

NHSX Funding Agreement re AI Health and Care Award Phase 3 & 4

RESEARCH CONTRACT

BETWEEN

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE (1)

AND

ULTROMICS LIMITED (2)

Version number: 1/20

AI Health and Care Award – Phase 3 & 4

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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

Ultromics Limited, [4630 Kingsgate, Cascade Way, Oxford Business Park South, OX4 2SU] ("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 and evaluation project entitled Automated Analysis of Echocardiograms in accordance with the work specified in SECTION 3 and including the Deliverables elements (as defined in SECTION 2 and detailed in SECTION 3), being project application 1950, dated [8 September 2020], the "**Research**".
2. The Authority will pay the Contractor the Approved Cost as set out in SECTION 4 in respect of undertaking the Research in accordance with this Contract and the Contractor's assignment of copyright and rights in the nature of copyright in the Reports to the Authority on behalf of the Crown made pursuant to Conditions 13 and 14 of SECTION 2.
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.


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SIGNED:

For the Authority:

SIGNATURE..........


FULL NAME..........

POSITION HELD..... Director of Policy & Strategy, NHSX

ON BEHALF OF THE AUTHORITY

DATE..... 11/19/2020

For the Contractor:

SIGNATURE..........

FULL NAME..........

POSITION HELD..... CFO

ON BEHALF OF THE CONTRACTOR

DATE..... 11/16/2020

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SECTION 2 TERMS AND CONDITIONS

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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:

"Applicable Law"	means: (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 provided to or in respect of; (b) the common law and laws of equity as applicable to the parties from time to time; (c) any binding court order, judgment or decree; (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.
"Authority Evaluator Agreement"	Means the agreement between the Authority and the Evaluators appointed to evaluate 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.
"Business Day"	means a day other than Saturday, Sunday and bank holidays in London.
"Care Services"	means in: England – NHS and adult Social Care; Wales – NHS and Social Care; Scotland – NHS and adult Social Care; Northern Ireland – Health and Social Care.
"Commencement Date"	Means September 8, 2020 notwithstanding the last day of signature of this Contract.

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“Commercial Use”

means any use that supports the generation of revenue including but not limited to:

- (a) any use in support of an application for regulatory approval for a product or service;
- (b) any use in support of the development, promotion or use of a product or service that will be made available on a fee paying basis;
- (c) any use in support of the development, promotion or provision of Health Care direct to an individual on a fee paying basis;
- (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 [September 8 2023] or such other date as mutually agreed by the Parties.

“Confidential Information”

means information of any form, however conveyed and irrespective of the media on which it is stored, that is:

- (a) information which has been designated as confidential by either Party; or
- (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 suppliers and commercial sensitive information of either Party; or
- (c) Personal Data and/or special category data within the meaning of the Data Protection Legislation; or
- (d) the Research Data.

"Contract"

means the contract concluded between the Parties, consisting of the following Sections:

SECTION 1: FORM OF CONTRACT

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	SECTION 2: TERMS AND CONDITIONS
	SECTION 3: RESEARCH
	SECTION 4: FINANCIAL ARRANGEMENTS
	SECTION 5: KEY STAFF
	SECTION 6: REPORTING SCHEDULE
"Contractor Background IP"	means any means any Intellectual Property or Know-How owned by the Contractor or to which the Contractor has rights and which (a) is in existence at the Commencement Date; or (b) created, devised or generated independently other than in the performance of the Research
"Contractor's Evaluator Agreement"	means the agreement(s) between the Contractor and the Evaluator.
"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, government agencies and particular bodies.
"Data Controller"	has the meaning ascribed to it in the Data Protection Legislation.
"Data Processor"	has the meaning ascribed to it in the Data Protection Legislation.
"Data Protection Legislation"	means any Applicable Law relating to the processing, privacy, and use of Personal Data, as applicable to the performance of the Research from time to time.
"Deliverables"	means those elements of the Research detailed in SECTION 3, Part B.
"Evaluator Evaluation Team"	means a person or organisation designated by the Authority to work with the Contractor to evaluate the Research being done under this Contract subject to Condition 15.6 and that is listed at SECTION 3, Part A.
"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

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of practice issued under this Act or by the Information Commissioner in relation to such legislation.

"Financial Year"

means the financial year running from 1 April each year to 31 March in the subsequent year.

"Foreground IP"

means Intellectual Property that is, or has been created, exemplified or developed (whether in whole or in part) during the course and for the purpose of the Research. For the avoidance of doubt, this:

- (a) includes Foreground IP generated by or on behalf of the Contractor in the course of performing the Research; and
- (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 the 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

"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.

"Insolvency Event"

means where a Party:

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- (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);
- (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;
- (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;
- (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 levied upon or enforced against any of its assets;
- (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;
- (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

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section 98 of the Insolvency Act 1986;

- (g) ceases or threatens to cease to carry on business;
- (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
- (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" ("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, 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 a package of practical information, resulting from experience and testing, which is:

- (i) secret, that is to say, not generally known or easily accessible,
- (ii) substantial, that is to say, significant and useful for the production of the contract products, and
- (iii) 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.

