DATED **2021**

The Clatterbridge Cancer Centre NHS Foundation Trust **(1)**

and

[company name]

(2)

SBRI Healthcare Late Phase (SBRI Healthcare Phase 3, SBRI Healthcare Cancer Programme) Development Agreement

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THIS AGREEMENT is made on 2021 **BETWEEN:**

1. **The Clatterbridge Cancer Centre NHS Foundation Trust** of Clatterbridge Road, Bebington, Wirral, CH63 4JY (the "**Hospital**"); and

2. **[Company name]** with registered company number [*insert number*] and registered office at [*insert address*] (the "**Company**").

WHEREAS

(A) The Company has developed a proposal for the development of a healthcare product which matches criteria set by the SBRI Healthcare programme (the "**Project**").

(B) The SBRI Healthcare programme is funded by NHS England and NHS Improvement and is intended to facilitate fully funded development contracts to address healthcare challenges.

(C) The Hospital has agreed to award a Late Phase (Phase 3/Cancer Programme) Contract to research the Real World Testing and Implementation study to generate evidence to support rapid local/regional/national spread of a healthcare product developed by the Company in accordance with its proposal (the "**Contract**").

(D) The Company shall undertake the development of the healthcare product in collaboration with health economists, clinicians and other members of the NHS.

(E) NHS England and NHS Improvement have appointed an agent to manage the SBRI Healthcare programme and to enforce certain rights and obligations granted to the Hospital under and pursuant to this Agreement.

1 Definitions

1.1 As used in the Agreement, the following terms and expressions shall have the meaning ascribed to them below:

"**Approved Cost**" means the costs to be paid by the Hospital to the Company under this Agreement and set out in Schedule 2;

"**Agent**" means the Agent appointed by NHS England and NHS Improvement to manage the SBRI Healthcare programme;

"**Background IPR**" means all Intellectual Property Rights used in the performance of this Agreement owned by or licensed to the parties, other than the Project Intellectual Property;

"**Business Day**" means a day on which banks are ordinarily open for the transaction of normal banking business in London;

"**Confidential Information**" means any information disclosed by a party to another party that has been designated in advance and in writing as confidential or that is confirmed as confidential in writing within 5 Business Days of disclosure or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored) including information which relates to the business, affairs, properties, assets, trading practices, developments, trade secrets, Intellectual Property Rights, know how, personnel, customers and supplier of either party, all personal data and sensitive personal data within the meaning of the Data Protection Act 2018 and any other commercially sensitive information;

"**Commencement Date**" means [*insert date*];

"**Completion Date**" means [*insert date*];

"**Contract Period**" means the period commencing at the Commencement Date and ending on the Completion date;

"**Data**" means information collected and/or used for the purposes of the Real World Testing and Implementation Study set out in this Agreement which can be processed manually, electronically or by other means;

"**Deliverables**" means the outputs of the Real World Testing and Implementation Study as agreed between the parties and as set out in Schedule 1;

"**Data Protection Legislation**" means the UK Data Protection Legislation and (for so long as and to the extent that the law of the European Union has legal effect in the UK) the General Data Protection Regulation (*(EU) 2016/679*) and any other directly applicable European Union regulation relating to the protection and processing of Personal Data;

"**Real World Testing and Implementation Study**" means the study as defined in Schedule 1 to be undertaken by the Company in collaboration with the NHS;

"**FOIA**" means the Freedom of Information Act 2000 and any subordinate legislation made under this Act from time to time together with any guidance and/or codes of practice issued by the Information Commissioner in relation to such legislation;

"**Force Majeure**" means any cause preventing any party from performing any or all of its obligations which arises from or is attributable to the acts, events, omissions or accidents beyond the reasonable control of the party so prevented, including without limitation any strike, lock-out or other form of industrial action, war, riot, civil commotion, terrorism, malicious damage, compliance with law or governmental order, rule, regulation or direction, accident, breakdown of plant or machinery, fire, flood, storm or act of God;

"**Insolvency Event**" has the meaning set out in clause 17.4.1;

"**Intellectual Property Rights**" means all intellectual property rights throughout the world for the full term of the rights concerned, whether or not registered and whether or not registerable, including without limitation, copyright, database rights, patents, rights in inventions, know-how and technical information, rights in designs, registered trademarks (including business and brand names, domain names, devices and logos), and all forms of protection of a similar nature which have an equivalent effect to any of them and the right to apply for any of the foregoing anywhere in the world;

"**Key Personnel**" means the employees of the Company, engaged in the performance of the Feasibility Study and set out in Schedule 3;

"**Personal Data**" has the meaning given to it in the UK Data Protection Legislation;

"**Project**" means the Real World Testing and Implementation Study;

"**Quarter**" means the periods ending on 3, 6, 9, 12, 15 and 18 months after the Commencement Date;

"**Results**" means any Data or information generated by the Project;

"Success Criteria" means the criteria set by the Hospital and recorded in Schedule 1 which must be complied with by the Company in its Proposal for the award of the Contract;

"UK Data Protection Legislation" means any data protection legislation from time to time in force in the UK including but not limited to the Data Protection Act 2018 and

any subordinate legislation made under that Act from time to time or any successor legislation;

"**Variation**" means a variation to this Agreement executed through the completion of a Variation to Agreement Form and signed on behalf of the Parties in accordance with clause 23;

"**Variation to Agreement Form**" means the form attached to this Agreement in Schedule 5.

