**CLINICAL MASTER SERVICES AGREEMENT**

This Master Services Agreement (this “**Agreement**”) is made and dated as of October 26, 2020 (the “**Effective Date**”) between AstraZeneca having its principal place of business *at* 1 The Strand, London(“**Client**”) and Quotient Sciences – Miami Inc., a Florida corporation having its principal place of business at 3898 NW, 7th Street, Miami, Florida, 33126 USA (“**Company**”). Client and Company may be referred to herein as a “**Party**” and collectively as the “**Parties**.”

RECITALS

WHEREAS, Client and its Affiliates provide services to entities engaged in the development, manufacture and sale of pharmaceutical products, biotechnology products and/or medical devices.

WHEREAS, Company and its Affiliates has experience in, and capabilities suitable for, conduct of clinical research and data science services in relation to pharmaceutical products.

WHEREAS, Company and Client desire to contract to provide the terms upon which Client may engage Company to provide Services (as defined below) by executing one or more Work Orders (as defined below) specifying the details of the Services and the related terms.

NOW, THEREFORE, the Parties agree:

# **Interpretation**

## **Definitions:**

**Affiliate(s):** for this Agreement, an Affiliate of a Party is any person, corporation, joint venture, or other business entity that directly (or indirectly through one or more intermediaries) controls, is controlled by, or is under common control with such Party. For the preceding definition only, the terms “controls,” “controlled,” and “control” shall mean possessing the power to direct or cause the direction of the management and policies of an entity, whether through ownership or control of stock (or other ownership interest), by contract, or otherwise.

**ABPI**: the Association of British Pharmaceutical Industry in the United States of America.

**API**: the substance or mixture of substances intended to be used in manufacturing an IMP and that, when used in the production of a drug, becomes an active ingredient in the IMP to be supplied by the Client.

**Applicable Law:** any statute, law, treaty, judgment, ordinance, rule, administrative interpretation, regulation, guidance, order, code, directive, guideline or other requirement of any Governmental Authority.

**Background Material:** any and all data, Materials, formulation methods, software, know-how, and other Intellectual Property, trade secrets, product samples, prototypes, processes, analyses, reports, manufacturing techniques, compilations, research notes, technology, equipment, providers, inventions and/or discoveries which is/are in existence at the date of this Agreement or which is/are developed or arise(s) independently of any Services.

**Business Day:** a day other than a Saturday, Sunday or public holiday in the jurisdictions of the Parties to this Agreement or a Work Order.

**Change Order:** a written specification of changes to a Work Order agreed and authorized by signature of each Party’s authorized representative(s), in a format substantially similar to Schedule 2 attached.

**Client Data:** documents, data and information relating to any API, IMP and/or Services.

**Clinical Protocol:** a protocol for the conduct of a clinical trial under a Work Order agreed in writing by the contracting Parties.

**Clinical Trial:** a clinical study involving testing experimental Materials on Trial Subjects under GCP conditions.

**Clinical Trial Site(s):** The location(s) where Clinical Trial(s) are actually conducted under Investigator supervision.

**Confidential Information:** Background Material, Intellectual Property and all other information disclosed by one Party to the other in relation to this Agreement, including in relation to the Services, the Services Output, Clinical Protocol, API, IMP, communications with the competent authorities and Ethics Committees, suppliers or employees, sales and marketing information; provided, that, Client Data, Services Output, Clinical Protocol shall be the Confidential Information of Client.

**Data Sciences Plan:** the documents pertaining to the scope and requirements of the execution of data science Services to be performed by Company’s Affiliate Data Sciences Department which includes a protocol document, data management plan and reporting and analysis plan.

**Discloser:** a party to this agreement when it discloses its Confidential Information, directly or indirectly, to the other party.

**Ethics Committee** or **Ethics:** the independent institution responsible for applications for research and giving an opinion about the proposed Trial Subject involvement and whether the research is ethical and specifically:

* 1. for ethics submissions completed in the USA, in accordance with the requirements of submissions to an Institutional Review Board (IRB) 45 CFR 46; or

* 1. for ethics submissions completed in the UK, in accordance with Medicines for Human Use (Clinical Trials) Regulations 2004 Schedules 2 and 3.

**FDA:** the USA Food and Drug Administration.

**Force Majeure:** any circumstance beyond the reasonable control of the Party affected by it and includes, in the case of a Company, industrial disputes, telecommunications failure, power supply failure, computer breakdown, failure of suppliers to meet delivery requirements and absence of personnel due to illness, injury or death.

**GCP:** good clinical practice which shall be defined per the jurisdiction where Services are to be performed:

### for Services performed in the USA as 21 CFR Title 21, Parts 50, 56, and 312; or

### for Services performed

### under any jurisdiction in accordance with the ICH Harmonised Tripartite Guidelines of Good Clinical Practice CPMP/ICH/135/95 and the principles of the World Medical Association Declaration of Helsinki entitled Ethical Principles for the Medical Research Involving Human Subjects (2013 version).

**GMP:** good manufacturing practice which shall be defined per the jurisdiction where Services are to be performed:

### for Services performed in the USA as 21 CFR Parts 210 and 211; or

### for Services performed in the EU as, the Rules Governing Medicinal Products in the European Community Volume 4, including the Investigational Medicinal Products Annex 13 as applied to APIs for Use in the Rules and Guidance to Good Manufacturing Practice Part II, Section 19 and ICH Q7 Section 19, Guidance for Pharmaceutical Manufacturers and Distributors 2017 (MHRA) the Good Manufacturing Practice Directive 2003/94/EC and implementing legislation in the respective territories where the Services are performed (which to avoid doubt shall include the relevant provisions of the Medicines Act (1968) in relation to Services performed in the UK); and

### for Services performed under any jurisdiction as and in accordance with the ICH Harmonised Tripartite Guidelines of Good Manufacturing Practice for Active Pharmaceutical Ingredients CPMP/ICH/4106/00.

**Governmental Authority:** any supranational, international, national, federal, state or local government, court, administrative agency, quasi-governmental or regulatory authority, commission or other governmental authority or instrumentality anywhere in the world.

**HIPAA:** the USA Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §1301 et seq.) as amended from time to time.

**IMP:** the investigational medicinal product to be developed and/or manufactured by Company under a Work Order to this Agreement.

**Informed Consent Form:** the legally effective informed consent of a Trial Subject or a Trial Subject’s legally authorised representative confirming such Trial Subject’s willingness to participate in a particular Clinical Trial, as defined:

### in relation to Services performed in the USA as those under 21 CFR § 50; or

### in relation to services performed in the UK as those under The Medicines for Human Use (Clinical Trials) Regulations 2004and Directive 2001/20/EC.

**Intellectual Property:** all patents, trade marks (trademarks) or trading names (whether or not registered), rights in know-how, design rights (whether or not registered), copyright, trade secret rights, database rights, rights in inventions and know-how, all applications for the same and all rights having equivalent or similar effect, in each case subsisting at anytime, anywhere in the world.

**Investigator:** A person or persons responsible for the conduct of the Clinical Trial at a Clinical Trial Site. If a Clinical Trial is conducted by a team of individuals at a Clinical Trial Site, the Investigator is the responsible leader of the team and may be called the “Principal Investigator”.

**Materials:** any materials and/or substances which are the subject of Services including any excipients, the API and IMP individually and/or collectively.

**MHRA:** the UKMedicines and Healthcare products Regulatory Agency.

**Payment Schedule:** a component of a Work Order that describes the timing of payments due to be made for Services delivered and pass-through expenses incurred.

**Personal Data:** the collection and processing of which may be implied by the Services and related to the Clinical Protocol to be conducted in:

* 1. the USA shall mean and be legally interpreted in line with HIPAA, 45 C.F.R. Parts 160, 162 and 164 as applicable; or

* 1. the EU shall mean the General Data Protection Regulation ((EU) 2016/679) and any national implementing laws.

