# RESEARCH CONTRACT

**BETWEEN**

**SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE (1)**

**AND**

**CARISTO DIAGNOSTICS LIMITED (2)**

Version number: 1/20

AI Health and Care Award – Phase 3

## CONTENTS

## SECTION 1 FORM OF CONTRACT

**This Form of Contract is made by and between**

**THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE** of 39 Victoria Street, Westminster, London, SW1H 0EU ("**the Authority**")

and

**CARISTO DIAGNOSTICS LIMITED**, a private limited company registered in England and Wales with company number 11429590 whose registered office address is at New Barclay House, 234 Botley Road, Oxford, United Kingdom (England), OX2 0HP ("**the Contractor**")

who may, from time to time, be hereinafter referred to individually as the "Party" or collectively as the "Parties".

IT IS AGREED THAT:

1. The Contractor will undertake a research project entitled CaRi-Heart: Real-world impact of AI cardiovascular risk prediction from routine CT scans in accordance with the work specified in SECTION 3 and including the Deliverables (as defined in SECTION 2 and detailed in SECTION 3), being project application AI_AWARD02443, dated 03 March 2021.
2. The Authority will pay the Contractor the Approved Cost as set out in SECTION 4 in respect of undertaking the Research and carrying out the obligations of the Contractor in accordance with this Contract.
3. This Form of Contract (SECTION 1) together with the attached SECTION 2 to SECTION 6 inclusive are the documents which collectively form the "Contract" (as defined in SECTION 2).
4. The Contract effected by the signing of this Form of Contract constitutes the entire agreement between the Parties relating to the subject matter of the Contract and supersedes all prior negotiations, representations or understandings.

***The remainder of this page is left blank intentionally.***

SIGNED:

For the Authority:

SIGNATURE..... [redacted] .....

FULL NAME... [redacted] .....

POSITION HELD..... Senior Category Manager (Testing, Technology & Digital) for DHSC

ON BEHALF OF THE AUTHORITY

DATE..... 13/07/2021

For the Contractor:

SIGNATURE [redacted] .....

FULL NAME..... [redacted]

POSITION HELD..... CEO

ON BEHALF OF THE CONTRACTOR

DATE..... 01-Jul-2021 | 14:57 BST

## SECTION 2 TERMS AND CONDITIONS

## CONDITIONS OF AGREEMENT

### 1. DEFINITIONS AND INTERPRETATION

1.1 As used in this Contract the following terms and expressions shall have the meaning shown below:

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| **“Applicable Law”** | means:<br>(a) any law, statute, regulation, byelaw or subordinate legislation in force from time to time to which a party is subject and/or in any jurisdiction that the Research is conducted;<br>(b) the common law and laws of equity as applicable to the parties from time to time;<br>(c) any binding court order, judgment or decree;<br>(d) any applicable direction, policy, rule or order that is binding on a party and that is made or given by any regulatory body having jurisdiction over a party or any of that party’s assets, resources or business. |
| **"Approved Cost"** | means the total cost agreed for the Research as set out in SECTION 4. |
| **“Arising Know How”** | means Know How that is created, devised or generated by or on behalf of the Contractor and/or any Collaborator in the course of the performance of the Research. |
| **"Authority's Representative"** | means a person authorised to represent the Authority in respect of this Contract as identified in SECTION 5. |
| **"Award"** | means the award letter addressed to the Contractor. |
| **"Background IP"** | means any Intellectual Property in existence at the Commencement Date or created, devised or generated other than in the performance of the Research. |
| **“Business Day”** | means a day other than Saturday, Sunday and bank holidays in London. |
| **“Care Services”** | means in:<br>England – NHS and adult Social Care;<br>Wales – NHS and Social Care;<br>Scotland – NHS and adult Social Care; |

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| | Northern Ireland – Health and Social Care. |
| **"Collaborator"** | means a person or organisation who works with the Contractor on the Research subject to Condition 14.5 and/or is listed at SECTION 3, Part A. |
| **"Commencement Date"** | means 1 July 2021 notwithstanding the last day of signature of this Contract. |
| **"Commercially Sensitive Information"** | Has the meaning ascribed to it by the FOIA |
| **"Commercial Use"** | means any use that supports the generation of revenue including but not limited to:<br>(a) any use in support of an application for regulatory approval for a product or service;<br>(b) any use in support of the development, promotion or use of a product or service that will be made available on a revenue generating basis;<br>(c) any use in support of the development, promotion or provision of Health Care direct to an individual on a fee paying basis;<br>(d) the provision of a product or a service to any Health Service Body or to any patient under the care of a Health Service Body. |
| **"Completion Date"** | means 31 December 2022. |
| **"Confidential Information"** | means information of any form, however conveyed and irrespective of the media on which it is stored, that is:<br>(a) information which has been designated as confidential by either Party; or<br>(b) information that reasonably ought to be considered as confidential including information which relates to the business, affairs, properties, assets, trading practices, goods/services, developments, trade secrets, Intellectual Property, Know How, personnel, customers and |

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| | suppliers and commercial sensitive information of either Party; or<br>(c) Personal Data and/or special category data within the meaning of the Data Protection Legislation; or<br>(d) the Research Data. |
| **"Contract"** | means the contract concluded between the Parties, consisting of the following Sections:<br>SECTION 1: FORM OF CONTRACT<br>SECTION 2: TERMS AND CONDITIONS<br>SECTION 3: RESEARCH<br>SECTION 4: FINANCIAL ARRANGEMENTS<br>SECTION 5: KEY STAFF<br>SECTION 6: REPORTING SCHEDULE |
| **"Contractor Background IP"** | means any Background IP or Know How:<br>(a) owned by the Contractor or to which the Contractor has rights; and/or<br>(b) created, devised or generated by or on behalf the Contractor (including staff, students, consultants or visiting researchers working in the research group of and/or supervised by the Contractor during the term of the Research but which arises outside of the performance of the Research). |
| **"Contractor's Collaboration Agreement"** | means the agreement(s) between the Contractor and its Collaborators to ensure the effective performance of the Research by Collaborators, Research Sites and sub-contractors in accordance with the terms of this Contract. |
| **"Contractor's Representative"** | means the person authorised to represent the Contractor in respect of this Contract as identified in SECTION 5. |
| **"Crown"** | means the government of the United Kingdom (including the governments of Northern Ireland, Scotland, and Wales), including, but not limited to, government ministers, government departments, |

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| | government agencies and particular bodies. |
| **"Data Protection Legislation"** | means any Applicable Law relating to the processing, privacy, and use of Personal Data, as applicable to the Contract and/or Research from time to time. |
| **"Data Subject"** | has the meaning ascribed to it in the Data Protection Legislation. |
| **"Deliverables"** | means those elements of the Research detailed in SECTION 3, Part B. |
| **"Drop Dead Date"** | means 1 October 2021 the last date by which work on doing the Research must have started. |
| **"FOIA"** | means the Freedom of Information Act 2000 and any subordinate legislation made under this Act from time to time together with any guidance and/or codes of practice issued under this Act or by the Information Commissioner in relation to such legislation. |
| **"Foreground IP"** | means Intellectual Property that is, or has been created, generated or developed (whether in whole or in part) during the course and for the purpose of the Research. For the avoidance of doubt, this:<br>(a) includes Foreground IP generated by or on behalf of the Contractor or any Collaborator in the course of performing the Research; and<br>(b) excludes Arising Know How and Research Data. |
| **"Fraud"** | means any offence under laws creating offences in respect of fraudulent acts or at common law in respect of fraudulent acts in relation to the Contract or defrauding or attempting to defraud or conspiring to defraud the Crown. |
| **"Good Industry Practice"** | means standards, practices, methods and procedures conforming to Applicable Law and the degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged in a similar type of undertaking under the same or similar circumstances |

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| **"Health Care"** | has the meaning ascribed to it in section 64 of the Health & Social Care Act 2012 and includes both health care and social care provided to individuals on a non-fee paying basis. For the avoidance of doubt, Health Care is deemed to include (but is not limited to) evaluation, training and teaching purposes relating to the provision of care and treatment. |
| **"Health Service Body"** | has the meaning ascribed to it in section 9 of the National Health Service Act 2006. |
| **"Information"** | has the meaning ascribed to it in FOIA. |
| **"Insolvency Event"** | means where a Party:<br>(a) goes into liquidation or passes a resolution for voluntary winding up or its directors convene a meeting of shareholders to consider passing such a resolution (except for the exclusive purpose of amalgamation or bona fide reconstruction not involving insolvency and in such manner that the entity resulting therefrom effectively agrees to be bound by or assumes the obligations imposed on that other party under this Contract);<br>(b) has an encumbrancer take possession of or receiver or similar officer appointed over all or any part of its assets or undertaking; or an application is made for the appointment of a receiver or similar officer over all or any part of its assets or undertaking;<br>(c) has an administrator appointed (by court order or otherwise (including without limitation by its directors or by a floating charge holder)), or has an application made either for the appointment of an administrator or for an administration order, or has a notice of intention to appoint an administrator given;<br>(d) is the subject of any judgment or order made against it which is not complied with or discharged within thirty (30) days or is the subject of any execution, distress, sequestration or other process |

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| | levied upon or enforced against any of its assets;<br>(e) has proposed in respect of it a company voluntary arrangement pursuant to the Insolvency Act 1986 or any other composition or scheme for the benefit of any of its creditors;<br>(f) has a petition presented for its winding up (which is not dismissed within fourteen (14) days of its service) or has an application made for the appointment of a provisional liquidator or has a creditors' meeting convened pursuant to section 98 of the Insolvency Act 1986;<br>(g) ceases or threatens to cease to carry on business;<br>(h) is or becomes unable to meet its debts as they fall due within the meaning of section 123 of the Insolvency Act 1986; or<br>(i) anything analogous to any of the events in (a) to (h) inclusive shall occur in relation to the Party under the law of any jurisdiction in relation to which it is subject. |
| **"Intellectual Property" or "IP"** | means all patents, rights to inventions, copyright and related rights, trademarks and trade names, rights to goodwill or to sue for passing off, rights in designs, database rights, rights in Confidential Information and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world. |
| **"Key Staff"** | means the persons named in SECTION 5. |
| **"Know How"** | means any information or know-how that is:<br>(a) secret, that is to say, not generally known or easily accessible; |

(b) substantial, that is to say, significant and useful for the purposes of this Contract; and
(c) identified, that is to say, described in a sufficiently comprehensive manner so as to make it possible to verify that it fulfils the criteria of secrecy and substantiality,

including formulae, methods, plans, inventions, discoveries, processes, performance methodologies, techniques, specifications, technical information, tests, results, component lists, manuals and instructions, names of suppliers, identity of materials, algorithms, operating procedures and similar matters;

**“Patient Benefit”** means achieving any one or more of the following:

(a) identifiable improvements in the quality of treatment and clinical care offered by any Health Service Body;

(b) identifiable improvements in the experience of patients receiving care from any Health Service Body;

(c) identifiable improvements in patient health outcomes;

(d) identifiable improvements in the efficiency of any Health Service Body;

(e) identifiable and measurable cost savings in any Health Service Body;

(f) generating revenue for any Health Service Body; or

(g) any other outcome that has been accepted in writing by the Authority and that is designed to benefit any Health Service Body or a significant number of patients receiving Health Care from any Health Service Body.

