

DATED 19 october 2020

- (1) DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY
- (2) IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY AND MEDICINE

SERVICE AGREEMENT

THIS AGREEMENT dated 19 October 2020 is between:-

- (1) **DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY** of 1 Victoria Street, London SW1H 0ET (the "**Authority**"); and
- (2) **IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY AND MEDICINE** of Exhibition Road, South Kensington, London SW7 2AZ ("**Imperial**")

each a "**Party**" and together the "**Parties**".

WHEREAS:-

- A. The Authority, by means of the Vaccines Taskforce, is involved in finding a solution to the SARS CoV-2 pandemic (the "**Pandemic**"), and is supporting and investing in vaccine programmes, as well as in building lasting health and economic benefits for the United Kingdom. The Authority sees the support of, investment in, and access to, human challenge studies as being an essential means by which these objectives may be met.
- B. Imperial is a leading academic institution with a wealth of expertise and a highly successful track record in leading and carrying out clinical research. Imperial is also actively involved in the efforts to understand and find a solution to the Pandemic.
- C. The Parties wish to use their collective expertise to collaborate on a project which aims to conduct GMP manufacture of SARS-CoV-2 virus generated from isolates, and design and carry out a study to characterise such virus in a human characterisation study (which will be conducted in accordance with GCP) to enable the development of a human challenge model specific to SARS CoV-2 (the "**Project**").
- D. This Agreement governs funding arrangements for the services to be provided by Imperial in respect of the Project. The Parties will execute a separate Project Collaboration Agreement with other Project Partners to agree the governance framework and other rights and obligations that will govern the operational and other aspects of the Parties' collaboration in relation to the Project.

IT IS AGREED as follows:-

1. DEFINITIONS

1.1 As used herein, the following terms shall be defined as follows:

" Background IPR "	means the background Intellectual Property Rights of each Party as set out in clauses 10.1.1 and 10.1.2;
" Bribery Laws "	means the Bribery Act 2010 and associated guidance published by the Secretary of State for Justice under the Bribery Act 2010 and all other applicable United Kingdom laws, legislation, statutory instruments and regulations in relation to bribery or corruption and any similar or equivalent laws in any other relevant jurisdiction;
" Business Day "	means a day other than a Saturday, Sunday or bank or public holiday in England;
" Characterisation Study " or " Study "	means the first-in-human study for the characterisation of SARS-CoV-2;

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"Commencement Date"	+	+
"Confidential Information"	any Background IPR, Know-how, any of the Results and/or any other information disclosed by a Party to the other Party for use in the Project or under this Agreement which, by its nature or from the circumstances of its disclosure, should reasonably be presumed to be confidential;	
"Contractor"	means, in relation to each Party as applicable: (a) all of its personnel and all direct and indirect subcontractors, suppliers, agents and other intermediaries of it; and (b) each person employed by or acting for or on behalf of any of those persons referred to in (a);	
"Developed Assays"	means the assays developed for the Project, including: ■ [REDACTED] ■ [REDACTED]	
"DSMB"	means the Study's independent data safety monitoring board, as established by Imperial in consultation with the Human Challenge Steering Committee;	
"Fees"	means the fees detailed in Schedule 2 against each Payment Milestone;	
"GCP"	means ICH Good Clinical Practice in accordance with the set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects as set forth in the International Conference on Harmonisation (ICH) guidelines 'Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance' and implemented by Directive 2001/20/EC, as amended, the Clinical Trials Directive, and Directive 2005/28/EC, the GCP Directive and other equivalent foreign regulations or standards, as applicable, as such standards, practices, procedures, requirements and regulations may be amended and implemented in the United Kingdom from time to time;	
"Gilead"	means Gilead Sciences, the biopharmaceutical company supplying use of their drug, [REDACTED], for the purposes and duration of the Study;	
"GLP"	means Good Laboratory Practice, the current good laboratory practices within the meaning of Directive 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version) and Directive 2004/9/EC	

on the inspection and verification of good laboratory practice (GLP) (codified version) (together the GLP Directives) and other equivalent regulations or standards, as applicable, as such current good laboratory practices, regulations and equivalent foreign regulations or standards may be amended and implemented in the United Kingdom from time to time;

"GMP"	means Good Manufacturing Practice in accordance with the Directive 2003/94/EC, Volume 4 of the Rules Governing Medicinal Products in the European Union and any other relevant legislation, regulations, standards or guidance, as such legislation, regulations, standards and guidance may be amended and implemented in the United Kingdom from time to time;
"Human Challenge Steering Committee"	means the Project's operational governing and advisory committee (including in relation to the scope, budget and timelines of the Project), established by the Authority in accordance with clause 4 of the Project Collaboration Agreement;
"Imperial Key Personnel"	has the meaning given to that term in Schedule 1 paragraph 2.1.2;
"Intellectual Property Rights"	means: <ul style="list-style-type: none"> (a) copyright, rights related to or affording protection similar to copyright, rights in data, databases, patents and rights in inventions, semi-conductor topography rights, trade marks, rights in Internet domain names and website addresses and other rights in trade names, designs, Know-how, trade secrets and other rights in Confidential Information; (b) applications for registration, and the right to apply for registration, for any of the rights listed at (a) that are capable of being registered in any country or jurisdiction; and (c) all other rights having equivalent or similar effect in any country or jurisdiction;
"Know-how"	all ideas, concepts, schemes, information, knowledge, techniques, methodology;
"Lease"	means the lease dated on or around the date of the Project Collaboration Agreement between (1) Royal Free London NHS Foundation Trust and (2) Secretary of State for Department for Business, Energy & Industrial Strategy, a copy of which will be appended in Schedule 6;
"Medical Oversight Committee"	means the Study's independent medical oversight committee, as established by Imperial in consultation with the Authority;
"Payment Milestone"	means each of the milestones set out in Schedule 2;
"Payment Plan"	means the payment plan set out in Schedule 2;
"Premises"	[REDACTED] (903.74 Sqm) and Logistics space (88.49 Sqm) Royal Free Hospital, Pond Street, Hampstead NW3 2QG;
"Project Collaboration"	means the Project collaboration agreement to be entered into by

"Agreement"	all Project Partners;
"Project Manager"	means the individual appointed by Imperial from time to time to manage the Services;
"Project Partners"	means the Authority, Imperial, Royal Free London NHS Foundation Trust and HVIVO Services Limited (" HVIVO ");
"Project Plan"	means the plan set out in Schedule 5 of this Agreement and as updated by the Parties in accordance with the Project Collaboration Agreement;
"Project Specific IPR"	has the meaning given to it in clause 10.1.3;
"Protocol"	means the protocol for the Characterisation Study;
"Results"	means all results, data, materials, samples, products, deliverables, information, Developed Assays, Know-how, Intellectual Property Rights and outcomes arising from the Projects, including the Study;
"Roles and Responsibilities Matrix"	means the RACI matrix of the overall roles and responsibilities of each Project Partner with respect to the Project as described in Schedule 1 of the Project Collaboration Agreement;
"Service Agreement"	means an agreement entered into by or on behalf of the Authority and individual Project Partner in relation to any services provided by such Project Partner in respect of the Project aspect of the Project and "Service Agreements" shall be construed accordingly;
"Services"	means the services set out in Schedule 1;
"Sponsor"	means Imperial;
"Study Delivery Team"	means the team responsible for the Study's operational management, as established by the Authority in accordance with clause 3 of the Project Collaboration Agreement; and
"Study Monitor"	means one or more persons appointed to monitor compliance of the Study with ICH GCP and to conduct source data verification.

- 1.2 The headings in this Agreement are for ease of reference only; they do not affect its construction or interpretation.
- 1.3 References in this Agreement to a person include a natural person, corporate or unincorporated body (whether or not it has a separate legal personality).
- 1.4 A reference in this Agreement to a statute or statutory provision is a reference to it as amended, extended or re-enacted from time to time and includes all subordinate legislation made from time to time under that statute or statutory provision.
- 1.5 A reference in this Agreement to writing or written includes email.
- 1.6 A reference in this Agreement to any other agreement or document is a reference to that other agreement or document as varied or novated (in each case, unless in breach of this Agreement) from time to time.

- 1.7 References in this Agreement to clauses and Schedules are to the clauses and Schedules of this Agreement and references to paragraphs are to paragraphs of the relevant Schedule.
- 1.8 Any words in this Agreement following the expression including, include or in particular, or any similar expression are to be construed as illustrative and do not limit the sense of the words preceding that expression.
- 1.9 Pursuant to the provisions of clause 14, the acts and omissions of its personnel are deemed to be within the control of a Party and the acts and omissions of any of that Party's Contractors are deemed to be within the control of the Party engaging that Contractor.

2. THE PROJECT

- 2.1 The Project will begin on the Commencement Date and will continue until the completion of the Project. The Project is estimated to be completed within thirty six (36) months from the Commencement Date.
- 2.2 The Parties agree to work collaboratively and in good faith to achieve the aims of the Project in accordance to the timelines set out in the Project Plan.

3. IMPERIAL OBLIGATIONS

- 3.1 In its capacity as Sponsor of the Study and a partner to the Project and in consultation with the Authority and other Project Partners as agreed in the Project Collaboration Agreement, Imperial will provide the Services in accordance with this Agreement and the Project Plan. Imperial does not undertake that any research will lead to any particular result, nor does it guarantee a successful outcome to the Project.
- 3.2 At all times, Imperial shall ensure that:
- 3.2.1 each of its personnel (including Key Imperial Personnel) is suitably qualified, adequately trained and capable of providing the applicable Services in respect of which they are engaged;
- 3.2.2 there is the required number of personnel to provide the Services properly; and
- 3.2.3 only those personnel who are authorised by Imperial are involved in providing the Services.

4. FEES

- 4.1 In consideration of Imperial complying with its obligations under this Agreement including as specifically set out in clause 3, the Authority shall pay the Fees in accordance with this clause 4.
- 4.2 Imperial shall issue an invoice for the relevant Fee amount as set out in the Payment Plan.
- 4.3 Subject to clause 4.6, the Authority shall pay all undisputed invoices in full in cleared funds within thirty (30) days of receipt of each properly submitted invoice in pounds Sterling to the bank account nominated by Imperial:

Bank: [REDACTED]

Account holder name: [REDACTED]

Sort Code: [REDACTED]

Account Number: [REDACTED]

Reference: [REDACTED]

- 4.4 The Authority shall pay any applicable UK Value Added Tax ("**VAT**") to Imperial on receipt of a valid VAT invoice.
- 4.5 Where undisputed sums due hereunder are not paid in full by the due date Imperial may, without limiting its other rights, charge interest at the applicable rate under the Late Payment of Commercial Debts (Interest) Act 1998, provided that Imperial shall first give the Authority not less than 40 days written notice of its intention to charge interest, such notice being served no earlier than the due date for payment of the relevant overdue sum. Interest shall accrue on a daily basis, and apply from the due date for payment until actual payment in full, whether before or after judgment. The Parties agree that this clause 4.5 is a substantial remedy for late payment of any sum payable under this Agreement in accordance with section 8(2) of the Late Payment of Commercial Debts (Interest) Act 1998.
- 4.6 If the Authority disputes any portion of an invoice, the Authority shall pay the undisputed portion of the invoice in full in accordance with clause 4.3. Within ten (10) Business Days of the Authority becoming aware of the reasons for any such dispute, the Authority shall notify Imperial in writing, specifying the reasons for disputing the invoice. Imperial shall provide all evidence as may be reasonably necessary to verify the disputed invoice. If the Authority determines that any sums are due to Imperial, then Imperial shall be entitled to issue an invoice in respect of such sums and the Authority shall pay such sums within thirty (30) days of receipt of the relevant invoice.
- 4.7 Unless otherwise expressly set out in this Agreement, the obligation to pay the Fees shall constitute the Authority's entire payment liability to Imperial in respect of Fees payable under this Agreement.
- 5. CHANGES TO THE SERVICES**
- 5.1 If either Party wishes to change the scope or execution of the Services, it shall submit details of the requested change to the other in writing.
- 5.2 If the Authority requests a change to the scope or execution of the Services, Imperial shall, within a reasonable time (and in any event not more than ten (10) Business Days after receipt of the Authority's request), provide a written estimate to the Authority of:
- 5.2.1 the likely time required to implement the change;
- 5.2.2 the likely effect of the change on the other Services (if any); and
- 5.2.3 any other impact of the change on this Agreement.
- 5.3 Notwithstanding clause 5.2, Imperial may, from time to time with prior written notice, change the Services in order to comply with any applicable safety or statutory requirements, provided that such changes do not materially affect the nature and scope of the Services.
- 6. LICENCE TO OCCUPY**
- 6.1 Imperial (for the purpose of this clause 6 the "**Licensee**") acknowledges that a licence is granted by the Authority (for the purposes of this clause 6 the "**Licensor**") to the Licensee to occupy the Premises for the purposes of the Project (the "**Licence**").
- 6.2 This Licence does not give the Licensee exclusive occupation of any part of the Premises; the Licensor and the other Project Partners together with representatives of regulatory authorities and the Study Monitor shall be entitled to enter the Premises at any time to the extent required to perform their responsibilities with regards to the Study.
- 6.3 This Licence is personal to the Licensee and cannot be transferred; the Licensee is not entitled to permit anyone other than the Licensee to have access to the Premises except as set out in clause 6.2.