**Recipient:** a party to this agreement when it receives Confidential Information, directly or indirectly, from the other party.

**Regulatory Authority or Regulatory Authorities:** shall be interpreted as

* 1. the FDA for Services performed in the United States;

## any state or local government agencies or any equivalent government authority in the country where Services are performed with jurisdiction over the conduct of clinical studies in human subjects, such as the European Medicines Agency (“EMA”EU), Health Canada, or the Ministry of Health Labor and Welfare (“MHLW” Japan), and their governing guidelines, laws, rules and regulations as applicable.

**Representative(s):** in relation to each Party:

### its officers and employees;

### its professional advisers, consultants or agents engaged to advise that Party or their Affiliates; and

### its contractors and Subcontractors engaged by that Party and/or their Affiliates.

**Services:** any formulation development, Clinical Trial, drug product manufacturing utilising Materials, data sciences, associated combined offering thereof and/or any other related services to be carried out by Company as to be set out in a Work Order.

**Services Output:** any data, and/or Materials produced by Company, in the course of and relating to Services (whether individually, collectively or jointly with Client on whatever media), which it must deliver to Client under the Work Order, including, without limitation, any reports and case report forms, but excluding any Background Intellectual Property.

**Services Proposal:** the costing and Services outline document set out in the Work Order provided from Company to Client.

**Sponsor:** theSponsor of a Clinical Trial. They are ultimately responsible for oversight of the Clinical Trial and take responsibility for the initiation, management and financing (or arranging of finance) of the Clinical Trial in accordance with and for Clinical Trials conducted in:

* 1. the USA, 21 CFR 312.52; or

* 1. the UK, Regulation 3 of The Medicines for Human Use (Clinical Trial) Regulations 2004.

**Subcontractor**: subcontractors (of whatever level) and Representatives to perform Services under a Work Order between the Parties and contracted by such Parties which are not party to this Agreement, an Affiliate or as otherwise defined this Agreement.

**Term:** has the meaning in **Clause 9.1**.

**Trial Subject:** a person administered and/or who consumes any Materials in connection with a Clinical Trial.

**Work Order**: a document (in substantially the same form as that set out in Schedule 1) describes the scope and price of Services and the payment schedule for such Services as envisaged under Clause 2.1. Any reference to a Work Order incorporates any Change Order (s).

## **Interpretation**.

### References to a statute or statutory provision includes that provision as from time to time modified or re-enacted or consolidated whether before or after this Agreement and any statutory instrument, order, by-law or other provision that may have been or may be made, enacted or re-enacted under it from time to time.

### Any words following the terms “including”, “include”, “in particular”, “for example” or any similar expression shall be construed as illustrative and shall not limit the sense of the words, description, definition, phrase or term preceding those terms.

### Any obligation on a Party not to do something includes an obligation not to allow that thing to be done.

### Any references in this Agreement to Clauses or Schedules are to Clauses of, or Schedules to, this Agreement, and references in a Schedule or part of a Schedule to a paragraph are to paragraphs of that Schedule or part of that Schedule. The Schedules shall have effect as part of this Agreement.

### Headings shall be ignored in construing this Agreement and/or any Work Order.

### In the case of conflict or ambiguity, the order of precedence for this Agreement and the Schedules and Appendix attached to it or under a Work Order and any associated documentation referenced or referred to herein this Agreement shall be:

#### the Clinical Protocol;

#### the clauses of this Agreement;

#### the schedules to this Agreement

### provided that, if any conflict occurs or inconsistency between a term of this Agreement and a term of a Work Order, the term of the Work Order shall (to interpret that Work Order) prevail. If any Schedules, Appendices and associated documentation referenced in this **Clause 1.2 (f)** are not required of the Services being performed under a Work Order, the order of precedence is maintained with the exclusion of such provisions.

# **General Service Requirements**

## **Form of Work Order.** The Parties agree that if, during the Term, Company will perform Services for Client, a Work Order in substantially the form set out in **Schedule 1** will be completed and issued by Client in relation to such Services, and will be executed by both Parties upon agreement.

## **Separate Agreement.** Each such Work Order will constitute a separate contract between the Parties to the Work Order for the performance by Company of Services, and the payment by Client of the amounts set out in the Work Order (and the performance by Client of it's other obligations), under this Agreement and the Work Order.

## **General Compliance.** The Parties to a Work Order shall carry out all obligations in accordance with this Agreement, Work Order and any associated Service Proposal, Clinical Protocol or Data Sciences Plan which may be required in relation to the Services to be performed. Additionally, the Parties shall carry out obligations with reasonable skill and care and in accordance with GCP and GMP as may be applicable in addition to all other Applicable Law and industry standard practices required of the Services under the legal jurisdiction where the Services are to be performed.

## **Notice of Breach.** Company must inform Client within forty eight (48) hours of any serious adverse events and significant deviations from, or breaches of the standards applied to the Services, to enable Client to meet its requirements for reporting such events under Applicable Law.

## **Commitment to Provision of Services.** Company shall use commercially reasonable endeavours to carry out all Services and to deliver the related Services Output under the Work Order and all other requirements set out in **Clause 2.3**.

## **Verification.** All Services to be provided by Company will be deemed provided at Client’s request and Client accepts that it is responsible for verifying those Services are suitable for its own needs.

## **Audit Requirements.**

### **Right to Audit.** During the term of this Agreement and for two (2) years after the expiration or termination of this Agreement and any Work Order, Client shall have the right to audit and inspect documentation related to the Services, including, but not limited to, any financial records of Company directly associated with this Agreement or any Work Order. The foregoing shall be subject to document retention requirements set out under Applicable Law.

### To the extent such records are not separable from other Company records, Company will give reasonable access to the records to an independent auditor selected and contracted by Client who will audit the records pertaining to the Services and may disclose the results of the audit only to the extent it relates to the Services. The Parties agree that such independent auditor may not be a competitor of Company and Company reserves the right to obtain a confidentiality agreement from such independent auditor.

### **Regulatory Authority Audits.** During the term of this Agreement and any Work Order, each Party to the Work Order will permit Regulatory Authorities to examine, (i) the facilities where the Services are being conducted; (ii) study documentation including Client Data; and (iii) any other relevant information, including information that may be designated by one or both Parties to be confidential, which is reasonably necessary for Regulatory Authorities to confirm that the Services are being conducted in compliance with Applicable Law. Each Party will within two (2) Business Days notify the other Party of the Work Order if any Regulatory Authority schedules, or without scheduling, begins an inspection that relates to the Services or to the Parties’ respective obligations. Company shall provide Client with a copy of any inspection report related to the Services under this Agreement or any Work Order.

## **Employee Requirements.** In performing Services, the Parties to a Work Order will (a) assign personnel adequately trained, qualified and experienced to conduct the associated Services and (b) obtain or have obtained from such personnel confidentiality, work-for-hire and intellectual property rights assignment agreements assigning to the Party to the Work Order all rights to any work product developed by such personnel in the performance of the Work Order. Either Party to a Work Order may, at its own discretion, assign elements of the Services to contract employees. The assigning Party will ensure that (a) any contract employees used to perform the Services will be adequately qualified, experienced and trained as required to perform the responsibilities to the Services in the same manner as the contracting Party qualifies and trains its own employees and (b) obtain or have obtained from such contract employees confidentiality, work-for-hire and intellectual property rights assignment agreements assigning to the contracting Party all rights to any work product developed by such contract employees in the performance of the Work Order. The contracting Party will remain responsible for satisfactory performance of all Services performed by contract employees.