1.2 In this Agreement (except where context otherwise requires):

1.2.1 any reference to a recital, clause, appendix or schedule is to the relevant recital, clause, appendix or schedule of or to this Agreement and any reference to a sub-clause or paragraph is to the relevant sub-clause or paragraph of the clause, appendix or schedule in which it appears;

1.2.2 the clause headings are included for convenience only and shall not affect the interpretation of this Agreement;

1.2.3 use of the singular includes the plural and vice versa;

1.2.4 use of any gender includes the other gender;

1.2.5 any references to "persons" includes natural persons, firms, partnerships, companies, corporations, associations, organisations, governments, states, foundation and trusts (in which case whether or not having separate legally personality); and

1.2.6 any reference to a statute, statutory provision or subordinate legislation ("legislation") shall (except where the context otherwise requires) be construed as referring to such legislation as amended and in force from time to time and to any legislation which re-enacts or consolidates (with or without modification) any such legislation.

1.3 The Schedules, appendices and recitals form part of this Agreement and shall have effect as if set out in full in the body of this Agreement and any reference to this Agreement includes the schedules, appendices and recitals.

1.4 In the event of any conflict between the provisions of this Agreement and the provisions of the schedules or appendices, the provisions of this Agreement shall prevail.

2 Term of this Agreement

2.1 This Agreement shall commence on the Commencement Date and shall continue for a period of up to 9/18 months.

3 Project Management

3.1 The Company shall appoint a project director to be responsible for overall direction of the Project.

3.2 The Company shall designate the Key Personnel to work on the Project.

3.3 The Company shall procure that the Key Personnel shall perform the Real World Testing and Implementation Study in accordance with this Agreement and any further or supplementary agreement entered into between the Parties and that such members of staff are advised of any changes in the scope of this Agreement or the Project.

3.4 The Company must comply with the objectives of the Project set out in Schedule 1 and the Success Criteria.

3.5 In addition to compliance with its reporting obligations under clause 9 the Company must notify the Agent and the Hospital and any relevant research ethics committee, if required, of any proposed deviation from the agreed protocol or if significant developments occur as the Project progresses, whether in relation to the safety of individuals or to scientific direction.

3.6 Company shall ensure that all Key Personnel obey the directions of the project director appointed pursuant to clause 3.1.

3.7 The Agent shall have the authority to and may enforce and rely on such rights and obligations including but not limited to those that are expressly stated in this Agreement and clues 4.7, 6.7, 13.6 and 17. The Agent shall be entitled to enforce such obligations and rely on such rights if as if it were a party to this Agreement.

4 Real World Testing and Implementation Study

4.1 The Company shall undertake the Real World Testing and Implementation Study from the Commencement Date for the Contract Period, in accordance with the provisions of

Schedule 1 and shall use its reasonable endeavours to complete the performance of the Real World Testing and Implementation Study pursuant to the timelines set out in Schedule 1 or as otherwise agreed in writing between the parties.

4.2 The Real World Testing and Implementation Study shall be subject to amendment in accordance with clause 23 as may be agreed in writing by the parties, including but not limited to as a result of collaboration undertaken pursuant to clause 4.6, and each party shall consider in good faith any reasonable amendments proposed by the other party from time to time during the term of this Agreement.

4.3 For the avoidance of doubt, the Approved Costs provided for in Schedule 2 to be paid by the Hospital shall not be increased as a result of any amendments to the Feasibility Study provided under this Agreement.

4.4 The Company shall at all times during the period of this Agreement use all reasonable care and skill in connection with the performance of the Real World Testing and Implementation Study and perform its obligations in accordance with the provisions of clause 16 (Ethics and Compliance*)*.

4.5 It is a condition for receipt of the funding from the Hospital that, in the performance of the Feasibility Study, the Company:

4.5.1 collaborates with clinicians and other members of NHS staff to ensure that the outcome of the Project meets the needs of the NHS;

4.5.2 collaborates with health economists appointed by the Agent at such location and at such times as directed by the Agent.

4.6 A representative from the Company engaged in the Real World Testing and Implementation Study shall meet once per 3 months with the Agent to discuss the progress of the Project. The Company shall be obliged to take into account the opinion of clinical feedback referred to in clause 4.5 in its research development and where reasonable make changes to the focus of the Real World Testing and Implementation Study should the parties agree it.

4.7 In the event of a failure by the Company to comply with its obligations under clauses 3.4, 4.5 and 4.6 above, the Hospital may in its discretion and/or at the direction of the Agent terminate this Agreement and give notice to the Company requiring repayment

by the Company of some or all of the Approved Costs paid to the Company up until the date of receipt of such notice.

5 Staff Appointments

5.1 The Company shall ensure compliance by its staff with the Hospital's Equality and Diversity policy and any other policies notified to the Company by the Hospital and/or the Agent in writing, from time to time.

5.2 The Company shall promptly notify the Hospital and the Agent following the occurrence of one or more of the following events:

5.2.1 if any one or more of the Key Personnel terminates their employment with the Company; or

5.2.2 if any one or more of the Key Personnel is unable or unwilling to continue working on the Project.

5.3 In the event of the occurrence of one or both of the events in clause 5.2 above, the Company shall use its reasonable endeavours to identify a suitable replacement which is acceptable to the Hospital and the Agent (such consent not to be unreasonably withheld or delayed).

5.4 In the event that either or both of the events specified in clause 5.2 occurs and the Company is unable to locate a suitable replacement within 30 days pursuant to clause 5.3 the Hospital instructed by the Agent shall be entitled to terminate the Agreement upon 30 days' notice where in the Hospital's reasonable opinion the lack of availability of the member of staff in question may cause a material risk to the satisfactory performance of the Project.

6 Payment

6.1 Subject to clause 6.2, the Hospital shall make payments to the Company as follows:

6.1.1 All payments shall be made on the Commencement Date and thereafter Quarterly provided always that the Company shall, throughout the term of this Agreement, submit to the Agent each Quarter a financial and progress report detailing actual expenses incurred and Deliverables achieved by such expenses, and;

6.1.2 The payment for the second, third, quarter, fifth and sixth quarters shall be made within 30 days of satisfactory completion of financial and progress reports pursuant to clause 6.1.1.

