



**MOD Terms and Conditions for Less
Complex Requirements**

PA0000002391

Preclinical *in vitro* Cardiovascular Studies

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1 Definitions - In the Contract:

Articles means, in relation to Clause 9 and Schedule 3 only, an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

The Authority means the Secretary of State for Defence of the United Kingdom of Great Britain and Northern Ireland, (referred to in this document as "the Authority"), acting as part of the Crown;

Business Day means 09:00 to 17:00 Monday to Friday, excluding public and statutory holidays;

Contract means the agreement concluded between the Authority and the Contractor, including all terms and conditions, , specifications, plans, drawings, schedules and other documentation, expressly made part of the agreement in accordance with Clause 2.c;

Contractor means the person, firm or company specified as such in the Contract. Where the Contractor is an individual or a partnership, the expression shall include the personal representatives of the individual or of the partners, as the case may be;

Contractor Deliverables means the goods and / or services including packaging (and supplied in accordance with any QA requirements if specified) which the Contractor is required to provide under the Contract in accordance with the schedule of requirements.

Effective Date of Contract means the date stated on the Contract or, if there is no such date stated, the date upon which both Parties have signed the Contract;

Firm Price means a price excluding Value Added Tax (VAT) which is not subject to variation;

Government Furnished Assets (GFA) is a generic term for any MOD asset such as equipment, information or resources issued or made available to the Contractor in connection with the Contract by or on behalf of the Authority;

Hazardous Contractor Deliverable means a Contractor Deliverable or a component of a Contractor Deliverable that is itself a hazardous material or substance or that may in the course of its use, maintenance, disposal, or in the event of an accident, release one or more hazardous materials or substances and each material or substance that may be so released;

Issued Property means any item of Government Furnished Assets (GFA), including any materiel issued or otherwise furnished to the Contractor in connection with the Contract by or on behalf of the Authority;

Legislation means in relation to the United Kingdom any Act of Parliament, any subordinate legislation within the meaning of section 21 of the Interpretation Act 1978, any exercise of Royal Prerogative or any enforceable community right within the meaning of Section 2 of the European Communities Act 1972.

Mixture means a mixture or solution composed of two or more substances;

Notices means all notices, orders, or other forms of communication required to be given in writing under or in connection with the Contract;

Parties means the Contractor and the Authority, and Party shall be construed accordingly;

PPT means a tax called "plastic packaging tax" charged in accordance with Part 2 of the Finance Act 2021;

PPT Legislation means the legislative provisions set out in Part 2 and Schedules 9-15 of the Finance Act 2021 together with any secondary legislation made under powers contained in Part 2 of the Finance Act 2021. This includes, but is not limited to, The Plastic Packaging Tax (Descriptions of Products) Regulations 2021 and The Plastic Packaging Tax (General) Regulations 2022;

Plastic Packaging Component(s) shall have the same meaning as set out in Part 2 of the Finance Act 2021 together with any associated secondary legislation;

Sensitive Information means the information listed as such in Schedule 4, being information notified by the Contractor to the Authority, which is acknowledged by the Authority as being sensitive, at the point at which the Contract is entered into or amended (as relevant) and remains sensitive information at the time of publication;

Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

Transparency Information means the content of this Contract in its entirety, including from time to time agreed changes to this Contract, except for (i) any information which is exempt from disclosure in accordance with the provisions of the Freedom of Information Act 2000 (FOIA) or the Environmental Information Regulations Act 2004 (EIR), which shall be determined by the Authority, and (ii) any Sensitive Information.

2 General

- a. The Contractor shall comply with all applicable Legislation, whether specifically referenced in this Contract or not.
- b. Any variation to the Contract shall have no effect unless expressly agreed in writing and signed by both Parties.
- c. If there is any inconsistency between these terms and conditions and the associated documents expressly referred to therein, the conflict shall be resolved according to the following descending order of priority:
 - (1) the terms and conditions;
 - (2) the schedules; and
 - (3) the documents expressly referred to in the agreement.
- d. Neither Party shall be entitled to assign the Contract (or any part thereof) without the prior written consent of the other Party.
- e. Failure or delay by either Party in enforcing or partially enforcing any provision of the Contract shall not be construed as a waiver of its rights or remedies. No waiver in respect of any right or remedy shall operate as a waiver in respect of any other right or remedy.
- f. The Parties to the Contract do not intend that any term of the Contract shall be enforceable by virtue of the Contracts (Rights of Third Parties) Act 1999 by any person that is not a Party to it.
- g. The Contract and any non-contractual obligations arising out of or in connection with it shall be governed by and construed in accordance with English Law, and subject to Clause 15 and without prejudice to the dispute resolution procedure set out therein, the Parties submit to the exclusive jurisdiction of the English courts. Other jurisdictions may apply solely for the purpose of giving effect to this Clause 2.g and for enforcement of any judgement, order or award given under English jurisdiction.

3 Application of Conditions

- a. These terms and conditions, schedules and the specification govern the Contract to the entire exclusion of all other terms and conditions. No other terms or conditions are implied.
- b. The Contract constitutes the entire agreement and understanding and supersedes any previous agreement between the Parties relating to the subject matter of the Contract.

4 Disclosure of Information

- a. Information received or in connection with the Contract shall be managed in accordance with DEFCON 531 (SC1) and Clause 5.

5 Transparency

- a. Notwithstanding any other condition of this Contract, including DEFCON 531 (SC1), the Contractor understands that the Authority may publish the Transparency Information to the general public.
- b. Subject to Clause 5.c, the Authority shall publish and maintain an up-to-date version of the Transparency Information in a format readily accessible and reusable by the general public under an open licence where applicable.
- c. If, in the Authority's reasonable opinion, publication of any element of the Transparency Information would be contrary to the public interest, the Authority shall be entitled to exclude such information from publication. The Authority acknowledges that it would expect the public interest by default to be best served by publication of the Transparency Information in its entirety. Accordingly, the Authority acknowledges that it shall only exclude Transparency Information from publication in exceptional circumstances and agrees that where it decides to exclude information from publication on that basis, it will provide a clear statement to the general public explaining the categories of information that have been excluded from publication and reasons for withholding that information.
- d. The Contractor shall assist and co-operate with the Authority as reasonably required to enable the Authority to publish the Transparency Information, in accordance with the principles set out above. Where the Authority publishes Transparency Information, it shall:
- (1) before publishing redact any information that would be exempt from disclosure if it was the subject of a request for information under the FOIA and/or the EIR, for the avoidance of doubt, including the Sensitive Information.
 - (2) taking into account the Sensitive Information set out in Schedule 4, consult with the Contractor where the Authority intends to publish information which has been identified as Sensitive Information. For the avoidance of doubt the Authority, acting reasonably, shall have absolute discretion to decide what information shall be published or be exempt from disclosure in accordance with the FOIA and/or the EIR; and
 - (3) present information in a format that assists the general public in understanding the relevance and completeness of the information being published to ensure the public obtain a fair view on how this Contract is being performed.

6 Notices

- a. A Notice served under the Contract shall be:
- (1) in writing in the English language;
 - (2) authenticated by signature or such other method as may be agreed between the Parties;
 - (3) sent for the attention of the other Party's representative, and to the address set out in the Contract;
 - (4) marked with the number of the Contract; and
 - (5) delivered by hand, prepaid post (or airmail), facsimile transmission or, if agreed in the Contract, by electronic mail.
- b. Notices shall be deemed to have been received:
- (1) if delivered by hand, on the day of delivery if it is the recipient's Business Day and otherwise on the first Business Day of the recipient immediately following the day of delivery;
 - (2) if sent by prepaid post, on the fourth Business Day (or the tenth Business Day in the case of airmail) after the day of posting;
 - (3) if sent by facsimile or electronic means:
 - (a) if transmitted between 09:00 and 17:00 hours on a Business Day (recipient's time) on completion of receipt by the sender of verification of the transmission from the receiving instrument; or
 - (b) if transmitted at any other time, at 09:00 on the first Business Day (recipient's time) following the completion of receipt by the sender of verification of transmission from the receiving instrument.

