

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE CONSULTANCY AGREEMENT FOR SPECIFIC PROJECT SERVICES

1. BASIC DETAILS

1.1.	NAME AND ADDRESS OF CONTRACTOR (including Company Registration Number if relevant)	RAND Europe Community Interest Company Westbrook Centre Milton Road, Cambridge CB4 1YG		
1.2.	DESCRIPTION OF CONTRACTOR	Evaluation services		
1.3.	DESCRIPTION OF PROJECT SERVICES	Independent evaluation partner for the AI multi-agency advice service		
1.4.	NICE BUDGET HOLDER	[REDACTED], Director, NICE Scientific Advice		
1.5.	NICE PROJECT MANAGER	[REDACTED], Principal Scientific Adviser		
1.6.	NOMINATED MANAGER OF CONTRACTOR	[REDACTED]		
1.7.	CONTRACTOR AUTHORISED SIGNATORY	[REDACTED]		
1.8.	DATE AGREEMENT SIGNED	18 Jun 2021		
1.9.	DATE AGREEMENT COMES INTO EFFECT (IF DIFFERENT FROM ABOVE)	14 D	06 M	21 Y
1.10.	DATE AGREEMENT ENDS (IF FIXED DATE)	31 D	03 M	23 Y
1.11.	CONTRACT NUMBER	[REDACTED]		
1.12.	PROJECT NUMBER	[REDACTED]		

IT IS AGREED AS FOLLOWS

2. DEFINITIONS

"Agreement"	this Agreement and any Annexes attached to it.
"Background"	means any Intellectual Property and Copyright owned or controlled by any Party prior to commencement of or independently from the Project, and which the owning Party contributes or uses in the course of performing the Project.
"the Contractor"	the person in 1.1 or any partner, employee, agent, sub-Contractor or other lawful representative of the person in 1.1.
"Digital Design Agency"	an organisation procured by NICE who will be a collaborator on the project being evaluated by the Contractor
"Intellectual Property and Copyright"	means any and all patents, trademarks, service marks, domain names, registered designs, utility models, applications for and the right to make applications for any of such rights, inventions, Know-How (as defined below), rights to restrain disclosure of any confidential information, unregistered trademarks and service marks, trade and business names, including rights in any get-up or trade dress, copyrights, (including rights in computer software and in websites) unregistered design rights and other rights in designs and rights in databases, database right; rights under licences, consents, orders, statutes or otherwise in respect of any rights of the nature specified in this definition "Intellectual Property"; and rights of the same or similar effect or nature as or to those above in each case in any jurisdiction.

"Know How"	means all information not publicly known which is used or required to be used in or in connection with the Services and Supply existing in any form (including, but not limited to, that comprised in or derived from engineering, chemical and other data, specifications, formulae, experience, drawings, manuals, component lists, instructions, designs and circuit diagrams, brochures, catalogues and other descriptions) and relating to the design, development, manufacture or production of any products; the operation of any process; the performance of any Services and Supply; the selection, procurement, construction, installation, maintenance or use of raw materials, plant, machinery or other equipment or processes; the rectification, repair or service or maintenance of products, plant, machinery or other equipment; the supply, storage, assembly or packing of raw materials, components or partly manufactured or finished products; quality control, testing or certification of any person.
"MAAS Partners"	employees of other organisations who participate in the MAAS, including: Health Research Authority; Medicines and Healthcare Products Regulatory Agency, and; Care Quality Commission.
"the Milestones"	the milestones as set out in Annex 2.
"NICE"	The National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester. M1 4BT
"the Project Services"	the Project Services set out in 1.3 as more fully described in Annex 1.

3. AGREEMENT

- 3.1. In consideration of NICE making certain payments to the Contractor, the Contractor has agreed to provide the Project Services to NICE on the terms and conditions of this Agreement
- 3.2. The payments for the Project Services are fixed and no further payments shall be made by NICE.

4. OBLIGATIONS OF THE CONTRACTOR

- 4.1. The Project Services
 - 4.1.1. The Contractor shall carry out the Project Services in accordance with Annex 1 and to a quality acceptable to NICE.
 - 4.1.2. No material changes to the Project Services shall be permitted without the written consent of NICE Project Manager.

- 4.1.3. The Contractor shall use its best endeavours to achieve the milestones set out in Annex 2 ("the Milestones").
- 4.2. Sub-Contractors
 - 4.2.1. The Contractor shall agree with NICE the use of any sub-Contractor to carry out any part of the Project Services.
 - 4.2.2. The Contractor shall ensure that any sub-Contractor it uses adheres to the obligations of this Agreement as if the sub-Contractor were the Contractor.
- 4.3. Instructions
 - 4.3.1. The Contractor shall comply fully with the instructions of the Project Manager and, if the Contractor is working in NICE, with the office rules of NICE.
- 4.4. Financial Control
 - 4.4.1. The Contractor shall keep accurate books and accounts in respect of the Project Services and, if requested in writing by NICE, shall (at its own expense) have them certified by a professional firm of auditors.
 - 4.4.2. The Contractor shall permit the NICE to inspect and take copies (at NICE's expense) of any financial information or records NICE requires which relate to this Agreement.
- 4.5. Communication
 - 4.5.1. The Contractor shall ensure that all communications with NICE concerning the Project Services shall only be between the nominated representatives of both Parties, that is, NICE Project Manager who shall be the Manager nominated by NICE from its own staff or such other person as NICE shall nominate in writing, and the nominated manager of the Contractor.
- 4.6. Laws and Regulation
 - 4.6.1 The Contractor shall adhere to all laws and regulations relating to the provision of the Project Services.
 - 4..6.2 The Contractor shall comply in all material respects with applicable environmental laws and regulations in force from time to time in relation to the Services. Where the provisions of any such legislation are implemented by the use of voluntary agreements or codes of practice, the Contractor shall comply with such agreements or codes of practices as if they were incorporated into English law subject to those voluntary agreements being cited in tender documentation.
 - 4.6.3 While at NICE's Offices, the Contractor shall comply, and shall ensure that its employees comply with, the requirements of relevant Health and Safety and other relevant legislation, including regulations and codes of practice issued thereunder, and with NICE's and any Beneficiary's own policies and procedures.

4.6.4 The Contractor shall at all times maintain a specific Health and Safety at Work policy relating to the employment of his own staff whilst carrying out their duties in relation to the Contract on the NICE's or any Beneficiary's premises. The Contractor shall ensure the co-operation of its employees in all prevention measures designed against fire, or any other hazards, and shall notify NICE's of any change in the Contractor's working practices or other occurrences likely to increase such risks or to cause new hazards.

4.7. Taxation

4.7.1 Where the Contractor or Key Individuals supplied by the Contractor are liable to be taxed in the UK in respect of consideration received under this contract, the Contractor shall, and ensure that the Key Individuals shall, at all times comply with the Income Tax (Earnings and Pension) Act 2003 (ITEPA) and all other statutes and regulations relating to income tax in respect of that consideration.

4.7.2 Where the Contractor or Key Individuals are liable for National Insurance Contributions (NICs) in respect of consideration received under this contract, , the Contractor shall, and ensure that the Key Individuals shall, at all times comply with the Social Security Contributions and Benefits Act 1992 (SSCBA) and all other statutes and regulations relating to NICs in respect of that consideration.

4.7.3 NICE may, at any time during the term of this contract, request the Contractor to provide information which demonstrates:

- (a) how the Contractor or the Key Individuals comply with clauses 4.7.1 and 4.7.2 above; or why
- (b) Clauses 4.7.1 and 4.7.2 are not applicable to the Contractor or the Key Individuals.

4.7.4 Where applicable, a request under clause 4.7.3 above may specify the information which the Contractor or the Key Individuals must provide and the period within which that information must be provided.

4.7.5 NICE may terminate this Contract if:

- (a) in the case of a request mentioned in clause 4.7.3 above:-
 - (i) The Contractor or the Key Individuals fails to provide information in response to the request within twenty [20] days, or
 - (ii) The Contractor or the Key Individuals provides information which is inadequate to demonstrate either compliance with clauses 4.7.1 and 4.7.2 above or why these

clauses do not apply to either the Contractor or the Key Individuals;

(b) in the case of a request mentioned in clause 4.7.4 above the Contractor fails to provide the specified information within twenty [20] days, or

(c) it receives information which demonstrates that, at any time when clauses 4.7.1 and 4.7.2 apply to the Contractor, the Contractor is not complying with those clauses.

4.7.6 NICE may supply any information which it receives under Clause 4.7.3 to the Commissioners of Her Majesty's Revenue and Customs for the purpose of the collection and management of revenue for which they are responsible.

