

Dated 14th May 2021

**Ivermectin Covid-19 Clinical Trial
Services Agreement**

between

(1) The Chancellor, Masters and Scholars of the University of Oxford

and

(2) Edenbridge Pharmaceuticals, LLC

and

(3) Torbay & South Devon NHS Foundation Trust

(Torbay Pharmaceuticals)

This Agreement is dated 14th May 2021

Parties

- (1) The Chancellor, Masters and Scholars of the University of Oxford, whose principal place of business is at University Offices, Wellington Square, Oxford, OX1 2JD, England ("**Oxford**"); and
- (2) Edenbridge Pharmaceuticals, LLC, a Delaware, USA limited liability company, with File Number 4498298, whose principal place of business is at 169 Lackawanna Avenue, Suite 110, Parsippany, New Jersey, NJ 07054, the United States of America ("**Edenbridge**"); and
- (3) Torbay & South Devon NHS Foundation Trust (trading as "Torbay Pharmaceuticals"), whose principal place of business is at Wilkins Drive, Paignton, Devon, TQ4 7FG, England ("**Torbay**");

individually, a "Party" and collectively the "Parties".

Recitals

- (A) At the date of this Agreement, Oxford is preparing to engage in conducting a clinical trial on the potential use of a pharmaceutical product, ivermectin in the treatment of Covid-19 (defined below as the "**Trial**").
- (B) Edenbridge has agreed to supply Oxford with a quantity of ivermectin for use in the Trial (defined below as the "**Products**").
- (C) Oxford and Edenbridge wish to jointly appoint Torbay to provide them with certain services to facilitate the use of the Products in the Trial, and Torbay wishes to accept such appointment, subject to the terms of this Agreement.

Operative Provisions

1 Definitions and Interpretation

- 1.1 In this Agreement, unless the context otherwise requires, the following expressions have the following meanings:

" Agreement "	this services agreement, including its schedules;
" Applicable Law "	all applicable legislation, regulations, rules, guidelines, and industry standards that apply on a country by country basis with respect to the activities under this Agreement, including with respect to the manufacture, storage, and shipment of the Products. Applicable Law includes GMP;
" Background Intellectual Property Rights "	means any and all Intellectual Property Rights owned by or licensed to a Party existing prior to the date of this Agreement and/or developed or acquired independently of this Agreement;
" Business Day "	any day other than: (i) a Saturday, (ii) a Sunday or (iii) a day which is a

bank holiday in England or in the United States (as appropriate);

"Collaborators"	means (collectively) Oxford and Edenbridge;
"Confidential Information"	the terms of this Agreement, and any information in any form or medium from or concerning another Party or another Party's business in connection with this Agreement which is expressly marked as confidential or which a reasonable person would regard as being confidential, whether obtained before, on, or after the Effective Date, including know-how, trade names, systems, methodologies, processes, business ideas, concepts, strategies, price lists, databases, drawings, diagrams, designs, samples, models, plans, data, reports, research, developments, documents, materials, functionality, specifications, plant details, factory details (including their location), intellectual property, customer details, supplier details, employee details and other technical, financial or commercial information, together with all notes, records, extracts, copies, reproductions, or analysis of any such information;
"Dataset"	means Summary Data and Trial Subject Data;
"Data Protection Legislation"	means any laws and regulations relating to the protection of individuals with regards the processing of personal data to which a Party is subject, including the Data Protection Act 2018 and the General Data Protection Regulation ((EU) 2016/679);
"Edenbridge Materials"	any and all Materials provided or to be provided by or on behalf of Edenbridge in relation to the Services;
"Effective Date"	the date on which this Agreement is last signed by each of the Parties or their authorised representatives;
"Event of Force Majeure"	any event beyond the reasonable control of any Party that materially impairs the ability of such Party from performing its obligations pursuant to this Agreement including any act of God, actions or omissions of third parties not in the same group of companies as the Party seeking to rely on Clause 13 (including hackers, suppliers, couriers, governments, quasi-governmental, supra-national, or local authorities), insurrection, riot, civil war, civil commotion, war, hostilities, threat of war, warlike operations, armed conflict, imposition of sanctions, embargo, seizure or forfeiture, breaking off of diplomatic relations or similar actions, national emergencies, terrorism, nuclear, chemical or biological contamination or sonic boom, piracy, arrests, restraints or detainments of any competent authority, blockade, strikes or combinations or lock-out of workmen, unusual traffic volumes, epidemic, pandemic, fire, explosion, storm, flood, drought, adverse weather conditions (including cold, heat, wind, rain, snow, ice, or fog), loss at sea, earthquake, volcano, natural disaster, accident, collapse of building structures, failure of machinery (other than used by the relevant Party) or third party computers or

	third party hardware or vehicles, failure or problems with public utility supplies (including general: electrical, telecoms, water, gas, postal, courier, communications, or Internet disruption or failure), or shortage of or delay in or inability to obtain supplies, stocks, storage, materials, equipment, or transportation;
"GMP"	all applicable principles, guidelines, and guidance for current good manufacturing practice as found in: (a) the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use <i>ICH Tripartite Guideline Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7</i> ; and (b) all other legal provisions, regulations, decisions or guidance of competent authorities which are applicable to any sites involved in the manufacture, quality control, quality assurance, or supply of the Products;
"Intellectual Property Rights"	copyright and related rights, trade marks and service marks, trade names and domain names, rights under licences, rights in get-up, rights to goodwill or to sue for passing off or unfair competition, patents, rights to inventions, rights in designs, rights in computer software, database rights, rights in Confidential Information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;
"Investigator Brochure"	the document containing a summary of the clinical and non-clinical data relating to the Products which are relevant to the study of the Products in human subjects;
"Liability"	liability in or for breach of contract (including under any indemnity), tort (whether deliberate or not), Negligence, breach of statutory duty, misrepresentation, restitution, or any other cause of action whatsoever relating to or arising under or in connection with this Agreement, including liability expressly provided for under this Agreement or arising by reason of the invalidity or unenforceability of any term of this Agreement (and for the purposes of this definition, all references to "this Agreement" shall be deemed to include any collateral contract);
"Materials"	any and all materials, works of authorship, deliverables, software (including source code and object code), products, routines, algorithms, files, multimedia and audiovisual material, tools, processes, systems, methodologies, flowcharts, blueprints, manuals, databases, data, database structures, a website's "look and feel", content, catalogues, descriptions, products, tooling, equipment, documents, notes, records, results, reports, discoveries, know-how, information, text, research, lists, inventions, creations, diagrams,