7 Intellectual Property

- a. The Contractor shall as its sole liability keep the Authority fully indemnified against an infringement or alleged infringement of any intellectual property rights or a claim for Crown use of a UK patent or registered design caused by the use, manufacture or supply of the Contractor Deliverables.
- b. The Authority shall promptly notify the Contractor of any infringement claim made against it relating to any Contractor Deliverable and, subject to any statutory obligation requiring the Authority to respond, shall permit the Contractor to have the right, at its sole discretion to assume, defend, settle or otherwise dispose of such claim. The Authority shall give the Contractor such assistance as it may reasonably require to dispose of the claim and will not make any statement which might be prejudicial to the settlement or defence of the claim.
- c. Notwithstanding any other provisions of the Contract and for the avoidance of doubt, award of the Contract by the Authority and placement of any contract task under it does not constitute an authorisation by the Crown under Sections 55 and 56 of the Patents Act 1977 or Section 12 of the Registered Designs Act 1949. The Contractor acknowledges that any such authorisation by the Authority under its statutory powers must be expressly provided in writing, with reference to the acts authorised and the specific intellectual property involved.

Notification of Intellectual Property Rights (IPR) Restrictions

- d. Where any of the Conditions listed below (1 to 4) have been added to these Conditions of the Contract as Project Specific DEFCONs at Clause 21, the Contractor warrants and confirms that all Intellectual Property Rights restrictions and associated export restrictions relating to the use or disclosure of the Contractor Deliverables that are notifiable under those Conditions, or of which the Contractor is or should reasonably be aware as at Effective Date of Contract, are disclosed in Schedule 5 (Notification of Intellectual Property Rights (IPR) Restrictions):
- (1) DEFCON 15 - including notification of any self-standing background Intellectual Property;
 - (2) DEFCON 90 - including copyright material supplied under clause 5;
 - (3) DEFCON 91 - limitations of Deliverable Software under clause 3b;
 - (4) DEFCON 703 – Intellectual Property Vesting in the Authority
- e. The Contractor shall promptly notify the Authority in writing if they become aware during the performance of the Contract of any required additions, inaccuracies or omissions in Schedule 5.
- f. Any amendment to Schedule 5 shall be made in accordance with DEFCON 503 (SC1).

8 Supply of Contractor Deliverables and Quality Assurance

- a. This Contract comes into effect on the Effective Date of Contract.
- b. The Contractor shall supply the Contractor Deliverables to the Authority at the Firm Price stated in the Contract.

- c. The Contractor shall ensure that the Contractor Deliverables:
- (1) correspond with the specification;
 - (2) are of satisfactory quality (within the meaning of the Sale of Goods Act 1979, as amended) except that fitness for purpose shall be limited to the goods being fit for the particular purpose held out expressly by or made known expressly to the Contractor and in this respect the Authority relies on the Contractor's skill and judgement; and
 - (3) comply with any applicable Quality Assurance Requirements specified in the Contract.
- d. The Contractor shall apply for and obtain any licences required to import any material required for the performance of the Contract in the UK. The Authority shall provide to the Contractor reasonable assistance with regard to any relevant defence or security matter arising in the application for any such licence.

9 Supply of Data for Hazardous Substances, Mixtures and Articles in Contractor Deliverables

- a. Nothing in this Clause 9 shall reduce or limit any statutory duty or legal obligation of the Authority or the Contractor.
- b. As soon as possible and in any event within the period specified in the Contract (or if no such period is specified no later than one month prior to the delivery date), the Contractor shall provide to the Authority's representatives in the manner and format prescribed in the Contract:
- (1) confirmation as to whether or not to the best of its knowledge any of the Contractor Deliverables contain hazardous Substances, Mixtures or Articles; and
 - (2) for each Substance, Mixture or Article supplied in meeting the criteria of classification as hazardous in accordance with the GB Classification, Labelling and Packaging (GB CLP) a UK REACH compliant Safety Data Sheet (SDS);
 - (3) where Mixtures supplied do not meet the criteria for classification as hazardous according to GB CLP but contain a hazardous Substance an SDS is to be made available on request; and
 - (4) for each Article whether supplied on its own or part of an assembly that contains a Substance on the UK REACH Authorisation List, Restriction List and / or the Candidate List of Substances of Very High Concern (SVHC) in a proportion greater than 0.1% w/w of the Article, sufficient information, available to the supplier, to allow safe use of the Article including, as a minimum, the name of that Substance.
- c. For substances, Mixtures or Articles that meet the criteria list in clause 9.b above:
- (1) if the Contractor becomes aware of new information which may affect the risk management measures or new information on the hazard, the Contractor shall update the SDS/safety Information and forward it to the Authority and to the address listed in Schedule 3; and
 - (2) if the Authority becomes aware of new information that might call into question the appropriateness of the risk management measures identified in the safety information supplied, shall report this information in writing to the Contractor.
- d. If the Substances, Mixtures or Articles in Contractor Deliverables are Ordnance, Munitions or Explosives (OME), in addition to the requirements of the GB CLP and UK REACH the Contractor shall comply with hazard reporting requirements of DEF STAN 07-085 Design Requirements for Weapons and Associated Systems.
- e. If the Substances, Mixtures or Articles in Contractor Deliverables, are or contain or embody a radioactive substance as defined in the Ionising Radiation Regulations SI 2017/1075, the Contractor shall additionally provide details on DEFFORM 68 of:
- (1) activity; and
 - (2) the substance and form (including any isotope).
- f. If the Substances, Mixtures and Articles in Contractor Deliverables have magnetic properties which emit a magnetic field, the Contractor shall additionally provide details on DEFFORM 68 of the magnetic flux density at a defined distance, for the condition in which it is packed.
- g. Failure by the Contractor to comply with the requirements of this Condition shall be grounds for rejecting the affected Substances, Mixtures and Articles in Contractor Deliverables. Any withholding of information concerning hazardous Substance, Mixtures or Articles in Contractor Deliverables shall be regarded as a material breach of Contract under Condition 18 (Material Breach) for which the Authority reserves the right to require the Contractor to rectify the breach immediately at no additional cost to the Authority or to terminate the Contract in accordance with Condition 18.
- h. Where delivery is made to the Defence Fulfilment Centre (DFC) and / or other Team Leidos location / building, the Contractor must comply with the Logistic Commodities and Services Transformation (LCST) Supplier Manual.

10 Delivery / Collection

- a. The Contract shall specify whether the Contractor Deliverables are to be delivered to the consignee by the Contractor or collected from the consignor by the Authority.
- b. Title and risk in the Contractor Deliverables shall pass from the Contractor to the Authority on delivery or on collection in accordance with Clause 10.a.
- c. The Authority shall be deemed to have accepted the Contractor Deliverables within a reasonable time after title and risk has passed to the Authority unless it has rejected the Contractor Deliverables within the same period.

11 Marking of Contractor Deliverables

- a. Each Contractor Deliverable shall be marked in accordance with the requirements specified in Contract, or if no such requirement is specified, the Contractor shall mark each Contractor Deliverable clearly and indelibly in accordance with the requirements of the relevant DEF-STAN 05-132 as specified in the contract or specification. In the absence of such requirements, the Contractor Deliverables shall be marked with the MOD stock reference, NATO Stock Number (NSN) or alternative reference number specified in the schedule of requirements.
- b. Any marking method used shall not have a detrimental effect on the strength, serviceability or corrosion resistance of the Contractor Deliverables.
- c. The marking shall include any serial numbers allocated to the Contractor Deliverable.
- d. Where because of its size or nature it is not possible to mark a Contractor Deliverable with the required particulars, the required information should be included on the package or carton in which the Contractor Deliverable is packed, in accordance with Condition 12 (Packaging and Labelling (excluding Contractor Deliverables containing Ammunition or Explosives)).

12 Packaging and Labelling of Contractor Deliverables (Excluding Contractor Deliverables Containing Ammunition or Explosives)

- a. The Contractor shall pack or have packed the Contractor Deliverables in accordance with any requirements specified in the Contract and Def Stan 81-041 (Part 1 and Part 6).
- b. The Contractor shall establish if the Contractor Deliverables are, or contain, Dangerous Goods as defined in the Regulations set out in this Clause 12. Any that do shall be packaged for UK or worldwide shipment by all modes of transport in accordance with the following unless otherwise specified in the Contract:
 - (1) the Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO), IATA Dangerous Goods Regulations;
 - (2) the International Maritime Dangerous Goods (IMDG) Code;
 - (3) the Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID); and
 - (4) the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR).
- c. Certification markings, incorporating the UN logo, the package code and other prescribed information indicating that the package corresponds to the successfully designed type shall be marked on the packaging in accordance with the relevant regulation.