5. OBLIGATIONS OF NICE

5.1. Monitoring

NICE shall monitor the provision of the Project Services at its discretion. To assist in this, the Contractor shall provide such written reports as NICE shall reasonably request.

6. TERM

6.1. Except for those clauses 10, 12 and 16 which shall continue after this Agreement terminates, this Agreement shall begin on the date set out in clauses 1.8 or 1.9 and end on the date set out in clause 1.10. If there is no date in clause 1.10 then this Agreement shall continue until the Project Services are completed to the satisfaction of NICE or such other time as shall be notified by NICE to the Contractor.

7. PAYMENT

- 7.1. Subject to the due performance of the Contractor's obligations, NICE will
- pay all invoices submitted by the Contractor in accordance with Annex 4 within 30 days of their receipt.
- 7.2. The Contractor shall send all invoices to NICE, T53 Payables 4545, Phoenix House, Topcliffe Lane, Wakefield WF3 1WE clearly quoting the contract number
- 7.3. Invoices sent to NICE shall be accurate and correct in all respects.
- 7.4. NICE reserves the unconditional right to withhold payment of the final invoice or invoices until the applicable Project Services are successfully concluded to the satisfaction of NICE and NICE receives a copy of any relevant work created as a result of the Project Services in a form acceptable to the NICE.

8. STAFF AND RESOURCES

- 8.1. The Contractor shall be fully responsible in every way for all its staff and all consultants (whether part-time or full-time).
- 8.2. The Contractor shall ensure that it complies with all current employment legislation and in particular, does not unlawfully discriminate within the meaning of the Race Relations Act 1976 (as amended), the Equal Pay Act 1970, the Sex Discrimination Act 1975 (as amended), the Disability Discrimination Act 1995 (as amended), the Part Time Workers (Prevention of Less Favourable Treatment) Regulations 2000, the Fixed Term Employees (Prevention of Less Favourable Treatment) Regulations 2002, the Equality Act 2006, the Employment Equality (Religion or Belief) Regulations 2003, the Employment Equality (Sexual Orientation) Regulations 2003, the Equality Act (Sexual Orientation) Regulations 2007, the Employment Equality (Sex Discrimination) Regulations 2005, the Employment Equality (Age) Regulations 2006, or any other relevant legislation relating to discrimination in the employment of employees for the purpose of providing the Services. The Contractor shall take all reasonable steps (at its own expense) to ensure that any employees employed in the provision of the Services do not unlawfully discriminate within the meaning of this Clause 8.2 and shall impose on any sub-Contractor obligations substantially similar to those imposed on the Contractor by this Clause 8.2; and
- 8.3 in the management of its affairs and the development of its equality and diversity policies, the Contractor shall co-operate with NICE in respect of NICE's obligations to comply with statutory equality duties. The Contractor shall take such steps as NICE considers appropriate to promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age in the provision of the Services.
- 8.4 The Contractor shall not:
- 8.4.1 discriminate directly or indirectly or by way of victimisation or harassment against any person on racial grounds within the meaning of the Race Relations Act 1976 (as amended) ("**the 1976 Act**") contrary to Part II (Discrimination in the Field of Employment) and/or Part III (Discrimination in Other Fields) of the 1976 Act;
 - 8.4.2 contravene Part IV (Other Unlawful Acts) of the 1976 Act.
- 8.5 The Contractor shall notify NICE immediately of any investigation of or proceedings against the Contractor under the 1976 Act and shall cooperate fully and promptly with any requests of the person or body conducting such investigation or proceedings, including allowing access to any documents or data required, attending any meetings and providing any information requested.
- 8.6 The Contractor shall indemnify NICE against all costs, claims, charges, demands, liabilities, damages, losses and expenses

incurred or suffered by NICE arising out of or in connection with any investigation conducted or any proceedings brought under the 1976 Act due directly or indirectly to any act or omission by the Contractor, its agents, employees or sub-Contractors.

- 8.7 The Contractor shall impose on any sub-Contractor obligations substantially similar to those imposed on the Contractor by this Clause 8.
- 8.8 NICE shall have the right to be consulted on what staff will be appointed to provide the Project Services.
- 8.9 The Contractor undertakes to NICE that any person assigned to NICE to supply the Project Services is a full-time employee of the Contractor and that employee shall not be transferred from this assignment without the prior written consent of NICE.

9. INSURANCE

- 9.1. The Contractor shall maintain an appropriate insurance policy to cover its liabilities to NICE under this Agreement.
- 9.2. The Contractor shall supply a copy of any relevant insurance policy to NICE together with proof of payments of all premiums if required.

10. INTELLECTUAL PROPERTY AND COPYRIGHT

- 10.1. The Contractor recognises that the Intellectual Property and Copyright in any work which is created as a result of the Project Services by the Contractor or its servants, agents, consultants or independent Contractors shall belong to NICE. Nothing in this Agreement shall serve to transfer or assign ownership in any Background that shall remain owned by the Party introducing the same. The Contractor hereby grants NICE a non-exclusive, royalty-free, worldwide licence to use the Contractor's Background in any work which is created as a result of the Project Services for the benefit of using that work.
- 10.2. In consideration of NICE paying for the Project Services the Contractor with full title guarantee assigns or agrees to procure the assignment to NICE of all vested contingent and future Intellectual Property rights and Copyright in any work created as a result of the Project Services to hold to NICE its successors and assigns absolutely throughout the world for the full period of those rights. NICE hereby grants the Contractor a non-exclusive, royalty-free, worldwide licence to use the Know-How in any work which is created as a result of the Project Services by the Contractor or its servants, agents, consultants or independent Contractors.
- 10.3. The Contractor warrants to NICE that in relation to any work created by itself, its servants, agents, consultants or independent Contractors, as a result of the Project Services, that:-

- 10.3.1. such work is not a violation of any existing copyright anywhere;
- 10.3.2. such work does not contain anything objectionable, obscene or libellous;
- 10.3.3. all statements contained in any such work which purport to be facts are true.
- 10.4. If the Contractor incorporates any copyrightable work in any work it produces or has produced on its behalf then it shall ensure that appropriate permissions to use that work are obtained in writing. The NICE Project Manager shall have the right to see such permissions.
- 10.5. The Contractor shall procure that any independent author or part-author of any copyrightable material created as a result of the Project Services, assigns the copyright with full title guarantee to NICE and waives any moral rights under the Copyright, Designs and Patents Acts 1988. Any assignment and/or waiver under this sub-clause shall be on NICE's standard terms set out in Annex 3. The Contractor shall do this as soon as reasonably possible after the creation of any such work.
- 10.6. It is the policy of NICE to associate authors with their works. However, there may be exceptional circumstances where this would be to the detriment of the NICE. In an exceptional circumstance NICE, as copyright owner, would reserve the right to disassociate the author from the work.

11. PUBLIC REPUTATION OF THE PARTIES

- 11.1. Both Parties recognise the other Party's public reputation and legal responsibilities. Each Party shall use all reasonable endeavours not to harm or compromise these.
- 11.2 The parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA and/or the DPA, the content of this Contract is not Confidential Information. NICE shall be responsible for determining in its absolute discretion whether any of the content of the Contract is exempt from disclosure in accordance with the provisions of the FOIA and/or the DPA.
- 11.3 Notwithstanding any other term of this Contract, the Contractor hereby gives his consent for NICE to publish the Contract in its entirety, including from time to time agreed changes to the Contract, to the general public. And agrees to the public re-use of the documents provided that such reuse cites the source and do not misuse or deliberately mislead.

12. CONFIDENTIALITY

- 12.1. In respect of any Confidential Information it may receive from the other party ("the Discloser") and subject always to the remainder of this clause 12, each party ("the Recipient") undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party, without the Discloser's prior written consent provided that:
- 12.2 the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the commencement of the Contract;
- 12.3 the provisions of this clause 12 shall not apply to any Confidential Information which:
- (a) is in or enters the public domain other than by breach of the Contract or other act or omissions of the Recipient;
 - (b) is obtained by a third party who is lawfully authorised to disclose such information; or
 - (c) is authorised for release by the prior written consent of the Discloser; or
 - (d) the disclosure of which is required to ensure the compliance of NICE with the Freedom of Information Act 2000 (the FOIA).
- 12.4 Nothing in this clause 12 shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable law or, where the Contractor is the Recipient, to the Contractor's immediate or ultimate holding company provided that the Contractor procures that such holding company complies with this clause 12 as if any reference to the Contractor in this clause 12 were a reference to such holding company.
- 12.5 The Contractor authorises NICE to disclose the Confidential Information to such person(s) as may be notified to the Contractor in writing by NICE from time to time to the extent only as is necessary for the purposes of auditing and collating information so as to ascertain a realistic market price for the goods supplied in accordance with the Contract, such exercise being commonly referred to as "benchmarking". NICE shall use all reasonable endeavours to ensure that such person(s) keeps the Confidential Information confidential and does not make use of the Confidential Information except for the purpose for which the disclosure is made. NICE shall not without good reason claim that the lowest price available in the market is the realistic market price.
- 12.6 The Contractor acknowledges that NICE is or may be subject to the FOIA. The Contractor notes and acknowledges the FOIA and both the respective Codes of Practice on the Discharge of Public Authorities'

Functions and on the Management of Records (which are issued under section 45 and 46 of the FOIA respectively) and the Environmental Information Regulations 2004 as may be amended, updated or replaced from time to time. The Contractor will act in accordance with the FOIA, these Codes of Practice and these Regulations (and any other applicable codes of practice or guidance notified to the Contractor from time to time) to the extent that they apply to the Contractor's performance under the Contract.

