Medicines & Healthcare products Regulatory Agency

Procurement Call for Competition

Invitation to Tender (ITT)

(Issued by The Secretary of State for Health and Social Care, acting through the Medicines and Healthcare products Regulatory Agency, acting as part of Crown)

Project Reference: C327833

Title: Support for Delivering Safety Communications for MHRA

Tender Submission Deadline: 11/02/2025 Midday/12:00

CONTENTS

1. BACKGROUND AND OBJECTIVES

1.1 The Medicines and Healthcare products Regulatory Agency (hereafter referred to as the Buyer or the MHRA) is the regulator of medicines, medical devices and blood components for transfusion in the UK, and is responsible for ensuring these products meet safety, quality and effectiveness standards. We put patients first in everything we do, right across the lifecycle of the products we regulate.

1.2 To fulfil our remit in regards to patient safety, we use a range of risk and safety communications to ensure the safe and effective use of medicines and medical devices, and to provide details of product recalls and other alerts and notices. The MHRA uses various approaches to communicate to the public, to patients, to Healthcare Professionals (HCPs) and to the health and care system (see section 5 below for further details).

1.3 On 17 September 2024, the MHRA launched the MHRA Strategy for Improving Safety Communications - GOV.UK. The aim of this three-year strategy is to deliver to HCPs and patients more co-ordinated, targeted, and impactful safety communications, when they need it, using the best possible communication channels. Effective communication is essential for patients to be informed of the benefits and risks of medical products, to assist HCPs in best protecting their patients, and to maintain confidence in medicines, medical devices and healthcare products, the broader health and care system and the MHRA.

1.4 The ambition for our safety communications is that:

- our trusted advice reaches those who need it, in a timely fashion to keep patients safe.
- every HCP is able to understand how the latest information from the MHRA affects their patients and their care.
- patients and caregivers have accessible, easily understandable information to inform their decisions on medical products.
- the UK public recognise MHRA as a respected and trusted voice for the latest safety information related to medical products used in the UK.
- our approach to risk and safety communications continues to be informed by the needs of providers, HCPs and patients, and for everything we do to be evaluated with defined routes for feedback and opportunities for further improvement.

1.5 We seek continuous improvement and are focussed to deliver effective, consistent, and engaging risk and safety communications to those who need it, when they need it, and in an accessible format that meets their needs. It is underpinned by the first strategic priority of the MHRA's Corporate Plan 2023-26, 'to maintain public trust through transparency and proactive communication'.

1.6 The recently launched strategy followed input from a 16-week consultation concluded in early 2023. The consultation sought information on the effectiveness

of the current risk and safety communications and how these could be improved. The open consultation period was followed up with some interviews and focus groups and the submission of some written responses to garner feedback. We had participation across the four UK nations and from primary care, secondary care, community care, NHS patient safety groups, and experts in patients' safety and quality improvement.

1.7 Over 800 healthcare professionals (HCPs) provided us with actionable information and insights on how current risk and safety communications were received and/or utilised, as well as views on how we can improve to further support the provision of timely and impactful advice.

1.8 The consultation responses were collated and can be reviewed at: Consultation on how MHRA communicate with healthcare professionals to improve medicines and medical devices' safety - GOV.UK.

1.9 The objective of this Procurement Call for Competition is to award one Contract to support delivery of the MHRA's communications to healthcare professionals/HCPs, and facilitate improved safety communications including optimising engagement rates and reach. The MHRA seeks the appointment of a Supplier who has experience of and expertise in (Technical and Professional ability):

- issuing broad email campaigns to a large audience including but not limited to NHS email addresses.

  Please note, the Supplier would need to own or have access to the email addresses/contacts for a range of HCPs (may be via their administrative staff or organisation representatives) as the MHRA cannot provide any contact/subscription details.

- maintaining contact details to ensure up-to-date, and seeking to expand the contacts database.

- formatting and dispatching communications/emails (including ability to deal with NHS firewall/security challenges).

While patients and the public are an important audience, our focus for this Procurement Call for Competition is on HCPs, who would inform patients about the benefits, risks, and instructions for use.

Full details of our Requirements can be found in section 5 below.

2. BACKGROUND TO THE BUYER

2.1 The Medicines Healthcare products Regulatory Agency (MHRA) is the regulator of medicines, medical devices and blood components for transfusion in the UK, and is responsible for:

- ensuring that medicines, medical devices and blood components for transfusion meet standards of safety, quality and efficacy (effectiveness);

- ensuring safe supply chains for medicines, medical devices and blood components;
- promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines;
- helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use;
- supporting innovation and research and development that is beneficial to public health; and
- working collaboratively with partners in the UK and internationally to support our mission to enable the earliest access to safe medicines and medical devices and to protect public health.

2.2 We act on behalf of the Secretary of State for Health and Social Care, under UK legislation, to regulate medicines, medical devices and blood products for transfusion. In this role, we balance public health expertise, operational delivery, scientific integrity, independence in regulatory decision-making and appropriate ministerial oversight and accountability to command public confidence.

2.3 Further information on the MHRA can be found at: www.gov.uk/mhra.

2.4 We put patients first in everything we do, right across the lifecycle of the products we regulate, from supporting early-stage development to ensuring the safety of products throughout their time on the market.

2.5 Our well-established products and services are offered at every step of the product lifecycle, to help the life sciences sector meet the highest standards, many of which drive income. Some have been outlined as follows:

- The British Pharmacopoeia provides written and chemical quality standards for UK pharmaceutical substances and medicinal products. pharmacopoeia.com
- Clinical Practice Research Datalink (CPRD) data services provide the life sciences sector with anonymised primary care (NHS) datasets that can be linked to other datasets. cprd.com
- National Institute for Biological Standards and Control (NIBSC) standards are available globally to set the quality of biological medicines. We also offer NIBSC contract and control testing services. nibsc.org
- The UK Stem Cell Bank offers quality-controlled stem cell lines to support scientific research and clinical development of stem cell therapies. nibsc.org/ukstemcellbank
- The Yellow Card scheme is how patients, the public and healthcare professionals report problems with healthcare products. yellowcard.mhra.gov.uk

3. DEFINITIONS

Term (pronouns may not be capitalised)	Definition
'We', 'Us', 'Our', 'the Buyer' and/or 'the MHRA' [terms used interchangeably	means the Medicines and Healthcare products Regulatory Agency, who is running this Procurement Call for Competition and requires the Contract and the Services. Please note the formal Contracting Authority is: The Secretary of State for Health and Social Care, acting through the Medicines and Healthcare products Regulatory Agency, acting as part of Crown.
'You', Your', and/or the 'Supplier' [terms used interchangeably]	means either the tendering or the appointed organisation (depending on the context). The term 'Potential Suppliers/Tenderers' and/or 'Tenderers' may also be used for the company bidding in this Procurement Call for Competition.
'Charges'	means the prices/fees, payable to the Supplier by the Buyer under the Contract, for the Services provided.
'Contract Period'	means the term of up to three years (Initial Term), with provision for optional extension(s) up to a maximum period of six years, and subject to earlier termination in accordance with the Contract.
'Invitation to Tender document' Also referred to as the 'ITT'.	means this document providing details for the Procurement Call for Competition e.g. the Statement of Requirements (attached in the Bid Pack in the Documents folder).
'Contract'	means the binding agreement between the contracting parties (the Buyer and the Supplier), awarded pursuant to this Procurement Call for Competition and subject to the relevant Contract Terms and Conditions.
'Party' or 'Parties'	means either the Buyer or the Supplier, or both.
'Procurement Call for Competition'	means the procurement process – an open competition above threshold.
'Requirements' and/or 'Services'	means the subject of this Procurement Call for Competition, which might be ordered under the Contract.

[terms used interchangeably]	
'Supplier Staff'	means the Supplier's personnel and any subcontractors' personnel. Some of the essential personnel will be defined as Key Staff e.g. the Contract/Account Manager, and all reasonable endeavours should be made to ensure continuity for Key Staff roles throughout the Contract Period.
'Tender', 'Tender Proposal' and/or 'Offer' [terms used interchangeably]	means the response/offer (technical, social value and commercial responses etc) submitted in response to this Procurement Call for Competition and potential Contract, available for acceptance. The successful Supplier's Tender/Solution will be included in the Contract.

4. CONTRACT PERIOD AND TERMS AND CONDITIONS

4.1 The Contract Period shall commence in early March 2025, with an implementation/kick-off meeting to make introductions and agree expectations and the communication process; with the first email/Services starting late March 2025 if possible. The Contract shall run for a period of three years (Initial Term) with provision for optional extension(s) up to a maximum period of six years (subject to earlier termination). The Buyer shall have the right to terminate the Contract at any time without reason or liability by giving the Supplier not less than 90 days' written notice.

4.2 The Procurement Timetable for this Procurement Call for Competition is appended at Annex A.

4.3 There shall be no commitment to commission Services nor guarantee of a minimum or any volume of work; nor any exclusivity with the appointed Supplier.

4.4 This Procurement Call for Competition is being issued by the Contracting Authority (the Secretary of State for Health and Social Care, acting through the Medicines and Healthcare products Regulatory Agency, acting as part of Crown), and is being run as an open competition.

4.5 The government's Mid-Tier Contract Terms and Conditions shall govern the ensuing Contract (template link at The Mid-Tier Contract - GOV.UK).

4.6 The Buyer shall only award a single Contract to one Supplier; the Supplier may subcontract relevant aspects to appropriate third parties – to be nominated and managed by the Supplier.

5. STATEMENT OF REQUIREMENTS/RESPONSIBILITIES

BACKGROUND/INTRODUCTION

5.1 Safety communication is a critical part of the MHRA's work, with the potential for a major and immediate impact on public health and safety, and consequently our corporate reputation. It is essential therefore that we issue effective communications and trusted advice via appropriate channels to relevant audiences/HCPs, in a timely manner, to support patient safety and public health. The information dispatched must be accessible and easy to understand including how it could affect patients' care.

5.2 Our new three-year strategy for Safety Communications across MHRA (MHRA Strategy for Improving Safety Communications - GOV.UK) was informed by the 16-week consultation completed in January 2023, which sought information on the effectiveness of our current risk and safety communications and how these could be improved. The consultation included an open period, followed up with some targeted interviews and focus groups, and written responses to garner feedback. General Practitioners, nurses, pharmacists, dentists, midwives, specialty care doctors, technicians and other registered medical professionals, including professional bodies and the Royal Colleges (also NHS patient safety groups, and experts in patients' safety and quality improvement) across the four UK nations provided comments and suggestions on how the MHRA could develop/improve its approach to deliver effective and actionable risk and safety communications.