13 Plastic Packaging Tax

- a. The Contractor shall ensure that any PPT due in relation to this Contract is paid in accordance with the PPT Legislation.
- b. The Contract Price includes any PPT that may be payable by the Contractor in relation to the Contract.
- c. On reasonable notice being provided by the Authority, the Contractor shall provide and make available to the Authority details of any PPT they have paid that relates to the Contract.
- d. The Contractor shall notify the Authority, in writing, in the event that there is any adjustment required to the Contract Price in accordance with section 70 of the Finance Act 2021 and, on reasonable notice being provided by the Authority, the Contractor shall provide any such information that the Authority requires in relation to any such adjustment.
- e. In accordance with DEFCON 609 (SC1) the Contractor (and their sub-contractors) shall maintain all records relating to PPT and make them available to the Authority when requested on reasonable notice for reasons related to the Contract.
- f. Where the Contractor manufactures, purchases or imports into the UK any Plastic Packaging Component in relation to the Contract the Contractor shall, on reasonable notice being given, provide the Authority with such information and documentation that it requires to enable the Authority to carry out due diligence checks and satisfy itself that the Contractor has complied with the requirements of the PPT Legislation. This shall include, but is not limited to the Contractor providing:
 - (1) confirmation of the tax status of any Plastic Packaging Component;
 - (2) documents to confirm that PPT has been properly accounted for;
 - (3) product specifications for the packaging components, including, but not limited to, the weight and composition of the products and any other product specifications that may be required; and
 - (4) copies of any certifications or audits that have been obtained or conducted in relation to the provision of Plastic Packaging Components.
- g. The Authority shall have the right, on providing reasonable notice, to physically inspect or conduct an audit on the Contractor, to ensure any information that has been provided in accordance with clause 13.f above is accurate.
- h. In the event the Contractor is not required to register for PPT they (and to the extent applicable, their sub-contractors) shall provide the Authority with a statement to this effect and, to the extent reasonably required by the Authority on reasonable notice, supporting evidence for that statement.
- i. The Contractor shall provide, on the Authority providing reasonable notice, any information that the Authority may require from the Contractor for the Authority to comply with any obligations it may have under the PPT Legislation.

14 Progress Monitoring, Meetings and Reports

The Contractor shall attend progress meetings and deliver reports at the frequency or times (if any) specified in the Contract and shall ensure that its Contractor's representatives are suitably qualified to attend such meetings. Any additional meetings reasonably required shall be at no cost to the Authority.

15 Payment

- a. Payment for Contractor Deliverables will be made by electronic transfer and prior to submitting any claims for payment under clause 15b the Contractor will be required to register their details (Supplier on-boarding) on CHES (CHES is the Dstl Finance and Payment System)
- b. Where the Contractor submits an invoice to the Authority in accordance with clause 15a, the Authority will consider and verify that invoice in a timely fashion.
- c. The Authority shall pay the Contractor any sums due under such an invoice no later than a period of 30 days from the date on which the Authority has determined that the invoice is valid and undisputed. Invoices shall only be valid: (1) following receipt of the associated Contractor Deliverables by the Authority and (2) once the Authority has had a reasonable chance to review the Contractor Deliverable.
- d. Where the Authority fails to comply with clause 15b and there is undue delay in considering and verifying the invoice, the invoice shall be regarded as valid and undisputed for the purpose of clause 15c after a reasonable time has passed.
- e. The approval for payment of a valid and undisputed invoice by the Authority shall not be construed as acceptance by the Authority of the performance of the Contractor's obligations nor as a waiver of its rights and remedies under this Contract.
- f. Without prejudice to any other right or remedy, the Authority reserves the right to set off any amount owing at any time from the Contractor to the Authority against any amount payable by the Authority to the Contractor under the Contract or under any other contract with the Authority, or with any other Government Department.

16 Dispute Resolution

- a. The Parties will attempt in good faith to resolve any dispute or claim arising out of or relating to the Contract through negotiations between the respective representatives of the Parties having authority to settle the matter, which attempts may include the use of any alternative dispute resolution procedure on which the Parties may agree.
- b. In the event that the dispute or claim is not resolved pursuant to Clause 16.a the dispute shall be referred to arbitration and shall be governed by the Arbitration Act 1996. For the purposes of the arbitration, the arbitrator shall have the power to make provisional awards pursuant to Section 39 of the Arbitration Act 1996.
- c. For the avoidance of doubt it is agreed between the Parties that the arbitration process and anything said, done or produced in or in relation to the arbitration process (including any awards) shall be confidential as between the Parties, except as may be lawfully required in

judicial proceedings relating to the arbitration or otherwise. No report relating to anything said, done or produced in or in relation to the arbitration process may be made beyond the tribunal, the Parties, their legal representatives and any person necessary to the conduct of the proceedings, without the concurrence of all the Parties to the arbitration.

17 Termination for Corrupt Gifts

The Authority may terminate the Contract with immediate effect, without compensation, by giving written notice to the Contractor at any time after any of the following events:

- a. where the Authority becomes aware that the Contractor, its employees, agents or any sub-contractor (or anyone acting on its behalf or any of its or their employees):
 - (1) has offered, promised or given to any Crown servant any gift or financial or other advantage of any kind as an inducement or reward;
 - (2) commits or has committed any prohibited act or any offence under the Bribery Act 2010 with or without the knowledge or authority of the Contractor in relation to this Contract or any other contract with the Crown;
 - (3) has entered into this or any other contract with the Crown in connection with which commission has been paid or has been agreed to be paid by it or on its behalf, or to its knowledge, unless before the contract is made particulars of any such commission and of the terms and conditions of any such agreement for the payment thereof have been disclosed in writing to the Authority.
- b. In exercising its rights or remedies to terminate the Contract under Clause 17.a. the Authority shall:
 - (1) act in a reasonable and proportionate manner having regard to such matters as the gravity of, and the identity of the person committing the prohibited act;
 - (2) give due consideration, where appropriate, to action other than termination of the Contract, including (without being limited to):
 - (a) requiring the Contractor to procure the termination of a subcontract where the prohibited act is that of a Subcontractor or anyone acting on its or their behalf;
 - (b) requiring the Contractor to procure the dismissal of an employee (whether its own or that of a Subcontractor or anyone acting on its behalf) where the prohibited act is that of such employee.
- c. Where the Contract has been terminated under Clause 17.a. the Authority shall be entitled to purchase substitute Contractor Deliverables from elsewhere and recover from the Contractor any costs and expenses incurred by the Authority in obtaining the Contractor Deliverables in substitution from another supplier.

18 Material Breach

In addition to any other rights and remedies, the Authority shall have the right to terminate the Contract (in whole or in part) with immediate effect by giving written notice to the Contractor where the Contractor is in material breach of their obligations under the Contract. Where the Authority has terminated the Contract under Clause 18 the Authority shall have the right to claim such damages as may have been sustained as a result of the Contractor's material breach of the Contract.

19 Insolvency

The Authority shall have the right to terminate the contract if the Contractor is declared bankrupt or goes into liquidation or administration. This is without prejudice to any other rights or remedies under this Contract.

20 Limitation of Contractor's Liability

- a. Subject to Clause 20.b the Contractor's liability to the Authority in connection with this Contract shall be limited to £5m (five million pounds).
- b. Nothing in this Contract shall operate to limit or exclude the Contractor's liability:
 - (1) for:
 - a. any liquidated damages (to the extent expressly provided for under this Contract);
 - b. any amount(s) which the Authority is entitled to claim, retain or withhold in relation to the Contractor's failure to perform or under-perform its obligations under this Contract, including service credits or other deductions (to the extent expressly provided for under this Contract);
 - c. any interest payable in relation to the late payment of any sum due and payable by the Contractor to the Authority under this Contract;
 - d. any amount payable by the Contractor to the Authority in relation to TUPE or pensions to the extent expressly provided for under this Contract;
 - (2) under Condition 7 of the Contract (Intellectual Property), and DEFCONs 91 or 638 (SC1) where specified in the contract;
 - (3) for death or personal injury caused by the Contractor's negligence or the negligence of any of its personnel, agents, consultants or sub-contractors;
 - (4) For fraud, fraudulent misrepresentation, wilful misconduct or negligence;
 - (5) in relation to the termination of this Contract on the basis of abandonment by the Contractor;
 - (6) for breach of the terms implied by Section 2 of the Supply of Goods and Services Act 1982; or
 - (7) for any other liability which cannot be limited or excluded under general (including statute and common) law.
- c. The rights of the Authority under this Contract are in addition to, and not exclusive of, any rights or remedies provided by general (including statute and common) law.

