

TERMS AND CONDITIONS

1. DEFINITIONS

- (a) "Compounds" shall mean development candidates, drug forms, formulations, process materials, chemical samples and chemical intermediates provided by the Client or FDAS; reaction products resulting from chemical or synthetic transformations performed on Client samples; and intermediates represented in reaction schemes related to such transformations; ingredients, enhancers, additives, intermediates or finished foodstuffs provided by the Client or FDAS.
- (b) "Services" shall mean the work to be performed by FDAS which is set forth in purchase orders.
- (c) "Technology" means and includes all technology and technical information that is specific to or has specific application to the Compounds which is developed by the Client, FDAS or its employees, technicians or others working at FDAS, solely or jointly with the Client, during the work set forth in the purchase order. The parties acknowledge and understand that 'Technology' does not include FDAS's Standard Operating Procedures or any software or innovative laboratory methods developed solely by FDAS prior to, during or subsequent to FDA'S provision of Services which has applicability broader than, or may be used to study or analyse matter other than, Compounds.
- (d) Confidential Information shall include but not be limited to:
- information of whatever nature relating to one party which is obtained by the other party, in written, pictorial, electronic or oral form.
 - information of whatever nature relating to FDAS or Client Information.
 - lists or details in relation to the working of any specification, formula, design, process, prototype, model or invention designed, carried on or used by either party or any invention belonging to either party or in respect of which the party is bound by an obligation of confidence to a third party, or any information that is commercially valuable and secret which affords that party a competitive advantage over its competitors.
 - FDAS Information shall include, without limitation information relating to its Standard Operating Procedures, software programs and innovative laboratory methods developed by FDAS.
 - Client Information shall include, without limitation, information relating to the compounds including but not limited to data; know-how; technical and non-technical materials; and compound samples and specification, which the Client shall deliver to FDAS pursuant to the purchase order, or which FDAS may develop during the performance of the services.
 - analyses, compilations, studies and other documents prepared by either party which contain or otherwise reflect or are generated from the information specified in the above paragraphs

The confidentiality obligations shall not apply to Confidential Information or such of it which at the time of disclosure is already within the public domain; is trivial or obvious, or after disclosure comes into the public domain, other than by reason of breach of a party's obligations of confidentiality or which may (otherwise than through the default of a party) become available to the public generally without requiring a significant expenditure of labour skill or money.

2. SCOPE OF WORK

The parties enter into a contract for services ("Services"), including but not limited to analytical testing as described and set out in purchase orders from time to time, on the terms and conditions stated herein. If there is any inconsistency between the special terms of a purchase order and the terms herein, the terms of the purchase order shall prevail. FDAS will perform the Services at the price and timeframe described in the applicable purchase order.

3. PAYMENT

- 3.1 The Client will pay FDAS for Services in accordance with the rates set out in the quotation and in accordance with matters set out in Schedule 2. FDAS will detail all charges for the Services in invoices to be provided to the Client. The Client will pay invoices in £GBP within thirty (30) days of FDAS invoice date. All invoices must list the relevant Client purchase order number and when requested by the Client, the invoice must also list the relevant Client project code.
- 3.2 The Client will reimburse FDAS for all costs associated with the maintenance and upkeep of all equipment purchased and owned by the Client or non-standard equipment purchased by the Client at the Client's request and is being used exclusively for the Client's programs. In cases where the Client has given FDAS written authorisation to use Client purchased equipment on non-Client programs, the Client at all times receive priority use of this equipment should a conflict arise.

4. INTELLECTUAL PROPERTY

- 4.1 FDAS acknowledges that the Client owns all intellectual property with respect to the Client Confidential Information, Compounds and

Technology disclosed by the Client to FDAS or discovered during the Services performed by FDAS under this purchase order, including all results and data related to Compounds.

- 4.2 FDAS agrees to assist in the preparation, prosecution, maintenance, defence, extension, and enforcement at the Client's expense, including executing and having executed, all documents necessary to the file and prosecute patent applications, and to issue, maintain, defend, extend and enforce patents with respect to such information, Compounds, and Technology in the Client's name. FDAS shall execute an assignment of rights to the Client with respect to such patent applications or patents.
- 4.3 Except, and only to the extent necessary for FDAS to use the Compounds to provide Services pursuant to a purchase order, no licence, express or implied, is granted to FDAS under any Client intellectual property right or application for such a right owned or licensed to the Client.
- 4.4 The Client will compensate FDAS on an indemnity basis against any damages (including costs) that may be awarded or agreed to be paid to any third party in respect of any claim or action against FDAS that it infringes the patent copyright registered or unregistered design right or registered or unregistered trade mark rights of any third party (an 'Intellectual Property Infringement') provided that FDAS:-
- Gives notice in writing to the Client of any Intellectual Property Infringement forthwith upon becoming aware of the same;
 - Gives the Client the sole conduct of the defence to any claim or action in respect of an Intellectual Property Infringement and does not at any time admit liability or otherwise settle or compromise or attempt to settle or compromise the said claim or action except upon the express instructions of the Client; and
 - Acts in accordance with the reasonable instructions of the Client and gives to the Client such assistance as it shall reasonably require in respect of the conduct of the said defence including (without prejudice to the generality of the foregoing) the filing of all pleadings and other court process and the provision of all relevant documents and The Client shall reimburse FDAS on an indemnity basis its reasonable costs incurred in complying with the provisions of this sub-clause.
- 4.5 The Client shall have no liability to FDAS in respect of an Intellectual Property Infringement if the same results from any breach of FDAS's obligations under this agreement.

