



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

Order Form

15th of December 2023

1. Contract Reference	C180693	
2. Buyer	Medicines and Healthcare products Regulatory Agency 10 South Colonnade, Canary Wharf, London E14 4PU	
3. Supplier	Medscience Distribution Ltd, Unit 8 Manor Park, Wildmere Industrial Estate, Banbury, Oxfordshire, OX16 3TB, United Kingdom	
4. The Contract	<p>This Contract between the Buyer and the Supplier is for the supply of Deliverables.</p> <p>The Supplier shall supply the Deliverables described below on the terms set out in this Order Form and the attached contract conditions ("Conditions") and Annexes.</p> <p>Unless the context otherwise requires, capitalised expressions used in this Order Form have the same meanings as in the Conditions.</p> <p>In the event of any conflict between this Order Form and the Conditions, this Order Form shall prevail.</p> <p>[Please do not attach any Supplier terms and conditions to this Order Form as they will not be accepted by the Buyer.]</p>	
5. Deliverables	Goods	<p>Description: Purchase of Pilot Freeze Dryer, Project reference C180693 [As set out below / in Annex 2]</p> <p>The Goods are to be Delivered in accordance with the following instructions:</p> <p>Delivery Address: Medicines & Healthcare Products Regulatory Agency (MHRA), Blanche Lane, South Mimms Potters Bar, Hertfordshire,</p>



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

		EN6 3QG Date of Delivery: [REDACTED]
	Services	Description: Purchase of Pilot Freeze Dryer, Project reference C180693 [As set out below / in Annex 2] To be performed at: Medicines & Healthcare Products Regulatory Agency, Blanche Lane, South Mimms Potters Bar, Hertfordshire, EN6 3QG
6. Specification	The specification of the Deliverables is as set out in Annex 2 / in the Supplier's tender response to C180693.	
7. Start Date	18 th of December 2023	
8. Expiry Date	18 th of December 2028	
9. Extension Period	For service maintenance and/or purchase of any bespoke kits/consumables and/or any IT related requirements, if applicable, the contract will be for the life of the equipment. The Conditions of the Contract shall apply throughout any such extended period.	
10. Optional Intellectual Property Rights ("IPR") Clauses	As stated under clause 10	
11. Charges	The Charges for the Deliverables shall be as set out in Annex 3 / the Supplier's tender response to C180693.	
12. Payment	Payment of undisputed invoices will be made within 30 days of receipt of invoice, which must be submitted promptly by the Supplier. All invoices must be sent, quoting a valid Purchase Order Number (PO Number), to: [REDACTED]	



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

	<p>Within 10 Working Days of receipt of your countersigned copy of this Order Form, we will send you a unique PO Number. You must be in receipt of a valid PO Number before submitting an invoice.</p> <p>To avoid delay in payment it is important that the invoice is compliant and that it includes a valid PO Number, item number (if applicable) and the details (name, email, and telephone number) of your Buyer contact (i.e. Buyer Authorised Representative). Non-compliant invoices may be sent back to you, which may lead to a delay in payment.</p> <p>If you have a query regarding an outstanding payment please contact our Accounts Payable team either by email to: [REDACTED]</p>		
13. Data Protection Liability Cap	In accordance with clause 12.5 of the Conditions, the Supplier's total aggregate liability under clause 14.7(e) of the Conditions is no more than the Data Protection Liability Cap, being £500,000.		
14. Progress Meetings and Progress Reports	<p>Not applicable</p> <ul style="list-style-type: none">• The Supplier shall attend meetings only(if) in an event of escalation.		
15. Buyer Authorised Representative(s)	<p>For general liaison your contact will continue to be</p> <p>[REDACTED]</p>		
16. Supplier Authorised Representative(s)	<p>For general liaison your contact will continue to be</p>		
17. Address for notices	<table><tr><td>Buyer: Medicines & Healthcare Products Regulatory Agency,</td><td>Supplier: Medscience Distribution Ltd, Unit 8 Manor Park, Wildmere Industrial Estate, Banbury,</td></tr></table>	Buyer: Medicines & Healthcare Products Regulatory Agency,	Supplier: Medscience Distribution Ltd, Unit 8 Manor Park, Wildmere Industrial Estate, Banbury,
Buyer: Medicines & Healthcare Products Regulatory Agency,	Supplier: Medscience Distribution Ltd, Unit 8 Manor Park, Wildmere Industrial Estate, Banbury,		