## **Employee Cooperation.** Client shall ensure that its employees cooperate fully with Company, its Representatives and any Subcontractors in relation to the provision of Services (including without limitation complying with Company’s normal and reasonable codes of staff and security practice when visiting Company’s site of operation). Client shall comply with its obligations as set out in a Work Order promptly.

## **Accuracy of Data.** The Parties warrant and represent that any and all information disclosed including Client Data and Personal Data shall be disclosed, recorded, stored, extrapolated and Processed accurately and so it is complete and not false or misleading.

## **Timelines.** The Parties will use commercially reasonable efforts to complete any Services under agreed upon timeframes. Such Services may however be subject to a reasonable extension of time to be mutually agreed between the Parties.

## **Use of Affiliates.** The Parties Agree that:

### Company may use the services of Company’s Affiliate(s) to fulfil Company obligations under this Agreement. In such event:

#### the Company Affiliate is to be identified on the Work Order they will be performing under;

#### any Company Affiliate completing Services shall be bound by the terms applicable to Company under this Agreement and entitled to the rights and protections afforded Company under this Agreement; and

#### Company shall be responsible for the performance of its Affiliate.

### Client’s Affiliate may use the services of Company (and its Affiliate) and such Client Affiliate may enter into Work Orders with Company under this Agreement. In such event:

#### the Client Affiliate is to be identified on the Work Order Services will be performed under;

#### Client’s Affiliate(s) shall be bound by the terms applicable to Client under this Agreement and entitled to all rights and protections afforded Client under this Agreement; and

#### Client shall be responsible for the performance of its Affiliate.

### Client may directly retain a Company Affiliate for the performance of Services under this Agreement by such Company Affiliate entering into a Work Order to perform Services. Each Company Affiliate that enters into a Work Order shall be bound by this Agreement and shall have all of the rights and obligations of Company under this Agreement regarding such Work Order. The execution of a Work Order between Client and Company Affiliate shall be evidence of their consent to be so bound.

### Notwithstanding anything to the contrary herein, Company shall have no liability regarding any Work Order entered into directly between Client and Company Affiliate except as otherwise expressly agreed in writing.

# **Clinical Trial Services**

## Client and Company may enter into a Clinical Protocol (which may be called a “**Protocol**”) or formal document under another name provided the relevant provisions are present.

## Under GCP, Client acknowledges its responsibility to ensure that these requirements are in place before Company will perform any Clinical Trial for Client under this Agreement:

* + 1. Informed Consent Forms are understood, agreed to and signed by each Trial Subject covering the details of the Clinical Trial as described in the Services Proposal. Company shall prepare the Services Proposal in accordance with any Clinical Protocol and any amendments supplied by Client;
    2. a suitably qualified Investigator has been selected to oversee the Clinical Trial;
    3. Ethics Committee and any other Regulatory Authority approval has been granted (where required) for the Clinical Trial;
    4. documentation for the transfer of obligations from Client as Sponsor or other entity acting as Sponsor where applicable is agreed upon in writing and formalised which shall for Clinical Trials performed in the USA fully comply with 21 CFR 312.52; and
    5. appropriate and full insurance coverage is in place for the Clinical Trial. This will cover Trial Subject(s) participation in the Clinical Trial.

## If Sponsor is based outside of the EU and the Clinical Trial is to be conducted in the EU, Client will ensure that as Sponsor or the entity acting as Sponsor obtains and retains a legal representative defined in Article 19 of Directive 2001/20/EC throughout the duration of the Clinical Trial. This may be achieved by including Schedule 3 in a contract with Sponsor if not Client so the EU based Company Affiliate acts as Sponsor’s legal representative.

## Company will conduct all aspects of the Clinical Trial under its control in full accordance with the Services Proposal, Clinical Protocol, with reasonable skill and care and GCP including but not limited to the protection of Trial Subject confidentiality including protection of their Personal Data.

## Company shall ensure that all appropriate records are kept in full accordance with GCP and other Applicable Law and shall retain or commit Sponsor to retaining the documentation for at least the minimum period required by Applicable Law.

## Client shall disclose to Company:

### all information and support necessary to enable Company to fulfil all of its obligations under the Applicable Law, including to avoid doubt completing any necessary applications or notifications to the licensing authority under Applicable Law, any Ethics Committee, Regulatory Authority, any Investigator, any other medical practitioner and/or any person subject to or connected with the Clinical Trial; and

### during any Clinical Trial and during preparing any report relating to the same, with all information and data relating to the safety and safe usage of the Materials and in particular all relevant preclinical, clinical and pharmacovigilance information and data, which it has in its possession and which relates to or may affect the Services, and/or Materials, and/or the health and safety of any individual whether before after or during any Clinical Trial relating to the Materials.

## The Client shall promptly notify Company of these events in relation to the Services to enable Company to comply with its regulatory obligations under FDA Final Rule on 21 CFR 320, published in the Federal Register of 28 April 1993 for retention of bioavailability and bioequivalence reserve samples:

### discontinuance of the development of the Services Output;

### submission of an application for approval of the Services Output;

### date of approval of an application for the Services Output;

### withdrawal of an application for the Services Output; and

### date of communication from the regulatory authority documenting that the application is not approved for the Services Output.

# **Supply of Materials and Client Data**

## Client shall promptly supply to Company (or ensure appropriate arrangements are in place thereof), the IMP (with any other agreed upon Materials) and Client Data reasonably required by Company to enable it to perform any Services and authorises Company, its Affiliates and its Subcontractors to use, modify and copy the same to the extent necessary to enable Company to carry out such Services.

## Company shall ensure that it uses IMP and Client Data solely to carry out the Services. Title and risk of loss to Materials supplied by Client shall remain with Client while such items are in the possession of Company and during the services, and Company shall have no obligation to insure such Materials against any loss or damage.

## Company shall maintain accurate records of its use and storage of the IMP, in such format as Client shall reasonably require and shall supply Client with copies thereof upon Client’s reasonable written request.

## As soon as is reasonably practicable following completion of Services Company shall, if so requested in writing by Client, return or destroy and appropriately dispose of any IMP that are Client property which remain unused and any copies of Client Data provided to Company by Client under this Agreement and the Work Order which are in Company’s power, possession or control, save that Company may retain one copy for internal audit or regulatory processes. If after sixty days Client has not taken possession or provided instructions regarding such Materials, they will be considered abandoned and may be discarded according to Company’s established procedures. If needed, Client will be billed for any fees associate with disposition of these materials, components or equipment at cost + 10%.

## Client warrants and represents that it has the right to give to Company the IMP (with any other agreed upon Materials) and Client Data which it provides to Company and that the use by Company and its Subcontractors of such IMP and/or Client Data will not infringe the Intellectual Property rights or other rights of any third party.

# **Financial Terms**

## **General.** The Parties agree that the fees and other reimbursements that Company will receive for performing the Services will be described in each Work Order and are subject to these terms and conditions.

## **Compensation for Services.** Client will pay Company under the terms in this **Section 5** and each applicable Work Order. Each Work Order will include a Payment Schedule for Services to be performed by Company. Company will not perform Services to a value which exceeds the total price in the Payment Schedule without the prior approval of Client in a Change Order, substantially in the form as set out in **Schedule 2** to this Agreement.

## **Pass-Through Costs.** Any pass-through costs will be invoiced to Client for payment and may or may not form part of the Payment Schedule as determined per Work Order.

## **Invoices.** Company will submit invoices to Client according to the Work Order, with referenced to the milestones achieved in the Payment Schedule, and pass-through expenses incurred if separate from the Payment Schedule.

## **Payment Terms.** Client will pay for all Services, pass-through costs and other correctly invoiced items within thirty (30) days of invoice date. All payments will be made in the currency noted in the Payment Schedule of the Work Order. All fees for Services and pass-through costs are exclusive of VAT (including non-refundable VAT), local taxes, charges or remittance fees, for which Client will be additionally liable where applicable.