5. REPORTS

At the conclusion of the Services pursuant to any purchase order, FDAS will provide a written report to the Client. FDAS warrants the accuracy of its work but what the Client does with the information in the report or what interpretation the Client puts on the information in the report, is the Client's responsibility. The Client will indemnify FDAS, its employees, consultants, directors and officers from and against any and all liability which FDAS may incur by reason of the Client's use of the results of the Services or use, sale or marketing of the Technology or Compounds.

6. INDEPENDENT CONTRACTOR

The relationship of FDAS to the Client in performance of a purchase order shall be that of independent contractor. No agency, partnership, joint venture or other joint relationship is created hereby, and neither party shall have the authority to bind the other in any respect except as specifically provided in accordance with a purchase order.

7. INDEMNITY

- 7.1 FDAS shall indemnify the Client, its employees, directors and officers for any claims for injuries to persons or damages to personal property which occur on FDAS premises or premises under the exclusive control of FDAS.
- 7.2 As an independent contractor, any personal injury or property damage suffered by FDAS, its employees, directors and officers in the course of carrying out any duties under a purchase order will be FDAS' sole responsibility, except to the extent such personal injury or property damage occurs on the Client's premises and is not wholly the fault of FDAS.
- 7.3 Subject to no limitation on liability for death or personal injury, neither party shall be liable to the other in respect of any event of default for loss of profits, goodwill, or any type of special indirect or consequential loss, even if such loss was reasonably foreseeable or if one party had been advised of the possibility of the other incurring the same.

8. FORCE MAJEURE

- 8.1 For the purpose of this document, "Force Majeure" shall mean any circumstances or events of a like kind which prevent or impede the performance of any party in the execution of a purchase order, which are beyond the reasonable control of the party affected and which are not reasonably foreseeable, or if foreseeable are not avoidable by the adoption of all reasonable precautions, and shall include (without prejudice to the generality of the foregoing) namely: - Acts of God; fire, explosion, flood; acts of terrorism; war; rebellion; riot; acts

of Government; relevant legislation; sabotage; or official strike or similar official labour dispute.

- 8.2 Where any party is unable to perform its obligations under a purchase order by Force Majeure, the party so affected shall give written notice to the other party, giving full details of the circumstances constituting Force Majeure and of the obligations affected. The purchase order shall be suspended for the period during which the Force Majeure continues but no longer, provided that all parties use reasonable commercial endeavours to avoid, circumvent or overcome the Force Majeure circumstances as soon as is reasonably practicable. Forthwith upon Force Majeure ceasing to exist, the party affected shall give written notice of this fact to the other party.
- 8.3 Each party shall be liable for and shall bear all of their own costs, expenses, losses and damages suffered and incurred as a result of Force Majeure.

9 NOTICES

- 9.1 all notices given shall be in writing sent to the other's registered office for the time being.
- 9.2 Notices may be sent by hand delivery, by pre-paid first class post by fax, or (in the case of routine communications relating to orders only) by E-Mail.
- 9.3 Notices will deemed to have been given: -
- 9.3.1 If by hand delivery: at the time of delivery
- 9.3.2 If sent by post on the second business day following the day of posting
- 9.3.3 If sent by fax at the time of transmission and a fax confirmation sheet shall be evidence of transmission
- 9.3.4 If sent by E-Mail (in the case of routine communications relating to orders only) when the notice is received by the party to whom it is addressed is able to access it in an intelligible form (as defined by S.56(1) of Regulation of Investigation Powers Act 1998) and whether the recipient chooses to access it is immaterial

10 COMPLIANCE WITH LAWS

The parties shall comply in all material respects with the requirements of all applicable laws, rules, regulations and orders of applicable government authorities. FDAS shall allow the Client and regulatory inspectors to visit the FDAS' testing laboratories on request.

11 USE OF NAME

The Client and FDAS shall not use, expressly, or by implication, any trademark, trade name, the name of the other, or the name of any other party's staff in any news, publicity release, policy recommendation, advertising, or any commercial communication without the express written approval of the other party.