"Loss"

means losses, liabilities, demands, damages (including any sum paid to compromise or settle any third party claim), fines and penalties, costs and expenses calculated on a full indemnity basis (including legal and other professional costs and internal management costs) and interest;

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“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 provided by the Contractor under this Contract pursuant to Conditions 13 and 14 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.

"Research"

means the scope of work specified in SECTION 3 and includes any Deliverables or Service Support element 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

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	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 unless otherwise determined in accordance with the terms of the Contract.
"Research Sites"	means any NHS Trust sites at which the Research will be performed.
"Service Support"	means any services that are to be provided by or on behalf of the Contractor to the Research Sites in accordance with the Site Agreement.
"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.
"Third Party IP"	means any Intellectual Property which is owned or controlled by any party other than the Contractor.
"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 where the context allows, references to male gender include the female gender and the neuter, and 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

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- 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 earlier termination in accordance with its terms, shall continue in full force and effect until the Completion Date.

3. ADMINISTRATION, PERFORMANCE AND DIRECTION OF RESEARCH

- 3.1 Research commissioned by the Authority is open and, subject to the provisions of this Contract, details of Research are normally published.
- 3.2 The Authority may publish details of the non-confidential research plan and project costs.
- 3.3 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.
- 3.4 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.
- 3.5 The Contractor shall provide the Authority with updates in respect of the Research in accordance with Condition 13 and SECTION 3.
- 3.6 The Contractor shall submit to the Authority a draft copy of the template Contractor's Evaluator Agreement for approval by the Authority prior to use.
- 3.7 Where the Research involves a Research Site:
- 3.7.1 the Contractor shall put in place a site agreement which shall include Service Support with each Research Site before commencing that element of the Research to be performed at the relevant Research Site and the procedure set out in Condition 3.6 regarding the approval of the template collaboration agreement shall apply to the site agreement accordingly. Once the template site agreement has been approved by the Authority it shall be known as the "Site Agreement";
- 3.7.2 the Contractor shall comply with and adhere to any compliance, governance or security standards, procedures or protocols required by the Site Agreement.
- 3.8 The Contractor shall perform the Research and use its reasonable efforts to complete the Deliverables in accordance with the details and timeline recorded in SECTION 3, Part A and Part B.
- 3.9 The Contractor shall provide the Service Support in accordance with the standards and timelines recorded in SECTION 3, Part C.

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- 3.10 The Contractor, the Authority and the Evaluator shall establish a project management committee ("**Joint Management Committee or JMC**") which shall meet from time to time to consider amendments to the Research which would not fundamentally change the overall Research outcome including without limitation amendments to the Milestones and Deliverables. The Authority shall be deemed to agree to any such amendments agreed by the JMC and this Contract shall be varied accordingly without the parties following the procedures set out in Condition 6.

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:

- 4.1.1 reasonable progress has not been made on achieving the agreed Milestones set out in SECTION 3 due to a fault of Contractor; or
- 4.1.2 reasonable progress has not been made towards meeting a Deliverable in accordance with the detail and timeline set out in SECTION 3; or
- 4.1.3 Contractor is in material breach of its obligation to provide the Service Support in accordance with the detail set out in SECTION 3; or
- 4.1.4 reports have not been submitted as required under Condition 13; or
- 4.1.5 the Contractor is in material breach of any of the terms and conditions of this Contract (including where any of the Evaluators or Research Sites have failed to comply with certain obligations as required by this Contract and the Contractor has failed to take appropriate action against the relevant Evaluator or Research Site).

Subject to these limits the Contractor is free to 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.

- 4.2 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 (a) the Authority instructs the Authority's Representative to apply a compounded annual inflationary uplift; or (b) the parties have agreed a revised accelerated payment schedule as part of a Variation. The Authority shall apply any inflationary uplift only after obtaining approval from finance and treasury. For illustration purposes: 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 $1.03 \times 1.01 = 1.0403$. Where there is an upper limit to programme funding the limit will be applied excluding inflation. Such adjustment as part of an inflationary uplift shall not require a Variation. 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.

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- 4.3 The Contractor is responsible for payments to third parties 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 by the end of that Financial Year. 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. The Authority shall give the Contractor no less than twenty one (21) days' written notice of its intention to conduct an audit of the relevant financial records.
- 4.8 The Contractor shall provide all reasonable cooperation and assistance at all times during the currency of this Contract 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 (other than a financial audit as covered by Condition 4.7) 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 the agreed specifications as detailed in SECTION 3 being delivery of the Final Report ;
 - 4.9.2 the reports required under Conditions 13 and 14 have been submitted by the Contractor to the Authority;
- 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

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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 (12) 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 by the Contractor and agreed by the Authority in writing.
- 4.12 The Contractor is subject to the additional clauses set out in SCHEDULE D: 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 Subject to clause 3.10 if at any time it appears likely that any provision of the Contract, in particular a material change to the scope 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, including without limitation any impact on the Research Period and/or Approved Costs. Upon receipt of such a request the Authority may acting reasonably:

- 6.1.1 agree to vary the Contract;
- 6.1.2 agree to vary the Research;
- 6.1.3 refuse the request and require the continuation of the Research in accordance with the Contract, or
- 6.1.4 give notice of termination in accordance with Condition 19.