## **Late Payment.** In the event that undisputed invoiced amounts are not paid by Company under the timeframe set out in **Clause 5.5**, Company reserves the right, at its sole discretion to (i) charge interest against any unpaid overdue balance at the lower of one and a half percent per month or the highest rate permitted by law or (ii) suspend performance of the Services until such time that the overdue amounts are paid. Company reserves the right to suspend work if any disputed invoices have not been resolved within forty-five (45) days of the notification of the dispute. In addition, Company shall be entitled to reimbursement from Client for all expenses (including attorneys’ fees and court costs) incurred by Company regarding collection of overdue invoices or any unpaid amounts owed to Company by Client.

## **Regulatory and Investigative Fees.** Where Clinical Trial Services are performed in the USA under a Work Order to this Agreement, Client will reimburse Company for any fees imposed by a Regulatory Authority imposed because of Company’s engagement by Client and which are not included in the Payment Schedule. Hourly costs of Company’s staff time in handling such Regulatory Authority fees or inquiries will be charged at Company’s then current hourly rates. Such fees and costs may include, without limitation:

### any fee or charge imposed by the FDA under 21 CFR 20.45; or

### Generic Drug User Fees (imposed by the Generic Drug User Fee Amendments of 2012); or Premarket Approvals (“PMAs”), Product Development Protocols (“PDPs”), Biologics Licensing Applications (BLAs for certain medical devices reviewed by FDA’s Center for Biologics Evaluation and Research), certain supplements, and Premarket Notification 510(k)s (authorized by the October 26, 2002 the Medical Device User Fee and Modernization Act of 2002); and any fees imposed by the Prescription Drug User Fee act (“PDUFA”).

# **Confidentiality Obligations.**

## In return for the Discloser providing Confidential Information to the Recipient, the Recipient undertakes to the Discloser it shall:

### keep the Confidential Information secret and confidential;

### not use or exploit the Confidential Information except as intended by the Parties;

### not directly or indirectly disclose or make available any Confidential Information in whole or in part to any person, except as expressly permitted by this Agreement; and

### not copy, reduce to writing or otherwise record the Confidential Information except as strictly necessary for completing Services. Any such copies, reductions to writing and records shall be the property of the Discloser.

## **Permitted disclosure**.

### **Disclosure to Representatives.** The Recipient may disclose the Confidential Information to its Representatives, Affiliates, or their Representatives on the basis that it:

#### informs those Representatives, Affiliates, or their Representatives of the confidential nature of the Confidential Information before it is disclosed;

#### procures those Representatives, Affiliates, or their Representatives comply with the confidentiality obligations in **Clause 6** as if they were the Recipient; and

#### The Recipient shall be liable for the actions or omissions of the Representatives, Affiliates, or their Representatives in relation to the Confidential Information as if they were the actions or omissions of the Recipient.

### **Disclosure to the Serious Fraud Office (UK) and/or the Department of Justice (USA).** The Recipient may, provided that it has reasonable grounds to believe that the Discloser is involved in activity that may constitute a criminal offence under the (UK) Bribery Act 2010, (USA) Foreign Corrupt Practices Act, disclose the Discloser’s Confidential Information to the Serious Fraud Office and/or Department of Justice respectively without first notifying the Discloser of such disclosure.

## **Mandatory disclosure**. Subject to this **Clause 6.3**, a Party may disclose Confidential Information to the minimum extent required by:

### an order of any court of competent jurisdiction or any regulatory, judicial, governmental or similar body or any taxation authority of competent jurisdiction;

### the rules of any listing authority or stock exchange on which its shares or those of any of any Affiliate are listed or traded;

### as required to support an insurance claim; or

### Applicable Law of any country to which its affairs or those of any of Affiliate are subject.

## **Return or destruction of Confidential Information.** If so requested by the Discloser (and in full accordance with Client’s written request) at any time by notice in writing to the Recipient, the Recipient shall:

### destroy or return to the Discloser all documents (and any copies) containing, reflecting, incorporating or based on the Discloser’s Confidential Information;

### erase all the Discloser’s Confidential Information from its computer and communications systems and devices used by it, or which is stored in electronic form;

### to the extent technically and legally practicable, erase all the Discloser’s Confidential Information which is stored in electronic form on systems and data storage services provided by third parties; and

### certify in writing to the Discloser it has complied with the requirements of this **Clause 5.11**.

## Nothing in this **Clause 5.12** shall require the Recipient to return or destroy any documents containing or based on the Discloser’s Confidential Information that the Recipient must retain by Applicable Law, or to satisfy the requirements of a regulatory authority or body of competent jurisdiction or the rules of any listing authority or stock exchange, to which it is subject.

# **Intellectual Property**

## At the request and expense of Client under a Work Order, Company shall do all such things and sign all documents or instruments reasonably necessary to vest as applicable in Client the rights in Services Output.

## Save as set out in **Clause 6.3** and **Clause 6.4**, nothing in this Agreement and/or any Work Order shall transfer or grant any right, title or interest to any Background Material and/or Background Intellectual Property of a Party to the other Party.

## Client grants to Company a royalty-free, non-exclusive licence to use its Background Intellectual Property or other Intellectual Property, in each case solely to the extent necessary for Company to perform its obligations set out in this Agreement and/or any Work Order.

## Company grants to Client as applicable a royalty-free, non-exclusive licence to use its Background Intellectual Property solely to the extent necessary for Client to use and/or develop any Services Output of a Work Order without restriction. Company shall own any improvements to its Background Intellectual Property arising and/or developed by Company in the performance of this Agreement and/or any Work Order and shall be fully entitled to use and exploit as it deems fit any skills, techniques, concepts or know-how acquired, developed or used while performing any Services. To avoid doubt, Company Background Intellectual Property shall in no event include Client Data, Materials (including the API and IMP) or Service Output.

# **Publication**

Each Party may use the name of the other Party in any reputable publication, advertising or news release without the prior written approval of an authorised representative of the respective Party for marketing.

# **Duration and Termination**

## This Agreement shall come into force on the date stated on the front page and shall continue thereafter, unless terminated earlier by agreement of the Parties or under the provisions of this Section 9 (and subject to Clause 9.5) below (“Term”). To avoid doubt, if one Party (or any number of Parties) ceases to be party by this Agreement, the remainder of the Parties shall continue to be bound by the Agreement. Each Work Order shall come into force on the date it has been signed by the Parties and shall (subject to earlier termination under this Section 9 and to Clause 9.5) remain in force until Client has received the final Services Output to be delivered by Company, and Company has received all sums payable to it, under that Work Order.

## Either Party may terminate this Agreement, and/or any Work Order (and the Services) immediately if the other Party enters into liquidation or a provisional liquidator is appointed regarding it, shall pass a resolution or suffer an order of a court to be made for its winding up, or if a receiver, administrator, administrative receiver or manager or similar officer is appointed regarding the whole or any part of its assets, or if a notice of intention to appoint an administrator or an application to appoint an administrator shall be presented or filed regarding it, or suffer a bankruptcy order or if anything analogous or similar to the above occurs to the other in any jurisdiction.

## Either Party may terminate any Work Order (and the Services), forthwith by giving notice in writing to the other Party, if that Party is in material breach of any of its obligations under or in connection with this Agreement and/or a Work Order and (where the breach is capable of remedy) fails to remedy the same within thirty (30) days of a request specifying the breach and requiring it to be remedied.

## Subject to **Clause 9.5**, Client may terminate any Work Order (and the Services) on giving Company not less than thirty (30) days’ notice in writing.