	artwork, designs, sketches, models, photographs, screenshots, drawings, plans, descriptions, specifications, images, logos, styles, graphics, names, devices, domain names, and marks (in whatever form and on whatever media); including any additions, enhancements, changes, alterations, modifications, or amendments to any of the foregoing;
"Negligence"	the breach of any: (i) obligation arising from the express or implied terms of a contract to take reasonable care or exercise reasonable skill in the performance of the contract or (ii) common law duty to take reasonable care or exercise reasonable skill (but not any stricter duty);
"Oxford Materials"	any and all Materials provided or to be provided by or on behalf of Oxford in relation to the Services;
"Pre-Existing Materials"	any Materials which form part of the Torbay Materials (and which are not Oxford Materials or Edenbridge Materials) but which were already in existence before Torbay used them for creating and developing the Torbay Materials;
"Personal Data"	any personal data (as defined in the Data Protection Legislation) Processed by either Collaborator in connection with this Agreement;
"Products"	the units of ivermectin to be manufactured by Edenbridge and supplied to Oxford for use in the Trial;
"Protocol"	the document that describes the objectives, design, methodology, statistical considerations, and organisation of the Trial;
"Regulatory Authority"/ "Regulatory Authorities"	a governmental agency/all governmental agencies (as applicable) having jurisdiction over the development, manufacturing, importation, packaging, labelling, storage, transport, testing, marketing, distribution, and/or sale of the Products;
"Safety Information"	all filings, submissions, and reports concerning the safety of the Products or pharmacovigilance with or to any Regulatory Authority, or a body designated or recognised by any Regulatory Authority for such purposes;
"Services"	the services provided or to be provided by Torbay to Oxford and Edenbridge pursuant to this Agreement, which are more particularly described in Schedule 1;
"Services Fees"	the price payable by Edenbridge to Torbay for the Services as set out in Schedule 2;
"Summary Data"	a tabular summary of the information, data, and results generated or obtained in the course of conducting the Trial Arm which matches the statistical analysis plan, as well as a tabular summary of the relevant control data from the same period during which Trial Subjects were

	randomised to the Trial Arm;
"Term"	has the meaning set out in Clause 8.1;
"Torbay Materials"	any and all Materials provided or to be provided by or on behalf of Torbay in relation to the Services, and any additions, enhancements, modifications, or amendments made by Torbay to any Oxford Materials or Edenbridge Materials;
"Trial"	the clinical trial entitled "Platform Randomised trial of INterventions against COVID-19 In older peoPLE" which is being conducted by Oxford on the potential use of ivermectin in the treatment of Covid-19;
"Trial Arm"	the arm of the Trial in which the Products are used;
"Trial Subject"	a person recruited to participate in the Trial Arm;
"Trial Subject Data"	all de-identified (in accordance with Data Protection Legislation as reasonably determined by Oxford) information collected about (i) each Trial Subject and (ii) each eligible control subject recruited during the same period as subjects randomised to the Trial Arm; and
"VAT"	any tax introduced pursuant to a direction of the Council of the European Community relating to turnover taxes including value added tax as provided for in the Value Added Tax Act 1994 and supplemental legislation (whether delegated or otherwise), any tax of a similar nature which any be substituted for or levied in addition to it and any sales tax.

1.2 In interpreting this Agreement:

- 1.2.1 headings shall not affect the interpretation of this Agreement;
- 1.2.2 references to Clauses and the Schedules are to the clauses of and the schedules to this Agreement;
- 1.2.3 words importing a gender shall include the other gender and the neutral;
- 1.2.4 references to "persons" shall include an individual, company, corporation, firm, partnership, or other business entity;
- 1.2.5 the singular includes the plural and vice versa;
- 1.2.6 where the words "include(s)", "including", or "in particular" are used in this Agreement, they are deemed to have the words "without limitation" following them unless expressly stated otherwise;
- 1.2.7 any obligation in this Agreement on a person not to do something includes an obligation not to agree, allow, permit, or acquiesce to that thing being done;
- 1.2.8 references to any statute or statutory provision shall include any subordinate

legislation made under it, any provision which it has modified or re-enacted (whether with or without modification), and any provision which subsequently supersedes it or re-enacts it (whether with or without modification); and

- 1.2.9 references to "written" or in "writing" (except in respect of sending a notice in accordance with Clause 15) includes in electronic form.

2 Appointment

- 2.1 Oxford and Edenbridge hereby appoint Torbay to provide the Services and Torbay accepts such appointment, subject to the terms of this Agreement.
- 2.2 This Agreement contains the entire agreement between the Parties regarding its subject matter and supersedes and excludes any prior agreement, understanding, or arrangement between the Parties, whether oral or in writing. No representation, undertaking, or promise shall be taken to have been given or be implied from anything said or written in negotiations between the Parties prior to this Agreement except as expressly stated in this Agreement. No Party shall have any remedy in respect of any untrue statement made by another Party upon which that Party relied in entering into this Agreement (unless such untrue statement was made fraudulently or as to a fundamental matter) and that Party's only remedies shall be for breach of contract as provided in this Agreement.
- 2.3 The terms of this Agreement apply to the exclusion of any terms and conditions submitted, proposed, or stipulated by any Party whether such terms and conditions are contained in that Party's invoices, other documents, or otherwise. This Agreement shall apply to the Services and shall override all other terms and conditions that are inconsistent with this Agreement whether express, implied, or otherwise.

3 The Services

- 3.1 Torbay shall:
- 3.1.1 provide the Services using reasonable skill and care in conformance with standard commercial practices and industry standards;
 - 3.1.2 obtain and pay for and at all times maintain and comply with and conform to, all necessary or desirable licences, authorisations, approvals, consents, permissions, and certificates of origin required for the provision of the Services and the performance of its obligations under this Agreement;
 - 3.1.3 observe all Applicable Laws, regulations, byelaws, and codes of practice, including Good Distribution Practice, in connection with the provision of the Services and the performance of its obligations under this Agreement;
 - 3.1.4 at the request of a Regulatory Authority, permit or procure permission for representatives of such Regulatory Authority to inspect all facilities at which the Services are conducted and all records relevant to such Services. Torbay shall notify Oxford and Edenbridge of all such inspections by a Regulatory Authority insofar as they are relevant to the provision of the Services or otherwise to the Trial;

- 3.1.5 make its representatives available, at all reasonable times and upon reasonable notice, to Oxford and Edenbridge for the purposes of consultation and advice relating to this Agreement and the Products; and
- 3.1.6 promptly provide Oxford and Edenbridge with such information and assistance reasonably required to enable Oxford and Edenbridge to fully and accurately carry out their obligations and exercise their rights under this Agreement.
- 3.2 Torbay will not be responsible for the provision of any services to Oxford or Edenbridge which are not expressly stipulated in this Agreement. Except for any matter upon which Torbay specifically agrees under this Agreement, Torbay shall have no Liability for advising on, or failing to advise on, or doing, or failing to do, anything else.