12.7 The Contractor agrees that:

12.7.1 Without prejudice to the generality of clause 12.2, the provisions of this clause 12 are subject to the respective obligations and commitments of NICE under the FOIA and both the respective Codes of Practice on the Discharge of Public Authorities' Functions and on the Management of Records (which are issued under section 45 and 46 of the FOIA respectively) and the Environmental Information Regulations 2004;

12.7.2 subject to clause 12.7.3, the decision on whether any exemption applies to a request for disclosure of recorded information is a decision solely for NICE;

12.7.3 where NICE is managing a request as referred to in clause 12.7.2, the Contractor shall co-operate with NICE and shall respond within five (5) working days of any request by it for assistance in determining how to respond to a request for disclosure.

12.8 The Contractor shall and shall procure that its sub-Contractors shall:

12.8.1 transfer any request for information, as defined under section 8 of the FOIA, to NICE as soon as practicable after receipt and in any event within five (5) working days of receiving a request for information;

12.8.2 provide NICE with a copy of all information in its possession or power in the form that NICE requires within five (5) working days (or such other period as NICE or a Beneficiary may specify) of NICE or a Beneficiary requesting that Information; and

12.8.3 provide all necessary assistance as reasonably requested by NICE to enable NICE to respond to a request for information within the time for compliance set out in section 10 of the FOIA.

12.9 NICE may consult the Contractor in relation to any request for disclosure of the Contractor's Confidential Information in accordance with all applicable guidance.

12.10 This clause 12 shall remain in force without limit in time in respect of Confidential Information which comprises Personal Data or which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in the Contract,

this clause 12 shall remain in force for a period of 3 years after the termination or expiry of this Contract.

- 12.11 In the event that the Contractor fails to comply with this clause 12, NICE reserves the right to terminate the Contract by notice in writing with immediate effect.

13. Data Protection

- 13.1 The Contractor shall comply with the (a) the UK GDPR; (b) the Data Protection Act 2018; (c) as applicable, General Data Protection (GDPR) Regulation, Regulation (EU) 2016/679 ("GDPR"); (d) any laws which implement any such laws; and (e) any laws that replace, extend, re-enact, consolidate or amend any of the foregoing, where "**UK GDPR**" means GDPR as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018, with adjustments as provided in the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019.
- 13.1.1 The Contractor undertakes to maintain technical and organisational security measures sufficient to comply at least with the obligations imposed on NICE and any Beneficiary by Section 66 of the DPA 2018;
- 13.1.2 The Contractor will only process Personal Data for and on behalf of NICE and any Beneficiary, in accordance with the instructions of NICE or such Beneficiary and for the purpose of performing the Services in accordance with the Contract and to ensure compliance with the 2018 Act;
- 13.1.3 to allow NICE to audit the Contractor's compliance with the requirements of this Clause 13 on reasonable notice and/or to provide NICE with evidence of its compliance with the obligations set out in this Clause 13
- 13.2 The Contractor agrees to indemnify and keep indemnified NICE and any Beneficiary against all claims and proceedings and all liability, loss, costs and expenses incurred in connection therewith by NICE and any Beneficiary as a result of any claim made or brought by any individual or other legal person in respect of any loss, damage or distress caused to that individual or other legal person as a result of the Contractor's unauthorised processing, unlawful processing, destruction of and/or damage to any Personal Data processed by the Contractor, its employees or agents in the Contractor's performance of the Contract or as otherwise agreed between the Parties.
- 13.3 Both Parties agree to use all reasonable efforts to assist each other to comply with the 2018 Act. For the avoidance of doubt, this includes the Contractor providing NICE and any Beneficiary with reasonable assistance in complying with subject access requests served on NICE and any Beneficiary under Article 15 of GDPR or other applicable Section of the 2018 Act and the Contractor consulting with NICE and

any Beneficiary prior to the disclosure by the Contractor of any Personal Data in relation to such requests.

14. GIFTS AND PAYMENTS OF COMMISSION

- 14.1. The Contractor shall not offer or give to any member of staff of NICE or a member of their family any gift or consideration of any kind (including the payment of commission) as an inducement or reward for doing something or not doing something or for having done something or having not done something in relation to the obtaining of or execution of this Agreement or any Agreement with NICE. This prohibition specifically includes the payment of any fee or other consideration for any work in respect of or in connection with the Project Services carried out by a member of staff of NICE to that member of staff or to a member of their family.
- 14.2. Any breach of this condition by the Contractor or anyone employed by the Contractor (with or without the knowledge of the Contractor) or the commission of any offence under the Bribery Act 2010 shall entitle NICE to terminate this Agreement immediately and/or to recover from the Contractor any payment made to the Contractor.

15. INDEMNITY

- 15.1. If the Contractor shall breach this Agreement in any way then it shall fully indemnify NICE from any losses, costs, damages or expenses of any kind, whether direct or indirect, which arise out of or are connected with that breach.

16. LIMITATION OF LIABILITY

- 16.1. NICE shall not be liable to the Contractor for any indirect or consequent loss, damage, injury or costs whatsoever which arise out of or are connected with NICE's adherence or non-adherence to the terms and conditions of this Agreement. Except in the case of death or personal injury caused by negligence, and fraudulent misrepresentation or in other circumstances where liability may not be so limited under any applicable law

17. TERMINATION

This Agreement shall terminate in the following circumstances -

- 17.1. Breach
- 17.1.1. In the event that either Party fails to observe or perform any of its obligations under this Agreement in any way then the other Party may end this Agreement on 30 days written notice; but
- 17.1.2. If the breach complained of by a Party, cannot be remedied to the satisfaction of that Party, then this Agreement shall end immediately on the service of such notice on the other Party;

17.1.3. In every other case if the breach complained of is remedied to the satisfaction of a Party within the notice period this Agreement shall not end;

17.2. Repeat of Breach

17.2.1. Either Party reserves the right to end this Agreement immediately by written notice if a Party repeats any breach of this Agreement after receiving a written notice from the other Party warning that repetition of the breach shall or may lead to termination (whether or not the repeated breach is remedied within 30 days);

17.3. Insolvency

17.3.1. This Agreement shall end immediately if the Contractor goes into liquidation or suffers a receiver or administrator to be appointed to it or to any of its assets or makes a composition with any of its creditors, or is in any other way unable to pay its debts;

17.4. Change of Management Control

17.4.1. NICE reserves the right to immediately end this Agreement upon any change of the Contractor's management or control within 28 days of NICE finding out of such change. The Contractor shall promptly notify NICE of any such change of management or control.

17.5. Unsatisfactory Evaluation of the Project Services

17.5.1. In the event that the outcome of any evaluation of the Project Services carried out by NICE under this Agreement is unsatisfactory NICE may terminate this Agreement on 30 days' written notice.

17.6 In addition to its rights under any other provision of the contract NICE may terminate the contract at any time by giving the Contractor three months' written notice

18. MISCELLANEOUS

It is further agreed between the Parties:

18.1. Waiver

18.1.1. No waiver or delay in acting upon or by NICE of any of the requirements of this Agreement shall release the Contractor from full performance of its remaining obligations in this Agreement.

18.2. Whole Agreement

18.2.1. The Parties acknowledge that this Agreement contains the whole Agreement between the Parties and supersedes all previous agreements whether express or implied.