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 Not used.
- 7.3 The Contractor will ensure that the terms and conditions of Contractor's staff employed to provide services in connection with this Contract contain provisions in respect of intellectual property compatible with the terms of this Contract and in particular allow those staff to publish the results in appropriate research journals.
- 7.4 Subject to Condition 9, the Contractor shall cause to be kept full, detailed and accurate records of all of activities and results obtained in connection with the

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Research. In this respect, the Contractor shall and shall procure that the staff and Research Sites and sub-contractors shall at all times:

- 7.4.1 observe professional standards; and
 - 7.4.2 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.
- 7.5 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 sub-contractors under Condition 7.4 and by any third parties working on the Research.

8. PUBLICITY

- 8.1 The Contractor shall (and shall procure that each member of staff engaged on the Research shall) comply with the Authority's guidance on the publication of research outputs which may be issued by the Authority from time to time. This condition shall not apply where the Contractor has a contractual, legal or similar obligation to publish specific details about the Contract or the Research.
- 8.2 Not used.
- 8.3 The Contractor shall 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.
- 8.4 Subject to the provisions of Condition 9 , the Authority's Representative may after giving 30 days notice to Contractor 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.
- 8.5 The Contractor shall assign to the Authority on behalf of the Crown all copyright and rights in the nature of copyright 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.
- 8.6 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 2020.

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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”.

- 8.7 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 the Research carried out under this Contract (if any), shall acknowledge the Authority’s financial support and carry such 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 NHSX (Artificial Intelligence in Health and Care Award, Ultromics Limited, 1950). 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.”

9. CONFIDENTIALITY

- 9.1 In respect of any Confidential Information it may receive from the other Party and subject always to the remainder of this Condition 9, the receiving Party undertakes to keep secret and strictly confidential and shall not 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:

9.1.1 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

9.1.2 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.

- 9.2 Condition 9.1 shall not apply to any Confidential Information received by one Party from the other:

9.2.1 which is or becomes public knowledge (otherwise than by breach of Condition 9.1);

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

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

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

9.2.5 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 32 (Freedom of Information).

- 9.3 The obligations of each of the Parties contained in Condition 9.1 above shall continue without limit of time. In the event that the Contractor fails to comply

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with this Condition 9, the Authority reserves the right to terminate this Contract with immediate effect by notice in writing.

10. DATA PROTECTION

Compliance

- 10.1 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 will, and is responsible for ensuring that each Site Agreement contain appropriate provisions to reflect the applicable requirements and obligations of the Data Protection Legislation in the performance of the Research including:

- 10.1.1 completing all appropriate data protection impact assessments before commencing the relevant elements of the Research;
- 10.1.2 putting in place all appropriate data processing agreements;
- 10.1.3 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.

- 10.2 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 10.

- 10.3 The Contractor shall, from time to time, comply with any reasonable request made by the Authority to ensure compliance with this Condition 10 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

- 10.4 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 collected handled, stored and processed by it and guard it against unauthorised access thereto or disclosure thereof or loss or destruction while in its custody.

- 10.5 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.

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

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

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- 10.6.2 the NHS Digital “Code of practice on confidential information”, as amended from time to time.
- 10.7 In performing the Research, the Contractor shall use reasonable endeavours, and shall ensure that any Research Site (by including corresponding obligations in the Site Agreement respectively) uses reasonable endeavours to, adhere to the relevant sections of the following, as available on the Commencement Date:
- 10.7.1 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](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);
- 10.7.2 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://www.nhsx.nhs.uk/media/documents/NHS_Digital_Health_Technology_Standard_draft.pdf](https://www.nhsx.nhs.uk/media/documents/NHS_Digital_Health_Technology_Standard_draft.pdf) as at the date of drafting);
- 10.7.3 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](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);
- 10.7.4 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](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).
- 10.7.5 A Guide to Good Practice for Digital and Data-Driven Health Technologies as updated from time to time (available [will be published prior to signature] as at the time of drafting)
- 10.8 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) 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 sub-contractors, employees, agents or person within its control.

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- 10.9 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 sub-contractors, employees, 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.
- 10.10 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.

11. RIGHTS TO RESEARCH DATA

- 11.1 Subject to the provisions of Conditions 9, 10 and 11.2, 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.

The Authority shall not be entitled to inspect, take or be supplied with copies of the Research Data other than in an anonymised form.

- 11.2 The Contractor shall ensure that all basic factual data is pseudonymised and that 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.

- 11.3 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:

11.3.1 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

11.3.2 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.

- 11.4 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 or exploitation of Foreground IP.
- 11.5 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:

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- 11.5.1 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
- 11.5.2 include a statement with the research materials detailing how such information and data can be accessed.