## On termination of any Work Order (whether by termination of the Agreement or by termination of that Work Order Client shall pay to Company (in full without set off or deduction of any kind) any:

### amounts which Company has invoiced to Client but which remain unpaid at the date of termination and/or which Company is entitled to invoice under the Payment Schedule; and

### reimburse and/or pay (as appropriate) to Company all Non-Cancellable Costs expenses as defined in the Work Order and and costs:

#### incurred by Company because of such termination;

#### which have been incurred regarding the Services at the date of termination but not yet invoiced; and/or

#### which Company has not yet incurred but will incur in the future regarding the Services.

## Termination of this Agreement and/or any Work Order shall be without prejudice to all rights and remedies which have accrued before such termination. Any provision of this Agreement and/or any Work Order which expressly or by implication is intended to survive (including, without limitation, **Clauses** **1.2**, **9.5, 9.7** and **Sections 6,** Error! Reference source not found., **7**, **62**, **133** and **18** shall survive the expiry or sooner termination of this Agreement or that Work Order (as applicable). To avoid doubt, if this Agreement terminates, each Work Order shall terminate, it being understood and agreed that termination or expiry of one Work Order shall not of itself affect the continuation of another Work Order or (subject to **Clause 9.1** above) this Agreement.

# **Delays**

## If any part of the Services is delayed at the request of the Client or due to the act or omission of the Client or due to any delay in approving the Services by any Regulatory Authority, Ethics Committee or similar body, then Client shall pay to Company any Non-Cancellable Costs as specified in a Work Order and all increased costs and expenses.

## Company shall use its reasonable endeavors to mitigate the costs and expenses referred to in **Clause 10.1**.

# **Representations and Warranties**

## **No Commitment to Achieving Desired Results**. Both Parties acknowledge and agree that the results of the Services to be provided are inherently uncertain and that, accordingly, there can be no assurance, representation or warranty by Company that the Service Output will be successfully developed or, if so developed, will receive the required approval by any Regulatory Authority.

## **Further USA Compliance.** Company or Affiliate, when conducting Services in the USA represents that it shall fully comply (in so far as applicable) with the Transparency Reporting Provisions of Section 6002 of the Affordable Care Act (42 CFR Parts 402 and 403) (“**the US Sunshine Act**”). Any payments or transfers of value made by Company to “Covered Recipients,” as that term is defined in the U.S. Sunshine Act that may be reportable by Client pursuant to the U.S. Sunshine Act shall be tracked and recorded by Company in sufficient detail.

## **ABPI Requirements.** If Client is commissioning a Clinical Trial in the UK this Agreement, Client confirms that it will ensure that it or Sponsor of the Services where applicable, accepts its obligations to provide compensation for Trial Subjects in line with the UK Regulations and the ABPI Guidelines for Phase 1 Clinical Trials published in 2018 and any relevant guidelines referenced, including but not limited to the Guidance for Insurance and Compensation in the event of injury in Phase I clinical trials and the Clinical Trial Compensation Guidelines issued in November 2014, and any further amendments to these Guidelines as appropriate.

# **Indemnity**

## **General Indemnity Requirements of the Parties.** Each Party shall indemnify and keep indemnified the other Party and shall pay such sums to the indemnified Party as would keep the indemnified Party’s employees, Representatives, Affiliates and Subcontractors indemnified, from and against any and all losses, costs, expenses (including legal expenses), claims, damages and liabilities (collectively “Losses”) arising out of or in connection with any claim made by a third party which result from such Party’s material breach of this Agreement or any Work Order, negligence and/or intentional misconduct or fraudulent misrepresentation (except to the extent caused by the indemnified Party’s negligence and/or intentional misconduct or fraudulent misrepresentation).

## **Client GCP Indemnity.** In relation to the conduct of a Clinical Trial, Client shall indemnify Company, Company’s employees, Representatives and Affiliates, from and against any and all Losses arising out of or in connection with any claim made by a third party which result from Company’s performance of Services and/or administration to and/or consumption by any person of Services Output and/or any Materials during the course of Services. Such indemnity is not subject to any liability limit in **Section 13**. Provided however, that Client shall not be liable under this **Clause 12.2** for any Losses to the extent that these are directly caused by the failure of Company, Company Affiliates or of any Subcontractors to comply with the relevant Clinical Protocol for the Services or to observe GCP.

## If Client is not Sponsor and cannot provide indemnity under this **Clause 12.2**, Client must ensure that a separate Indemnity Agreement is put in place between Sponsor and Company in the form of **Schedule 4** to the Agreement. Client acknowledges that Company cannot begin screening activities on Trial Subjects or undertake a Clinical Trial until such Indemnity Agreement is in place.

## **Client Intellectual Property Indemnity.** Client shall indemnify Company, Company employees, Representatives and Affiliates in respect of any Losses arising from any third party allegation or claim that any use of the Materials and/or Client Data infringes the Intellectual Property of a third party.

## **Further Requirements.** If either Party receives written notice of any third party claim which may cause a right to indemnification from any other Party, the Party seeking indemnification (the “**Indemnified Party**”) shall give written notice thereof to the other Party (the “**Indemnifying Party**”) setting forth the nature and amount of the claim and the basis of the claim for indemnification. The Indemnifying Party, and/or its insurers, may, upon written notice to the Indemnified Party within thirty (30) days of its receipt of the claim for indemnification, subject to the Indemnified Party providing such security as to costs and damages as may reasonably be required, elect to assume defence of the claim; provided, however, that the Indemnifying Party may not, in defence of such claim, consent to the entry of any judgment or enter into any settlement without the consent of the Indemnified Party which does not include, as an unconditional term thereof, a full release of the Indemnified Party in respect thereof. If the Indemnifying Party elects to assume the defence of the third party claim, the Indemnified Party may retain legal counsel at its own expense to participate in the defence; provided, however, that the Indemnifying Party shall be liable to the Indemnified Party for any legal or other expenses incurred by the Indemnified Party in connection with its subsequent assumption of the defence at the request of the Indemnifying Party. If the Indemnifying Party does not elect to assume control of the defence, the Indemnified Party will allow the Indemnifying Party to participate in such defence, at the Indemnifying Party’s own cost and expense, and will not settle or otherwise dispose of the claim without the consent of the Indemnifying Party, which such consent shall not be withheld unreasonably.

# **Limitations of Liability**

## Nothing in this Agreement or any Work Order shall exclude or restrict either Party’s liability for death or personal injury caused by that Party’s negligence and/or intentional misconduct or fraudulent misrepresentation, or to the extent that any restriction or exclusion of liability is prohibited by Applicable Law.

## Subject to **Clause 13.113.1**, Company shall not be liable in contract (including under any indemnity), tort (including negligence), breach of statutory duty or otherwise howsoever for:

### any loss of profit, loss of business, loss of goodwill, loss of contracts, loss of revenues or loss of anticipated savings;

### any increased costs or expenses; or

### any special, indirect, or consequential loss or damage of any nature whatsoever, whatever the cause thereof

in each case arising out of or in connection with this Agreement or any Work Order.

## Subject to **Clause 13.1** the entire liability of any Company to Client arising out of or in connection with a relevant Work Order, whether arising from contract (including under any indemnity), tort (including negligence), or otherwise, shall not exceed the amount stipulated in the Services Proposal for the applicable Work Order or affected Work Orders as to be paid by Client to Company.

## To avoid doubt, if Company becomes liable to Client because of an act or omission in the course of or in relation to a particular Work Order (including, without limitation any act or omission which breaches a term of this Agreement) Client shall subject to Clause 13.1 and Clause 13.2 be entitled only to make a claim against Company under the relevant Work Order or affected Work Orders referred to above and the limit at Clause 13.3 will apply.