18.3. Variation

18.3.1. This Agreement cannot be varied except in writing and signed by the lawful representatives of both Parties.



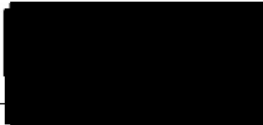

18.4. Governing Law

18.4.1 This Agreement shall be governed in all respects by English Law.

**Signed for and on behalf
of NICE**

	Signature	Name	Date
Procurement Manager			18 Jun 2021
Contract Manager			17 Jun 2021
Budget Holder			18 Jun 2021

**Signed for and on behalf
of the Provider**

	Signature	Name	Date
Project Supervisor			17 Jun 2021
Authorised Signatory:			17 Jun 2021

This contract is not valid until all Signatures have been completed

ANNEX 1

The Project Services

Scope of the project

- 1) The independent evaluation partner (CONTRACTOR) will deliver a formative evaluation and hand-over a robust summative evaluation strategy (including proposed metrics and data sources) by March 2023. The CONTRACTOR will deliver emerging learning throughout the project.
- 2) The CONTRACTOR will use a mixed-methods approach (i.e., quantitative and qualitative methods) to understand both scale of impact and to effectively attribute causality and identify counterfactual impact. Due to the nature of this programme and its potential impact in shaping national policy, the CONTRACTOR's evaluation will use elements of the four main evaluation designs:
 - a. Contribution (whether, how and how far did the programme or intervention contribute to the intended benefits?);
 - b. Process (how was the programme delivered?);
 - c. Economic (at this stage of the MAAS, what are the main benefits and how far do these justify the costs?); and
 - d. Theory-based (what contributed to change?)
- 3) The CONTRACTOR must work with multiple parties in a collaborative and constructive way, including all MAAS collaborators, NHSx (the commissioner) and the developer (TBC).
- 4) The purpose of the formative evaluation is to support the MAAS to be as effective in implementation as possible. This will be done through activities such as analysing baseline data in order to make recommendations on focus of the service, and undertaking process evaluation, particularly with regard to the project's interdependencies within the wider innovation ecosystem. As this is a complex intervention which will necessarily evolve, the CONTRACTOR will work in an ambiguous environment, and providing us with emergent messages on what they see is working and not working and why.

- 5) The summative evaluation strategy, once implemented, will be used by MAAS collaborators and commissioners in order to make future decisions about funding for this and other similar initiatives. It will also allow NHSX to report back to HM Treasury on the contribution being made by the MAAS to achieving the intended outcomes as described in the Theory of Change. It will be co-developed with the developer and the MAAS collaborators. It will focus on a range of outputs, outcomes and benefits including near-term (for example, but not limited to satisfaction of developers / adopters using the service) to long-term impacts (for example, but not limited to patients and citizens benefitting from AI and data-driven technologies). It will be underpinned by a logical and plausible theory of change or logic model. It will also have clearly defined metrics which are prioritised and have recommendations for gathering data.
- 6) Some deliverables from the evaluation will be used for external purposes such as communications; either as whole items or used as inputs by the MAAS Partners for developing these outputs.
- 7) The AI MAAS secretariat will support contact with the MAAS partners at predetermined time points, and potentially with wider stakeholders involved in the project in order complete the requisite activities and deliverables. The CONTRACTOR will agree with the secretariat such meetings with 1 month lead time.
- 8) The deliverables of the CONTRACTOR are described in detail in the attached updated evaluation protocol, and summarised below:
 - Evaluation protocol at inception, which will describe in more detail the methods to be used for this evaluation
 - Theory of Change (ToC)
 - 1 baseline data report (after the first quarterly meeting), which will describe what data is available, its quality and robustness, data gaps and where further data may be needed
 - 5 brief process evaluation reports (after 5 quarterly meetings), which will provide an update on the progression of MAAS, focusing on key areas of improvement
 - Draft and final summative evaluation strategy, which will provide a strategy for a future impact evaluation of MAAS, including economic components and suggested metrics

- 9) It should be noted that the Digital Design Agency will be a critical partnership for the evaluator. The CONTRACTOR and developer will work collaboratively; particularly as the developer will be gathering data to inform iterative design, delivery and then sustainable running of the service, which the evaluation partner should also benefit from. **The role of the CONTRACTOR is not to evaluate the work of the Digital Design Agency**; responsibility for this lies with the MAAS secretariat.
- 10) The CONTRACTOR will be required, as necessary, to link in with evaluation work being done on other projects funded by the AI lab for consistency and to minimise duplication of effort.

Supplier's agreed delivery plan is included within the attached evaluation protocol

RAND Europe will deliver the work as outlined in the submitted proposal, and detailed in the evaluation protocol that will be delivered at inception. Our data collection methods will include:

- Documentary review of documents held by MAAS
 - Interviews (10 initial, 15 follow up)
 - Half day theory of change workshop
 - Initial survey and 2 follow up surveys
 - Review of existing data held by MAAS
 - Desk research
- .

How the work will be delivered is described in the attached evaluation protocol.

11) Constraints and Dependencies

- a. The MAAS working group currently meet on a bi-weekly basis and use Zoom and Microsoft Teams to meet and share documentation and so IT equipment that will allow the use of these platforms would be required.
- b. 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, the working group hope to be able to conduct certain key meetings in person in future.
- c. Most of the work will be carried out remotely, in line with current Government guidance in response to the COVID-19 pandemic, but there will 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.

12) Roles and Responsibilities

- a. The CONTRACTOR 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 (6 quarterly meetings with RAND Europe evaluation team, fortnightly meetings with RAND Europe project manager to update on progress).
- b. The CONTRACTOR will openly and proactively identify any risks to contract delivery, prioritisation issues and bring this information along with considered options for moving forward to the MAAS contract manager. The CONTRACTOR will do this in a time-sensitive manner so that appropriate action can be taken when needed.
- c. The CONTRACTOR and MAAS contract manager will review plans for evaluation delivery on a bimonthly basis to ensure the contract is delivered smoothly. The CONTRACTOR should still bring any issues outside of these intervals for discussion and resolution as necessary

13) Monitoring contract delivery

- a. As a means to measure progress in the delivery of this evaluation, a range of outputs and outcomes will be monitored in advance of the due dates for these tasks; ranging from 2-12 weeks depending on the complexity of the deliverable or output.
 - i. Draft evaluation protocol (2 weeks)
 - ii. Draft baseline data collection plan (2 weeks)
 - iii. Evaluation instruments (e.g., surveys, interview guides, etc) (2 weeks)
 - iv. Agree the aims and outlines of the workshop (2 weeks)
 - v. Communication materials (2 weeks)

- vi. Interim brief process evaluation reports (2 weeks for first report; 1 week for subsequent unless there are substantive changes from contents of the meeting)
- vii. Outlines of reports (i.e. before work is commenced on gathering data / writing)
- viii. Outline of summative evaluation strategy with key questions / issues presented for MAAS working group feedback (2 weeks)

14) Ways of working

- a. The CONTRACTOR will meet remotely (e.g. video conferencing) on a biweekly basis with nominated MAAS Partners to discuss issues and report on delivery of the project. This will continue indefinitely unless otherwise agreed by both parties.
- b. The CONTRACTOR will make the MAAS secretariat aware of their support needs such as but not limited to contact details for interviewees or arrangements of workshops for delivery of the contract with as much notice as is possible so that the MAAS secretariat can support them optimally.
- c. The CONTRACTOR, MAAS Partners and MAAS contract manager and secretariat will primarily correspond via email.
- d. The CONTRACTOR, MAAS Partners and MAAS contract manager and secretariat will openly and proactively discuss any aspects of ways of working which could be improved.
- e. The CONTRACTOR and MAAS contract manager will review the contract delivery against milestones and delivery dates on a bimonthly basis. This will continue indefinitely unless otherwise agreed by both parties. Deliverables for this evaluation are described in the table below. If there are delays in beginning this evaluation, receiving data or documents from MAAS or other similar delays, this timeline would be discussed with RAND Europe and MAAS and reasonable adjustments would be made.

Deliverable	Date
Evaluation protocol	June 2021
Theory of Change	September 2021

Baseline data collection report	October 2021
Process evaluation report 1	January 2022
Process evaluation report 2	April 2022
Process evaluation report 3	July 2022
Process evaluation report 4	October 2022
Process evaluation report 5	January 2023
Draft summative evaluation strategy	December 2022
Final summative evaluation strategy	March 2023

15)Project management

- a. The CONTRACTOR's delivery will be overseen by key roles and contacts, which are:
 - i. Dr Tom Ling; as Project Leader, he will be responsible for the overall direction, quality and delivery,
 - ii. A project manager responsible for the day-to-day management, ensuring the project is delivered to agreed timescales and budget
 1. Project management will be further aided by the supplier's Programme Support Office, who will provide administrative assistance, and lead contractual and financial processes.

16)Ensuring effective communication between the evaluation team and the MAAS Secretariat.