12. NOT USED

13. MONITORING AND REPORTING

- 13.1 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 provided to the Sites under the Site Agreement) and SECTION 6. the Contractor acknowledges that the Authority is entitled to suspend payments in accordance with Condition 3.1 in the event that Contractor has not made reasonable progress to meet the agreed milestone set out in SECTION 3 due to a fault of Contractor; or reports have not been submitted as required under Condition 13; or the Contractor is in material breach of any of the terms and conditions of this Contract (including where the Research Sites have failed to comply with certain obligations as required by this Contract and the Contractor has failed to take appropriate action against the relevant Research Site).
- 13.2 The Contractor shall provide written reports on the progress of the Research according to the schedule set out in SECTION 6. The reports shall be in a form and format agreed by the parties and shall include an outline of the Research Data, an outline of the methods, an outline of any Foreground IP, Arising Know How, results, financial analysis relating to the outputs of the Research, 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.
- 13.3 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.
- 13.4 During the Research Period, the Contractor shall regularly gather feedback from Research Sites and report such feedback to the Authority. This feedback:
 - 13.4.1 shall as a minimum address the issues listed at Section 6; and
 - 13.4.2 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.

14. FINAL REPORT

- 14.1 The Contractor shall provide a draft final report on the Research within SIXTY (60) CALENDAR DAYS of the Completion Date or date of termination of this Contract. 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

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Authority's Representative and shall include an outline of the Research Data, methods, an outline of any Foreground IP, Arising Know How, results, 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.

- 14.2 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.
- 14.3 If after one (1) year of the end of the Research Period the Contractor has not produced a final report, the Authority may prepare and publish, or arrange for the preparation and publication of, such a final report.
- 14.4 The Authority reserves the right to reproduce the findings of the final report or to provide a summary of the findings.

15. INTELLECTUAL PROPERTY RIGHTS

- 15.1 Not used
- 15.2 Foreground IP, Research Data and Arising Know How that may arise from the Research shall be vested in the Contractor.
- 15.3 The Contractor shall ensure that Arising Know How may be used by the Contractor on a world-wide, royalty free, non-exclusive, transferable and sub-licensable basis in the course of the Contractor's normal activities or to achieve Patient Benefit.
- 15.4 The Contractor shall ensure that Research Sites shall keep detailed records including of those activities relevant to the Research and preparing the Final Report and upon request shall make available copies to the Authority by including appropriate provisions in the Site Agreements it will enter into with the Research Sites.
- 15.5 The Contractor shall make available the Contractor Background IP that is necessary or useful for undertaking the Research and the protection, dissemination or exploitation of the Foreground IP and Research Data. Where it is reasonable to do so and is an appropriate means of achieving Patient Benefit, the Contractor has responsibility for filing, prosecuting, maintaining, defending and enforcing protection for such Contractor Background IP, and shall retain this responsibility unless otherwise agreed in writing and in any event at no cost to the Authority. If the Contractor wishes to cease doing so in relation to any of such Contractor Background IP necessary for the dissemination, use or exploitation of the Foreground IP, it shall notify the Authority no less than two (2) months prior to discontinuing its maintenance, defence or enforcement of such Contractor Background IP.
- 15.6 The Contractor shall use reasonable endeavours to make available 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 or Research Data.
- 15.7 The Contractor shall 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:
 - 15.7.1 use and publish (in accordance with Conditions 8 and 9):

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- (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 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

- 15.7.2 use the Contractor's Background IP and Third Party IP (subject to the agreement of licencing terms between the Authority and the Contractor) but solely to the extent that it is necessary in order to exercise the licence granted in sub-Condition 15.7.1 above.

- 15.8 The Contractor shall ensure that it enters into Contractor's Evaluator Agreement with Evaluators, Site Agreements with Research Sites and suitable agreements with any subcontractors as required to ensure the effective performance of the Research in accordance with the terms of this Contract.

- 15.9 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:

- 15.9.1 any agreements in which the Intellectual Property arrangements would adversely affect the Contractor's ability to comply with the terms of this Contract.

16. EXPLOITATION OF INTELLECTUAL PROPERTY

- 16.1 The Contractor shall inform the Authority in a timely manner of any outcomes from the Research, including any Foreground IP which is capable of exploitation either by direct adoption into the healthcare service or via commercialisation.

- 16.2 The Contractor shall develop, implement and maintain procedures for the management of Foreground IP and in particular, but without limitation, shall use all reasonable endeavours to ensure that:

- 16.2.1 the Foreground IP (if any) is identified and recorded;
- 16.2.2 it notifies the Authority within SIX (6) months of receipt of disclosure of potentially Foreground IP and in the event that the Contractor decides not to protect the invention by filing a patent application, the relevant Foreground IP shall remain as confidential Know How of the Contractor.
- 16.2.3 prior to any publication of the Results of the Research, patentable inventions arising from the Results are identified, duly considered for

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patentability and, where it is commercially reasonable to do so, 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;