6.2 The Hospital either itself or though the Agent reserves the right to recover any part of the payments made to the Company at any time during the term of this Agreement in the event that:

6.2.1 the Company fails to achieve the Deliverables;

6.2.2 the Company uses such payment for purposes which are other than the provision of the Real World Testing and Implementation Study;

6.2.3 there are material variations to the Real World Testing and Implementation Study which have not been previously agreed in writing with the Hospital, or;

6.2.4 there is any material breach of this Agreement by the Company.

6.3 The total amount to be paid by the Hospital to the Company shall not exceed the Approved Costs. Subject to these limits the Company is free to administer the funds within the terms of this Agreement without further reference to the Hospital.

6.4 The parties acknowledge and agree that all sums paid by the Hospital to the Company under this Agreement are inclusive of any applicable value added or sales tax or any other duties, taxes or imports.

6.5 On completion of the Project and subject to clause 6.2 above, any final payments in respect of costs properly incurred under the Agreement will be paid by the Hospital to the Company within 90 days, provided that:

6.5.1 a written claim has been provided by the Company in accordance with clause 6.1;

6.5.2 financial and progress reports required under clauses 8 and 9 have been supplied in writing; and

6.5.3 the Project has been completed to the satisfaction of the Agents.

6.6 In the event of early termination of this Agreement prior to completion of the Project, and without prejudice to the Hospital's rights to bring a claim against the Company

pursuant to clause 17.4, the Hospital, either itself or through the Agent, shall be entitled to recover any part of the payments for which the Company has failed to satisfactorily deliver the Deliverables prior to the date of termination.

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

6.8 If any sum of money shall be due from the Company to the Hospital, the same may be deducted from any sum then due or which at any time thereafter may become due to the Company under this Agreement or any other agreement with the Hospital.

7 Equipment

7.1 The Company shall take all practical steps to purchase any materials and equipment to be used in connection with the Project at a fair and reasonable price. The Agent may require to inspect original quotations and invoices issued to the Company for equipment or materials purchased in connection with the Project and may refuse payment in relation to any claim made in respect of such purchases if the Company does not provide this documentation on request.

7.2 Following the Completion Date, and after the final presentation of the Results and Data of the Project, all equipment purchased for use on the Project with funds provided by the Hospital shall become the property of the Company.

8 Accounting obligations and Audit

8.1 Company shall maintain during the term of this Agreement and for 7 years following termination or expiry of this Agreement proper, full and accurate financial and accounting records regarding its use of funding received from the Hospital pursuant to this Agreement.

8.2 Company grants to the Agent and to any statutory or regulatory auditors of the Hospital the right to access the Company’s financial records upon reasonable notice for audit and inspection (including the right to take copies) at all reasonable times during business hours.

8.3 The Company shall provide all reasonable assistance at all times during the term of this Agreement and during the period of two years after termination or expiry of this

Agreement for the purposes of allowing the Agents and the Hospital to obtain such information as is necessary to fulfil the Hospital's obligations to supply information for any parliamentary, governmental, judicial or other administrative purposes and/or to carry out an audit of the Company's compliance with this Agreement including all activities, performance, security and integrity in connection with the Agreement.

8.4 The Agent shall have the right to retain all Data and any financial information received from the Company including but not limited to the financial and progress reports made by the Company pursuant to clause 6.1 for 7 years following termination or expiry of this Agreement.

9 Monitoring and reporting

9.1 Company shall provide a written report to the Agent in the form specified in Schedule 4 within 5 Business Days of the end of the first Quarter on the progress of the Project to date, specifying all Results and Data created or obtained or which have otherwise arisen in connection with the Project up until the end of that Quarter.

9.2 Progress of the Project will be monitored generally by the Agent including, but not limited to, monitoring for compliance with the Deliverables detailed in Schedule 1 and the Criteria.

9.3 Within 15 Business Days of the Completion Date or the date of termination of this Agreement, the Company shall provide to the Agent a final report providing the Results and Data and all other outcomes of the Project in the form described in Schedule 4, showing all Data, methods, Results and provisional conclusions together with management information, a schedule for the development of the healthcare product and any other information relating to the Project.

9.4 The Agent shall have the right, at any time during the term of this Agreement to visit the Company’s premises to evaluate the performance by the Company of its obligations under this Agreement and in connection with the Project.

9.5 The Company agrees to participate in surveys and other activities organised by the Agent for the purpose of collating suitable metrics, updated and published from time to time by the SBRI Healthcare management board, in order to demonstrate impact and the return on investment to funders of the programme for a period not less than 4 years from the Completion Date.

10 Confidential Information

10.1 In respect of any Confidential Information it may receive from the other party, the receiving party undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party (apart from staff, professional advisors or consultants), without the disclosing party's prior written consent provided that:

10.1.1 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 the Agreement or are acquired or developed other than in the performance of this Agreement; and

10.1.2 nothing shall be construed in this Agreement as to prevent either party from using data processing techniques, ideas, know-how and the like gained during the performance of the Agreement in the furtherance of its normal business, to the extent that this does not result in a disclosure of Confidential Information or the unauthorised processing of any Personal Data.

10.2 Clause 10.1 above shall not apply to any Confidential Information received by one party from the other which:

10.2.1 is or becomes public knowledge (otherwise than by breach of this clause);

10.2.2 was in the possession of the receiving party, without restriction as to its disclosure, before receiving it from the disclosing party;

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

10.2.4 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 clause 12 (Freedom of Information).

10.3 Each party shall ensure that its staff or its professional advisors or consultants who have access to the Confidential Information are aware of such party’s confidentiality obligations under this Agreement.