- a. Along with feeding back findings at quarterly meetings to ensure this evaluation improves the value of MAAS to the health and innovation system, the CONTRACTOR will also schedule fortnightly meetings to update on progress, discuss any challenges that arise and ensure that the evaluation is meeting the needs of the project. These meetings will be attended by the project manager, who will also bring members of the evaluation team as needed.

17)Quality assurance

- a. A senior continuous QA reviewer and a final QA reviewer will be assigned to this project, with expertise in healthcare innovation and/or AI. The continuous QA reviewer will be available for advice throughout the evaluation and will provide critical input. They will also review all interim and final outputs including the initial evaluation protocol, the ToC and interim evaluation reports, and will provide a rigorous peer-review of the final outputs.
- b. The final QA reviewer will be independent from the evaluation team and will provide a rigorous peer-review of the final outputs for the project.
- c. The quality standard for all deliverables within the contract are defined in detail here https://www.rand.org/about/standards/standards_high.html and summarised below:
 - i. The problem should be well formulated, and the purpose of the study should be clear.
 - ii. The study approach should be well designed and executed.
 - iii. The study should demonstrate understanding of related studies.
 - iv. The data and information should be the best available.
 - v. Assumptions should be explicit and justified.
 - vi. The findings should advance knowledge and bear on important policy issues.
 - vii. The implications and recommendations should be logical, warranted by the findings, and explained thoroughly, with appropriate caveats.
 - viii. The documentation should be accurate, understandable, clearly structured, and temperate in tone.
 - ix. The study should be compelling, useful, and relevant to stakeholders and decisionmakers.
 - x. The study should be objective, independent, and balanced.

18) Where quality standards pre-agreed in the contract kick-off meeting are not met, the CONTRACTOR will ensure that the relevant outputs are iterated to the standard required within five working days of receiving feedback (unless otherwise agreed) at its own expense. The quality standards will include the following as principles:

- a. the deliverables must be clearly written, free from jargon and designed to be intelligible to a wide audience which could also include patients and the public
- b. the deliverables must be comprehensive, and require minimal further elaboration to impart sufficient knowledge to the MAAS working group. As a rule of thumb, the work shouldn't raise more questions than it answers
- c. the deliverables, and process evaluation reports in particular, should suggest potential solutions and options for improving the design and delivery of the MAAS, and not only identify gaps or issues. While we accept not all challenges will have easily identifiable solutions, and that

there is sometimes value in surfacing a gap alone, we would expect the majority of process evaluation findings to be amenable to solutions and therefore point to them.

19)Adhering to best practice and international standards

- a. The CONTRACTOR will adhere to robust, effective business processes as per international best practice certification, which includes but is not limited to:
 - i. ISO 9001:2015 on good quality management practices for knowledge-intensive organisations
 - ii. international standards for information security
 - iii. collecting, storing and analysing all data in a secure manner, and the management of any personal data is compliant with GDPR regulation; engaging the Data Protection Officer of the CONTRACTOR as appropriate to oversee data protection, and to advise on all data protection-related concerns.
- b. The CONTRACTOR will engage its Research Ethics Advisory Group to advise on all ethics-related concerns arising in any of its research.
- c. Regarding research ethics, the CONTRACTOR will ensure that:
 - i. all participants in this evaluation are fully briefed on the purpose of the evaluation and data collection exercise
 - ii. how their data will be used and stored
 - iii. their rights to remove their data from analysis, and
 - iv. will have the opportunity to ask questions before agreeing to participate in the evaluation.
- d. The CONTRACTOR does not expect the project to need additional ethics approval as it will not involve patients directly, and NHS staff will be involved in their professional capacity.

ANNEX 2

The Milestones

Deliverable	Due date
Produce a robust evaluation protocol , that meets the quality standards expected by the MAAS collaborative and their evaluation consultants	June 30 2021
Gather baseline data and recommend areas of focus for the MAAS. MAAS collaborative and commissioners will endeavour to provide the evaluation partner with quantitative and qualitative data to undertake this step, but may be required to collect primary data through means such as surveys or interviews. MAAS collaborators will guide the evaluation partner on research questions and areas to focus on, such as: e.g. identifying current barriers for adopters to help establish counterfactual impact from the MAAS; or estimating the length of time taken from development to deployment of an AI technology.	Sept 30 2021
Produce a logic model or theory of change in collaboration with key stakeholders, including metrics to measure outputs / outcomes / benefits / impacts. This should complement the service design work of the developer.	Sept 30 2021
Maturity matrix developed.	Nov 30 2021
Iterative, brief process evaluation reports and / or feedback sessions , which focus on key blockers to the programme's success and is used to develop the maturity matrix.	Iterative, on quarterly basis from January 2022 onwards. Indicative dates: <ul style="list-style-type: none">• January 31 2022• April 31 2022• July 30 2022• Oct 30 2022• Jan 31 2023
Produce an evaluation strategy, including appropriate metrics and proposed	Mar 31 2023

measurement plan, linked to the logic model / theory of change to handover to the MAAS collaborative. There will likely be requests for draft strategies 6-12 months before the final due date, which will be an opportunity for the evaluation partner to ensure they are producing a suitable strategy; details on this can be arranged once the contract is awarded.

Work stream	Task	Year 2												Year 3											
		Q1			Q2			Q3			Q4			Q1			Q2			Q3			Q4		
		Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23
Evaluation protocol	Develop protocol																								
	Inception meeting			★																					
Theory of Change development	Documentary review																								
	Interviews																								
	Developing draft ToC																								
	ToC workshop																								
	Iteration of ToC																								
Baseline data	Initial survey																								
	Review routine data																								
	Desk research																								
Process evaluation	Develop maturity matrix																								
	Follow up interviews																								
	Survey of stakeholders																								
	Quarterly meetings																								
	Process evaluation reports																								
	Final evaluation strategy																								
Summative evaluation strategy	Draft evaluation strategy																								
	Final evaluation strategy																								

ANNEX 3

Waiver of Moral Rights and Assignment of Copyright

This Deed is made the day of 14/06/2021

RAND Europe Westbrook Centre Milton Road, Cambridge CB4 1YG

1. PARTIES

- 1.1. The National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester. M1 4BT ("NICE").
- 1.2. RAND Europe, Westbrook Centre, Milton Road, Cambridge CB4 1YG("the Author").

2. WAIVER AND ASSIGNMENT

- 2.1. The Author agrees in relation to any work created by the Author in connection with the Agreement of 14/06/21 ("the Work") and made between NICE and RAND Europe to waive his/her moral rights under Sections 77 to 89 of the Copyright Designs and Patent Act 1988.
- 2.2. The Author further agrees to assign with full title guarantee the present and future copyright in the Work of which it is the author or part-author to NICE to hold to NICE its successors and assigns absolutely anywhere for the length of the copyright in the Work.
- 2.3. The Author warrants to NICE that in relation to the Work:-
 - 2.3.1. it is not a violation of any existing copyright anywhere;
 - 2.3.2. it does not contain anything objectionable, obscene or libellous;
 - 2.3.3. all statements contained in the Work which purport to be facts are true.

SIGNED AND DELIVERED
as a Deed by the Author
Witnessed

SIGNED AND DELIVERED
as a Deed by an authorised
signatory of NICE
Witnessed

Signature	Name	Date

ANNEX 4

Payment

Specify amount of payment for the Services (including or excluding VAT), timing and method of payment.

Amount of Funding		Financial Year	Date(s) for Submission of Invoice(s)
Net			September 2021
VAT (if applicable)			
TOTAL			
Net			December 2021
VAT (if applicable)			
TOTAL			
Net			March 2022
VAT (if applicable)			
TOTAL			
Net			June 2022
VAT (if applicable)			
TOTAL			
Net			September 2022
VAT (if applicable)			
TOTAL			
Net			December 2022
VAT (if applicable)			
TOTAL			
Net			March 2023
VAT (if applicable)			
TOTAL			
GRAND TOTAL	£146,340		

ANNEX 5 Protocol

Introduction

AI in healthcare

Artificial Intelligence (AI) is increasingly applied to healthcare solutions, offering opportunities for a broad range of tools to support healthcare practitioners in their decision making, management systems to organise the operational delivery of healthcare, and applications to advise and support patients directly. In particular, the mobile health (mhealth) market has grown dramatically in recent years, with over 300,000 health apps now available,¹ many of which are now using AI; the sector is forecast to be worth over \$56bn by 2026.² This activity promises significant opportunities to streamline care, improve efficiency, and provide tailored solutions. However there remain substantial questions around the potential risks that these technologies introduce, including relating to quality, how they are to be regulated, their effectiveness and cost-effectiveness, and whether they are appropriately diverse in relation to the populations they represent and serve. The MAAS creates an opportunity for innovators to optimise efforts, and regulators to coordinate approaches, leading to stronger regulatory submissions and quicker decisions.