4 Oxford's and Edenbridge's Additional Obligations

4.1 Oxford shall:

- 4.1.1 observe all Applicable Laws, regulations, byelaws, and codes of practice in respect of the conduct of the Trial and in connection with the performance of its obligations under this Agreement;
- 4.1.2 obtain and pay for and at all times maintain and comply with and conform to, all necessary or desirable licences, authorisations, approvals, consents, permissions, and certificates of origin required for the conduct of the Trial, including the storage of the Products;
- 4.1.3 make its representatives available, at all reasonable times and upon reasonable notice, to Torbay for the purposes of consultation and advice relating to this Agreement and the Products; and
- 4.1.4 promptly provide Torbay with such information and assistance reasonably required to enable Torbay to fully and accurately carry out its obligations and exercise its rights under this Agreement.

4.2 Edenbridge shall:

- 4.2.1 at its own cost, use commercially reasonable efforts to supply the Products in sufficient quantities for the conduct of the Trial in accordance with delivery times as agreed by Edenbridge, Torbay, and Oxford. If there are no agreed delivery times for the supply of the Products, Edenbridge shall use commercially reasonable efforts to deliver the Products in sufficient time for the conduct of the Trial provided that Edenbridge has at least 15 days' advance written notice of the date on which Products are required.
- 4.2.2 in relation to the Products, be responsible for compiling the Investigator Brochure and for validating and updating the Investigator Brochure at any time upon request from Oxford. Edenbridge shall use commercially reasonable efforts to:
 - 4.2.2.1 ensure that the Investigator Brochure, and any update, presents the information it contains in a concise, simple, objective, balanced, and non-promotional form that enables a clinician or potential investigator to

understand it and make an unbiased risk-benefit assessment of the appropriateness of the Trial Arm;

4.2.2.2 provide to Oxford the Investigator Brochure, any update and reasonable evidence of validation in a timely manner sufficient to meet Oxford's obligations under Applicable Law provided that Oxford provides Edenbridge with reasonable notice of Oxford's obligations under Applicable Law; and

4.2.2.3 during the Term, promptly report to Oxford all Safety Information relating to other clinical trials that test or use the Products which it has contributed to the Trial Arm and for which Oxford is not the Sponsor.

4.2.3 at the request of a Regulatory Authority, permit or use commercially reasonable efforts to procure permission for representatives of such Regulatory Authority to inspect all facilities at which the Products are manufactured and all records relevant to such manufacture. Edenbridge shall notify Oxford of all such inspections by a Regulatory Authority.

4.2.4 transport the Products at its own cost and risk to Torbay at Heathrow Airport, England;

4.2.5 before delivery of the Products to Torbay, use adequate facilities for performing its activities under this Agreement, including the manufacture and the storage of the Products;

4.2.6 observe all Applicable Law, regulations, byelaws, and codes of practice in respect of the manufacture, sale, supply, storage, and packaging of the Products as are applicable in Edenbridge's place of manufacture;

4.2.7 make its representatives available, at all reasonable times and upon reasonable notice, to Torbay for the purposes of consultation and advice relating to this Agreement and the Products; and

4.2.8 promptly provide Torbay with such information and assistance reasonably required to enable Torbay to fully and accurately carry out its obligations and exercise its rights under this Agreement, including providing Torbay any copy documentation required for release of the Products.

5 Intellectual Property Rights

5.1 To the extent that Oxford is not already the owner, Torbay hereby assigns to Oxford (by way of present and future assignment) so far as is legally permissible absolutely with full title guarantee all Intellectual Property Rights in all and any part of the world in: (i) the Torbay Materials (other than the Pre-Existing Materials) and (ii) the Oxford Materials for the full term of such rights and all renewals and extensions, together with all accrued rights of action.

5.2 Where the creation of any Torbay Materials involves the use of any Pre-Existing Materials, Torbay hereby grants to Oxford for use by Oxford, its assignees and licensees, and their respective agents and sub-contractors, an irrevocable, worldwide, royalty-free, perpetual, transferable, sub-licensable licence to use the Pre-Existing Materials owned or used by Torbay.

- 5.3 The Parties hereby grant to each other a non-exclusive, non-transferable licence to use such of their respective Background Intellectual Property Rights to the extent necessary only for each Party to perform its obligations under this Agreement.
- 5.4 For the avoidance of doubt, Oxford shall retain all Intellectual Property Rights arising from the conduct of the Trial.
- 5.5 Within thirty (30) days of completion of the statistical report for the Trial Arm evaluation, Oxford shall provide to Edenbridge the Dataset. Oxford grants to Edenbridge a non-exclusive, worldwide, perpetual, and royalty-free licence to the Intellectual Property Rights subsisting in the Dataset to such extent as is necessary to enable Edenbridge to make reasonable use of the Dataset for international regulatory purposes (including commercialization of any products that rely on, or were approved utilizing, such Dataset) and its own internal, non-commercial purposes. Edenbridge shall use the Dataset strictly in accordance with Applicable Law. If this Agreement is terminated by Oxford under Clause 8.2.1, Clause 8.2.2, or Clause 8.2.3 because of a breach by Edenbridge, Oxford shall have the right to terminate this license immediately.
- 5.6 Edenbridge acknowledges that the Dataset may contain information which is owned or controlled by third parties. Notwithstanding anything to the contrary in this Agreement, Oxford shall not provide any such information to Edenbridge unless and until it has obtained all necessary licenses, consents, and approvals from the relevant third parties. Oxford shall use its best efforts to ensure such licenses, consents, and approvals are obtained as soon as possible. Nothing in this clause shall prevent Oxford from sharing the Dataset with Regulatory Authorities.
- 5.7 Each Collaborator shall, and shall use its reasonable endeavours to procure that any necessary third party shall, promptly execute and deliver such documents and perform such acts as may reasonably be required, at the requesting Collaborator's cost, for the purpose of giving full effect to this Clause 5.
- 5.8 Any publication or other public dissemination of the Dataset (or any part of them) by Edenbridge shall not occur until Oxford has published the results of the Trial Arm in the primary publication (the "Primary Publication"). Authorship of the Primary Publication shall be in accordance with normal academic practice. For the avoidance of doubt, Edenbridge shall have the ability to utilize the Dataset for submission to a regulatory authority for purposes of drug approval.
- 5.9 Where Oxford wishes to submit the results of the Trial Arm and relevant usual care data for publication, Oxford will submit details of such publication to Edenbridge in writing not less than fifteen (15) days in advance of the submission for publication, for review and comment. Edenbridge shall be entitled to suggest amendments to any proposed publication, which Oxford will reasonably consider in good faith.

6 Service Fees and Payment

- 6.1 In consideration of Torbay providing the Services, Edenbridge shall pay to Torbay the Services Fees in accordance with the provisions of this Clause 6.
- 6.2 In addition to the Service Fees, Edenbridge shall reimburse Torbay for any reasonable expenses incurred by Torbay in the provision of the Services, provided that Torbay supplies Edenbridge

with reasonable documentary evidence of the same.