10.4 The obligations of each of the parties contained in this clause 10 shall continue without limit in point of time. In the event that the Company fails to comply with this clause the Hospital reserves the right to terminate the Agreement by notice in writing with immediate effect.

11 Personal Data and Data Protection

11.1 The expectation is that Personal data will be processed in relation to (i) the administration and performance of this Agreement (other than the Project) and the SBRI healthcare Programme; and (ii) the performance of the project. Unless agreed otherwise in writing between NHS England and NHS Improvement, the Hospital and the Company:

11.1.1 The Company will be the controller in respect of Personal data processed in the performance of the Project;

11.1.2 NHS England and NHS Improvement will be the controller in respect of Personal Data processed in the administration and performance of this Agreement)other than the project) and the SBRI Healthcare programme;

11.1.3 The Agent acts as processor on behalf of NHS England and NHS Improvement:

And each Party is responsible for complying with the relevant provisions of the Data Protection Legislation and for consulting and co-operating with the other Parties in order to ensure a transparent and consistent approach.

11.2 Personal Data shall be treated as confidential at all times and the Company shall comply with the provisions of the Data Protection Legislation.

11.3 The Hospital shall promptly supply copies of any guidance which may be required by the Company in the performance of the Project, including but not limited to the following documents:

11.3.1 the Medical Research Council's “Personal Information in Medical Research”, as amended from time to time; and

11.3.2 the “NHS Confidentiality Code of Practice”, guidelines on the use and protection of patient information, as amended from time to time.

11.4 The Company shall ensure compliance with any guidance documents provided to it pursuant to clause 11.2 above, and with any other guidance or regulations in relation to Personal Data as the Hospital or the Agent may advise from time to time.

11.5 The Company shall at all times be responsible for ensuring that all Personal Data (including Data in any electronic format) is stored securely. The Company shall take appropriate measures to ensure the security of all Personal Data and guard against unauthorised access, disclosure, loss or destruction of all Personal Data while in its custody.

11.6 Personal Data shall not be made available to anyone other than those employed directly on the Project by the Company, to the extent that they need access to such information for the performance of their duties.

11.7 The Company shall fully indemnify and hold harmless the Hospital and/or the Agents, their employees and agents against all liabilities, losses, costs, charges and expenses incurred as a result of any claims, demands, actions and proceedings made or brought against the Hospital and/or the Agents by any person in respect of any loss or distress to that person by the loss, unauthorised disclosure of Personal Data or medical records by the Company, or any sub-contractor, servant or agent of the Company or any person within the control of the Company.

11.8 The Company shall, at its own expense, conduct any litigation arising from any claims relating to its use of Personal Data brought by any person in respect of any loss or distress to that person by the loss, unauthorised disclosure of Personal Data or medical records by the Company.

11.9 No Personal Data shall be included in any publications made by the Company without the prior agreement in writing of the individual concerned. No mention shall be made of individual officers of the Hospital, nor shall information be included which might lead to their identification, without the prior agreement in writing of the Hospital.

11.10 The Company shall ensure that all Personal Data is pseudonymised as and when it is obtained and that the key to personal identities of all persons to whom the Personal Data relates is kept in a separate and secure place. The Company shall not supply the Agents or the Hospital with copies of Personal Data obtained in connection with the Project other than in an anonymised form.

12 Freedom of Information

12.1 The Company acknowledges that the Hospital and the Agents are subject to the requirements of the FOIA and the Environmental Information Regulations 2004 and shall provide all reasonable assistance to and cooperate with (at its own expense) the Hospital and/or the Agents to enable the Hospital or the Agents as appropriate to comply with any information disclosure requirements.

12.2 Notwithstanding the generality of clause 12.1, the Company shall provide the Hospital and/or the Agents within five Business Days of receipt of a request for assistance from the Hospital and/or the Agents with such information in its possession or power as may be reasonably requested in order to assist the Hospital to comply with its obligations under the FOIA.

13 Publicity

13.1 Subject to the other provisions of this clause, the Hospital may publish details of the Project for any non-commercial purpose.

13.2 If either party wishes to make any press or other public announcements, or release in any form any marketing or other publicity materials or releases, whether in written or oral form, relating to this Agreement, the Project Intellectual Property, the Project, Results or Data, or relating to the other party's Background Information, such party (the "**Publishing Party**") shall

13.2.1 obtain the prior written approval of the other party (the "**Owning Party**") in accordance with clause 13.3 and 13.4 below, which will include approval of the form and content of the announcement or release of materials; and

13.2.2 name the Owning Party should such party require it in such material (which naming, in the case of the Hospital, shall be subject to the provisions of clause 13.5).

13.3 To obtain the approval described in clause 13.2.1 the Publishing Party shall no less than 60 calendar days before using the material referred to in clause 13.2 submit in writing all drafts of such material (the "**Draft Material**") to the Owning Party.

13.4 Following receipt of the Draft Material in accordance with clause 13.3, the Owning Party shall have a period of 30 calendar days in which to:

13.4.1 approve the Draft Material; or

13.4.2 withhold approval where either in the Owning Party's reasonable opinion the Draft Material may prejudice any future applications for registered Intellectual Property Rights in respect of such materials or in the case of the Hospital where the publication of the Draft Material may otherwise prejudice the Hospital's interests.

13.5 Any publication resulting from work carried out under this Agreement shall acknowledge the SBRI Healthcare programme's financial support, carry the SBRI Healthcare and AHSN Networks logos and carry a disclaimer such as the Monitoring Agent may require or in the absence of direction from the Monitoring Agent a notice as follows:

"This work was commissioned and funded by the SBRI Healthcare programme. SBRI Healthcare is an NHS England initiative, championed by the Academic Health Science Networks (AHSNs). The views expressed in the publication are those of the author(s) and not necessarily those of the SBRI Healthcare programme or its stakeholders."