**"Personal Data"** has the meaning ascribed to it in the Data Protection Legislation.

**“Reports”** means any report, executive summary, paper, abstract or other document

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| | provided by the Contractor under this Contract pursuant to Conditions 12 and 13 and SECTION 6. For the avoidance of doubt this does not extend to Arising Know How, Research Data, Foreground IP or other Intellectual Property described therein nor to reports generated by the Contractor's artificial intelligence products. |
| **"Research"** | means the scope of work specified in SECTION 3 and includes any Deliverables or Service Support element defined in SECTION 2 and/or specified in SECTION 3, Parts B and C. |
| **“Research Data”** | means information or data which is not Personal Data that is collected or generated in the performance of the Research and includes (but is not limited to) information that is collated or stored in searchable form. For the avoidance of doubt, Research Data does not include information or data that has been analysed. |
| **"Research Period"** | means the period commencing on the Commencement Date and ending on the Completion Date or such later date as may be agreed between the Parties unless otherwise determined in accordance with the terms of the Contract. |
| **“Research Site”** | means any site at which the Research will be performed. |
| **“Service Support”** | means any services outlined in SECTION 3 that are to be provided by or on behalf of the Contractor to support the performance of the Research. |
| **"State Aid"** | means any advantage granted by public authorities through state resources on a selective basis to any organisations that could potentially distort competition and trade in the European Union (for so long as it is directly applicable) and/or any relevant legislation with similar or comparable effect. |
| **“State Aid Legislation”** | means any and all legislation of the United Kingdom and the European Union (for so long as it is directly applicable) regarding the provision of State Aid . |

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| **"Third Party IP"** | means any Intellectual Property which is owned or controlled by any party (including any Collaborator) other than the Contractor and over which the Contractor has or can reasonably expect to secure a formal agreement or license to use in the performance of the Research or to perform the provisions of this Contract. |
| **"Variation"** | means a variation to this Contract agreed and executed in accordance with Condition 6. |

1.2 The interpretation and construction of this Contract shall be subject to the following provisions:

1.2.1 a reference to any statute, enactment, order, regulation or other similar instrument shall be construed as a reference to the statute, enactment, order, regulation or instrument as subsequently amended or re-enacted;

1.2.2 references to Sections and Schedules are to sections of and schedules to this Contract and references to Conditions are references to conditions in the Section of this Contract in which they appear, unless otherwise stated;

1.2.3 the singular includes the plural and vice versa;

1.2.4 references to a Party shall include that Party's personal representatives, successors or permitted assignees;

1.2.5 general words are not to be given a restrictive meaning because they are followed by particular examples, and any words introduced by the terms "including", "include", "in particular" or any similar expression will be construed as illustrative and the words following any of those terms will not limit the sense of the words preceding those terms; and

1.2.6 the headings in this Contract are for convenience only and shall not affect its interpretation.

## 2. COMMENCEMENT AND DURATION

2.1 This Contract shall commence on the Commencement Date and, subject to Condition 2.2 or to earlier termination in accordance with its terms, shall continue in full force and effect until the Completion Date.

2.2 If the Research has not effectively commenced by the Drop Dead Date or by such other date as the Parties may agree in writing, the Authority may withdraw the Award and/or any offer of funding and this Contract will terminate.

## 3. ADMINISTRATION, PERFORMANCE AND DIRECTION OF RESEARCH

3.1 The Authority may publish details of the non-confidential Research plan and project costs.

3.2 The Contractor shall ensure that each member of staff engaged on the Research undertakes to observe the Conditions of this Contract and any further or supplementary Contract entered into between the Parties hereto and that such members of staff are advised promptly of any changes in the scope of this Contract or the Research.

3.3 The objectives and general timeline of the Research are set out in SECTION 3. Within such objectives details of the exact programme to be followed and the day-to-day responsibility for carrying out this programme will be under the control of the Contractor, in consultation, as appropriate, with the Authority's Representative.

3.4 The Contractor shall ensure full communication takes place between the Parties and any other persons as may be notified to the Contractor by the Authority and the Contractor shall advise and report to the Authority as required by this Contract or by the reasonable request of the Authority. In particular the Contractor must notify the Authority and the relevant research ethics committee of any proposed deviation from the agreed protocol or if significant developments occur as a study progresses, including developments in relation to the safety of individuals or to scientific direction.

3.5 Where the Research involves Collaborators, the Contractor shall submit to the Authority a draft copy of the Contractor's Collaboration Agreement for approval by the Authority prior to signature by the Contractor. This shall be submitted to the Authority's Representative within a timeframe to be agreed.

3.6 Where the Research involves a Research Site (including where the Research Site is also a Collaborator):

3.6.1 the Contractor shall put in place an agreement with each Research Site before commencing that element of the Research to be performed at the relevant Research Site using an agreement that has been submitted to and approved by the Authority prior to signature by the Contractor.

3.6.2 the Contractor shall comply with and adhere to any compliance, governance or security standards, procedures or protocols required by the relevant Research Site.

3.7 The Contractor shall perform the Research and complete the Deliverables in accordance with the details and timeline set out in SECTION 3, Part A and Part B.

3.8 The Contractor shall provide the Service Support in accordance with the standards and timelines set out in SECTION 3, Part C.

## 4. ACCOUNTING AND PAYMENTS

4.1 Payments will be made by the Authority during the Research Period in accordance with dates and amounts specified in SECTION 4. The Authority

may suspend its payment of amounts due under this payment schedule at any time if in the view of the Authority:

4.1.1 progress on the Research has not been maintained in line with the timeline set out in SECTION 3, Part A and Part B; or

4.1.2 any element of the Service Support or any Deliverable has not been provided in accordance with the detail and timeline set out in SECTION 3; or

4.1.3 reports have not been submitted as required under Condition 12; or

4.1.4 the Contractor has materially failed to comply with the Conditions of this Contract (including where the Contractor has failed to procure that any of the Collaborators or Research Sites comply with certain obligations as required by this Contract).

Subject to these limits the Contractor is free to administer the funds within the terms of this Contract without further reference to the Authority.

4.2 The total amount to be paid by the Authority to the Contractor in any financial year shall not exceed the relevant amount detailed in SECTION 4 unless the Authority instructs the Authority's Representative to apply a compounded annual inflationary uplift. The Authority shall apply uplifts only after obtaining approval from Finance and Treasury. For illustration if the inflationary uplift in year 2 is set at 3% and year 3 at 1%, year 2 fees would be increased by 1.03 and year 3 by 1.03 x 1.01 = 1.0403. Where there is an upper limit to programme funding the limit will be applied excluding inflation. Such adjustment shall not require a Variation but each Party will make and retain a record of such adjustment. Subject to these limits the Contractor may administer the funds paid in accordance with SECTION 4 within the terms of this Contract and in connection with the Research without further reference to the Authority.

4.3 The Contractor is responsible for payments to third parties involved in the delivery of the Research and shall ensure that such payments are made promptly. In particular, where the Contractor is required to make payments to a Health Service Body, such payments will be made within 30 days of the relevant payment date.

4.4 The Authority reserves the right to recover from the Contractor any sum of money allocated in a specific financial year but not actually spent in that financial year (ending 31st March). Where reasonably possible, such recovery will be by way of set off against future payments. In the event of the Authority exercising its right under this Condition 4.4, a new payment schedule will be issued with the Approved Cost adjusted accordingly.

4.5 The Authority may request from the Contractor at any time such evidence as may reasonably be required to show that the Contractor has used the amounts paid in accordance with SECTION 4 within the terms of this Contract and in connection with the Research. The Contractor shall maintain proper financial records relating to the Research at all times during the Research Period and for a period of six (6) years after the end of the Research Period.

4.6 The Contractor shall not make any change in the total remuneration, conditions of service or numbers of staff engaged on the Research which will require a change in the total amount payable, or make material changes to

the Research detailed in SECTION 3, without prior written approval being given by the Authority.

4.7 The Contractor grants to the Authority and to any statutory or regulatory auditors of the Authority and to its or their authorised agents the right of reasonable access to (and if necessary to copy) the relevant financial records and/or other information relating to the financial records during normal business hours for the duration of the Research Period and for a period of six (6) years after the end of the Research Period.

4.8 The Contractor shall provide all reasonable cooperation and assistance at all times during the Research Period and for a period of six (6) years after termination or expiry of this Contract for the purposes of allowing the Authority to obtain such information as is necessary to fulfil the Authority's obligations to supply information for Parliamentary, Governmental, Judicial or other regulatory or administrative purposes and/or to carry out an audit of the Contractor's compliance with this Contract including all activities, performance, security and integrity in connection therewith.

4.9 On completion of the Research Period, the final payment in respect of costs properly incurred under this Contract will be paid by the Authority to the Contractor within thirty (30) calendar days of all of the following objectives being satisfied:

4.9.1 the Research has been completed in accordance with this Contract;

4.9.2 the Reports required under Conditions 12 and 13 have been submitted by the Contractor to the Authority;

4.9.3 agreement has been reached between the Parties in respect of any items remaining for disposal.

4.10 If at any time an overpayment has been made to the Contractor for any reason whatsoever, the amount of such overpayment shall be taken into account in assessing any further payments, or shall be recoverable from the Contractor at the Authority's discretion.

4.11 The Authority shall be under no obligation to make any payment on claims received more than twelve months after the completion of the Research Period and there will be a general presumption against paying claims received after this date, unless an extension has been requested and agreed in writing.

4.12 The Contractor is subject to the additional obligations set out in SCHEDULE E: STATE AID.

## 5. SET OFF

If any sum of money shall be due from the Contractor to the Authority or any other Government Department, the same may be deducted from any sum then due or which at any time thereafter may become due to the Contractor under this Contract or under any other agreement with the Authority or with any other department, office or agency of the Crown.

## 6. VARIATION

6.1 If at any time it appears likely that any provision of the Contract, or any aspect of the Research, needs to be varied the Contractor shall immediately inform

the Authority in writing requesting a Variation to the Contract, giving full details of the justification for the request and giving proposals for the Variation to the Contract. Upon receipt of such a request the Authority may:

6.1.1 agree to vary the Contract;

6.1.2 vary the Research in a manner which the Contractor agrees can be carried out within the Research Period and Approved Cost;

6.1.3 refuse the request and require the continuation of the Research in accordance with the Contract; or

6.2 The Parties shall act reasonably and in good faith in seeking to agree any requested Variation but if they are unable to agree such a Variation then this Contract may be terminated in accordance with Condition 17.

6.3 Any variation to the Contract shall be set out in a Variation to Contract Form as set out at SCHEDULE B to this SECTION 2 and signed by both Parties.

## 7. STAFF APPOINTMENTS

7.1 The Contractor agrees to use sufficient appropriately skilled resources to enable it to comply with its obligations under this Contract.

7.2 All Contractor's staff providing services in connection with this Contract shall be bound by the same terms and conditions of service which are normally applicable to the Contractor's staff and in any event which contain provisions in respect of Intellectual Property and confidentiality compatible with the terms of this Contract and allow those staff to publish the results in appropriate research journals in accordance with this Contract.

7.3 Subject to Condition 8, the Contractor shall keep and cause to be kept full, detailed and accurate records of all of activities and results obtained in connection with the Research. In this respect, the Contractor shall and shall procure that the staff and the staff of Collaborators and Research Sites and sub-contractors shall at all times:

7.3.1 observe professional standards; and

7.3.2 where relevant keep scientific notebooks recording all research, development and other work carried out in respect of the Research and the results of such research, development and other work, including keeping bound note books with page numbering recording all results and observations signed by the persons obtaining such results or making such observations, and countersigned appropriately.

7.4 The Contractor shall upon request make available to the Authority copies of all records generated in connection with the Research, including for the avoidance of doubt, records generated by its staff or Collaborators or sub-contractors under Condition 7.3 and by any third parties working on the Research.