- 6.4 Licence shall not confer on the Licensee any tenancy or lease of the Premises and the Licensor shall be entitled at all times during the subsistence of this Licence to exercise and do without any hindrance by the Licensee all such rights, acts and things in respect of the Premises as the Licensor may require.
- 6.5 The Licensor hereby grants to the Licensee a licence to occupy the Premises for the Term of the Lease in common with the Licensor and all others authorised by the Licensor subject to termination in accordance with clause 6.7 of this Licence.
- 6.6 The Licensee covenants with the Licensor to observe and perform the terms of the Lease (save in relation to Clause 3.4 and 3.5 of the Lease) and not put the Licensor in breach of the terms of the Lease.
- 6.7 The licence to occupy granted by this Licence shall end on the earlier of:-
- 6.7.1 the termination or expiry of this Agreement;
- 6.7.2 the expiry of any notice given by the Licensor to the Licensee at any time of breach of any of the Licensee's obligations contained in clause 6.6;
- 6.8 Termination of this Licence pursuant to clause 6.7 is without prejudice to the rights and remedies of either Party against the other in respect of any antecedent breach of any obligation subsisting under this Licence.

7. ACCESS, RESEARCH MISCONDUCT AND APPLICABLE REGULATORY AUTHORITIES

The Authority shall permit Imperial, Study Monitor and any regulatory auditor access to all relevant clinical data of subjects for monitoring and source data verification, such access to be arranged at mutually convenient times and on reasonable notice. Such monitoring or auditing may take such form as the Parties reasonably agree appropriate including the right to inspect any facility or systems to be or being used for the conduct of the Study and to examine any procedures or records relating to the Study.

8. WARRANTIES

- 8.1 Each Party represents and warrants that it has the right, power and authority to enter into this Agreement and grant to the other Party the rights (if any) contemplated in this Agreement.
- 8.2 Imperial represents and warrants to the Authority that:
- 8.2.1 it is not party to any agreement which would prevent it from fulfilling its obligations under this Agreement;
- 8.2.2 it has (or will obtain in accordance with the Project Plan) all governmental, regulatory, and other approvals and licences necessary for it to perform the Services; and
- 8.2.3 it has the necessary skill, experience and resources to carry out the Services in a timely manner.
- 8.3 The Authority represents and warrants to Imperial that it has agreements in place with the Project Partners in respect of their obligations for the Project.

9. CONFIDENTIALITY AND PUBLICATION

- 9.1 The Parties recognise that the conduct of the Project may require the transfer of Confidential Information between their representatives. It is therefore agreed that each Party shall, and shall procure that its representatives shall, retain in confidence the Confidential Information received from other representatives during the term of this Agreement and for a period of 5 years from its termination or expiry. Each Party shall, and shall procure that its representatives shall use such Confidential Information only for the Project and for no other purpose.

- 9.2 The obligations of confidentiality set forth herein shall not apply to any information or materials to the extent that such information or materials:
- 9.2.1 are required to be disclosed by order of a court of law or appropriate government agency provided that the recipient inform the disclosing party as soon as possible and the disclosing party be given the opportunity, if time permits, to make appropriate representations to such court, authority or stock exchange or take such action as it feels necessary, at its cost, to attempt to secure the information is kept confidential;
 - 9.2.2 are submitted to governmental agencies to facilitate the issuance of marketing approvals or other regulatory approvals for products which emerge from the Project;
 - 9.2.3 are reasonably required to be disclosed to professional advisers (such as patent agents in the filing, prosecution and issuance of patents as permitted under the terms of this Agreement);
 - 9.2.4 have been approved for publication by the Parties; or
 - 9.2.5 are product-related information which is reasonably required to be disclosed in connection with marketing or sub-licensing activities with respect to products.
- 9.3 The Parties agree that all proposed publications that discuss or disclose any part of the Results will be submitted to the Human Challenge Steering Committee and governed by the publication terms in the Project Collaboration Agreement.
- 9.4 Subject to clause 9.3, the Parties agree that they will not make any public announcements, press releases or otherwise publicise any matters relating to the Project except as permitted under the Project Collaboration Agreement.
- 9.5 No Party shall use the name of any other party in any form of publicity, advertising or promotion without the written permission of that Party. Such approval shall not be unreasonably withheld and if given shall be given promptly. Nothing in this clause shall prevent a Party from using another Party's name when properly referencing use of publications or parts thereof.
10. **INTELLECTUAL PROPERTY RIGHTS**
- 10.1 Except as expressly set out in this Agreement:
- 10.1.1 the Authority shall not acquire any right, title or interest in or to the Intellectual Property Rights of Imperial which existed before this Agreement or was developed independently of the Project (being "**Imperial Background IPR**") or its licensors (being "**Third Party IPR**");
 - 10.1.2 Imperial shall not acquire any right, title or interest in or to the Intellectual Property Rights of the Authority which existed before this Agreement or was developed independently of the Project (being "**Authority Background IPR**") or its licensors;
 - 10.1.3 all Results and all Intellectual Property Rights in and to the Results (being "**Project Specific IPR**") shall be the property of the Authority; and
 - 10.1.4 the Protocol and all Intellectual Property Rights therein shall be and remain the property of the Authority.
- 10.2 Where either Party acquires, by operation of law, title to Intellectual Property Rights that is inconsistent with the allocation of title set out in clause 10.1, it hereby does assign and where such Intellectual Property Rights cannot be prospectively assigned, shall assign in writing such Intellectual Property Rights as it has acquired to the other Party on the request of the other Party (whenever made).

- 10.3 Imperial hereby transfers to the Authority, or shall procure the transfer to the Authority of, all rights (subject to Clause 10.1.1) in the Project Specific IPR.
- 10.4 Imperial hereby grants to the Authority a perpetual, fully paid-up, royalty-free, sub-licensable through multiple tiers, non-exclusive licence to use Imperial Background IPR, to the extent such are applicable, for any purpose relating to (a) the Project, and (b) in so far as Imperial is free and able to do so and subject to clauses 10.5 and 10.6, if required for the utilisation of the Protocol, the Results and/or any Project Specific IPR outside of the Project.
- 10.5 Imperial shall:
- 10.5.1 execute all such assignments as are required to ensure that any rights in the Project Specific IPR are properly transferred to the Authority; and
 - 10.5.2 provide full details to the Authority and to the Human Challenge Steering Committee (whose remit shall include review of Intellectual Property Rights reported by the Project Partners) of any Imperial Background IPR or Third Party IPR which it intends to introduce into the Project and which it believes are i) an integral part of any element of the Protocol and ii) required for the use of Project Specific IPR.
- 10.6 If the Human Challenge Steering Committee unanimously agrees that any Imperial Background IPR or Third Party IPR is integral to the Project, the use of the Protocol and/or required for use of Project Specific IPR, it may request Imperial conducts its standard due diligence to determine any encumbrances or restrictions that may exist on such Imperial Background IPR or Third Party IPR.
- 10.7 Imperial shall report back to the Authority the results of any due diligence, and where no encumbrances or restrictions are identified, the provisions of clause 10.4 shall apply. Where any encumbrances or restrictions are identified Imperial shall meet with the Authority to discuss a) obtaining necessary rights to allow it to grant the licence under to the Authority under clause 10.4, or b) the Authority directly obtaining rights pertaining to the Imperial Background IPR or Third Party IPR.
- 10.8 The Authority may sub-license the rights granted under clause 10.4 to a third party, provided that the sub-licence is on terms no broader than those granted to the Authority, and only for the specified purpose in clause 10.4.
- 10.9 The Authority may assign, novate or otherwise transfer its rights and obligations under the licences granted pursuant to clause 10.4 to:
- 10.9.1 a Central Government Body; or
 - 10.9.2 to any body (including any private sector body) which performs or carries on any of the functions and/or activities that previously had been performed and/or carried on by the Authority.
- 10.10 Any change in the legal status of the Authority which means that it ceases to be a Central Government Body shall not affect the validity of any licence granted in clause 10.4. If the Authority ceases to be a Central Government Body, the successor body to the Authority shall still be entitled to the benefit of the licence granted in clause 10.4.
- 10.11 If a licence granted in clause 10.4 is novated under clause 10.9 or there is a change of the Authority's status pursuant to clause 10.10, the rights acquired on that novation or change of status shall not extend beyond those previously enjoyed by the Authority.
- 10.12 For the avoidance of doubt, the termination or expiry of this Agreement shall not of itself result in any termination of any of the licences granted by Imperial or relevant third party pursuant to or as contemplated by this clause 10.
- 10.13 The Authority hereby grants to Imperial a royalty-free, non-exclusive, non-transferable licence to use the Authority Background IPR and the Project Specific IPR:

10.13.1 to the extent necessary for performing its obligations under and in accordance with this Agreement, including (but not limited to) the right to grant sub-licences provided that:

- (a) any relevant sub-licensee has entered into a confidentiality undertaking with Imperial with respect to such Authority Background IPR and Project Specific IPR on the same terms as set out in clause 9; and
- (b) Imperial shall not, without the Authority's prior written consent, use such Authority Background IPR and Project Specific IPR for any other purpose or for the benefit of any person other than the Authority;

10.13.2 for the purposes of academic teaching and academic research, including research projects which are sponsored by a third party. Imperial may not use the Project Specific IPR for any commercial exploitation purpose; and/or

10.13.3 to the extent necessary for Imperial to perform its obligations under the Project Collaboration Agreement.

11. **ANTI-BRIBERY**

11.1 For the purposes of clause 11 the expressions "**adequate procedures**" and "**associated with**" shall be construed in accordance with the Bribery Act 2010 and guidance published under it.

11.2 Each party shall ensure that it and each person referred to in clauses 11.2.1 to 11.2.3 (inclusive) does not, by any act or omission, place the other party in breach of any Bribery Laws. Each party shall comply with all applicable Bribery Laws in connection with the performance of the Services and this Agreement, ensure that it has in place adequate procedures to prevent any breach of clause 11 and ensure that:

11.2.1 all of its personnel and all direct and indirect subcontractors, suppliers, agents and other intermediaries of it;

11.2.2 all others associated with it; and

11.2.3 each person employed by or acting for or on behalf of any of those persons referred to in clauses 11.2.1 and/or 11.2.2,

involved in connection with this Agreement, so comply.

11.3 Without limitation to clause 11.2, each party shall not in connection with the performance of the Services and/or this Agreement make or receive any bribe (which term shall be construed in accordance with the Bribery Act 2010) or other improper payment or advantage, or allow any such to be made or received on its behalf, either in the United Kingdom or elsewhere, and will implement and maintain adequate procedures to ensure that such bribes or improper payments or advantages are not made or received directly or indirectly on its behalf.

11.4 A party shall immediately notify the other as soon as it becomes aware of a breach of any of the requirements in this clause 11.

12. **MODERN SLAVERY**

12.1 Each party undertakes, warrants and represents that:

12.1.1 neither it nor any of its officers, employees, agents or subcontractors has:

- (a) committed an offence under the Modern Slavery Act 2015 (an "**MSA Offence**"); or
- (b) been notified that it is subject to an investigation relating to an alleged MSA Offence or prosecution under the Modern Slavery Act 2015; or

- (c) is aware of any circumstances within its supply chain that could give rise to an investigation relating to an alleged MSA Offence or prosecution under the Modern Slavery Act 2015;

12.1.2 it shall comply with the Modern Slavery Act 2015;

12.1.3 it shall notify the other party immediately in writing if it becomes aware or has reason to believe that it, or any of its officers, employees, agents or subcontractors have breached or potentially breached any of its obligations under clause 12. Such notice to set out full details of the circumstances concerning the breach or potential breach of the breaching party's obligations.

13. DATA PROTECTION

Each Party agrees that, in the performance of their respective obligations under this Agreement, it shall comply with the provisions of Schedule 3.

14. LIMITATION OF LIABILITY

14.1 The extent of the Parties' liability under or in connection with this Agreement (regardless of whether such liability arises in tort, contract or in any other way and whether or not caused by negligence or misrepresentation) shall be as set out in clause 14.

14.2 Subject to clause 14.6, neither Party's liability to the other Party shall exceed the amount payable to Imperial under this Agreement.

14.3 Subject to clause 14.6, neither Party shall be liable for any consequential, indirect or special loss.

14.4 Subject to clause 14.6, neither Party shall be liable for any of the following (whether direct or indirect):

14.4.1 loss of profit;

14.4.2 loss of or corruption to data;

14.4.3 loss of use;

14.4.4 loss of production;

14.4.5 loss of contract;

14.4.6 loss of commercial opportunity;

14.4.7 loss of savings, discount or rebate (whether actual or anticipated);

14.4.8 harm to reputation or loss of goodwill.

14.5 Except as expressly stated in this Agreement, and subject to clause 14.6, all warranties and conditions whether express or implied by statute, common law or otherwise are excluded to the extent permitted by law.

14.6 Notwithstanding any other provision of this Agreement, the liability of the Parties shall not be limited in any way in respect of the following:

14.6.1 death or personal injury caused by negligence;

14.6.2 fraud or fraudulent misrepresentation;

14.6.3 any other losses which cannot be excluded or limited by applicable law.

