**Requirements Specification**

**For**

**Academic Collaboration on Artificial Intelligence**

**Contract Details**

 Contract: Services on Artificial Intelligence

 Contract Duration: Fixed term to 30 June 2022

 Contract Commences: 05/07/2021

 Procedure: Open Procedure

 Contract value: £100,000 excluding VAT

# Specification of Requirements

## Background to the requirements

The requirements in this specification are supplementary to and complement the Multi-Agency Advice Service (MAAS) project which is a 2.75 year project, funded by the NHSx AI Lab. Further background notes about this project are provided at Appendix 1: Additional Background to the Requirements.

## Requirements for this Project

NICE is looking for an academic partner (or a joint bid or consortium) to work with the NICE project team on developing aspects of content for the MAAS, relevant to NICE’s specific role and purpose. The academic partner will support NICE on the delivery of a project to develop the [NICE Evidence Standards Framework for Digital Health Technologies](https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies) to fully incorporate data driven technologies with embedded artificial intelligence, including those that use adaptive algorithms. Artificial intelligence (AI) technologies are broadly defined as technologies which include algorithms that can learn from new experiences, adjust outputs and perform human-like tasks. For this project the requirement will be to design and describe an approach to the classification of AI technologies that is sufficiently granular to be useful for the purposes of triage for HTA assessment. The framework will define standards for the levels and types of evidence that should be available, or developed, for each technology category within the classification that can be used to provide advice on the levels of evidence and types of evidence needed to demonstrate clinical and economic value in the UK health and care system. This includes evidence of effectiveness relevant to the intended use(s) of the technology and evidence of economic impact relative to the financial risk.

The outputs from this project will inform key content components of the MAAS service from NICE’s perspective by providing a standard reference and benchmark for describing appropriate evidence-generation plans by category of AI technology. This advice can then be aimed at those involved in the development and deployment of AI including innovators and technology developers and commercial organisations; commissioners and research funders and other investors who are considering funding the development of data driven technologies that incorporate AI, as well as evaluators and commissioners and a wide range of stakeholders.

There is a lot of interest in the development and application of AI technologies into health care and the field is developing rapidly. NICE’s focus is on the health technology assessment (HTA) of these technologies. Reporting standards for clinical trials of AI-based interventions and their protocols have been developed ([CONSORT-AI](https://www.clinical-trials.ai/consort) and [SPIRIT-AI](https://www.clinical-trials.ai/spirit), respectively) for non-adaptive AI algorithms. There is no equivalent of these reporting standards for HTA or for economic evaluations of AI-based interventions or consideration of technologies that incorporate adaptive algorithms.

NICE is committed to its leadership in being at the forefront of evaluating new and emerging technologies, including digital technologies. To achieve this, we need to commence this work which will support our work programmes and the wider system, building on our existing methods for assessing health technologies to deliver a robust framework for validating and evaluating the use of AI in digital health technologies, both their clinical effectiveness and their economic value.

## Scope of the Procurement

### Aims & Objectives

#### Some initial work has already been completed by NICE and its partners that has looked at the potential classification of data driven technologies that incorporate AI. For further details, see Appendix 2. This work focussed on developing an understanding of the ‘building blocks’ of these technologies that could inform an approach to classification that would be sufficiently granular to be useful for the purpose of triage for health technology assessment.

#### The output of the next phase of work and the subject of this tender will be to formulate a proposal for the pragmatic and proportionate classification of AI technologies, with a focus on health technology assessment. It is expected that this phase will build upon this initial work, refining it and completing it, ensuring that the resulting classification is fit for purpose by validating it through expert review and demonstrating its applicability by developing and using the classification to describe current examples of AI technologies and by developing a range of illustrative case studies against each of the proposed category sections (and subsections).

#### The approach to the classification should be constructed so that it can be applied across the broad spectrum of data driven and AI based technologies used in healthcare settings and will consider the numerous ‘elements’ of the technology which will impact on the evaluation methods and clinical evidence required for HTA, such as, for example:

* + - The algorithm(s) and type of learning e.g. supervised learning (classification and regression), unsupervised learning (clustering), Semi-supervised learning and human-AI interactions
		- The main purpose and sensory activities and inputs (e.g. images or sound)
		- Function and risk associated with using the technology
		- The type of AI or complexity of the technology
		- Autonomy and clinical risk.