- 6.3 Torbay shall invoice Edenbridge on a monthly basis for the Service Fees and expenses described in Clause 6.2. Torbay shall be entitled to invoice Edenbridge in respect of any Service provided, and any expenses incurred, in any month at any time after the end of such month.
- 6.4 Edenbridge shall pay Torbay for all Services Fees and expenses within sixty days of Edenbridge's receipt of each invoice of Torbay (and the accompanying documentation in respect of any expenses described in Clause 6.2).
- 6.5 Edenbridge shall pay all sums due to Torbay under this Agreement in pounds sterling or such other currency as in force in England from time to time.
- 6.6 Edenbridge shall pay all sums due to Torbay under this Agreement by way of bank transfer or such other method reasonably requested by Torbay from time to time.
- 6.7 All sums due to Torbay pursuant to this Agreement are exclusive of VAT and other duties or taxes (if applicable), which Edenbridge shall pay to Torbay in addition at the same time as payment of the Services Fees and expenses described in Clause 6.2.
- 6.8 Without prejudice to any other right or remedy available to Torbay, if Edenbridge is late in paying any Service Fees or expenses described in Clause 6.2, Torbay may exercise either or both of the following remedies:
 - 6.8.1 charge interest on the amount due but unpaid at a rate equal to two per cent above the base rate of the National Westminster Bank from time to time, such interest to run from day to day and to be compounded monthly; or
 - 6.8.2 suspend Torbay's performance of this Agreement until Edenbridge has made payment of all outstanding sums in full.

In the case of this Clause 6.8.2, Torbay agrees to inform Oxford in writing of any suspension of Torbay's performance of this Agreement, as soon as reasonably practicable.
- 6.9 For the avoidance of doubt, Edenbridge alone is responsible for paying to Torbay the Service Fees and any other fees or expenses referred to in this Clause 6. Oxford shall not, in any event, be liable to Torbay for breach of this Clause 6 by Edenbridge.

7 Confidentiality

- 7.1 Each Party shall keep and procure to be kept secret and confidential the Confidential Information of each other Party and shall not use nor disclose the same save:
 - 7.1.1 for the purposes of the proper performance of this Agreement;
 - 7.1.2 as otherwise permitted by this Agreement;
 - 7.1.3 as required under any Applicable Law, or by order of a court or governmental body or authority of competent jurisdiction (including any tax authority); or

- 7.1.4 with the prior written consent of the relevant Party.
- 7.2 Each Party shall protect the Confidential Information of each other Party with at least the same degree of care (which shall not be less than a reasonable standard of care) that it uses in connection with the protection of its own confidential information.
- 7.3 Where one Party discloses Confidential Information of another Party to its representative, employee, consultant, subcontractor, supplier, customer, agent, professional adviser, auditor, or insurer, it shall do so on a need-to-know basis and subject to obligations equivalent to those set out in this Clause 7. Each Party shall use its reasonable endeavours to ensure that any such representative, employee, consultant, subcontractor, supplier, customer, agent, professional adviser, auditor, or insurer complies with such obligations, and such Party shall be liable for breach by any such representative, employee, consultant, subcontractor, supplier, customer, agent, professional adviser, auditor, or insurer.
- 7.4 The obligations of confidentiality in this Clause 7 shall not extend to any information which any Party can show:
- 7.4.1 is in, or has become part of, the public domain other than as a result of a breach of the confidentiality obligations of this Agreement;
- 7.4.2 was already in its written records prior to receipt;
- 7.4.3 was independently developed by it; or
- 7.4.4 was independently disclosed to it by a third party in circumstances where it has no reason to believe that third party is bound by a duty of confidentiality to the disclosing Party.
- 7.5 If any Party is required to disclose any Confidential Information of another Party under any Applicable Law, or by order of a court or governmental body or authority of competent jurisdiction (including any tax authority), then the Party so required may disclose the Confidential Information to the extent required but shall, prior to any disclosure where practicable, give the other Party as much warning as practicable and consult with the other Party in writing and, at the other Party's request and cost, fully co-operate with and assist that other Party in opposing any such disclosure.
- 7.6 Except to the extent necessary for another Party to continue exercising its rights and performing its obligations under this Agreement or at law (or for its own normal retention of records which any reasonable business would wish to retain, including to show performance of its obligations under this Agreement or any agreement or for dealing with customers' issues or for regulatory reasons), a Party owning Confidential Information disclosed hereunder may reasonably request at any time that another Party delete or return promptly all Confidential Information belonging to the Party owning the disclosed Confidential Information.
- 7.7 No Party shall make any announcement of any kind in respect to the Services or this Agreement except with the prior written consent of the other Parties or as is required by law.
- 7.8 The obligations in respect of the other Parties' Confidential Information in this Clause 7 shall continue in perpetuity after expiry or termination of this Agreement for whatever reason.

8 Term and Termination

- 8.1 This Agreement will commence on the Effective Date and, subject to earlier termination pursuant to this Agreement, shall continue in force until the transactions contemplated by this Agreement are complete (the "Term").
- 8.2 Any Party may terminate this Agreement immediately by notice to the other Parties with immediate effect if:
- 8.2.1 another Party is in material breach of any of its obligations under this Agreement which is incapable of remedy;
 - 8.2.2 another Party fails to remedy, where capable of remedy, any material breach of any of its obligations under this Agreement after having been required in writing to remedy such breach within a period of no less than thirty days;
 - 8.2.3 another Party is in persistent material breach of its obligations under this Agreement; or
 - 8.2.4 another Party gives notice to any of its creditors that it has suspended or is about to suspend payment or if it shall be unable to pay its debts, or an order is made or a resolution is passed for the winding-up of that Party or an administration order is made or an administrator is appointed to manage the affairs, business and property of that Party or a receiver and/or manager or administrative receiver is appointed in respect of all or any of that Party's assets or undertaking or circumstances arise which entitle the court or a creditor to appoint a receiver and/or manager or administrative receiver or administrator or which entitle the court to make a winding-up or bankruptcy order or that Party takes or suffers any similar or analogous action in any jurisdiction in consequence of debt.
- 8.3 For the purposes of Clause 8.2.1, a breach shall be considered capable of remedy if the Party in breach can comply with the provision in question in all respects other than as to the time of performance (provided that time of performance is not of the essence).
- 8.4 Each Party (in its absolute discretion) may elect to suspend, rather than terminate or before terminating, this Agreement if another Party is suffering an event described in Clause 8.2.4.
- 8.5 The expiry or termination of this Agreement will be without prejudice to any other rights or remedies which either Party may be entitled to under this Agreement or at law and will not affect any accrued rights or liabilities of any Party.
- 8.6 The provisions of Clauses 1, 5, 6, 7, 9, 10, 11, 12, 14, 15, 16, 17, 18, 19, 20, 21, 21, and 23, together with those provisions that either are expressed to survive its expiry or termination or from their nature or context it is contemplated that they are to survive such termination, shall survive expiry or termination of this Agreement.
- 8.7 Subject to Clause 7.6, upon expiry or termination of this Agreement for any reason Torbay shall deliver up to Oxford all quantities of the Products in its possession or control (if any) and all of the Oxford Materials.