- 14.7 Imperial shall not be liable for breach of the terms of this Agreement to the extent Imperial's breaching conduct or misconduct is a result of delays or failure to perform on the part of any of the other Project Partners in respect of their obligations in relation to the Project.
- 14.8 In the event of any delay in the Project caused by the delays or failure to perform on the part of any of the other Project Partners in respect of their obligations in relation to the Project, the Authority shall continue to make payments due to Imperial under this Agreement for a period of six (6) weeks from the commencement of the delay at which point the Parties shall review the position.
- 14.9 Each Party acknowledges and agrees that the Study cannot commence prior to conclusion of an appropriate agreement with Gilead for the supply of [REDACTED]. Imperial will use all reasonable endeavours to conclude such an agreement with Gilead, but where it is unable to do so in a timely manner, Imperial shall notify the parties to the Project Collaboration Agreement of the delay in agreement, and shall consult directly with the Authority to find a resolution, in the interests of all parties and the Study. In the event an agreement can be concluded between Gilead and Imperial, Imperial shall provide the Authority with a copy prior to execution, and the Authority shall provide final approval to sign, such approval by the Authority not to be unreasonably withheld or delayed.
- 14.10 In the event of any claim or proceeding in respect of personal injury being made or brought against the Authority by a subject of the Study, Imperial shall indemnify the Authority against any claims, proceedings and related costs, expenses, losses and damages arising from Imperial's negligent performance of the Study save to the extent that they were caused, or contributed to, by the negligence, wrongful acts, omissions, or breach of statutory duty of the Authority.
- 14.11 Subject to clause 14.6, neither Party shall be liable to the other Party for any claims, proceedings or related costs, expenses, losses or damages arising from any use by that Party of the Results.

15. INSURANCE

- 15.1 Imperial shall take out with a reputable insurance company and maintain at all times during the term of this Agreement adequate insurance cover in respect of its obligations under this Agreement, including employer liability insurance, public liability insurance, and clinical trial liability insurance. Such insurance may be limited in respect of one claim provided that such limit must be at least ten million pounds sterling (£10,000,000). Imperial shall make its insurance policy and renewal receipts available for inspection by the Authority from time to time upon the Authority's request.
- 15.2 Where:
- 15.2.1 a third party claim (a "**Claim**") relating to the Study is brought by a trial participant against:
- (a) Imperial; and/or
 - (b) the Authority; and/or
 - (c) one or more Project Partners for which Imperial is required to indemnify the Authority and/or Project Partner; and
- 15.2.2 the Claim requires Imperial to claim from its clinical trial liability insurance policy (an "**Insurance Claim**"); and
- 15.2.3 Imperial is not entitled to recover any losses relating to the Claim from the indemnities it benefits from in its agreements with the Project Partners; and
- 15.2.4 the Claim does not arise from the negligence and/or misconduct of Imperial and/or the Project Partners,
- then Imperial may claim relief (a "**Relief Claim**") from the Authority.

- 15.3 The amount of the Relief Claim shall be a sum equal to the lower of:
- 15.3.1 the excess payment Imperial is required to make relating to the Insurance Claim; or
 - 15.3.2 £15,000,
- (each, the "**Claimed Amount**").
- 15.4 The Authority shall reimburse Imperial for the Claimed Amount within 30 calendar days from the date on which Imperial submits such Relief Claim to the Authority.
- 15.5 Where:
- 15.5.1 the provisions of clauses 15.2.1 to 15.2.4 apply; and
 - 15.5.2 Imperial is not entitled to recover its losses relating to the Claim from its clinical trial liability insurance policy because the aggregate limit of cover as required by clause 15.1 for that policy has been reached,
- the Authority shall indemnify Imperial for any claims, proceedings and related costs, expenses, losses and damages arising from the Claim, provided that:
- 15.5.3 Imperial does not admit liability, compound or otherwise settle such Claim without the Authority's prior written consent such consent not to be unreasonably withheld, delayed or conditioned;
 - 15.5.4 Imperial uses its best endeavours to mitigate the losses it suffers in relation to the Claim;
 - 15.5.5 Imperial keeps the Authority fully informed of the conduct of the Claim and does not take any substantive step in the defence of the Claim without the prior written consent of the Authority such consent not to be unreasonably withheld, delayed or conditioned;
 - 15.5.6 Imperial use external counsel approved by the Authority in the defence of the Claim, such approval not to be unreasonably withheld, delayed or conditioned.
16. **TERMINATION**
- 16.1 The Authority may terminate this Agreement for convenience with immediate effect by giving notice to Imperial. Either Party may terminate this Agreement if the Project Collaboration Agreement is terminated for any reason.
- 16.2 Subject to clause 16.3, in the event of termination for any reason by any Party, including a situation where the Parties agree the Project should be terminated:
- 16.2.1 the Authority shall pay Imperial or where payment in advance has been made allow for (i) all payments due in accordance with the Payment Milestones, and subject to clause 4.6, prior to the date of termination; and (ii) any additional activities associated with the termination of this Agreement that the Parties have agreed to complete; and (iii) any committed or non-cancellable costs and expenses falling due after the date of termination as evidenced in writing;
 - 16.2.2 in no event, however, shall the total amounts to be paid by the Authority following any termination when added to the amounts already paid by the Authority under this Agreement exceed the total amounts specified for the Project; and
 - 16.2.3 any amounts previously paid by the Authority in excess of the amounts described in clause 16.2.2 shall be promptly reimbursed by Imperial to the Authority.
- 16.3 Without prejudice to the generality of the foregoing, clause 16.2 shall not apply to the extent this Agreement is terminated by the Authority under clause 16.5.

- 16.4 On termination of this Agreement, Imperial shall ensure that all data relating to the Project including but not limited to records of all Results are held to the Authority's order and promptly returned directly to the Authority or made available for collection by or on behalf of the Authority.
- 16.5 Either Party may terminate this Agreement at any time by giving notice in writing to the other Party if:
- 16.5.1 the other Party commits a material breach of this Agreement and such breach is not remediable; or
 - 16.5.2 the other Party commits a material breach of this Agreement which is not remedied within 40 days of receiving written notice of such breach.
- 16.6 Either Party may terminate this Agreement at any time by giving notice in writing to the other Party if that other Party:
- 16.6.1 in the case of Imperial, stops carrying on all or a significant part of its business, or indicates in any way that it intends to do so;
 - 16.6.2 is unable to pay its debts either within the meaning of section 123 of the Insolvency Act 1986 or if the non-defaulting party reasonably believes that to be the case;
 - 16.6.3 becomes the subject of a company voluntary arrangement under the Insolvency Act 1986;
 - 16.6.4 has a receiver, manager, administrator or administrative receiver appointed over all or any part of its undertaking, assets or income;
 - 16.6.5 has a resolution passed for its winding up;
 - 16.6.6 has a petition presented to any court for its winding up or an application is made for an administration order, or any winding-up or administration order is made against it;
 - 16.6.7 is subject to any events or circumstances analogous to those in clauses 16.6.1 to 16.6.6 in any jurisdiction;
 - 16.6.8 takes any steps in anticipation of, or has no realistic prospect of avoiding, any of the events or procedures described in clauses 16.6.1 to 16.6.7 including for the avoidance of doubt, but not limited to, giving notice for the convening of any meeting of creditors, issuing an application at court or filing any notice at court, receiving any demand for repayment of lending facilities, or passing any board resolution authorising any steps to be taken to enter into an insolvency process.
- 16.7 If a Party becomes aware that any event has occurred, or circumstances exist, which may entitle the other party to terminate this Agreement under this clause 16, it shall immediately notify the other party in writing.
- 16.8 Termination or expiry of this Agreement will not affect any accrued rights and liabilities of either party at any time up to the date of termination.
17. **DISPUTE RESOLUTION**
- 17.1 Any dispute arising between the Parties under this Agreement (and not under the Project Collaboration Agreement) (a "**Dispute**") shall be dealt with in accordance with the dispute resolution procedure in Schedule 4.
- 17.2 Any dispute arising between the Parties under the Project Collaboration Agreement shall be dealt with in accordance with the dispute resolution procedure in Schedule 8 of the Project Collaboration Agreement.

18. FORCE MAJEURE

18.1 In this clause, Force Majeure means an event or sequence of events beyond a Party's reasonable control preventing or delaying it from performing its obligations under this Agreement. Inability to pay is not Force Majeure.

18.2 A Party shall not be liable if delayed in or prevented from performing its obligations under this Agreement due to Force Majeure, provided that it:

18.2.1 promptly notifies the other of the Force Majeure event and its expected duration; and

18.2.2 uses reasonable endeavours to minimise the effects of that event.

18.3 If, due to Force Majeure, Imperial:

18.3.1 is or is likely to be unable to perform a material obligation; or

18.3.2 is or is likely to be delayed in or prevented from performing its obligations for a total of more than three months,

the Authority may terminate this Agreement on not less than four weeks' written notice.

19. GENERAL

19.1 Conflicts within Agreement

19.1.1 In the event of any conflict or inconsistency between this Agreement and the provisions of any other agreement between the Parties, the following descending order of priority applies:

(a) the Project Collaboration Agreement;

(b) the provisions of this Agreement;

(c) any other agreement between the Project Partners.

19.1.2 Subject to the above order of priority between documents, later versions of documents shall prevail over earlier ones if there is any conflict or inconsistency between them.

19.2 Entire Agreement

The parties agree that this Agreement and the Project Collaboration Agreement constitute the entire agreement between them and supersedes all previous agreements, understandings and arrangements between them, whether in writing or oral in respect of its subject matter.

19.3 Amendment

No variation or amendment of this Agreement will be effective unless it is made in writing and signed by each Party's representative.

19.4 Assignment

The Authority may assign or otherwise transfer any rights or obligations under this Agreement without the prior written consent of the other Party.

19.5 Waiver

No failure or delay on the part of either Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.

19.6 No Agency

None of the Parties shall act or describe itself as the agent of the other Party, nor shall it make or represent that it has authority to make any commitments on the other Party's behalf.

19.7 Audit

19.7.1 Imperial shall keep and maintain until six years after termination or expiry of this Agreement, or as long a period as may be agreed between the Parties, full and accurate records of this Agreement including:

- (a) the Services provided under it;
- (b) all expenditure reimbursed by the Authority; and
- (c) all payments made by the Authority.

19.7.2 Imperial shall on request afford the Authority or the Authority's representatives such access to those records as may be reasonably required in connection with this Agreement.

19.8 Notices

19.8.1 Any notice to be given under this Agreement shall be in writing and shall be sent by first class mail to the address of the relevant Party set out at the head of this Agreement, or to the relevant email address set out below, or such other address or email address as that Party may from time to time notify to the other Party in accordance with this clause 19.8.

19.8.2 The contact names and email addresses of each of the Parties are as follows:-

Authority – **Contact:** The Secretary of State

Email address: [REDACTED]

Imperial - **Contact:** [REDACTED]

Email address: [REDACTED]

19.8.3 Notices sent as above shall be deemed to have been received three Business Days after the day of posting, or on delivery to the recipient's email address.

19.9 Severance

If any provision of this Agreement (or part of any provision) is or becomes illegal, invalid or unenforceable, the legality, validity and enforceability of any other provision of this Agreement shall not be affected and shall remain in full force and effect.

19.10 Counterparts

19.10.1 This Agreement may be signed in any number of separate counterparts, each of which when signed and dated shall be an original, and such counterparts taken together shall constitute one and the same agreement.

19.10.2 Each party may evidence their signature of this Agreement by transmitting a signed signature page of this Agreement in PDF format together with the final version of this Agreement in PDF or Word format, which shall constitute an original signed counterpart of this Agreement. Each party adopting this method of signing shall, following circulation, provide the original, hard copy signed signature page to the other parties as soon as reasonably practicable.

19.11 Law and Jurisdiction

The validity, construction and performance of this Agreement shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the parties hereby submit, except that a Party may seek an interim injunction in any court of competent jurisdiction.

19.12 Further action

Each Party agrees to execute, acknowledge and deliver such further instruments, and do all further similar acts, as may be necessary or appropriate to carry out the purposes and intent of this Agreement.

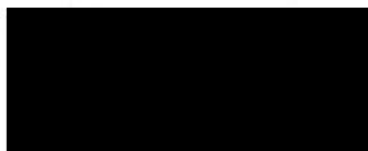
AGREED by the Parties through their authorised signatories:-

SIGNED for and on behalf of **DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY:**

Name 

Position: Director General Vaccine Taskforce

Signature

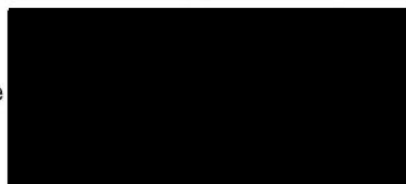


SIGNED for and on behalf of **IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY AND MEDICINE:**

Name: 

Position: Head of Research Operations, Faculty of Medicine

Signature



SCHEDULE 1

SERVICES

1. SERVICES

1.1 Virus Selection

1.1.1 To undertake human challenge studies with SARS-CoV-2 virus there is requirement for the manufacture and release of GMP standard virus for use in such studies. The objective of this work stream is to generate virus isolates and oversee the scientific quality of the GMP virus manufacture.

1.1.2 Imperial have expert laboratories suitable for isolating and characterising the virus to non GMP quality. Seed generation and manufacture under GMP guidelines will be conducted through HVIVO. Scientific and technical oversight will be required by Imperial during generation of virus isolates, transfer to GMP facilities and during GMP manufacture.

1.1.3 To achieve the objective, the following services will be provided by the Sponsor through a separate contract with HVIVO:

(a)

[REDACTED]

(b)

[REDACTED]

(c) Provide expert knowledge through collaboration with HVIVO during GMP seed production, manufacture and virus testing during the Study

1.1.4 For the avoidance of doubt all costs incurred by Imperial in relation to this paragraph 1.1, will be charged to HVIVO under a separate agreement, and do not form part of the Fees under this Agreement.

