

TERMS AND CONDITIONS FOR THE SUPPLY OF ASSAY DEVELOPMENT SERVICES

1. INTERPRETATION

THE FOLLOWING DEFINITIONS AND RULES OF INTERPRETATION APPLY IN THESE CONDITIONS.

1.1 Definitions:

Business Day: a day other than a Saturday, Sunday or public holiday in England when banks in London are open for business.

Charges: the charges payable by the Customer for the supply of the Services in accordance with clause 7 (Charges and payment).

Commencement Date: has the meaning given in clause 2.2.

Conditions: these terms and conditions as amended from time to time in accordance with clause 12.5.

Contract: the contract between Biofortuna and the Customer for the supply of Services in accordance with these Conditions.

Control: has the meaning given in section 1124 of the Corporation Tax Act 2010, and the expression change of control shall be construed accordingly.

Customer: the person or firm who purchases Services from Biofortuna.

Customer Default: has the meaning set out in clause 4.3.

Customer Materials: all materials, reagents and any other component that the Customer provides for Biofortuna to utilise as part of the Services.

Deliverables: the deliverables set out in the Quote or Project Plan produced by Biofortuna as agreed with the Customer.

Intellectual Property Rights: patents, rights to inventions, copyright and related rights, trade marks, business names and domain names, rights in get-up and trade dress, goodwill and the right to sue for passing off rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets), and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

Order: the Customer's order for Services as set out in the Customer's written acceptance of Biofortuna's Quote or Project Plan, as the case may be.

Product: the assay developed and/or manufactured under these Conditions as described in an Order.

Project Plan: the detailed description or specification of the Services provided in writing by Biofortuna to the Customer

Quality Standards: the Services as set out in the Quote or Project Plan will be conducted, as far as reasonably practicable, to the ISO13485 standard for Medical Devices which is updated from time to time by the regulatory authorities. Any additional regulatory quality standard that applies to the Services will be detailed in the Quote or the Project Plan.

Quote: a quotation for Services including a description and specification.

Services: the research, development and manufacturing services, including the Deliverables, supplied by Biofortuna to the Customer as set out in the Quote or Project Plan.

Slot(s): the allocated and scheduled time period for the utilisation of the laboratory and manufacturing facilities as required for the Services.

Supplier: Biofortuna Limited registered in England and Wales with company number 06514391 (Biofortuna).

Tests and Testing: means the tests carried out by Biofortuna, the Customer or an agreed third party, as described in the Quote or Project Plan (as applicable) or otherwise agreed between the parties, to ascertain the extent to which the Products comply with the specification in the Order.

1.2 Interpretation:

- (a) A reference to a statute or statutory provision is a reference to it as amended or re-enacted. A reference to a statute or statutory provision includes all subordinate legislation made under that statute or statutory provision.
- (b) 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.
- (c) A reference to **writing** or **written** includes faxes and emails.

2. BASIS OF CONTRACT

- 2.1 The Order constitutes an offer by the Customer to purchase Services in accordance with these Conditions.
- 2.2 The Order shall only be deemed to be accepted when Biofortuna issues written acceptance of the Order at which point and on which date the Contract shall come into existence (**Commencement Date**).
- 2.3 Any samples, drawings, descriptive matter or advertising issued by Biofortuna, and any descriptions or illustrations contained in Biofortuna's catalogues or brochures, are issued or published for the sole purpose of giving an approximate idea of the Services described in them. They shall not form part of the Contract or have any contractual force.
- 2.4 These Conditions apply to the Contract to the exclusion of any other terms that the Customer seeks to impose or incorporate, or which are implied by trade, custom, practice or course of dealing.
- 2.5 Any quotation given by Biofortuna shall not constitute an offer, and is only valid for a period of 20 Business Days from its date of issue.

3. SUPPLY OF SERVICES

- 3.1 Biofortuna shall supply the Services to the Customer in accordance with the Quote or Project Plan in all material respects.
- 3.2 Biofortuna shall supply the Services to the Customer in accordance with the Quality Standards
- 3.3 Biofortuna shall use all reasonable endeavours to meet any performance dates specified the Quote or Project Plan, but any such dates shall be estimates only and time shall not be of the essence for performance of the Services.
- 3.4 Biofortuna reserves the right to amend the specification, if necessary, to comply with any applicable law or regulatory requirement, or if the amendment will not materially affect the nature or quality of the Services, and Biofortuna shall notify the Customer in any such event.
- 3.5 Biofortuna warrants to the Customer that it will use commercially reasonable endeavours to complete the Services and the Services will be provided using reasonable skill and care.
- 3.6 The Customer expressly acknowledges that Biofortuna provides no warranty that the Products developed will meet the Testing requirements or otherwise be fit for purpose as the Services constitute research or development and carry a risk of failure.