- 8.8 The Parties acknowledge and agree that Oxford cannot: (i) start the Trial Arm or cause the Trial Arm to be started; or (ii) conduct the Trial Arm; unless the following conditions have been satisfied: (a) receipt of a valid favourable opinion from an applicable ethics committee; and (b) receipt of approval from the Regulatory Authority as required by Applicable Law.

9 Indemnification

- 9.1 Subject to Clause 10, Oxford shall indemnify Torbay against any liabilities, costs, claims, expenses, losses, or damages (including reasonably incurred legal costs) incurred by Torbay arising from or in connection with any third party claim against Torbay by a Trial subject (or their dependents) that result from any personal injury (including death) to a Trial Subject arising out of related to the administration of the Products or any clinical intervention or procedure undertaken pursuant to the Trial Arm which the Trial Subject would not otherwise have been exposed but for their participation in the Trial Arm; except to the extent the relevant liabilities, costs, claims, expenses, losses, or damages arise as a result of an act or omission of Torbay.
- 9.2 Subject to Clause 10, Oxford shall indemnify Edenbridge against any liabilities, costs, claims, expenses, losses, or damages (including reasonably incurred legal costs) incurred by Edenbridge arising from or in connection with any third party claim against Edenbridge made or brought (whether successfully or otherwise) by a Trial Subject (or their dependents) that result from any personal injury (including death) to a Trial Subject arising out of related to the administration of the Products or any clinical intervention or procedure provided for or required by the Protocol to which the Trial Subject would not otherwise have been exposed but for their participation in the Trial Arm; except to the extent the relevant liabilities, costs, claims, expenses, losses, or damages arise as a result of an act or omission of Edenbridge.
- 9.3 Subject to Clause 10, Edenbridge shall indemnify Oxford against any liabilities, costs, claims, expenses, losses, or damages (including reasonably incurred legal costs) incurred by Oxford arising from or in connection with any third party claim against Oxford made or brought (whether successfully or otherwise) by a Trial Subject (or their dependents) that result from the Products supplied by Edenbridge's failure to comply with any requirement of this Agreement, GMP, and/or Applicable Law; except to the extent the relevant liabilities, costs, claims, expenses, losses, or damages arise as a result of an act or omission of Oxford.
- 9.4 Subject to Clause 10, Edenbridge shall indemnify Torbay against any liabilities, costs, claims, expenses, losses, or damages (including reasonably incurred legal costs) incurred by Torbay arising from or in connection with any third party claim against Torbay arising from any defect in the Products at delivery to Torbay; except to the extent the relevant liabilities, costs, claims, expenses, losses, or damages arise as a result of an act or omission of Torbay.
- 9.5 Subject to Clause 10, Torbay shall indemnify Oxford against any liabilities, costs, claims, expenses, losses, or damages (including reasonably incurred legal costs) incurred by Oxford arising from or in connection with any third party claim against Oxford arising from any defect in the Products caused by: (i) Torbay's inappropriate storage or mishandling of the Products after their delivery to Torbay by Edenbridge and/or (ii) Torbay's failure to comply with any requirement of this Agreement, GMP, and/or Applicable Law; except to the extent the relevant liabilities, costs, claims, expenses, losses or damages arise as a result of the act or omission of Oxford.
- 9.6 Subject to Clause 10, Torbay shall indemnify Edenbridge against any liabilities, costs, claims,

expenses, losses, or damages (including reasonably incurred legal costs) incurred by Edenbridge arising from or in connection with any third party claim against Edenbridge arising from any defect in the Products caused by Torbay's inappropriate storage or mishandling of the Products after their delivery to Torbay by Edenbridge; except to the extent the relevant liabilities, costs, claims, expenses, losses or damages arise as a result of the act or omission of Edenbridge.

10 Limitation of Liability

- 10.1 This Clause 10 prevails over all other clauses of this Agreement and sets out each Party's entire Liability to the other Parties and the other Parties' sole and exclusive remedies in respect of each Party's performance, non-performance, purported performance, delay in performance, or mis-performance of this Agreement or otherwise in relation to this Agreement or entering into this Agreement.
- 10.2 No Party excludes or limits Liability for:
- 10.2.1 death or personal injury caused by its Negligence;
 - 10.2.2 its fraud;
 - 10.2.3 fraudulent misrepresentation, or to any other representations that it would be unreasonable in law to exclude; or
 - 10.2.4 any other Liability which cannot be excluded or limited by Applicable Law.
- 10.3 Subject to Clause 10.2, no Party shall have any Liability to any of the other Parties for any: (i) loss of actual or anticipated profits; (ii) loss of use of money; (iii) loss of revenue; (iv) loss of goodwill; (v) loss of reputation; (vi) loss of business or contracts; (vii) ex gratia losses; or (viii) loss of opportunity; suffered by another Party; whether or not such losses were reasonably foreseeable or the relevant Party had been advised of the possibility of another Party incurring such losses. For the avoidance of doubt, this Clause 10.3 applies whether such losses are direct, indirect, consequential, or otherwise.
- 10.4 Subject to Clauses 10.2 and 10.3, and the exclusions and limits set out in this Agreement, and in the case of Edenbridge, subject to its indemnification obligations in Clause 9.3, the total aggregate Liability of any Party arising under or in connection with its obligations under Clause 9 shall not exceed £5,000,000 (five-million pounds sterling).
- 10.5 Subject to Clause 10.2 and 10.3, and the exclusions and limits set out in this Agreement, the total aggregate Liability of any Party arising under or in connection with this Agreement, except for Liability of any Party arising under or in connection with its obligations under Clause 9, shall not exceed a sum equal to: (i) the Services Fees plus (ii) Torbay's expenses payable by Edenbridge, multiplied by two.
- 10.6 The limitations and exclusions of Liability under Clauses 10.3, 10.4 and 10.5 have effect in relation both to any Liability expressly provided for under this Agreement and to any Liability arising by reason of the invalidity or unenforceability of any term of this Agreement.
- 10.7 Each Party to this Agreement undertakes to make no claim in connection with this Agreement or its subject matter against any officer, employee, agent, adviser and student of the other, except for claims in relation to fraud or wilful misconduct. This undertaking is intended to give

protection to individuals: it does not prejudice any right which a Party might have to claim against another Party. The benefit conferred by this clause is intended to be enforceable by the persons referred to in it.

10.8 Oxford makes no representation or warranty that advice or information given by its personnel, or the content or use of any Dataset provided in connection with the Trial, will not constitute or result in infringement of third-party rights.

10.9 Oxford accepts no responsibility for any use which may be made of any work carried out under or pursuant to this Agreement, or of the Dataset, nor for any reliance which may be placed on such work or Dataset, nor for advice or information given in connection with them.