1.2 Virus Characterisation Study

1.2.1 Imperial as the Sponsor will provide the services outlined below to deliver the Study, which will be delivered to and meet the appropriate regulatory, ethics and HSE requirements including GCP and GLP, with assistance as necessary from HVIVO. The Study will be delivered in compliance with the approved Protocol.

1.2.2 The following services will be provided by Imperial as Sponsor in accordance with GCP guidelines and as detailed in the Protocol, as further outlined in Roles and Responsibilities Matrix:

(a) Appoint the Chief Investigator;

(b) To develop the Protocol;

(c) To oversee the overall safety and quality of clinical trial conduct

(i) Ensure that the Study and its Protocol have received robust and favourable scientific and statistical peer review

- (ii) Oversee ethical and regulatory submission, including any amendments
- (iii) Ensure challenge virus and IMP are compliant with regulations and correctly documented
- (iv) Ensure compliance, staff training, supervision and proper conduct of the Study
- (v) Ensure that the Study is managed, monitored and reported as agreed in the Protocol and/or agreed monitoring plan
- (vi) Ensure appropriate analysis of Study data
- (vii) Maintain investigator site file, trial master file (TMF) and pharmacy site file at participating site, ensuring compliance with Sponsor requirements and applicable guidance/legislation
- (viii) Ensure that the TMF and all Study records held at site are archived appropriately on conclusion of the Study and retained as required by the Protocol
- (ix) Ensure appropriate insurance & indemnities are in place for the design and management of the Study
- (d) To oversee all regulatory and ethical licences, consents and approvals necessary to allow the Study to be performed by the Project Partners
- (e) To oversee all sites at which the Study is to be performed to ensure compliance with standards and the requirements of the Study;
- (f) To oversee that all personnel involved in engaged to perform the Study are suitably qualified, observe the conditions attaching to any regulatory and ethical licences, consents and approvals, keep complete and accurate records of all research, development and other work carried out in connection with the Study;
- (g) To oversee that all processes and procedures used in the performance of the Study are compliant with the Protocol, applicable laws, regulations and standards;
- (h) To cooperate with other Project Partners to assist on public engagement in relation to the Study and the Project;
- (i) To provide such other facilities, resources and support as may be agreed with the Authority from time to time;
- (j) Decision making at key points in the Study
 - (i) Decision to start recruitment, enrolment and inoculations
 - (ii) Dose escalation/de-escalation decisions (with DSMB and other experts)
 - (iii) Halting Study (with DSMB and other experts) on basis of safety data or data from other trials
- (k) To oversee clinical safety and safety reporting of the Study
 - (i) Set-up and management of DSMB;

- (ii) Assessment of adverse events (AEs) or other safety issues
 - (iii) Referral of participants to NHS pathway in event of severe COVID-19 or other clinical events
 - (iv) Report serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs) according to Protocol
- (l) To oversee preparation and delivery of patient engagement activities necessary for HRA ethical submission
 - (i) Lead planning and execution of screening and Protocol-specific patient engagement activities in collaboration with partners (Southampton university and HVIVO)
 - (ii) Deliver outputs in line with the Project Plan
- (m) To oversee and conduct assays required to fulfil Sponsor obligations to ensure data generated follows GCP standards, utilizes the relevant expertise and generates the totality of data for the right level of decision making. Imperial will utilise in-house expertise for virology oversight and back-up contingency, flow cytometry (assays already established) and MSD (platform established with ISARIC study):
 - (i) Conduct virus culture work to determine viral load in nasal and pharyngeal epithelium as a back-up contingency in case the GCP assay can not be set up and validated with HVIVO
 - (ii) Provide expertise in to the set up and conduct of the GCP virus culture work;
 - (iii) Conduct exploratory flow cytometry and MSD immunological assays in fresh blood and musical nasal and pharyngeal epithelium
 - (iv) Transfer to the Authority the technical know-how to conduct the assays for this and future studies
- (n) Appoint a Project Manager and such other representatives as are necessary for the purpose of complying with its obligations in respect of this Agreement and:
 - (i) the Human Challenge Steering Committee; and
 - (ii) the Study Delivery Team,in each case always in accordance with the Project Collaboration Agreement.
- (o) To procure such agreed access and use of [REDACTED] from Gilead Sciences, free of charge, as is reasonably required for the Project.

2. KEY PERSONNEL

2.1 The Key Personnel shall be:

- 2.1.1 in the case of the Authority: [REDACTED]
[REDACTED] and
- 2.1.2 in the case of Imperial: [REDACTED]
[REDACTED] (together the "Imperial Key Personnel").

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- 2.2 Subject to paragraphs 2.3 and 2.5 of this Schedule 1, Imperial shall engage and use Imperial Key Personnel to perform the Services and Imperial shall not engage or use any other personnel other than the Imperial Key Personnel to perform the Services.
- 2.3 Imperial shall not change any Key Personnel during the course of the Services without obtaining the Authority's prior written consent, which consent shall not be unreasonably withheld.
- 2.4 The Authority reserves the right, within reason, to require the replacement of any Key Personnel.
- 2.5 Imperial shall ensure that Imperial Key Personnel:
 - 2.5.1 shall not carry out any other work of a similar nature which might give rise to any conflict of interest or duty that may jeopardise or adversely affect the carrying out of the Services;
 - 2.5.2 are technically competent and suitably qualified and experienced to carry out the parts of the Services assigned to them;
 - 2.5.3 will, at the request of the Authority and subject to Imperial's institutional policies, where the Authority reasonably believes the Imperial Key Personnel are unsuitable to provide the Services, be removed immediately from the Services and suitable replacement Imperial Key Personnel be appointed to the reasonable satisfaction of the Authority within five Business Days or other mutually agreed time; and
 - 2.5.4 will at all times be and be deemed to be employees of Imperial or Imperial's sub-contractors or agents and not of the Authority. Imperial will be responsible for taking all disciplinary action in respect of Imperial Key Personnel and for paying any salaries, taxes, contributions and charges payable in respect of the Imperial Key Personnel.

SCHEDULE 2**FEES & PAYMENT MILESTONES**

The total Fee of £1,812,899.22 will cover all of Imperial's obligations under this Agreement, including the following:

- **Sponsor Related Costs:** include costs associated with academic oversight, virology research activity, academic expertise (immunology), academic expertise (PPI), Project management and support, general costs (Sponsor), PPI support staff, PPI group reimbursements, research partner – Southampton, publications and insurance;
- **Virology Costs:** include costs associated with: 2 postdoctoral research assistants ("PDRAs"), research technician and laboratory consumables and equipment access;
- **Immunology Costs:** include costs associated with: Academic oversight, 3 PDRAs, Laboratory consumables and equipment access.

The aforementioned total Fee is a fixed fee regardless of the number of patients between 50 and 90 involved in the Study

Fees will be payable in monthly instalments in accordance with the dates in the Payment Plan.

Imperial shall submit an invoice to the Authority in accordance with the Payment Plan. Imperial shall submit brief quarterly progress reports summarising the work undertaken with respect to the Project.

At the Authority's request, Imperial shall immediately supply the Authority or its nominee with true copies of all records maintained and stored by Imperial in respect of its obligations under clause 19.7.

% of Total Fee	Fee Instalment	Payment Date	Expected activities & achievement points during the payment period
████	████	30-Nov-20	Sponsor services rendered for Protocol finalisation, assay provision, PPIE & project management – FTE rate. Protocol finalised, submitted to ethics and MHRA and approval received. PPIE activities completed and submitted to ethics committee, approval received.
████	████	31-Dec-20	Sponsor services rendered for clinical study set-up, assay provision, project management – FTE rate. Site initiated and staff training, volunteer screening initiated. First progress report submitted.
████	████	31-Jan-21	Sponsor services rendered for clinical study conduct, project management, virology & immunology assay provision – FTE rate.

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			First subject inoculated & DSMB functioning.
████	████████	28-Feb-21	Sponsor services rendered for clinical study conduct, project management, virology & immunology assay provision – FTE rate. 1 st cohort completed (assumes Study not paused or stopped for safety concerns)
████	████████	31-Mar-21	Sponsor services rendered for clinical study conduct, project management, virology & immunology assay provision – FTE rate. 2 nd to 3 rd cohort completed (assumes Study not paused or stopped for safety concerns) Second progress report submitted.
████	████████	30-Apr-21	Sponsor services rendered for clinical study conduct, project management, virology & immunology assay provision – FTE rate. 3 rd to 4 th cohort completed (assumes Study not paused or stopped for safety concerns).
████	████████	31-May-21	Sponsor services rendered for clinical study conduct, project management, virology & immunology assay provision – FTE rate. All cohorts completed for quarantine and inoculation phase (assumes up to 50 patient scenario). For 90 patients the relevant date is 31 August 21. Decision on viability of clinical model and virus dose selected for appropriate attack rate.
████	████████	30-Jun-21	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate. Third progress report including summary of data from first phase of Study and on-going safety monitoring.
████	████████	31-Jul-21	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate.
████	████████	31-Aug-21	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate.
████	████████	30-Sep-21	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate.

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			Fourth progress report including on-going safety monitoring.
████	████	31-Oct-21	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate.
████	████	30-Nov-21	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate.
████	████	31-Dec-21	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate. Fifth progress report including on-going safety monitoring.
████	████	31-Jan-22	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate.
████	████	28-Feb-22	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate.
████	████	31-Mar-22	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate. Sixth progress report including on-going safety monitoring.
████	████	30-Apr-22	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate.
████	████	31-May-22	Sponsor services rendered for clinical study safety oversight during follow up periods, project management, virology & immunology assay provision – FTE rate. Last patient out and final database lock (assumes up to 50 patient scenario). For a 90 patient scenario the relevant date is 31 August 2022.
████	████	30-Jun-22	Sponsor services rendered for review of final data and CSR, project management – FTE rate. Seventh progress report including final data set.

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████	████████	31-Jul-22	Sponsor services rendered for study report & project management – FTE rate.
████	████████	31-Aug-22	Sponsor services rendered for study report & project management – FTE rate.
████	████████	30-Sep-22	Sponsor services rendered for study report & project management – FTE rate.
████	████████	31-Oct-22	Sponsor services rendered for study report & project management – FTE rate.
████	████████	30-Nov-22	Sponsor services rendered for study report & project management – FTE rate.
████	████████	31-Dec-22	Sponsor services rendered for study report & project management – FTE rate. Final CSR.
100.00%	████████		

SCHEDULE 3

DATA PROTECTION

1. DEFINITIONS

In this Schedule 3 the following definitions shall apply:

"Controller", "" "Data Subject" and "Data Protection Officer"	shall have the meaning given to those terms in the applicable Data Protection Laws;
"Data Protection Laws"	means (a) any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the Processing of Personal Data to which a Party is subject, including the Data Protection Act 1998 (" DPA ") and EC Directive 95/46/EC (the " DP Directive ") (up to and including 24 May 2018) and on and from 25 May 2018, the GDPR and all legislation enacted in the UK in respect of the protection of personal data; and (b) any code of practice or guidance published by the ICO (or equivalent regulatory body) from time to time;
"Data Processing Particulars"	<p>means, in relation to any Processing under this Agreement:</p> <ul style="list-style-type: none">(a) the subject matter and duration of the Processing;(b) the nature and purpose of the Processing;(c) the type of Personal Data being Processed; and(d) the categories of Data Subjects; <p>as set out in Appendix 1 (<i>Data Processing Particulars</i>).</p>
"Data Subject Request"	means an actual or purported request or notice or complaint from or on behalf of a Data Subject exercising his rights under the Data Protection Laws in relation to Personal Data including without limitation: the right of access by the Data Subject, the right to rectification, the right to erasure, the right to restriction of processing, the right to data portability and the right to object;
"GDPR"	means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119/1, 4.5.2016;
"Good Industry Practice"	means at any time the exercise of that degree of care, skill, diligence, prudence, efficiency, foresight and timeliness which would be reasonably expected at such time from a leading and expert seeking to comply with its contractual obligations in full and complying with all applicable laws including the Data Protection Laws;
"ICO"	means the UK Information Commissioner's Office, or any successor or replacement body from time to time;

"ICO Correspondence"	means any correspondence or communication (whether written or verbal) from the ICO in relation to the Processing of Personal Data;
"Permitted Recipients"	means the third parties to whom each Party is permitted to disclose the Personal Data, as set out in more detail in Appendix 1 (<i>Data Processing Particulars</i>);
"Personal Data"	means any personal data (as defined in the Data Protection Laws) Processed by either Party in connection with this Agreement, and for the purposes of this Agreement includes Sensitive Personal Data (as such Personal Data is more particularly described in Appendix 1 (<i>Data Processing Particulars</i>));
"Personal Data Breach"	has the meaning set out in the Data Protection Laws and for the avoidance of doubt, includes a breach of Paragraph 2.2.2(d);
"Processing"	has the meaning set out in the Data Protection Laws (and "Process" and "Processed" shall be construed accordingly);
"Restricted Country"	means a country, territory or jurisdiction outside of the European Economic Area which the EU Commission has not deemed to provide adequate protection in accordance with Article 25(6) of the DP Directive and/or Article 45(1) of the GDPR (as applicable);
"Security Requirements"	means the requirements regarding the security of Personal Data, as set out in the Data Protection Laws (including, in particular, the seventh data protection principle of the DPA and/ or the measures set out in Article 32(1) of the GDPR (taking due account of the matters described in Article 32(2) of the GDPR)) as applicable;
"Sensitive Personal Data"	means Personal Data that reveals such special categories of data as are listed in Article 9(1) of the GDPR; and
"Third Party Request"	means a written request from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by law or regulation.