4. CUSTOMER'S OBLIGATIONS

- 4.1 The Customer shall:
 - (a) ensure that the terms of the Order and any information it provides as part of the specification in the Order are complete and accurate;
 - (b) co-operate with Biofortuna in all matters relating to the Services;

- (c) provide Biofortuna with such information as Biofortuna may reasonably require in order to supply the Services, and ensure that such information is complete and accurate in all material respects;
 - (d) obtain and maintain all necessary licences, permissions and consents which may be required for the Services before the date on which the Services are to start;
 - (e) comply with all applicable laws, including health and safety laws; and
 - (f) comply with any additional obligations as set out in the Order.
- 4.2 In respect of the Customer Materials, the Customer shall:
- (a) certify to Biofortuna that all Customer Materials are non-hazardous;
 - (b) declare the value of all Customer Materials before shipment to Biofortuna;
 - (c) supply full details and specifications of all Customer Materials prior to and along with any shipment;
 - (d) remain liable for the Customer Materials in the event that the quality of such materials has an impact on the Services or the Deliverables;
 - (e) acknowledge that Biofortuna will use a Goods Inward Material Specification ('GIMS') to control the acceptance of the Customer Materials and, if GIMS is not agreed, that Biofortuna will not be liable for the outcome of the assay development. In these circumstances, Biofortuna will not accept any liability should the Customer subsequently deem the Product unsatisfactory at any point after delivery to the Customer and Biofortuna will invoice the Customer in accordance with the Order;
 - (f) pay for removal, destruction or return of any Customer Materials provided to Biofortuna that do not meet the specification as provide by the Customer in 4.2 (c) above.
- 4.3 If Biofortuna's performance of any of its obligations under the Contract is prevented or delayed by any act or omission by the Customer or failure by the Customer to perform any relevant obligation (**Customer Default**):
- (a) without limiting or affecting any other right or remedy available to it, Biofortuna shall have the right to suspend performance of the Services until the Customer remedies the Customer Default, and to rely on the Customer Default to relieve it from the performance of any of its obligations in each case to the extent the Customer Default prevents or delays Biofortuna's performance of any of its obligations;
 - (b) Biofortuna shall not be liable for any costs or losses sustained or incurred by the Customer arising directly or indirectly from Biofortuna's failure or delay to perform any of its obligations as set out in this clause 4.3; and
 - (c) the Customer shall reimburse Biofortuna on written demand for any costs or losses sustained or incurred by Biofortuna arising directly or indirectly from the Customer Default.

5. DELIVERY AND TESTING OF PRODUCT

- 5.1 Testing of Product:
- (a) The parties shall agree the process for Testing the Product and shall define in writing the parameters for a satisfactory and unsatisfactory outcome from Testing. The agreed and defined process for Testing and outcomes will be specified in the Order. Testing may be the responsibility of either the Customer, Biofortuna or a third party.
 - (b) If Testing is not specified in the Order then Biofortuna and the Customer can rely only on Biofortuna's reasonable commercial endeavours to deliver suitable Product to the Customer. In these circumstances Biofortuna will not accept any liability should the Customer deem the Product unsatisfactory at any point after delivery and Biofortuna will invoice the Customer in accordance with the Order.
 - (c) The party responsible for Testing shall arrange for samples of the Product to be tested according to the specification and within the test period as defined in the Order and shall report the result of the Test to the other party.

- (d) If the result of the Test is not satisfactory (as described in the Order), Biofortuna will utilise the ISO135485 Quality Management System for a root cause analysis of the non-conformance. The parties will cooperate in the investigation and shall discuss the next steps in relation to the development of the Product and whether the Customer requires additional Services.

5.2 Biofortuna shall ensure that:-

- (a) Each delivery of Product is accompanied by a delivery note which shows the date of the Order and the type and quantity of Product (including the code number of Product, where applicable), special storage instructions (if any);
- (b) It states clearly on the delivery note any requirement for the Customer to return any packaging material to Biofortuna. The Customer shall make any such packaging materials available for collection at such times as Biofortuna shall reasonably request. Returns of packaging materials shall be at Biofortuna's expense;
- (c) Each delivery of Product is accompanied by additional documentation (if any) as set out in the Quote or Project Plan.

5.3 Biofortuna shall deliver Product to the location set out in the Order or such other location as the parties may agree at any time after Biofortuna notifies the Customer that Products are ready.