11 Insurance

11.1 During the Term and for a minimum of six years after its expiry or termination of this Agreement, Edenbridge shall take out and maintain in full force and effect at its own expense and cost (and not do anything to adversely affect the effectiveness of) insurance to cover its public liability liabilities under or in connection with this Agreement with a limit of indemnity of not less than £5,000,000 (five-million pounds sterling) for each and every claim and £5,000,000 (five-million pounds sterling) in the aggregate.

11.2 During the Term and for a minimum of six years after its expiry or termination of this Agreement, Oxford shall take out and maintain in full force and effect at its own expense and cost (and not do anything to adversely affect the effectiveness of) insurance to cover its professional indemnity and public liability liabilities under or in connection with this Agreement or otherwise in connection with the Trial with a limit of indemnity of not less than £5,000,000 (five-million pounds sterling) for each and every claim.

11.3 During the Term and for a minimum of six years after its expiry or termination of this Agreement, Torbay shall take out and maintain in full force and effect at its own expense and cost (and not do anything to adversely affect the effectiveness of) insurance to cover its professional indemnity and public liability liabilities under or in connection with this Agreement or otherwise in connection with the Trial with a limit of indemnity of not less than £5,000,000 (five-million pounds sterling) for each and every claim.

11.4 Upon request, each of Party shall provide the requesting Party with documentary evidence that such insurance is being maintained.

12 Data Protection

12.1 The Collaborators acknowledge and agree that, notwithstanding any other provision contained in this Agreement, Oxford shall not disclose any Personal Data of a Trial Subject to Edenbridge, except where strictly necessary and where permitted by the Data Protection Legislation.

12.2 The Collaborators acknowledge and agree that to the extent Oxford transfers Personal Data to Edenbridge, it shall be transferring Personal Data outside the European Economic Area. Prior to such transfer, the Collaborators shall enter into the Standard Contractual Clauses (approved by the European Commission for such Controller-to-Controller transfers, as updated and/or amended from time to time). In the event of a conflict between the terms of the Standard Contractual Clauses and the rest of this Agreement, the Standard Contractual Clauses shall take precedence.

- 12.3 Edenbridge undertakes, subject to Clause 12.1, not to identify, or attempt to identify, a Trial Subject from any information supplied to it by Oxford under this Agreement.
- 12.4 Edenbridge shall take appropriate technical and organisational measures against the unauthorised or unlawful processing and/or use of the Dataset and against the accidental loss or destruction of, or damage to, the Dataset.
- 12.5 Edenbridge shall (on request) cooperate with Oxford's compliance regarding a data subject rights request (as defined in the Data Protection Legislation). Oxford shall manage mediation and legal obligations associated with an information security breach (as defined in the Data Protection Legislation) relating to Personal Data under the controllership of Oxford.
- 12.6 The Parties shall comply with the Data Protection Legislation in conducting the Trial Arm or otherwise in connection with this Agreement.

13 **Force Majeure**

- 13.1 No Party shall have any Liability for any breach, hindrance, or delay in the performance of its obligations under this Agreement which is caused by an Event of Force Majeure, regardless of whether the circumstances in question could have been foreseen.
- 13.2 Each of the Parties agrees to notify the other Parties upon becoming aware of an Event of Force Majeure, such notice to contain details of the circumstances giving rise to the Event of Force Majeure.
- 13.3 The performance of each Party's obligations shall be suspended during the period that the circumstances persist and such Party shall be granted an extension of time for performance equal to the period of the delay.
- 13.4 Each Party shall bear its own costs arising in relation to an Event of Force Majeure.
- 13.5 Should any performance of obligations be delayed under this Clause 13, each Party shall nevertheless accept performance as and when each other Party shall be able to perform.
- 13.6 If an Event of Force Majeure continues without a break for more than three months, any Party may terminate this Agreement immediately by providing notice to the other Parties, in which event no Party shall have any Liability to any other Party by reason of such termination.
- 13.7 Each Party shall use its reasonable endeavours to assist and co-operate with the other Parties to mitigate the effects of an Event of Force Majeure, but no Party shall be required to take steps that it would be unreasonable to expect it to take.

14 **Anti-Bribery Compliance**

- 14.1 The Parties agree that it is important that they comply with all relevant anti-bribery and anti-corruption laws, regulations, codes of practice, and guidance, including under English law.
- 14.2 Each Party shall:
 - 14.2.1 comply with all Applicable Laws, statutes, regulations, and codes relating to anti-bribery and anti-corruption;

- 14.2.2 use reasonable endeavours to fully adhere to all of the other Parties' reasonable anti-bribery and anti-corruption policies and procedures brought to its attention from time to time, to the extent that these do not conflict with its own policies and procedures;
 - 14.2.3 maintain and fully adhere to its own anti-bribery and anti-corruption policies and procedures based on its own reasonably assessed risks; and
 - 14.2.4 ensure that any employees, agents, or third parties directly or indirectly acting on behalf of or providing services on its behalf fully adhere to the policies and procedures described in Clauses 14.2.2 and 14.2.3.
- 14.3 Each Party warrants to each other Party that, to the best of its knowledge and without having made specific checks, it has not offered, promised, given, paid, requested, agreed to receive, received, or accepted any bribe or anything that at law could be considered to be a bribe, at any time (whether or not in respect of its relationship with the other Parties in connection with this Agreement).
- 14.4 Each Party shall inform the other Parties immediately and with full details upon reaching any suspicion that:
 - 14.4.1 a bribe has been offered, promised, given, paid, requested, agreed to be received, received, or accepted at any time by any person acting, directly or indirectly, on its behalf;
 - 14.4.2 any policies or procedures referred to in this Clause 14 have not been complied with; or
 - 14.4.3 any relevant anti-bribery or anti-corruption laws, regulations, codes of practice, or guidance, including under English law, have not been complied with.

15 Notices

- 15.1 Any notice required or authorised to be given under this Agreement shall be in writing and shall be served by personal delivery or by a generally recognised commercial courier to the relevant Party at its address stated in this Agreement or at such other address as is notified by the relevant Party to the other Parties for this purpose from time to time or at the address of the relevant Party last known to the other Parties.
- 15.2 Any notice so delivered personally shall be deemed served at the time of delivery and any notice so given by commercial courier shall be deemed to have been served two Business Days after the same shall have been despatched, and in proving such service it shall be sufficient to prove that the letter was properly addressed, and despatched and delivered.

16 Waiver

- 16.1 Unless a Party expressly states in writing that it is waiving a particular power, right, or remedy in a particular stated instance, no failure or delay or omission by any Party in exercising any power, right, or remedy under this Agreement or at law shall operate as a waiver of such power, right, or remedy; and no waiver in any particular instance shall extend to or affect any other or subsequent event or impair any powers, rights, or remedies in respect of it or in any way modify

or diminish that Party's other powers, rights, or remedies under this Agreement or at law.

17 Third Party Rights

- 17.1 Subject to Clause 10.7, a person who is not a party to this Agreement has no rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement.
- 17.2 The rights of the Parties to terminate, rescind, or agree to any variation, waiver, or settlement under this Agreement are not subject to the consent of any other person.