21 Project Specific DEFCONs

Many **DEFCONs** and **DEFFORMs** can be obtained from the MOD Internet site:

<https://www.kid.mod.uk/maincontent/business/commercial/index.html>. You will need to complete a short account registration in order to access this site.

If the required forms or documentation are not available on the MOD Internet requests should be submitted through the Commercial Officer named in Section 1 of the Appendix to Schedule 3 – Contract Data Sheet.

The project specific DEFCONs and DEFCON SC variants that apply to this Contract are:

DEFCON 127 Edn 08/21 - Price Fixing Condition for Contracts of Lesser Value

DEFCON 514A Edn 03/16 – Failure of Performance under Research and Development Contracts

DEFCON 601 (SC1) Edn 03/15 – Redundant Materiel

DEFCON 611 (SC1) Edn 12/22 – Issued Property

DEFCON 658 (SC1) Edn 10/22 – Cyber

DEFCON 703 Edn 06/21 – Intellectual Property Rights – Vesting In the Authority

a. In accordance with DEFCON 703 and in addition to Condition 11, the Contractor shall mark each Technical Deliverable in such a manner that the ownership of the Intellectual Property Rights and the rights of the Authority under DEFCON 703 are clearly stated. For this purpose the Contractor shall follow the document marking scheme here:

<i>Only information generated under the contract</i>	<i>Third party information or information not generated under the Contract also included in document</i>
© Crown-owned Copyright [insert year of production] Supplied to MOD under DEFCON 703 in accordance with Contract No [e.g ABC/1234, task XYZ/9876] (see note 1).	© Crown-owned Copyright [insert year of production] Supplied to MOD under DEFCON 703 in accordance with Contract No [e.g. ABC/1234, task XYZ/9876] (see note 1).
	This document contains additional information proprietary to [insert Third Party Rights Owner] (see note 2) and which has been supplied in confidence for the purposes of the Contract. Such information is identified. (see note 3)
	Requests for permission for wider use or dissemination of such proprietary information should be made to the relevant [insert Third Party Rights Owner] Account Manager.

Notes:

1. This must always be the Authority's contract number.
2. Include name of the Third Party Rights Owner(s), for example: a supplier name, or other third party, as appropriate.
3. Where third party information or information not generated under the Contract is included in a document subject to DEFCON 703, the information in question must be identified in the body of the document, except where this is impracticable and the Authority has agreed that such identification is not required.

22 Special Conditions

The special conditions that apply to this Contract are:

22A. Contractor's Records

a. it shall be a Condition of this Contract that all Contractors records/documents created in the performance of this Contract shall be maintained for a minimum of 10 years from the date the record/document is created. The Contractor shall approach the Authority 6 months prior to the 10 year point to enquire if any further period of retention is required. The Contractor hereby agrees to accommodate all requests for extended record/document retention periods. No records/documents shall be disposed of without the prior written permission of the Authority's Study Lead (as per Box 6 of DEFFORM 111)

b. The requirements of clause 22A a. above are included within the Contract Price(s). The Authority and the Contractor shall agree a fair and reasonable price for satisfying any provisions of any Authority requested record retention beyond the 10 year point referred to in clause 22A a. above.

22B. Procurement with suppliers from Russia and Belarus

- a. The Contractor shall, and shall procure that their Subcontractors shall, notify the Authority in writing as soon as they become aware that:
 - i. the Contract Deliverables and/or Services contain any Russian/Belarusian products and/or services; or
 - ii. that the Contractor or any part of the Contractor's supply chain is linked to entities who are constituted or organised under the law of Russia or Belarus, or under the control (full or partial) of a Russian/Belarusian person or entity. Please note that this does not include companies:
 - (a) registered in the UK or in a country with which the UK has a relevant international agreement providing reciprocal rights of access in the relevant field of public procurement; and/or
 - (b) which have significant business operations in the UK or in a country with which the UK has a relevant international agreement providing reciprocal rights of access in the relevant field of public procurement.
- b. The Contractor shall, and shall procure that their Subcontractors shall, include in such notification (or as soon as reasonably practicable following the notification) full details of the Russian products, services and/or entities and shall provide all reasonable assistance to the Authority to understand the nature, scope and impact of any such products, services and/or entities on the provision of the Contract Deliverables and/or Services.
- c. The Authority shall consider the notification and information provided by the Contractor and advise the Contractor in writing of any concerns the Authority may have and/or any action which the Authority will require the Contractor to take. The Contractor shall be required to submit a response to the concerns raised by the Authority, including any plans to mitigate those concerns, within 14 Business Days of receipt of the Authority's written concerns, for the Authority's consideration.
- d. The Contractor shall include provisions equivalent to those set out in this clause in all relevant Subcontracts.

22C. Options

- a. In addition to the Contract line items within the Schedule of Requirements at Schedule 2, the Contractor hereby grants to the Authority the following irrevocable option to purchase the Options detailed in the Schedule of Requirements in accordance with the terms and conditions set out in this Contract or any such subsequent Contract or Contracts where such Options are taken up, it being agreed that the Authority has no obligation to exercise such Options.
- b. The Authority shall have the right to exercise the Options at any point during the Contract term, which the Contractor hereby agrees shall be revised to reflect and align with any variations made to the delivery of prior items, due to delays or changes agreed by the Authority.
- c. Options cannot be withdrawn or altered at any time, without the express agreement of the Authority.
- d. The Authority may exercise the Options in the Schedule of Requirements by no later than the end of the Contract period.

22D. Cyber Security

- a. Further to DEFCON 658 the Cyber Risk profile of the Contract is 'Very Low', as defined in Def Stan 05-138.
- b. The Cyber Risk Assessment Reference for this requirement is RAR-684379375
- c. The Contractor shall implement the outcome of the Supplier Assessment Questionnaire undertaken during the tendering process, prior to Contract award.
- d. The Contractor shall adhere to DEFCON 658 and the requirements of Def Stan 05-138 during the remainder of the life of the Contract.
- e. Should there be a need for a Cyber Implementation Plan (CIP) in lieu of Cyber Essentials accreditation at any point, the Contractor agrees to engage with the CIP process and produce a CIP acceptable to the Authority, following which the Authority will provide a formal acceptance to recognise that the Contractor has met the requirement. Any CIP shall be subject to an annual review by the Parties, with any additional mitigation measures identified requiring attention by the Contractor in a time-bound manner.

22E. Government Furnished Assets (GFA)

- a. In accordance with DEFCON 611 the GFA detailed in Schedule 6 shall be issued to the Contractor on loan in support of the work to be carried out under the Contract. The Contractor shall provide a minimum of four weeks notice of them requiring the GFA, to enable dispatch and or/shipping to be arranged (as necessary).
- b. The Contractor shall ensure that the Issued Property is stored appropriately and safely in accordance with the Authority's instructions.
- c. All Issued Property shall remain the property of the Authority. The Contractor shall be fully responsible for the safe custody and protection from damage of all Issued Property
- d. In addition to DEFCON 611, on Contract completion the Contractor shall forward a list of any Issued Property that has not been used to the Authority's Commercial Officer named in Box 1 of the DEFFORM 111 Appendix to Contract and shall return or dispose of such Issued Property as advised in writing by the Authority.

- e. The Government Furnished Assets as detailed in Schedule 6, shall be made available to the Contractor by the Authority, free of charge, for the purpose of performing the Contract.

22F. Subcontracting

- a. The Contractor shall obtain the prior written consent of the Commercial Officer detailed at Box 1 of the DEFFORM 111, Appendix to Contract, before entering into any subcontracts in connection with the performance of the Contract which are in addition to those notified to and accepted by the Authority prior to Contract award.
- b. Where the Contractor Sub-contracts any element of the Contract this shall not relieve the Contractor of any of its obligations under the Contract and the Contractor shall be fully responsible for the management of sub-contractors or agents and accept responsibility for the delivery of the required outputs.