13.6 The Hospital may terminate this agreement immediately on written notice in the event that it becomes aware that the Company has published material in contravention of this clause 13.

14 Intellectual Property

14.1 All Background IPR used or supplied under this Agreement in connection with the Project shall remain the property of the party introducing the same and nothing contained in this Agreement or any licence agreement pertaining or pursuant to the Project shall affect the rights of either party in its Background IPR.

14.2 The Company shall confirm in writing that as at the Commencement Date it possesses all the Background IPR necessary to enable it to complete the Real World Testing and Implementation Study. In the event that one of the parties proposes an amendment to be made to the Real World Testing and Implementation Study pursuant to clause 4.2, the Company shall notify the Hospital if it does not possess the Background IPR necessary to enable it to complete the proposed amended Real World Testing and Implementation Study.

14.3 Subject to Clause 14.4 the Intellectual Property Rights arising out of the Project (the "**Project Intellectual Property**") shall in the first instance belong to the Company.

14.4 The Company hereby grants the Hospital irrevocable, royalty-free non-exclusive right together with the right to grant sub-licences to use or publish Background IPR, Project Intellectual Property, information, Data, Results or conclusions arising from the Project for the purposes of research, evaluation, teaching and learning in relation to the provision of clinical patient care.

15 Exploitation of Intellectual Property

15.1 The Company shall promptly inform the Monitoring Agent in writing of:

15.1.1 any Project Intellectual Property upon its creation, which is capable of exploitation whether patentable or not; and

15.1.2 any Project Intellectual Property upon its creation which consists of results, designs, discoveries, inventions or matters which may form the subject of an application for a patent or other form of Intellectual Property Rights protection.

15.2 The Company shall devise, publish, implement and maintain procedures for the management of Project Intellectual Property and in particular, but without limitation, shall use all reasonable endeavours to ensure that:

15.2.1 the Results arising out of the Project are identified, recorded and distinguished from the outputs of its other research;

15.2.2 prior to any publication of the Results of the Project, patentable inventions arising from the Results are identified, duly considered for patentability and, where it is reasonable so to do, patent applications in respect thereof are filed at the British or European Patent Office; and

15.2.3 all such patent applications are diligently prosecuted having regard to all relevant circumstances.

15.3 The Company shall permit the Monitoring Agent to monitor the operation and effectiveness of the Company's procedures for the management of Intellectual Property Rights in such a way as the Hospital considers reasonably necessary.

15.4 The Company shall ensure that no provisions are included in employment contracts with its staff which are inconsistent with the requirements of this Agreement that the Company is the first owner of Project Intellectual Property.

15.5 The Company will provide the Agent with such information that the Agent and/or the Hospital may reasonably request from time to time to demonstrate that the Company is exploiting or is taking reasonable steps towards exploiting the Project Intellectual Property.

15.6 Subject to any of its obligations of confidentiality under this Agreement, the Company shall use its best endeavours to:

15.6.1 promote the dissemination of the Results of the Project; and

15.6.2 where reasonable, exploit commercially such Results to generate capital, revenue or other monetary return.

15.7 The Company will notify the Agent if the Company decides not to proceed with the exploitation of any of the Project Intellectual Property and will, if requested to do so by Agent or the Hospital, assign the Project Intellectual Property to the Hospital or its successors or nominee.

15.8 Within 1 year of the date of the creation of any Project Intellectual Property the parties shall meet to evaluate the progress of the Company in exploiting the Project Intellectual Property commercially. If in the reasonable opinion of the Hospital or the Agent the Company has not made reasonable endeavours to exploit some or all of the Project Intellectual Property commercially the Hospital may require the relevant Project Intellectual Property to be assigned to or licensed to the Hospital or its nominees.

15.9 Any dispute over whether or not the Company has used reasonable endeavours for the purpose of Clause 15.8 shall be settled in London by a barrister specialising in intellectual property law, who has no prior connection with either the Hospital or the Company, or who is otherwise acceptable to the Hospital and the Company. He or she shall be nominated for the purpose by the then Chairman of the General Council of the Bar and shall act as an arbitrator. His or her costs and expenses shall be met by the parties in equal shares. Each party shall supply him or her with such evidence as he or she reasonably requests and shall allow him or her access on reasonable notice to any laboratories or other premises which he or she asks (on reasonable grounds) to inspect. His or her decision shall be a ruling on whether or not the

Company has used reasonable endeavours to exploit the relevant Project Intellectual Property commercially.

15.10 For the avoidance of doubt, the parties agree that for the purpose of clause 15.8, the following circumstances shall be conclusive evidence that the Company has failed to use reasonable endeavours:-

15.10.1 the Company is subject to an Insolvency Event; or

15.10.2 the Company has taken steps to exploit the Project Intellectual Property, but in the reasonable opinion of the Hospital:

(i) the resulting product is of insufficient quality or being produced in insufficient quantities to meet the requirements of the NHS; and/or

(ii) the resulting product is offered for a price which is over and above market price and/or the level which would be normally charged for a comparably similar product to the NHS.

15.11 The Company 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 Hospital may from time to time require for the purpose of giving the Hospital the full benefit of the provisions of this Agreement.

16 Ethics and Compliance with Regulations

16.1 The Company shall comply, and shall procure compliance by any of its officers or agents, with all applicable laws, statutes, regulations, and guidance in the performance of the Real World Testing and Implementation Study (if applicable) and with any guidance as may be advised by the Hospital, from time to time.