## Client accepts that Company cannot act other than in accordance with the terms of any authorisation issued by the Regulatory Authority for any Services and in accordance with the applicable regulations and all other relevant legal duties and obligations, including Applicable Law. Accordingly, Company is not responsible for, and shall have no liability to a Client for any delay, damage, liability or loss of or to Client (whether arising in contract, tort (including negligence) or otherwise) arising from the actions or failure to act of any Regulatory Authority, Governmental Authority or Ethics Committee or as a result of Company’s complying with its obligations under Applicable Law or other legal duty or obligation including any obligation to provide notice or information to others regarding any Services and/or any obligation to safeguard the health and safety of any of its employees, the Trial Subjects or any other person who may be affected by any such Clinical Trial.

## Client will reimburse the Company and/or Trial Subject for reasonable, out-of-pocket standard medical costs incurred for diagnosis and/or treatment of study-related injuries to a Trial Subject to the extent that such diagnosis, injury or illness arose from the study and provided that these conditions are met: (1) the illness or injury reasonably appears at the time to result from the properly administered drug or study procedure; and (2) the illness or injury are not the result of the study doctor/facility’s negligence, wilful misconduct or failure to comply with the Clinical Protocol or any FDA or other governmental requirements or regulations. Payment for Trial Subjects’ lost wages, profits or lost business opportunity will not be provided by Client as part of any Trial Subject injury obligation. The foregoing obligation to reimburse the Company for any costs they may incur is also subject to: (a) the Company’s representation to Client it has not billed to, or sought reimbursement from, any Trial Subject’s insurance provider, a governmental healthcare program or other third party provider for any such medical expenses; and (b) Company’s agreement to receive and, where permissible and medically feasible, treat all Trial Subjects seeking medical diagnoses and treatment of any bodily injury or illness reasonably suspected to be directly related to study procedure or the study drug.

# **Insurance**

## **Insurance of the Parties.** Each Party shall maintain insurance policies adequate to protect against liabilities and risks associated with its respective obligations and responsibilities under this Agreement and any Work Order. Each Party shall provide to the other Party, upon such other Party’s reasonable request from time-to-time, policy documents, certificates and any other relevant documents, as required, evidencing such insurance.

## **Sponsor Requirements.** If a Clinical Trial is to be conducted in the UK, Client must procure in accordance with **Clause 11.3** theappropriate Clinical Trials insurance coverage of Trial Subjects sustaining bodily injury as a result of their participation in the Clinical Trial and the use of the Materials. Such coverage shall provide for no fault insurance with a minimum coverage of GBP five million (£5,000,000). If a Clinical Trial is to be conducted in the US, the Client must procure the appropriate Clinical Trials insurance with a minimum coverage of five million US Dollars ($5,000,000).

# **Data Protection**

## **Compliance with Applicable Law.** Each Party shall, at all times, comply with their respective obligations:

### for USA data subjects under the protection of healthcare information defined under HIPAA, including federal security standards in 45 C.F.R. Part 142 to the extent applicable; and

### for EU data subjects under the General Data Protection Regulation ((EU) 2016/679) and the Privacy, Electronic Communications (EC Directive) Regulations 2003 and specifically for the UK data subjects under the Data Protection Act 2018 and any amendment or superseding directive as appropriate; and

### any other Applicable Law, issued guidance, codes of conduct and similar documents relating to the privacy and security of Personal Data processed by that Party while performing obligations or exercising rights under this Agreement or any applicable Work Order.

## **Further Compliance.** Each Party shall obtain and maintain all necessary notifications or registrations regarding any Processing. The Parties agree to:

### collect, use, disclose, retain and otherwise Process any Personal Data solely as required by this Agreement and any applicable Work Order limited to that which is necessary to perform Services or carry out any other obligations;

### will only grant access to persons who need to have access to the Personal Data for the performance of the Services and or carrying out any other obligations with sufficient obligations of confidentiality in place;

### will notify the other Party if applicable of any legally binding request for disclosure of the Personal Data, unless such disclosure is otherwise prohibited under Applicable Law, and such Disclosing Party commits to reject any non-legally binding requests for disclosure;

### will cooperate with regard ensuring each Party’s right to monitor Processing operations, facilitate the exercise of data subjects’ rights to access/correct/erase their data, where applicable; and

### when Processing Personal Data in relation to Services, the Parties will comply with all applicable privacy policies and any other applicable policies, including, without limitation, ones related to confidentiality and data security as stipulated from time to time.

## **Unauthorised Access.**

### Company will establish adequate controls to prevent a Personal Data Security Breach and/or use or disclosure of Personal Data.

### Company will implement all safeguards that reasonably and appropriately protect the confidentiality, integrity, and security of Personal Data.

# **Debarment**

## **Definitions.** For this **Section 16**, “**Debarred**” or “**Debarment**” includes by reference to USA 21 U.S.C. 335a (a) or (b), US 42 U.S.C. 1320a-7b (f), inclusive, and any and all restrictions or sanctions by the European Commission or any other Governmental Authority or Regulatory Authority or professional body with respect to the performance of scientific or clinical investigations or related to the regulation of a health related product or the provision of health related services.

## **No Debarment.** Company warrants and represents that it has not been Debarred, and has not been convicted of a crime which could lead to debarment of its provision of Services under this Agreement by the FDA in the USA, General Medical Council in the UK or in any relevant jurisdiction pursuant to applicable regulations. Company further warrants and represents that no employee of their Affiliates that shall be involved in the Services has been Debarred, and has been convicted of a crime which could lead to debarment of its provision of services under this Agreement by the FDA in the USA, General Medical Council in the UK or in any relevant jurisdiction pursuant to applicable regulations.

## **Future Notice.** In the event that either Party becomes aware or receives notice of the Debarment of any individual, corporation, partnership or association providing Services to another Party, which relate to the Services being provided under this Agreement or any Work Order, then that Party shall notify the other Party within twenty four (24) hours.

# **General**

## **Bribery**. Each Party warrants it shall not directly or indirectly pay or promise to pay, or authorise the payment of any money, or give, promise to give or authorise giving anything of value on behalf of the other Party to any person or entity, including any government official, political party, healthcare professional or person affiliated with a healthcare organisation, for (a) obtaining or retaining business or securing an improper advantage, (b) influencing their acts or decisions, (c) influencing such person or political party to use its influence with a government or any of its instrumentality, or (d) for any other purpose prohibited by public policies and any anti-bribery laws, including the (UK) Bribery Act 2010, (USA) Foreign Corrupt Practices Act, industry standards and all other applicable professionals codes governing anti-bribery and anti-kickback practices.

## **Subcontracting.** Company may use Subcontractors to conduct elements of a Work Order if Company has obtained in writing consent from Client for each such Subcontractor. If Client objects to any such Company Subcontractor, Client will propose an alternative Subcontractor acceptable to all Parties to a Work Order within a mutually agreeable timeframe.

## Client Selected Subcontractors. If Client requires Company to use a specific subcontractor (“Client Subcontractor”), Company will not be responsible for the performance of Client Subcontractor, and Client will manage the performance of Client Subcontractor (unless the Parties to the Work Order agree in writing to do otherwise, and such management is included as a Service in a Work Order) and be responsible for any delays or changes to the Services timelines or Payment Schedule for Services that result from the performance of Client Subcontractor. Company will notify Client promptly of any performance issues arising out of the use of any such Client Subcontractor. If Client engages a Client Subcontractor, but requires that Company manage or oversee the performance of Client Subcontractor, then Client supply Company with a copy of the contract with Client Subcontractor. If Client requires that Company contract with Client Subcontractor, then Client authorizes Company to do so as Representative on behalf of Client. Client remains responsible for any delays or changes to the Services timelines or Payment Schedule for Services that result from the performance of Client engaged Client Subcontractor.

## **Company Selected Subcontractors**. For Subcontractors selected and contracted directly by Company (“Company Subcontractor”), Company will be responsible for the performance of and will manage the performance of Company Subcontractor.