22G. Social value – Performance Indicators

- a. The Contractor hereby agrees to comply with the Performance Indicator(s) relating to social value included within Schedule 7, as agreed during negotiations prior to Contract Award.

22H. Insurance

- a. The Contractor is required to meet its United Kingdom and all other statutory or insurances required by applicable law worldwide in full. Insurances are required to comply with all statutory requirements including, but not limited to, United Kingdom employers' liability insurance and motor third party liability insurance.

22I. Agreeing of Amendments to the Technical Work and Associated Pricing

- a. the following process shall be followed where it becomes necessary and is agreed by the Authority that in order to progress the Contract, the Contractor will need to vary the originally intended work as listed on the Schedule of Requirements at Schedule 2 and included in the Statement of Requirements at Annex A to Schedule 2.
 - i. Step 1: The Contractor and the Authority (represented by the Dstl Technical Lead as detailed at Box 6 of the DEFFORM 111 – Appendix to Contract) shall agree that a variation is necessary to the work. Absolute agreement must exist.
 - ii. Step 2: The Contractor shall clearly detail the difference in terms of activity, and cost the variation – providing a detailed explanation of the change and a full breakdown of the costs concerned. The variation may include an increase or a decrease of such components. The proposal shall be submitted to the Authority's Commercial Officer at Box 1 of DEFFORM 111 and the Dstl Technical Lead at Box 6 of the DEFFORM 111.
 - iii. Step 3: The Authority shall consider the proposal and determine whether the change and the cost is deemed to be fair and reasonable.
 - iv. Step 4: Acceptance of the change shall be by means of a formal Contract amendment agreed between the Parties.
- b. Under no circumstances shall the Authority be liable for payment of any re-work due to a failure or mistake wholly attributable to the actions of the Contractor. However, where a case arises of unexpected results, the Authority shall act reasonably in respect of the cost of rework and in such cases, where rework is necessary at no fault of the Contractor, the Authority agrees to meet the costs concerned.

22J. Pricing

- a. The Contractor shall provide the Contractor Deliverables to the Authority at the Contract Prices as specified in the Schedule of Requirements at Schedule 2. The Contract Prices (including Daily Rates provided as part of a Rate Card) shall be Firm Prices for the duration of the Contract. Where prices required a number of days to be agreed, the Contractor and Authority shall agree in good faith, the number and levels of staff required to undertake the work to meet the Authority's requirement.
- b. The Contract Prices shall be inclusive of any UK custom and excise or other duty payable. The Contractor shall not make any claim for drawback of UK import duty on any part of the Contract Deliverables supplied which may be for shipment outside of the UK.

22K. Quality Assurance Audits and Monitoring

- a. The Authority, or the authorised representative or agent, shall have the right of access to the premises where the work of the Contract is being undertaken and to all information relevant to the Contract for the purpose of keeping in touch with the nature and progress of the work and to complete a general quality audit.

Schedules

Schedule 1 – Additional Definitions of Contract

- a. **Options** - shall mean options to the Contract exercisable at the sole discretion of the Contractor. Options cannot be withdrawn or altered at any time, without the express agreement of the Authority;
- b. **Subcontractor or Sub-Contractor** means any subcontractor engaged by the Contractor or by any other subcontractor of the Contractor at any level of subcontracting to provide Contractor Deliverables wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Contract and 'subcontract' shall be interpreted accordingly.
- c. **Contract Price(s)** - means the amount set out in Schedule 2 (Schedule of Requirements) to be paid (inclusive of Packaging and exclusive of any applicable VAT) by the Authority to the Contractor, for the full and proper performance by the Contractor of its obligations under the Contract.

Schedule 2 – Schedule of Requirements for Contract No: PA0000002391

for

PRECLINICAL IN VITRO CARDIOVASCULAR STUDIES

Contract Item No	Study Item	Requirement Description (All Contract Items must be provided in line with the Statement of Requirements at Annex A to Schedule 2 (Statement of Requirements))	Firm Price £ Sterling (Excluding VAT)
1a	1	hERG assessments – monotherapy	Redacted
1b	3	hERG assessments – monotherapy, long duration exposure	
2	2	hERG assessments - combination therapy	
3	4a	Multiple cell cardiac action potential duration assessments – monotherapy	
4	4b	Multiple cell cardiac action potential duration assessments - combination therapy	
5		NOT USED	
6		<p>Specialist review</p> <p><i>The Contractor is required to undertake a specialist review of the relevant in house and published cardiovascular safety data. The output from this review will be a written expert opinion/position statement including any evidenced recommendations. The review is expected to provide a risk assessment and data interpretation of the relevant in house and published cardiovascular safety data to help make informed decisions on the requirement for any further cardiovascular assessments and prepare for regulatory submission to the UK MHRA.</i></p>	<p>Rate card – comprising daily rates of levels of staff to be inserted upon contract award</p> <p>Level 1 Specialist (Scientific Advisor) Redacted</p> <p>Level 2 Study Director Redacted</p> <p>The number of days in the contractors proposal is 5</p>

		<p>(Five days). The Authority will not accept additional days being carried out without prior agreement in writing.</p> <p>To be paid upon completion of the work once accepted by the Authority</p>
7 (OPTION 1)	<p>OPTION</p> <p>ICH S7B Integrated risk assessment - monotherapy</p> <p><i>Provision of an integrated risk assessment report for the monotherapy in line with current ICH S7B guidance, following the completion of the studies. The integrated risk assessment report will need to encompass ion channel, stem cell, cardiovascular telemetry and toxicology data in context with the projected human exposure profile to enable a clear understanding of any potential cardiovascular risk.</i></p>	<p>Rate card – comprising daily rates of levels of staff to be inserted upon contract award</p> <p>Level 1 Specialist (Scientific Advisor) Redacted</p> <p>Level 2 Study Director</p> <p>Redacted</p> <p>The number of days in the contractors proposal is 1 (One day) for Specialist Scientific Advisor & 3 (Three days) Study Director . The Authority will not accept additional days being carried out without prior agreement in writing.</p> <p>To be paid upon completion of the work once accepted by the Authority</p>

8 (OPTION 2)	<p>OPTION</p> <p>ICH S7B Integrated risk assessment - combination therapy</p> <p><i>Provision of an integrated risk assessment report for the combination therapy in line with current ICH S7B guidance, following the completion of the studies. The integrated risk assessment report will need to encompass ion channel, stem cell, cardiovascular telemetry and toxicology data in context with the projected human exposure profile to enable a clear understanding of any potential cardiovascular risk.</i></p>	<p>Rate card – comprising daily rates of levels of staff to be inserted upon contract award</p> <p>Level 1 Specialist (Scientific Advisor) Redacted</p> <p>Level 2 Study Director</p> <p>Redacted</p> <p>The number of days in the contractors proposal is 1 (One day) for Specialist Scientific Advisor & 3 (Three days) Study Director . The Authority will not accept additional days being carried out without prior agreement in writing.</p> <p>To be paid upon completion of the work once accepted by the Authority</p>
9 (OPTION 3)	<p>OPTION</p> <p>Undertaking of any further cardiovascular assessments recommended in the Specialist Review. The requirement for and acceptance of any part of the recommendation provided will be at the full discretion of the Authority.</p>	<p>This will be a non-costed option at the time of initial contracting. Costs and full proposals will be requested by the Authority if required</p>

		<p>following receipt and acceptance of the expert specialist review.</p> <p>This will be priced in accordance with DEFCON 127 utilising the Rate cards for Items 5 – 7 above.</p>
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Note 1: the Authority does not expect the composition of levels of staff and proportions of their time to vary considerably from the tendered response.