12 DISPUTE RESOLUTION

In the event of any dispute arising between parties in relation to this contract which cannot be settled by negotiation, or in the case of any other dispute between any of the parties which cannot be settled by negotiation, the parties in question will in good faith, seek to resolve that dispute through mediation under the auspices of the ADR Group of Grove House, Grove Road, Redland, Bristol BS6 6UL before resorting to expert determination. If the dispute is not resolved by mediation within 15 days, or if one of the parties will not participate in the mediation, the dispute may be referred for determination by an expert appointed jointly by the parties or in default of agreement appoint by the President for the time being of the Law Society of England and Wales. The expert's decision shall be final and binding on the parties. The expert's fees shall be borne by such parties, as the expert shall decide.

13 ENTIRE AGREEMENT AND WAIVER

- 13.1 These Terms set out the entire agreement between the parties in relation to the subject matter hereof and supersedes any previous agreement whether written or oral. Each party acknowledges that in entering into this agreement it places no reliance on any representation or warranty in relation to the subject matter of this agreement save as expressly set out in these Terms;
- 13.2 No partial exercise of or failure or delay in exercising any right under these Terms shall constitute a waiver or preclude any other or further exercise of that or any other right;
- 13.3 Save as otherwise provided in these Terms any amendments or variations of or supplements to these Terms shall be of no effect unless agreed in writing and signed by or on behalf of all parties to these Terms;
- 13.4 Neither this agreement nor any terms or conditions contained herein shall be counted as creating a partnership, joint venture, agency or franchise.

14 ASSIGNMENT

Neither party shall be entitled to assign, sub-contract, or otherwise transfer this agreement nor any of its rights or obligations hereunder without the prior written consent of the other (not to be unreasonably withheld or delayed).

15 VAT

Save insofar as otherwise expressly provided all amounts stated in Quotations are expressed exclusive of Value Added Tax and any Value Added Tax arising in respect of any supply made hereunder shall on the issue of a valid tax invoice in respect of the same be paid to the party making such supply by the party to whom it is made in addition to any other consideration payable therefore.

16 SEVERABILITY

- 16.1 In the event that any law, regulation or judicial authority renders any of these terms void or unenforceable to any extent the same shall be deleted from these Terms and be of no further force or effect and the enforceability of the remainder of these Terms shall not be affected;
- 16.2 The restrictions contained in these Terms are considered reasonable by the parties (having taken independent legal advice) but in the event that any such restriction shall be found to be void but would be valid if some part thereof were deleted, or the period of area of application reduced, such restriction shall apply with such modification as may be necessary to make it valid and effective.

17 JURISDICTION AND LAW

The jurisdiction and law applicable to this contract is that of England and Wales

Schedule 1 - Confidentiality

- 1 FDAS shall use any Compounds provided by the Client only for the performance of the Services under these Terms and Conditions, to keep confidential the results of such Services with respect to such Compounds, and return to the Client, or destroy or dispose of any remaining portions of such Compounds at the conclusion of the Services.
- 2 The parties agree to maintain each other's Confidential Information in confidence with the same degree of care it holds its own confidential information. FDAS will not use the information except to perform the Services. Each party will disclose the Information only to its officers and employees directly concerned with the Services, but will neither disclose the information to any third party nor use the Information for any other purpose.
- 3 Each party accepts that the other shall be entitled to injunctive relief in any court of competent jurisdiction restraining the first from committing a breach of these Terms or continuing to disclose any Confidential Information to any legal or natural person. The party in breach will compensate the other on an indemnity basis for any costs, claims, demands or liabilities (including, but not limited to, lawyers' and experts' fees, costs of investigation and costs of settlement) of whatsoever nature arising directly or indirectly out of a breach or threatened breach of its obligations under these Terms. Nothing contained herein shall be construed as prohibiting any party from pursuing any other remedies available to it, either at law or in equity, for such breach or threatened breach including specific performance and recovery of monetary damages.
- 4 In consideration of Confidential Information being made available to the receiving party, it undertakes (as a trustee of such confidential information) to the giving party that
 - (a) it will treat and safeguard as private and confidential all the other party's Confidential Information received or held by it at any time;
 - (b) it will not at any time use the other party's Confidential Information, or permit or assist a third party to use the other party's Confidential Information, to procure a commercial advantage over the other party or in any way which is likely to be directly or indirectly detrimental to the other party;
 - (c) except as may be required by law, or any regulatory body, neither party will at any time without the other party's prior written consent disclose or reveal, or solicit the disclosure of, any of the other party's Confidential Information, whether directly or indirectly, to any person;
 - (d) each party will keep the other party's Confidential Information separate from all other documents and information it may hold;
 - (e) Each party will ensure that proper and secure storage is provided for the other party's Confidential Information and will keep a record of the other party's Confidential Information provided to it and of the location of the Confidential Information and of any persons holding it;
- 5 Upon written request from one party, the other party will immediately return all Confidential Information supplied by the other together with any copies, it will expunge all the other party's Confidential Information from any computer, word processor or other device containing it and will confirm compliance with the above in writing to the requesting party.
- 6 In the event that a party becomes (or is reasonably likely to become) legally required to disclose any Confidential Information, prompt notice shall be given to the other party at the above address so that it may seek an appropriate remedy to prevent disclosure or waive compliance with the provisions of this agreement preventing

7 disclosure. Each will fully cooperate with the other in the event that it elects to challenge the validity of such requirements.