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

	Blanche Lane, South Mimms Potters Bar, Hertfordshire, EN6 3QG United Kingdom	Oxfordshire, OX16 3TB, United Kingdom									
18. Key Staff	<table><tr><th>Key Staff Role:</th><th>Key Name:</th><th>Staff</th><th>Contact Details:</th></tr><tr><td></td><td></td><td></td><td></td></tr></table>			Key Staff Role:	Key Name:	Staff	Contact Details:				
Key Staff Role:	Key Name:	Staff	Contact Details:								
19. Procedures and Policies	<p>For the purposes of the Contract the:</p> <p>Contractors must undergo and pass any security checks deemed necessary by NIBSC. Failure to do so could result in access to NIBSC being denied. It is the service provider's responsibility to ensure service engineers progress the security clearance in a timely manner when required and are mindful of new engineers who may attend site, and try and pre-empt the process, with a request for security clearance prior to them attending site.</p>										
20. Special Terms	<p>1. Liability Cap: Clause 12.1 of the Conditions is deleted and replaced with the following:</p> <p>Each Party's total aggregate liability under or in connection with the Contract (whether in tort, contract or otherwise) is no more than 125% of the Charges paid or payable to the Supplier.</p> <p>2. Modern Slavery: A new clause is inserted into clause 13 of the Conditions (Obeying the law):</p> <p>The Supplier shall comply with any request by the Buyer to complete the Modern Slavery Assessment Tool, which can be found online at:</p>										



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

	https://supplierregistration.cabinetoffice.gov.uk/msat , within sixty (60) days of such request. Guidance attached to PPN 05/19 (Modern Slavery) 1.
21. Incorporated /terms	<p>The following documents are incorporated into the Contract. If there is any conflict, the following order of precedence applies:</p> <ul style="list-style-type: none">a) The cover letter from the Buyer to the Supplier dated 15th of December 2023b) This Order Formc) Any Special Terms [see row 20 (Special Terms) in this Order Form]d) Conditionse) The following Annexes in equal order of precedence:<ul style="list-style-type: none">i. [Annex 1 – Processing Personal Data]ii. [Annex 2 – Specification]iii. [Annex 3 – Charges]

Signed for and on behalf of the Supplier	Signed for and on behalf of the Buyer
Name: [REDACTED]	Name: [REDACTED]
Date: 19 TH of December 2023	Date: 22 nd of December 2023
Signature: [REDACTED]	Signature: [REDACTED]



[Where appropriate, this Order Form may be signed electronically by both Parties.]



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

I. Annex 1 – Processing Personal Data

II.

A. Part A - Authorised Processing Template

Contract:	C180693
Date:	15.12.2023
Description of authorised processing	Details
Identity of Controller and Processor for each category of Personal Data	No Personal Data will be processed.
Subject matter of the processing	MHRA staff work contract details will be held by the supplier.
Duration of the processing	The life of the contract.
Nature and purposes of the processing	NA
Type of Personal Data	Work contract details.
Categories of Data Subject	MHRA staff including temporary staff.
Plan for return and destruction of the data once the processing is complete UNLESS requirement under law to preserve that type of data	N/A
Locations at which the Supplier and/or its Subcontractors process Personal Data under this Contract	Any in UK
Protective Measures that the Supplier and, where applicable, its Subcontractors have implemented to protect Personal Data processed under this Contract against a breach of security (insofar as that breach of security relates to data) or a Personal Data Breach	N/A