Milestone Payment Plan

Contract Item No	Milestone number	Description	Amount
1a	1	-40% payment at the finalisation of the study protocol	Redacted
1a	2	-40 % payment at the receipt, by the Authority, of raw data	
1a	3	-10% payment at the receipt, by the Authority, of the draft report	
1a	4	-10% payment at the finalisation of the final report	
	Sub-Total		
1b	1	-40% payment at the finalisation of the study protocol	
1b	2	-40 % payment at the receipt, by the Authority, of raw data	
1b	3	-10% payment at the receipt, by the Authority, of the draft report	

1b	4	-10% payment at the finalisation of the final report	Redacted	
	Sub-Total			
2	1	40% payment at the establishment of study protocol		
2	2	-40 % payment at the raw data given		
2	3	-10% payment at the draft report giving		
2	4	-10% payment at the final report giving		
	Sub-Total			
3	1	-40% payment at the establishment of study protocol		
3	2	-40 % payment at the raw data given		
3	3	-10% payment at the draft report giving		
3	4	-10% payment at the final report giving		
	Sub-Total			
4	1	-40% payment at the establishment of study protocol		
4	2	-40 % payment at the raw data given		
4	3	-10% payment at the draft report giving		
4	4	-10% payment at the final report giving		
	Sub-Total			

Annex A to Schedule 2 – Schedule of Requirements: Statement of Requirements

STATEMENT OF REQUIREMENTS for Preclinical In Vitro Cardiovascular Studies

1. The Authority has a requirement for a preclinical in vitro cardiovascular package of work; this includes the requirement for electrophysiological studies including hERG (human ether a go go related gene) assays (or an equivalent alternative) and action potential assessments such as either human pluripotent stem cell-cardiomyocyte assays or Purkinje Fibre assays.
2. The Authority is developing a new drug combination therapy consisting of 3 non-biological Active Pharmaceutical Ingredients (APIs) for intramuscular administration against nerve agent poisoning and a new monotherapy for intravenous administration to treat nerve agent poisoning.
3. The requirement for cardiac electrophysiological assays is driven by the need to establish the potential for delayed cardiac action potential repolarisation as set out in the ICH S7B guideline and other pro-arrhythmic activities. These studies will aim to de-risk adverse cardiovascular arrhythmias such as Torsade de Pointes (TdP).
4. The Authority wishes to fulfil the ICH S7B regulatory guidance requirements and understand the cardiovascular risk associated with the APIs under development in preparation for regulatory submission to the UK MHRA. It is suggested that this includes the studies summarised in the table below but alternative proposals will also be considered.

5. hERG (or equivalent)	<p>Provision of hERG (or equivalent) assay IC₅₀ and associated data in line with current ICH S7B guidance.</p> <ul style="list-style-type: none"> a) Monotherapy - determine the IC₅₀ for single API. b) Monotherapy - long-duration exposure of monotherapy to determine possible translocation effects. c) Combination therapy - determine the IC₅₀ for the combination of three APIs. d) Appropriate vehicle control and positive controls (in compliance with ICH S7B). e) Assay preparations must be sampled and API concentrations measured using appropriately assured bioanalytical methods for each preparation. It is considered likely that two analytical methods will be required to quantify the three APIs. f) Formulation analysis supported by appropriate method validation and stability.
6. Action potential assessments such as Purkinje Fibre or cardiomyocyte assays	<p>Determination of the action potential duration and provision of associated data in line with current ICH S7B guidance.</p> <ul style="list-style-type: none"> a) Monotherapy - the ability of the monotherapy to affect action potential duration has previously been assessed using a Purkinje fibre assay. If the use of a Purkinje fibre assay is proposed, the monotherapy will be assessed to enable comparison with existing data. If an alternative assay is proposed the Contractor must describe how the monotherapy will be assessed to enable comparison with existing data. b) Combination therapy - determine the action potential duration for the combination of the three APIs. c) Appropriate vehicle control and positive controls (in compliance with ICH S7B). d) Assay preparations must be sampled and API concentrations measured using appropriately assured bioanalytical methods for each preparation. It is considered likely that two analytical methods will be required to quantify the three APIs. e) Formulation analysis supported by appropriate method validation and stability.

7. The Authority will supply the Contractor with sufficient API (50g) of the monotherapy (HI-6) and the relevant safety data to enable safe handling of the material. The Contractor will be required to procure the remaining two APIs (licenced products – atropine and midazolam) for the combination therapy assessments.

Specialist Review

8. The Contractor is required to undertake a specialist review of the relevant in house data (which will be provided to the Contractor as Government Furnished Information) and published cardiovascular safety data. The output from this review will be a written expert opinion/position statement including any evidenced recommendations. The review is expected to provide a risk assessment and data interpretation of the relevant in house and published cardiovascular safety data to help make informed decisions on the requirement for any further cardiovascular assessments and prepare for regulatory submission to the UK MHRA.

Mandatory Requirements

9. The Contractor must hold a Schedule 1 Home Office licence (Animals (Scientific Procedures) Act 1986 or equivalent if a non-UK company is undertaking the work) if required for the proposed assays to be undertaken.
10. The Contractor must hold the appropriate controlled drug licence for schedule 3 materials (Misuse of Drugs Regulations, 2001 or equivalent if a non-UK company). The Contractor must safely store all APIs (where provided by the Authority and where procured directly) within a suitable storage environment.
11. For hERG, the use of a suitable cell line stably expressing the human ether-a-go-go-related gene is required.
12. For action potential duration, purkinje assays or other suitable multicellular electrophysiological studies will be acceptable.
13. If the Contractor is based in the USA, they must either confirm their agreement that the US Department of Defence's International Traffic in Arms Regulations (ITAR) do not apply to this package of work or ensure any timeframes associated with approvals required are fully factored into the delivery dates. In addition, results will be required to be shared with international partners and UK regulatory agency.
14. All Reports must be provided in .pdf format.

OPTION 1

15. Provision of an integrated risk assessment report for the monotherapy in line with current ICH S7B guidance, following the completion of the studies. The integrated risk assessment report will need to encompass available ion channel, stem cell, cardiovascular telemetry and toxicology data in context with the projected human exposure profile to enable a clear understanding of any potential cardiovascular risk.

OPTION 2

16. Provision of an integrated risk assessment report for the combination therapy in line with current ICH S7B guidance, following the completion of the studies. The integrated risk assessment report will need to encompass available ion channel, stem cell, cardiovascular telemetry and toxicology data in context with the projected human exposure profile to enable a clear understanding of any potential cardiovascular risk.

OPTION 3

17. Undertaking of any further cardiovascular assessments recommended in the Specialist Review. The requirement for and acceptance of any part of the recommendation provided will be at the full discretion of the Authority.
18. Intellectual Property Rights - All Intellectual Property generated under this Contract will vest in the Authority under the terms of DEFCON 703 (Edn 06/21).

19. Standard Deliverable Acceptance Criteria

19a. Study documentation:

- i. Study protocols and full study reports in line with ICH S7B and suitable for submission to the MHRA shall be provided for all studies.
- ii. Reports shall describe the entire work performed under the Contract in sufficient detail to explain comprehensively the work undertaken and results achieved including all relevant technical details. The technical detail shall be sufficient to permit independent reproduction of any such process or study. Reports must be Quality Control checked and peer reviewed to meet Quality Assurance requirements. All raw data, study plans and amendments should be included as Annexes.
- iii. The format and structure of reports shall be agreed at the kick-off meeting, shortly after Contract award. Final reports are required to be provided in indexed .pdf format.
- iv. A tabulated summary in the CTD/eCTD (common technical document / electronic common technical document) format is also required.
- v. All deliverables will be reviewed by the Authority and decision on approval will be made by the Authority's Technical Point of Contact within an agreed period as detailed in the table in Schedule 3 under clause 14 – Progress Reports.

20. Quality Control and Quality Assurance processes and standards that must be met by the contractor

- ☐ **ISO9001** (Quality Management Systems)
- ☐ **ISO14001** (Environment Management Systems)
- ☐ **ISO12207** (Systems and software engineering — software life cycle)
- ☐ **TickITPlus** (Integrated approach to software and IT development)
- ☒ **Other:** (Please specify below)

The data required is in support of clinical trials with the API(s) and therefore must be completed to satisfactory quality standards which must be adequately demonstrated to the authority. The work is not required to be performed to Good Laboratory Practice (GLP), however the quality management system to be used should be fully described in compliance with ICH S7B guidance. A QA audit by the authority was undertaken on 3rd June 2024.