2. DATA PROTECTION

2.1 Nature of the Processing

2.1.1 The Parties acknowledge that the factual arrangements between them dictate the role of each Party in respect of the Data Protection Laws. Notwithstanding the foregoing, each Party agrees that the nature of the Processing under this Agreement will be as follows:

- (a) the Parties shall each Process the Personal Data;
- (b) each Party shall act as a Controller in respect of the Processing of the Personal Data on its own behalf and in particular each shall be a Controller of the Personal Data acting individually and in common, in relation to the activities set out in the Project Plan and the Roles and Responsibilities Matrix;
- (c) Notwithstanding Paragraph 2.1.1(b), if either Party is deemed to be a joint Controller with the other in relation to the Personal Data, the Parties agree that they shall be jointly responsible for the compliance obligations imposed on a Controller by the Data Protection Laws, and the Parties shall cooperate to do all necessary things to enable performance of such compliance obligations, except that each Party shall be responsible, without limitation, for compliance with its data security obligations set out in Paragraph 2.2.2(d) where Personal Data has been transmitted by it, or while Personal Data is in its possession or control.

- 2.1.2 Each of the Parties acknowledges and agrees that Appendix 1 (*Data Processing Particulars*) to this Schedule 3 is an accurate description of the Data Processing Particulars.

2.2 Data Controller Obligations

- 2.2.1 Each Party shall in relation to the Processing of the Personal Data comply with its respective obligations under the Data Protection Laws.

- 2.2.2 Without limiting the generality of the obligation set out in Paragraph 2.2.1, in particular, each Party shall:

- (a) where required to do so make due notification to the ICO;
- (b) ensure it is not subject to any prohibition or restriction which would:
 - (i) prevent or restrict it from disclosing or transferring the Personal Data to the other Party as required under this Agreement;
 - (ii) prevent or restrict it from granting the other Party access to the Personal Data as required under this Agreement; or
 - (iii) prevent or restrict either Party from Processing the Personal Data, as envisaged under this Agreement;
- (c) ensure that all fair processing notices have been given (and/or, as applicable, consents obtained) and are sufficient in scope to enable each Party to Process the Personal Data as required in order to obtain the benefit of its rights and to fulfil its obligations under this Agreement in accordance with the Data Protection Laws;
- (d) ensure that appropriate technical and organisational security measures are in place sufficient to comply with:
 - (i) at least the obligations imposed on the Controller by the Security Requirements; and
- (e) notify the other Party promptly, and in any event within forty-eight (48) hours of receipt of any Data Subject Request or ICO Correspondence which relates directly or indirectly to the Processing of Personal Data under, or in connection with, this Agreement and together with such notice, provide a copy of such Data Subject Request or ICO Correspondence to the other Party and reasonable details of the circumstances giving rise to it. In addition to providing the notice referred to in this Paragraph 2.2.2(e), each Party shall provide the other Party with all reasonable co-operation and assistance required by the other Party in relation to any such Data Subject Request or ICO Correspondence;
- (f) use reasonable endeavours to notify the other Party if it is obliged to make a disclosure of any of the Personal Data under any statutory requirement, such notification to be made in advance of such disclosure or immediately thereafter unless prohibited by law;
- (g) notify the other Party in writing without undue delay and, in any event, within twenty-four (24) hours of it becoming aware of any actual or suspected Personal Data Breach in relation to the Personal Data received from the other Party and shall, within such timescale to be agreed by the Parties (acting reasonably and in good faith):
 - (i) implement any measures necessary to restore the security of compromised Personal Data; and

- (ii) support the other Party to make any required notifications to the ICO and/or other equivalent relevant regulator and affected Data Subjects;
- (h) take reasonable steps to ensure the reliability of any of its personnel who have access to the Personal Data;
- (i) not do anything which shall damage the reputation of the other Party or that Party's relationship with the Data Subjects;
- (j) not transfer any Personal Data it is Processing to a Restricted Country;
- (k) hold the information contained in the Personal Data confidentially and under at least the conditions of confidence as such Party holds Personal Data Processed by it other than the Personal Data;
- (l) not disclose the Personal Data to a third party (including a sub-contractor) in any circumstances without the other Party's prior written consent, save in relation to: (i) disclosures to Permitted Recipients; and (ii) Third Party Requests. For Third Party Requests, the Party seeking to disclose the Personal Data shall use reasonable endeavours to advise the other Party in advance of such disclosure, unless that Party is prohibited by law or regulation from notifying the other Party of that disclosure, in which case it shall do so as soon as practicable thereafter (where permitted by law or regulation); and
- (m) at the other Party's option or direction, arrange for the prompt and safe return and/or secure permanent destruction (in accordance with Good Industry Practice) of all Personal Data, together with all copies in its possession or control within 10 (ten) days and, where requested by the other Party certify that such destruction has taken place.

2.3 The Parties agree:

2.3.1 to obtain and keep in full force and effect at all times, in respect of the Processing of the Personal Data, a policy or policies of insurance covering liability for damage arising to persons as a result of the Party's breach of this Schedule 3 and/or failure to comply with the Data Protection Laws and which meet the following conditions:

- (a) it must cover liability for damage arising to any person;
- (b) it must apply in relation to the Processing of Personal Data;
- (c) it must have policy limits and provisions conforming to such requirements as the other Party may from time to time reasonably prescribe;

2.3.2 to deliver to the other Party

- (a) copies of all applicable insurance policies taken out pursuant to the provisions of this Agreement;
- (b) evidence of premiums paid in relation to such insurance; and
- (c) ensure that the other Party shall be entitled to the benefit of such insurance.

APPENDIX 1**Data Processing Particulars**

The subject matter and duration of the Processing	Duration of the Project
The nature and purpose of the Processing	To fulfil the obligations of the Parties under this Agreement, including for the Study, the Study Delivery Team, the Human Challenge Steering Committee, the DSMB and the Medical Oversight Committee, as well as for any publications of any Study data.
The type of Personal Data being Processed	Names, qualifications, places of work, phone numbers, email addresses
The categories of Data Subjects	Employees, consultants and other persons engaged by the Parties in performance of that Party's obligations under this Agreement

SCHEDULE 4

Dispute Resolution Procedure

1 DEFINITIONS

1.1 In this Schedule, the following definitions shall apply:

"Authority Representative"	the representative appointed by the Authority under this Schedule 4;
"CEDR"	the Centre for Effective Dispute Resolution of International Dispute Resolution Centre, 70 Fleet Street, London, EC4Y 1EU;
"Counter Notice"	has the meaning given in Paragraph 7.2;
"Expert"	in relation to a Dispute, a person appointed in accordance with Paragraph 6.2 to act as an expert in relation to that Dispute;
"Expedited Dispute Timetable"	means the timetable set out in Paragraph 3.2;
"Expert Determination"	determination by an Expert in accordance with Paragraph 6;
"Imperial Representative"	the representative appointed by Imperial under this Schedule 4;
"Imperial Request"	a notice served by Imperial requesting that the Dispute be treated as a Multi-Party Dispute, setting out its grounds for that request and specifying each Related Third Party that it believes should be involved in the Multi-Party Dispute Resolution Procedure in respect of that Dispute;
"Mediation Notice"	has the meaning given in Paragraph 4.2;
"Mediator"	the independent third party appointed in accordance with Paragraph 5.2 to mediate a Dispute;
"Multi-Party Dispute"	a Dispute which involves the Parties and one or more Related Third Parties;
"Multi-Party Dispute Representatives"	has the meaning given in Paragraph 9.6;
"Multi-Party Dispute Resolution Board"	means the Human Challenge Steering Committee; and
"Multi-Party Dispute Resolution Procedure"	has the meaning given in Paragraph 9.1;
"Multi-Party Procedure Initiation Notice"	has the meaning given in Paragraph 9.2;

- "Related Third Party"** a party to:
- (a) another contract with the Authority or Imperial which is relevant to this Agreement; or
 - (b) a sub-contract.

2 DISPUTE NOTICES

- 2.1 If a Dispute arises then:
- (a) the Authority Representative and the Imperial Representative shall attempt in good faith to resolve the Dispute; and
 - (b) if such attempts are not successful within a reasonable period, not being longer than 20 Business Days, either Party may issue to the other a Dispute Notice.
- 2.2 A Dispute Notice:
- (a) shall set out:
 - (i) the material particulars of the Dispute;
 - (ii) the reasons why the Party serving the Dispute Notice believes that the Dispute has arisen; and
 - (iii) if the Party serving the Dispute Notice believes that the Dispute should be dealt with under the Expedited Dispute Timetable, the reason why; and
 - (b) may specify in accordance with the requirements of Paragraphs 9.2 and 9.3 that the Party issuing the Dispute Notice has determined (in the case of the Authority) or considers (in the case of Imperial) that the Dispute is a Multi-Party Dispute, in which case Paragraph 2.3 shall apply.
- 2.3 If a Dispute Notice specifies that the Dispute has been determined or is considered to be a Multi-Party Dispute pursuant to Paragraph 2.2(b), then:
- (a) if it is served by the Authority it shall be treated as a Multi-Party Procedure Initiation Notice; and
 - (b) if it is served by Imperial it shall be treated as a Imperial Request,
- and in each case the provisions of Paragraph 9 shall apply.
- 2.4 Subject to Paragraphs 2.5 and 3.2 and so long as the Authority has not served a Multi-Party Procedure Initiation Notice in respect of the relevant Dispute, following the issue of a Dispute Notice the Parties shall seek to resolve the Dispute:
- (a) first by commercial negotiation (as prescribed in Paragraph 4);
 - (b) then, if either Party serves a Mediation Notice, by mediation (as prescribed in Paragraph 5); and
 - (c) lastly by recourse to arbitration (as prescribed in Paragraph 7) or litigation (in accordance with clause 19.11 (*Law and Jurisdiction*)).
- 2.5 Specific issues shall be referred to Expert Determination (as prescribed in Paragraph 6) where specified under the provisions of this Agreement and may also be referred to Expert Determination where otherwise appropriate as specified in Paragraph 6.1.
- 2.6 Unless agreed otherwise in writing, the Parties shall continue to comply with their respective obligations under this Agreement regardless of the nature of the Dispute and notwithstanding any

issue of a Dispute Notice or a Multi-Party Procedure Initiation Notice or proceedings under Paragraph 8 (*Urgent Relief*).

3 EXPEDITED DISPUTE TIMETABLE

- 3.1 In exceptional circumstances where the use of the times in this Schedule would be unreasonable, including (by way of example) where one Party would be materially disadvantaged by a delay in resolving the Dispute, the Parties may agree to use the Expedited Dispute Timetable. If the Parties are unable to reach agreement on whether to use the Expedited Dispute Timetable within five (5) Business Days of the issue of a Dispute Notice, the use of the Expedited Dispute Timetable shall be at the sole discretion of the Authority.
- 3.2 If the Expedited Dispute Timetable is to be used pursuant to the provisions of Paragraph 3.1 or is otherwise specified under the provisions of this Agreement, then the following periods of time shall apply in lieu of the time periods specified in the applicable Paragraphs:
- (a) in Paragraph 4.2(c), ten (10) Business Days;
 - (b) in Paragraph 5.2, ten (10) Business Days;
 - (c) in Paragraph 6.2, five (5) Business Days; and
 - (d) in Paragraph 7.2, ten (10) Business Days.
- 3.3 If at any point it becomes clear that an applicable deadline cannot be met or has passed, the Parties may (but shall be under no obligation to) agree in writing to extend the deadline. If the Parties fail to agree within two (2) Business Days after the deadline has passed, the Authority may set a revised deadline provided that it is no less than five (5) Business Days before the end of the period of time specified in the applicable paragraphs (or two (2) Business Days in the case of Paragraph 6.2). Any agreed extension shall have the effect of delaying the start of the subsequent stages by the period agreed in the extension. If the Authority fails to set such a revised deadline then the use of the Expedited Dispute Timetable shall cease and the normal time periods shall apply from that point onwards.

4 COMMERCIAL NEGOTIATION

- 4.1 Following the service of a Dispute Notice, then, so long as the Authority has not served a Multi-Party Procedure Initiation Notice in respect of the relevant Dispute, the Authority and Imperial shall make reasonable endeavours to resolve the Dispute as soon as possible by commercial negotiation between the Authority Representative and Imperial Representative.
- 4.2 If:
- (a) either Party is of the reasonable opinion that the resolution of a Dispute by commercial negotiation, or the continuance of commercial negotiation, will not result in an appropriate solution;
 - (b) the Parties have already held discussions of a nature and intent (or otherwise were conducted in the spirit) that would equate to the conduct of commercial negotiation in accordance with this Paragraph 4; or
 - (c) the Parties have not settled the Dispute in accordance with Paragraph 4.1 within 30 Business Days of service of the Dispute Notice,

either Party may serve a written notice to proceed to mediation in accordance with Paragraph 5 (a "**Mediation Notice**").

5 MEDIATION

- 5.1 If a Mediation Notice is served, the Parties shall attempt to resolve the Dispute in accordance with the version of CEDR's Model Mediation Procedure which is current at the time the Mediation Notice is served (or such other version as the Parties may agree).