## 8. CONFIDENTIALITY

8.1 In respect of any Confidential Information it may receive from the other Party and subject always to the remainder of this Condition 8, the receiving Party undertakes to keep secret and strictly confidential and shall not use for any purpose other than as contemplated by this Contract, nor disclose any such Confidential Information to any third party other than those involved in the Research who are bound by similar confidentiality obligations, without the disclosing Party's prior written consent provided that:

8.1.1 the receiving Party shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the commencement of this Contract; and

8.1.2 nothing herein shall be so construed as to prevent either party from using data processing techniques, ideas, know-how and the like gained during the performance of this Contract in the furtherance of its normal business, to the extent that this does not result in a disclosure of any Confidential Information or infringement of any valid Intellectual Property rights of either Party or the unauthorised processing of any Personal Data.

8.2 Condition 8.1 shall not apply to any Confidential Information received by one Party from the other:

8.2.1 which is or becomes public knowledge (otherwise than by breach of Condition 8.1);

8.2.2 which was in the possession of the receiving Party, without restriction as to its disclosure, before receiving it from the disclosing Party;

8.2.3 which is received from a third party who lawfully acquired it and who is under no obligation restricting its disclosure;

8.2.4 is independently developed without access to the Confidential Information; or

8.2.5 which must be disclosed pursuant to a statutory, legal or parliamentary obligation placed upon the Party making the disclosure, including any requirements for disclosure under the FOIA or the Environmental Information Regulations pursuant to Condition 31 (Freedom of Information).

8.3 The obligations of each of the Parties contained in Condition 8.1 above shall continue for a period of ten (10) years from the date of termination or expiry of this Contract. In the event that the Contractor fails to comply with this Condition 8, the Authority reserves the right to terminate this Contract with immediate effect by notice in writing.

## 9. DATA PROTECTION

### Compliance

9.1 In relation to the performance of this Contract and the Research and/or as required for the proper and lawful operation of this Contract and the Research, the Contractor shall be responsible for ensuring that each Collaborator and any Research Site will comply with the directly applicable requirements and

obligations of the Data Protection Legislation in the performance of the Research including:

9.1.1 completing all appropriate data protection impact assessments before commencing the relevant elements of the Research;

9.1.2 putting in place all appropriate data processing agreements;

9.1.3 making available any data or information reasonably required in order to fulfil transparency or other obligations under the Data Protection Legislation including in respect of automated decision making.

9.2 The Authority reserves the right upon giving reasonable notice and within normal working hours to request the Contractor to provide reasonable evidence in order to enable it to ascertain compliance with the Data Protection Legislation and the terms of this Condition 9.

9.3 The Contractor shall, from time to time, comply with any reasonable request made by the Authority to ensure compliance with this Condition 9 or any minimum standard required by the Authority and with the Data Protection Legislation or other directly applicable data protection and/or privacy laws.

**Confidentiality and security**

9.4 The Contractor shall ensure that any Personal Data shall be treated as confidential at all times including during collection, handling and use, and that the Personal Data (including in any electronic format) shall be stored securely at all times and with all technical and organisational security measures that would be necessary for compliance with Data Protection Legislation. The Contractor shall take appropriate measures to ensure the security of all Personal Data and guard against unauthorised access thereto or disclosure thereof or loss or destruction while in its custody.

9.5 No information which would lead to the identification of an individual shall be included in any publications without the prior agreement in writing of the individual concerned. No mention shall be made of individual officers of the Authority, nor shall information be included which might lead to their identification, without the prior agreement in writing of the Authority.

9.6 The Contractor shall ensure that medical information relating to the individuals who are the subjects of the Research shall be used in accordance with:

9.6.1 the Medical Research Council's "Personal Information in Medical Research", as amended from time to time; and

9.6.2 the NHS Digital “Code of practice on confidential information”, as amended from time to time.

9.7 In performing the Research, the Contractor shall, and shall use reasonable endeavours to procure that any Collaborator or Research Site, adhere to the following (to the extent relevant and applicable to the Research):

9.7.1 DHSC Code of Conduct for Data Driven Technology, setting out Government’s expectations for the development, deployment and use of data driven technology as updated from time to time

(available here: https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-

of-conduct-for-data-driven-health-and-care-technology as at the date of drafting);

9.7.2 NHSX's Digital Health Technology Standard, setting out how suppliers can develop digital health technologies in a manner which enables accelerated review and commissioning into the NHS as updated from time to time

(available here: https://assets.nhs.uk/prod/documents/NHS_Digital_Health_Technology_Standard_draft.pdf as at the date of drafting);

9.7.3 NICE Evidence Standards Framework for Digital Health Technologies, describing standards for the evidence that should be available, or developed, for digital health technologies to demonstrate their value in the UK health and care system

(available here: https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf as at the date of drafting);

9.7.4 Govt Security Classifications describing HM Government's administrative system for the secure, timely and efficient sharing of information

(available here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/715778/May-2018_Government-Security-Classifications-2.pdf as at the date of drafting).

9.8 The Contractor shall defend, fully indemnify and keep indemnified and shall hold harmless the Authority, its officers, employees and agents from and against any and all liabilities, losses, costs, charges and expenses incurred (either directly or, notwithstanding Condition 21.5, indirectly) as a result of any claims, demands, actions and proceedings made or brought against the Authority by any third party in respect of any loss or distress suffered by the loss or unauthorised disclosure of Personal Data or medical records by the Contractor, or any of its Collaborators, sub-contractors, employees, agents or person within its control, excepting in so far as such liabilities can be demonstrated by the Contractor to be due to any act or omission of the Authority, or their officers, servants or agents

9.9 The Contractor shall at its own expense conduct any litigation arising from any claims, demands, actions or proceedings by any third party in respect of the loss or unauthorised disclosure of Personal Data or medical records by the Contractor or any of its Collaborators, sub-contractors, servants, agents or persons within its control and all the negotiations for the settlement of the same and the Authority hereby agrees to grant the Contractor exclusive control of any such litigation or the negotiations for the settlement of the same.

9.10 The Contractor shall not, by any statement, act or omission, cause the Authority to be in breach of or to incur any civil, criminal or other liability under any other law or regulation relating to data protection or privacy.

## 10. RIGHTS TO RESEARCH DATA

10.1 Subject to the provisions of Conditions 8, 9 and 10.1, and in the event that in the Authority's reasonable opinion the Research Data is not being appropriately managed, disseminated or used, the Authority reserves the right to have access to and to use the Research Data compiled during the course of the Research, and will respect existing confidentiality obligations in respect of any Research Data which it obtains, and to permit any Health Service Body to access and use the Research Data in order to: (i) support the development, promotion or provision of Health Care; or, (ii) for any other purpose that is not a Commercial Use. For the avoidance of doubt, the Authority shall not be entitled to inspect, take or be supplied with copies of the Research Data other than in an anonymised form.

10.2 The Contractor shall ensure that all basic factual data is either anonymised or pseudonymised (in which case the key to personal identities of all persons to whom the Research Data relates is kept in a separate and secure place). As a minimum, the Contractor shall ensure that such pseudonymisation satisfies the appropriate standard recommended by the Information Commissioner's Office from time to time.

10.3 In the event that the Contractor does supply the Authority with Personal Data or Personal Data that has been pseudonymised or anonymised, the Contractor warrants to the Authority that:

10.3.1 any Personal Data provided (whether by way of reporting progress or results or otherwise) is provided with the consent of the Data Subjects involved or on the basis of a specified legal justification; or

10.3.2 any Personal Data that has been pseudonymised or anonymised before being provided has been pseudonymised or anonymised to the appropriate standard recommended by the Information Commissioner's Office from time to time;

And in each case, the Contractor further warrants that it may be used by the Authority without restriction.

10.4 The Contractor shall, at the request of the Authority, deposit both qualitative and quantitative Research Data in a relevant data archive subject to any reasonable delay necessary to enable the protection of Foreground IP.

10.5 In order to reflect the Authority's position on open access to research materials, where research materials recording the outcome of the Research or details of the progress of the Research are submitted for publication, the Contractor shall either:

10.5.1 subject to confidentiality requirements and to applicable data protection considerations, make all information and data (including but not limited to Research Data) on which the research materials are based available on an open access basis; or

10.5.2 include a statement with the research materials detailing how such information and data can be accessed.

## 11. RESEARCH PRACTICE AND ETHICS

11.1 The Contractor will ensure that research in any way connected with this Contract is conducted in accordance with the Health Research Authority guidance “UK Policy Framework For Health and Social Care Research”, with “The Concordat to support Research Integrity” and, if relevant, in accordance with the Health Research Authority guidance "Governance Arrangements for Research Ethics Committees” (GAfREC) or such other guidelines as may be issued from time to time by the Department of Health and Social Care or the Health Research Authority and copies of which are made available to the Contractor.

11.2 The Contractor shall comply with all relevant legislation including but not limited to:

11.2.1 The Medicines for Human Use (Clinical Trials) Regulations (SI2004/1031) as Amended;

11.2.2 The Human Tissue Act 2004; and

The Mental Capacity Act 2005.

11.3 The Contractor shall (and shall procure that each Collaborator and Research Site shall) use all reasonable endeavours to comply with guidance and advice from the Authority and the Health Research Authority on research governance and the use and implementation of the Authority model research agreements or those issued by Health Research Authority where possible, which may be issued from time to time.

11.4 Unless any of the exceptions or other exclusions described in GAfREC apply, the Contractor will submit the Research for review by a Research Ethics Committee recognised by the Authority if the Research proposed involves:

11.4.1 potential research participants (including those who have died within the last 100 years) identified from, or because of, their past or present use of the Care Services (including Care Services provided under contract with the private or voluntary sectors), including participants recruited through these Care Services as healthy controls;

11.4.2 potential research participants (including those who have died within the last 100 years) identified because of their status as relatives or carers of past or present users of Care Services;

11.4.3 collection of tissue (i.e. any material consisting of or including human cells) or information from users of Care Services;

11.4.4 use of previously collected tissue or information from which individual past or present users of Care Services could be identified, either directly from that tissue or information, or from its combination with other tissue or information in, or likely to come into, the possession of someone to whom the tissue or information is made available;

11.4.5 xenotransplantation;

11.4.6 human DNA extracted from acellular material;

11.4.7 prisoners; or

11.4.8 social care;

with a view to obtaining the Research Ethics Committee's favourable opinion of the Research.

11.5 The Contractor will provide the Authority's Representative with a copy of the Research Ethics Committee's favourable opinion and the HRA approval once they have been given (whether unconditionally or subject to conditions) or inform the Authority's Representative if either is withheld.

11.6 Research activity requiring ethical approval shall not commence until such favourable opinion is given.

11.7 In the event of any animals being used in research, all requirements of the Animals (Scientific Procedures) Act 1986 must be followed. In addition, the Department of Health and Social Care's mission statement and Home Office advice on ethical review process in relation to this Act must be effective and in operation.

## 12. MONITORING AND REPORTING

12.1 Progress of the Research will be reviewed periodically by the Authority's Representative against the specifications detailed in SECTION 3 (including the Deliverables and the Service Support) and SECTION 6. The Contractor acknowledges that the Authority is entitled to suspend payments in accordance with Condition 3.7 in the event that reasonable progress on the Research has not been maintained; or any element of the Deliverables or the Service Support have not been provided as required; or reports have not been submitted as required under Condition 12; or the Contractor has substantially failed to comply with the terms of this Contract (including where the Contractor has failed to procure that any of the Collaborators or Research Sites comply with certain obligations as required by this Contract).

12.2 The Contractor shall provide an interim written report on the progress of the Research according to the schedule set out in SECTION 6. The interim report shall be in a form and otherwise in compliance with the format set out by the Authority's Representative as amended from time to time and shall include an outline of the Research Data, methods, an outline of any Foreground IP, Arising Know How results, financial analysis relating to the outputs of the Research, Background IP and provisional conclusions together with management information, financial information relating to the costs and progress of the Research and any other relevant information relating to the Research up to the relevant date.