5.3 The aim of the strategy is to deliver to HCPs and patients more co-ordinated, targeted, and impactful safety communications, when they need it, using the best possible communication channels.

5.4 At present, the MHRA uses a range of approaches and routes to communicate risk and safety messages/notices and news/guidance to help with the prescribing of safe and effective medical products. We provide information on a wide group of medical products, including medical devices, medicines, vaccines, innovative health technologies, and blood components, and provide details of product recalls and other alerts. Much information is published on our website at www.gov.uk/mhra as well as delivered through direct email/cascade routes and subscriptions, and/or through the Central Alerting System (CAS - Home).

5.5 While the MHRA owns some lists of subscribers (please note we would not be able to share these contacts), we do not have enough direct contacts to be reassured on reach for important safety communications nor provision for active maintenance to add, remove, or amend details. And while there are cascade routes through partners, it remains a priority that the MHRA can reach a diverse number of HCPs with messages. The MHRA is the regulator of medical products, not healthcare professionals and so does not have access to curated lists of individuals.

5.6 We have operated a regular monthly electronic bulletin in the form of the Drug

Safety Update (DSU) since 2007; all information can also be found on our website at https://www.gov.uk/drug-safety-update and examples of the Drug Safety Update newsletters at Drug Safety Update: monthly PDF newsletter - GOV.UK. It alerts and informs HCPs such as General Practitioners/doctors, nurses, and pharmacists to safety issues with medicines, vaccines and other healthcare products, and provides advice on the ways these may be used more safely. A summary of DSU content has also been dispatched by a trusted third-party provider on a monthly basis by email to a wide list of HCPs; the provider uses their own database of contacts, with a distribution to >100,000 contacts/addressees. A similar monthly requirement is incorporated as an ongoing core need; a minimum one email campaign/mail-out per month of our new safety round up bulletin) - see the baseline requirements below.

5.7 We issue many other communications a month to HCPs (ranging from 2 to 12 including the DSU). Examples can be found on our website – see links Alerts, recalls and safety information: medicines and medical devices - GOV.UK and Drug Safety Update - GOV.UK

5.8 This current approach is not optimising the engagement rates and reach we would like to achieve, to as many relevant HCPs as possible across the UK and all sectors of health and care; nor some of the functionality features we would be keen to explore e.g. other communication channels like WhatsApp. The proposed Contract shall support delivery of our strategy to improve risk and safety communications.

5.9 The MHRA would like a more consistent approach to our messaging across medicines and devices. We would also like to incorporate more flexibility in frequency so emails can be issued across the month. As requested by those taking part in the consultation, we would also like to bring in more subscription and targeting options, so HCPs can select to receive topics only relevant for them. As part of the new strategy, the MHRA plan to launch a new monthly safety round up bulletin, summarising all safety communications issued that month (should be in operation by the time the new contract goes live), which needs to go to a wide audience of HCPs and supporting staff in the last week of each month.

SCOPE OF REQUIREMENTS/RESPONSIBILITIES

5.10 The MHRA seeks the appointment of a Supplier who has experience of and expertise in:

- issuing broad email campaigns to a large audience including but not limited to NHS email addresses.

  Please note, the Supplier would need to own or have access to the email addresses/contacts for a range of HCPs (may be via their administrative staff or organisation representatives) as the MHRA cannot provide any contact/subscription details.

- maintaining contact details to ensure up-to-date, and seeking to expand the contacts database.

- formatting and dispatching communications/emails (including ability to deal with NHS firewall/security challenges).

To note, all subject matter content shall be provided by the MHRA so the Supplier will not require any specialist/medical knowledge.

5.11 The audience for our communications is all UK healthcare professionals (HCPs) who may prescribe, administer, implant, or use/dispense medicines, vaccines, medical devices, and/or blood components, including:

- General Practitioners
- Hospital and specialist doctors and surgeons
- Nurses (in all sectors of care, including hospital nurses and those working in GP practices, schools, prisons, and care homes) and Nursing Associates
- Midwives
- Pharmacists (community, hospital, clinical, medicines management, procurement, and specialist) and pharmacy technicians
- Dentists and dental support staff such as dental technicians
- Medical Associate Professions, including anaesthesia associates (AA), physician associate (PA), and surgical care practitioner (SCP)
- Managers in general practice, pharmacy, dental care, and hospitals (both NHS and independent)
- Quality leads in trusts, ICBs and equivalent in Scotland, Wales, and Northern Ireland
- Engineers (in hospital) and equipment stores
- Medical physicists
- Opticians and optometrists
- IVD related areas, biochemistry laboratories
- Clinical pathologists
- Microbiologists
- Phlebotomists
- Point of Care testing co-ordinators
- Allied Healthcare Professionals including:
    - Dietitians
    - Occupational therapists
    - Operating department practitioners
    - Orthoptists
    - Osteopaths

- Paramedics
- Physiotherapists
- Podiatrists
- Prosthetists and orthotists
- Radiographers

Communication may be direct or through administrative staff or other organisation representatives, as appropriate. While patients and the public are also an important audience, our focus for this Procurement Call for Competition is on HCPs as the group, who would inform patients about the benefits, risks, and instructions for use.

5.12 Although the MHRA is seeking improvements and enhancements to communications (some outlined in heading 5.13), we still need to deliver ongoing core requirement(s). The Baseline Requirements are as follows:

A. Access to a database/contacts list(s) of HCPs across key healthcare areas and the UK – GPs, pharmacists, specialist doctors, nurses, and those in the audience list above (where possible); and demonstration of ability to actively maintain the details, with amendments to subscriptions, new registrations, unsubscribing/removals and/or other administration requests actioned as soon as possible (service turnaround times may be agreed). The database may be owned by the Supplier, purchased or licensed for the intended use (including having the ability to make updates) from a third party, or be provided by a named subcontractor. *Our expectation of the extent of the database (as a starting point) is that it can reach more than 100,000 HCPs across the UK and disciplines/specialisms; good representation across the healthcare sector.* Ideally, the database may also capture some high level information on the healthcare professional role (i.e. doctor, nurse); or even something more in-depth e.g. profiles with areas of interest/specialisms etc. Also the system should allow subscribers to directly unsubscribe, subscribe if forwarded the email, register, and ideally amend their profile (which might include customising what they wish to receive).

   The Supplier shall have a strategy to grow/expand the database/contacts list(s) to provide broader exposure for relevant healthcare individuals, and to potentially expand with further information on each HCP.

B. Design and building of a few email templates, tailored to specific communication campaigns (including safety round up bulletin); user tested and accessible across a range of devices (including mobile devices) and internet browsers, with MHRA branding and custom domain name. The email templates must be engaging and in HTML format or other appropriate format (compatible with/acceptable to be delivered through most recipients' NHS/IT systems and firewalls), and could contain

hyperlinks and simple graphics within MHRA brand and accessibility guidelines.

C. Formatting of the MHRA content into the agreed email template, allowing for a test mailer to verify content before sending. The email must meet relevant accessibility standards. The required service turnaround time shall be no longer than 24 working hours between receipt of content and the final dispatch of the email communication; allowing for occasional situations when this may need to be shorter when an urgent communication is needed. Timings/deadlines are critical for the Services.

D. Delivery of **at minimum** one email campaign per month (safety round up bulletin) to all selected contacts on a Supplier's database of HCPs (UK-wide) – typically emailed in the last week of each month; with additional/specialist email campaigns dispatched as needed. The Supplier would need to be aware of developments in, and have the ability to deal with, NHS email firewall/system security protocols to ensure delivery. Initially, there would be no need for any tailoring or targeting of this communication, nor any other methods of distribution.

E. A system in place to allow regular feedback of metrics to the MHRA to enable evaluation, including **at minimum** a report with rates for display/email open and click throughs to each link; segmented by HCP type and clinical role, and shown with comparisons across the month and month on month. An additional reporting requirement shall be to confirm receipt/delivery statistics for each mailer.

F. Robust IT systems and information/data security procedures in place in accordance with ISO27001 and/or Cyber Essentials certification or equivalents and to ensure UK GDPR compliance for handling and Processing Personal Data, including for the transfer of contacts to any new database (as required).

The Supplier should also provide a Help Desk function to support – further details provided in heading 5.18 below.

G. Maintain a registration function to record referrals and registrations that come from the MHRA's own recruitment channels and efforts. At the end of the Contract, the Supplier shall be required to transfer these contact details to the MHRA or to a new supplier (if requested to do so) in an agreed format.

A budget for delivering the Baseline Requirements is estimated at around £0–£50,000 per year. Contract Management also to be included.

5.13 The **Desirable Areas** which could enhance communications/the service provision and support our ambitions, supplementary to the Baseline Requirements, are as follows:

A. Flexibility to scale up the number of communications per month by email – to between 2 and 12 dependent on priorities and any segmentation of

the audience.

B. A system which would send out automated follow-up emails targeted to contacts who have not read or actioned the communication, including those on sub-lists by geographic area, clinical speciality, and/or sector of care.

C. Functionality for the MHRA to tailor defined target lists/groups for specific communications issues based e.g. on geographic area, clinical speciality, and/or sector of care etc, so that email communications issued are only delivered to the relevant audience.

D. Functionality to tailor/target the communications to what each HCP wants to receive based on self-declared interests, roles, or sectors of care (areas of relevance to a recipient).

E. Ability to allow recipients to provide more granular feedback and quantitative metrics on action, relevance and free text responses built into the emails, with collation and reporting fed back to the MHRA. This two-way communication would ensure audiences feel heard and support MHRA evaluation of the effectiveness of communications.

We would also be open to other innovations which could add value and support our ambitions/strategy.

5.14 The MHRA shall retain responsibility for:

- PR activity
- Digital and social media
- Relationship management with the HCPs and any representatives
- Branding – providing direction on brand application and the review and sign-off of any branded materials.

We will also provide all subject matter content.

5.15 The MHRA shall have no rights over the Supplier's databases/contacts lists; however the MHRA will own the rights in any referral records we provide.

5.16 The Supplier shall be required to provide report(s) for every mailshot/dispatch within two working days of the dispatch (a more detailed report shall follow one to two weeks later). The reporting requirements have been outlined in heading 5.12 above. We will use reporting to evaluate the effectiveness of our risk and safety communications/campaigns.

