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

1. BASIC DETAILS

1.1. NAME AND ADDRESS OF CONTRACTOR (including Company Registration Number if relevant)	**I C Consultants Limited,** registered in England under number 2478877 with its business address located at 58 Prince's Gate, Exhibition Road, London, SW7 2PG
1.2. DESCRIPTION OF CONTRACTOR	Wholly owned subsidiary of an Academic Centre
1.3. DESCRIPTION OF PROJECT SERVICES	Academic Collaboration on Artificial Intelligence
1.4. NICE BUDGET HOLDER	[redacted]
1.5. NICE PROJECT MANAGER	[redacted]
1.6. NOMINATED MANAGER OF CONTRACTOR (the "Lead Consultant")	[redacted]
1.7. CONTRACTOR AUTHORISED SIGNATORY	[redacted]
1.8. DATE AGREEMENT SIGNED	
1.9. DATE AGREEMENT COMES INTO EFFECT (IF DIFFERENT FROM ABOVE)	05 07 2021
1.10. DATE AGREEMENT ENDS (IF FIXED DATE)	30 06 2022
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.
“UK GDPR 2018”	means all laws and regulations pertaining to processing and protection of Personal Data as applicable to either Party in relation to this Agreement or the Project Services including: (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
"NICE"	The National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester. M1 4BT
"the Contractor"	the person in 1.1 or any partner, employee, agent, sub-contractor or other lawful representative of the person in 1.1
"the Milestones"	the milestones as set out in Annex 2.
"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 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 Project 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 Agreement, 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 Agreement, , 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 Agreement, 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 Agreement 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

5.1.1. 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.

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 3 within 30 days of their receipt.

7.2. The Contractor shall send all invoices, clearly quoting the contract number, to [redacted], alternatively the Contractor can register with [redacted] to send invoices electronically and have access to [redacted] updates of the progress of invoices.

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 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 Equality Act 2010 (as amended) the Part Time Workers (Prevention of Less Favourable Treatment) Regulations 2000, the Fixed Term Employees (Prevention of Less Favourable Treatment) Regulations 2002, or any other relevant legislation relating to discrimination in the employment of employees for the purpose of providing the Project Services. The Contractor shall take all reasonable steps (at its own expense) to ensure that any employees employed in the provision of the Project 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 Project Services.

8.4. The Contractor shall notify NICE immediately of any investigation of or proceedings against the Contractor under the Equality Act 2010 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.

8.5. 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 Equality Act 2010 due directly or indirectly to any act or omission by the Contractor, its agents, employees or sub-contractors.

8.6. The Contractor shall impose on any sub-contractor obligations substantially similar to those imposed on the Contractor by this Clause 8.

8.7. NICE shall have the right to be consulted on what staff will be appointed to provide the Project Services.

8.8. NICE acknowledges and agrees that the Contractor's ability to provide the Project Services is reliant on the Lead Consultant and other members of the team, who are experts in the field of the Project Service, being able and available to provide the Project Services. Accordingly, if at any time during the term of this Agreement the Lead Consultant becomes unable or unavailable to perform the Project Services, the Contractor shall have the right, upon notification to NICE, to substitute the Lead Consultant with a replacement consultant of equivalent expertise, such replacement consultant to be approved by NICE (consent not to be unfairly withheld or delayed). If despite using such reasonable efforts the Contractor is unable to provide a suitable replacement consultant within thirty (30) days following notification to NICE of the Lead Consultant's incapacity or unavailability, either Party may terminate this Agreement on written notice with immediate effect.

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.

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.