16.2 The Company will ensure that work in any way connected with this Project is conducted in accordance with, where applicable, the ICH GCP**,** the current version of the World Medical Association Declaration of Helsinki entitled “Ethical Principles for Medical Research Involving Human Subjects”, the Department of Health Guidance “Research Governance Framework For Health and Social Care” and, if relevant, in accordance with the Department of Health guidance “Governance Arrangements for NHS Research Ethics Committees” or such other guidelines as may be issued from time to time by the Department of Health or other health authority and copies of which shall be made available to the Company.

16.3 The Company will submit for review by a Research Ethics Committee recognised by the Hospital any Project involving:

16.3.1 NHS patients and users including those treated under agreement with private sector providers;

16.3.2 individuals identified as potential research participants because of their status as relatives or carers of NHS patients;

16.3.3 NHS staff – recruited as research participants by virtue of their professional role;

16.3.4 access to data, organs or other bodily material of past and present individual and identifiable NHS patients;

16.3.5 fetal material and IVF involving NHS patients;

16.3.6 the recently dead in NHS premises;

16.3.7 the use of, or potential access to, NHS premises or facilities

with a view to obtaining the approval of the Research Ethics Committee to the Project and will inform the Hospital when such approvals have been given (whether unconditionally or subject to conditions) or withheld.

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

17 Termination

17.1 Either the Hospital or the Company shall have the right to terminate this Agreement upon giving 90 days' prior written notice to the other party.

17.2 The Hospital may by notice in writing terminate this Agreement without liability for any damage, loss or expenses arising as a result of or in connection with such termination if there is a change of Control of the Company which, in the reasonable opinion of the Hospital, has affected or is likely to materially affect the performance by the Company of its obligations under this Agreement (including but not limited to its obligations under clause 15). For the purposes of this definition, "**Control**" means direct or indirect

beneficial ownership of more than 50% of the share capital, stock or other participating interest carrying the right to vote or to distribution of profits of the Company, as the case may be, and/or to direct the affairs of the Company whether by virtue of the ownership of shares, contract or otherwise.

17.3 The Hospital shall only be permitted to exercise its rights pursuant to clause 17.2 for 6 months after any such change of Control and shall not be permitted to exercise such rights where the Hospital has agreed in advance in writing to the particular change of Control and such change of Control takes place as proposed. The Company shall notify the Hospital in writing 4 weeks prior to any proposed change of Control.

17.4 The Hospital may terminate immediately by notice in writing this Agreement without liability for any damage, loss or expenses arising as a result of or in connection with such termination if:

17.4.1 the Company has breached this Agreement and;

(i) in the case of a breach which is capable of remedy, the Company has failed to remedy the breach within 30 days of written notice being sent to the Company specifying the breach and requiring its remedy; or

(ii) the breach is incapable of remedy;

17.4.2 the Hospital has the right to terminate pursuant to an express provision in this Agreement.

17.5 This Agreement will terminate automatically and immediately and without the Hospital incurring any liability for any damage, loss or expenses arising as a result of or in connection with such termination in the event that the Company passes a resolution, or the court makes an order that:

(i) the Company be wound up (otherwise than for the purpose of a bona fide and solvent reconstruction or amalgamation); or

(ii) a receiver, manager or administrator on behalf of a creditor is appointed in respect of all or part of the business of the Company; or

(iii) circumstances arise which entitle a court or creditor to appoint a receiver, manager or administrator or which entitle the court

(otherwise than for the purpose of a solvent and bona fide reconstruction or amalgamation) to make a winding up order; or

(iv) the Company ceases to trade or is unable to pay its debts within the meaning of the Insolvency Act 1986 or any similar event occurs under the law of any other jurisdiction,

any one or more of these being an "**Insolvency Event**".

18 Consequences of termination

18.1 The following clauses shall survive termination of this Agreement for any reason: clauses 3.7, 8.1, 8.3, 8.4, 9.5, 10, 11.1, 11.6, 11.7, 12, 13, 14, 15, 18, 20, 21, 24 and 26.

18.2 Except for the licence granted to the Hospital under clause 14.4 which shall continue following termination, all parties shall cease to use the Intellectual Property Rights of the other party immediately upon termination of this Agreement.

18.3 All Confidential Information and any other materials supplied to the Company by the Hospital or by the Agents and any copies made of the same shall be immediately returned by the Company to the Hospital or to the Agents, as appropriate upon termination of this Agreement.

19 Warranties

19.1 The Company warrants and represents that:

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

19.1.2 the Project will be carried out by appropriately experienced, qualified and trained personnel with skill, care and diligence;

19.1.3 the Company will discharge its obligations under this Agreement with skill, care and diligence including, but not limited to, in compliance with good

industry practice and (without limiting the generality of the foregoing) in accordance with its own established internal procedures; and

19.1.4 to the best of its knowledge, the performance of the Project and the Hospital's use of any Results and/or Data shall not infringe any Intellectual Property Rights of any third party.

20 Liability and indemnity

20.1 Subject to clause 20.2, none of the Hospital, the Agent or the Company shall (except in the case of death or personal injury caused by its negligence or in the case of its fraudulent misrepresentation or in other circumstances where liability may not be so excluded or limited under any applicable law) be liable to any of the Hospital, the Agent or the Company (as relevant) in contract, tort, negligence, breach of statutory duty or otherwise for loss of profit, loss of data, use, anticipated savings, goodwill, reputation or opportunity, economic loss and/or any consequential or indirect loss or damage, costs or expenses incurred or suffered by the other party as a result of any breach by the relevant party of the terms of this Agreement.