- 16.3 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:
- 16.3.1 where reasonable and practicable, promote the dissemination of the Foreground IP, in order to achieve Patient Benefit;
 - 16.3.2 where reasonable and practicable and subject to obtaining the prior written consent of the Authority, exploit such Foreground IP to generate either capital or revenue or both; and
 - 16.3.3 keep proper records showing the description of the Contractor Foreground IP generated (if any).
- 16.4 The Contractor shall seek the prior written consent of the Authority before it makes any Commercial Use of, or permits any third party to make any Commercial use of any Foreground IP. The Authority shall not unreasonably withhold or delay such consent, but as a condition of granting consent, the Contractor 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 if the Authority requires the Contractor to enter into a commercialisation agreement with the Authority and if the Authority does not make such request within such time period the Contractor shall not be under any obligation to enter into a commercialisation agreement with the Authority. Any such commercialisation agreement shall as a minimum:
- 16.4.1 address the distribution of revenue, equity or other benefits arising from the proposed commercialisation arrangements and rights to use the Foreground IP;
 - 16.4.2 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;
 - 16.4.3 take into consideration the relative contribution of the Authority, the Contractor, and other third-party funders or contributors to the Foreground IP.
- 16.5 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 of Foreground IP are distributed according to the terms of the relevant revenue sharing agreement.
- 16.6 In the event that the Contractor decides to seek approval for commercialisation under Condition 16.4, then the Contractor must take due consideration of the Authority's attitude to access to essential health related technologies including medicines in the developing world.
- 16.7 If the Contractor does not reasonably protect, manage or exploit any Foreground IP according to the terms of this Contract or if this Contract is

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terminated according to Condition 19.4, then the Authority shall have the right, acting reasonably and subject to the rights of third party licensees, 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 could be lost if more immediate action is not taken. The Contractor agrees to do all reasonable 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.

- 16.8 Not used.
- 16.9 The Authority may, by notice in writing, require any Foreground IP to be promptly assigned to the Authority if the Contractor is subject to an Insolvency Event.
- 16.10 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 reasonably require for the purpose of giving the Authority the full benefit of the provisions of this Contract.

17. NOT USED**18. NOT USED****19. TERMINATION UPON OCCURRENCE OF EVENTS**

- 19.1 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 19.1, 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.
- 19.2 The Authority will not pay any sum under Condition 19.1 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.
- 19.3 Not used.
- 19.4 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:
 - 19.4.1 the Contractor is subject to an Insolvency Event; or
 - 19.4.2 the Contractor is in material breach of any of the terms and conditions of this Contract, and either:

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- (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
- 19.4.3 the Contractor fails to deliver the Service Support in accordance with SECTION 3 Part C; or
- 19.4.4 an event of Force Majeure exists for more than six (6) months; or
- 19.4.5 Not used.
- 19.4.6 if the Contractor is in Persistent Breach of its obligations under this Contract and "Persistent Breach" for the purpose of this Condition shall mean that the Contractor has committed at least three (3) breaches of this Contract (whether or not they are of the same or a similar nature) in any twelve (12) month period or it has committed the same or a similar breach at least twice within any twelve (12) month period.

20. CONSEQUENCES OF TERMINATION

- 20.1 Termination of this Contract, however caused, shall not:
 - 20.1.1 release either Party 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
 - 20.1.2 prejudice or affect any rights, action or remedy which shall have accrued before termination or shall accrue thereafter to any Party.

21. EQUIPMENT

- 21.1 The Contractor shall take all practical steps to purchase all materials and equipment required for the Research 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.
- 21.2 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.

22. FORCE MAJEURE

- 22.1 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, destruction of essential equipment by fire,

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explosion, storm, flood or earthquake, and delay caused by failure of power supplied or transport facilities, epidemic, pandemic, actions mandated or recommended by government or public authorities or any other cause beyond the control of the Parties which renders performance of this Contract impossible.

- 22.2 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.
- 22.3 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.

23. WARRANTIES AND LIABILITY

23.1 The Contractor warrants that:

- 23.1.1 it has the requisite capacity and authority and all necessary licences, permits and consents to enter into this Contract;
- 23.1.2 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;
- 23.1.3 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;
- 23.1.4 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,
- 23.1.5 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 will be the legal and beneficial owner(s) of all right, title and interest in and to the Foreground IP 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).
- 23.1.6 the Research (including the Service Support) will be carried out by appropriately experienced, qualified and trained personnel with all due skill, care and diligence;
- 23.1.7 in carrying out the Research, the Contractor will use all reasonable efforts to ensure that sufficient authorisation has been obtained to

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permit the use of any Intellectual Property that is reasonably necessary to enable the use of the Foreground IP, or Arising Know How or Research Data to the extent necessary to exercise any rights under, or to perform, this Contract;

- 23.1.8 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.
- 23.2 Except as expressly provided in this Contract, none of the Parties gives any warranties or makes any representations:
- 23.2.1 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
- 23.2.2 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.
- 23.3 Subject to Condition 23.6 the Contractor shall indemnify the Authority, its officers, servants and agents fully against any Loss whatsoever arising under any statute or at common law in respect of:
- 23.3.1 any damage to property arising out of or in connection with a defect in the EchoGo Platform; and,
- 23.3.2 any infringement of third party Intellectual Property rights arising out of or in connection with the use of the Reports;
- 23.3.3 any injury to persons including injury resulting in death arising out of or in connection with a defect in the EchoGo Platform
- 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 or the Research Sites.
- 23.4 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.
- 23.5 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.
- 23.6 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.
- 23.7 Nothing in this Contract shall limit the liability of any Party in respect of:

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

23.7.2 fraud or fraudulent misrepresentation.