5.4 Customer shall pay Biofortuna for the shipping costs of any Products and shall be responsible for the insurance for the shipment of Product from its collection at Biofortuna's premises.

5.5 Any requests for documentation outside of that in the Quote or Project Plan will be subject to an administrative charge which will be separately quoted for.

6. PRICING

6.1 The Customer and Biofortuna shall agree allocated Slots for the Services and one of the two following options for the calculation of the Charges for the Services prior to the commencement of the Services.

6.2 Flexible pricing shall include the following provisions: -

- (a) No penalty will be charged by Biofortuna to the Customer for cancellation, delay or amendment where such cancellation, delay or amendment occurs no later than one calendar month prior to the allocated Slot.
- (b) One amendment or delay to a Slot within one calendar month will be allowed free of charge. Each and any further amendment or delay will be charged at an additional 25% of the value of the Order applicable to that Slot.
- (c) Cancellation by the Customer within one calendar month of any Slot will incur a Charge which represents 50% of the value of the Order applicable to that Slot as compensation for laboratory days lost to production.

6.3 Fixed pricing shall include the following provisions: -

- (a) Amendments to the Order will not be accepted
- (b) Any delay of more than one week will incur a Charge of £5,000 or 10% of the Order value, whichever is the greater, for each week or part week of delay.
- (c) The maximum Charge for delay will be 100% of the Order value.
- (d) Cancellation at any time after the Order has been placed will be subject to a Charge of 100% of the Order value applicable to that Slot.

7. CHARGES AND PAYMENT

7.1 The Charges for the Services shall be as set out in an Order.

7.2 Biofortuna reserves the right to increase the Charges on an annual basis with effect from each anniversary of the Commencement Date in line with the percentage increase in the Retail Prices Index in the preceding 12-month period and the first such increase shall take effect on the first

anniversary of the Commencement Date and shall be the latest available figure for the percentage increase in the Retail Prices Index.

7.3 Biofortuna shall invoice the Customer:

- (a) in accordance with the milestones as set out in the Order or Project Plan; or
- (b) on completion of the Services; or
- (c) in relation to invoices raised for amendment, delay of cancellation as set out in:
 - (i) Clause 6.3, where the invoice shall be raised on the cancellation of the Slot; or
 - (ii) Clause 6.4, where the invoice shall be raised either on the re-commencement of the Services, the cancellation of the Slot or in the event of the circumstances set out in Clause 6.5.

7.4 The Customer shall pay each invoice submitted by Biofortuna:

- (a) within 30 days of the date of the invoice; and
- (b) in full and in cleared funds to a bank account nominated in writing by Biofortuna; and
- (c) time for payment shall be of the essence of the Contract.

7.5 All amounts payable by the Customer under the Contract are exclusive of amounts in respect of value added tax chargeable from time to time (**VAT**). Where any taxable supply for VAT purposes is made under the Contract by Biofortuna to the Customer, the Customer shall, on receipt of a valid VAT invoice from Biofortuna, pay to Biofortuna such additional amounts in respect of VAT as are chargeable on the supply of the Services at the same time as payment is due for the supply of the Services.

7.6 If the Customer fails to make a payment due to Biofortuna under the Contract by the due date, then, without limiting Biofortuna's remedies under Clause 9, the Customer shall pay interest on the overdue sum from the due date until payment of the overdue sum, whether before or after judgment. Interest under this Clause 7.6 will accrue each day at 4% a year above the Bank of England's base rate from time to time.

7.7 All amounts due under the Contract shall be paid in full without any set-off, counterclaim, deduction or withholding (other than any deduction or withholding of tax as required by law).

8. INTELLECTUAL PROPERTY RIGHTS

8.1 The Intellectual Property Rights in any Customer Materials shall remain with the Customer.

8.2 The Customer shall own the Intellectual Property Rights in any Products developed as part of the Services.

8.3 All Intellectual Property Rights in or arising out of or in connection with the methods for delivery of the Services shall be owned by Biofortuna.

8.4 Biofortuna grants to the Customer, or shall procure the direct grant to the Customer of, a fully paid-up, worldwide, non-exclusive, royalty-free licence during the term of the Contract to copy the Deliverables (excluding materials provided by the Customer) for the purpose of receiving and using the Services and the Deliverables.

8.5 The Customer shall not sub-license, assign or otherwise transfer the rights granted in Clause 8.4.

8.6 The Customer grants Biofortuna a fully paid-up, non-exclusive, royalty-free, non-transferable licence to develop the Products, copy and modify the Customer Material and any other materials provided by the Customer to Biofortuna for the term of the Contract for the purpose of providing the Services to the Customer.