- 5.2 If the Parties are unable to agree on the joint appointment of an independent person to mediate the Dispute within 20 Business Days from (and including) the service of a Mediation Notice then either Party may apply to CEDR to nominate such a person.
- 5.3 If the Parties are unable to reach a settlement in the negotiations at the mediation, and only if both Parties so request and the Mediator agrees, the Mediator shall produce for the Parties a non-binding recommendation on terms of settlement. This shall not attempt to anticipate what a court might order but shall set out what the Mediator suggests are appropriate settlement terms in all of the circumstances.
- 5.4 Any settlement reached in the mediation shall not be legally binding until it has been reduced to writing and signed by, or on behalf of, the Parties. The Mediator shall assist the Parties in recording the outcome of the mediation.

6 EXPERT DETERMINATION

- 6.1 If a Dispute relates to any aspect of the technology underlying the provision of the Services or otherwise relates to a technical matter of an IT, accounting or financing nature and the Dispute has not been resolved by commercial negotiation in accordance with Paragraph 4 or, if applicable, mediation in accordance with Paragraph 5, then either Party may by written notice to the other request (agreement to which request shall not be unreasonably withheld or delayed) that the Dispute be referred to an expert for determination.
- 6.2 The expert shall be appointed by agreement in writing between the Parties, but in the event of a failure to agree within ten (10) Business Days of the relevant request made pursuant to Paragraph 6.1, or if the person appointed is unable or unwilling to act, the expert shall be appointed:
 - (a) if the Dispute relates to any aspect of the technology underlying the provision of the Services or a matter of an IT technical nature, on the instructions of the President of the British Computer Society (or any other association that has replaced the British Computer Society);
 - (b) if the Dispute relates to a matter of a financial technical nature, on the instructions of the President of the Institute of Chartered Accountants of England and Wales; or
 - (c) if the Dispute relates to a matter of a technical nature not falling within Paragraphs 6.2(a) or (b), on the instructions of the president (or equivalent) of:
 - (i) an appropriate body agreed between the Parties; or
 - (ii) if the Parties do not reach agreement on the relevant body within 15 Business Days of the relevant request made pursuant to Paragraph 6.1, such body as may be specified by the President of the Law Society on application by either Party.
- 6.3 The Expert shall act on the following basis:
 - (a) he/she shall act as an expert and not as an arbitrator and shall act fairly and impartially;
 - (b) the Expert Determination shall (in the absence of a material failure to follow the agreed procedures) be final and binding on the Parties;
 - (c) the Expert shall decide the procedure to be followed in the determination and shall be requested to make his/her determination within 30 Business Days of his appointment or as soon as reasonably practicable thereafter and the Parties shall assist and provide the documentation that the Expert requires for the purpose of the determination;
 - (d) any amount payable by one Party to another as a result of the Expert Determination shall be due and payable within 20 Business Days of the Expert Determination being notified to the Parties;
 - (e) the process shall be conducted in private and shall be confidential; and

- (f) the Expert shall determine how and by whom the costs of the determination, including his/her fees and expenses, are to be paid.

7 ARBITRATION

- 7.1 Subject to compliance with its obligations under Paragraph 4.1 and to the provisions of Paragraph 6, the Authority may at any time before court proceedings are commenced refer the Dispute to arbitration in accordance with the provisions of Paragraph 7.5.
- 7.2 Before Imperial commences court proceedings or arbitration, it shall serve written notice on the Authority of its intentions and the Authority shall have 15 Business Days following receipt of such notice to serve a reply (a "**Counter Notice**") on Imperial requiring the Dispute to be referred to and resolved by arbitration in accordance with Paragraph 7.5 or be subject to the exclusive jurisdiction of the courts of England and Wales. Imperial shall not commence any court proceedings or arbitration until the expiry of such 15 Business Day period.
- 7.3 If the Authority serves a Counter Notice, then:
 - (a) if the Counter Notice requires the Dispute to be referred to arbitration, the provisions of Paragraph 7.5 shall apply; or
 - (b) if the Counter Notice requires the Dispute to be subject to the exclusive jurisdiction of the courts of England and Wales, the Dispute shall be so referred to those courts and Imperial shall not commence arbitration proceedings.
- 7.4 If the Authority does not serve a Counter Notice within the 15 Business Day period referred to in Paragraph 7.2, Imperial may either commence arbitration proceedings in accordance with Paragraph 7.5 or commence court proceedings in the Courts of England and Wales which shall (in those circumstances) have exclusive jurisdiction.
- 7.5 The Parties hereby confirm that if any arbitration proceedings are commenced pursuant to Paragraphs 7.1 to 7.4:
 - (a) the Dispute shall be referred to and finally resolved by arbitration under the Rules of the London Court of International Arbitration ("**LCIA**") (subject to Paragraphs 7.5(e), (f) and (g));
 - (b) the arbitration shall be administered by the LCIA;
 - (c) the LCIA procedural rules in force at the date that the Dispute was referred to arbitration shall be applied and are deemed to be incorporated by reference into this Agreement and the decision of the arbitrator shall be binding on the Parties in the absence of any material failure to comply with such rules;
 - (d) if the Parties fail to agree the appointment of the arbitrator within ten (10) Business Days from the date on which arbitration proceedings are commenced or if the person appointed is unable or unwilling to act, the arbitrator shall be appointed by the LCIA;
 - (e) the chair of the arbitral tribunal shall be British;
 - (f) the arbitration proceedings shall take place in London and in the English language;
 - (g) the seat of the arbitration shall be London; and
 - (h) the Authority may join any other party in the arbitration.

8 URGENT RELIEF

- 8.1 Either Party may at any time take proceedings or seek remedies before any court or tribunal of competent jurisdiction:
 - (a) for interim or interlocutory remedies in relation to this Agreement or infringement by the other Party of that Party's Intellectual Property Rights; and/or

- (b) where compliance with Paragraph 2.1 and/or referring the Dispute to mediation may leave insufficient time for that Party to commence proceedings before the expiry of the limitation period.

9 MULTI-PARTY DISPUTES

- 9.1 All Multi-Party Disputes shall be resolved in accordance with the procedure set out in this Paragraph 9 (the "**Multi-Party Dispute Resolution Procedure**").
- 9.2 If at any time following the issue of a Dispute Notice, the Authority reasonably considers that the matters giving rise to the Dispute involve one or more Related Third Parties, then the Authority shall be entitled to determine that the Dispute is a Multi-Party Dispute and to serve a notice on Imperial which sets out the Authority's determination that the Dispute is a Multi-Party Dispute and specifies the Related Third Parties which are to be involved in the Multi-Party Dispute Resolution Procedure, such notice a "**Multi-Party Procedure Initiation Notice**".
- 9.3 If following the issue of a Dispute Notice but before the Dispute has been referred to Expert Determination or to arbitration in accordance with Paragraph 7, Imperial has reasonable grounds to believe that the matters giving rise to the Dispute have been contributed to by one or more Related Third Parties, Imperial may serve an Imperial Request on the Authority.
- 9.4 The Authority shall (acting reasonably) consider each Imperial Request and shall determine within five (5) Business Days whether the Dispute is:
 - (a) a Multi-Party Dispute, in which case the Authority shall serve a Multi-Party Procedure Initiation Notice on Imperial; or
 - (b) not a Multi-Party Dispute, in which case the Authority shall serve written notice of such determination upon Imperial and the Dispute shall be treated in accordance with Paragraphs 3 to 8.
- 9.5 If the Authority has determined, following an Imperial Request, that a Dispute is not a Multi-Party Dispute, Imperial may not serve another Imperial Request with reference to the same Dispute.
- 9.6 Following service of a Multi-Party Procedure Initiation Notice a Multi-Party Dispute shall be dealt with by a board (in relation to such Multi-Party Dispute, the "**Multi-Party Dispute Resolution Board**") comprising representatives from the following parties to the Multi-Party Dispute, each of whom shall be of a suitable level of seniority to finalise any agreement with the other parties to settle the Multi-Party Dispute:
 - (a) the Authority;
 - (b) Imperial;
 - (c) each Related Third Party involved in the Multi-Party Dispute; and
 - (d) any other representatives of any of the Parties and/or any Related Third Parties whom the Authority considers necessary,

(together "**Multi-Party Dispute Representatives**").
- 9.7 The Parties agree that the Multi-Party Dispute Resolution Board shall seek to resolve the relevant Multi-Party Dispute in accordance with the following principles and procedures:
 - (a) the Parties shall procure that their Multi-Party Dispute Representatives attend, and shall use their best endeavours to procure that the Multi-Party Dispute Representatives of each Related Third Party attend, all meetings of the Multi-Party Dispute Resolution Board in respect of the Multi-Party Dispute;
 - (b) the Multi-Party Dispute Resolution Board shall first meet within ten (10) Business Days of service of the relevant Multi-Party Procedure Initiation Notice at such time and place as the Parties may agree or, if the Parties do not reach agreement on the time and place within five (5) Business Days of service of the relevant Multi-Party Procedure Initiation

Notice, at the time and place specified by the Authority, provided such place is at a neutral location within England and that the meeting is to take place between 9.00am and 5.00pm on a Business Day; and

- (c) in seeking to resolve or settle any Multi-Party Dispute, the members of the Multi-Party Dispute Resolution Board shall have regard to the principle that a Multi-Party Dispute should be determined based on the contractual rights and obligations between the Parties and the Related Third Parties and that any apportionment of costs should reflect the separate components of the Multi-Party Dispute.

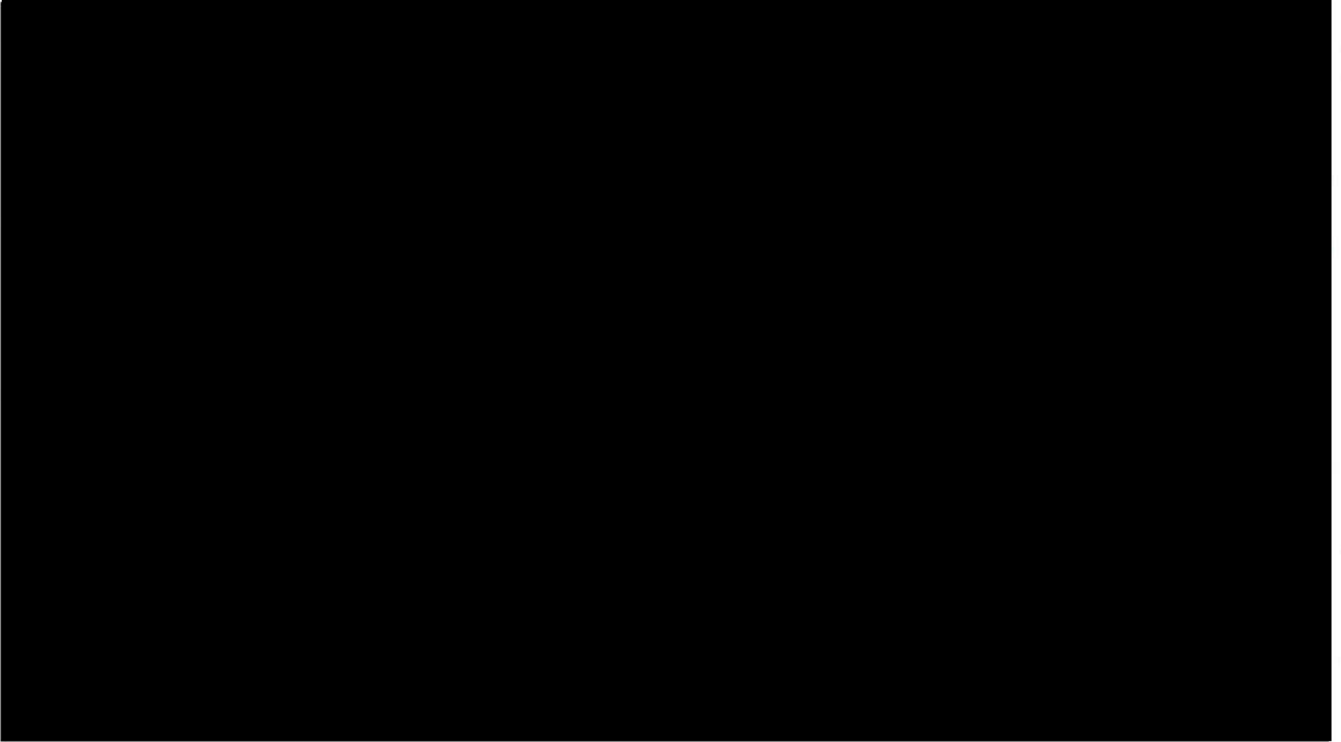
9.8 If a Multi-Party Dispute is not resolved between the Parties and all Related Third Parties within 25 Business Days of the issue of the Multi-Party Procedure Initiation Notice (or such longer period as the Parties may agree in writing), then:

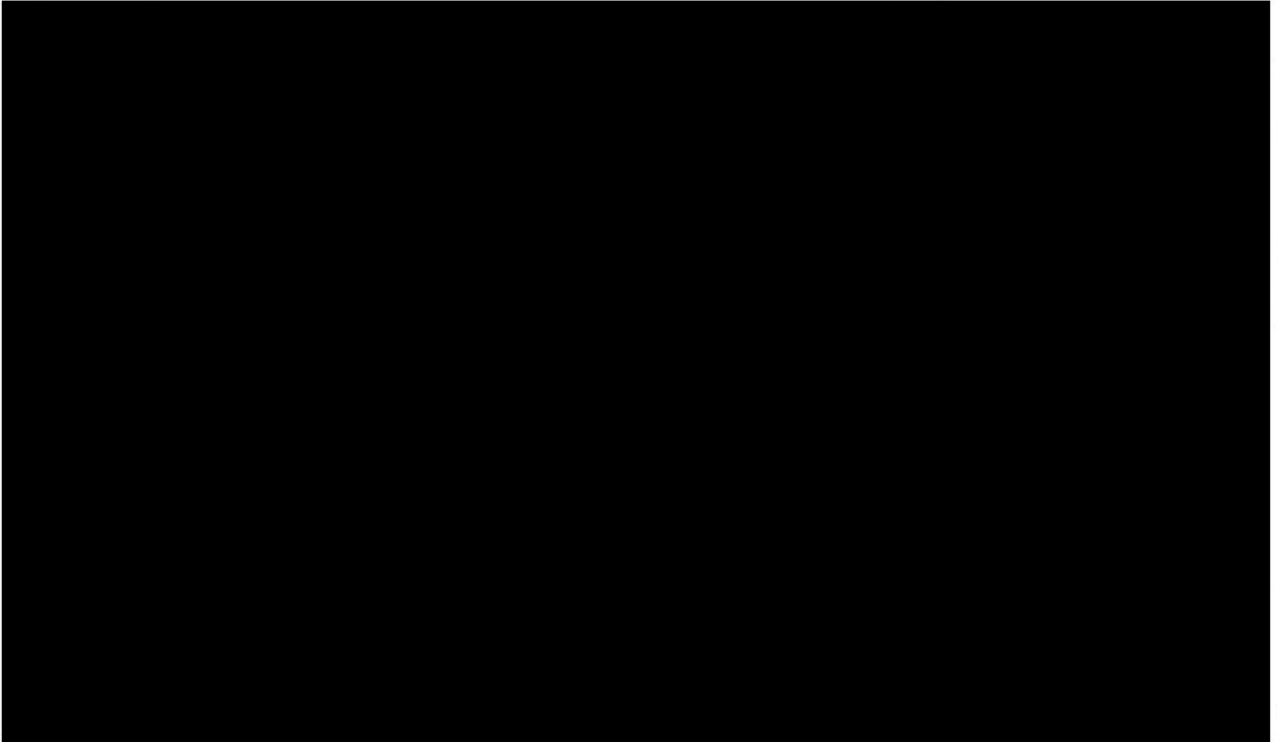
- (a) either Party may serve a Mediation Notice in respect of the Multi-Party Dispute in which case Paragraph 5 shall apply;
- (b) either Party may request that the Multi-Party Dispute is referred to an expert in which case Paragraph 6 shall apply; and/or
- (c) subject to Paragraph 9.9, Paragraph 7 shall apply to the Multi-Party Dispute,

and in each case references to "Imperial" or the "Parties" in such provisions shall include a reference to all Related Third Parties.

9.9 If a Multi-Party Dispute is referred to arbitration in accordance with Paragraph 7 or a Dispute becomes a Multi-Party Dispute during the course of arbitration proceedings and either Party is unable to compel a Related Third Party to submit to such arbitration proceedings, the Authority or Imperial may discontinue such arbitration proceedings and instead initiate court proceedings. The costs of any such discontinued arbitration proceedings shall be borne by the Party which is in a direct contractual relationship with the Related Third Party or, where the Related Third Party is a sub contractor, by Imperial.

SCHEDULE 5
PROJECT PLAN





SCHEDULE 6

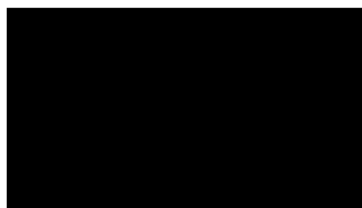
LEASE

DATED _____ 2020

(1) ROYAL FREE LONDON NHS FOUNDATION TRUST

(2) SECRETARY OF STATE FOR HOUSING, COMMUNITIES AND LOCAL GOVERNMENT

LEASE
of [REDACTED] (903.74 Sqm) and Logistics
space (88.49 Sqm) Royal Free Hospital, Pond Street,
Hampstead, NW3 2QG



THIS LEASE is made on

2020

BETWEEN:-

- (1) **ROYAL FREE LONDON NHS FOUNDATION TRUST** of Royal Free Hospital, Pond Street, London NW3 2QG (the "**Landlord**"); and
- (2) **SECRETARY OF STATE FOR HOUSING, COMMUNITIES AND LOCAL GOVERNMENT** of 2 Marsham Street, London, England, SW1P 4DF (the "**Tenant**").

IT IS AGREED as follows:-

1. INTERPRETATION

1.1 In this Lease:-

"1954 Act"	means the Landlord and Tenant Act 1954
"Authorised Use"	means use of the Premises as medical space
"Break Date"	means a date which is at least 3 months after service of the Break Notice
"Break Notice"	means written notice to terminate this lease specifying the Break Date
"Building"	means the building (forming part of the Estate) of which the Premises form part as shown edged blue on the plan at Annex 3
"Characterisation Study"	means the characterisation study to be carried out pursuant to the terms of the Collaboration Agreement
"Collaboration Agreement"	means the collaboration agreement of even date between (1) Department for Secretary of State for Business, Energy and Industrial Strategy (2) Imperial College of Science Technology and Medicine (3) Royal Free London NHS Foundation Trust and (4) hVIVO Services Limited
"Common Parts"	means the areas and amenities made available from time to time by the Landlord for use in common by the tenants and occupiers of the Estate including the structural parts of the Building, any common Conducting Media and any footpaths, forecourts, car parks, loading bays, service roads, roads at the Estate, landscaped areas, entrance halls, landings, lifts, lift-shafts, staircases, passages and areas designated for the keeping and collecting of refuse
"Conducting Media"	means gutters, gullies, pipes, sewers, drains, watercourses, channels, ducts, flues, wires, aerials, cables, mains, cisterns, tanks and all other conducting media together with all meters and other apparatus used in connection with them
"Estate"	means:- (a) for the purposes of the rights granted and reserved by this Lease and their registration at

the Land Registry, means the Landlord's estate at Royal Free Hospital, Pond Street, Hampstead, NW3 2QG shown edged red on the Plan at Annex 3 and

- (b) for all other purposes connected with this Lease, that estate:-
 - (i) including all alterations, additions and improvements and all landlord's fixtures forming part of it at any time during the Term
 - (ii) including any adjoining land and buildings that the Landlord adds to it and
 - (iii) excluding any land or buildings that the Landlord removes from it

"Nominated Agents"

means those persons permitted to share occupancy of the Premises in common with the Tenant, being:-

- (a) hVIVO Limited (company number 08008725) of Queen Mary Bioenterprises Innovation Centre, 42 New Road, London, E1 2AX; and
- (b) Imperial College of Science Technology and Medicine (Royal Charter number RC000231) of Exhibition Road, South Kensington, London SW7 2AZ

"Premises"

means rooms [REDACTED] (903.74 Sqm) and logistics space (88.49 Sqm) Royal Free Hospital, Pond Street, Hampstead, NW3 2QG as shown tinted green on the plans at Annex 1 and Annex 2 respectively subject always to clause 5.3 of the Project Services Agreement

"Premises Specification"

means the specification attached at Annex 4

"Project Services Agreement"

means the project services agreement dated [REDACTED] between (1) Department for Business, Energy and Industrial Strategy and (2) Royal Free London NHS Foundation Trust

"Rent"

means a peppercorn per annum

"Service Media"

means pipes, drains, wires, sewers, watercourses, cables, conduits and any other service media of any description

"Term"

means from today's date until and including 31st August 2021

1.2 In this Lease the Tenant is acting as part of the Crown.

2. **DEMISE, RENT AND INSURANCE CHARGE**

- 2.1 In consideration of the Rent and the Tenant's covenants in this Lease the Landlord leases the Premises to the Tenant for the Term and subject to all matters, rights and interests affecting the Premises.
- 2.2 There are reserved to the Landlord and anyone authorised by the Landlord the rights referred to in Schedule 2.
- 2.3 The Tenant must pay the Rent on the date of this Lease.

3. **TENANT'S COVENANTS**

- 3.1 The Tenant shall not:
- 3.1.1 use the Premises otherwise than for the Authorised Use.
 - 3.1.2 assign, underlet, charge, part with or share possession of, or otherwise dispose of the Premises or any part of it or any interest in it;
 - 3.1.3 share occupation of the Premises or any part of it, save for with the Nominated Agents and any regulatory bodies and trial and study monitors that require access and / or shared occupation of the Premises;
 - 3.1.4 make any alteration or addition whatsoever to the Premises;
 - 3.1.5 put any signs at the Premises, save for that which is permitted by para 4 of Schedule 1; and
 - 3.1.6 cause any nuisance or annoyance to the Landlord, or to any occupiers of the Building or the Estate, or to any owners or occupiers of neighbouring property.
- 3.2 The Tenant shall keep the Premises clean and tidy and make good any damage it causes to the Premises to the satisfaction of the Landlord (acting reasonably).
- 3.3 The Tenant shall act at all times in a reasonable and responsible manner and in accordance with any reasonable regulations that may be made by the Landlord from time to time.
- 3.4 Save where included in the Rent, the Tenant shall be responsible for all charges in connection with the supply to or removal from the Premises of electricity, telecommunications, gas, water, sewage, and other utilities and shall indemnify the Landlord in respect of such charges. Where no separate charge is made by the supplier of a utility in respect of the Premises, the Tenant shall be responsible for and shall indemnify the Landlord in respect of a proper proportion of the relevant charge, such proportion to be determined conclusively by the Landlord.
- 3.5 Save where included in the Rent, the Tenant shall be responsible for and shall indemnify the Landlord in respect of a proper proportion of the non-domestic rates and water rates charged for the Landlord's Estate such proportion to be determined by the Landlord acting reasonably and save for in the case of manifest error.
- 3.6 The Tenant shall pass on any notices or other correspondence received at the Premises and addressed to the Landlord or relevant to the Landlord's interest in the Premises or Landlord's Estate.
- 3.7 The Tenant shall allow the Landlord (and all others authorised by the Landlord) to enter the Premises at any reasonable time upon at least 72 hours written notice (save in the case of emergency where no notice would be required) for the purpose of ascertaining whether the terms set out in this Lease are being complied with and for any other purposes connected with the Landlord's interest in the Premises or the Landlord's Estate **PROVIDED THAT** in exercising any rights of entry, such rights shall be exercised in compliance with the Tenant's reasonable requirements in relation to patient confidentiality and security as previously notified to the Landlord

or as visibly displayed at the Premises provided that such requirements do not, in the reasonable opinion of the Landlord, interfere with the Landlord's statutory obligations.

- 3.8 the Tenant shall not (and shall procure that no other parties occupying and accessing the Premises pursuant to Clause 3.1.3 of this Lease shall not) interfere with the Landlord exercising the licence granted to it pursuant to clause 5.3 of the Project Services Agreement.

4. RETURN OF THE PREMISES

When the Tenant vacates the Premises at the termination of the tenancy created by this Lease, it shall immediately:

- 4.1 give vacant possession of the whole of the Premises;
- 4.2 remove all furniture (and other items belonging to it) and shall clear all rubbish from the Premises;
- 4.3 make good all damage caused to the Premises to the satisfaction of the Landlord (acting reasonably); and
- 4.4 shall have complied with all its obligations under the terms of this Lease.

5. LANDLORD'S COVENANT

- 5.1 The Landlord covenants with the Tenant that:

- 5.1.1 the Tenant may peaceably and quietly hold and enjoy the Premises during the Term without any interruption or disturbance by the Landlord or any person rightfully claiming through or under the Landlord;
- 5.1.2 it will ensure that the Premises adhere to the Premises Specification; and
- 5.1.3 in exercising the licence granted to it pursuant to clause 5.3 of the Project Services Agreement the Landlord shall not interfere with use of the remainder of the Premises by the Tenant and other parties occupying and accessing the remainder of the Premises pursuant to Clause 3.1.3 of this Lease.

6. DECLARATIONS

- 6.1 A person who is not a party to this Lease has no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Lease but this does not affect any right or remedy of a third party which exists or is available apart from that Act.
- 6.2 The Landlord does not warrant that the Authorised Use is lawfully permitted under the Town and Country Planning Act 1990 or any other legislation.
- 6.3 This Lease and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of England and Wales and the parties agree to submit to the exclusive jurisdiction of the High Court of England and Wales.
- 6.4 The Tenant's covenants in Clause 3 of this Lease are subject to the following Clause 6.5.
- 6.5 The Tenant shall not be found to be in breach of any of the terms of this Lease if and to the extent that such breach arises as a result of the Landlord's use of the Premises pursuant to clause 5.3 of the Project Services Agreement.
- 6.6 The Parties hereby acknowledge that this Lease is granted at the best rent reasonably obtainable without taking a fine or premium, and such rent is detailed under the Project Services Agreement.

7. **EXCLUSION OF THE LANDLORD AND TENANT ACT 1954**

- 7.1 The Tenant confirms that prior to entering into this Lease, or being contractually bound to do so:-
- 7.1.1 the Landlord served on the Tenant a notice complying with the requirements of section 38A(3) of the 1954 Act;
- 7.1.2 the Tenant, or a person duly authorised by the Tenant, made a statutory declaration (the "**Tenant's Statutory Declaration**") complying with the requirements of Schedule 2 to the Regulatory Reform (Business Tenancies) (England and Wales) Order 2003.
- 7.2 Where the Tenant's Statutory Declaration was made by a person other than the Tenant, the Tenant confirms that the declarant was duly authorised to make the Tenant's Statutory Declaration on the Tenant's behalf.
- 7.3 The Landlord and the Tenant agree that sections 24 to 28 (inclusive) of the 1954 Act shall be excluded in relation to the tenancy created by this Lease.