## **Assignment and other dealings.** No Party shall assign, novate, transfer, mortgage, charge, subcontract, declare a trust over or deal in any other manner with any of its rights and obligations under this Agreement unless all Parties have agreed to such action in writing if under this Agreement or, if such action occurs under a Work Order this Agreement, the Parties to that Work Order.

## **Entire Agreement.**

### This Agreement constitutes the entire Agreement between the parties and supersedes and extinguishes all previous Agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject.

### Each Party agrees that it shall have no remedies in respect of any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this Agreement.

### Except as expressly stated in this Agreement (or a Work Order, in which case such exception will only apply for the purposes of that Work Order) all conditions, warranties, stipulations and other statements whatsoever (except as to title to goods) that would otherwise be implied or imposed by statute, at common law, by a course of dealing or otherwise howsoever are excluded to the fullest extent permitted by Applicable Law.

### The Parties intend each provision of this Agreement and each Work Order to be severable and distinct from the others. If a provision of this Agreement or a Work Order is held to be illegal, invalid or unenforceable, in whole or in part, the Parties intend that the legality, validity and enforceability of the remainder of this Agreement or Work Order (as relevant) shall not be affected.

## **Force Majeure.** Neither Party shall be liable for any failure to perform, or delay in performing, any of its obligations (other than payment and indemnity obligations) if and to the extent that the failure or delay is caused by Force Majeure and the time for performance of the obligation, the performance of which is affected by Force Majeure, shall be extended accordingly.

## **Variation.** No variation or amendment of this Agreement shall be effective unless it is in writing and signed by the parties (or their authorised representatives).

## **Waiver.**

### No failure or delay by a Party to exercise any right or remedy provided under this Agreement or by Applicable Law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy. The rights and remedies of the Parties in connection with this Agreement and any Work Order are cumulative and, except as expressly stated in this Agreement or that Work Order as applicable, are without prejudice to and are not exclusive of any other rights or remedies provided by law or equity or otherwise. Except as expressly stated in this Agreement or any Work Order any right or remedy may be exercised (wholly or partially) from time to time.

### Each Party acknowledges that in entering into this Agreement and/or any Work Order (and any other document to be entered into pursuant to it) it does not rely on any representation, warranty, collateral contract or other assurance of any person (whether Party to this Agreement or otherwise) that is not set out in this Agreement or that Work Order (as applicable) or any document referred to in it. Each Party waives all rights and remedies which, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance. The only remedy available to any Party in respect of any representation, warranty, collateral contract or other assurance set out in this Agreement or a Work Order (or any document referred to in it) is for breach of contract under this Agreement or that Work Order (or the relevant document) as applicable.

### In relation to all matters arising out of or in connection with this Agreement or a Work Order, each of the Parties:

#### waives any objections on the grounds of venue or forum non conveniens or any similar ground; and

#### consents to service of process by mail or in any other manner permitted by Applicable Law.

## **Severance.** If any provision or part-provision of this Agreement is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible, the relevant provision or part-provision shall be deemed deleted. Any modification to or deletion of a provision or part-provision under this clause shall not affect the validity and enforceability of the rest of this Agreement.

## **Notices.**

### Any notice or other communication given to a Party under or in connection with this Agreement shall be in writing, addressed to that Party at its registered office or such other address as that Party may have specified to the other Party in writing in accordance with this clause, and shall be delivered personally, or sent by pre-paid first class post or other next Business Day delivery service or commercial courier.

### A notice or other communication shall be deemed to have been received: if delivered personally, when left at the address stated in herein this Agreement or associated Work Order as applicable if sent by internationally recognized overnight delivery service, at 9 a.m. on the second Business Day after posting; or if delivered by commercial courier, on the date and when the courier’s delivery receipt is signed.

### This clause shall not apply to the service of any proceedings or other documents in any legal action.

### Notices between the Parties shall be sent to “Notices” at the corresponding address given by the parties to the Agreement.

## **Third party rights.** Any person who is not a Party to this Agreement (or a Work Order) cannot enforce any term of this Agreement (or that Work Order, as applicable) under the Contracts (Rights of Third Parties) Act 1999, but this does not affect any right or remedy of a third party which exists or is available apart from that Act.

## **Counterparts.** This Agreement and any associated Work Order may be entered into in several counterparts and by the Parties on separate counterparts, which taken together shall constitute the same instrument. However, this Agreement shall not come into force until all parties have signed at least one counterpart and all Parties have received a copy of such counterparts, or if a Work Order occurs, the Parties to that Work Order.

## **Governing law.** This Agreement and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the laws of the State of Florida.

## **Jurisdiction.** Each Party irrevocably agrees that the courts of the State of Florida shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with this Agreement or its subject matter or formation.

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

| Signed by: .......................................          for and on behalf of Quotient Sciences – Miami Inc.    Position: ..........................................    Date: ………………………………… | Signed by: .......................................          for and on behalf of [**Client**]      Position: ..........................................    Date: ..………………………………. |
| --- | --- |

**Schedule 1**

**WORK ORDER**

**(NUMBER [**♦])

Quotient Reference: QSC [XXXXXX]

Sponsor reference: [e.g. protocol number, study number, molecule name & v.brief description of service (e.g. Ibuprofen CMC, AZD4635 ADME, etc)

**This Agreement** is made on [date]

This Work Order is entered into between [***Insert same details for Customer as used at the start of the main Agreement***] (“Client”) and Quotient Sciences – Miami Inc., a Florida corporation having its principal place of business at 3898 NW, 7th Street, Miami, Florida, 33126 (“**Company**”) and is supplemental, and entered pursuant, to the Master Services Agreement dated [♦] between the Client and Company (“**Agreement**”).

The Parties agree;

1 **Work Order**

This document and its appendices constitute a “Work Order” under the Agreement. The terms set out in the Agreement (including, without limitation, Clause 11 of the Agreement) shall apply to this Work Order.

2 **Services and Payment of Fees and Expenses**

2.1 The specific services to be provided by Company, and the amount(s) to be paid by the Client to Company in return, under this Work Order (with the related timescales, invoicing dates, and invoicing and payment details) are in the following appendices which shall for all purposes form part of this Work Order:

Appendix 1 Proposal

Appendix 2 Payment Schedule

The Services will be conducted at the Company facility at [♦]

3 **Term**

This Work Order shall come into force on the date it has been signed by or on behalf of both Parties and shall remain in force under Clause 8 of the Agreement.

4 **Amendments**

No modification, amendment, or waiver of this Work Order shall be effective unless in writing and duly executed and delivered by each Party to the other.

5 **Signatures**

Signed by the Parties or their duly authorised representatives on the dates set out below

| Signed by  duly authorised for and on behalf of  Quotient Sciences – Miami Inc. | ) |  |
| --- | --- | --- |
| ) |  |
| ) |  |
| Date |  | ……………………………………………… |

| Signed by  duly authorised for and on behalf of  **[*the Customer*]**    Date | ) |  |
| --- | --- | --- |
| ) |  |
| ) | ……………………………………………… |

**Appendix 1 (Work Order Number** [♦])

**Proposal**

[♦][Insert agreed proposal and costing document]

Amount to be paid by the Client: [♦]

**Appendix 2 (Work Order Number** [♦])

**Payment Schedule**

|  | **Payment Milestone – Invoicing Dates** | **Amount** |
| --- | --- | --- |
| 1 |  | 40% |
| 2 |  | 30% |
| 3 |  | 10% |
| 4 |  | 10% |
| 5 |  | 5% |
| 6 |  | 5% |

\*or 4 weeks after dispatch of draft report, whichever is sooner.