5.17 Reporting of metrics back to the MHRA is essential for us to be assured of receipt. As part of our strategic aim and as stated as a desirable requirement above, we would like to have the opportunity for greater two-way communications so that our audiences feel heard and understood, and we can gather feedback on the communication and action elicited.

5.18 The Supplier shall offer a Help Desk function for recipients to contact the Supplier with any queries (e.g. unsubscribes, registrations, queries and/or technical issues with reading/accessing content) available from 09.00 to 17.00 Monday to Friday excluding bank holidays all year (office-based support). A chat function may also be made available 24/7. The Help Desk team must, after filtering the issue, pass any MHRA-related issues onto the MHRA to review or for information. Timely resolution of any user or technical issues is essential. The Supplier's system may also facilitate some of these functions directly e.g. unsubscribing and registrations.

6. SUPPLIER STAFF AND RESOURCING

6.1 The Supplier shall ensure that all Supplier Staff engaged in delivering the Services have relevant experience and expertise for their proposed role to assure the Buyer of their ability to take responsibility for and undertake relevant activities, with professionalism. Sufficient numbers of Supplier Staff should be provided to deliver the Contract.

6.2 If subcontractor(s) are to be used in this service delivery, this intention should be declared with details of the nomination(s), proposed input, and your management procedures. Any relevant terms and conditions should be cascaded.

6.3 The Supplier's Contract Manager shall be considered Key Staff, and all reasonable endeavours should be made to ensure continuity for any Key Staff roles throughout the Contract Period. The Supplier shall not replace Key Staff unless absolutely necessary, and any change must be communicated to the Buyer no less than one month in advance of the planned change; the replacement for a key role must be for an equivalent resource with similar level of qualifications and experience appropriate for that role.

6.4 Nominated team members should have undergone pre-employment checks in accordance with HMG Baseline Personnel Security Standard (BPSS) – see link https://www.gov.uk/government/publications/government-baseline-personnel-security-standard.

6.5 The Supplier and the nominated Supplier Staff/resourcing must be free from having any actual or potential conflicts of interest. The Supplier must ensure it checks and confirms its position and makes any relevant declarations where an actual or potential conflict is identified with possible mitigations. Should a conflict exist, mitigations should be put in place, for example instituting ethical walls to ensure confidentiality of content from other parts of the business group or associated organisations (as applicable).

7. CONTRACT IMPLEMENTATION AND EXIT

7.1 The Supplier shall implement the Services, aligning with the Buyer's requirements. The Contract Period shall commence in early March 2025, with the Parties holding an implementation/kick-off meeting to make introductions, agree expectations and

the communication process, and any transitional activities; with the first email/Services starting late March 2025 if possible.

7.2 The Supplier shall provide an implementation plan, outlining key milestones and timelines, any risks and/or dependencies identified, and any Buyer or incumbent provider input to ensure a seamless transition (if applicable).

7.3 The following milestones shall apply:

Description	Delivery Date (from start of the Contract)
Implementation/kick-off meeting	Within Week 1
Set up systems and ways of working between the Parties, and agree any input/support required from the incumbent provider (if applicable)	Within Week 2
Commencement of the Services – with the first email dispatched. Thereafter, mailed out at a similar time each month	Last week of the month

7.4 On Contract termination or expiry. the Supplier shall be expected to support the exit process with termination assistance for any future re-competition and the potential transition of Services to any new/replacement Supplier, as appropriate. This may also include the transfer of any contact or referral details provided by the Buyer (from own recruitment channels) in an agreed format to the Buyer or to a new Supplier (if requested to do so).

8. VOLUMES AND LOCATION

8.1 The budget for delivering the Baseline Requirements and Contract Management is estimated at around £0–£50,000 per year (the budget will be reviewed after the Initial Term of three years if a Contract extension is required). In addition, additional fees/Charges for extra campaigns or mailshots or for associated Services/support shall be agreed. In the event of any one-off/upfront implementation charges and/or annual database licence fees, these costs should be kept to a minimum and where possible to be covered in the above budget, but can be reviewed separately subject to affordability. Affordability is important due to tight budgets.

8.2 There shall be no commitment to commission Services nor guarantee of a minimum or any volume or value of work; nor any exclusivity with the appointed Supplier in relation to these Services.

8.3 There is no requirement for any of the Services to take place at/from the Buyer's offices; however the Performance Review/Progress Meetings may take place at our Canary Wharf offices or as otherwise agreed, but likely to be held virtually by

video conference.

9. SOCIAL VALUE COMMITMENTS

9.1 The Supplier shall agree, in providing the required Services and performing its obligations under the Contract, that it will deliver social value commitments.

9.2 These are the five main themes and eight subsequent policy outcomes within the social value model:

Theme 1 COVID-19 Recovery	Policy outcome: Help local communities to manage and recover from the impact of COVID-19.
Theme 2 Tackling Economic Inequality	Policy outcome: Create new businesses, new jobs and new skills. Policy outcome: Increase supply chain resilience and capacity.
Theme 3 Fighting Climate Change	Policy outcome: Effective stewardship of the environment.
Theme 4 Equal Opportunity	Policy outcome: Reduce the disability employment gap. Policy outcome: Tackle workforce inequality.
Theme 5 Wellbeing	Policy outcome: Improve health and wellbeing. Policy outcome: Improve community cohesion

9.3 The Buyer has asked for details of a commitment in regards to Themes 4: Equal Opportunity and 5: Wellbeing.

10. CONTRACT MANAGEMENT, PERFORMANCE AND QUALITY, AND CONTINUOUS IMPROVEMENT

10.1 Each Party shall nominate Contract Management representatives to act as their primary contacts and manage performance of the Contract and Services. The relationship between the Parties shall be collaborative, with regular communication/dialogue to ensure mutual understanding and optimise performance.

10.2 The Supplier shall assign an experienced Contract Manager and deputy/cover to oversee Contract performance and quality (including ensuring the Service Levels/KPIs are achieved), and manage the Contract relationship with the Buyer's representatives: to include attending the scheduled Performance Review/Progress

Meetings (face to face or virtually by video conference) and providing Progress Reports/MI; and risk and cost management etc. The Contract Manager shall be considered Key Staff and all reasonable endeavours should be made to ensure continuity in this role throughout the Contract Period.

10.3 The Supplier shall manage any subcontractors where used, to ensure their performance and seamless delivery across the supply chain.

10.4 The Supplier's Contract Manager and Help Desk (for HCPs) should be contactable between 09.00 to 17.00 Monday to Friday (excluding bank holidays) all year (business hours for office-based support). A chat function may also be made available 24/7 to assist with technical issues. Timely resolution of any technical issues is essential.

10.5 The Parties shall communicate with each other by email, telephone and face-to-face channels. Quarterly Performance Review/Progress Meetings shall be held (either virtually by video conference or face-to-face at the Buyer's Canary Wharf offices or as otherwise agreed) within the first week of each quarter, with the Contract Managers/representatives attending and the agenda to include the review of: the Progress Reports and any ad hoc Management Information (MI); the mailshot reports detailing display/email open rates and click throughs to links broken down by HCP type/clinical role (other metrics may be agreed) and the effectiveness of safety communications/campaigns; financials; and proposals for potential continuous service improvements and efficiencies etc.

10.6 The Services must be carried out using all reasonable skill and due diligence, and in accordance with good industry practice. The Supplier should have robust quality management systems and processes in place to implement for these Services and embed quality, equivalent to quality certification ISO 9001 standard or other equivalent standard, and may also hold this accreditation.

10.7 The Buyer shall monitor the quality of the Supplier's Services and deliverables. The Supplier shall be required to work to these proposed Service Levels; some linked KPIs shall be agreed:

Tasks/Indicators	Targets (timelines may be extended as agreed)
Acknowledgement of an instruction for a campaign/assignment (by email – telephone contact may also be made).	Within two working days.
Format content into agreed email template and dispatch communication.	Dispatch of communication/email no longer than 24 working hours between receipt of content and dispatch.

	There may be times of urgency, when this service turnaround time may need to be shorter.
Ability to actively maintain/keep up-to-date the database/contacts list(s) of HCPs, and have a strategy to grow/expand the database/lists.	Throughout the Contract. (service turnaround times may be agreed for actioning subscriber/ administration requests – otherwise should be asap).
Secure data handling and processing procedures to safeguard the confidentiality/protection of information/Personal Data.	No suspected or confirmed/actual security breaches involving the Buyer's information/data or any data (e.g. HCP database/contacts) used for the Services/Requirements.
Submission of a report for each mailshot/dispatch, covering as a minimum the following metrics - display/email open rates and click throughs to each link, segmented by HCP type and clinical role, and shown with comparisons across the month and month on month.	Within two working days of dispatch. A more detailed report shall follow one to two weeks later.
Submission of a report confirming receipt/delivery statistics for each mailer.	Within two working days of dispatch. A more detailed report shall follow one to two weeks later. (Target receipt statistics may also be agreed).
Availability of Supplier's Contract Manager and Help Desk team (for HCPs); and potentially a chat function. Technical assistance for recipients e.g. in accessing emails and/or opening links/content.	Monday to Friday excluding bank holidays 09.00 to 17.00 all year (business hours for office-based support). If there is a chat function – this should be available 24/7 to assist users/HCPs. Urgent review and resolution where possible. Timely resolution of technical issues is essential.
Supplier's Contract Manager (and/or deputy/cover) attendance at the scheduled Performance Review/Progress Meetings – held either virtually by video conference or face-to-	Within the first week of each quarter. Agenda to be agreed.

face if required (at the Buyer's Canary Wharf offices or as otherwise agreed).	
Submission of Progress Reports. (other ad hoc Management Information may also be requested by the Buyer – the timescales shall be agreed).	Within the first week of each calendar month (this may be changed to quarterly frequency). Content to be agreed.
Seek continuous service improvements, innovations, and efficiencies in the delivery of these Services. (proposals will be reviewed at the Performance Review/Progress Meetings).	Throughout the Contract – including starting to explore options to introduce the Desirable Areas (where possible).
Acknowledgement and resolution of a complaint (by email).	Within one working day of receipt. Answers to and resolution of a complaint – within a further 24 hours or as may be reasonably requested by and agreed with the Buyer.
All invoices right first time and presented electronically with supporting breakdowns within agreed times.	To be submitted accurately and as per payment terms.

Any changes to this list (e.g. in relation to the Desirable Areas, Social Value) shall be agreed with the Buyer and be implemented by the Supplier within 30 days of the request or as otherwise agreed.