10.3. NICE hereby grants to the Supplier a world-wide, irrevocable, royalty-free, non-exclusive licence to:

10.3.1. to use or publish in full or in part, strictly for its own purposes the Deliverables or any other material containing or relying upon any part of the Deliverables; and

10.3.2. use any part of the Deliverables or any other material containing or relying upon any part of the Deliverables for teaching purposes,

In all cases provided that:

10.3.3. prior to such publication or use the Contractor submits the relevant material to NICE for review following which NICE shall respond to the Contractor, such response not to be unreasonably withheld or delayed, stating either its consent to such publication or use (including whether or not consent is subject to amendments to such material) or its lack of consent to such publication or use;

10.3.4. where NICE consents to such publication or use, the Contractor shall make due acknowledgement to NICE as owner of the relevant Deliverables and to NHSX as the Funder of the project in a form to be specified by NICE, save that where such consent is subject to amendments to the relevant material and such amendments are not made by the Contractor, NICE shall be deemed to have not consented to such publication or use;

10.3.5. where NICE does not or, in accordance with Clause 10.3.4, is deemed not to consent to such publication or use, the Contractor shall make no reference which links such material, its publication or use in any way to NICE or NHSX;

10.3.6. The Contractor publishes and uses at its own cost; and

10.3.7. The Contractor complies with any relevant obligations of confidentiality

10.4. 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:-

10.4.1. it shall use reasonable endeavours to ensure that such work is not a violation of any existing copyright anywhere;

10.4.2. such work does not contain anything objectionable, obscene or libellous;

10.4.3. all statements contained in any such work which purport to be facts are true.

10.5. 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.

10.6. 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.

10.7. 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 NICE. In an exceptional circumstance NICE, as copyright owner, would reserve the right to disassociate the author from the work.

10.8. NICE shall use all reasonable endeavours to acknowledge the contributions made by the Contractor’s representatives engaged for the purposes of the project, in addition to naming them on any NICE publications subsequent to the deliverables in Annex 2.

11. PUBLIC REPUTATION OF THE PARTIES AND PUBLICITY

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 UK GDPR, the content of this Agreement is not Confidential Information. NICE shall be responsible for determining in its absolute discretion whether any of the content of the Agreement is exempt from disclosure in accordance with the provisions of the FOIA and/or the UK GDPR.

11.3. Subject to clause 11.4 below, the Contractor hereby gives his consent for NICE to publish this Agreement in its entirety, including from time to time agreed changes to the Agreement, 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.

11.4 NICE shall not publicly use, or give approval for the public use by any third party of, in each case, directly or indirectly (by implication) and in or via any medium (and including, for the avoidance of doubt and without limitation, via any social media outlets): (i) the name, crest, logos, images or other identifying marks (whether registered or unregistered) of the Contractor or Imperial College of Science, Technology and Medicine ("Imperial College London") or their respective internal departments; (ii) the name of the Lead Consultant; (iii) the name of any employee, consultant or other representative of Imperial College London or the Contractor; and/or (iv) the name of any student of Imperial College London, in each case, for any purpose, without the express, prior written permission of the Contractor.

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 this Agreement;

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 this Agreement 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 this Agreement, 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 this Agreement.

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. GIFTS AND PAYMENTS OF COMMISSION

13.1. 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.

13.2. 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.

14. INDEMNITY

14.1. Contractor shall indemnify NICE from any direct losses, costs, damages or expenses of any kind, which arise out of or are connected with Contractor's negligence or breach of statutory duty

15. LIMITATION OF LIABILITY

15.1. Neither Party shall not be liable to the other Party for any indirect or consequential losses, damage, injury or costs whatsoever which arise out of or are connected with a Party'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.

15.2 Subject to the exclusions under clause 15.1 above, whether in contract, tort (including negligence), breach of statutory duty or otherwise, the aggregate liability of each Party to the other Party will not exceed three times the total amount payable by NICE to the Contractor for the Project Services.

16. TERMINATION

This Agreement shall terminate in the following circumstances -

16.1. Breach

16.1.1. 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

16.1.2. 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;

16.1.3. 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;

16.2. Repeat of Breach

16.2.1. 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);

16.3. Insolvency

16.3.1. 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;

16.4. Change of Management Control

16.4.1. 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.