The non-cancellable costs for the Services are:

| **Period** | **Dates** | **Amount** |
| --- | --- | --- |
| 1 | [♦] | £[♦] |
| 2 | [♦] | £[♦] |
| 3 | [♦] | £[♦] |
| 4 | [♦] | £[♦] |

Invoices will be addressed to:

Name [♦]

Address [♦]

Phone [♦]

Fax [♦]

Email [♦]

Payments will be made by wire transfer to our HSBC Bank Plc accounts:

| Account number | 271136 |
| --- | --- |
| Account name | QUOTIENT SCIENCES-MIAMI INC |
| Bank name | HSBC Bank USA NA |
| BIC | MRMDUS33 |

Or such other account and/or payment method as Quotient may notify to the Client for that purpose from time to time.

**SCHEDULE 2**

| **Change Order Form** | | |
| --- | --- | --- |
| **Amendment to Master Services Agreement/Work Order*(specify number)*** | | |
| **STUDY/PROJECT NUMBER:** | **CHANGE ORDER NUMBER:** | |
| **COMPANY:** | **COMPANY REFERENCE #:** | |
| **CLIENT:** |  | |
| **DRUG NAME:** | **CLIENT REFERENCE #:** | |
| **PROJECT MANAGER:** | | |
| **DATE OF REQUEST:** | **PREPARED BY:** | |
| **BRIEFLY DESCRIBE ORIGINAL ASSUMPTION AND NEW REQUEST BELOW:**  1.  2.  3. | | |
| **IMPACT:**  o | | |
| **TIMELINES:**  The study Gantt chart version *[number]* dated *[Month] \_\_,* 20\_\_ is included in Appendix 1 by reference. | | |
| **REVISED NON-CANCELLABLE COSTS:**  No modification to non-cancellable costs required/The revised non-cancellable costs for this project are: | | |
| **TIMING:** Effective immediately upon signature | | |
| **REVISED BUDGET:** | | |
| **PAYMENT TERMS:**  Original payment terms:    The revised payment terms for this project are: | | |
| **Amendment:**  This Change Order Form shall constitute a (“**Contract Amendment**”) to the *[****Agreement Name****]* Quotient Sciences – Miami Inc.and ***[Client]*** effective on *[Month] \_\_,* 20\_\_ and shall apply only to the scope of services and revised payment schedule listed or attached. In all other respects the terms of the Agreement shall remain in full force and effect and shall be applied to this Contract Amendment. | | |
| Quotient Sciences – Miami Inc.  Signature……………………………….  Name …………………………………..  Title……………………………………...  Date ……………………………………. | | **Client:**    Signature……………………………….  Name …………………………………..  Title………………………………………  Date ……………………………………. |

*[****SCHEDULE 3***

***[To apply only where Company Affiliate acts as the Legal Representative for Client See Clause 3.3 of the Agreement where clinical services are to be performed in the EU.]***

1. ***The Medicines for Human use (Clinical Trials) Regulations 2004***

*For the purposes of the Regulations, Company agrees that it shall act as Legal Representative for the relevant Services throughout the duration of the Services in addition to the other Services described in this Agreement and/or the Work Order provided that Client fulfils and continues to fulfil all its obligations to Company under this Agreement and the Work Order, including to avoid doubt the obligation to pay all monies due to Company in accordance with this Agreement and the Work Order.*

*Company shall not provide any undertaking to any regulatory authority on behalf of Client without the prior written consent of Client.*

*For the purposes of this* ***Schedule 3*** *any word or phrase with a defined meaning in the regulations shall be construed in this Schedule in accordance with the meanings ascribed in the Medicines for Human Use (Clinical Trials) Regulations 2004 and as amended in 2006.*

*Company shall provide Client with a copy of all correspondence from the regulatory authority relating to the relevant Services upon request from Client and will provide a copy of any authorisation and any notice received from the regulatory authority related to the Services within 2 Business Days of its receipt by Company.]*

**SCHEDULE 4**

**INDEMNITY AGREEMENT**

Quotient Sciences – Miami Inc. (the “**Company**”) has contracted with [\_\_\_\_] (the “**Client**”)**,** who have contracted with [\_\_\_\_](the “**Sponsor**”)**,** to perform Services involving a Clinical Trial**.**

In consideration for Company performing a Clinical Trial and on its undertaking to perform as such in accordance with the agreed Clinical Protocol and with the current industry standards and agreement to comply with the *[Agreement]* and dated *[Month] \_\_,* 20\_\_ between Company and Sponsor, Sponsor has agreed to indemnify Company under these terms:

1. Sponsor indemnifies and holds harmless Company, and their respective employees and Representatives against all claims and proceedings (to include any settlements or ex gratia payments made with the consent of the Parties and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise):

1.1 by or on behalf of Trial Subjects and (or their dependants) against Company or any of their respective employees or Representatives for personal injury (including death) to Trial Subjects arising out of or relating to the administration of Materials under investigation or any clinical intervention or procedure provided for or required by the Clinical Protocol to which the Trial Subjects would not have been exposed but for their participation in the Clinical Trial;

1.2 by Company, their respective employees or Representatives or by or on behalf of a Trial Subject for a declaration concerning the treatment of a Trial Subject who has suffered such personal injury.

2.0 The above indemnity by Sponsor shall not apply to any such claim or proceeding:

2.1 to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of Company, their respective employees or Representatives;

2.2 to the extent that such personal injury (including death) is caused by the failure of Company*,* their respective employees or Representatives to conduct the Clinical Trial in accordance with the Clinical Protocol;

2.3 unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, Companyshall have notified Sponsor in writing of it and shall, upon Sponsor’s request, and at Sponsor’s cost, have permitted Sponsor to have full care and control of the claim or proceeding using legal representation of its own choosing;

2.4 if Company, their respective employees, or Representatives, including the Investigator, shall have made any admission in respect of such claim or proceeding or taken any action relating to such claim or proceeding prejudicial to the defence of it without the written consent of Sponsor such consent not to be unreasonably withheld provided this condition shall not be treated as breached by any statement properly made by Company, or their respective employees or Representatives in connection with the operation of Company’s internal complaint procedures, accident reporting procedures or disciplinary procedures or where such a statement is required by law.

3. Sponsor shall keep Company and its legal advisors fully informed of the progress of any such claim or proceeding, will consult fully with Company on the nature of any defence to be advanced and will settle no such claim or proceeding without the written approval of Company (such approval not to be unreasonably withheld).

1. Without prejudice to **Clause 2.3** above, Company will use its reasonable endeavours to inform Sponsor promptly of any circumstances reasonably thought likely to give rise to any such claim or proceeding of which it is directly aware and shall keep Sponsor reasonably informed of developments in relation to any such claim or proceeding even where Company decides not to make a claim under this indemnity. Likewise, Sponsor shall use its reasonable endeavours to inform Company of any circumstances and shall keep Company reasonably informed of developments in relation to any such claim or proceeding made or brought against Sponsor alone.

1. Company and Sponsor will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Trial Subjects (or their dependants) or concerning such a declaration as referred to in **Clause 1.2** above.

1. *Without prejudice to the foregoing if injury is suffered by a Trial Subject while participating in the Clinical Trial, Sponsor agrees to operate in good faith the guidelines published in 2012 by The Association of the British Pharmaceutical Industry and entitled “Clinical Trial Compensation Guidelines” and shall request the Investigator to make clear to the Trial Subjects that the Clinical Trial is being conducted subject to the Association Guidelines.*

1. For this indemnity, the expression “Representatives” shall be deemed to include without limitation any nurse or other health professional providing Services to Company under a contract for Services or otherwise and any person carrying out work for Company under such a contract connected with such of Company*’s* facilities and equipment as made available for the Clinical Trial.

**This Indemnity Agreement has been entered into on the date stated at the beginning.**

| Signed by: .......................................  for and on behalf of Quotient Sciences – Miami Inc.          Position: ..........................................    Date: ............................................... | Signed by: .......................................  for and on behalf of *[****Sponsor****]*            Position: ..........................................    Date: ............................................... |
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