#### In addition to clarifying the elements of the classification, it would also be important to understand how these elements relate to the system in which they operate. This is likely to require input from experts in AI who are familiar with the technical aspects of these technologies.

#### A literature review will be needed to underpin this work to supplement the work already undertaken, including the work described in Appendix 2. This would build on initial work and focus on broadening and updating the search for relevant classification systems and existing approaches to HTA of AI technologies and include a review of grey literature and including relevant international approaches.

#### Additional outputs for this work will be a report describing the literature review undertaken, the different elements of AI technologies considered for the classification, the range of classification approaches considered, a proposed classification and the rationale for it and a suggestion for the associated evidence levels, a PowerPoint presentation describing the proposed classification including some worked examples to illustrate its use and a manuscript for publication in a peer-reviewed journal. A checklist will also be developed which can be used to classify AI technologies into groups for evaluation. This checklist could be used, for example, by the AAC AI Award Teams to assist topic selection and programme planning, or by NICE evaluation teams to help them understand the various aspects of the technology that need to be taken into account for the purposes of HTA.

#### Of particular importance is how the proposed AI classification and evidence requirements sits alongside the classification in NICE’s evidence standards framework for digital health technologies. A further output will be for the academic partner to make recommendations on whether it is possible to expand the ESF to include AI technologies or if it should be a separate framework and, for each of these options, a recommendation is needed to suggest how the AI classification can be related to the evidence tiers for digital health technologies in the original evidence standards framework.

#### It will also be important to link and cross reference any proposals for a classification of AI technologies (for the purposes of HTA) back to MHRA’s approach to describing medical device classification rules in their guidance: medical device standalone software including apps (including IVDMDs) for the purposes of regulating the safety of medical devices, considering MHRA’s approach to describing function and intended purpose. A further output will be for the academic partner to make recommendations on how best to relate the proposed AI classification to the MHRA guidance, and to the new SaMD regulatory framework as it emerges, so it is clear to Industry and other partners what the nature of the clinical evidence requirements are along the various stages of the regulatory pathway. A further output will therefore be a mapping document, which explains the links and overlaps between the proposed classification and the MHRA’s approach to classification, highlighting where evidence standards overlap and where they are different.

#### The academic partner must be comfortable working with multiple parties in a collaborative and constructive way, including NICE staff and MAAS collaborators, NHSx (the commissioner) and colleagues at MHRA, which the NICE Team will support.

#### There are additional projects being funded as part of the NHSx AI Lab and so the Supplier may be required to link in with the evaluation work being done on other projects for consistency and to minimise duplication of effort.

#### It should be noted that the NICE Team will be a critical partnership for the academic partner. The NICE team will put in place a Steering Group for the project to guide the work and ensure system wide collaboration. The NICE team and the academic partner should work collaboratively. The NICE Team will provide specific HTA skills, experience and input into the project to help populate the clinical evidence standards element of the classification framework drawing on wider NICE teams and expertise including data and analytics and diagnostics. The academic partner will provide expertise in AI and an understanding of technology classifications and have the skills and capabilities to understand the relationships between the classification elements and requirements for HTA.

#### The deliverables for this contract are:

|  |  |
| --- | --- |
| **Deliverable** | **Due date** |
| **A report** describing the literature review undertaken, the different elements of AI technologies considered for the classification, the range of classification approaches considered and **the first iteration of the proposed classification and the rationale for it,** including how this relates to the current evidence standards framework for digital health technologies. | Q2 of FY202122 |
| The report should also **provide suggestions** **for evidence requirements** and evidence considerations for the different elements and sub-elements for the classification.  | Q2 of FY202122 |
| **A power-point presentation describing the proposed classification** including some worked examples to illustrate its use. | Q2 of FY202122 |
| **A checklist will also be developed which can be used to classify AI technologies into groups for evaluation**. This checklist could be used, for example, by the AAC AI Award Teams to assist programme planning, or by NICE evaluation teams to help them understand the various aspects of the technology that need to be taken into account for the purposes of HTA.  | Q3 of FY202122 |
| **A mapping document** suitable for publication as advice, which explains the links and overlaps between the proposed classification and the MHRA approach to classification highlighting where evidence standards overlap and where they are different. | Q4 of FY202122 |
| A **validation process** that the classification is fit for purpose through expert review.  | Q1 of FY 202223 |
| A final **iteration of the proposed classification and the rationale for it,** including how this relates to the current evidence standards framework for digital health technologies. | Q1 of FY 202223 |
| **A range of illustrative case studies** against each of the proposed category sections (and subsections) illustrating both the classification and the evidence standards.  | Q1 of FY 202223 |
| **A manuscript for publication** in a peer-reviewed journal. The manuscript may be jointly authored with members of the NICE team. | Q1 of FY 202223 |