All confidentiality obligations under these Terms shall survive for a minimum period of five (5) years after the purchase order date.

Schedule 2 - Operating guidelines for the Client

Study initiation

FDAS will begin preparing a Test Protocol upon receiving the Client's written acceptance of a Quotation for any study to be performed. FDAS cannot initiate work on any study until authorised by the Client through the Client's approval of a Test Protocol for the study.

Revisions, Amendments and Additions

FDAS reserves the rights to revise quoted costs for any study due to revisions in testing procedures, modifications of test methods, undocumented requirements, or any unforeseen difficulty in executing the study. Test revisions, amendments, report modifications, alternate report formats, copies of laboratory records, additional requests or unforeseen difficulties will be performed and invoiced at the current standard hourly rate, unless other written arrangements exist. All retesting performed that is not directly due to an FDAS error will be billed to the Client. In no event will FDAS begin any work contemplated pursuant to this section without prior written approval provided to FDAS by the Client. All retesting performed due to a FDAS error will not be billed to the Client. Responsibility for charges will be as follows:

Issue	Responsible for associated charges
Assignable Cause due to FDAS	FDAS
Assignable Cause due to the Client	The Client billed at applicable quoted rates for instrument set up and reparations of samples.
Un-assignable Cause	The Client billed at applicable quoted rates for instrument set up and reparations of samples.
FDAS testing errors during an Investigation	FDAS

All required investigational studies or additional Client requests not outlined in the purchase order will be invoiced for the cost of analysis at the current standard hourly rate, plus any associated fees. In no event will FDAS begin any work contemplated by pursuant to this section without prior written approval provided to FDAS by the Client.

Quotation expiration period

A Quotation is valid for thirty (30) days from the date of quotation unless extended by FDAS.

Items billable to the Client

The Client will pay FDAS the actual cost for all reference standards, speciality chemicals, and HPLC or GC columns ordered by FDAS for any study performed pursuant to this purchase order. All out of pocket travel costs incurred by FDAS at the Client's request and on the Client's behalf (such as travel by FDAS staff) shall be billed to the Client as detailed below. FDAS personnel costs for travel time payable by the Client shall be agreed to in advance in writing as per applicable quotations.

Fees

The fees for each study are as per the attached quotation.

Laboratory Record Retention

FDAS will retain laboratory records generated in the conduct of any Study for two (2) years after the date of data generation. Longer retention times can be negotiated if required. Copies of records may be forwarded to a designated archive site at the request (and expense) of the Client. If FDAS should cease business operations before the retention time has elapsed, the records will be returned to the Client or as it directs.

Samples

The Client will provide all samples and reference material required for each study. The samples and standards must arrive at FDAS with all the proper relevant documentation.

Upon issuance of the final report per interval, samples will be stored at FDAS for a period of 60 days. After the 60-day period, samples will not be returned to the Client (unless prior written arrangements for return of the samples have been made). Samples will be disposed of at FDAS, at FDAS's cost. No sample shipped from FDAS for this study will be used in human clinical trials.

Safety

The Client will provide an (MSDS) and all safety and handling data for the samples, standards, and additional materials associated with

each study. If samples are controlled drug substances, teratogenic, cytotoxic, mutagenic, or have any other safety hazards, the Client will provide this information prior to the initiation of the final test protocol. All samples must be shipped in appropriate packaging and clearly labelled.

Sample Handling and Waste Disposal

The Client agrees to provide full information regarding the known hazards and properties of all substances and materials involved in any Study, and where appropriate Material Safety Data Sheets to FDAS. FDAS will return unused portions of test materials unless otherwise instructed by the Client. Laboratory waste will be disposed in accordance with UK regulations. All samples remain the property of the Client.

Regulatory Compliance and Inspection

Unless otherwise agreed upon in writing, each Study will be conducted in compliance with UK Good Laboratory Practices best practice in accordance with all applicable standards from time to time. Prior to participating in any regulatory inspection, FDAS will obtain permission from the Client. The Client in good faith will comply with regulatory requirements pertaining to any Study. To control Study costs, the Client accepts reasonable and documented costs associated with regulatory inspections of the Study.