12.3 During the Research Period the Contractor shall provide verbal or written reports as reasonably required by the Authority or the Authority's Representative on any aspect of the Research.

12.4 During the Research Period, the Contractor shall regularly gather feedback from Research Sites and report such feedback to the Authority. This feedback:

12.4.1 shall as a minimum address the issues listed at SECTION 6; and

12.4.2 may be gathered by any appropriate means including by using questionnaires offered to individuals (whether Research Site staff or other participants in the Research) and by offering such individuals other opportunities to provide feedback.

12.5 The Authority's use of reports provided by the Contractor pursuant to this Contract shall be in compliance with the provisions of this Contract, including in particular with regard to the obligations of confidentiality and protection of Intellectual Property.

## 13. FINAL REPORT

13.1 The Contractor shall provide a draft final report on the Research within FOURTEEN (14) CALENDAR DAYS of the Completion Date or date of termination howsoever terminated. The draft final report shall be in a form to be agreed with the Authority as amended from time to time or as otherwise required by the Authority's Representative and shall include an outline of the Research Data, methods, an outline of any Foreground IP, Arising Know How, results relevant to the Research, Background IP and the final conclusions of the Research together with management information and any other information relating to the Research up to the Completion Date.

13.2 The Contractor shall also provide, in a form to be agreed with the Authority, a draft summary final report of the findings for the Research.

13.3 If within one (1) year of the end of the Research Period the Contractor has not produced a report which satisfies the Authority, the Authority may prepare and publish, or arrange for the preparation and publication of, such a report.

13.4 For the duration of the Research Period and for a period of up to five (5) years after completion of the Research the Contractor will comply with requests for annual research outputs information collected through Authority-authorised web-based systems.

13.5 The Authority reserves the right to reproduce the findings of the final report or to provide a summary of the findings, subject to the obligations of this Contract in respect of confidentiality and Intellectual Property

## 14. INTELLECTUAL PROPERTY RIGHTS

14.1 The Contractor shall identify, protect and maintain Intellectual Property in accordance with its standard institutional policy ("**Contractor IP Policy**") insofar as this does not conflict with the rights of the Authority under this Contract. The Contractor will make available a copy of the Contractor IP Policy on the request of the Authority.

14.2 Foreground IP and Research Data that may arise from the Research shall either vest in the Contractor, or shall be managed in accordance with the Contractor's Collaboration Agreement or agreement with the relevant Research Site, pursuant to Condition 3.5 and 3.6 and Schedule D as periodically updated.

14.3 The Contractor shall ensure that Arising Know How may be used by the Contractor and the Authority on a world-wide, royalty free, non-exclusive, transferable and sub-licensable basis:

14.3.1 in the course of the Contractor's normal activities:

14.3.2 or to achieve Patient Benefit; or

14.3.3 For Commercial Use provided that such Commercial Use does not prevent use for Patient Benefit.

(a) the Contractor may not, and shall ensure that the Collaborator(s) may not, use, or permit any other party to use, the Arising Know How for any Commercial Use without the prior written consent of the Authority obtained in accordance with Condition 15.5;

(b) the Contractor and Collaborator(s) may only use the Arising Know How in accordance with Condition 8.1.2.

14.4 The Contractor shall and shall ensure that the Collaborator(s) and Research Sites shall keep detailed records including where relevant scientific notebooks of all of its activities and upon request shall make available copies to the Authority.

14.5 The Contractor shall utilise in its Research any Contractor Background IP that is necessary or useful for undertaking the Research. The Contractor shall use reasonable endeavours to make available to the Collaborators and to the Authority the Third Party IP that is necessary or useful for undertaking the Research and the protection or exploitation of the Foreground IP, Arising Know How and Research Data.

14.6 The Contractor shall grant (and shall procure that all Collaborators and Research Sites grant) to the Authority a non-exclusive, irrevocable, royalty-free, worldwide licence together with the right to grant sub-licences to Health Service Bodies or others directly engaged in providing Health Care, permitting the Authority to:

14.6.1 use and publish (solely in accordance with this Contract and, in particular, such provisions relating to the protection of Intellectual Property and Confidential Information):

(a) any information relating to the Research which is not Confidential Information of the Contractor;

(b) any Foreground IP;

(c) Research Data;

(d) Reports;

(e) Arising Know How; and,

(f) conclusions arising from the Research

and in each case, the Authority intends to exercise this right only where in the Authority's reasonable opinion the Contractor or Collaborator (as appropriate) is not appropriately managing, disseminating or using such items and in each case the Authority is permitted to use or make available such items as it sees fit in support of the development, promotion or provision of Health Care or for any other purpose that is not a Commercial Use; and

14.6.2 use the Contractor's Background IP and Third Party IP but solely to the extent that it is necessary in order to exercise the licence granted in sub-Condition 14.6.1 above.

In each case, where any third party has rights existing at the date of the licence granted in this Condition such licence will be subject to the third party rights and the Contractor shall: (i) notify the Authority of such rights; and (ii) make reasonable efforts to overcome or to negotiate exclusions from such rights for the benefit of the Authority.

14.7 The Contractor shall ensure, and shall ensure that the Collaborator(s) shall ensure that a suitable agreement is in place to ensure the effective performance of the Research by Collaborators, Research Sites and sub-contractors in accordance with the terms of this Contract.

14.8 Unless the Authority has given its prior consent in writing (such consent not to be unreasonably withheld or delayed), the Contractor shall not enter into any agreements in which the Intellectual Property arrangements would adversely affect the Contractor's ability to comply with the terms of this Contract

14.8.1

## 15. EXPLOITATION OF INTELLECTUAL PROPERTY

15.1 The Contractor shall inform the Authority in a timely manner of any outcomes from the Research, including any Deliverables, Foreground IP, Arising Know How or Research Data, which are capable of exploitation either by direct adoption into the healthcare service or via commercialisation.

15.2 The Contractor shall develop, implement and maintain procedures for the management of Foreground IP, Arising Know How and Research Data and in particular, but without limitation, shall use all reasonable endeavours to ensure that:

15.2.1 the Foreground IP is identified and recorded;

15.2.2 it notifies the Authority within six (6) months of receipt of disclosure of potential patentable Foreground IP and in the event that the Contractor decides not to protect the invention by filing a patent application, the Contractor agrees to communicate this decision to the Authority, save that the Contractor may reasonably request an extension of up to one (1) year from the date of any such notification under this Condition 15.2 to enable further validation or development of the Foreground IP prior to protection;

15.2.3 prior to any publication of any Arising Know How, Research Data, Foreground IP or results or outcomes of the Research, patentable inventions arising from the Research are identified, duly considered for patentability and, where it is commercially reasonable to do so and is an appropriate means of achieving the public benefit, patent applications are filed in respect thereof at patent offices in territories where products or services arising from the inventions may be made, sold or used in accordance with the Contractor IP Policy;

15.2.4 in exercising the rights in Condition 15.2 the Contractor takes due consideration of the Authority's attitude to access to essential medicines in the developing world.

15.2.5 in exercising the rights in Condition 15.2 the Contractor takes due consideration of the Authority's attitude to the inappropriate use of patents;

15.2.6 all such patent applications are diligently prosecuted having regard to all relevant circumstances; and

15.2.7 in the event that the Contractor elects to abandon prosecution of a patent application protecting applications of the outcome of the

Research (including the Foreground IP), the Contractor shall inform the Authority's Representative as soon as reasonably practical and in any event no less than two (2) months in advance of the patent application lapsing and the Authority shall have the right but not the obligation to take assignment of the Intellectual Property associated with the application free of charge and to manage its prosecution.

15.3 The Contractor shall permit the Authority to monitor the operation and effectiveness of the Contractor's procedures for the management of Intellectual Property in such ways as the Authority considers reasonably necessary to ensure that any Foreground IP generated is disseminated and/or exploited for the public benefit. This right shall include but not be limited to the right of the Authority (or its authorised representative) to inspect and audit the Contractor's records kept pursuant to Condition 16.4.3, subject to the Authority providing ten (10) Business Days' written notice to the Contractor. This right of inspection and audit may be performed once in each twelve (12) month period following the Commencement Date.

15.4 Consistent with the good management of Intellectual Property and subject to the written agreement of the Authority, the Contractor shall use all reasonable endeavours to:

15.4.1 where reasonable and practicable, promote the dissemination of the Foreground IP, Arising Know How and Research Data in order to achieve Patient Benefit;

15.4.2 where reasonable and practicable and subject to obtaining the prior written consent of the Authority, exploit such Foreground IP, Arising Know How and Research Data to generate either capital or revenue or both; and

15.4.3 keep proper records showing the description of the Contractor Background IP or Third Party Background IP used and Foreground IP generated.

15.5 The Contractor shall (and shall procure that any Collaborator or Research Site shall) seek the prior written consent of the Authority before it or any Collaborator, as the case may be, makes any Commercial Use of, or permits any third party to make any Commercial Use of the Foreground IP or Arising Know How or Research Data. The Authority shall not unreasonably withhold or delay such consent, but as a condition of granting consent, the Contractor shall or shall procure that any Collaborator or Research Site shall provide all appropriate details of any proposed commercialisation arrangements, including but not limited to any deal sheet or commercial terms in circulation, which information the Authority shall keep confidential. The Authority shall within thirty (30) Business Days of such a written consent request inform the Contractor and/or Collaborator if the Authority requires the Contractor and/or Collaborator to enter into a commercialisation agreement with the Authority. Any such commercialisation agreement shall as a minimum:

15.5.1 address the distribution of revenue, equity or other benefits arising from the proposed commercialisation arrangements and rights to use the Foreground IP, Arising Know How or Research Data;

15.5.2 reflect the Authority's policy from time to time relating to the allocation and use of revenue, equity or other benefits arising from the

proposed commercialisation arrangements and rights to use the Foreground IP, Arising Know How or Research Data;

15.5.3 take into consideration the relative contribution of the Authority, the Contractor, the Collaborator(s) and other third party funders or contributors to the Foreground IP, the Arising Know How or the Research Data.

15.5.4 Where the Collaborator is an NHS organisation, the Contractor will ensure they:

(a) Abide by the five principles governing the sharing of patient data: https://www.gov.uk/government/publications/creating-the-right-framework-to-realise-the-benefits-of-health-data/creating-the-right-framework-to-realise-the-benefits-for-patients-and-the-nhs-where-data-underpins-innovation

(b) Give due consideration to payment and royalties to NHS Collaborators for the sharing of health and care data

(c) Take advice from NHSX on any commercial arrangements with NHS Collaborators for the sharing of health and care data

15.6 Unless agreed otherwise in writing, the Contractor shall ensure that any proceeds of commercialisation allocated to the Authority as a result of any Commercial Use are distributed according to the terms of the relevant revenue sharing agreement.

15.7 In the event that the Contractor and/or a Collaborator decides to seek approval for commercialisation under Condition 15.5, then the Contractor and/or Collaborator must take due consideration of the Authority's attitude to access to essential health related technologies including medicines in the developing world.

15.8 If the Contractor does not reasonably protect, manage or exploit any Foreground IP arising out of the Research according to the terms of this Contract or if this Contract is terminated according to Condition 17.4 then the Authority shall have the right, acting reasonably and subject to the rights of third party licensees or Collaborators, but not the obligation, to take assignment of and protect, manage and exploit such Foreground IP. Such right shall be exercised no earlier than six (6) months after the Authority has given the Contractor notice in writing that it is failing to protect, manage and exploit such Foreground IP to the Authority's reasonable satisfaction. However, the Authority may exercise such right sooner where it reasonably considers that the opportunity to protect, manage or exploit such Foreground IP for the public benefit and/or Patient Benefit could be lost if more immediate action is not taken. The Contractor agrees to do, and will ensure that its employees, students and any third party acting on its behalf do, all acts required by the Authority to further such protection and exploitation including the delivery of all necessary written information including copies of any notebooks maintained throughout the Research.