16.5. Unsatisfactory Evaluation of the Project Services

16.5.1. 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.

16.6. 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.

17. MISCELLANEOUS

It is further agreed between the Parties:

17.1. Waiver

17.1.1. 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.

17.2. Whole Agreement

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

17.3. Variation

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

17.4. Governing Law and Jurisdiction

17.4.1. This Agreement shall be governed in all respects by English Law and each Party agrees that the English Courts shall have exclusive jurisdiction in dealing with any matter or dispute arising out of or in connection with this Agreement.

Signed for and on behalf of NICE

	Signature	Name and title	Date
Procurement		[redacted] **Associate Director of Procurement**	12 Sep 2022
Contract Manager		[redacted] **Content & Quality Assurance Programme Manager**	12 Sep 2022
Budget Holder		[redacted] **Programme Director – Information Resources**	12 Sep 2022

Signed for and on behalf of the Contractor

	Signature	Name and title	Date
Authorised Signatory:		[redacted]	14 Jun 2022

This contract is not valid until all Signatures have been completed

ANNEX 1

The Project Services

Specification of Requirements

1. 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.

2. Requirements for this Project

The Contractor (academic partner) will 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 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. The project will 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 and SPIRIT-AI, 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, this work 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.

3. Scope of the Procurement

3.1. Aims & Objectives

3.1.1. 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. 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.

3.1.2. The output of this contract will be to formulate a proposal for the pragmatic and proportionate classification of AI technologies, with a focus on health technology assessment. 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).

3.1.3. The approach to the classification is to 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.

3.1.4. In addition to clarifying the elements of the classification, it is 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.

3.1.5. A literature review will underpin this work to supplement the work already undertaken. This will 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.

3.1.6. 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.

3.1.7. 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. The academic partner will 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 d to suggest how the AI classification can be related to the evidence tiers for digital health technologies in the original evidence standards framework.

3.1.8. 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.

3.1.9. 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.

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

3.1.11. 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 will 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.

3.1.12. The deliverables for this contract are listed in Annex 2.

3.2. Constraints and Dependencies

3.2.1. 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 is required.

3.2.2. 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 being held virtually for example, via Zoom at point of contract award, it is hoped to be able to conduct certain key meetings in person in future.

3.2.3. It is anticipated that a lot of the work may 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.

3.3. Roles and Responsibilities

3.3.1. The academic partner will have weekly 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.

3.3.2. The primary contacts for NICE are [redacted] Programme Director Information Resources [redacted] and [redacted], Senior Service Development Manager [redacted]

3.3.3. The primary contacts for the academic partner are [redacted], [redacted]

3.4. Monitoring contract delivery

3.4.1. As a means to measure progress in the delivery of this project, a range of outputs and outcomes will be monitored, including:

3.4.1.1. Draft literature search

3.4.1.2. Draft classification frameworks, evidence proposals and case studies

3.4.1.3. Draft checklists and mapping documents

3.4.1.4. Delivery plans, facilitation notes for any planned workshops and proposals, plans and arrangements for consultations and peer review

3.4.1.5. Communication materials and draft papers for publication

3.4.1.6. Interim progress reports and draft reports.

3.5. Acceptance Criteria

3.5.1.1. The deliverables should be delivered with the reasonable skill care and diligence as may reasonably and ordinarily be expected from an equally skilled and experienced person or body engaged in a similar type of undertaking under the same or similar circumstances.

3.5.1.2. The deliverables should:

- Be written in precise, accurate and grammatically correct English, suitable to a professional audience,
- State clearly the outcome or research question that deliverable is intended to achieve or answer and the methods that will be used to achieve the stated outcome.

- Contain complete, comprehensive and accurate content that explicitly addresses the outcome or research question that the deliverable in intended to achieve or answer,
- Be logically structured and organized,
- Contain relevant and illuminating examples,
- Employ clear, understandable and well-constructed data visualizations and data tables,
- Provide definitions for all complex or technical concepts

3.5.1.3.