24. INSURANCE

24.1 Without prejudice to Condition 23.3, 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.

24.2 The Contractor shall produce on demand by the Authority documentary evidence that any insurance policies required by Condition 24.1 are in force.

24.3 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 23.3.

25. ASSIGNABILITY

25.1 Except as set out in SECTION 3, 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 such consent not to be unreasonably withheld or delayed.

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

25.3 Notwithstanding Condition 25.2, 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 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.

26. 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.

27. CORRUPT GIFTS OR PAYMENTS

27.1 The Contractor shall not do (and warrants that in entering the Contract he has not done) any of the following (referred to in this Condition as "prohibited acts"):

27.1.1 offer, give or agree to give to any servant of the Crown any gift or consideration of any kind as an inducement or reward for doing or not doing (or having done or not having done) any act in relation to the obtaining or performance of this or any other contract with the

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- Crown, or for showing or not showing favour or disfavour to any person in relation to this or any other contract with the Crown;
- 27.1.2 enter into this or any other contract with the Crown in connection with which commission has been paid or has been agreed to be paid by him or on his behalf, or to his knowledge, unless before the Contract is made particulars of any such commission and the terms and conditions of any such agreement for the payment of it have been disclosed in writing to the Authority.
- 27.2 If the Contractor, his employees, agents or any sub-contractor, or anyone acting on his or their behalf, does any of the prohibited acts or commits any offence as the case may be under the Bribery Act 2010 with or without the knowledge of the Contractor, in relation to this or any other contract with the Crown, the Authority shall be entitled:
- 27.2.1 to terminate the Contract immediately by giving notice in writing and recover from the Contractor the amount of any loss resulting from the termination;
- 27.2.2 to recover from the Contractor the amount or value of any such gift consideration or commission; and
- 27.2.3 to recover from the Contractor any other loss sustained in consequence of any breach of this Condition, whether or not the Contract has been terminated.
- 27.3 In exercising its rights or remedies under this Condition, the Authority shall:
- 27.3.1 act in a reasonable and proportionate manner having regard to such matters as the gravity of, and the identity of the person performing the prohibited act;
- 27.3.2 give all due consideration, where appropriate, to action other than termination of the Contract, including (without limitation to):
- (a) requiring the Contractor to procure the termination of a sub-contract where the prohibited act is that of a sub-contractor;
 - (b) requiring the Contractor to remove from association with the Research an employee (whether his own or that of a sub-contractor) where the prohibited act is that of such employee.

28. FRAUD

- 28.1 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.
- 28.2 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.
- 28.3 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:
- 28.3.1 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

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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

- 28.3.2 recover in full from the Contractor any other loss sustained by the Authority in consequence of any breach of this Condition 28.

29. DISPUTE RESOLUTION

- 29.1 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.
- 29.2 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.
- 29.3 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.
- 29.4 The decision of the arbitrator shall be final and binding on the Parties.
- 29.5 Notwithstanding anything to the contrary in this Condition 29, either Party may at any time apply to a competent court for injunctive, interlocutory or emergency relief.

30. 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.

31. 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.

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32. FREEDOM OF INFORMATION ACT 2000

- 32.1 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.
- 32.2 The Contractor shall and shall procure that its sub-contractors shall:
- 32.2.1 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;
 - 32.2.2 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
 - 32.2.3 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.
- 32.3 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.
- 32.4 In no event shall the Contractor respond directly to a request for information unless expressly authorised to do so by the Authority.
- 32.5 The Contractor acknowledges that (notwithstanding the provisions of Condition 9) 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:
- 32.5.1 in certain circumstances without consulting the Contractor; or
 - 32.5.2 following consultation with the Contractor and having taken their views into account;
- provided always that where 32.5.1 applies the Authority shall, in accordance with any recommendations of the Code, take reasonable steps, where appropriate, to give the Contractor advance notice, or failing that, to draw the disclosure to the Contractor's attention after any such disclosure.

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33. TRANSPARENCY

- 33.1 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 consultation with the Contractor, 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.
- 33.2 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.
- 33.3 The Authority may redact information from the Contract prior to publishing for one or more of the following reasons:
- 33.3.1 Commercial sensitive information (as determined by the Contractor)
 - 33.3.2 national security;
 - 33.3.3 personal data;
 - 33.3.4 information protected by intellectual property law;
 - 33.3.5 third party, or Evaluator confidential information;
 - 33.3.6 IT security; or
 - 33.3.7 prevention of Fraud.
- 33.4 The Contractor shall assist and cooperate with the Authority to enable the Authority to publish this Contract suitably redacted.
- 33.5 Notwithstanding any other term of the Contract, the Contractor hereby gives consent for the Authority to publish the Contract, in accordance with Condition 9, in its entirety, including from time to time any agreed changes to the Contract, to the general public.

34. UNLAWFUL DISCRIMINATION

- 34.1 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**”).
- 34.2 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.
- 34.3 The Contractor shall indemnify the Authority against all costs, claims, charges, demands, liabilities, damages, losses and expenses arising out of or

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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.

- 34.4 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.

35. 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.

36. 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.

37. 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 29 the parties irrevocably submit to the exclusive jurisdiction of the courts of England.