10.8 Performance against Service Levels/KPIs will be monitored and documented in the monthly Progress Reports, and reviewed and discussed by the Parties at the scheduled quarterly Performance Review/Progress Meetings. In the event of any Service Level failures or issues, remedial actions shall be agreed to improve performance before the next review period.

10.9 The Supplier shall supply the Progress Reports within the first week of each calendar month (may be changed to quarterly frequency as agreed); the format and content shall be agreed, but shall include: an overview of performance against the Service Levels/KPIs; a financial overview; click and receipt statistics – targets may be set etc. In addition, mailshot reports detailing display/email open rates and click throughs to links broken down by HCP type/clinical role (other metrics may be agreed) shall be supplied within two working days of the dispatch; a more detailed report shall follow one to two weeks later. On occasion, the Buyer may request ad hoc MI (to be provided at no additional cost).

10.10 The Buyer will use reporting to evaluate the effectiveness of risk and safety communications/campaigns.

10.11 The Supplier shall have a complaints and escalation procedure in effect.

10.12 The Supplier shall seek continuous service improvements, innovations, and efficiencies in the delivery of these Services to optimise performance and value for money throughout the Contract Period. Proposals will be reviewed at the Performance Review/Progress Meetings.

11. SECURITY AND DATA PROTECTION

11.1 The Supplier must have robust IT systems and security procedures in place (including ensuring compliance from any third party providers as appropriate) to prevent unauthorised access to/disclosure, misuse or leakage of, the Buyer's information and data collected and held (e.g. HCP database/contacts) used for the Services/Requirements. The Supplier shall have Cyber Essentials certification or equivalent https://www.ncsc.gov.uk/cyberessentials/overview, and may also hold ISO 27001: Information Security Management certification or equivalent.

11.2 The Buyer's Infosec team have identified a list of non-functional technical system requirements at Appendix A, which should be met where possible.

11.3 Any web accessed assets and systems used for these Services must adhere to the public sector accessibility requirements as per https://www.gov.uk/guidance/accessibility-requirements-for-public-sector-websites-and-apps and Understanding WCAG 2.2 - Service Manual - GOV.UK (www.gov.uk). There shall be no integration with the Buyer's systems.

11.4 The Supplier shall ensure that information and data (including Personal Data) used in the delivery of these Services shall be collected, held, maintained and transmitted in a secure and confidential manner and in accordance with the Terms of the Contract and in full compliance with prevailing Data Protection legislation and UK GDPR. The resilience of the Supplier's systems must safeguard the confidentiality and the integrity of information/Personal Data.

11.5 The Supplier should have clear and documented procedures for Data handling and Processing, and the retention and disposal of Personal Data which should be rigorously observed to ensure the protection of the rights of data subjects. The Buyer's preference is for Personal Data not to be transferred, held or processed outside the UK where possible; however, alternative proposals will be reviewed. HCP contact details with Personal Data will be received and collected as part of the Requirements/Services.

11.6 Any suspected or confirmed/actual security breaches involving the Buyer's information/data or data used for the Requirements/Services must be reported immediately to the Buyer, with details of impact and proposals for mitigation, rectification and prevention of recurrence.

11.7 The Supplier shall hold and operate an up-to-date and robust business continuity and disaster recovery (BCDR) plan.

12. BUDGET/COMMERCIAL DETAILS AND INVOICING

BUDGETS AND PRICING/CHARGES

12.1 The budget for delivering the Baseline Requirements and Contract Management is estimated at around £0–£50,000 per year (the budget will be reviewed after the Initial Term of three years if a Contract extension is required). In addition, additional fees/Charges for extra campaigns or mailshots or for associated Services/support shall be agreed. In the event of any one-off/upfront implementation charges and/or annual database licence fees, these costs should be kept to a minimum and where possible to be covered in the above budget, but can be reviewed separately subject to affordability. Affordability is important due to tight budgets.

12.2 The Buyer requires details of the applicable pricing/Charges (presented in pounds sterling/GBP) excluding VAT. The pricing/Charges offered should be capped for the Initial Term; however, the Buyer will review price variation requests after 24 months - these must be based upon proven cost pressures and will be limited to a maximum increase equivalent to the rate of prevailing Consumer Price Index (CPI).

INVOICING AND PAYMENT TERMS

12.3 All invoices must be submitted electronically to accounts.payable@mhra.gov.uk in accordance with the payment terms and paid subject to satisfactory delivery (usually in arrears).

12.4 The Buyer shall pay the Supplier the Charges within 30 days of receipt of a valid, undisputed invoice. Each Invoice must include a supporting breakdown of the work that has been completed.

12.5 The Buyer has a “no purchase order no pay policy” in place. Any work or expense the Supplier undertakes prior to receipt of a purchase order shall be undertaken solely at their risk. Any invoice submitted must display a valid purchase order number and the invoice value must not exceed the value of the purchase order. Invoices not meeting these requirements could be rejected and therefore payment may be delayed.

APPENDIX A: NON-FUNCTIONAL TECHNICAL SYSTEM REQUIREMENTS

The Buyer's Infosec team have identified the following list of non-functional technical system requirements which should be satisfied where applicable:

CATEGORY	REQUIREMENTS
Access Control/Data Access and password resetting	Authorised users must authenticate onto any system/platform using a unique user name and login credentials, to ensure unauthorised access. The system must be able to detect & report in a log file unauthorised access attempts Approach for users authenticating from outside the Agency network (i.e., over the Internet) must be subject to Multi-Factor Authentication (MFA). The system should monitor inappropriate access, and/or have an audit trail of access or activities (i.e. read, write, modify, delete) that can be traced to an individual. The system shall automatically log the user out of after 15 minutes of inactivity. The solution must provide a security framework to control and administer user access including managing permissions. Users must be able to reset their password in a secure manner.
Compliance and Standards	The solution/system shall adhere to industry standard security and auditing principles/protocols including maintaining a tamper-proof audit log of users accessing the systems (e.g. log in/out times, IP address).

	The Supplier shall undertake regular penetration testing from third party sources and ensure any potential security vulnerabilities are reported to the MHRA and appropriate action is agreed to ensure security and integrity of the system. The system must provide user access audit logs and these are to be retained according to the Agency Retention and Destruction schedule, including deletion of user data where required by the data privacy requirements. The Supplier shall adopt appropriate transport level security protocols agreed with the agency to ensure data can be securely exchanged between the Supplier's systems and with the existing MHRA systems. The supplier of a cloud solution must establish/demonstrate their compliance with the Cloud security principles outlined/issued by the National Cyber Security Centre and published on their website: https://www.ncsc.gov.uk/collection/cloud-security/implementing-the-cloud-security-principles https://www.ncsc.gov.uk/section/information-for/public-sector#section_2
Configuration Assessment	The systems must be 'hardened' and secure. The condition of the systems can be verified periodically, depending on the level within the requirement, for example by using vulnerability scans of systems and application code. The application code should be written and tested in accordance with a formal software development practice.
Configuration Integrity	Configuration changes must be detectable and be recorded in immutable audit trail. This implies that technologies such as routine,

	scheduled, continuous, or near-continuous configuration auditing. The configuration of a system can be recovered back to the state that the system was in prior to the modification.
Data Encryption	Transport layer security is implemented for data that is transmitted over a less trusted network, and that encryption is implemented for data at rest.
Resilience	The systems shall be resilient to the loss of some of the logical or physical infrastructure. The system shall ensure no data loss due to unavailability of one or more of underlying infrastructure components. The Supplier shall ensure that the system is safeguarded against any third party security threats such as (but not limited to) DDoS attacks, SQL injections and any hacking attempts.
Secure Development	The solution must be tested again the OWASP Top 10 vulnerabilities. OWASP Top Ten | OWASP Foundation

ANNEX A: PROCUREMENT TIMETABLE

The Procurement Timetable below shall apply but may be changed at any time at the discretion of the Buyer.

Activity/Milestone	Indicative Dates
Procurement Call for Competition commences	09/01/2025
Deadline for Receipt of Tender questions and/or requests for clarification	27/01/2025 Midday/12:00
Tender Submission Deadline (return of Tender)	11/02/2025 Midday/12:00
Evaluation period (which may include seeking clarification from Tenderers as required)	11/02/2025 to 13/02/2025
Presentation (for shortlisted Suppliers/Tenderers if required) (OPTIONAL)	18/02/2025
Further and final evaluation period (if presentations conducted)	18/02/2025
Standstill period	24/02/2025 to 06/03/2025
Provisional Contract Award	07/03/2025
Expected execution (signatures) date for the Contract	w/c 10/03/2025
Commencement Date (Contract Implementation to start)	w/c 17/03/2025

ANNEX B: FORM OF PROPOSAL/TENDER

Introduction

Tenders/offers must remain valid and capable of acceptance by the Buyer for a period of 60 calendar days following the Tender Submission Deadline.

In submitting a Tender, a Tenderer is acknowledging the Buyer's right to publish information contained within those documents, when incorporated into or referred to in the Contract awarded.

See Appendix D for the summary tendering instructions; see also the Atamis envelopes.

There are four envelopes on the Atamis e-Procurement portal which must be reviewed and completed with the requested responses: the Qualification envelope, Technical envelope, Social Value envelope, and the Commercial envelope, to participate in the Procurement Call for Competition.

Qualification response

Responses to the Selection Questionnaire and some general compliance checks must be input in the Atamis response text boxes (also some attachment questions as well) in the Qualification envelope not later than the Tender Submission Deadline of 11/02/2025 Midday/12:00.

All information requested should be provided in the English (UK) language. Please refrain from including any embedded files.

This section is not weighted. Qualification responses will be marked as pass or fail. Those Tender submissions/proposals which pass, will be further evaluated.

Question areas in the Selection Questionnaire

Selection Questionnaire Headings
Part 1 Questions (General Information) and Bidding Model
Part 2 Questions (Exclusion Grounds Questions) • Grounds for mandatory exclusion • Grounds for discretionary exclusion
Part 3 Questions (Selection Criteria Questions) • Economic and Financial Standing • Technical and Professional Ability • Insurance • Data Protection • Tackling Modern Slavery in Supply Chain

Question areas – General Compliance Checks

General Compliance Check Headings
Tender Validity Period check
Terms of Contract check
Confidentiality check
Intellectual Property Rights check
Transparency check
Freedom of Information Act (FOIA) and Environmental Information Regulations (EIR) check
Conflicts of Interest check
Hospitality and Gifts check
Business Continuity Management
Approach to Quality Management
Inducements and Canvassing check
Collusive Behaviour and Bona Fide Tender Declaration

Technical/Quality response

Technical/Quality responses must be provided as a consolidated Technical Tender Proposal and uploaded into the Atamis technical envelope not later than the Tender Submission Deadline of 11/02/2025 Midday/12:00. The Tender Proposal must include a response to each question (N/A may be used if not applicable/not relevant) and have clear question headings and numberings. No word or character limits shall apply.

