handling of them.

5.9 In the event that complaints regarding the Services are made by Patients to an NHS Organisation, the NHS Organisation will forthwith inform the Supplier and supply relevant correspondence.

5.10 The Supplier will co-operate as required with any statutory and regulatory bodies in relation to the complaints procedure and with any independent investigation of complaints. Accordingly, the Supplier will:

5.10.1 Appoint a complaints manager or individual with complaints remit

5.10.2 Provide the Awarding Authority and any NHS Organisation with relevant details of the complaints manager

5.11 The Supplier will undertake to provide information to the NHS Organisation to support the NHS Organisation's adherence to national or local frameworks for performance reporting.

5.12 The collection of data to assess Patient Reported Outcome Measures will remain the responsibility of the NHS Organisation. The Supplier will provide assistance to the NHS Organisation where the Supplier can help in gathering additional information

5.13 The NHS Organisation shall on reasonable notice in writing be entitled to request additional information from the Supplier covering the provision of the Services if such information is reasonably required by the NHS Organisation and to comply with any written requests under the Freedom of Information Act 2000 (as amended) or under the Freedom of Information (Scotland) Act 2002 (as amended) or under the Environmental Information Regulations 2004 (as amended) or under the Environmental Information Regulations (Scotland) 2004 (as amended).

5.14 The Supplier must commit to comply with any NHS Organisation's policies and procedures appropriate to the performance of the Services, including but not restricted to clinical governance policies and risk management strategies. NHS Organisations will provide these to the Supplier as necessary or upon written request

5.15 The Supplier must operate a defined quality assurance system for the management of its service delivery which will ensure:

5.15.1 effective and efficient service delivery at all times.

5.15.2 Adherence to the NHS Organisation's policies and procedures appropriate to the performance of the Services

5.15.3 Effective measures of infection prevention and control are used including, where relevant, decontamination and/or sterilisation of medical equipment;

5.15.4 All requirements relating to health and safety in the workplace are satisfied;

5.15.5 Professionals are appropriately trained and competent to perform duties required of their role

Details of this quality assurance system will be made available to NHS Organisations on request.

5.16 The Supplier will implement specific audit arrangements and submit evaluation of audits to the Awarding Authority or to any NHS Organisation on request.

5.16.1 Topics for audit will be agreed between the NHS Organisation and the Supplier and will be detailed in tailored agendas for review meetings. The Supplier will ensure attendance at such meetings by an appropriately senior office of the Supplier who will be named within the Call Off Contract

5.17 The Supplier will have access to the NHS Organisation's full range of clinical and non-clinical risk assessments, including written policies on business continuity, and will use them as agreed with the NHS Organisation for each Call Off Contract.

5.18 The Supplier must have a robust system in place for reporting patient safety incidents and reviewing of this data at appropriate levels. Details of this system will be made available to NHS Organisations on request.

5.19 The Supplier will assist the NHS Organisation with any investigation and management of Serious Untoward Incidents and complaints relating to the Service in line with the NHS Organisation's complaints and incident reporting procedures.

5.20 Where applicable and to the extent defined in each of the following points in this clause 5.20, the Supplier must comply with the following:

- Data Protection Act 2018
- Caldicott Guidelines 1997
- The relevant requirements of the Access to Health Records Act 1990
- Freedom of Information Act 2000
- Access to Medical Reports Act 1988
- Confidentiality Code of Practice 1998
- The relevant requirements of the Care Standards Act 2000
- Any other relevant statutory requirements.
- Any amendments to the above.
- Any equivalents to the above that are applicable to Scotland, Wales or Northern Ireland

6 Social Value

The principal aim of procurement undertaken by NHS organisations is to deliver essential goods and services and improve patient outcomes, while increasing value from every pound spent in the NHS. NHS procurement also has an essential role to play in the delivery of the NHS commitment to reach net zero by 2045, as more than 60% of NHS carbon emissions occur in the supply chain. Social value, when incorporated effectively, will help reduce health inequalities, drive better environmental performance, and deliver even more value from procured products and services. Classification: Official Publication approval reference: PAR1030 1 | Applying net zero and social value in the procurement of NHS goods and services

Adopting central government's Social Value Model complements strategic initiatives and policy within the NHS, including the 2019 NHS Long Term Plan, and our commitments within the 2020 Delivering a 'Net Zero' National Health Service report. Its adoption will be supported by a new Sustainable Supplier Assessment available in 2022, and a suite of supplier expectations and requirements from 2023 to 2030, ensuring that all suppliers meet or exceed the NHS commitment to be net zero by 2045. These requirements build on the Government's 'Taking Account of Carbon Reduction Plan' (PPN 06/21) and are outlined in the recently published NHS Net Zero Supplier Roadmap.

Countess of Chester Hospital Commercial Procurement Services has selected the Social Value Model themes of "Fighting Climate Change" and "COVID-19 recovery" for this framework.

6.1 The Supplier will continually develop and redesign its services to reduce its environmental impact throughout the duration of the Framework Agreement and of any Contracts called off from the Framework Agreement..

6.2 The Supplier will continually develop its services to provide new ways of working for NHS organisations with an emphasis on increasing support for NHS organisation to reduce covid-19 related patient waiting times.

6.3 The Supplier will participate if required in a Sustainable Supplier Assessment process and will be expected to meet all relevant 'Net Zero' supplier expectations and requirements introduced during the period of the Framework Agreement and of any Contracts called off from the Framework Agreement.