3.6. Contract term

3.6.1. 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.

3.7. Budget

3.7.1. The budget for the evaluation work done within the lifespan of the project is fixed at £100,000 plus VAT or any other applicable taxes which shall be paid by NICE to the Contractor at the prevailing rate from time to time. See Annex 3 for Payment Schedule.

4. Requirements

4.1. Quality of the methodology

4.1.1. **Overview**

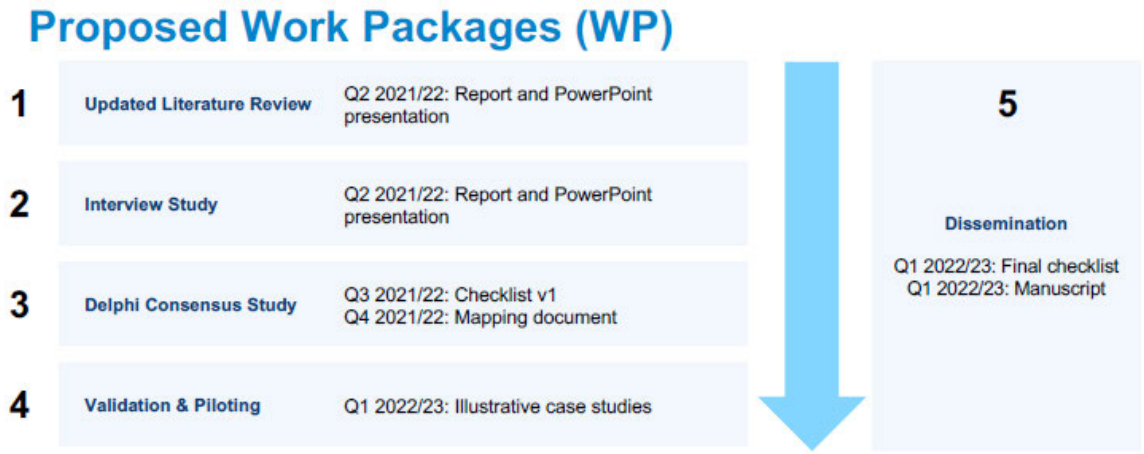
To achieve a classification checklist that is both accepted and representative of the key needs across multiple stakeholder groups, the project consists of primary and secondary research methodologies in 5 main Work Packages detailed below.

Work Packages 1 to 3 will serve as a mixed-methods evidence generation process related to the content and structure of the first iteration of the classification (and subsequent checklist). Elements of these 3 Work Packages will be conducted concurrently to each other so that they may

inform each other in terms of content and direction. Moreover, by employing 3 separate yet complimentary evidence generation methodologies, we can offset the impact of limitations and bias that would be incurred through reliance upon a singular methodology. As such, both researcher and participant biases, in its many guises, may be minimised.

Work Package 4 will serve as a robust validation process, using both internal and external stakeholders, to ensure that the proposed classification is functional amongst end-users. This step will allow for iterative changes regarding both structure and items prior to finalisation of the document. Work Package 5 is related to the writing of academic papers, reports and overall project finding dissemination. In practice, this will span across the course of the project as it is understood that there will be multiple deliverables spanning across the length of the contract.

The following figure demonstrates the work packages.



4.1.2. Work Package 1: Literature review and classification matrix

Methodologies, activities and activity measurement:
A formal literature review will be undertaken to highlight the different AI classification systems that are available and what would be best suited for the regulatory and evaluation requirements that will require representation within a HTA checklist. This will involve a systematised search of both academic, grey and non-traditional literature sources, led by at least two members of the Project Team. Specific extraction criteria will require discussion amongst team members, however, content related to (1) the different AI classification systems, (2) regulatory requirements and (3) evaluation requirements (clinical and economic) will be collated and summarised into a classification matrix.