### Constraints and Dependencies

#### The NICE Team and the academic partner will utilise Zoom and Microsoft Teams to meet and share documentation and so IT equipment that will allow the use of these platforms would be required.

#### The work is not based in a specific location. There may be requirements to travel to various locations for some meetings at set points in the process. Whilst all meetings are currently being done virtually via Zoom, it is hoped to be able to conduct certain key meetings in person in future.

#### It is anticipated that a lot of the work could be conducted remotely, in line with current Government guidance in response to the COVID-19 pandemic, but there may be a need to attend certain meetings / workshops / focus groups in person and so some travel will be required. Appropriate risk assessment will be conducted in order to accommodate any parties with specific health or work needs as best as practical.

### Roles and Responsibilities

#### The academic partner will have meetings with the primary contacts to report on progress against key deliverables/milestones and discuss next steps at appropriate intervals during different stages of the project (TBD).

### Monitoring contract delivery

### As a means to measure progress in the delivery of this project, a range of outputs and outcomes may be monitored. The list below is indicative, and will be confirmed once the contract has commenced:

### Draft literature search

### Draft classification frameworks

### Draft checklists

### Plans / facilitation notes for any planned workshops

### Communication materials

### Interim progress reports.

### Contract term

#### The contract will commence on 05/07/2021 and conclude on 30 June 2022. The contract cannot be extended beyond this date as the funding is time limited.

### Budget

#### The maximum budget for the evaluation work done within the lifespan of the project is fixed at £100,000 ex VAT.

## Requirements

### To submit a proposal that will be assessed, suppliers must include the following information within their proposals on the enclosed bidder response template:

#### A proposal, which outlines key aspects of the deliverables (see table in section 3.1.12), including:

#### Quality of the proposed methodology, which should cover:

#### Methodologies, activities and activity measurement for achieving each deliverable; including resources, systems or processes needed to achieve these deliverables as relevant.

#### Details of any assumptions you have made in developing your proposal and any risks with mitigation for those risks that you identify.

#### A proposed delivery plan for all aspects of the project, which includes milestones, dependencies and indicates resources required.

* + - 1. Project assurance, which should cover:
				1. Please state the project governance that you would use in order to ensure project delivery.
				2. Please state how your proposal complies with relevant legislation, regulations or industry standards that would be applicable to this work.

#### Experience, skills and expertise, which should cover:

#### Personnel who will be involved in delivery in the project, including their expertise (i.e. methodologies and subject-matter) they bring and examples of work previously undertaken. This should include two examples of their contributions to and achievements on past projects; especially any projects of similar complexity, and of relevance to the subject of this tender project. We expect for the leads of the project to be named and their experience outlined as a minimum.

#### Costs, which should include:

#### Clear costings for each element of the plan.

* + - * 1. This section of the application should be completed in the table below within the Response and Costing template.

|  |  |
| --- | --- |
| **Deliverable** | **Cost** |
| **A report** describing the literature review undertaken, the different elements of AI technologies considered for the classification, the range of classification approaches considered and **the first iteration of a proposed classification and the rationale for it,** including how this relates to the current evidence standards framework for digital health technologies. |  |
| The report should also **provide suggestions for evidence requirements** and evidence considerations for the different elements and sub-elements for the classification. |  |
| **A power-point presentation describing the proposed classification** including some worked examples to illustrate its use. |  |
| **A checklist will also be developed which can be used to classify AI technologies into groups for evaluation**. This checklist could be used, for example, by the AAC AI Award Teams to assist programme planning, or by NICE evaluation teams to help them understand the various aspects of the technology that need to be taken into account for the purposes of HTA.  |  |
| **A mapping document** suitable for publication as advice, which explains the links and overlaps between the proposed classification and the MHRA approach to classification highlighting where evidence standards overlap and where they are different. |  |
| A **validation process** that the classification is fit for purpose through expert review. |  |
| **A range of illustrative case studies** against each of the proposed category sections (and subsections) illustrating both the classification and the evidence standards.  |  |
| A **final** **iteration of the proposed classification and the rationale for it,** including how this relates to the current evidence standards framework for digital health technologies. |  |
| **A manuscript for publication** in a peer-reviewed journal. The manuscript may be jointly authored with members of the NICE team.  |  |