There is an opportunity to create a regulatory space that strengthens safe and cost-effective innovation in AI, and which can deliver health and care benefits at speed and scale. We anticipate that the MAAS can add value, for example, by: providing clarity to help innovators focus on how to evidence the value of their innovations; joining up regulators and distributing regulatory tasks to where they can be best managed; enhancing the capacity of regulators to work at scale and at pace; communicating across regulators, innovators, providers, service users and the public to avoid ill-informed conflicts and supporting evidence-based debate where interests differ. These are complex tasks in a novel setting, which requires learning and adaptation. Our evaluation will generate evidence that would allow MAAS to learn and adapt, and improve the services offered.

¹ mHealth App Economics 2017: Current Status and Future Trends in Mobile Health. 7th edition. Berlin, Germany: Research2Guidance; 2017 Nov. URL: <https://research2guidance.com/product/mhealth-economics-2017-current-status-and-future-trends-in-mobile-health/>

² mHealth Apps Market Size, Share, Growth | Industry Report, 2026 (fortunebusinessinsights.com)

AI Multi-Agency Advice Service

The AI Multi-Agency Advice Service (MAAS) has been set up to provide information and support for innovators that develop AI technology and health and care providers that adopt these technologies. The MAAS is funded by the NHSx AI lab, and is a collaboration between four regulatory bodies: the National Institute for Health and Care Excellence (NICE); the Care Quality Commission (CQC); the Health Research Authority (HRA); and the Medicines and Healthcare products Regulatory Agency (MHRA). The goal of the MAAS is to support the UK in becoming a world-leading ecosystem for the development and development of AI technologies. To accomplish this, the MAAS will test the need for online advice service around AI and other data-driven technologies in health and care, and assess the current state of AI regulatory and health technology assessment.

Purpose of evaluation

We will conduct a mixed-methods, theory-based process evaluation of the MAAS. This evaluation is designed to:

- produce a shared understanding of the focus and goals of the service and the mechanisms through which it hopes to support the UK ecosystem around AI
- provide insight into the needs of MAAS users (innovators and healthcare providers) and the areas where it creates the most value, along with understanding the experiences of both those using the MAAS and the collaborating organisations
- identify key metrics that can be used to help collect data to demonstrate impact
- provide a written strategy for a summative impact evaluation, which will help the team delivering the MAAS plan to measure the impact of the service, including economic elements that focus on big ticket items where the MAAS is most likely to be able to quantify economic impacts.

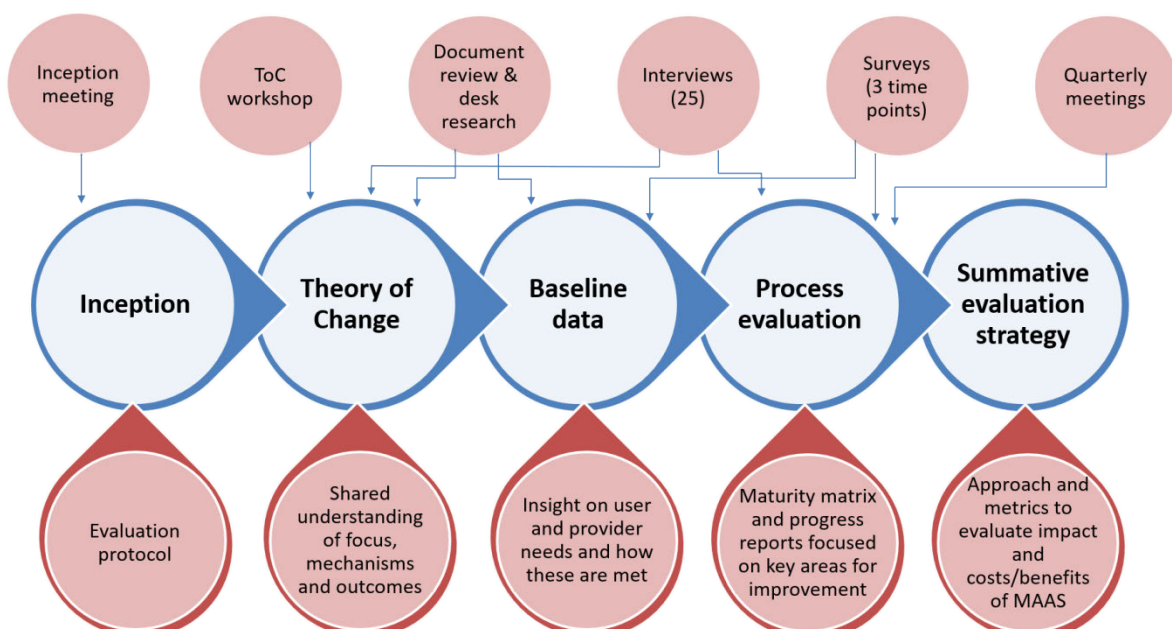
The evaluation will be both independent and embedded, and will seek to provide timely, actionable feedback to the MAAS team to be able to improve the service.

Overview of methodology

As noted in section 1.3, this evaluation is designed to be both independent and embedded. This means that the team conducting the evaluation will remain objective and use robust, transparent methods, while also working alongside the team delivering the MAAS to provide relevant insights and practical feedback to improve the service as it develops. Rather than wait until the end of the evaluation to provide findings, we will share emerging findings that focus on learning and how the MAAS can be improved, and clearly state the strength of the evidence to support these emerging findings.

Figure 1 below provides an overview of the methodology for this evaluation, showing the data collection methods and how they feed into the main evaluation activities, along with what each evaluation activity will provide in terms of insights and deliverables. These activities are described in more detail in the sections below.

Figure 1: Overview of evaluation methodology



Inception

The evaluation team will have an initial meeting with the team delivering the MAAS in order to discuss the evaluation protocol (this document) and further understand how the evaluation can support the learning and development of the MAAS. During the inception meeting, it would also be helpful to discuss the goals and main activities of the MAAS, and documents and data that will be used by the evaluation team to understand the service. We will also agree on how to work with one another over the course of this evaluation, including through quarterly team meetings and fortnightly meetings with the project manager.

Theory of change

A theory of change (ToC) is a document that shows the steps by which inputs and activities to a programme are intended to produce outcomes and impacts. It provides a graphical representation of the goals of a programme, and how a programme hopes to achieve these goals. A ToC should be a living document that is periodically re-visited to determine if the inputs and activities are achieving their expected outcomes and impacts, and whether there are any new or unexpected impacts of the programme that might be incorporated into the ToC. The ToC underpins and provides focus for the evaluation.

After the inception meeting, the evaluation team will produce a draft theory of change (ToC) based on initial discussions with partners, along with documentary review and initial interviews with the partner organisations that are collaborating to deliver the service. This will be followed by a half day ToC workshop to discuss and refine the ToC, described in more detail in the sections below.

Documentary review

A documentary review will inform our understanding of the MAAS. We anticipate the documents we would review may include documents relating to the governance of the MAAS and information about the structure of the MAAS, who will be included in the group and how it will operate. We would also seek to review documents which report the remit and aims of the MAAS. We would work with the four partner organisations to identify other documents relevant for review. The documentary review aims to enhance our knowledge of the MAAS, it's membership, it's aims and objectives and how it functions.

Initial interviews

Initial interviews will be conducted with 10 participants, 2 from each partner organisation and 2 with members of the MAAS team. Interviewees will be identified through discussion with the MAAS team and sent an invitation to participate in the interview and an information sheet about the study. Written or verbal consent will be obtained from all participants prior to interviews. Interviews will be conducted via MSTeams, or by telephone if that is the preference of the participant. Initial interviews will seek to explore:

- Context to the issues within their organisation of managing enquiries from innovators that develop AI technology
- The creation of the MAAS, and its aims and objectives
- An exploration of what success of the MAAS would look like and how this might be measured/monitored
- Reflections on how the MAAS will integrate with their organisations and what they perceive to be barriers and facilitators to the MAAS groups success

Interviews will be recorded, and notes made of the interview, with verbatim quotes noted as appropriate. All transcripts will be anonymised. Systematic coding of interview notes will be conducted by the research team and findings written up.