The academic partner will liaise with the authors of the KITEC work in order to avoid duplication of work.

The academic partner will identify stakeholders of established and ongoing initiatives, such as the NICE Evidence Standards Framework for Digital Health Technologies and MHRA approach to medical device classification, and develop close partnerships to facilitate mapping of work.

Resources required:
Nil specific

4.1.3. Work Package 2: Semi-structured interviews and iterative classification matrix

Methodologies, activities and activity measurement:
To further supplement the literature review from Work Package 1, the academic partner will run a series of semi-structured interviews with selected experts from multiple stakeholder groups. Key stakeholder groups include, but are not limited to, clinician scientists, computer scientists, epidemiologists, statisticians, industry leaders (e.g., clinician scientists, computer scientists and product managers from health technological companies), funders, legal experts, public representatives and medical ethicists.

The experts chosen will be through purposive recruitment, following a key informant strategy. The list of experts for this Work Package will be collectively agreed upon from both NICE and Academic Steering Groups in order to ensure appropriate coverage of expertise and experience.

These interviews will (1) highlight pertinent issues that are poorly covered by Work Package 1 as well as (2) serve as a vital horizon scanning exercise so that the final classification may adequately accommodate the future direction of these technologies. Moreover, through the means of semi-structured interviews, the academic project team can discern a greater level of detail that would otherwise not be attainable through a literature review alone. This also accommodates issues, such as publication bias, that are recognised limitations within literature reviews (Work Package 1). The interviews will be driven by a broad topic guide that will be generated by the findings of Work Package 1. The interviews will be transcribed verbatim alongside field notes. A deductive approach to data analysis will be undertaken through which a process of coding and indexing is adopted. Coded data is then summarised into a classification matrix.

This matrix will be subsequently merged with that from Work Package 1 producing an iterative version of the classification.

Resources required:
(1) Business communication platform (e.g., Microsoft Teams), (2) qualitative data analysis computer software package (e.g., NVivo)

4.1.4. **Work Package 3: Delphi consensus study**

Methodologies, activities and activity measurement:
To further minimise bias that may be instilled through Work Package 2 (participant/researcher bias), a larger scale anonymised consensus process will be undertaken.

The domains and items within the draft classification will be subject to a Delphi Technique. This will serve as a complementary systematic communication technique through which we may derive group consensus with respect to both content and structure of the proposed classification and subsequent checklist. The Delphi Technique has long served as a means through which expert opinion may be summarised on subjects in which more rigorous experimental methodology may not be feasible. It involves a panel of anonymised experts who answer a standardised questionnaire; in this case, detailing the content and structure of the classification. Findings from this questionnaire are summarised by a moderator who subsequently relays these aggregated findings back to the same group of experts so that they may revise their answers for subsequent questionnaire rounds. This process is repeated on an iterative basis until a predefined criterion is achieved, such as group consensus, result stability or following a set number of rounds.

In achieving consensus or result stability, this process acts as a form of expert validation regarding the key contents as to construction and content of the classification. Moreover, this serves as a robust methodology that, when performed well, has been published in impactful biomedical journals.

As in Work Package 2, the experts that will be invited to this process will consist of clinician scientists, computer scientists, epidemiologists, statisticians, industry leaders (e.g., clinician scientists, computer scientists and product managers from health technological companies), regulators, funders, legal experts and medical ethicists.

Resources required:
(1) Experience management software (e.g., Qualtrics), (2) Business communication platform (e.g., Microsoft Teams)

4.1.5. **Work Package 4: Validation and piloting**

Methodologies, activities and activity measurement:
Validation of the proposed checklist is a critical step prior to dissemination through formal reports and academic papers.

In addition to the validation attained through group consensus in Work Package 3, validation will be undertaken through a separate series of consultations with both internal and external expert groups. Experts from MAAS Project who are not directly involved in the creation of this

framework will be invited to both critique and pilot the checklist. Moreover, external experts (similar stakeholder distribution to those employed in Work Packages 2 and 3) will also be invited to participate in this process. Feedback will be captured through surveys, focus groups and further semi-structured interviews.