#### Please provide hourly rates for team members you consider necessary for delivering the work.

|  |  |
| --- | --- |
| **Role** | **Rate** |
|  |  |
|  |  |
|  |  |
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|  |  |
|  |  |
|  |  |

### Please provide one copy of each of the following policies and financial statements for your organisation:

* Health and Safety
* Environmental
* Equal Opportunities.

### NICE recognises that some SMEs (less than 50 people for a Small Enterprise and less than 250 for a Medium Enterprise) may not have formal policies available but still operate their businesses in a manner that is conducive to the above. If you are a SME and do not have formal policies in place, please submit with your response, a written statement on how your company operates in light of the above three areas of legislation and best practice.

### If your organisation (whole organisation including parent, group or subsidiary) has a turnover of £36 million pounds or greater then please provide a Modern Slavery Act Transparency Statement: this should set out the steps you have taken to ensure there is no modern slavery in your own organisation/business and that of your supply chain. If your organisation has taken no steps to ensure there is no modern slavery in your own organisation, then your statement should say so. [Please note: a parent organisation/ group statement is acceptable; this is compliance with the Modern Slavery Act 2015.]

### Please provide the last three years of audited accounts for your organisation and a current Balance Sheet. If your organisation is a Small, Medium Enterprise (SME) and you do not have audited accounts, please provide 3 years of balance sheets.

## Tender Evaluation and Selection Criteria

* 1. Evaluation
		1. NICE will review all tenders to ensure they are fully compliant with these instructions. Any non-compliant bid may be rejected.
		2. The Evaluation Methodology set out in this section will be used to evaluate the Suppliers’ submission/offer to this Invitation to Tender (ITT).
	2. Cost Evaluation
		1. The cost will be evaluated using the following formula:

Lowest Price / Suppliers Price X 30 (the weighting).

* 1. Criteria and Scoring Guide
		1. Each evaluator will independently evaluate each tender submitted and use the following guide to score each criterion. The scores of all evaluators per criterion will then be averaged and weighting applied to give an adjusted score. All clarifications required by NICE will be incorporated into the final evaluation.

|  |  |
| --- | --- |
| **Score** | **Guide** |
| -5  | The point is omitted |
| 0  | The point is mentioned but not explained |
| 1 |  Not acceptable |
| 2 | The point is possibly acceptable |
| 3  | The point is acceptable |
| 4  | The point is well made and acceptable |
| 5  | Exceeds Expectations / Best |

* 1. Selection Criteria
		1. The selection criteria that will be applied to this tender are:

|  |  |
| --- | --- |
| **Criteria** | **Weighting** |
| **Cost**  | **30%** |
| **Quality** | **30%** |
| **Experience**  | **30%** |
| **Project assurance** | **10%** |
| **Total** | **100%** |