15.9 If the Contractor wishes to use any third party (excluding its professional advisors) to carry out its obligations with respect to this Condition 15, which is different from that proposed in the Contractor IP Policy, then it must provide details of the proposed third party to the Authority and obtain the Authority's prior written approval to such third party carrying out exploitation activities with respect to the Foreground IP.

15.10 The Contractor shall do or procure to be done all such further acts and things and execute or procure the execution of all such other documents as the Authority may from time to time require for the purpose of giving the Authority the full benefit of the provisions of this Contract.

## 16. PUBLICATION

16.1 The Contractor shall (and shall procure that each member of staff engaged on the Research shall) use all reasonable endeavours to comply with the Authority's policy of publication of outputs and results of Research (subject to the obligations of this Contract regarding Confidentiality and Intellectual Property). This condition shall not apply where the Contractor and/or Collaborator has a contractual, legal or similar obligation to publish specific details about the Contract or the Research. For the avoidance of doubt this obligation continues after the end of the Research Period.

16.2 In the event that the Contractor fails to comply with Condition 16.1 the Authority reserves the right to:

16.2.1 deem this to be a material breach and terminate this Contract in accordance with Condition 17.4; and/or

16.2.2 suspend or reduce its payment of amounts due under the payment schedule in SECTION 4 of the Contract; and/or

16.2.3 require repayment of all or part of the funding provided under this Contract.

16.3 The Contractor further acknowledges that a breach of Condition 16.1 by the Contractor may be taken into account by the Authority when considering future applications for Authority funding from the Contractor.

16.4 The Contractor shall comply, and shall ensure that the Collaborator(s) comply, with guidance and advice from the Authority on branding and publicity which may be issued from time to time including, but not limited to, permitted use of the NHS, NHSx and Department of Health and Social Care brands, names and logos.

16.5 Subject to the provisions of Condition 8 and notwithstanding the provisions of Condition 14 and 15, the Authority's Representative may at any time publish the Reports for any non-commercial purpose and in conjunction with the Authority's statement on open access to research "Statement on DHSC funded research and UK PubMed Central". Such purposes may include any entry in a register of research findings or an individual issue of or a review article in a monograph series prepared on the Authority's behalf by the Authority's Representative. The timing of any such publication will be subject to consultation with the Contractor and will take account of publication timetables in other peer-reviewed journals and the need to make research findings publicly available as soon as practicable.

16.6 The Contractor shall assign to the Authority on behalf of the Crown all Intellectual Property rights in the Reports to which the Contractor is legally entitled, by signing a document in the form shown at the SCHEDULE A to this SECTION 2 and returning it to the Authority on signature of this Contract. For the avoidance of doubt this assignment relates to the copyright in the Report and does not extend to the Intellectual Property described therein.

16.7 The Contractor undertakes to obtain an assignment to the Authority of any Intellectual Property rights in the Reports where such rights are the property of a person or organisation other than the Contractor. The Contractor shall provide the Authority with all appropriate details, including proof that the Contractor has obtained such an assignment and details of the acknowledgements required by owners of the rights assigned.

16.8 The Authority will ensure that any Queen's Printer and Controller of HMSO copyright publication arising from the Reports carries the following statement:

"© Queen's Printer and Controller of HMSO 2021 [year of publication].

This work was produced by (name of author/organisation) under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care".

16.9 The Contractor shall ensure that the outcome of the Research is prepared for publication in a suitable peer-reviewed journal and shall ensure that it, and any other publication, including patent applications, of or resulting from research carried out under this Contract shall acknowledge the Authority's financial support and carry a disclaimer as the Authority may require or in the absence of direction from the Authority a notice as follows:

"This report is independent research funded by the Department of Health and Social Care (Artificial Intelligence, CaRi-Heart: Real-world impact of AI cardiovascular risk prediction from routine CT scans, AI_AWARD02443). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, NHSX or the Department of Health and Social Care."

## 17. TERMINATION UPON OCCURRENCE OF EVENTS

17.1 Without prejudice to any other provision of this Contract, this Contract may be terminated by either Party giving three (3) months' notice in writing to the other. Should the option to terminate be exercised by the Authority under this Condition 17.1, it shall indemnify the Contractor from and against all and any actual loss unavoidably incurred by reason or in consequence of the termination provided that the Contractor takes all immediate and reasonable steps to minimise the loss.

17.2 The Authority will not pay any sum under Condition 17.1 which, when taken together with any sums paid or due or becoming due to the Contractor under this Contract, will exceed such total sums as would have been payable under this Contract if the Contractor had fulfilled its obligations under this Contract.

17.3 The Authority may at any time by notice in writing terminate this Contract without liability for any damage, loss or expenses arising as a result of or in connection with such termination if there is a change of control (as defined by sections 450 and 451 of the Corporation Taxes Act 2010) in Contractor.

17.4 The Authority shall be permitted to exercise its rights pursuant to this Condition 17.3 for only six (6) months after any such change of control and shall not be permitted to exercise such rights where the Authority has agreed in advance in writing to the particular change of control and such change of control takes place as proposed. The Contractor shall notify the Authority within two (2) weeks of any change of control taking place.

17.5 The Authority may at any time by notice in writing terminate this Contract without liability for any damage, loss or expenses arising as a result of or in connection with such termination if:

17.5.1 the Contractor is subject to an Insolvency Event; or

17.5.2 the Contractor is in material breach of any of the terms and conditions of this Contract, and either:

(a) in the case of a breach capable of remedy, it fails to remedy that breach within thirty (30) days of the service of a written notice by the Authority specifying the breach and requiring its remedy; or

(b) the breach is not capable of remedy; or

17.5.3 the Contractor fails to deliver the Service Support in accordance with SECTION 3 Part C; or

17.5.4 an event of Force Majeure exists for more than six (6) months; or

17.5.5 in accordance with Condition 16.2 of this Contract

17.6 The Authority may terminate this Contract with immediate effect at any time:

17.6.1 if any member of the Contractor's Key Staff is not available to fulfil his part in the Research for any part of the Research Period, subject to prior discussion with the Contractor to first attempt to identify a mutually acceptable replacement;

17.6.2 if the Contractor is unable or unwilling for any reason to continue with the Research or if in the reasonable opinion of the Authority the Contractor is consistently failing to achieve an acceptable standard in relation to the Research in which case no financial compensation shall be payable to the Contractor.

## 18. CONSEQUENCES OF TERMINATION

18.1 Termination of this Contract, however caused, shall not:

18.1.1 release the Contractor from any duty or obligation of confidence, , which falls on it, or its sub-contractors, agents, employees or former employees, under this Contract or under the general law governing Confidential Information; or

18.1.2 prejudice or affect any rights, action or remedy which shall have accrued before termination or shall accrue thereafter to any Party.

## 19. EQUIPMENT

19.1 The Contractor shall take all practical steps to purchase all materials and equipment at a fair and reasonable price. The Authority may inspect the

original quotations and invoices issued to the Contractor for equipment purchased in connection with the Research and recover any funds provided for the purchase if the Contractor does not provide this documentation on request.

19.2 At the end of the Research Period, and after the final presentation of the final report all equipment purchased for use on the Research with funds provided by the Authority shall become the property of the Contractor.

## 20. FORCE MAJEURE

20.1 In the event that any Party is prevented or delayed in the performance of its obligations under this Contract by an event of Force Majeure, the obligations of the Parties under this Contract shall remain in suspense until the cause thereof has ceased. "**Force Majeure**" shall include any of the following: riots, sabotage, acts of war or piracy, epidemic or pandemic, destruction of essential equipment by fire, explosion, storm, flood or earthquake, and delay caused by failure of power supplied or transport facilities or any other cause beyond the control of the Parties which renders performance of this Contract impossible.

20.2 Neither of the parties shall be liable to the other for any loss including but not limited to any damages or abatement of charges whether directly or indirectly caused or incurred by any failure or delay in the performance of its obligations due to Force Majeure.

20.3 If either of the parties shall become aware of Force Majeure which give or are likely to give rise to any failure or delay on its part it shall forthwith notify the other by the most expeditious method then available and shall say how long it is estimated that such failure or delay shall continue.

## 21. WARRANTIES AND LIABILITY

21.1 The Contractor warrants that:

21.1.1 it has the requisite capacity and authority and all necessary licences, permits and consents to enter into this Contract;

21.1.2 it has full capacity, power and authority and all necessary licences, permits and consents to assume and fully perform all of its obligations under this Contract;

21.1.3 it has, or has access to, sufficient resources to perform the Research as contemplated under this Contract and to meet its other obligations under this Contract;

21.1.4 there are no actions, suits or proceedings pending or, to the Contractor's knowledge, threatened against or affecting the Contractor before any court or administrative body or tribunal that might affect the ability of the Contractor to meet and carry out its obligations under this Contract,

21.1.5 to the best of its knowledge and belief:

(a) except for the items listed in the declaration set out in SCHEDULE C, the Contractor has an unrestricted and free

right to use and to make available the Contractor Background IP for the purposes of the Research;

(b) it and/or a Collaborator will be the legal and beneficial owner(s) of all right, title and interest in and to the Foreground IP and where reasonable and practicable the Collaborator will own and manage such Foreground IP in accordance with, and subject to the terms of this Contract; and

(c) it has not granted any third party any right in respect of the Foreground IP (other than in accordance with the provisions of this Contract), and has not charged or encumbered and will not charge or encumber any of the same.

21.1.6 the Research (including the Service Support) will be carried out by appropriately experienced, qualified and trained personnel with all due skill, care and diligence;

21.1.7 in carrying out the Research, the Contractor will use all reasonable efforts to ensure that sufficient authorisation has been obtained to permit the use of any Intellectual Property that is reasonably necessary to enable the use of the Foreground IP, Arising Know How or Research Data to the extent necessary to exercise any rights under, or to perform, this Contract;

21.1.8 the Contractor will discharge its obligations under this Contract with all due skill, care and diligence including Good Industry Practice and (without limiting the generality of the foregoing) in accordance with its own established internal procedures.

21.2 Except as expressly provided in this Contract, none of the Parties gives any warranties or makes any representations:

21.2.1 with respect to any of the Foreground IP and/or Contractor Background IP or any products derived from them, or their fitness for any purpose; or

21.2.2 that any material produced or supplied by any Party and any processes or techniques used, proposed or recommended by any Party will not infringe any patent or other intellectual property rights of any person in any country.

21.3 Subject to Condition 21.6 the Contractor shall indemnify the Authority, its officers, servants and agents fully against any liability, loss, claim or proceedings whatsoever arising under any statute or at common law in respect of:

21.3.1 any damage to property, real or personal, including any infringement of third party Intellectual Property rights; and,

21.3.2 any injury to persons including injury resulting in death arising out of, or in the course of, or in connection with this Contract,

excepting in so far as such damage or injury shall be demonstrated by the Contractor to be due to any act or neglect of the Authority, or their officers, servants or agents.

21.4 Notwithstanding any other provision of this Agreement, each Party shall use its reasonable endeavours to mitigate losses it may incur that are covered by indemnities provided by the other Party.

21.5 The Contractor shall promptly notify the Authority if any claim or demand is made or action brought against the Contractor for infringement or alleged infringement of Intellectual Property rights which might affect the Research and the Contractor shall discuss with the Authority the steps it proposes to take to keep the Authority informed of the progress in respect of such claims, demands or action.

21.6 Except in circumstances of fraud or wilful misconduct by a Party or its affiliates, no Party or any of its affiliates shall be liable to another Party or any affiliate of another party for special, indirect, incidental or consequential damages, whether in contract, warranty, negligence, tort, strict liability or otherwise, arising out of any breach of or failure to perform any of the provisions of this Contract.