20.2 The Company hereby indemnifies the Hospital and the Agents, their officers and agents, in full and shall keep the Hospital and Agents and such officers, and agents indemnified from and against all claims, demands, actions and proceedings made or brought against the Hospital, the Agents, their officers or agents, and all damages, losses, costs and expenses (including legal and other professional advisers' fees) whatsoever arising under statute or at common law whether or not foreseeable at the date of entering into this Agreement, incurred or suffered by the Hospital, the Agents or their agents or officers, whether directly or indirectly in respect of:

20.2.1 the breach or non-performance of any provision of clauses 4.5, 16 or 19 of this Agreement by the Company, or

20.2.2 any damage to any property or to persons, including personal injury

arising out of or in the course of or in connection with the Project except in so far as such liability arises out of the negligence or wilful misconduct of the Hospital.

20.3 The Company shall promptly notify the Hospital and the Agent if any claim or demand is made or action brought against the Company for infringement or alleged

infringement of the Intellectual Property Rights of a third party in connection with the performance of the Project.

20.4 The Company shall 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 Company, arising out of the Company's performance of the Agreement.

20.5 The Company shall produce to the Hospital and the Agent, on request, copies of all insurance policies referred to in this clause or other evidence confirming the existence and extent of the cover given by those policies, together with receipts or other evidence of payment of the latest premiums due under those policies.

20.6 The terms of any insurance or the amount of cover shall not relieve the Company of any liabilities under the Agreement.

21 Additional Funding

21.1 The Company hereby acknowledges and accepts that the award of the Contract and the entry into this Agreement by the Hospital:

21.1.1 does not mean that the Hospital will make any further funding available for the Project or any other project of the Company; and

21.1.2 that if any funding is made available by the Hospital for any other project, nothing in this Agreement imposes any obligation on the Hospital to grant such funding or the contract relating to such funding to the Company.

22 Force Majeure

22.1 If any party is affected by Force Majeure it shall forthwith notify the other party of the nature and extent thereof.

22.2 No party shall be deemed to be in breach of this Agreement by reason of any delay in performance, or non-performance, of any of its obligations hereunder, to the extent that such delay or non-performance is due to any Force Majeure of which it has notified the other party, and the time for performance of these obligations shall be extended accordingly as may be fair and reasonable in all circumstances, provided always that if the duration of any such delay or impediment exceeds 6 months, then any party may give 30 days' notice to terminate this Agreement.

23 Variation

23.1 If at any time it appears likely that any provision of the Agreement, in particular the Project, needs to be varied, the Company shall immediately inform the Hospital and the Agent in writing requesting a Variation to the Agreement, giving full details of the justification for the request and giving proposals for the Variation to the Agreement. Upon receipt of such a request the Hospital and/or the Agent may:

23.1.1 agree to vary this Agreement;

23.1.2 vary the Project in such a manner which the Company agrees can be carried out within the Approved Cost;

23.1.3 refuse the request and require the continuation of the Project in accordance with this Agreement;

23.1.4 give notice of termination in accordance with clause 17.

23.2 Any variation to this Agreement agreed pursuant to clause 23.1 shall be set out in a Variation to Agreement Form authorised by the Agent and signed by both parties.

24 Applicable law and Dispute Resolution

24.1 If any dispute arises out of, or in connection with this Agreement, the parties will attempt in good faith to settle it by negotiation between the designated representatives of each party.

24.2 In the event that the dispute is not resolved by such representatives as provided under clause 24.1 the matter will be referred to the signatories to this Agreement.

24.3 If, following the process described in clauses 24.1 and 24.2 above, the parties are unable to settle any dispute by negotiation within thirty days, the parties will attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure in the United Kingdom.

24.4 To initiate mediation a party must give notice in writing to the other parties requesting mediation in accordance with clause 24.4. If the parties do not resolve the dispute within 30 days of the commencement of the mediation, either party may take such lawful steps as it considers necessary to resolve the dispute (including but not limited to the commencement of legal proceedings).

24.5 Nothing in this clause 24 shall prevent either party from instituting legal proceedings against the other party in order to preserve any legal right or remedy that they may have.

24.6 This Agreement and all questions of construction, validity and performance under this Agreement shall be governed by English law and shall be subject to the non- exclusive jurisdiction of the English courts.

25 Corrupt Gifts and Payments

25.1 The Company shall not:

25.1.1 offer or give, or agree to give, to any employee or representative of the Hospital or the Agents any gift or consideration of any kind as an inducement or reward for doing, or refraining from doing or having done or refrained from doing, any act in relation to the obtaining or execution of this Agreement or any other agreement with the Hospital or for showing or refraining from showing favour or disfavour to any person in relation to this Agreement or any other agreement; or

25.1.2 enter into this or any other Agreement with the Hospital in connection with which commission has been paid by him or on his behalf, or with his knowledge, unless before the Agreement is made, particulars of any such commission and the terms and conditions of any agreement for the payment thereof have been disclosed in writing to the Hospital.

25.2 Any breach of this clause, by the Company or by anyone acting on his behalf or employed by him, whether with or without his knowledge, or the commission of any offence by the Company or by anyone acting for him or employed by him under the Bribery Act 2010 in relation to this or any other agreement shall entitle the Hospital to terminate this Agreement and recover from the Company the amount of any loss resulting from such a termination and/or recover from the Company the amount or value of such gift, consideration or commission.

26 General

26.1 The Company shall not be entitled to perform any of its obligations through any other company or entity or to assign, mortgage, sub-contract, charge or dispose of any of its rights or otherwise delegate any of its obligations under this Agreement without the

prior written consent of the Hospital whose consent may be subject to such terms as the Hospital may see fit to impose, and the Company shall be responsible for the acts and omissions of any sub-contractors as though they were its own.

26.2 This Agreement contains the entire agreement between the parties with respect to the subject matter hereof save and except and supersedes all previous agreements and understandings between the parties with respect thereto, and may not be modified except by an instrument in writing pursuant to clause 23.

26.3 Each party acknowledges that in entering into this Agreement, it does not do so on the basis of, and does not rely on, any representation or warranty or other provision except as expressly provided. However, nothing in this Agreement purports to exclude liability for any fraudulent statement or act.