Specific case studies will also be assessed and evaluated. The cases will be chosen in close consultation with the NICE Steering Group, and can be for example, recent examples of applicants submitted for MHRA regulatory approval, AI Fund technologies or AI technologies identified from NICE guidance development processes.

Resources required:
(1) Business communication platform (e.g., Microsoft Teams), (2) qualitative data analysis computer software package (e.g., NVivo)

4.1.6. **Work Package 5: Dissemination**

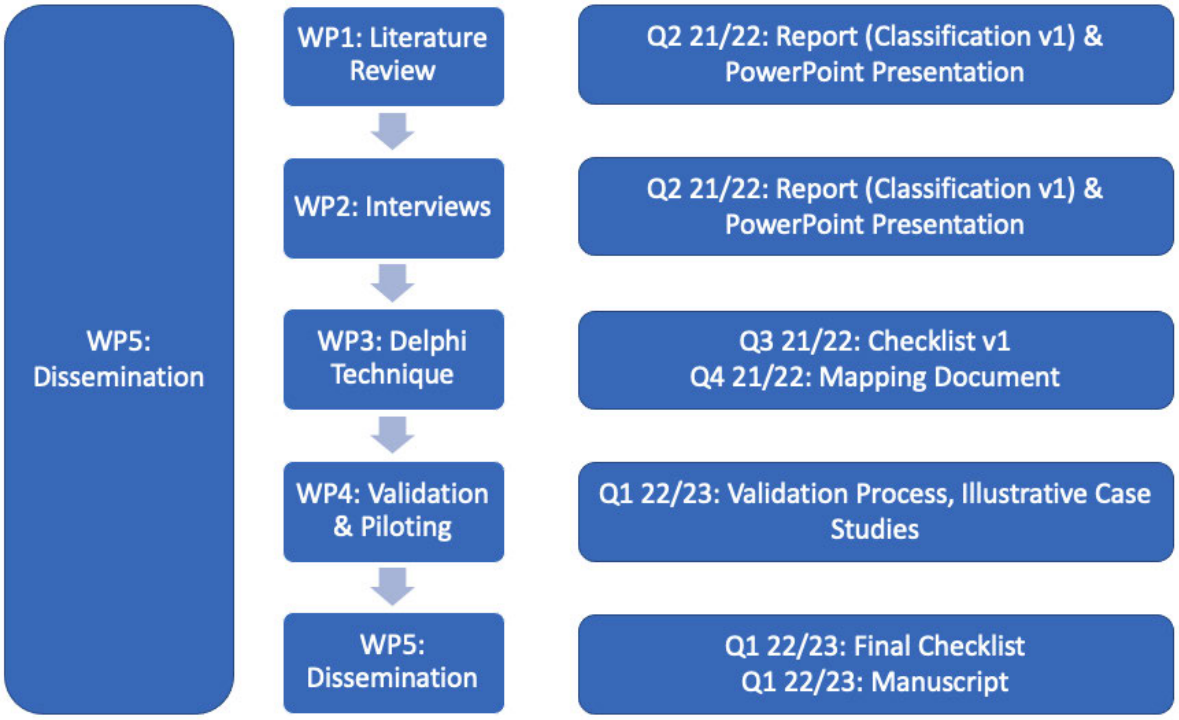
Methodologies, activities and activity measurement:
Dissemination of findings through reports, presentations and academic papers both internally and externally over the course of the project. As such, Work Package 5 will span the length of the project.

With respect to reports and manuscripts derived from this work, Writing Teams will be formed between the NICE Steering Group and Academic Steering Group in order to streamline this process.

Resources required:
Nil specific

4.1.7. **Project delivery plan**

The following figure demonstrates how the Work Packages map to the key deliverables and timelines (see Annex 2).