21.7 Nothing in this Contract shall limit the liability of any Party in respect of:

21.7.1 personal injury or death arising out of that party's negligence or wilful misconduct; or

21.7.2 fraud or fraudulent misrepresentation.

## 22. INSURANCE

22.1 Without prejudice to Condition 21.3 the Contractor shall throughout the duration of this Contract effect and maintain with a reputable insurance company a policy or policies of insurance providing an adequate level of cover in respect of all risks which may be incurred by the Contractor arising out of the Contractor's performance of this Contract.

22.2 The Contractor shall produce on demand by the Authority documentary evidence that any insurance policies required by Condition 22.1 are in force.

22.3 The terms or the amount of cover of any insurance shall not relieve the Contractor of any liabilities under the Contract. It shall be the responsibility of the Contractor to determine the amount of insurance that will be adequate to enable the Contractor to satisfy any liability referred to in Condition 21.3.

## 23. ASSIGNABILITY

23.1 Except as set out in SECTION 3 (where sub-contractors intended to be used by the Contractor may be listed and deemed approved by the Authority), the Contractor shall not sub-contract, transfer or assign the whole or any part of this Contract or collaborate with any third party in the performance of its obligations under this Contract without the prior written consent of the Authority, which consent may be subject to such terms and conditions as the Authority may specify.

23.2 The Contractor shall be responsible for the acts and omissions of its sub-contractors as though they were its own.

23.3 Notwithstanding Condition 23.2, the Contractor shall ensure that, to the extent that they are relevant, and where reasonable to do so, the Conditions of this Contract are incorporated into any sub-contract (including any Contractor's

Collaboration Agreement between the Contractor and any Collaborator) and that all reasonable steps are taken by it to ensure that its sub-contractors are aware of and adhere to the Conditions of this Contract.

## 24. WAIVER

The waiver by the Authority of any right or remedy in respect of any breach of any term or condition or requirement of this Contract shall not prevent the subsequent enforcement thereof and shall not be deemed to be a waiver of any right or remedy in respect of any subsequent breach.

## 25. COMPLIANCE WITH BRIBERY ACT

25.1 The Contractor shall:

25.1.1 comply with all Applicable Laws, statutes, regulations and codes relating to anti-bribery and anti-corruption including but not limited to the Bribery Act 2010 ("Relevant Requirements");

25.1.2 not engage in any activity, practice or conduct which would constitute an offence under sections 1, 2 or 6 of the Bribery Act 2010 if such activity, practice or conduct had been carried out in the UK

25.1.3 comply with the Bribery Act policies of the Authority, such policies to be provided on request;

25.1.4 have and shall maintain in place throughout the Contract Period its own policies and procedures, including but not limited to adequate procedures under the Bribery Act 2010, to ensure compliance with the Relevant Requirements and will enforce them where appropriate;

25.1.5 promptly report to the Authority any request or demand for any undue financial or other advantage of any kind received by the Authority in connection with the performance of this Contract; and

25.1.6 immediately notify the Authority (in writing) if a foreign public official becomes an officer or employee of the Contractor or acquires a direct or indirect interest in the Contractor and the Contractor warrants that it has no foreign public officials as direct or indirect owners, officers or employees at the date of this Contract.

25.2 For the purpose of this Condition 25, the meaning of adequate procedures and foreign public official and whether a person is associated with another person shall be determined in accordance with section 7(2) of the Bribery Act 2010 (and any guidance issued under section 9 of that Act), sections 6(5) and 6(6) of that Act and section 8 of that Act, respectively. For the purposes of this Condition 25 a person associated with the Contractor includes but is not limited to any subcontractor of the Company.

## 26. COMPLIANCE WITH MODERN SLAVERY ACT

26.1 The Contractor shall ensure that it, its officers and employees comply with the Modern Slavery Act 2015 and shall (i) take all reasonable steps to identify, address, remove and avoid slavery and/or human trafficking from anywhere in its business or supply chain; and (ii) shall notify the Authority as soon as it becomes aware of any actual or suspected slavery or human trafficking in a supply chain which has a connection with the Contract and the Contractor shall use reasonable endeavours to procure that its sub-contractors and agents comply with the Modern Slavery Act 2015.

26.2 If the Contractor fails to take steps to deal adequately with any actual or suspected slavery or human trafficking in its business or supply chain, the Authority shall be entitled to terminate this Contract with immediate effect by giving written notice to the Contractor.

26.3 The Contractor warrants that it is not and has not been the subject of any investigation, inquiry or enforcement proceedings by any governmental, administrative or regulatory body regarding any offence or alleged offence of or in connection with slavery and human trafficking.

## 27. FRAUD

27.1 The Contractor shall take all reasonable steps, in accordance with Good Industry Practice, to prevent Fraud by Contractor's staff and the Contractor (including its shareholders, members, directors) in connection with the receipt of monies from the Authority.

27.2 The Contractor shall notify the Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.

27.3 If the Contractor or Contractor's staff commits Fraud in relation to this or any other contract with the Crown (including the Authority) the Authority may:

27.3.1 terminate the Contract immediately by giving notice in writing and recover from the Contractor the amount of any loss suffered by the Authority resulting from the termination, including the cost reasonably incurred by the Authority of making other arrangements for the supply of the Research and any additional expenditure incurred by the Authority throughout the remainder of the Research Period; or

27.3.2 recover in full from the Contractor any other loss sustained by the Authority in consequence of any breach of this Condition 27.

## 28. DISPUTE RESOLUTION

28.1 Any dispute, difference or question between the Parties with respect to any matter arising out of or relating to this Contract shall be resolved by negotiation.

28.2 If the matter cannot be resolved through negotiation, the Parties will, at the request of either of them, attempt in good faith to resolve the dispute through an agreed alternative dispute resolution ("ADR") procedure.

28.3 If the matter has not been resolved by an agreed ADR procedure within one (1) month of the initiation of such procedure, the dispute shall be referred to a single arbitrator to be agreed upon by the Parties or in default of agreement

within fourteen (14) days to be nominated by the President for the time being of the Chartered Institute of Arbitrators in accordance with the Arbitration Act 1996. The arbitration shall take place in London and shall be in accordance with the Arbitration Act 1996 and such arbitration rules as the Parties may agree or, in default of agreement, in accordance with the Rules of the London Court of International Arbitration which Rules are deemed to be incorporated by reference into this Condition.

28.4 The decision of the arbitrator shall be final and binding on the Parties.

## 29. NOTICES

All notices to be given hereunder shall be in writing and may be served either personally at or by registered post to the address of the relevant Party as set out in SECTION 5, or as it may from time-to-time be notified in writing to the other Party and in the case of postal service shall be deemed to have been given 3 working days after the day on which the notice was posted.

## 30. RELATIONSHIPS

This Contract does not make any Party the employee, agent, partner or legal representative of the other Party for any purpose whatsoever. No Party is granted any right or authority to assume or create any obligation or responsibility, expressed or implied, on behalf of or in the name of the other Party. In fulfilling obligations pursuant to this Contract the Contractor shall be acting as an independent contractor.

## 31. FREEDOM OF INFORMATION ACT 2000

31.1 The Contractor acknowledges that the Authority is subject to the requirements of the FOIA and the Environmental Information Regulations and shall assist and cooperate with the Authority at the Contractor's expense to enable the Authority to comply with these requirements.

31.2 The Contractor shall and shall procure that its sub-contractors shall:

31.2.1 transfer to the Authority all requests for information that it receives under FOIA and the Environmental Information Regulations ("Requests for Information") that in its opinion are for the Authority consulting the Authority where it has any doubt whether the request is for the Authority as soon as practicable and in any event within two working days of receiving a request for information;

31.2.2 provide the Authority with a copy of all Information in its possession, or power in the form that the Authority requires within five working days, or such other period as the Authority may specify, of the Authority's request; and

31.2.3 provide all necessary assistance as reasonably requested by the Authority to enable the Authority to respond to the Request for Information within the time for compliance set out in section 10 of the FOIA or regulation 5 of the Environmental Information Regulations.

31.3 The Authority shall be responsible for determining in its absolute discretion, and notwithstanding any other provision in this Contract or any other

agreement, whether the Commercially Sensitive Information and/or any other Information is exempt from disclosure in accordance with the provisions of the Code of Practice on Government Information, FOIA or the Environmental Information Regulations. However, the Contractor is entitled to provide the Authority a description of any information which it considers to be Commercially Sensitive Information.

31.4 In no event shall the Contractor respond directly to a Request for Information unless expressly authorised to do so by the Authority.

31.5 The Contractor acknowledges that (notwithstanding the provisions of Condition 8) the Authority may, acting in accordance with the former Department of Constitutional Affairs' Code of Practice on the Discharge of the Functions of Public Authorities under Part 1 of the Freedom of Information Act 2000 ("the Code"), be obliged under the FOIA, or the Environmental Information Regulations to disclose information concerning the Contractor or the Research:

31.5.1 in certain circumstances without consulting the Contractor; or

31.5.2 following consultation with the Contractor and having taken their views into account;

provided always that where Condition 31.5.1 applies the Authority shall, in accordance with any recommendations of the codes of practice under the FOIA or the Environmental Information Regulations, take reasonable steps, where appropriate, to give the Contractor advance notice, in a reasonable time before such proposed disclosure and in order to afford the Contractor an opportunity to challenge such proposed disclosure.

## 32. TRANSPARENCY

32.1 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA and or the Environmental Information Regulations, the content of this Contract is not Confidential Information. The Authority shall be responsible for determining in its absolute discretion whether any of the content of this Contract is exempt from disclosure in accordance with the provisions of the FOIA and or the Environmental Information Regulations.

32.2 The Authority may consult with the Contractor to inform its decision regarding any redactions but the Authority shall have the final decision in its absolute discretion.

32.3 The Authority may, at its sole discretion, redact information from the Contract prior to publishing for one or more of the following reasons:

32.3.1 national security;

32.3.2 Personal Data;

32.3.3 information protected by intellectual property law;

32.3.4 third party or Collaborator confidential information;

32.3.5 IT security; or

32.3.6 prevention of Fraud.

32.4 The Contractor shall assist and cooperate with the Authority to enable the Authority to publish this Contract.

32.5 Notwithstanding any other term of the Contract, the Contractor hereby gives consent for the Authority to publish the Contract in its entirety, including from time to time any agreed changes to the Contract, to the general public.

## 33. UNLAWFUL DISCRIMINATION

33.1 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 or any other relevant legislation relating to discrimination in the employment of employees, for the avoidance of doubt this includes having due regard, where so required, for any additional equality duties imposed on public authorities (collectively, the "**Employment Legislation**").

33.2 The Contractor shall notify the Authority immediately of any investigation of or proceedings against the Contractor under the Employment Legislation relating to any individual involved in the Research 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.

33.3 The Contractor shall indemnify the Authority against all costs, claims, charges, demands, liabilities, damages, losses and expenses arising out of or in connection with any investigation conducted or any proceedings brought under the Employment Legislation due directly or indirectly to any act or omission by the Contractor, its agents, employees or sub-contractors.

33.4 The Contractor shall, and shall use reasonable endeavours to ensure that its employees or agents and/or sub-contractors shall, at all times, act in a way which is compatible with the Convention rights with the meaning of Section 1 of the Human Rights Act 1998.

## 34. FURTHER ASSURANCE

The Contractor will, at the request of the Authority, do (or procure others to do) everything necessary to give the Authority the full benefit of this Contract.

## 35. CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999

No person who is not a Party to this Contract is intended to receive a benefit under or have the right to enforce any terms of this Contract whether pursuant to the Contracts (Rights of Third Parties) Act 1999 or otherwise.