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SCHEDULE A ASSIGNMENT

In consideration of the Authority’s support for the Research detailed in the contract dated between the Contractor and the Secretary of State for Health and Social Care (“the Contract”), I/We[Ultromics Limited] hereby assign all copyright and rights in the nature of copyright 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 by:.....

11/16/2020
Date:

Name in Block Capitals:

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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
[.....] (“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:

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**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

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SCHEDULE D 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 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 or withhold 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.

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SECTION 3 RESEARCH

Part A: Strategy

EchoGo Pro provides automated analysis of DICOM 3.0 compliant echocardiograms for patients undergoing echocardiographic assessment for suspected cardiac pathology. EchoGo Pro is a cloud-based artificial intelligence service which provides reports to support physicians in the treatment of patients with suspected coronary artery disease. Through specialized image-based machine learning, EchoGo Pro assists physicians identify heart disease risk rapidly to enable appropriate care. It is intended for use with echocardiogram protocols that contain at least one of routine resting A2 or A4 chamber views for quantitative analysis, or A2, A4 and mid-ventricular short-axis views at rest and at peak stress for coronary artery disease detection.

The Research will enable the rapid implementation and deployment of EchoGo Pro in sites agreed by NHSX/AAC. As guided by the Evaluation Team, part of the Research will assess EchoGo Pro which is being deployed as a “Software as a Service” offering, to understand and evaluate the real-world impact and utility of Echo Go Pro.

Ultromics will collaborate with 27 sites who have been identified from the Everest Trial, National Consortium of Intelligent Medical Imaging (NCIMI) network or other NHS Trusts. Ultromics will work with the Evaluation Team to agree the appropriate mix of sites.

Key Personnel are:

Dr [REDACTED] Chief Technical Officer at Ultromics

[REDACTED] Chief Commercial Officer at Ultromics

[REDACTED] Clinical Project Manager at Ultromics

Part B: Deliverables

Key deliverables by Contractor will be as follows:

Site specific

1. Agree deployment plan with site
2. Site specific contract (including information governance) to include service provisions and evaluation criteria
3. Integrate into existing IT infrastructure
4. Full round trip testing between Ultromics and site
5. Local training at site
6. Go live and on-going support
7. Evaluation data collection

NHSX specific

- Quarterly Reports which may include progress on infrastructure set-up, education, training, deployment, installation, usage, and data collection for the evaluation piece (as directed by the Evaluation Team)
- Annual Reports, including progress on deployment, installation, usage, and data collection (as directed by the Evaluation Team)
- Final Project Report, detailing all project activity from Contractor perspective

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Oxford Academic Health Science Network (AHSN)

Progress of these deliverables will be monitored through the competition of the following milestones:

Phase 4 Milestone	Due date
Reports as stated in the deliverables	First quarterly report to be provided no later than January 31, 2021 and every three months thereafter for the duration of the award.
Agreement with evaluation partner to enable delivery of evaluation	To be agreed in line with the evaluation partner
Evaluation Scope Agreed: (including agreed research sites, metrics and outcome measures to evidence the deployment, implementation and evaluation of EchoGo Pro service). Finalise project plan (with Evaluation scope included).	31/01/2021
Centralised contractor infrastructure in place to enable successful deployment	31/01/2021
Draft service level and data sharing agreements in place with sites agreed by the NHSX/AAC appointed Evaluation Team (final agreements will be executed in a phased manner, in line with deployment milestones)	31/01/2021
Project plan and milestone update sign off – across phases	31/03/2021
Deployment of EchoGo service in 25% of sites as agreed by the NHSX/AAC appointed Evaluation Team	30/06/2021
Assess progress against evaluation goals and alter agreed evaluation sites if deemed necessary to support effective evaluation	30/09/2021
Joint review with NHSX and Accelerated Access Collaborative of service progress to assess need for any change of scope to contract term.	31/10/2021
Deployment of EchoGo service in 75% of sites agreed by the NHSX/AAC appointed Evaluation Team	31/12/2021
Deployment of EchoGo service in 100% of sites agreed by the NHSX/AAC appointed Evaluation Team	31/03/2022

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Annual report 2020/2021	31/10/2021
Annual report 2021/2022	31/10/2022
Final report	31/10/2023

Phase 3 Milestone	Project month
<ul style="list-style-type: none"> • PPI group established • Collaboration agreement signed • Protocol finalised 	<ul style="list-style-type: none"> • Month 3
<ul style="list-style-type: none"> • Trial oversight committees (TSC, DMC) established • First TSC/DMC meeting • PPI meeting • Central regulatory approvals secured (REC, HRA, MHRA) • Trial registration on central registry • Protocol submitted for publication • Sponsor approval <p><u>Workstream 1</u></p> <ul style="list-style-type: none"> • 4 sites and opened to recruitment • First recruit <p><u>Workstream 2</u></p> <ul style="list-style-type: none"> • Research Assistant appointed <p><u>Workstream 3</u></p> <ul style="list-style-type: none"> • Health Economic Assessment of CRF • Detailed Health Economic Assessment workplan produced 	<ul style="list-style-type: none"> • Month 6
<ul style="list-style-type: none"> • PPI meetings x2 <p><u>Workstream 1</u></p> <ul style="list-style-type: none"> • 12 sites open to recruitment • 470 recruits <p><u>Workstream 2</u></p>	<ul style="list-style-type: none"> • Month 12