18 Variation

- 18.1 No variation of this Agreement shall be effective unless it is in writing and signed by each Party (or their authorised representatives).

19 Relationship of the Parties

- 19.1 The relationship of the Parties is that of independent contractors dealing at arm's length. Except as otherwise stated in this Agreement, nothing in this Agreement shall constitute the Parties as partners, joint venturers, or co-owners, or constitute any Party as the agent, employee, or representative of another Party, or empower any Party to act for, bind, or otherwise create or assume any obligation on behalf of another Party, and no Party shall hold itself out as having authority to do the same.
- 19.2 No Party shall use the name nor any trade mark or logo of the other Party in connection with any publicity, press release or advertising, sales or promotional material, without the prior written approval of that Party, except as otherwise expressly permitted in this Agreement or required under Applicable Law. For the avoidance of doubt, the foregoing right of approval shall not apply to disclosure by Oxford of Edenbridge's support for the Trial in any publications of the results.

20 Assignment

- 20.1 No Party shall or shall purport to assign, transfer, novate, sub-license, charge, or otherwise encumber, create any trust over, or deal in any manner with this Agreement or any of its rights, liabilities, or obligations under this Agreement to any person or entity (whether orally, in writing, by operation of law, or otherwise) without the prior written consent of the other Parties, such consent to not be unreasonably withheld, delayed, or conditioned. Notwithstanding the foregoing, Edenbridge shall have the right to assign this Agreement without prior written consent of the other Parties if in connection with (i) the sale of all or substantially all of its assets to which this Agreement relates or (ii) the sale, license, or other conveyance of Edenbridge's rights to the Products.
- 20.2 This Agreement shall be binding upon and take effect for the benefit of the Parties and their successors and permitted assigns.

21 **Severability**

- 21.1 If any provision of this Agreement (or part of any provision) is found by any court or other authority of competent jurisdiction to be invalid, illegal, or unenforceable, that provision or part-provision shall, to the extent required, be deemed not to form part of this Agreement, and the validity and enforceability of the other provisions of this Agreement shall not be affected.
- 21.2 If a provision of this Agreement (or part of any provision) is found illegal, invalid, or unenforceable, the Parties shall negotiate in good faith to amend such provision such that, as amended, it is legal, valid, and enforceable, and, to the greatest extent possible, achieves the Parties' original commercial intention.

22 **Counterparts**

- 22.1 This Agreement may be signed in counterparts, each of which is an original and all of which together evidence the same agreement. No counterpart shall be effective until each Party has signed at least one counterpart.

23 **Governing Law and Jurisdiction**

- 23.1 This Agreement, and any dispute or claim arising out of or in connection with it or its subject matter or its formation, shall be governed by, and construed in accordance with, the laws of England.
- 23.2 All disputes arising out of or in connection with this Agreement, including any question regarding its existence, validity, or termination, shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce in London by one arbitrator appointed in accordance with the said Rules. The language to be used in the arbitral proceedings shall be English.
- 23.3 All dealings, correspondence, and contacts between the Parties shall be made or conducted in the English language.

This Agreement has been entered into on the date stated at the beginning of it.

Signed by

for and on behalf of

THE UNIVERSITY OF OXFORD

Sophie Baines
.....

14th May 2021
.....

(Dated)

Signed by M. Ryan Collins

for and on behalf of

EDENBRIDGE PHARMACEUTICALS, LLC


.....
CEO


.....

(Dated)

Signed by Emma Rooth

for and on behalf of

TORBAY & SOUTH DEVON NHS FOUNDATION TRUST


.....
Director


.....

(Dated)

Schedule 1

The Services

Verification of Edenbridge & Torbay

	Responsibilities	Torbay	Oxford	Edenbridge
1	Edenbridge warrants that it is the licence holder (Abbreviated New Drug Application) of a current FDA-approved product licence for Products.			X
2	Torbay warrants that it holds a current MIA(IMP) Licence that contains secondary packaging & import activities granted by the MHRA.	X		
3	Edenbridge will advise Torbay of any GMP issues and or changes in the manufacturer of the Products, including supply chain of critical raw material suppliers/intermediates & any such sites have been risk assessed.			X
4	Torbay will advise Oxford of the results of any audit by any agency or company, which could prejudice the quality of any product or service provided.	X		
5	Edenbridge will advise Torbay of the results of any audit by any agency or company, which could prejudice the quality of Products or service provided by Edenbridge related to the Products or services provided by Edenbridge.			X
6	Edenbridge will, at the request of a Regulatory Authority, permit or use commercially reasonable efforts to procure permission for representatives of such Regulatory Authority to inspect all facilities at which the Products are manufactured and all records relevant to such manufacture.			X
7	Edenbridge will, at the request of Torbay, use commercially reasonable efforts to procure permission for Torbay to perform a desktop audit of the finished product manufacturer for Products for the purposes of the QP Declaration of GMP compliance (equivalent to EU GMP) of an investigational medicinal product (IMP) manufactured in a non-EU member state or U.K.			X
8	Torbay will provide reasonable access to its premises for the purpose of quality audit or inspection of ongoing processes by the client/sponsor, their representative or an officer of a competent authority.	X		
9	Edenbridge will forward to Torbay a current supply chain map for the Products.			X
10	Edenbridge will forward Torbay evidence of authorisation granted by the competent authority under which they are supplying pharmaceutical products to Torbay.			X
11	Torbay will import Products into the UK for use in the Trial.	X		
12	Ensure that the relevant import/export documentation is in place before Products are shipped to Torbay.	X		X
13	Torbay will undertake to best endeavours to ensure that over labelling & distribution operations are in accordance with good manufacturing & distribution practice as detailed in The Rules Governing Medicinal Products in the EU - Volume IV (Good Manufacturing Practice for medicinal products) and to annexes governing investigational medicinal products as amended, to meet the requirements stated in IMPD for the Trial.	X		

14	Torbay will not sub-contract work (other than supply of components) without approval from Edenbridge and Oxford.	X		
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Reconciliation

	Responsibilities	Torbay	Oxford	Edenbridge
1	Edenbridge will ensure that the quantities shipped to Torbay are correctly reflected in shipment documentation.			x
2	Torbay will ensure that full reconciliation of the Ivermectin batches is carried out following importation of the batches intended for clinical trial use and any discrepancies communicated to Edenbridge within two (2) business days.	x		
3	Edenbridge is responsible for investigating any stock discrepancies of batches received at Torbay.			x
4	Torbay will ensure that the clinical batches supplied are in accordance with the Order to Manufacture issued by Oxford and that quantities are correctly reflected in all shipment paperwork and QP certification documentation.	x		
5	Oxford shall notify Torbay of any discrepancies in clinical trial batch quantities within two (2) business days.		x	
6	Torbay is responsible for investigating any stock discrepancies shipped to Oxford.	x		