## 36. LAW

This Contract and any non-contractual obligations arising out of or in connection with it shall be considered as a contract made in England and be construed in accordance with the laws of England and Wales and subject to Condition 28 the parties irrevocably submit to the exclusive jurisdiction of the courts of England.

## SCHEDULE A ASSIGNMENT

In consideration of the Authority's support for the Research detailed in the contract dated 1 July 2021 between the Contractor and the Secretary of State for Health and Social Care ("the Contract"), I/We Caristo Diagnostics Limited hereby assign all Intellectual Property rights which exist now or come into existence in the future and to which I am / we are legally entitled in the Reports defined in the Contract to the Secretary of State for Health and Social Care on behalf of the Crown.

Signed b [redacted].....

Date: 06-Jul-2021 | 12:02 BST .....

Name in Block Capitals: [redacted]

## SCHEDULE B VARIATION TO CONTRACT FORM

Project Title :

Project Application No:

Contract between the Secretary of State for Health and Social Care ("the Authority") and

Caristo Diagnostics Limited ("the Contractor") dated ("the Contract")

Variation No: _____

Date: _____

1. The Contract is varied as follows:

2. Words and expressions in this Variation shall have the meanings given to them in the Contract.

3. The Contract, including any previous Variations, shall remain effective and unaltered except as amended by this Variation.

SIGNED:

| | | | |
|---|---|---|---|
| For: | The Authority | For: | The Contractor |
| By: | ..... | By: | ..... |
| Full Name: | ..... | Full Name: | ..... |
| Position: | ..... | Position: | ..... |
| Date: | ..... | Date: | ..... |

## SCHEDULE C SCHEDULE OF ENCUMBERED OR RESTRICTED BACKGROUND IP

| Description of Background IP | Owner of relevant Background IP | Nature of restriction | Risk to Research and outcomes |
|---|---|---|---|
| Patents on measurements of fat inflammation from CT images | University of Oxford | Exclusive license to Caristo for commercial use | None |
| Patents on use of fat inflammation as a biomarker | University of Oxford | Exclusive license to Caristo for commercial use | None |

## SCHEDULE D SCHEDULE OF ANTICIPATED FOREGROUND IP ARRANGEMENTS

For use only in those contracts where the Contractor will not be the sole owner of arising Foreground IP, and all/some Foreground IP will be held by a Collaborator(s).

This schedule should be used to set out at the Commencement Date all parties agreed intentions with regard to Foreground IP ownership and the resulting management and licensing mechanism to be put in place.

| **Description of Foreground IP** | **Owner of relevant Foreground IP** | **Is it severable o r non-severable?** |
|---|---|---|
| Health economics data set | Caristo Diagnostics | Severable |
| Health economics analysis and NHS adoption plan | Caristo Diagnostics | Severable |

## SCHEDULE E STATE AID

1. The Contractor agrees that it will not make any change to the structure of funding of the Research as set out in SECTION 4, knowingly or otherwise, which will lead to a breach of State Aid Legislation.
2. The Contractor understands and acknowledges that the funding from the Authority under this Contract may be classed as State Aid.
3. The Authority may:

a. withhold payments and/or reclaim any part of the payments paid to the Contractor to the extent necessary to ensure that any assistance given under this Contract taken together with any other assistance which, in the Authority's opinion, has been or is likely to be received towards the Research, is within the State Aid limits laid down by State Aid Legislation; and

b. vary, withhold or recover from the Contractor any part of the payment under this Contract with interest at the rate set by the European Commission, calculated from the date the relevant monies were made available to the Contractor, if required to do so under State Aid Legislation and/or any decision of the European Commission, provided that the Authority may not recover any part of the payment already recovered.

4. If any payment made under this Contract is considered to be unlawful State Aid by any of the European Commission, the European Court of Justice or any national court and an order for its repayment is made, the Contractor will repay the relevant payment within fifteen (15) days of demand together with any such interest as may be applicable.

## SECTION 3 RESEARCH

### Part A: Research and Collaborators

Research is:

### Plain English summary

Cardiovascular diseases (CVD) are increasing worldwide, driven by the global epidemics of obesity and diabetes. CVD affects 7 million people in the UK alone, and costs the country over £16 billion. Prediction of CVD risk, such as who will have a heart attack, is currently based on simple clinical risk factors, and scans that aim to detect the formation of fatty build-up ('plaques') in the wall of the coronary artery, which supplies blood to the heart. However, the risk of a plaque causing a heart attack or death is not simply linked to the presence of the plaque but is also driven by inflammation (swelling) in the wall of the coronary artery, that is not visible to any of the wide range of tests currently used by doctors to diagnose CVD. This major 'gap' in diagnostic technology gives inaccurate advice to patients, is inefficient and wasteful of tests and drug treatments, and fails to take full advantage of powerful new drugs, that cannot be 'targeted' to the patients who need them most. We have recently discovered that the fat tissue surrounding the artery 'senses' the presence of inflammation, and this can be detected by a new analysis technique that can be used on existing computed tomography (CT) heart scans that many patients are already having. This method can identify people at high risk of heart attack and CVD death more accurately than current diagnostic tests. The research work has already been published in leading scientific journals and generated international media interest. This new technology has been developed by Caristo Diagnostics, a spin-out company from the University of Oxford, and engineered into a carefully tested, commercial product (CaRi-Heart) that now has regulatory approval to help improve the diagnosis and treatment of CVD, for patients and doctors. In this project, CaRi-Heart will be deployed in real-world clinical practice in NHS hospitals, in order to evaluate how the information provided by CaRi-Heart is used by doctors to make the most clinically useful and cost-effective treatment decisions. We will work closely with NHS Hospital Trusts in Oxford, Milton Keynes, Leicester and Wolverhampton, and experts in heath economics from the Oxford Health Economics Centre. We will also work with patient groups to evaluate the clinical effectiveness of CaRi-Heart in a real-world setting in people at high risk of heart attack and CVD death. We will work with established system integrators (Academic Health Science Networks) to speed up adoption of CaRi-Heart into routine clinical practice, and with regulators (e.g. National Institute for Health and Care Excellence (NICE)) to improve clinical outcomes and patient experience and add value to the NHS by making CaRi-Heart part of every CT scan reported in the UK.

Collaborators are:

1. Caristo Diagnostics Limited
2. University of Oxford
3. Oxford Academic Health Science Network
4. NIHR Oxford Biomedical Research Centre
5. Oxford University Hospitals NHS Foundation Trust
6. Milton Keynes Hospital NHS Foundation Trust
7. University Hospitals of Leicester NHS Trust
8. The Royal Wolverhampton NHS Trust

## Part B: Deliverables

The proposed project has 3 main aims.

**Aim 1:** to pilot CaRi-Heart in the CCTA service in multiple NHS settings, in order to test operational deployment (both set-up and ongoing use) and gather feedback from clinical stakeholders as to its usability. The hospitals involved in this project have been carefully selected to reflect the following important characteristics:

- Academic Teaching Hospitals and District General Hospitals
- Urban and suburban locations
- Diverse population for both socioeconomic and ethnic perspectives

**Aim 2**: to collect data on the use of CaRi-Heart in order to conduct a health economic modelling exercise, which will aim to highlight the benefits of CaRi-Heart adoption into the wider NHS.

**Aim 3:** to research and formulate a detailed NHS adoption plan, leveraging the results of the first two Aims, so that the benefits may be realised across the whole healthcare system.

To achieve these aims, the project is divided into 3 Work Packages, as follows:

### WP1: Real-world implementation and evaluation of CaRi-Heart in clinical workflows

We will work closely with a multidisciplinary team involved in chest pain management within our NHS partners to implement CaRi-Heart into the everyday CCTA workflow of an NHS department. We propose to undertake the below activities and have developed plans to address the potential risks. Key risks and mitigations are summarised below, with a full analysis in the attached Risk Register.

1. **Install Caristo's clinical image gateway (CaRi-CLOUD) in participating Trusts in Leicester, Milton Keynes, Oxford and Wolverhampton**
   Caristo's image transfer gateways allow simple, seamless transfer of CCTA data directly from the PACS of individual Trusts to Caristo for analysis, with a simple process that takes minutes. A research-grade version of CaRi-CLOUD is already installed in Milton Keynes and Leicester NHS Trusts.
   **Milestone 1**: CaRi-CLOUD gateways connected in all pilot sites.
   **Risk**: a gateway of this type requires Trust Information Governance/Privacy sign off, which may cause start-up delay. Caristo is experienced with helping Trusts through Data Protection Impact Assessments and its Information Security Management System has recently been certified for ISO 27001 (information security).

2. **Prepare all training materials for site staff (IT, radiographers, clinicians) and conduct a half-day training session for each of the referring clinical teams.**
   **Deliverable 1**: Operational & clinical training package.
   **Milestone 2**: all implementation sites trained.

**Risk**: site staff are currently unfamiliar working with the new technology, and the perception of additional steps into their workflow. Caristo has close ties with all hospitals involved in this project. Some of the sites have been involved in Innovate UK-funded clinical trials using Caristo's technology and are therefore familiar with the important role that CaRi-Heart can play in enhancing and personalising clinical decision making. We will ensure they review the training materials and approach, to ensure an optimal process. Site clinical leads will also be responsible for monitoring the process and reinforcing the training where necessary.

3. **Transfer of CCTA scans to Caristo for analysis**
   Once sites are live, they will send consecutive CCTAs to Caristo for analysis. A research nurse on site will be responsible for sending the scans. The nurse will also enter a small set of clinical risk factors (e.g. into a web portal, which is linked to CaRi-CLOUD). These are necessary for full risk modelling within CaRi-Heart. We aim to collect at least 200 CCTAs from each site. Given the numbers of CCTAs undertaken per year for chest pain evaluation at each site (ranging from 600-2000 per year at the sites), the pilot period is expected to be up to 4 months in duration, but we will set this period at 6 months to allow contingency in start-up activities and project operationalisation. The scans will be those performed for the evaluation of chest pain (e.g. from Rapid Access Chest Pain Clinics). Caristo will analyse the scans using theCE-marked device CaRi-Heart and return the analysis results within 3 working days.
   **Milestone 3**: first clinical CaRi-Heart analysis performed.
   **Milestone 4**: 800 scans analysed with CaRi-Heart.

4. **Return of CaRi-Heart reports to the sites**
   Results reports will be returned via the same CaRi-Cloud gateway pathway as the scans, with the reports being re-integrated into the PACS of the sending site by the gateway. Clinicians will be notified when a new report is ready for viewing, and its contents will feed into their patient management decisions.
   **Risk**: cardiologists will require education in the CaRi-Heart report significance and interpretation. Caristo will be proactive in education and communication with clinical stakeholders, to ensure effective adoption. Our site clinical leads will be fully involved in driving the key messages to their colleagues.

5. **Integration with NHS Rapid Access Chest Pain Clinic (RACPC) services**
   The NHS Rapid Access Chest Pain Clinics are set up to identify patients with cardiac symptoms (i.e. chest pain), initiate appropriate treatment and investigation plans and identify those who merit 'fast track' management. Many patients who undergo CCTA come via the RACPC. It is also an important liaison point between primary and secondary care within the NHS. Hence, evaluating the impact of CaRi-Heart on RACPC activities and workflow is important. Jan Keenan, Consultant Nurse for Cardiac Medicine, has managed the Oxford RACPC for over 15 years, and will lead the integration of CaRi-Heart into RACPC services.
   **Risk and mitigation**: See point 2.
   We will monitor the end-to-end process of CaRi-Heart scan analysis and reporting, in order to evaluate the fit with existing clinical workflows in the participating hospitals. Feedback on the process will be sought from all members of the multidisciplinary team, including radiographers, chest pain nurses and physicians.
   **Deliverable 2**: Clinical, operational and patient feedback reports.