In the relevant Atamis response text box for each question please state 'Please see page(s) _ in attached Tender Proposal'.

All information requested should be provided in the English (UK) language. Although, there could be some duplication, please answer each question in turn and without cross-referencing with other questions. Please refrain from including any embedded files.

Please provide the following information to form your Technical Tender Proposal – weightings for each question/criterion have also been outlined. Screenshots can be included to illustrate answers, as appropriate.

Technical/Quality response (weighted at 65%) – Technical envelope

1) Suitability of Supplier and Subcontractors and Demonstration of Understanding – weighted at 12% (no sub-weightings)

    a) An executive summary with an introduction to your company and any subcontractors you plan to use (confirming any relevant corporate accreditations/memberships held); and showing your understanding of the Buyer's

remit, our strategy and the Requirements.

(questions on the bidding model also included in the Qualification Selection Questionnaire).

b) A description of how your expertise (project examples for comparable contracts to MHRA requirements may be used to help illustrate) and proposed input could support service delivery and MHRA's ambition of improving risk and safety communications including optimising engagement rates and reach.

2) Relevance of Capability and Methodology – weighted at 32%

A - BASELINE REQUIREMENTS (weighted at 24% - no sub-weightings)

a) Details of your capability and approach for delivering the Baseline Requirements as follows:

Extent of Database/Contacts Lists of HCPs

i) A description of the database/contacts list(s) of HCPs you will be using/have access to, including overall size/numbers of contact addresses with breakdowns of representation across key healthcare areas/HCP audience (professions), organisation type, clinical specialisms and the four nations of the UK. Also, state what information has been captured e.g. email addresses, other contact channels, role/title, profiles with areas of interest/specialisms etc. Please confirm if owned, the purchasing or licensing route, or if provided by a named subcontractor; and any limitations (the Supplier would need the ability to make updates)?

[Our expectation of the extent of the database as a starting point is that it can reach more than 100,000 HCPs across the UK and disciplines/specialisms; good representation across the healthcare sector. A score of 0 may be given if not able to provide this].

ii) Will your system allow subscribers to directly unsubscribe, subscribe/register and/or amend their profile (which might include customising what communications they wish to receive)?

iii) Strategy to grow/expand the database/contacts list(s) to provide broader exposure for relevant healthcare individuals, and to potentially expand with further information on each HCP.

IT Security and Data Protection requirements covered in question 4 below.

Database Management/Maintenance

i) Approach to actively maintaining the database/contacts list(s) to keep up-to-date and add new registrations and/or action subscription removals etc, covering: the procedures for and the frequency of checks for ensuring the records are kept up to date and monitoring for duplications; and the process and service turnaround times for actioning any amendments, registrations/unsubscribing, administration requests etc.

Email Template Designs

i) Designs for some engaging email templates in HTML format or other appropriate formats used for other clients (up to 3 examples - where not commercially sensitive) and possible template designs relevant for the MHRA, confirming these can be tailored easily for specific campaigns and can include MHRA branding and custom domain name. Please confirm which format you plan to use?

ii) Approach to testing the templates (both technically and with users) to include ensuring accessible across a range of devices (including mobile devices) and internet browsers, and compatible for delivery through most recipients' NHS/IT systems and firewalls. Hyperlinks and simple graphics may need to be included in communications.

Formatting of Content and Delivery of Communication

i) Process for formatting MHRA content into agreed email template (should meet relevant accessibility standards), including allowing for a test mailer to verify content before sending, and for meeting the service turnaround time of no longer than 24 working hours between receipt of content and final dispatch of a communication (fulfilling service timings/deadlines are critical). Please confirm also your ability to flex to shorter timelines in the event of an urgent communication need?

ii) Confirmation of ability to deliver/dispatch at minimum one email campaign per month to all selected contacts on a Supplier's database of HCPs UK-wide in agreed email template and within the service turnaround time (see above), and how you deal with NHS email firewall/system security protocols/challenges to ensure delivery. Please also confirm you have the capacity/flexibility to scale up and action additional/specialist emails/campaigns as needed?

MHRA Referrals/Registrations

i) An outline of how you will record any referrals and registrations from the MHRA's own recruitment channels and efforts; noting that at the end of the Contract, these MHRA contacts must be transferred/returned to the MHRA or to a new supplier (as appropriate).

Reporting and Metrics per Mailshot

i) System to capture pertinent metrics to feedback to the MHRA to enable evaluation, including confirming you can provide at minimum rates for display/email open and click throughs to each link, segmented by HCP type and clinical role, and shown with comparisons across the month and month on month. Please indicate any other metrics/data and/or support you can offer to help the MHRA evaluate the effectiveness of communications.

ii) Include an example report(s) detailing these metrics. Confirm the turnaround time?

iii) Include an example report detailing receipt/delivery statistics per mailer. Confirm the turnaround time?

iv) Please include other example reports you feel relevant and propose to offer to support service delivery.

Helpdesk Function

i) An outline of your Help Desk function, including responsibilities e.g. resolving recipient queries (unsubscribes, registrations, and/or technical issues with reading/accessing content), and expected service turnaround times (timely resolution is essential)? Also, confirm if any of these functions can be done directly on the Supplier's system as well?

ii) Please confirm business hours for the office-based support, and if a chat function would be made available 24/7?

B - DESIRABLE AREAS AND ENHANCEMENTS (weighted at 8% - no sub-weightings)

a) Details of your proposals and how you might achieve delivering the Desirable Areas (if possible) as follows:

i) Capacity/flexibility to scale up the number of communications per month by email – to between 2 and 12 dependent on priorities and any segmentation of the audience.

ii) A system which would send out automated follow-up emails targeted to contacts who have not read or actioned the communication, including those on sub-lists by geographic area, clinical speciality, and/or sector of care.

iii) Functionality for the MHRA to tailor defined target lists/groups for specific communications issues based e.g. on geographic area, clinical speciality, and/or sector of care etc, so that email communications issued are only delivered to the relevant audience.

iv) Functionality for the tailoring/targeting of communications to what each HCP wants to receive based on self-declared interests, roles, or sectors of care (areas of relevance to a recipient).

v) Ability to allow recipients to provide more granular feedback and quantitative metrics on action, relevance and free text responses built into the emails, with collation and reporting feedback to the MHRA.

Also outline any other opportunities for greater two-way communications with our audiences so they feel understood and we have valuable feedback.

b) Identification of any innovations or improvements/efficiencies you could offer which could add value and/or support our ambition/strategy and potentially help optimise engagement rates and reach e.g. technology, ability to use other communication channels like WhatsApp etc.

3) Quality of Supplier Staff/Resourcing and Robustness of Contract Management, Performance and Quality Arrangements – weighted at 11% (no sub-weightings)

a) Details of resourcing (including Supplier Staff and any subcontractor personnel) to be engaged in delivering the Services and/or in a Contract Management function, to assure MHRA we would have access to a sufficiently experienced and professional team (should be BPSS checked - https://www.gov.uk/government/publications/government-baseline-personnel-security-standard). Include bios for proposed team with name, job title, outline of role, relevant qualifications, and experience.

b) Confirmation that you believe that no actual or potential conflicts of interest exist (for Supplier/subcontractor and nominated resourcing)? If any do or could exist, please declare and confirm what possible mitigations you could offer e.g. ethical walls etc.

c) A description of proposed management and performance/quality arrangements, including:

- The responsibilities of the nominated Contract Manager and deputy/cover e.g. overseeing Contract performance and quality, managing the Contract relationship, communication, attending the Performance Review/Progress Meetings and providing Progress Reports, and risk and cost management etc. Also confirm the business times for the Contract Manager.

  {The Contract Manager shall be considered Key Staff and all reasonable endeavours should be made to ensure continuity in this role throughout the Contract Period}.

- Approach to working and communicating with the Buyer's representatives and fostering a collaborative working relationship, with regular dialogue to ensure mutual understanding and optimising performance.

- Approach to monitoring performance, including confirmation you can work to the proposed Service Levels in section 10 (provide any comments as applicable).

- Method for embedding quality and maintaining robust quality management systems and processes equivalent to certification ISO 9001 standard (indicate if you hold quality accreditation ISO 9001 standard or equivalent).

- Outline of subcontractor management procedures (if applicable) and how you manage and maintain healthy supply chains to ensure performance and seamless delivery.

- Robust complaints and escalation procedure in effect.

- Expectations for the quarterly Performance Review/Progress Meetings (held either virtually by video conference or face-to-face at the Buyer's Canary Wharf offices or as otherwise agreed).

d) Include examples of a Progress Report you could offer (MHRA format and content shall be agreed), but expected to include: an overview of performance against the Service Levels; financial overview; click and receipt statistics etc.

e) Provision of an Implementation Plan with key milestones and timelines, any risks and/or dependencies identified, and any expected Buyer or incumbent provider input needed to transition us seamlessly to your Services (if applicable) aligning with the Buyer's requirements.

f) Strategy for seeking continuous improvement and efficiencies.

4) Assurances on Information/IT Security and Data Protection – weighted at 10% (no sub-weightings)

a) A description of your robust systems, processes and documented procedures for maintaining information/IT security (including ensuring third-party provider compliance as appropriate) and data handling and Processing (Personal Data) in compliance with prevailing Data Protection legislation and UK GDPR, and for safeguarding the confidentiality and integrity of information/Personal Data from unauthorised access, disclosure or misuse to ensure the protection of the rights of data subjects. Also, confirm where any Personal Data will be transferred to, held or processed - the MHRA's preference is for Personal Data not to be transferred outside the UK where possible; however, alternative proposals will be reviewed.

b) Confirmation of whether you hold Cyber Essentials certification https://www.ncsc.gov.uk/cyberessentials/overview or equivalent and/or ISO 27001 Information Security Management certification or equivalent, and how these/any security accreditations will be used in the service delivery and how you mitigate against any security breaches.

c) Confirmation that you can satisfy the MHRA non-functional technical system requirements listed in Appendix A where applicable; if there are any issues, please outline the issue.

d) Confirmation of adherence to relevant public sector web accessibility requirements (e.g. https://www.gov.uk/guidance/accessibility-requirements-for-public-sector-websites-and-apps and Understanding WCAG 2.2 - Service Manual - GOV.UK (www.gov.uk)) for any web accessed systems used for these Services.

e) Include your up-to-date business continuity and disaster recovery (BCDR) plan; confirm also if you hold certification ISO 22301 Business Continuity Management.