4.2. Project assurance

4.2.1. Project governance to ensure project delivery

The Academic Project Team will be responsible for the day-to-day progress of the project, in collaboration with the Steering Group established at NICE. This Project Team will consist of representatives from Imperial College London, the University of Birmingham and The Alan Turing Institute. This team will be in regular contact through email, virtual weekly meetings and meetings in person, when permitted. The Project Team will maintain planning documents and risk registers to support the delivery of the work against planned milestones.

In addition to this Project Team, a broader Academic Steering Group will be established, which will meet on a fortnightly basis. This Group will consist of senior members of pertinent stakeholder groups. This will serve as a check of rigour to ensure that the overall direction and content is consistent with the overarching goals of the project. These wider meetings with the NICE and Academic Steering Groups will allow for joint goals to be set as well as task assignment, which will allow for timely project delivery.

Key literature and documentation will be regularly maintained through a business communication platform, such as Microsoft Teams. This includes Work Package protocols as well as weekly group goals so that team

members are aware of communal progress and direction in a manner independent to the meetings.

The following figure demonstrates the project governance structure.

4.2.2. Compliance with relevant legislation, regulations or industry standards

This structure of the project will be compliant with relevant regulation. The project, consisting of a series of projects compartmentalised as Work Packages, will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. Both local ethical and formal HRA ethical approval will be sought prior to undertaking this work.

Informed and written consent will be attained for Work Packages 2, 3 and 4. Signed consent to enter the study will be sought from each participant only after a full explanation has been given, an information leaflet offered, and time allowed for consideration. The right of the participant to refuse to participate without giving reasons will be respected and all participants are free to withdraw at any time.

The Project Team, as led by Professor [redacted] as the Offeror, will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the General Data Protection Regulation for health and care research.

Indemnity and sponsorship will be sought through Imperial College London.

As this proposal will be quantitatively focussed in methodology, we do not anticipate any adverse events. Any that are perceived to occur will be recorded as well as reported directly to the Professor [redacted] within 24 hours.

In addition to the aforementioned regulation, this proposal will adhere to all standards set forth by NICE, MHRA and other project partners.

4.3. Experience, skills and expertise

4.3.1. As this project aims to create intersectional outputs that will be used by a range of stakeholders, the academic partner will bring together a representative team that will provide holistic coverage of the requisite considerations.

4.3.2. This proposal is led by Imperial College London in partnership with researchers at the University of Birmingham and The Alan Turing Institute.

4.3.3. The overall team consists of senior NHS clinicians [redacted], [redacted]), technical experts from The Alan Turing Institute (Professor [redacted]), health policy leads ([redacted]) as well as academics who have led upon applied AI projects in healthcare. A minimum of two full time researchers will be available to support the project.

4.3.4. **ANNEX 2**

Project milestones for each meeting for tasks to be undertaken by the contractor

Work package	Milestone	Date to be Completed
1	Undertake **literature review**; a systematised search of both academic, grey and non-traditional literature sources, led by at least two members of the Project Team.	Q2 of FY 202122
1	**A report** describing the literature review undertaken, the different elements of AI technologies considered for the classification, the range of classification approaches considered.	Q2 of FY 202122
1	A **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 • **suggestions for evidence requirements** and evidence considerations for the different elements and sub-elements for the classification.	Q2 of FY 202122
1	**A power-point presentation describing the proposed classification** including some worked examples to illustrate its use.	Q2 of FY 202122
2	**Semi structured interviews** with selected experts from multiple stakeholder groups. Data analysis: coding and indexing.	Q2 of FY 202122
3	**Delphi consensus study** on content and structure of the proposed classification and subsequent checklist.	Q3 of FY 202122
3	**A checklist 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 FY 202122