26.4 Nothing contained in this Agreement shall be construed to imply a partnership, or employer and employee or principal and agent relationship between the parties, and save to the extent permitted under this Agreement, no party shall have any right, power or authority to create any obligations, express or implied on behalf of the other parties either jointly or severally.

26.5 Except as provided under clause 3.7 and the remaining provisions of this clause 26.5, no person who is not party to this Agreement shall have any right under the Contracts (Rights of Third Parties) Act 1999 to enforce any terms of this Agreement but this does not affect any right or remedy of a third party which exists or is available apart from that Act. For the avoidance of doubt, the Agent shall be entitled to enforce any term of this Agreement which grants rights to the Hospital, or entitles the Hospital to enforce obligations upon the Company or which confers a benefit onto the Agent (including but not limited to clause 20).

26.6 Each party warrants to the other party that it has full power and authority to enter into this Agreement.

26.7 The failure to exercise or delay in exercising a right or remedy provided by this Agreement or by law does not constitute a waiver of the right or remedy or a waiver of other rights or remedies. A waiver of a breach of any of the terms of this Agreement or of a default under this Agreement does not constitute a waiver of any other breach or default and shall not affect the other terms of this Agreement. A waiver of a breach of any of the terms of this Agreement or of a default under this Agreement will not prevent a party from subsequently requiring compliance with the waived obligation.

26.8 If any provision of this Agreement shall be held to be unlawful, invalid or unenforceable, in whole or in part, under any enactment or rule of law, such provision or part shall to that extent be severed from this Agreement and rendered ineffective as far as possible without modifying or affecting the legality, validity or enforceability of the remaining provisions of this Agreement which will remain in full force and effect.

26.9 Any notice or other communication given under this Agreement will be in writing and signed by or on behalf of the party giving it and will be served by delivering it personally or sending it by pre-paid recorded delivery or registered post or fax or email to the address and for the attention of the relevant party set out in clause 26.11 (or as otherwise notified by that party for the purposes of this Agreement.)

26.10 Any such notice will be deemed to have been received:

26.10.1 if delivered personally, at the time of delivery;

26.10.2 in the case or pre-paid recorded delivery or registered post, two Business Days from the date of posting;

26.10.3 in the case of registered airmail, five Business Days from the date of posting; and

26.10.4 in the case of email one Business Day from the date of despatch provided that no error notification is received

provided that if deemed receipt occurs before 9am on a Business Day the notice will be deemed to have been received at 9am on that day, and if deemed receipt occurs after 5pm on a Business Day, or on a day which is not a Business Day, the notice will be deemed to have been received at 9am on the next Business Day.

26.11 The addresses and contact details of the parties for the purposes of this clause 26 are:

Hospital:	The Clatterbridge Cancer Centre NHS Foundation Trust
Address:	Clatterbridge Road, Bebington, Wirral, CH63 4JY
Fax number:	*deliberately left blank*
For the attention of:	The Finance Director
Agent:	LGC Group
Address:	Grange House, 15 Church Street, Twickenham TW1 3NL
Fax number:	*deliberately left blank*
For the attention of:	Ben Patient
Company:	insert
Address:	insert
Fax number:	*deliberately left blank*
For the attention of:	insert

or such other address or email address as may be notified in writing from time to time by the relevant party to the other party.

AS WITNESS whereof this Agreement has been entered into by the above parties on the date and year first above written.

SIGNED for and on behalf of **The Clatterbridge Cancer Centre NHS Foundation Trust**	**SIGNED** for and on behalf of [**Company]**
Name:	Name:
Position:	Position:
Signature:	Signature:

Schedule 1

Real World Testing and Implementation **Study**

Project title

Deliverables

Milestone	Date	Resource	Success Criteria

Schedule 2

Approved Costs

Cost Categories	Total Costs (£)
Labour Costs	
Materials Cost	
Capital Equipment Costs	
Sub Contract Costs	
Travel & Subsistence Costs	
Indirect Costs	
Other Costs	
Net Costs	
VAT	
Total Costs (including VAT)	

Quarter	Net Amount	VAT	Gross Amount
1			
2			
3			
4			
5			
6			

The payment for the first quarter (months 1-3) shall be made within 30 days of the Commencement Date. The payment for the second, third, fourth, fifth and sixth quarter shall be made 30 days of satisfactory completion of financial and progress reports pursuant to clause 6.1.1. Where the Company is VAT registered, the VAT component (at 20% for all costs), should be included in payment invoices.

Schedule 3

Key Personnel

Role:

Time allocated to project:

Advisors/Subcontractors

Role:

Time allocated to project:

Cost:

Schedule 4

Format of the Real World Testing and Implementation **Study Report**

Real World Testing and Implementation **Study Report**

Reports should be submitted using the specific format provided to companies by the SBRI Healthcare programme. The information required from companies includes, but is not limited to:

a. An account of progress against the agreed Deliverables, milestones and outputs included in Schedule 1;
b. A breakdown of all expenditure to date on the Project;
c. Any changes in management structure or personnel administering the award;
d. Plan for continued and/or future exploitation of the Project Intellectual Property Rights including an estimated date of market entry;

Schedule 5

VARIATION TO AGREEMENT FORM

Development Agreement between the The Clatterbridge Cancer Centre NHS Foundation Trust (the "**Hospital**") and [insert] (the "**Company**") dated 2021 (the "**Agreement**")

Variation No: _____

Date: _____

1. The Agreement is varied as follows:

   [……..]

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

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

SIGNED:

For and on behalf of the Hospital	For and on behalf of the Company
By:	By:.....
Full Name:.....	Full Name:.....
Position:.....	Position:.....
Date:	Date:.....