Workshop

In order to refine the ToC, we will hold a half day workshop with roughly 20 participants from relevant stakeholder groups, including partner organisations, regulators, developers and adopters of AI. Along with refining the ToC and building a shared understanding around the aims and mechanisms of the MAAS, the workshop will also help to identify relevant metrics that would demonstrate RAND Europe will prepare an agenda and reading material prior, facilitate and take notes for the workshop, which is currently planned to take place online (e.g. using Microsoft Teams or Zoom) based on COVID-19 restrictions. We will coordinate with the team delivering the MAAS on identifying and inviting relevant stakeholders to attend the workshop, and if the workshop is to be held in person it would be expected that the MAAS partners provide suitable facilities for the workshop. An indicative agenda is presented in **Box 1** below, but this is subject to discussion and revision.

Box 1: Indicative agenda for ToC workshop

- 1 1. Brief introductions of research team and participants
- 2 2. Presentation of initial ToC
- 3 3. Break out groups to discuss initial ToC
- 4 4. Plenary discussion – How should ToC be amended?
- 5 5. Plenary discussion – Key metrics that would indicate the MAAS is making an impact

Baseline data

Baseline data allow us to track the progress of the MASS. They should therefore be both data that can be collected before or early in the proposed changes and can then be collected in future. As far as possible they should reflect the theory of change as triangulated against the documentary evidence and interviews. We see considerable merit in using data that is easy to collect, where possible using administrative data, and be the minimum data set that will support a balanced account. From experience, we find that little, accurate and frequent data collection provides all stakeholders with more useful information than large, infrequently collected, and cumbersome data collection.

Desk research

The desk review will include a targeted review of existing academic/grey literature offering perspectives relating to the main priorities of the MAAS. This will involve analysing literature pertaining to support and regulation for artificial intelligence application in healthcare, including obtaining information on the current landscape of governance, decision-making, and innovator, regulator, and provider behaviour. Moreover, by learning from similar initiatives implemented elsewhere, we hope to extract key enablers and barriers of development, implementation, and stakeholder engagement that are imperative to streamlining this service and the potential opportunities for impact. We will also identify ‘big ticket’ costs and monetizable benefits to support the economic analysis that we will propose for the summative evaluation. Examples of relevant citations may include: ‘Thinking on its own: AI in the NHS’ (Harwich and Laycock, 2018) and ‘Of Regulating Healthcare AI and Robots’ (Terry, 2019).

Our search will adopt a targeted approach, using medical databases and online search engines to identify academic and grey literature.

Review of routine data

Alongside the findings from the desk-based research, we will also draw on data and evidence provided by the MAAS. This may include data relating to projects that the MAAS or constituent partners have

previously interacted with, including questions raised during AI review, queries relating to how to develop and implement projects incorporating AI, guidelines or terms of reference which have been drafted to outline the functions of the MAAS, or previous activities within the partner organisations that might be relevant its future operations. It is anticipated that documentation could include meeting minutes, email exchanges between constituent partners (where appropriate), reports or briefing papers, spreadsheets covering project information or other records. The methods for analysis will be tailored as appropriate for the evidence provided, once we have oversight of the data and information available.

Initial survey

We will conduct an online survey to establish a baseline understanding of: the experience of using the MAAS and participating in the collaboration; the perceived focus of the MAAS; and the needs of innovators and adopters. The design of this survey will be informed by insight gained from initial work (e.g. key metrics identified during the ToC workshop; desk research), along with existing data in the area of AI in health and care (e.g. from existing and ongoing work by the AHSN Network).³ An indicative list of the topics the initial online survey will cover is provided in **Box 2** below, although this will be refined working closely with the team delivering the MAAS.

Box 2: Indicative topics in initial online survey

- | | |
|----|--|
| 6 | •Experiences of how the collaboration is implemented; |
| 7 | •Perceptions of how gather evidence on whether and for whom the MAAS creates value; |
| 8 | •Needs of regulators, developers and providers, and how these are being addressed, including areas where advice is most frequently sought and seen as most valuable; |
| 9 | •The internal burden associated with participating in the collaboration; |
| 10 | •Attitudes related to trust and alignment with other parties; |
| 11 | •Costs related to programme implementation and examples of value added (actual and potential); and |
| 12 | •Other data sources that can be useful in understanding how the MAAS progresses and its effectiveness. |

The survey will be administered using Smart Survey,⁴ an online platform that RAND Europe uses regularly, that meets data security and GDPR requirements. To ensure a high response rate, the survey will be clearly worded, succinct and well presented, and initial invitations to participate will be followed up with up to two reminders to complete the survey.

³ The AHSN Network Department of Health and Social Care, and NHS (2018). Accelerating Artificial Intelligence in health and care: results from a state of the nation survey. <https://ai.ahsnnetwork.com/about/aireport/>

⁴ Smart Survey platform. <https://www.smartsurvey.co.uk/>

Process evaluation

The majority of this work will consist of an ongoing process evaluation, which will help understand progress and will importantly feed back key insight to the team delivering MAAS to help inform decision making. This process evaluation is described in more detail below.

Interviews

An additional 15 interviews will be conducted during the evaluation, five interviews at three time points (Q4 of Y2, Q2 of Y3 and Q4 of Y3). These interviews will provide an in-depth understanding of how the MAAS has progressed, the needs of MAAS users, and key challenges which have been experienced. Interview processes and analysis will be as those for the initial interviews

Follow up surveys

We will conduct two follow up online surveys to understand changes over time after the initial online survey discussed above. These surveys will consist of some of the same measurements as the initial survey to understand change over time, and will also include questions based on insight gained during the process evaluation and areas where the MAAS can incorporate actionable feedback on the service the collaboration provides.

Maturity matrix

A maturity matrix is a tool that allows potentially complex information to be communicated clearly and helps identify what is working as anticipated and what might require more attention. If it were thought by the MASS that this would be a helpful addition to the evaluation (and support continuing improvement beyond the life of this evaluation) then we would work with stakeholders to design a maturity matrix. The maturity matrix could then help the MAAS identify where it has reached and set goals for further progress. We anticipate that doing so would help the MAAS to understand what is required for the collaboration to excel, overcome blockages, and deliver incremental and achievable improvements. The maturity matrix might, for example, include ways to assess the MAAS partnership on: vision, design, leadership, alignment, communication, and partnership infrastructure. There would be specific rubric or descriptors in each cell which would be agreed with the MAAS. We would work with the MAAS to assess the partnership against each dimension using descriptors ranging from 'inadequate' to 'excellent', with the aim of understanding what is needed to progress along the matrix. At each of our six feedback sessions we will review progress along these dimensions, supported by information from routinely collected data, follow up surveys and interviews. The maturity matrix will be an important part of our formative working

with the MAAS team and will be a visual representation of progress towards delivering the anticipated impacts. An illustrative example is the ‘7 Lenses Maturity Matrix’ used by the Home Office in 2018 replicated in **Figure 2** below.⁵

Figure 2: Illustrative example of maturity matrix



Summative evaluation strategy

Lastly, a summative evaluation strategy will be designed providing a plan to understand the impact of the MAAS. This strategy will build on insights identified throughout the process evaluation (including the expected impacts of the MAAS, key metrics to understand impact), while meeting the requirements of the Magenta Book.⁶ We recognise that very often, as in the case of the MAAS, both costs and benefits ‘ripple outward’ from the immediate work of the MAAS to wider costs and benefits, making it hard to draw a

⁵ <https://www.gov.uk/government/publications/7-lenses-maturity-matrix>

⁶ HM Treasury (2020). Magenta Book: Central Government guidance on evaluation. London. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879438/HMT_Magenta_Book.pdf

non-arbitrary line around which costs and benefits should be measured. As such, we propose focusing on the main items linked to the immediate costs and anticipated benefits. We will follow 4 steps in designing the economic component of the summative evaluation:

- Development of a conceptual framework based on the ToC
- Testing the framework to ensure it fully captures the impacts of the intervention.
- Data collection (primary and secondary) to measure the costs and benefits
- Analysis of costs and benefits.

This detailed summative evaluation strategy will provide a concrete plan to measure impacts and outcomes of the service, including costs and benefits.

Project management, deliverables and timelines

We expect to work closely with the team delivering the MAAS throughout the evaluation, both to ensure that key milestones and deliverables are met as expected, and to ensure that the evaluation is relevant to decision making. Below, we provide additional information on how we plan to work together, and how we will ensure the efficient delivery of this evaluation up to a high quality standard.

Project management

Dr Tom Ling, as Project Leader will be responsible for the overall direction, quality and delivery of this evaluation. Sarah Parkinson has been assigned as project manager for this evaluation, and will be responsible for the day-to-day management of this evaluation, along with serving as the first point of contact for client regarding this evaluation. Project management will be further aided by RAND Europe's Programme Support Office, who will provide administrative assistance, and lead contractual and financial processes.