Social Value response

Social Value responses must be provided as a consolidated Social Value Tender Proposal and uploaded into the Atamis social value envelope not later than the Tender Submission Deadline of 11/02/2025 Midday/12:00. The Tender Proposal must include a response to each question (N/A may be used if not applicable/not relevant) and have clear question headings and numberings. No word or character limits shall apply.

In the relevant Atamis response text box for each question please state 'Please see page(s) _ in attached Tender Proposal'.

All information requested should be provided in the English (UK) language. Although,

there could be some duplication, please answer each question in turn and without cross-referencing with other questions. Please refrain from including embedded files.

Please provide the following information to form your Social Value Tender Proposal – weightings for each question/criterion have also been outlined. Screenshots can be included to illustrate answers, as appropriate.

Social Value response (weighted at 10%) – Social Value envelope

1) Theme 4: Equal Opportunity: Tackle workforce inequality – weighted at 5%

   Describe in a short method statement the effective measures or activities/plans you have in place and/or will develop to show commitment to ensuring that opportunities under the Contract could deliver the policy outcome and demonstrate action to tackle workforce inequality. Please include any expected measurable impacts and any planned initiatives to ensure greater opportunities for your workforce including promoting diversity.

2) Theme 5: Wellbeing: Improve health and wellbeing policy – weighted at 5%

   Describe in a short method statement the effective measures or activities/plans you have in place and/or will develop to show commitment to ensuring that opportunities under the Contract could deliver the policy outcome and demonstrate action to support health and wellbeing, including promoting awareness of physical and mental health matters, in the Contract workforce and more broadly in the community as applicable. Please include any expected measurable impacts and any planned initiatives, and in relation to your employees how do you ensure a healthy work life balance.

<u>Commercial/Price response</u>

Commercial/Price responses must be provided as a consolidated Commercial Tender Proposal and uploaded into the Atamis Commercial envelope not later than the Tender Submission Deadline of 11/02/2025 Midday/12:00. The Tender Proposal must include a response to each question (N/A may be used if not applicable/not relevant) and have clear question headings and numberings.

All information requested should be provided in the English (UK) language. Although, there could be some duplication, please answer each question in turn and without cross-referencing with other questions. Please refrain from including embedded files.

The applicable pricing/Charges must be presented in pounds sterling/GBP excluding VAT. Any figures requested should be stated in full (i.e. £4,000 not £4K). The pricing/Charges offered should be capped for the Initial Term of three years. However, the Buyer will review price variation requests after 24 months; these must be based upon proven cost pressures and will be limited to a maximum increase equivalent to the rate of prevailing CPI.

The budget for delivering the Baseline Requirements and Contract Management is estimated at around £0–£50,000 per year (the budget will be reviewed after the Initial

Term of three years); may also include any one-off/upfront implementation Charges and/or annual database licence fees where possible (although these can be reviewed separately subject to affordability). Affordability is important due to tight budgets.

Please provide the following information to form your Commercial Tender Proposal (Excel spreadsheets may be used).

Commercial/Price response (weighted at 25%) – Commercial envelope:

1) A Total Price excluding VAT for delivering the Baseline Requirements and Contract Management for the Initial Term of three years. Please also include a cost breakdown.

   Inclusive of, but not limited to (based on 100,001 recipients):

   - Access to a database/contacts list(s) of HCPs across key healthcare areas and the UK with a reach of more than 100,000 HCPs. The system should also allow subscribers to directly unsubscribe, register, amend profiles etc. (To note, there may be a one-off/annual licence charge for the database – to be included in question 2).
   - Actioning the strategy to grow/expand the database/contacts lists.
   - Regular maintenance of database/contacts list(s) to keep up-to-date; actioning any amendments, registrations/unsubscribing, administration requests etc.
   - Design of a few engaging and accessible email templates (including for safety round up bulletin) – to include testing to ensure compatible for delivery through most recipients' NHS/IT systems and firewalls.
   - Formatting of MHRA content into email template, including allowing for a test mailer, and delivery/dispatch of the one email campaign per month (safety round up bulletin) to all selected contacts on a Supplier's database of HCPs.
   - Maintaining a registration function to record MHRA referrals and registrations.
   - System to capture metrics and reporting of metrics per mailshot (based on one per month).
   - Seeking continuous improvement, innovations, and efficiencies. (To note, there may be some Charges levied for the introduction of some of these).
   - Help Desk function for HCPs/users.
   - Relevant resources (IT and personnel).
   - Contract Management (including attendance at quarterly Performance Review Meetings and providing monthly Progress Reports).

   Please highlight any costs which are relevant but not included and itemise in question 2 below. Also confirm the impact on the Total Price if there is an increase or decrease in the number of recipients?

2) Any one-off/upfront implementation Charges and/or annual database licence fees

(excluding VAT) for the Initial Term of three years (where possible to be covered in the budget); please itemise.

3) Overall Total Price excluding VAT (covering Initial Term of 3 yrs):

   Total Price (from question 1) + Charges/fees (from question 2). This Overall Total Price should also be separately inserted in the relevant Atamis response text box as requested; this will be used for the evaluation.

4) Confirmation of your typical payment terms e.g. monthly, quarterly, any advance payments. The MHRA usually pay in arrears and on satisfactory delivery.

5) Please complete this table (included as a word document in the ITT Bid Pack for you to incorporate/replicate in your Proposal); this will form the Ratecard for potential/additional Services. Where not known or not applicable, please state N/A.

   Ratecard for potential/additional Services

Services	Unit of measurement (please amend as appropriate)	Prices/Charges (excluding VAT)	Notes (please add comments e.g. what is included /excluded)
Email template design. (may include free text responses built into).	Each.	£	
Template (for other communication channel e.g. WhatsApp etc).	Each.	£	
Additional email campaign/dispatch (for safety round up bulletin), and associated mailshot report(s) and management. (based on 100,001 recipients and including test mailer). Please also confirm at what point this price would increase or decrease and impact if more recipients.	Per complete mailshot (a banding approach may also be used e.g. 1 – X etc).	£	
Additional email campaign/dispatch (other/specialist campaigns), and associated mailshot	Per complete mailshot (a banding approach may also be used e.g. 1 – X etc).	£	

report(s) and management. (based on 100,001 recipients and including test mailer). Please also confirm at what point this price would increase or decrease and impact if more recipients.			
Campaign/dispatch using another communication channel like WhatsApp etc, and associated mailshot report(s) and management. (based on 100,001 recipients). Please also confirm at what point this price would increase or decrease and impact if more recipients.	Per complete mailshot (a banding approach may also be used e.g. 1 – X etc).	£	
Subdivision of database/contacts lists into targeted subset/lists e.g. by geographic area, clinical speciality, and/or sector of care, to be used for targeted communication campaigns.	Per hour/other	£	
System to send out automated follow-up emails targeted to certain contacts (who have not read or actioned a communication). (One or more follow-ups). Confirm also any one-off set up charges.	Per mailshot	£ £	

Targeted email campaign/dispatch, and associated mailshot report(s) and management. (based on approx. 10,000 to 20,000 targeted recipients and including test mailer). Please also confirm at what point this price would increase or decrease and impact if more recipients.	Per complete mailshot (a banding approach may also be used e.g. 1 – X etc).	£	
System to allow/encourage greater two-way communications with audiences.	Per hour/other	£	
Support for greater collation of more granular feedback from recipients and quantitative metrics.	Per hour/other	£	
Introduction of any innovations or improvements/ efficiencies.	To be agreed	To be agreed	
Itemise any other possible costs/Charges	Other	£ £	

Questions/Clarifications on the Procurement Call for Competition

You may raise questions or seek clarification regarding any aspect of a Procurement Call for Competition at any time prior to the Deadline for Receipt of Tender questions and/or requests for clarification of 27/01/2025 Midday/12:00. Questions must be submitted using the Atamis secure messaging facility up to this deadline. Questions received after the deadline date may not be answered.

If the Buyer considers any question or request for clarification to be of relevance or importance (with the exception of commercially sensitive or proprietary-related questions where disclosure could prejudice commercial interests), both the query and the answer shall be published anonymously, to ensure all Tenderers have equal access to information.

If a Tenderer wishes to ask a question or seek clarification in confidence they must notify the Buyer and provide justification for withholding the question and answer. If we do not

consider that there is sufficient justification for withholding the question and the corresponding answer, we shall inform that Tenderer, who will have an opportunity to withdraw the question/clarification request. If the question or clarification is not withdrawn, then the answer will be issued to all Tenderers.

ANNEX C: EVALUATION METHODOLOGY

The Contract shall be awarded on the basis of the Most Economically Advantageous Tender. That is to say, when considering all the factors, the Tender that enables the Buyer to meet Requirements and achieve value for money.

There are 4 envelopes (Qualification, Technical, Social Value & Commercial) in the Atamis system which must be reviewed and completed. The evaluation shall cover the assessment of the following:

- Qualification envelope - This envelope includes the Selection Questionnaire and some general compliance check questions. This section is not weighted and the responses will be marked as pass or fail (Self Cleaning information will also be reviewed where applicable). Those Tender submissions/proposals which pass, will be further evaluated as follows.
- Technical envelope - The Technical/Quality responses shall be scored in accordance with the stated range of marks, criteria and weightings, as outlined in the scoring matrix/grid below. This section is weighted at 65%.
- Social Value envelope - The Social Value responses shall be scored in accordance with the stated range of marks, criteria and weightings, as outlined in the scoring matrix/grid below. This section is weighted at 10%.
- Commercial envelope - The Commercial/Price responses shall be evaluated using a relative pricing method with the Tenderer offering the lowest Overall Total Price excluding VAT allocated full marks, with the other Tenderers then allocated marks on a relative standard differential basis to this Price. This section is weighted at 25%.

  The Overall Total Price in this context shall be calculated from the Total Price (excluding VAT) for delivering the Baseline Requirements and Contract Management plus any one-off/upfront implementation Charges and/or annual database licence fees (excluding VAT) for the Initial Term of three years.