8. **BREAK PROVISION**

- 8.1 Either the Landlord or the Tenant may terminate this lease by serving a Break Notice on the other party at any time on or after the Characterisation Study has completed as notified by the Tenant to the Landlord and the Tenant shall provide such notification to the Landlord immediately on such completion.
- 8.2 Following service of a Break Notice this lease shall terminate on the Break Date.
- 8.3 Termination of this lease on the Break Date shall not affect any other right or remedy that either party may have in relation to any earlier breach of this lease.

9. **VAT**

- 9.1 All sums payable by either party under or in connection with this lease are exclusive of any VAT that may be chargeable.
- 9.2 A party to this lease must pay VAT in respect of all taxable supplies made to that party in connection with this lease on the due date for making any payment or, if earlier, the date on which that supply is made for VAT purposes.
- 9.3 Every obligation on either party, under or in connection with this lease, to pay any sum by way of a refund or indemnity, includes an obligation to pay an amount equal to any VAT incurred on that sum by the receiving party (except to the extent that the receiving party obtains credit for such VAT).

10. **RE-ENTRY AND FORFEITURE**

- 10.1 The Landlord may re-enter the Premises (or any part of the Premises in the name of the whole) at any time after any of the following occurs:
- 10.1.1 the whole or any part of the Rents is unpaid 21 days after becoming payable (whether it has been formally demanded or not); or
- 10.1.2 a material breach of any condition of, or tenant covenant in, this lease.
- 10.2 If the Landlord re-enters the Premises (or any part of the Premises in the name of the whole) pursuant to this clause, this lease shall immediately end but without prejudice to any right or remedy of the Landlord in respect of any breach of covenant by the Tenant or any guarantor.

SIGNED by the parties on the date which first appears in this lease:-

SCHEDULE 1

RIGHTS GRANTED

Each of the rights contained in this Schedule 1 shall be granted to the Tenant **PROVIDED THAT** in exercising any rights of entry, or rights that involve entry to any part of the wider Estate being required, such rights shall be exercised at reasonable times of the day and on reasonable prior written notice (save in an emergency when as much notice as is reasonably possible shall be given) and in compliance with the Landlord's reasonable requirements in relation to patient confidentiality and security as previously notified to the Tenant or as visibly displayed on the Estate provided that such requirements do not, in the reasonable opinion of the Tenant, interfere with the Tenant's statutory obligations.

1. RIGHT TO USE THE COMMON PARTS

The right, subject to temporary interruption for repair, alteration, rebuilding or replacement, for the Tenant and all persons expressly or by implication authorised by him, in common with the Landlord and all other persons having a like right, to use all appropriate areas of the Common Parts for all proper purposes in connection with the use and enjoyment of the Premises at such times as they are open in accordance with the Landlord's obligations in this Lease.

2. RIGHT TO USE THE COMMON CONDUCTING MEDIA

The right, subject to temporary interruption for repair, alteration or replacement, in common with the Landlord and all other persons having a like right, to the free passage and running of amenities to and from the Premises through the Conducting Media in, on, over or under the Estate and not exclusively serving the Premises.

3. SUPPORT AND PROTECTION

The right of support and protection for the benefit of the Premises that is now enjoyed from all other parts of the Estate.

4. SIGNS

The right to have two nameplates or signs displayed in positions on the outside of the Building adjacent to its main entrance and in the reception area of the Building, of sizes to be specified by the Landlord acting reasonably and a sign displayed in any nameboard which may be provided by the Landlord at the entrance to the Estate showing the Tenant's name and any other details approved by the Landlord, whose approval may not be unreasonably withheld or delayed.

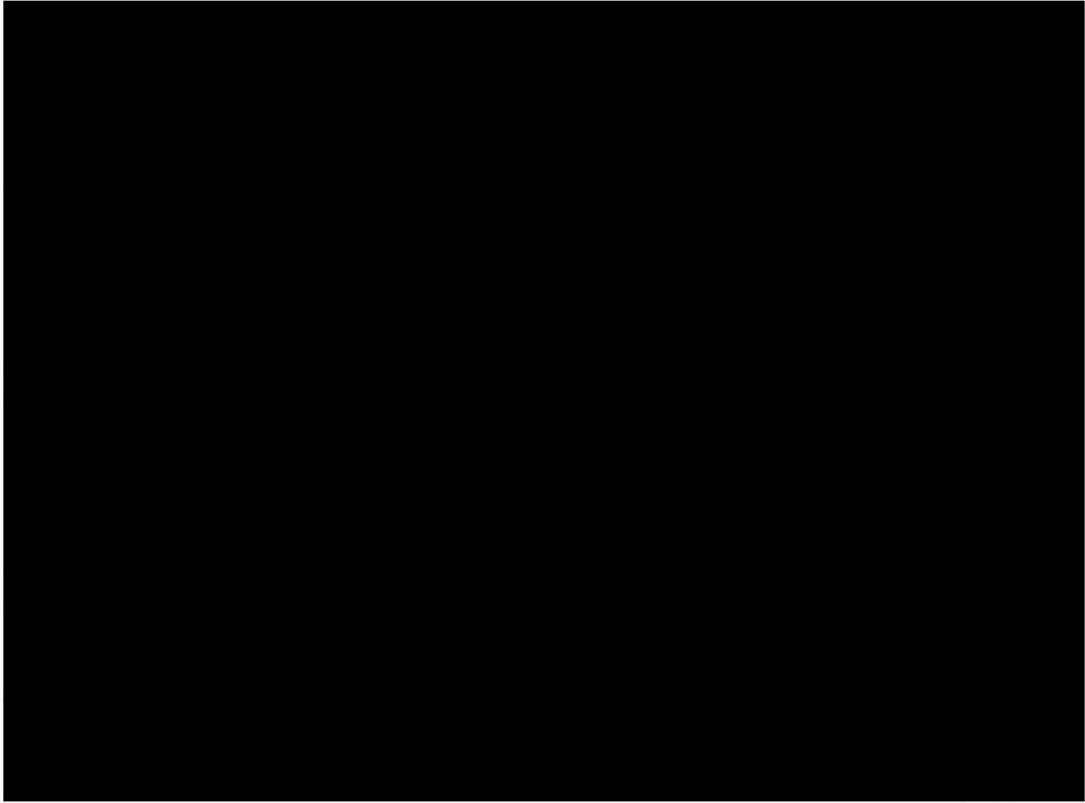
SCHEDULE 2

RIGHTS EXCEPTED AND RESERVED OUT OF THE PREMISES

1. The right to the free passage and running of water, soil, gas, electricity and other services to and from any other part or parts of the Landlord's Estate or any neighbouring property in and through the Service Media now or during the Term in, under or over the Premises.
2. All rights of support, light or air and other easements, privileges or similar rights now or hereafter capable of being used or enjoyed for the benefit of any neighbouring property or any other part or parts of the Landlord's Estate.
3. The right;
 - 3.1 to inspect the Premises to ensure the Tenant is complying with its obligations in this Lease; and
 - 3.2 on reasonable notice for all reasonable purposes connected with the Landlord's ownership of the Premises or to fulfil its obligations in this Lease;
 - 3.3 at any time during the Term, the full and free right to build, rebuild, alter or develop the Estate or any neighbouring or adjoining property in which the Landlord acquires an interest during the Term as the Landlord may think fit; and
 - 3.4 on 72 hours' notice (except in cases of emergency where as much notice as reasonably practicable must be given) to both the Tenant and the Nominated Agents to access the three landlocked rooms identified in white on the plan at Annex 1 for the purposes of repair and maintenance only. Such access must be in compliance with any protocols for the Building, having obtained all necessary permits for contractor access to the Building, complying with the reasonable requirements of the Tenant and / or the Nominated Agents and observing patient confidentiality at all times.

ANNEX 1

[REDACTED]



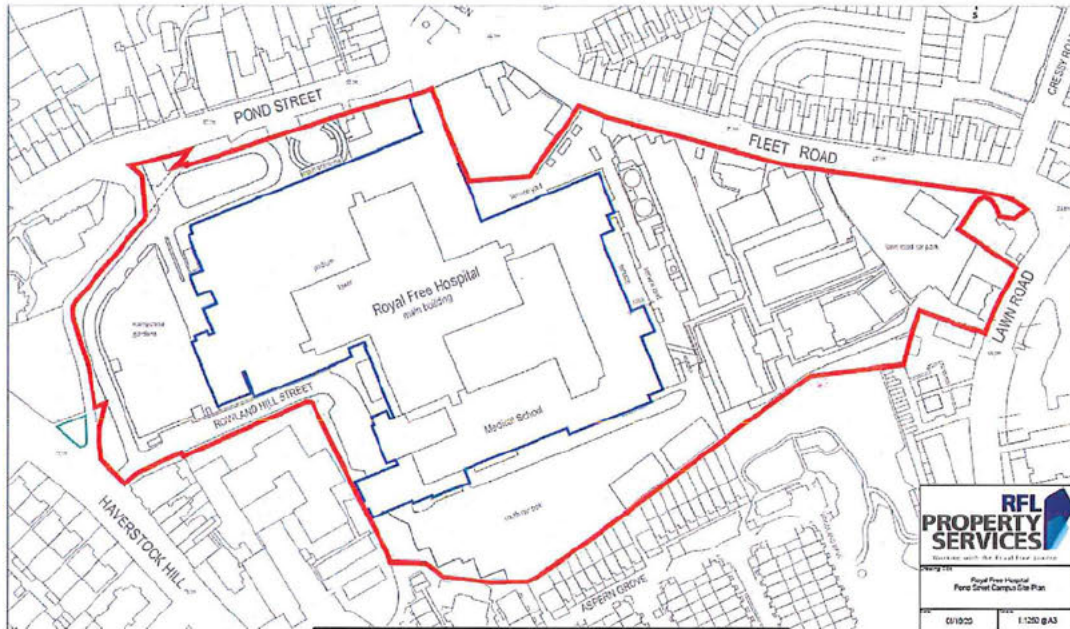
ANNEX 2

[REDACTED]



ANNEX 3

Building and Site Plan



ANNEX 4
PREMISES SPECIFICATION

1. BACKGROUND

This annex details how the Premises meets the specifications approved by the Tenant on the 17 July 2020. The specification was developed by the Landlord in partnership with hVIVO Services Limited ("hVIVO").

2. FACILITY CHARACTERISTICS

2.1 The Premises has the following characteristics:

- 2.1.1 isolation suite with a HEPA filtered environment, estimated at circa 940m² ("**Isolation Suite**");
- 2.1.2 19 bedrooms with en-suite facilities;
- 2.1.3 negative air pressure in the room relative to the lobbies ensuring any airborne infection remains in the room;
- 2.1.4 positive air pressure in the lobbies which contain PPE for the clinical staff to use prior to entering the room;
- 2.1.5 supply air provided over beds and via the lobby for air leakage into each room via the door with extract located in each en-suite;
- 2.1.6 ceiling extract in each room has a terminal HEPA filter that ensures that any airborne virus is held in the room and does not enter the ductwork; and
- 2.1.7 visual monitoring system located outside each room to monitor the efficiency of the filter,
- 2.1.8 room control panel displays with the following characteristics:
 - (a) Presence detection (to confirm room occupied and person moving);
 - (b) Air pressure differential (negative);
 - (c) Room temperature;
 - (d) CO2 level;
 - (e) HEPA condition; and
 - (f) Vacuum Condition;
- 2.1.9 SOPs for infection control are provided;
- 2.1.10 treatment room of a size of;
- 2.1.11 reception and nurses' station;
- 2.1.12 dedicated changing facilities on the floor available to be used by staff on the Premises;
- 2.1.13 offices, welfare space and support areas provided in the central area;

- 2.1.14 support services from the hospital which can be transported to the Premises via dedicated lifts;
- 2.1.15 SOPs available for waste transfer, cleaning and provisions;
- 2.1.16 transport of samples capable by hand or by use of the hospital sample transport system;
- 2.1.17 clean molecular Virology lab;
- 2.1.18 design which enables normal clothing to be worn within the corridors; and
- 2.1.19 data provision through the Landlord's own hospital data system (and the Landlord will assist hVIVO in installation and provision of a data and communications space to the extent this is required, including some local IPS where required for hVIVO's critical data capture equipment).

2.2 Visual characteristics:

2.2.1 Room control panel display:



2.2.2 HEPA Filter:



2.2.3 Air Shute – Pneumatic Sample Tube Station



2.2.4 Visual display at nurses' station on all rooms:



2.2.5 Dedicated lift and waste area within suite:



2.2.6 Offices within central area of suite:



2.2.7 Sluice with macerator:



2.2.8 Welfare area:



2.2.9 Shared changing rooms:



2.2.10 Dispensary:



2.2.11 Nurses station:



2.2.12 : Laboratory



SIGNED for and on behalf of
ROYAL FREE LONDON NHS FOUNDATION TRUST:

Name:

Position:

Signature:

SIGNED for and on behalf of **SECRETARY OF
STATE FOR HOUSING, COMMUNITIES AND
LOCAL GOVERNMENT:**

Name

Position

Signature