* 1. Short Listed Suppliers for Interview and Evaluation
		1. NICE may choose to shortlist a bidder or Suppliers to present to the evaluation panel and clarify any outstanding areas or their proposal where NICE may have concerns or further questions. However, if no further concerns or questions are raised, NICE reserves the right to proceed to Contract Award.
		2. Each bidder interviewed will be re-scored independently of the tender response, based on their responses in the interview alone and re-ranked against each of the other bidders that were shortlisted for interview. This evaluation will have no bearing on the evaluation that resulted in the bidder being shortlisted to interview or not. Suppliers not invited to interview will be notified at the same time as shortlisted Suppliers.
		3. The scoring guide and criteria above will be used to score the interviewed bidder, however the weightings will not be applied, the composite score of the interview panel will form the basis of award. The interview will be in direct relation to the outstanding areas of the Suppliers proposal.
		4. Shortlisted Suppliers will be notified of the evaluation process on invitation to interview. It is critical that the Project Lead and at least one other prospective team member working on the project are in attendance and take a lead on the interview.
1. **Instructions and Guidance**
	1. Supplier Invitation to Tender
		1. Submission of final offers to this ITT shall be in accordance with Section 3 and 6.
		2. On receipt of final offers from Suppliers in response to this ITT, NICE and will evaluate each response using the Evaluation Methodology set out in section 5.5.
		3. The evaluation will form the basis of NICE’s decision to proceed to interview or Contract Award. Should NICE deem that interviews are required prior to finalising its decision to proceed to awarding the contract, the following procedure will be followed (see 6.2 below).
	2. Short-listed Suppliers for Interview
		1. NICE envisages that a number of Suppliers could be selected to attend a further interview post the tender evaluation. The shortlist for interview will be determined by the evaluation procedure, applying the criteria as described in section 4.5 of this document. Suppliers must ensure they are available to attend the interviews on the dates stated below.

|  |  |  |
| --- | --- | --- |
| **DAY** | **DATE** | **LOCATION** |
| Thursday | 17th June 2021 | Zoom Video Conference |

* 1. Procurement Timetable
		1. The estimated timetable for the remainder of this procurement is as follows:

|  |  |
| --- | --- |
|  **Stage** | **Date** |
| Issue final ITT documentation | 04/05/21 |
| Deadline for Expression of Interests  | 17:00 on 23/05/21 |
| Deadline for bidder questions | 23/05/21 |
| NICE final response to bidder questions deadline | 28/05/21 |
| Tender responses submission deadline | **16:00 on 04/06/21** |
| Tender evaluation period | 07/06/21 - 11/06/21 |
| Notify shortlisted Suppliers of Interview (if required) | 14/06/21 |
| Interviews | 17/06/21 |
| Preferred Bidder Notice and Unsuccessful Suppliers Debriefed | 21/06/21 |
| Alcatel period (10 days) | 21/06/21 - 01/07/21 |
| Contract Award | 02/07/21 |
| Contract Commences | 05/07/21 |

1. **Suppliers Instructions**
	1. This section sets out the general instructions for the submission of the tender / final offer from the Suppliers in response to this ITT. These instructions must be followed and adhered to. Any deviation from these instructions may result in your tender being rejected.
	2. Bidders must provide an Expression of Interest (EOI) to this tender. Bidders must email barney.wilkinson@nice.org.uk with a statement of interest in this tender no later than 17:00 (5.00pm) UK time on the 23rd May 2021. Failure to EOI may result in your tender being rejected.
	3. The tender submission offer must be returned no later than **16:00** (4.00pm) UK time on **04th June 2021**.
	4. All tender submission and final offers must be written in English and to be submitted electronically by email in a Microsoft word format to: contract.bids@nice.org.uk.
	5. The following appendices only must be completed, signed and provided as part of your bid submission no later **16.00** (4.00pm) UK time on **04th June 2021:**
* Bidders Response and Costing Document