  Example of relative pricing method

  Lowest Overall Total Price tendered x Maximum Score Available

  Tender Price

  In the event of an abnormally low priced Tender, the Buyer shall ask for clarification to substantiate understanding and sustainability, before accepting the bid.

  A ratecard had also been requested (not evaluated).

  The Buyer will also do a CreditSafe credit report on Tenderers, for assurance purposes.

- In addition, an optional Presentation may also be undertaken with shortlisted Suppliers/Tenderers only. No separate scoring approach, just a validation of the Technical, Social Value, and Commercial scores (as appropriate).

The scoring matrix/grid with the criteria and weightings (the weighted scores shall be calculated to up to 2 decimal places) are as follows:

Qualification response evaluation – Pass or Fail questions as above				
Technical/Quality response evaluation – 65%				
Questions/Criteria	**Weighting**	**Score 0-60 (definitions below)**	**Weighted Scores**	**Evaluator comments**
Suitability of Supplier and Subcontractors and Demonstration of Understanding	12%			
Relevance of Capability and Methodology - 32%:				
• Baseline Requirements	24%			
• Desirable Areas and Enhancements	8%			
Quality of Supplier Staff/Resourcing and Robustness of Contract Management, Performance and Quality Arrangements	11%			
Assurances on Information /IT Security and Data Protection	10%			
	Sub Total	XXXXX	XXXXX	
Social Value response evaluation – 10%				
Questions/Criteria	**Weighting**	**Score 0-60 (definitions below)**	**Weighted Scores**	**Evaluator comments**
Theme 4: Equal Opportunity	5%			
Theme 5: Wellbeing	5%			
	Sub Total	XXXXX	XXXXX	
Commercial/Price response evaluation – 25%				
Criteria	**Weighting**	**Score (Lowest Total Price**		**Procurement comments**

		divided by Tender Total Price multiplied by 25) – relative calculation	
Commercial response (Overall Total Price)	25%		
	Sub Total	XXXXX	
Total weighted score (Technical, Social Value, and Commercial scores added) for provisional Contract award		XXXXX	

The following scoring scheme/scale and definitions shall apply to the marking of the Technical/Quality evaluation areas – please note that no intermediate scores shall be permitted:

Mark/Score	Definition
0	Unanswered/does not meet requirements – unanswered or failing to provide confidence that the proposal will meet the requirements (serious reservations).
15	Average response/partially meets requirements - poor response with reservations. Response lacks convincing detail, and there is risk that the proposal will not be successful in meeting requirements.
30	Mostly meets requirements - response generally meets most of the requirements but lacks sufficient detail and/or has some weaknesses.
45	Good response/meets the requirements – good response with some supporting evidence, which demonstrates good understanding and provides a good level of confidence in the proposal.
60	Excellent response/fully meets requirements - comprehensive response that meets the requirements with detailed supporting evidence and no weakness, resulting in a high level of confidence in the proposal.

The following scoring scheme/scale and definitions shall apply to the marking of the Social Value evaluation areas – please note that no intermediate scores shall be permitted:

Mark/Score	Definition
0	Unacceptable - no response submitted, or the response fails entirely to demonstrate an ability to meet any of the Social Value requirements.
15	Poor - the response does not address all requirements and contains insufficient/limited detail or explanation to demonstrate how the Social

	Value requirements will be fulfilled and/or contains major inconsistencies.
30	Fair - the response addresses requirements and demonstrates a fair understanding of the requirements but lacks details on how certain Social Value offers made will be delivered and/or contains some inconsistencies.
45	Good - the response addresses all requirements and is sufficiently detailed to demonstrate a good understanding and provides details on how the Social Value requirements will be fulfilled (but some minor reservations), as to how Social Value offers made will be delivered.
60	Excellent - the response is completely relevant and excellent overall, and demonstrates a thorough understanding of the requirements and provides comprehensive and clear details of how Social Value offers made will be delivered.

Please note that a score of '0' for any criterion will give grounds for excluding/disqualifying that Tender from further consideration.

Optional Presentation stage (for shortlisted Suppliers/Tenderers only)

- No separate scoring approach, just a validation of the Technical, Social Value, and Commercial scores (as appropriate). We expect to invite the 3 highest scoring/ranked Tenderers (this may be increased in the event of tied scoring or decreased on review of the scoring differentials) in the Tender Proposal evaluation.

Evaluation Process

All scoring shall be carried out by an assigned evaluation panel. During the independent evaluation of the Tender submissions/Proposals, each evaluator shall separately (i.e. without conferring with other evaluators) scrutinise the quality of the answers/information given in each Tender (Qualification, Technical/Quality and Social Value responses). The Qualification responses will be marked as pass or fail. Those Tender submissions/proposals which pass, will be further evaluated, with each evaluator allocating a mark for each Technical/Quality and Social Value response in accordance with the scoring scheme and providing remarks supporting the score awarded (clear comments).

The Procurement representative shall review the Commercial Envelope with the Commercial/Price responses.

The panel will then come together for a moderation meeting, where the consensus scores for each Technical/Quality and Social Value response shall be agreed by the panel. During this meeting, the evaluators will discuss their independent marks until they reach a consensus regarding the marks that should be allocated to each Tenderer's answer to each question or response area.

The moderated Technical/Quality and Social Value Scores shall be added to the Commercial/Price Scores to determine the total weighted score for each Tenderer, which shall be used to identify a shortlist of Tenderers to proceed to presentation (optional) or provisional Contract award (subject to standstill period). We expect the 3 highest scoring/ranked Tenderers (this may be increased in the event of tied scoring or decreased on review of the scoring differentials) may be invited to meet and present to the evaluation panel if required.

A further evaluation stage will take place (for the relevant tenderers only) if a presentation takes pace and a final moderation meeting convened to agree the overall total weighted scores for the final ranking for provisional Contract award (subject to standstill period).

On completion of the evaluation in accordance with this evaluation methodology, the Tenderer which offers the most economically advantageous tender (highest ranked) shall provisionally be awarded the Contract (after standstill period). In the event that multiple Tenderers rank equally, then the Supplier with the highest score for the Technical/Quality evaluation shall be deemed the winner and provisionally awarded the Contract. Should the Tenderer ranked first decline to accept the Contract, then it will be offered to the next ranked Tenderer until it has been accepted (dependent upon the quality and viability of the remaining Tenders).

Unsuccessful Tenderers shall be offered feedback on their Tender.

The Buyer shall not be bound to accept the Tender/offer with the lowest Overall Total Price or any Tender, nor do we guarantee any value or volume. We also reserve the right not to award any Contract pursuant to this Procurement Call for Competition, and in no circumstances shall the Buyer be liable for any costs incurred by Tenderers.

ANNEX D: TERMS OF PARTICIPATION & SUMMARY TENDERING INSTRUCTIONS

Terms of Participation

The following Terms of Participation set out the conditions of participation in this Procurement Call for Competition including the rules in relation to the conduct of Tenderers and the specific rights of the Buyer and limits to Buyer's liability, which apply throughout this Procurement Call for Competition; failure for the Tenderer to comply may result in exclusion/disqualification.

1. Introduction

This Procurement Call for Competition/Invitation to Tender (ITT) is issued by the Secretary of State for Health and Social Care, acting through the Medicines and Healthcare products Regulatory Agency, acting as part of Crown (the Contracting Authority) and is being run as an open competition (above threshold).

Tender responses submitted must be in accordance with the requirements/instructions set out in the Invitation to Tender.

2. Purpose

The Tenderer should only use the information contained within the ITT/Bid Pack for the purposes intended for it (i.e. tendering for a Procurement Call for Competition).

3. Canvassing

The Tenderer must not directly or indirectly canvass any Minister, officer, public sector employee, member or agent regarding this Procurement Call for Competition or attempt to obtain any information from the same regarding this Procurement (except where and as permitted by the ITT). Any attempt by the Tenderer to do so may result in the Tenderer's disqualification from this Procurement.

4. Collusive Behaviour

The Tenderer must not:

- Fix or adjust any element of its Tender by agreement or arrangement with any other person, except where, such prohibited acts are undertaken with persons who are also participants in the Tender, or where disclosure to such person is made in confidence in order to obtain quotations necessary for the preparation of its Tender or obtain any necessary insurances;
- Communicate with any person other than the Buyer the value, price or rates set out in its Tender or information which would enable the precise or approximate value, price or rates to be calculated by any other person, except where such communication is undertaken with persons who are also participants in the Tender, or where disclosure to such person is made in confidence in order to obtain quotations necessary for the preparation of its Tender or obtain any necessary security;

- Enter into any agreement or arrangement with any other person, so that person refrains from submitting a Tender;
- Offer or agree to pay or give or do pay or give any sum or sums of money, inducement or valuable consideration directly or indirectly to any other person for doing or having done or causing or having caused to be done in relation to its Tender, any other Tender or proposed Tender, any act or omission.

If a Tenderer is in breach of this clause, the Buyer may (without prejudice to any other criminal or civil remedies available to it) exclude/disqualify the Tenderer from further participation in this Procurement Call for Competition.

5. Right to verify information

The Buyer may contact any of the Tenderer's customers, subcontractors or other third parties to whom information relates in the Tender, to ask that they testify that such information is accurate and true.

The Buyer reserves the right to seek third party independent advice or assistance to validate information submitted by a Tenderer and/or to assist in the tender evaluation process.

The Buyer reserves the right to conduct site visits of any premises, as appropriate.

The Buyer may require the Tenderer to clarify aspects of its Tender in writing and/or provide additional information. Failure to respond adequately may result in the rejection of the Tenderer/Tender and its elimination from further participation in all or part of this Procurement Call for Competition.

If the Tenderer has indicated it has certifications/accreditations or other documentary evidence, the Buyer may request copies as part of its due diligence.

6. Right to cancel or vary this Procurement Call for Competition

The Buyer reserves the right, subject to the rules set out in the Regulations, to:

- Change the basis of or the procedures for this Procurement Call for Competition at any time;
- Amend, clarify, add to or withdraw all or any part of the ITT at any time during this Procurement Call for Competition, including varying any timetable or deadlines set out in the ITT;
- Cancel all or part of this Procurement Call for Competition at any stage at any time;
- Accept or not accept any part, or all, of any Tender at its sole discretion; and/or
- Not award a Contract for some or all of the Goods and/or Services for which tenders are invited.

Tenderers accept and acknowledge that, and in accordance with the Regulations, the Buyer is not bound to accept any Tender or award a Contract with any Tenderer at all.