3	**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 FY 202122
4	A **validation process** that the classification is fit for purpose through a separate series of consultations with both internal and external expert groups.	Q1 of FY 202223
4	**A range of illustrative case studies** against each of the proposed category sections (and subsections) illustrating both the classification and the evidence standards. To be agreed with NICE.	Q1 of FY 202223
5	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 and a final version of **the checklist**.	Q1 of FY 202223
5	**A manuscript for publication** in a peer-reviewed journal. The manuscript will be jointly authored with members of the NICE team.	Q1 of FY 202223

ANNEX 3

Waiver of Moral Rights and Assignment of Copyright

This Deed is made the [redacted] day of [redacted] 2021

1. PARTIES

1.1. The National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester. M1 4BT ("NICE").

1.2. ("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 [redacted] ("the Work") and made between NICE and Imperial College London 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.

		Date
SIGNED AND DELIVERED as a Deed by the Author Witnessed	[redacted]	28 Jun 2022
		12 Sep 2022
SIGNED AND DELIVERED as a Deed by an authorised signatory of NICE Witnessed		12 Sep 2022
		12 Sep 2022

		Date
SIGNED AND DELIVERED as a Deed by the Author	[redacted]	28 Jun 2022
Witnessed		2 Sep 2022
SIGNED AND DELIVERED as a Deed by an authorised signatory of NICE		12 Sep 2022
Witnessed		12 Sep 2022

		Date
SIGNED AND DELIVERED as a Deed by the Author	[redacted]	29 Jun 2022
Witnessed		12 Sep 2022
SIGNED AND DELIVERED as a Deed by an authorised signatory of NICE		12 Sep 2022
Witnessed		12 Sep 2022

	Signature	Name	Date
SIGNED AND DELIVERED as a Deed by the Author	[redacted]		02 Jul 2022
Witnessed			12 Sep 2022
SIGNED AND DELIVERED as a Deed by an authorised signatory of NICE			12 Sep 2022
Witnessed			12 Sep 2022

	Signature	Name	Date
SIGNED AND DELIVERED as a Deed by the Author	[redacted]		26 Jul 2022
Witnessed			12 Sep 2022
SIGNED AND DELIVERED as a Deed by an authorised signatory of NICE			12 Sep 2022
Witnessed			12 Sep 2022

	Signature	Name	Date
SIGNED AND DELIVERED as a Deed by the Author	[redacted]		01 Aug 2022
Witnessed			12 Sep 2022
SIGNED AND DELIVERED as a Deed by an authorised signatory of NICE			12 Sep 2022
Witnessed			12 Sep 2022

	Signature	Name	Date
SIGNED AND DELIVERED as a Deed by the Author	[redacted]		09 Aug 2022
Witnessed			12 Sep 2022
SIGNED AND DELIVERED as a Deed by an authorised signatory of NICE			12 Sep 2022
Witnessed			12 Sep 2022

	Signature	Name	Date
SIGNED AND DELIVERED as a Deed by the Author	[redacted]		18 Aug 2022
Witnessed			12 Sep 2022
SIGNED AND DELIVERED as a Deed by an authorised signatory of NICE			12 Sep 2022
Witnessed			12 Sep 2022

	Signature	Name	Date
SIGNED AND DELIVERED as a Deed by the Author	[redacted]		12 Sep 2022
Witnessed			12 Sep 2022
SIGNED AND DELIVERED as a Deed by an authorised signatory of NICE			12 Sep 2022
Witnessed			12 Sep 2022

ANNEX 4

Payment

Schedule for payment for the Project Services, timing and method of payment.

Date of meeting and amount of funding		Financial Year	Date(s) for Submission of Invoice(s)
[redacted]		2022	[redacted]
Net	£100,000		
VAT (if applicable)	£20,000		
TOTAL	£120,000		
GRAND TOTAL	**£100,000 (plus any VAT or other applicable taxes)**		

Signable

Issuer	National Institute for Health and Care Excellence
Document generated	Mon, 13th Jun 2022 15:23:54 BST
Document fingerprint	[redacted]

Parties involved with this document

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