**Forms requiring original signatures:**

* Form of Offer including Terms and Conditions queries form
* Competing Interest form
* Redaction Requests form
	1. All responses must be referenced as detailed in the final ITT for ease of evaluation.
	2. All offers must be submitted in GBP sterling and must be exclusive of Value Added Tax (VAT).
	3. Suppliers should answer all questions in section 3 as accurately and concisely as possible in the same order as the questions are presented. Where a question is not relevant to the Supplier, this should be indicated, with an explanation.
	4. Suppliers must be explicit and comprehensive in their responses to this ITT as this will be the single source of information on which responses will be scored and ranked. Suppliers are advised neither to make any assumptions about their past or current supplier relationships with NICE, nor to assume that such prior business relationships will be taken into account in the evaluation procedure.
	5. NICE reserves the right at any time:
		1. to issue amendments or modifications to the documents contained in the Invitation to Tender pack during the tender;
		2. to not bind itself to accept the lowest or any offer and reserves the right to accept an offer either in whole or in part, each item being for this purpose treated as offered separately;
		3. to purchase the most cost effective and economically advantageous offer from this tender and does not bind itself to the cheapest price or the overall winner of the scoring evaluation that may result from this procurement;
		4. to terminate this procurement at any time;
		5. to require Suppliers to provide additional information supplementing or clarifying any of the information provided in response to the requests set out in this ITT. NICE may seek independent financial and market advice to validate information declared, or to assist in the evaluation.
	6. NICE will not be liable for any cost incurred in relation to any part of this procurement activity throughout its lifecycle to close, including any costs or expenses incurred by any Supplier or the Supplier's Team or any other person in resource time, preparation of responses, attendance of meeting, or any other cost that the Supplier may incur.
	7. Costs shall be fixed for the duration of the contract and not subject to change, unless agreed in writing by both NICE and the Contractor.
	8. The costing spreadsheet of your offer must be transparent to NICE and not be password protected or have any part of the model hidden. All costs breakdowns must be shown within your response and provided in GBP sterling.
	9. Non Compliance and/or disqualification
		1. NICE expressly reserves the right to reject any proposal that:
* does not meet any minimum requirement in the tender;
* does not follow the instruction to tender guidance;
* is incomplete, or does not provide either an answer to any question or a reasonable explanation of why an answer to any question has been omitted;
* refuses to adhere to the Terms and Conditions of Contract.
	+ 1. NICE reserves the right to reject or disqualify a Supplier and/or the members of the Supplier’s Team where:
* the Supplier and/or the members of the Supplier’s Team contravene any of the terms and conditions of this ITT and/or any Associated Documents.
1. **Queries about the Procurement**
	1. All requests for clarification or further information in respect of this procurement should be addressed to NICE’s named contact point (section 9) or discussed during the relevant dialogue meeting with the representatives of NICE. No approach of any kind in connection with this procurement should be made to any other person within, or associated with, NICE.
	2. NICE will ensure that all applicants receive equal treatment during this procurement, and we will share all information requests and responses with all applicants.
	3. Any questions and answers will be collated and distributed by email to all the Suppliers throughout the tender period. The final clarification responses will be issued no less than 5 days prior to the tender submission deadline.
	4. Please note that that there will be no telephone or any informal or other kind of discussion between Suppliers and officers or directors of NICE after this document is dispatched other than the representative of NICE named in section 9.
	5. If NICE considers any question or request for clarification to be of material significance, both the question and the response will be communicated, in a suitably anonymous form to all Suppliers.
	6. All responses received and any communication from Suppliers will be treated in confidence but will be subject to paragraph 12.
2. **NICE’s Named Point of Contact**
	1. NICE’s named point of contact for this procurement is:

Barney Wilkinson

Procurement Manager
National Institute for Health and Care Excellence
2 Redman Place

London E20 1JQ

Email: barney.wilkinson@nice.org.uk

1. **Suppliers Named Point of Contact**
	1. Suppliers are asked to include a single point of contact in their organisation. NICE will not be responsible for contacting the Supplier through any route other than the nominated contact. The Supplier must therefore undertake to notify any changes relating to the contact promptly.
2. **Additional Information**
	1. NICE expressly reserves the right to require a Supplier to provide additional information supplementing or clarifying any of the information provided in response to the requests set out in the final ITT. NICE may seek independent financial and market advice to validate information declared, or to assist in the evaluation.
3. **Freedom of Information**
	1. In accordance with the obligations and duties placed upon public authorities by the Freedom of Information Act 2000 (“the FoIA”), all information submitted to NICE may be disclosed in response to a request made pursuant to the FoIA.
	2. In respect of any information submitted by a Potential Supplier that it considers to be commercially sensitive the Potential Supplier should:
* clearly identify such information as commercially sensitive;
* explain the potential implications of disclosure of such information; and
* provide an estimate of the period of time during which the Potential Supplier believes that such information will remain commercially sensitive.
	1. Please submit responses to Barney Wilkinson in the redaction request form with the completed tender offer.
	2. Where a Potential Supplier identifies information as commercially sensitive, NICE will endeavour to maintain confidentiality. Suppliers should note, however, that, even where information is identified as commercially sensitive, NICE might be required to disclose such information in accordance with the FoIA. Accordingly, NICE cannot guarantee that any information marked ‘commercially sensitive’ will not be disclosed.
1. **Procurement Transparency**
	1. In light of the Coalition Government’s need for greater transparency, Suppliers and those organisations looking to bid for public sector contracts should be aware that if they are awarded a contract for this work, the resulting contract between the supplier and NICE will be published in its entirety.
	2. In some circumstances, limited redactions will be made to some contracts before they are published in order to comply with existing law and for the protection of national security. Suppliers are asked to make any sections of their tender that they regard as Commercial in Confidence or subject to the non disclosure clauses of the FOIA or DPA clear within the submission documents. Please note that the total value (bottom line) of the agreement is required to be published under current EU regulations and the UK governments Transparency Agenda. Please do not hesitate to contact us if you require clarity upon this point.
	3. Please complete Annex 4 - Redaction Requests of the ITT, to notify NICE of any sections of the tender you regard as Commercial in Confidence.