9. LIMITATION OF LIABILITY:

THE CUSTOMER'S ATTENTION IS PARTICULARLY DRAWN TO THIS CLAUSE

- 9.1 The restrictions on liability in this Clause 9 apply to every liability arising under or in connection with the Contract including liability in contract, tort (including negligence), misrepresentation, restitution or otherwise.
- 9.2 Nothing in the Contract limits any liability which cannot legally be limited, including but not limited to liability for:
- (a) death or personal injury caused by negligence;
 - (b) fraud or fraudulent misrepresentation; or
 - (c) breach of the terms implied by section 2 of the Supply of Goods and Services Act 1982 (title and quiet possession).
- 9.3 Subject to Clause 9.2, Biofortuna total liability to the Customer shall not exceed the total value of the Services.
- 9.4 Notwithstanding the total liability set out in Clause 9.3, in the event that the Customer would like to extend the limitation of liability in Clause 9.3 then the Customer shall notify Biofortuna who may then accept an extended liability to a level agreed in writing prior to the Contract being entered into, upon payment by the Customer of the cost of a single insurance premium (if such an insurance policy is available).
- 9.5 This Clause 9.5 sets out specific heads of excluded loss:
- (a) Subject to Clause 9.1, the types of loss listed in Clause 9.5(b) are wholly excluded by the parties.
 - (b) The following types of loss are wholly excluded:
 - (i) loss of profits
 - (ii) loss of sales or business.
 - (iii) loss of agreements or contracts.
 - (iv) loss of anticipated savings.
 - (v) loss of use or corruption of software, data or information.
 - (vi) loss of or damage to goodwill; and
 - (vii) Indirect or consequential loss.
- 9.6 Biofortuna has given commitments as to compliance of the Services with relevant specifications in Clause 3. In view of these commitments, the terms implied by sections 3, 4 and 5 of the Supply of Goods and Services Act 1982 are, to the fullest extent permitted by law, excluded from the Contract.
- 9.7 Unless the Customer notifies Biofortuna that it intends to make a claim in respect of an event within the notice period, Biofortuna shall have no liability for that event. The notice period for Product is 10 days from dispatch of Product to the Customer, the notice period for any other event shall start on the day on which the Customer became, or ought reasonably to have become, aware of its having grounds to make a claim in respect of the event and shall expire 3 months from that date. The notice must be in writing and must identify the event and the grounds for the claim in reasonable detail.
- 9.8 This Clause 9 shall survive termination of the Contract.

10. TERMINATION

- 10.1 Without affecting any other right or remedy available to it, either party may terminate the Contract by giving the other party three months' written notice.
- 10.2 Without affecting any other right or remedy available to it, either party may terminate the Contract with immediate effect by giving written notice to the other party if:

- (a) the other party commits a material breach of any term of the Contract and (if such a breach is remediable) fails to remedy that breach within 30 days of that party being notified in writing to do so;
 - (b) the other party takes any step or action in connection with its entering administration, provisional liquidation or any composition or arrangement with its creditors (other than in relation to a solvent restructuring), being wound up (whether voluntarily or by order of the court, unless for the purpose of a solvent restructuring), having a receiver appointed to any of its assets or ceasing to carry on business or, if the step or action is taken in another jurisdiction, in connection with any analogous procedure in the relevant jurisdiction;
 - (c) the other party suspends, or threatens to suspend, or ceases or threatens to cease to carry on all or a substantial part of its business; or
 - (d) the other party's financial position deteriorates to such an extent that in the terminating party's opinion the other party's capability to adequately fulfil its obligations under the Contract has been placed in jeopardy.
- 10.3 Without affecting any other right or remedy available to it, Biofortuna may terminate the Contract with immediate effect by giving written notice to the Customer:
- (a) if the Customer fails to pay any amount due under the Contract on the due date for payment; or
 - (b) there is a change of Control of the Customer.
- 10.4 Without affecting any other right or remedy available to it, Biofortuna may suspend the supply of Services under the Contract or any other contract between the Customer and Biofortuna if the Customer fails to pay any amount due under the Contract on the due date for payment, the Customer becomes subject to any of the events listed in clause 10.2(b) to clause 10.2(d) or Biofortuna reasonably believes that the Customer is about to become subject to any of them.