Transportation

	Responsibilities	Torbay	Oxford	Edenbridge
1	Edenbridge will provide Torbay with information on the supply of packs for importation – inclusive of amount, packs, shippers, delivery documents, etc.			X
2	Edenbridge is responsible for a secure transportation process/GDP (good distribution) aspects until picked up by a courier approved by Torbay from the agreed UK airport, including no unapproved transport hubs, temperature is monitored through the chain, times are monitored & excessive journey times avoided. Any deviations will be notified to Torbay.			X
3	Product from Edenbridge will be collected from the agreed UK airport by a courier approved and certified by Torbay and transported to Torbay under GDP requirements.	X		
4	Torbay is responsible for the transportation of clinical trial batches to Oxford in accordance with the storage conditions stipulated in the IMPD using an approved courier.	x		
5	Edenbridge is responsible for evaluation of any temperature excursions outside the recommended storage conditions and supplying Torbay with a statement confirming any impact on the quality of the batches shipped to Torbay.			x
6	Excursions generated during the shipment of clinical trial batches from Torbay to Oxford will be investigated by Torbay with support from Edenbridge to determine the any impact on the quality of the batches.	x		

Storage

	Responsibilities	Torbay	Oxford	Edenbridge
1	Torbay is responsible for receipt, sampling, and Quality Control inspection of Products in accordance with in-house procedures and /or additional processes requested by Oxford.	X		
2	Edenbridge & Oxford will keep reference samples of product at their site for a minimum period of two years following completion or discontinuation of the last clinical trial in which the batch was used, whichever is longer.		X	X
3	Torbay will keep retention samples of the finished clinical trial product for a period of two years following completion or discontinuation of the last clinical trial in which the batch was used, whichever is longer.	x		
4	Edenbridge is responsible for the storage of stability samples, stability studies, and stability data for Products.			X

Labelling

	Responsibilities	Torbay	Oxford	Edenbridge
1	Oxford will provide to Torbay details of the CTA including: • Clinical Trial Reference number & sponsor protocol number; • Critical information in the CTA to enable Torbay to correctly perform operations in accordance with the project requirements; and • Copy of the CTA & the approval (sponsor, regulator etc.)		X	
2	Oxford will provide the text to be included on the label that is to be added to the trial pack (or a copy of the label).		X	
3	Torbay will originate batch documentation where required.	X		
4	Torbay will refrain from any activity, which will knowingly adversely affect the quality of the Products.	X		
5	Torbay will retain documentation pertaining to the Trial in accordance with its archiving procedures unless otherwise agreed.	X		
6	Oxford will provide Torbay with a written request for the specified operations, including any information detailed within the IMPD.		X	
7	Any subsequent amendments requested will be specified and/or approved in writing.		X	
8	Oxford will provide the approved text & format required for the product label.		X	
9	Torbay will ensure that all materials used comply with regulations surrounding TSE.	X		
10	Torbay will advise Oxford as soon as practical for any unplanned deviations that occur which are not in compliance with agreed specifications.	X		

QP Certification and Release

	Responsibilities	Torbay	Oxford	Edenbridge
1	Edenbridge will supply a GMP compliance statement & a CoA detailing results of testing & checks supporting the quality of the Products is in accordance with applicable product licence.			X
2	Edenbridge will supply Torbay with: • Current BSE/TSE statement for the Products; • Nitrosamine assessment for the Products no later than March 1, 2021; • Evidence of compliance with ICH Q3C on residual solvents (where applicable); and • Copy of the Abbreviated New Drug Application Approval Letter issued by the FDA for the Products.			X
3	Certification for Importation and EU/UK GMP equivalence, and QP batch certification will be generated by Torbay & provided to Oxford to certify each batch has been manufactured to equivalent GMP & is consistent with requirements set out in the IMPD and clinical trial application (CTA), including any conditions for approval as accepted by the MHRA.	X		
4	Torbay will provide Qualified Person certification that the product has been processed in compliance with UK/EU GMP and Oxford's requirements described in this Technical Agreement and Product Specification File.	X		
5	Torbay will perform the final QP certification of the finished clinical product for clinical use in accordance with the IMPD and the Clinical Trial Authorisation (and any conditions for approval)	X		
6	Oxford will perform the regulatory green light including ethics committee approval of the Products in the Trial.		X	

Storage & Supply to Oxford

	Responsibilities	Torbay	Oxford	Eden-bridge
1	Torbay will store the product under monitored conditions (temp. 15-25°C) in controlled access areas.	X		
2	Torbay will ship product to Oxford under temperature-controlled conditions in accordance with the IMPD.	X		
3	Torbay will not ship any clinical trial product to clinical sites without formal authorisation to ship issued by Oxford following regulatory green light approval of the clinical trial batches.	x		

Disposal

	Responsibilities	Torbay	Oxford	Edenbridge
1	Torbay will dispose of any used product that is surplus to Oxford's requirements with prior agreement from Edenbridge and the sponsor. This will be documented & records available to Edenbridge and the sponsor, if required.	X		

Complaints & Recall

	Responsibilities	Torbay	Oxford	Edenbridge
1	Any investigation arising from product quality will be discussed between the manufacturer, importer & sponsor. Any quality defect that becomes known will be communicated to all parties.	X	X	X
2	Torbay warrants it has recall procedures in place. Oxford will be responsible for recall of product from Trial sites. Edenbridge will be responsible for recall of the licensed product in the US.	X	X	X
3	Torbay will reserve the right to contact the appropriate regulatory authority in the event of a confirmed quality defect that may result in a recall of stock or restrict of supply in line with requirements of the MHRA's Defective Medicines Reporting Centre with prior notification to Edenbridge and Oxford. A copy of this notification will be provided to Edenbridge and Oxford.	X		

Pharmacovigilance

	Responsibilities	Torbay	Oxford	Edenbridge
1	Oxford is responsible for investigating & reporting any adverse events/reactions that occur during the trial in accordance with UK/EU pharmacovigilance legislation and shall report all serious adverse events to Edenbridge within three (3) calendar days. Oxford will report all other adverse events (i.e., not serious adverse events) to Edenbridge periodically and in parallel with the generation of DMEC reports.		X	
2	Edenbridge is responsible for investigating & reporting any adverse events/reactions that occur in the US in accordance with US pharmacovigilance legislation.			X

Schedule 2

The Service Fees

- All prices quoted are in UK Pounds
- Transportation costs are quoted on next day delivery, for same day delivery process on request
- Any Covid-19 related surcharges will be at cost
- Payment terms – 30 days from date of invoice
- Torbay will be responsible for delivery once the shipment has cleared UK customs

Activity	Fee
Waiting time, if applicable, at Heathrow	£25 per hour – first hour is free
Transportation from Heathrow to Paignton – next day delivery	£250 – maximum charge
QP Release per batch – includes over labelling	£1500
Packaging	FOC
Warehousing & Storage	FOC
Transportation from Torbay Paignton to Oxford	Passthrough expense at Torbay's cost not to exceed £15.00 per carton