**Appendices**

Please see other uploaded documents on Contracts Finder

1. Additional Background to the Requirements (below)
2. KITEC Report – RX264 Classification of AI Technologies Phase 1

# Appendix 1: Additional Background to the Requirements

**Multiagency Advice Service (MAAS) Project**

The requirements in this specification are supplementary to and complement the Multi-Agency Advice Service (MAAS) project which is a 2.75 year project, funded by the NHSx AI Lab.

The aim of the MAAS project is to collaboratively research, test and develop a multi-agency advice service that will offer support, information and advice on the regulation and health technology assessment pathways for artificial intelligence (AI) in health and care, and potentially other data-driven technologies. The project will facilitate collaboration between the partner agencies to identify challenges and barriers in the regulatory pathway and to resolve these.

The service will provide easy access to comprehensive information and support so that innovators (‘developers’) can meet robust measures of assurance in safety and quality, and health and care providers (‘adopters’) have the knowledge and tools to help them adopt and deploy the best AI technologies. The ambition is that the MAAS, along with other AI lab priorities, will support the UK to become a world-leading, thriving ecosystem for development and deployment of AI technologies.

The MAAS project is a collaboration between four regulatory bodies:

* the National Institute for Health and Care Excellence (NICE; with project oversight) provides national guidance and advice to improve health and social care,
* the Care Quality Commission (CQC) is the independent regulator of health and social care in England,
* the Health Research Authority (HRA) provides a unified national system for the governance of health research, and;
* the Medicines and Healthcare products Regulatory Agency (MHRA) ensures that medicines and medical devices work and are acceptably safe.

The MAAS project will be focused on the needs of people involved in the development (‘developers’) or deployment (‘adopters’) of AI and data-driven technologies in health and social care, whilst ensuring these technologies are deployed in a way that supports delivery of high-quality care. Developers could be from industry, academic researchers or professionals within the health and social care system. Adopters could be people working within care and health provider organisations, such as primary care, care homes, NHS trusts, clinical commissioning groups (CCGs) and local authorities to name a few.

The MAAS project will undertake the following activities:

* test the need for an online advice service that will provide support, information and guidance on regulation, evaluation, adoption and deployment for artificial intelligence (AI) and (possibly) other similar data-driven technologies in health and care. An external contractor will likely be procured to lead delivery of this aspect of the project;
* assess the current state of AI regulatory and health technology assessment (HTA), and identify regulatory gaps, overlaps between and opportunities for better collaboration among regulators, in order to make recommendations and develop new ways of working and to develop guidance that meets needs of key users.

The MAAS project commenced in July 2020 and will run to March 2023, by which time the service should have been developed, tested and running in public beta.

**Critical Need Access Pathway (CNAP) Project**

A further project funded by NHSx from April 2021 to June 2022, intimately linked to this procurement, is the Critical Need Access Pathway project. The academic partner will be required to liaise with this project team, which will be facilitated by NICE as it will require close links and collaborative working. The objective here is for NICE and MHRA to work jointly to research, design and scope an innovative licensing and access pathway for selected data driven technologies (with embedded AI) that meet certain “critical need” criteria to allow the technology to be fast tracked to a supported route to market, based on similar work that has been undertaken by NICE and MHRA for medicines. This will involve consideration of a minimum/appropriate level of evidence for deployment in the NHS and the appropriate form of managed access arrangements, including requirements for continuous data (evidence) collection regimes for different types of data driven technologies and consideration of appropriate reimbursement models. This work will be jointly led by the NICE/MHRA team but will be closely linked to the first project and close communications between the two projects will be needed to ensure a consistent approach.