**WP2: Health Economic Evaluation**

Following recommendations of national (e.g. NICE) and international (e.g. European Medicines Agency) reimbursement authorities, we will undertake a model-based early economic evaluation alongside the implementation to provide the potential cost-effectiveness of adding CaRi-Heart to conventional CCTA analysis. We will compare data from the implementation sites with data from a large registry study linking CaRi-Heart with the risk of fatal and non-fatal cardiac events, in patients who have had a clinically-indicated CCTA.

Data collected from each site will include:

a. Clinical presentation of patients referred for CCTA, enabling mapping of the referral patient pool for CaRi-Heart analysis in the NHS;
b. Patient risk reclassification, to model the cost of the change in the patient's medication to the NHS and to model the total effect size of CaRi-Heart analysis on downstream events and costs to the NHS;
c. Costs to the NHS of adding CaRi-Heart to CCTA, including cardiologists' time in training to interpret CaRi-Heart analyses, and the implementation costs per CCTA (if any) added to the price of a CaRi-Heart analysis to estimate the total cost per CCTA of introducing CaRi-Heart into the NHS.

Patients from the sites will be matched with patients from an existing CCTA registry (https://oxhvf.com/the-orfan-study/) using Propensity Score Matching (PSM), as recommended in the MRC guidelines on performing natural or quasi-experimental studies. A range of PSM techniques will be compared based on Rubin's rules, and the one that achieves the best covariate balance will be chosen.

Incremental cost-effectiveness ratios will be expressed as cost per Life Year gained. Bootstrapping with replacement will be used to construct cost-effectiveness planes in order to display uncertainty around the ICERs. The probability of CaRi-Heart to be cost-effective at different willingness-to-pay values of a Life Year will be displayed on cost-effectiveness acceptability curves. Heterogeneity will be explored in subgroup analysis based on the different pathways where CaRi-Heart will be implemented (e.g. stable chest pain vs. acute setting).

This early health economic evaluation of CaRi-Heart (**Deliverable 3**) will be used to inform the design of larger experimental studies. We will follow NICE guidance and estimate the expected value of perfect information (EVPI).22-24This value represents the monetary value of eliminating the uncertainty in the cost-utility results. In other words, it provides decision makers with the value of acquiring further information on costs and outcomes for a number of people who may benefit from the additional research. EVPI can potentially be used to set research priorities.

**WP3: Building the NHS adoption strategy**

As CaRi-Heart provides new data from the analysis of CCTAs that are already widely performed in the NHS to identify people who are at high risk of heart attack and CVD death, the barriers to adoption are perceived to be relatively low. Nevertheless, all potential barriers to adoption will be investigated as part of this work package from the perspective of all stakeholders. Given that the intervention is expected to have mid- to long-term improvement in clinical and economic outcomes for the patient population, through early detection of at-risk patients, reimbursement would most likely be through

local commissioning or local/national public health initiatives and will be investigated as part of the stakeholder engagement process. Co-Applicant Julie Hart, Commercial Director Oxford AHSN and Senior Research Fellow, University of Reading, will lead the work using proven methodology for stakeholder analysis to understand all the potential barriers to adoption and develop an adoption plan for uptake at pace and scale across the NHS. This will include:

1. evaluate pathway mapping to confirm the key stakeholders.
2. conduct qualitative stakeholder analysis to investigate the stakeholder requirements and identify all potential barriers to adoption.
3. consult with the National Institute of Health and Care Excellence (NICE) to understand the evidence required to amend the current guidelines
4. develop case studies to serve as adoption exemplars from at least 2 of the reference sites and use these as part of an implementation pack designed for use by other AHSNs to drive adoption at pace and scale across NHS Hospital Trusts in England, using PlGF-based testing for pre-eclampsia as a model https://www.oxfordahsn.org/our-work/strategic-and-industry-partnerships/the-innovation-exchange/spread-and-adoption-of-supported-innovations/pre-eclampsia/

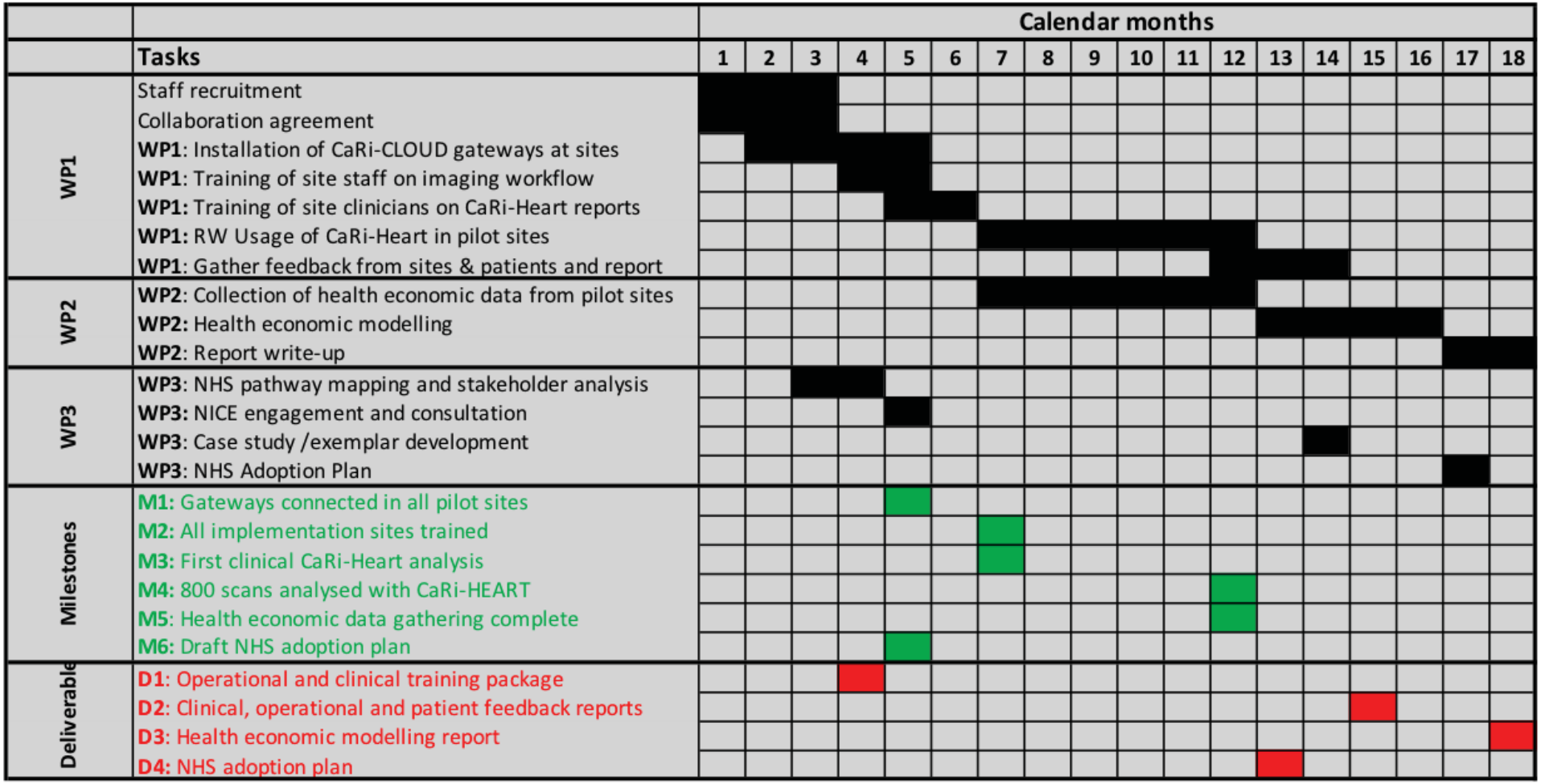
**Deliverable 4**: Value proposition and implementation pack for Caristo defining clinical impact, incorporating the health economic modelling, a strategy to roll out the product and for future working with the AHSN Network to disseminate more widely across the NHS.

**Risk**: As above, slow engagement from site staff and investigators. Members of the Caristo team have strong academic and clinical collaborations with all proposed sites. There is considerable anticipation around Caristo's technology being adopted into the NHS, given the strong scientific underpinnings of CaRi-Heart and the fact that the original research was funded by the British Heart Foundation and NIHR Biomedical Research support.

We will work closely with potential payers to ensure that the product is well-positioned for adoption; these activities will proceed in parallel with the engagement with NICE. The UK reimbursement model is likely to be through Clinical Commissioning Groups (CCG's) and/public health budgets, but we will also investigate whether this technology would be covered under existing tariffs, or options for novel reimbursement methods such as payment by outcomes. Identifying people at risk early on will deliver downstream saving; we will work with the health economists to demonstrate a business case that shows the value of short-term cost delivering significant long-term savings for the NHS.

## Part C: Service Support and Continuity

The start date of the research is 1 July 2021 and the end date is 31 December 2022. Once this funded pilot phase is completed, Caristo intends to work with the Trusts to continue the use of the CaRi-Heart service for their patients. NHS adoption and reimbursement are key facets of the project which will enable the parties to switch over to a commercial service model after project completion.



## SECTION 4 FINANCIAL ARRANGEMENTS

PAYMENT SCHEDULE

It is intended that the indicated amounts will be paid by the Authority to the Contractor within thirty (30) days of the dates listed.

| **Date** | **Amount (£)** |
|---|---|
| 1. 30 September 2021 | [redacted] |
| 2. 31 December 2021 – Milestones 1 & 6 stage gate payment | [redacted] |
| 3. 31 March 2022 – Milestones 2 & 3 stage gate payment | [redacted] |
| **Financial Year 2021/22 sub-total** | [redacted] |
| 4. 30 June 2022 – Milestones 4 & 5 stage gate payment | [redacted] |
| 5. 30 September 2022 | [redacted] |
| 6. 31 December 2022 | [redacted] |
| **Financial Year 2022/23 sub-total** | [redacted] |
| **TOTAL** | **441,043.00** |

An appropriate inflation uplift may be added by the Authority to these payments.

Upon conclusion of the Research, the Contractor shall submit a final statement of expenditure to the Authority, accounting for all costs properly incurred under the Contract. Only upon receipt of this document, and with agreement from the Authority's Representative, will the final payment of any outstanding funds be made.

## SECTION 5 KEY STAFF

The Contractor's Representative name and address:

[redacted]
Caristo Diagnostics Limited
New Barclay House
234 Botley Road
Oxford
Oxfordshire
OX2 0HP

The Authority's Representative for contract management purposes:

[redacted]
1st Floor Skipton House
80 London Road
Elephant and Castle
London
SE1 6LH

The Authority's Representative for project management purposes:

[redacted]
Skipton House
80 London Road
Elephant and Castle
London
SE1 6LH

## SECTION 6 REPORTING SCHEDULE

The feedback required under Condition 12.4 shall be obtained by or on behalf of the Contractor using the following methods:

- Monthly high level update reports
- Quarterly reports
- Formal Quarterly review meetings
- Final report

The feedback required under Condition 12.4 shall address the following issues:

1. Progress against plan – Quarterly review outcome letter

Active Risk log should be included in monthly and quarterly reports

The interim report schedule is set out in the following table:

| Report | Due date |
|---|---|
| Monthly | Exact schedule and deadlines to be agreed with the Relationship Manager. |
| Quarterly | Exact schedule and deadlines to be agreed with the Relationship Manager. |
| Annual | Report to be submitted annually on the anniversary of the Commencement Date. Exact schedule and deadlines to be agreed with the Relationship Manager. |
| Final report | To be submitted within fourteen calendar days of the Completion Date. |