If the Buyer deems that none of the Tenders received in response to the ITT are satisfactory, it reserves the right to terminate all or part of this Procurement Call for Competition.

7. Right to Exclude/Disqualify

The Buyer may exclude/disqualify a Tenderer/Tender from this Procurement Call for Competition if the Tenderer fails to provide to the Buyer:

- Any information requested;
- A full and satisfactory response to any question or information request;
- A Tender, or response to the Buyer's queries, within any specified timescales; and/or
- Documentation referred to in its Tender.

The Buyer may exclude a Tenderer from participation in this Procurement Call for Competition at any stage, if it:

- Fails to comply fully with the requirements of this Procurement Call for Competition as set out in the ITT/Bid Pack;
- Has breached these Terms of Participation; or
- Has committed a wilful omission or misrepresentation in the Tender.

The Buyer may exclude a Tenderer from participation in this Procurement Call for Competition where there is a change in identity, control, financial standing or other factor impacting on the selection and/or award process, which would affect or would have affected the Buyer's evaluation of that Tender.

8. Status of the Invitation to Tender

No information contained in the ITT or in any communication made between the Buyer and a Tenderer in connection with this Procurement Call for Competition shall be relied upon as constituting agreement or representation that any contract be entered into in accordance with a Tender or at all.

The Buyer shall not be committed to any course of action as a result of:

- Issuing the ITT relating to this Procurement Call for Competition;
- Any communications with Tenderers or their representatives, agents or advisers in respect of this Procurement Call for Competition; and/or
- Any communications between Tenderers and the Buyer (whether directly or through their agents or representatives) in respect of this Procurement Call for Competition.

The ITT has been prepared in good faith but does not purport to be a comprehensive statement of all matters relevant to this Procurement nor has it been independently verified. Neither the Buyer nor its advisers, directors, officers, members, employees or other staff or agents:

- Accept any liability or responsibility for the adequacy, accuracy or completeness of the ITT/Bid Pack, or
- Make any representation or warranty, express or implied, with respect to the information the ITT contains nor shall any of them be liable for any loss of damage arising as a result of reliance on such information or any subsequent communication.

The Tenderer shall form its own conclusions and make its own independent assessment

of the Requirements and the Contract Terms and Conditions.

The Tenderer is responsible at its own expense, for obtaining all information required to prepare its Tender.

Any exclusions of liability of the Buyer do not apply to the extent of any deceit or fraudulent misrepresentation made by or on behalf of the Buyer.

9. Conflicts of Interest

The Buyer contracts with a number of third parties/suppliers to assist it in meeting its objectives, and the independence and impartiality of that support is critical. Tenderers and their nominated personnel must be free from having any actual or potential conflicts of interest, which could conceivably compromise the judgement and objectivity of the personnel and the impartiality and robustness of the Services.

10. Costs

The Buyer shall not reimburse any costs or expenses incurred by a Tenderer, Subcontractors or its advisors in connection with the preparation and/or submission of the Tender, including (without limit) where:

- This Procurement Call for Competition is cancelled, shortened or delayed for any reason (including, without limitation, where such action is necessary due to non-compliance or potential non-compliance with the law, including the Regulations);
- All or any part of the ITT is at any time amended, clarified, added to or withdrawn for any reason;
- A Contract is not awarded in respect of some or all of the Goods and/or Services for which Tenders are invited; or
- The Tenderer and/or its Tender is excluded/disqualified from participation in this Procurement Call for Competition for any reason, including breach of these Terms of Participation.

11. Confidentiality

Subject to the exceptions referred to below, the contents of the ITT/Bid Pack are being made available by the Buyer on the conditions that the Tenderer:

- Treats the ITT and its annexes/appendices as confidential at all times, unless the information is already in the public domain;
- Does not disclose, copy, reproduce, distribute or pass any of the information to any other person at any time or allow any of these things to happen, except where, and to the extent that, the Information has been publicised in accordance with Freedom of Information and/or Transparency;
- Only uses the information for the purposes of preparing a Tender (or deciding whether to respond); and
- Does not undertake any promotional or similar activity related to this Procurement Call for Competition within any section of the media.

A Tenderer may disclose, distribute or pass any of the Information to its Subcontractors, advisers or to any other person provided that:

- This is done for the sole purpose of enabling the Tenderer to submit its Tender and the person receiving the information undertakes in writing to keep the information confidential on the same terms imposed by these Terms of Participation; or
- It obtains the Buyer's prior written consent in relation to such disclosure, distribution or passing of Information; or
- The disclosure is made for the sole purpose of obtaining legal advice from external lawyers in relation to this Procurement; or
- The Tenderer is legally required to make such a disclosure; or
- The information has been published in accordance with the Freedom of Information and/or Transparency sections.

The Buyer may disclose information submitted by Tenderer during this Procurement Call for Competition to its officers, employees, agents or advisers or other government departments who are stakeholders in this Procurement Call for Competition.

All Central Government Departments and their Executive Agencies and Non-Departmental Public Bodies are subject to control and reporting within Government. In particular, they report to the Cabinet Office and HM Treasury for all expenditure. Further, the Cabinet Office has a cross Government role delivering overall Government Policy on public procurement – including ensuring value for money and related aspects of good procurement practice. For these purposes, the Buyer may disclose within HM Government any of the Tenderer's documentation or information (including any that the Tenderer considers to be confidential and/or commercially sensitive such as specific information in its Tender) submitted by the Tenderer to the Buyer during this Procurement Call for Competition. Tenderers taking part in this procurement consent to such disclosure as part of their participation in the Procurement Call for Competition.

12. Freedom of Information Act (FOIA) and Environmental Information Regulations (EIR)

In accordance with the obligations and duties placed upon public authorities by the FOIA and the EIR and in accordance with any government Code of Practice on the discharge of public authorities' functions under the FOIA, all information submitted to the Buyer may be disclosed under a request for information made pursuant to the FOIA and the EIR.

A Tenderer should note that the information disclosed pursuant to a FOIA or EIR request may include, but is not limited to, the disclosure of its Tender (including any attachments or embedded documents) and/or any score or details of the evaluation of its Tender.

If the Tenderer considers any part of its Tender or any other information it submits to be confidential or commercially sensitive, the Tenderer should:

- Clearly identify such information as confidential or commercially sensitive;
- Explain the potential implications of disclosure of such information taking into account and specifically addressing the public interest test as set out in the FOIA;

and

- Provide an estimate of the period of time during which it believes that such information will remain confidential or commercially sensitive.

If the Tenderer identifies that part of its Tender or other information it submits is confidential or commercially sensitive, the Buyer in its sole discretion will consider whether or not to withhold such information from publication. The Tenderer should note that, even where information is identified as confidential or commercially sensitive, the Buyer may be required to disclose such information in accordance with the FOIA or the EIR.

The Buyer is required to form an independent judgement of whether the Tenderer's information is exempt from disclosure under the FOIA or the EIR and whether the public interest favours disclosure or not. The Buyer cannot guarantee that any information indicated as being confidential or commercially sensitive by the Tenderer will be withheld from publication.

If the Tenderer receives a request for information under the FOIA or the EIR during and in relation to this Procurement Call for Competition, it should be immediately referred to the Buyer.

13. Transparency

In accordance with the Government's policy on transparency, the Buyer reserves the right to make all or part of the information/Tender publicly available (subject to any redactions made at the discretion of the Buyer by considering and applying relevant exemptions under the FOIA).

A Tender will not be published unless such disclosure is required in accordance with the Freedom of Information Act and/or the Transparency agenda. Tenderers should note that the terms of the proposed Contract shall permit the Buyer to publish the full text of such Contract after considering (at the Buyer's sole discretion) any representations made by the Tenderer/Supplier regarding the application of any relevant FOIA or EIR exemptions.

The Tenderer acknowledges and agrees that information contained within its Tender may be incorporated by the Buyer into any Contract awarded and as a result, it may be published in accordance with this section.

14. Intellectual Property Rights

The ITT/Bid Pack issued in connection with this Procurement Call for Competition shall remain the property of the Buyer and shall be used by the Tenderer only for the purposes of this Procurement Call for Competition.

The Tenderer grants the Buyer an irrevocable, perpetual, non-exclusive licence to copy, amend and reproduce any intellectual property contained within its Tender for the purposes of carrying out this Procurement Call for Competition; complying with the law and/or any government guidance; and/or carrying out the Buyer's business activities. This licence shall also permit the Buyer to sublicense the use of the Tender to its advisers or other Contracting Authorities for the same purposes.

15. Law and Jurisdiction

Any dispute (including non-contractual disputes or claims) relating to this Procurement Call for Competition shall be governed by and construed in accordance with the laws of England and Wales. The courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Procurement Call for Competition (including non-contractual disputes or claims).

Summary Tendering Instructions

1. Atamis e-Procurement portal

The Buyer shall be using the Atamis e-Procurement portal/system to run this Procurement Call for Competition and all communications and the submission of Tenders must be made through this system. Tenderers must ensure that their Tenders are submitted and received in full not later than the Tender Submission Deadline of 11/02/2025 Midday/12:00. The Buyer reserves the right to accept late submissions. Tenderers may also ask clarification questions before the deadline of 27/01/2025 Midday/12:00 (late questions may be answered).

There are 4 envelopes (Qualification, Technical, Social Value & Commercial) in the Atamis system. The relevant Tender responses must be uploaded into the respective envelopes. Further tendering instructions and notes may also be found in the qualification envelope in Atamis.

2. Instructions for Responding

Tenderers must answer all mandatory/required questions and requests for information accurately and as fully as possible. All information requested should be provided in the English (UK) language; no embedded files should be included in Tenders and the only information provided should be direct answers to the stated questions/requests for information. A range of questions may be asked including yes/no, options lists, text area questions (max. 32,768 character limit including spaces) and attachment questions. Failure to comply or the submission of incomplete proposals e.g. questions not answered or attachments not included (where requested) may result in the Tender being excluded/disqualified.

Do not answer questions by cross referring to other answers or to other materials. Each question answered must be complete in its own right; so there may be some duplication across areas in the Tender.

3. Tender Clarification

Where information or documentation is or appears to be incomplete, where specific documents are missing, or something is not clear, the Buyer (at its discretion) may ask the Tenderer to submit, supplement, clarify or complete the relevant information or documentation within an appropriate time limit.

4. Atamis Helpline

If you have an issue with the portal/system, please contact the Atamis helpdesk at support-health@atamis.co.uk with a clear description of the problem (ensuring that you leave plenty of time for issues to be resolved prior to any deadlines).