21. Safety, Environmental, Social, Ethical, Regulatory or Legislative aspects of the requirement

- a. Material Safety Data sheets for Active Pharmaceutical Ingredient will be provided as GFI to the Contractor by the Authority.
- b. Studies conducted must comply with ICH S7B guideline requirements.
- c. The Contractor is responsible for the health and safety of their staff and ensuring appropriate health and safety measures are in place at their organisation.
- d. As part of the Contract initiation, the Contractor will be asked whether they deem the contracted work to require additional H&S measures above and beyond their 'normal' safe working practices. If yes, they will be tasked to provide email confirmation of the additional measures implemented.
- e. All work must be completed in accordance with the UK Animals (Scientific Procedures) Act 1986 and the principles of the 3Rs guidelines.

Plan for end of Contract/closure

22. Quality assured and peer reviewed written reports are to be provided with full findings, test data and details of all methods and results. These reports must be quality assured and peer reviewed by the Contractor, agreed and signed off by the Authority.

23. The Contractor is required to retain any study samples for a period of 4 weeks after the final report is signed off until disposal following authorisation from the Authority.

24. All study documentation (e.g. plans and raw data) will need to be returned to the Authority for archiving after storing for an agreed retention period following the sign off of the final report.

25. Any remaining APIs will be destroyed by the Contractor using an appropriate method and this shall be confirmed to the Authority in writing.

Status of the Contractor's proposal

26. The Authority's Statement of Requirement will take precedent over the Contractor's proposal reference PS23XXXX.PF – a PDF document dated 15/12/2023 with 41 pages as submitted to the Defence Sourcing Portal during the tender submission.

Study Plan Gannt Chart

		W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12	W13	W14	W15	W16	W17	W18	W19	W20	W21	W22	W23	W24	W25	W26	W27		
Study 1	Contract Item 1	Expert review	Controlled drug import license 1-2 months (Administrative work)								Analytic Method Development/Validation						hERG assays monotherapy				raw data		Draft Report				Expert review	Final report and interpretation		
Study 2 (?)	Contract Item 2										Analytic Method Development/Validation						hERG assays Combination				raw data		Draft Report							
Study 3	Contract Item 1																Analytic Method Development/Validation						hERG trafficking		Draft Report					
Study 4	Contract Item 3												Analytic Method Development/Validation						Cell cardiac assays monotherapy											
Study 4	Contract Item 4												Analytic Method Development/Validation						Cell cardiac assays combination											

Schedule 3 - Contract Data Sheet for Contract No: PA0000002391

Contract Period	<p>Effective date of Contract: 30th July 2024</p> <p>The Contract expiry date shall be:31st August 2025</p>
Clause 6 – Notices	<p>Notices served under the Contract can be transmitted by electronic mail</p> <p>Yes <input type="checkbox"/></p> <p>No <input checked="" type="checkbox"/></p> <p>Notices served under the Contract shall be sent to the following address:</p> <p>Authority: Dstl, Porton Down, Salisbury Wiltshire , SP4 0JQ</p> <p>Contractor: Physiostim, 10 rue Henri Regnault, 81100 Castres, FRANCE</p>
Clause 8 – Supply of Contractor Deliverables and Quality Assurance	<p>Is a Deliverable Quality Plan required for this Contract?</p> <p>Yes <input type="checkbox"/></p> <p>No <input checked="" type="checkbox"/></p> <p>Other Quality Assurance (QA) Requirements:</p> <p>The data required is in support of clinical trials with the API(s) and therefore must be completed to satisfactory quality standards which must be adequately demonstrated to the authority. The work is not required to be performed to Good Laboratory Practice (GLP), however the quality management system to be used should be fully described in compliance with ICH S7B guidance. A QA audit by the authority will be undertaken prior to study start.</p>

Clause 9 – Supply of Data for Hazardous Substances, Mixtures and Articles in Contractor Deliverables	A completed DEFFORM 68 (Hazardous and Non-Hazardous Substances, Mixture and Articles Statement), and if applicable, UK REACH Article 31 compliant Safety Data Sheet(s) including any related information to be supplied in compliance with the Contractor's statutory duties under Clauses 9.b, and any information arising from the provisions of Clause 9 are to be provided by e-mail with attachments in Adobe PDF or MS WORD format to The Authority's Representative (Commercial) by the following date: 2 nd September 2024
Clause 10 – Delivery/Collection	Contract Deliverables are to be: Delivered by the Contractor <input checked="" type="checkbox"/> Special Instructions: Please see the reports section below for required deliverables
Clause 12 – Packaging and Labelling of Contractor Deliverables	Additional packaging requirements: N/A
Clause 14 – Progress Meetings	The Contractor shall be required to attend the following meetings: Type: Teleconference Frequency: Fortnightly Location: Teleconference

Clause 14 – Progress Reports

The Contractor is required to submit the following Reports:

Type: as set out in the table below

Frequency: as set out in the table below

Method of Delivery: electronically

Delivery Address: Porton Down, Salisbury Wiltshire , SP4 0JQ

Progress updates (via teleconference) will be a minimum of once per month but may more frequent during busy periods. A face to face meeting hosted by the contractor will be required at start-up and further visits may be arranged during the contract if necessary.

Progress updates should summarise the results of work done during the period covered and an explanation of any difference between planned progress and actual progress, why the differences have occurred, and if behind planned progress what corrective steps are planned.

The Contractor is to supply, at no additional cost to the Authority, minutes of the meetings.

The Contractor is required to submit the following Reports

Deliverable /Output	Deliverable Requirements	Format	Due By	Government Furnished Information and/or Dstl technical input to the Deliverable/work
Study Plans	Draft study plans to be supplied to the Authority 6 weeks prior to when the study begins for review and comment. The Authority will review and comment within 4 weeks of receipt of the draft study plan.	Reports (.pdf)	Prior to start of study	GFI-1 API Material - Safety Data Sheet GFI-2 -API - Certificate of Analysis GFI-3 - Report: Redactedv2 Redactedv2 GFI-4 - Report: Redactedv2

					GFI-5 - Report: Redactedv2 [Redacted]
					GFI-6 - Report: Redactedv2 [Redacted]
	Final reports	<p>Reports will be in UK English with full findings, test data and details of all methods and results.</p> <p>Final reports must be quality and peer reviewed. A tabulated summary in the CTD/eCTD (common technical document / electronic common technical document) format is also required.</p> <p>Raw data from each study to be retained by the Contractor for an agreed retention period and subsequently transferred to the Authority. The Authority will review the report within 4 weeks.</p>	Reports (.pdf)	Within 8-10 weeks of completion of each study	GFI-2 -API - Certificate of Analysis
	Specialist Review	<p>Report will be in UK English. The output from this review will be a written expert opinion/position statement including any evidenced recommendations. The review is expected to provide a risk assessment and data interpretation. The Authority will review this in 8 weeks.</p>	Reports (.pdf)	Within 8-12 weeks of contract start	<p>GFI-3 - Report: Redactedv2 [Redacted]</p> <p>Redactedv2 [Redacted]</p> <p>GFI-4 - Report: Redactedv2 Redactedv2 [Redacted]</p> <p>GFI-5 - Report: Redactedv2 [Redacted]</p>

					GFI-6 - Report: Redactedv2 Redactedv2
	Integrated Risk assessment (Option 1)	Producing a risk assessment report in line with ICH S7B suitable for submission to the MHRA.	TBC on award of Contract		GFI-3 - Report: Redactedv2 Redactedv2 GFI-4 - Report: Redactedv2 GFI-5 - Report: Redactedv2 GFI-6 - Report: Redactedv2 Redactedv2
	Integrated Risk assessment (Option 2)	Producing a risk assessment report in line with ICH S7B suitable for submission to the MHRA.	TBC on award of Contract		GFI-3 - Report: Redactedv2 Redactedv2 GFI-4 - Report: Redactedv2 GFI-5 - Report: Redactedv2 GFI-6 - Report: Redactedv2
	Significant Deviations	The contractor shall ensure that any significant deviations from the agreed protocols, e.g. dosing deviations, are promptly reported to the Authority. All deviations and an assessment of their impact	Reports (pdf)		

		on the study should be documented in the report.			
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Appendix - Addresses and Other Information

1. Commercial Officer

Name: **Redacted**
Address: Porton Down, Salisbury SP4 0JQ
Email: **Redacted**
☎ **Redacted**

2. Project Manager, Equipment Support Manager or PT Leader (from whom technical information is available)

Name: **Redacted**
Address: Porton Down, Salisbury SP4 0JQ
Email: **Redacted**
☎ + **Redacted**

3. Packaging Design Authority

Organisation & point of contact:

(Where no address is shown please contact the Project Team in Box 2)



4. (a) Supply / Support Management Branch or Order Manager:
Branch/Name:



(b) U.I.N.