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<ul style="list-style-type: none"> • Interview schedules piloted • Development of study & recruitment materials (e.g. information sheets, consent forms) • Qualitative interviews and focus groups arranged and commenced • Transcribing interview audio-files • Set up database management system 	
<p>PPI meetings x2</p> <p><u>Workstream 1</u></p> <ul style="list-style-type: none"> • Recruitment complete (1400 participants) <p><u>Workstream 2</u></p> <ul style="list-style-type: none"> • Qualitative interviews and focus groups complete • Qualitative data entry • Qualitative data cleaning • Qualitative data analysis completed • Write draft report <p><u>Workstream 3</u></p> <ul style="list-style-type: none"> • Pathway mapping complete for health economic modelling • Health economic data analysis to be completed month 20 (dependent on data availability) 	Month 18
<ul style="list-style-type: none"> • Last participant followed up (WS1) • Database lock (WS1) • End of study notice submitted • Data analysis (WS1 and WS3 health economic report) • Final DMC meeting • Final TSC meeting • Final PPI meeting • Draft final report submitted • Draft and submit publications • Trial closure activities completed 	<ul style="list-style-type: none"> • Month 24

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Part C: Phase 4 Service Support and Continuity

This Research project will run for 36 months beginning on September 8 2020 and concluding on September 8 2023. It is anticipated that a range of deliverables will be required from Contractor, the evaluation specific team and assigned NHS deployment and evaluation sites.

Service Support criteria will be included within each individual agreement with Research Sites which will include breach criteria for the purposes of Condition 4 of Section 2. The application of Condition 4.1.3 shall under no circumstances be more onerous or punitive on or to the Contractor than the provisions of the Contractor's proposed commitments to Research Sites in relation to the definition of 'service level failures' and 'persistent service level failures' (or similar or analogous concepts) under the Contractor's Site Agreements.

Service support encompasses the following:

- Customer onboarding and training, with access to a regular performance dashboard
- First line support during normal hours of operation (typically 8am – 5pm but to be agreed and confirmed by local sites) all days of the year
- Direct telephone line / e-mail support set-up and permanently manned for any queries or issues
- Customer Service Manager assigned to sites as an escalation point and to provide on-going support and customer feedback
- If site service is down and the solution is not working, Ultromics will guarantee fixing the issue within 48 hours
- There will be provision for planned maintenance on the system so some downtime will be pre-agreed with sites

Specific service levels and breach criteria will be tailored to and agreed with each individual Research Site.

NHSX Funding Agreement re AI Health and Care Award Phase 3 & 4**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.

Phase 4 Payment Schedule	
Date	Amount (£)
1. 30 th November 2020	£ [REDACTED]
2. 31 March 2021	£ [REDACTED]
Financial Year 2020/21 sub-total	£ [REDACTED]
3. 30 June 2021	£ [REDACTED]
4. 30 September 2021	£ [REDACTED]
5. 31 December 2021	£ [REDACTED]
6. 31 March 2022	£ [REDACTED]
Financial Year 2021/22 sub-total	£ [REDACTED]
7. 30 June 2022	£ [REDACTED]
8. 30 September 2022	£ [REDACTED]
9. 31 December 2022	£ [REDACTED]
10. 31 March 2023	£ [REDACTED]
Financial Year 2022/23 sub-total	£ [REDACTED]
11. 30 June 2023	£ [REDACTED]
12. 31 October 2023	£ [REDACTED]
Financial Year 2023/24 sub-total	£ [REDACTED]
TOTAL	£1,466,972

Phase 3 Payment Schedule	
Date	Amount (£)
1. 30 th November 2020	£ [REDACTED]
2. 31 st December 2020	£ [REDACTED]
3. 31 st March 2021	£ [REDACTED]
4. 30 th June 2021	£ [REDACTED]
5. 30 th September 2021	£ [REDACTED]
6. 31 st December 2021	£ [REDACTED]
7. 31 st March 2022	£ [REDACTED]
8. 30 th June 2022	£ [REDACTED]

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9. 31 st August 2022	£ [REDACTED]
TOTAL	£1,319,819

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

Upon conclusion of the Research, the Contractor shall submit the Final Report 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.

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SECTION 5 KEY STAFF

The Contractor's representative name and address

NAME AND ADDRESS

The Authority's Representative for contract management purposes

██████████ - NHSX

The Authority's Representative for project management purposes

██████████ NHS England and NHS Improvement

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SECTION 6 REPORTING SCHEDULE

The interim report required under Condition **Error! Reference source not found.** shall be obtained by or on behalf of the Contractor using the following methods:

1. Monthly high level update reports
2. Formal quarterly review meetings with a supporting reporting submission
3. Annual report [detail to follow]

Reporting shall combine activities undertaken for both phases 3 and 4 of the research.

The feedback required under Condition **Error! Reference source not found.** shall be agreed by the parties prior to the first Milestone.