After the inception meeting, we will hold six quarterly meetings with the MAAS team, during which the evaluation team will present emerging findings and feed back insight to the MAAS team to help improve the service. These meetings will also help the evaluation team understand the experience of delivering MAAS, and understand how the collaboration is functioning. During these meetings, we may refer to the maturity matrix (described above) to discuss progress of the service and collaboration.

We will also schedule biweekly meetings between the project manager and a representative from the MAAS team managing this contract to check in on how the evaluation is progressing and discuss any emerging challenges in the evaluation. Other members of the evaluation team may join these biweekly meetings, where relevant.

Deliverables

This document (Evaluation protocol) is the first deliverable for this project. Other deliverables for this project will include six process evaluation reports (one after each of six quarterly meetings), a draft summative evaluation strategy and a final summative evaluation strategy. The schedule of deliverables is provided in **Table 1** below.

Table 1: Schedule of deliverables

13 Deliverable	14 Date
Evaluation protocol	June 2021
Process evaluation report 1	October 2021
Process evaluation report 2	January 2022
Process evaluation report 3	April 2022
Process evaluation report 4	July 2022
Process evaluation report 5	October 2022
Process evaluation report 6	January 2023
Draft summative evaluation strategy	December 2022
Final summative evaluation strategy	March 2023

Where the MAAS team is providing feedback on deliverables, we request that the team provides one consolidated set of feedback to the evaluation team in order to improve efficiency, and to avoid contradictory feedback from different partners.

To ensure the quality of our outputs, each deliverable will be thoroughly reviewed through RAND Europe's internal Quality Assurance (QA) process. The QA procedure assesses the quality of all outputs based on RAND's Quality Assurance Standards.⁷ A senior continuous QA reviewer, Jon Sussex (Chief Economist, RAND Europe) has been assigned to this evaluation, and a final QA reviewer will also be assigned with expertise in healthcare innovation and/or AI. The continuous QA reviewer will be available for advice throughout the evaluation and will provide critical input. They will also review all interim and final outputs and will provide a rigorous peer-review of the final outputs. The final QA reviewer will be

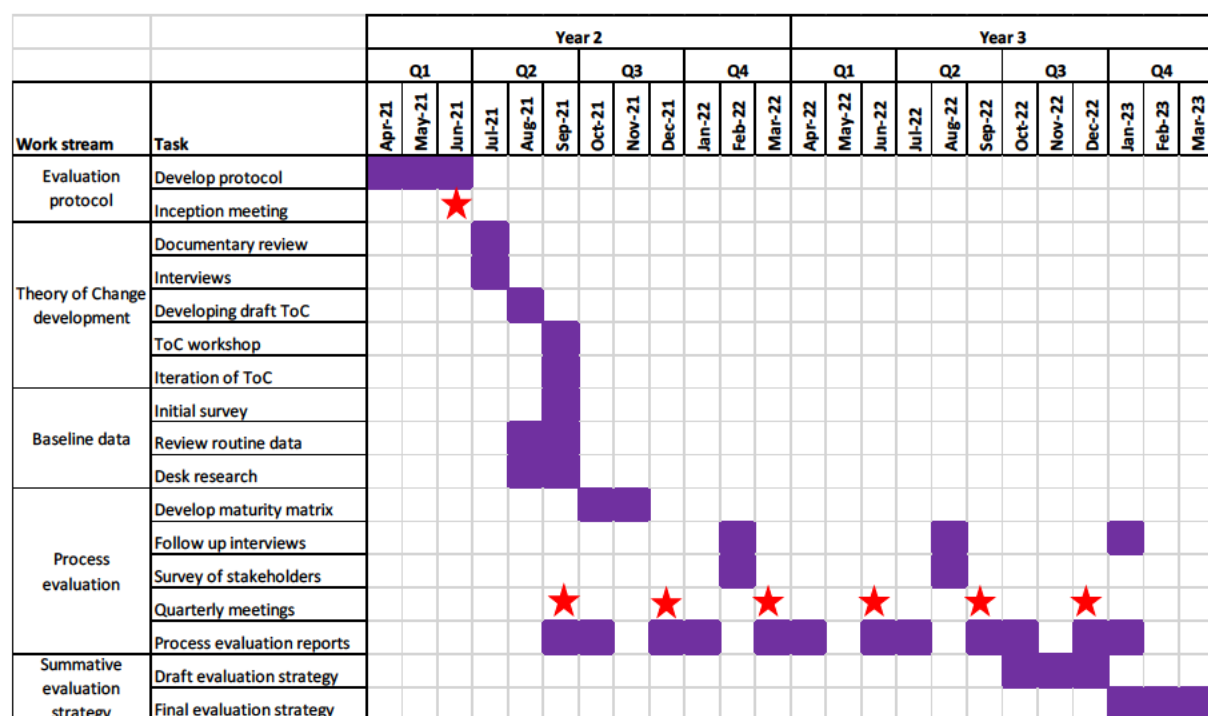
⁷ https://www.rand.org/about/standards/standards_high.html

independent from the evaluation team and will provide a rigorous peer-review of the final outputs for the project.

Timeline

This project will run from April 2021 until March 2023. **Figure 3** below provides an overview of the timeline for this project, including key milestones, deliverables and meetings with the MAAS team (indicated by a red star).

Figure 3: Gantt chart





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Thu, 17th Jun 2021 13:48:34 BST	[REDACTED] - Signer [REDACTED]
Thu, 17th Jun 2021 14:05:26 BST	[REDACTED] - Signer [REDACTED]
Thu, 17th Jun 2021 16:05:12 BST	[REDACTED] - Signer [REDACTED]
Fri, 18th Jun 2021 12:06:09 BST	[REDACTED] - Signer [REDACTED]
Fri, 18th Jun 2021 14:42:24 BST	[REDACTED] - Signer [REDACTED]

Audit history log

Date	Action
Fri, 18th Jun 2021 14:42:24 BST	The envelope has been signed by all parties. [REDACTED]
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Fri, 18th Jun 2021 12:06:09 BST	Sent the envelope to [REDACTED] for signing. [REDACTED]
Fri, 18th Jun 2021 12:06:09 BST	[REDACTED] signed the envelope. [REDACTED]
Fri, 18th Jun 2021 12:02:24 BST	[REDACTED] viewed the envelope. [REDACTED]
Fri, 18th Jun 2021 11:57:25 BST	Document emailed to [REDACTED]
Fri, 18th Jun 2021 11:57:25 BST	Sent [REDACTED] a reminder to sign the document. [REDACTED]
Thu, 17th Jun 2021 16:05:12 BST	Document emailed to [REDACTED] [REDACTED]
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Thu, 17th Jun 2021 15:32:00 BST	[REDACTED] viewed the envelope. [REDACTED]
Thu, 17th Jun 2021 14:14:02 BST	[REDACTED] viewed the envelope. [REDACTED]
Thu, 17th Jun 2021 14:05:26 BST	Document emailed to [REDACTED]

Thu, 17th Jun 2021 14:05:26 BST	Sent the envelope to [REDACTED]
	[REDACTED] for signing. [REDACTED]
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Thu, 17th Jun 2021 14:04:57 BST	[REDACTED] viewed the envelope. [REDACTED]
Thu, 17th Jun 2021 13:58:57 BST	[REDACTED] viewed the envelope. [REDACTED]
Thu, 17th Jun 2021 13:58:49 BST	[REDACTED] viewed the envelope. [REDACTED]
Thu, 17th Jun 2021 13:48:40 BST	[REDACTED] opened the document email. [REDACTED]
Thu, 17th Jun 2021 13:48:35 BST	Document emailed to [REDACTED]
Thu, 17th Jun 2021 13:48:34 BST	Sent the envelope to [REDACTED] for signing.
	[REDACTED]
Thu, 17th Jun 2021 13:48:34 BST	[REDACTED] signed the envelope. [REDACTED]
Thu, 17th Jun 2021 13:46:18 BST	[REDACTED] viewed the envelope. [REDACTED]
Thu, 17th Jun 2021 13:45:45 BST	Document emailed to [REDACTED]
Thu, 17th Jun 2021 13:45:45 BST	Sent [REDACTED] a reminder to sign the document.
	[REDACTED]
Tue, 15th Jun 2021 16:54:26 BST	[REDACTED] viewed the envelope. [REDACTED]
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Tue, 15th Jun 2021 16:54:17 BST	Document emailed to [REDACTED]
Tue, 15th Jun 2021 16:54:17 BST	Sent the envelope to [REDACTED] for signing.
	[REDACTED]
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Tue, 15th Jun 2021 16:48:25 BST	Envelope generated by [REDACTED]