5. Drawings/Specifications are available from

www.contracts.mod.co.uk/ **Redacted**

6. The Authority's Technical Lead

Name: **Redacted**
Address: Porton Down, Salisbury SP4 0JQ
Email: **Redacted**
☎ **Redacted**

7. Quality Assurance Representative:

Name: **Redacted**
Commercial staff are reminded that all Quality Assurance requirements should be listed under the General Contract Conditions.
AQAPS and **DEF STANs** are available from UK Defence Standardization, for access to the documents and details of the helpdesk visit <http://dstan.gateway.isg-r.r.mil.uk/index.html> [intranet] or <https://www.dstan.mod.uk/> [extranet, registration needed].

8. Public Accounting Authority

1. Returns under DEFCON 694 (or SC equivalent) should be sent to DBS Finance ADMT – Assets In Industry 1, Level 4 Piccadilly Gate, Store Street, Manchester, M1 2WD
☎ 44 (0) 161 233 5397
2. For all other enquiries contact DES Fin FA-AMET Policy, Level 4 Piccadilly Gate, Store Street, Manchester, M1 2WD
☎ 44 (0) 161 233 5394

9. Consignment Instructions

The items are to be consigned as follows:

See box 2

10. Transport. The appropriate Ministry of Defence Transport Offices are:

A. DSCOM. DE&S, DSCOM, MoD Abbey Wood, Cedar 3c, Mail Point 3351, BRISTOL BS34 8JH
Air Freight Centre
IMPORTS ☎ 030 679 81113 / 81114 Fax 0117 913 8943
EXPORTS ☎ 030 679 81113 / 81114 Fax 0117 913 8943
Surface Freight Centre
IMPORTS ☎ 030 679 81129 / 81133 / 81138 Fax 0117 913 8946
EXPORTS ☎ 030 679 81129 / 81133 / 81138 Fax 0117 913 8946

B. JSCS

JSCS Helpdesk No. 01869 256052 (select option 2, then option 3)
JSCS Fax No. 01869 256837
Users requiring an account to use the MOD Freight Collection Service should contact UKStratCom-DefSp-RAMP@mod.gov.uk in the first instance.

11. The Invoice Paying Authority

Dstl Accounts Payable
PO Box 325
Portsmouth West, Portsmouth Hill Road
FAREHAM, HAMPSHIRE, PO14 9HL
United Kingdom
Tel: 01980 950001
Fax: 01980 958118
Invoices for payment may be submitted via e-mail in PDF format to accountspayable@dstl.gov.uk

12. Forms and Documentation are available through *:

Ministry of Defence, Forms and Pubs Commodity Management
PO Box 2, Building C16, C Site
Lower Arncott
Bicester, OX25 1LP (Tel. 01869 256197 Fax: 01869 256824)
Applications via fax or email: Leidos-FormsPublications@teamleidos.mod.uk

*** NOTE**

1. Many **DEFCONs** and **DEFFORMs** can be obtained from the MOD Internet Site: <https://www.kid.mod.uk/maincontent/business/commercial/index.htm>
2. If the required forms or documentation are not available on the MOD Internet site requests should be submitted through the Commercial Officer named in Section 1.

Schedule 4 - Contractor's Sensitive Information (i.a.w. Clause 5) for Contract No: PA0000002391

This list shall be agreed in consultation with the Authority and the Contractor and may be reviewed and amended by agreement. The Authority shall review the list before publication of any information.

Contract No: PA0000002391
Description of Contractor's Sensitive Information: None
Cross Reference(s) to location of Sensitive Information:
Explanation of Sensitivity:
Details of potential harm resulting from disclosure:
Period of Confidence (if applicable):
Contact Details for Transparency / Freedom of Information matters: Name: Position: Address: Telephone Number: Email Address:

Schedule 5 – Notification of Intellectual Property Rights (IPR) Restrictions (i.a.w. Clause 7) for Contract No PA0000002391
PART A – Notification of IPR Restrictions

1. <u>ITT / Contract Number</u>		PA0000002391		
2. <u>ID #</u>	3. <u>Unique Technical Data Reference Number / Label</u>	4. <u>Unique Article(s)* Identification Number / Label</u>	5. <u>Statement Describing IPR Restriction</u>	6. <u>Ownership of the Intellectual Property Rights</u>
1	None	None	None	None
2				
3				
4				
5				
6				
7				
8				
9				

Please continue on additional sheets where necessary.

* Article(s), for the purpose of this form only, means part or the whole of any item, component or process which the Contractor is required under the Contract to supply or in connection with which it is required under the Contract to carry out any service and any other article or part thereof to the same design as that article.

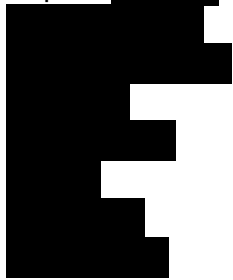

PART B – System / Product Breakdown Structure (PBS)

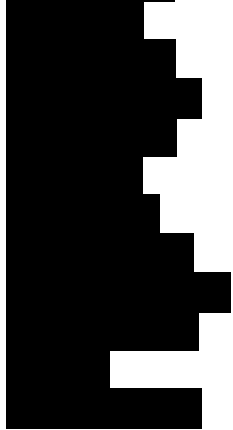
The Contractor should insert their PBS here. For software, please provide a Modular Breakdown Structure.

(Please see the [DEFFORM 711 Completion Notes](#) for guidance on completing Schedule 5)

Schedule 6 – Government Furnished Assets

Type of Government Furnished (X) GFI = Information GFE = Equipment GFF = Facilities GFR = Resources GFA = Assets	Unique Identifier (e.g. Serial No)	Description	Available Date	Issued by:
GFA – 1	<div style="background-color: black; color: red; padding: 2px;">Redactedv2</div>	Supply of Good Manufacturing Practice Investigational Medicinal Product (GMP API). 50g aliquot to be provided.	4 weeks after contract award	The Authority

Type of Government Furnished (X) GFI = Information GFE = Equipment GFF = Facilities GFR = Resources GFA = Assets	Unique Identifier (e.g. Serial No)	Description	Available Date	Issued by:
GFI – 4	Report: Redactedv2	Report: Redactedv2 	Contract start	The Authority
GFI – 5	Report: Redactedv2	Report: Redactedv2 	Contract start	The Authority

Type of Government Furnished (X) GFI = Information GFE = Equipment GFF = Facilities GFR = Resources GFA = Assets	Unique Identifier (e.g. Serial No)	Description	Available Date	Issued by:
GFI – 6	Report: Redactedv2	Report: Redactedv2 	Contract start	The Authority

Schedule 7 – Social Value Performance Indicator Data Report (i.a.w. Condition 22G) for Contract No PA0000002391

Key Performance Indicator (KPI) – Social Value	
Description	Social Value
Type	Key Performance Indicator.
KPI criteria	The Supplier shall maintain facilities to enable those with disabilities to access the Suppliers premises. The Supplier shall maintain a balance between the number of male and female employees and continue to provide an offer of maternity leave where appropriate. The Supplier shall offer suitable training opportunities to all staff.
Monitoring frequency	Bi-annually (March 31 st and September 30 th) and in accordance with reporting requirements within the Contract
Reporting frequency	Bi-annually (March 31 st and September 30 th) and in accordance with reporting requirements within the Contract
Performance Criteria	
Green	The Contractor shall be scored green where he meets the requirement and delivers a report confirming compliance with the KPI criteria no later than the agreed Due Date.
Amber	The Contractor shall be scored amber where he meets the requirement but delivers a report confirming compliance with the KPI criteria more than two (2) working weeks but within (4) working weeks after the agreed Due Date.

Red	The Contractor shall be scored red where he either fails to confirm compliance with the KPI criteria and / or the report is delivered more than (4) four working weeks after the agreed Due Date.
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