11. CONSEQUENCES OF TERMINATION

- 11.1 On termination of the Contract:
- (a) the Customer shall immediately pay to Biofortuna all of Biofortuna's outstanding unpaid invoices and interest and, in respect of Services supplied but for which no invoice has been submitted, Biofortuna shall submit an invoice that includes but is not necessarily limited to those matters in Clauses 6 and 7 of this agreement, which shall be payable by the Customer immediately on receipt; and
 - (b) the Customer shall return all Products and any Deliverables which have not been fully paid for. If the Customer fails to do so, then Biofortuna may enter the Customer's premises and take possession of them. Until they have been returned, the Customer shall be solely responsible for their safe keeping and will not use them for any purpose not connected with the Contract.
- 11.2 Termination or expiry of the Contract shall not affect any rights, remedies, obligations or liabilities of the parties that have accrued up to the date of termination or expiry, including the right to claim damages in respect of any breach of the Contract which existed at or before the date of termination or expiry.
- 11.3 Any provision of the Contract that expressly or by implication is intended to come into or continue in force on or after termination or expiry of the Contract shall remain in full force and effect.

12. GENERAL

- 12.1 **Force majeure.** Neither party shall be in breach of the Contract nor liable for delay in performing, or failure to perform, any of its obligations under the Contract if such delay or failure result from events, circumstances or causes beyond its reasonable control.
- 12.2 **Assignment and other dealings.**
- (a) Biofortuna may at any time assign, mortgage, charge, subcontract, delegate, declare a trust over or deal in any other manner with any or all of its rights and obligations under the Contract.

- (b) The Customer shall not assign, transfer, mortgage, charge, subcontract, delegate, declare a trust over or deal in any other manner with any of its rights and obligations under the Contract without the prior written consent of Biofortuna.

12.3 **Confidentiality.**

- (a) Each party undertakes that it shall not at any time during the Contract, and for a period of five years after termination of the Contract, disclose to any person any confidential information concerning the business, affairs, customers, clients or suppliers of the other party, except as permitted by clause 12.3(b).
- (b) Each party may disclose the other party's confidential information:
 - (i) to its employees, officers, representatives, subcontractors or advisers who need to know such information for the purposes of carrying out the party's obligations under the Contract. Each party shall ensure that its employees, officers, representatives, subcontractors or advisers to whom it discloses the other party's confidential information comply with this clause 12.3; and
 - (ii) as may be required by law, a court of competent jurisdiction or any governmental or regulatory authority.
- (c) Neither party shall use the other party's confidential information for any purpose other than to perform its obligations under the Contract.

12.4 **Entire agreement.**

- (a) The Contract 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 matter.
- (b) Each party acknowledges that in entering into the Contract it does not rely on, and shall have no remedies in respect of any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in the Contract. Each party agrees that it shall have no claim for innocent or negligent misrepresentation or negligent misstatement based on any statement in the Contract.
- (c) Nothing in this clause shall limit or exclude any liability for fraud.

12.5 **Variation.** Except as set out in these Conditions, no variation of the Contract shall be effective unless it is in writing and signed by the parties (or their authorised representatives).

12.6 **Waiver.** A waiver of any right or remedy under the Contract or by law is only effective if given in writing and shall not be deemed a waiver of any subsequent right or default. A failure or delay by a party to exercise any right or remedy provided under the Contract or by law shall not constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict any further exercise of that or any other right or remedy. No single or partial exercise of any right or remedy provided under the Contract or by law shall prevent or restrict the further exercise of that or any other right or remedy.

12.7 **Severance.** If any provision or part-provision of the Contract 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 the Contract.

12.8 **Notices.**

- (a) Any notice or other communication given to a party under or in connection with the Contract shall be in writing and shall be delivered by hand or by pre-paid first-class post or other next working day delivery service at its registered office (if a company) or its principal place of business (in any other case); or sent by fax to its main fax number or sent by email to an address specified in the Quote.
- (b) Any notice or other communication shall be deemed to have been received:

- (i) if delivered by hand, on signature of a delivery receipt or at the time the notice is left at the proper address;
 - (ii) if sent by pre-paid first class post or other next working day delivery service, at 9.00 am on the second Business Day after posting or at the time recorded by the delivery service; or
 - (iii) if sent by email, at the time of transmission, or, if this time falls outside business hours in the place of receipt, when business hours resume. In this *Clause* 12.8(b)(iii), business hours means 9.00am to 5.00pm Monday to Friday on a day that is not a public holiday in the place of receipt.
- (c) This clause does not apply to the service of any proceedings or other documents in any legal action or, where applicable, any other method of dispute resolution.

12.9 Third party rights.

- (a) Unless it expressly states otherwise, the Contract does not give rise to any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of the Contract.
- (b) The rights of the parties to rescind or vary the Contract are not subject to the consent of any other person.

12.10 Governing law. The Contract, 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 law of England and Wales.

12.11 Jurisdiction. Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with the Contract or its subject matter or formation.