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

B. Part B – Joint Controller Agreement

1. Joint Controller Status and Allocation of Responsibilities

- 1.1 With respect to Personal Data for which the Parties are Joint Controllers, the Parties envisage that they shall each be a Controller in respect of that Personal Data in accordance with the terms of this *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data* in replacement of Clauses 14.9(a) to 14.9(q) of the Conditions of this Contract. Accordingly, the Parties each undertake to comply with the applicable Data Protection Legislation in respect of their processing of such Personal Data as Controllers.
- 1.2 The Parties agree that the [Supplier/Buyer]:
- (a) is the exclusive point of contact for Data Subjects and is responsible for using all reasonable endeavours to comply with the UK GDPR regarding the exercise by Data Subjects of their rights under the UK GDPR;
 - (b) shall direct Data Subjects to its Data Protection Officer or suitable alternative in connection with the exercise of their rights as Data Subjects and for any enquiries concerning their Personal Data or privacy;
 - (c) is solely responsible for the Parties' compliance with all duties to provide information to Data Subjects under Articles 13 and 14 of the UK GDPR;
 - (d) is responsible for obtaining the informed consent of Data Subjects, in accordance with the UK GDPR, for processing in connection with the Deliverables where consent is the relevant legal basis for that processing; and
 - (e) shall make available to Data Subjects the essence of this *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data* (and notify them of any changes to it) concerning the allocation of responsibilities as Joint Controller and its role as exclusive point of contact, the Parties having used their best endeavours to agree the terms of that essence. This must be outlined in the [Supplier's/Buyer's] privacy policy (which must be readily available by hyperlink or otherwise on all of its public facing services and marketing).
- 1.3 Notwithstanding the terms of paragraph 1.2 of this *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data*, the Parties acknowledge that a Data Subject has the right to exercise their legal rights under the Data Protection Legislation as against the relevant Party as Controller.

2. Undertakings of both Parties

- 2.1 The Supplier and the Buyer each undertake that they shall:
- (a) report to the other Party every [x] months on:
 - (i) the volume of Data Subject Access Requests (or purported Data Subject Access Requests) from Data Subjects (or third parties on their behalf);
 - (ii) the volume of requests from Data Subjects (or third parties on their behalf) to rectify, block or erase any Personal Data;



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (iii) any other requests, complaints or communications from Data Subjects (or third parties on their behalf) relating to the other Party's obligations under applicable Data Protection Legislation;
 - (iv) any communications from the Information Commissioner or any other regulatory authority in connection with Personal Data; and
 - (v) any requests from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law, that it has received in relation to the subject matter of the Contract during that period;
- (b) notify each other immediately if it receives any request, complaint or communication made as referred to in Paragraphs 2.1(a)(i) to (v) of this *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data*;
- (c) provide the other Party with full cooperation and assistance in relation to any request, complaint or communication made as referred to in Paragraphs 2.1(a)(iii) to (v) of this *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data*; to enable the other Party to comply with the relevant timescales set out in the Data Protection Legislation;
- (d) not disclose or transfer the Personal Data to any third party unless necessary for the provision of the Deliverables and, for any disclosure or transfer of Personal Data to any third party, (save where such disclosure or transfer is specifically authorised under the Contract or is required by Law) that disclosure or transfer of Personal Data is otherwise considered to be lawful processing of that Personal Data in accordance with Article 6 of the UK GDPR or EU GDPR (as the context requires). For the avoidance of doubt, the third party to which Personal Data is transferred must be subject to equivalent obligations which are no less onerous than those set out in this of this *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data*;
- (e) request from the Data Subject only the minimum information necessary to provide the Deliverables and treat such extracted information as Confidential Information;
- (f) ensure that at all times it has in place appropriate Protective Measures to guard against unauthorised or unlawful processing of the Personal Data and/or accidental loss, destruction or damage to the Personal Data and unauthorised or unlawful disclosure of or access to the Personal Data;
- (g) use all reasonable endeavours to ensure the reliability and integrity of any Processor Personnel who have access to the Personal Data and ensure that Processor Personnel:
 - (i) are aware of and comply with their duties under this of this *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data*; and those in respect of Confidential Information



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (ii) are informed of the confidential nature of the Personal Data, are subject to appropriate obligations of confidentiality and do not publish, disclose or divulge any of the Personal Data to any third party where the that Party would not be permitted to do so;
 - (iii) have undergone adequate training in the use, care, protection and handling of personal data as required by the applicable Data Protection Legislation;
- (h) ensure that it has the capability (whether technological or otherwise), to the extent required by Data Protection Legislation, to provide or correct or delete at the request of a Data Subject all the Personal Data relating to that Data Subject that the Supplier holds; and
- (i) ensure that it notifies the other Party as soon as it becomes aware of a Personal Data Breach;
- (j) where the Personal Data is subject to UK GDPR, not transfer such Personal Data outside of the UK unless the prior written consent of the non-transferring Party has been obtained and the following conditions are fulfilled:
 - (i) the transfer is in accordance with Article 45 of the UK GDPR or DPA 2018 Section 73; or
 - (ii) the transferring Party has provided appropriate safeguards in relation to the transfer (whether in accordance with Article 46 of the UK GDPR or DPA 2018 Section 75) as agreed with the non-transferring Party which could include the relevant parties entering into International Data Transfer Agreement (the “**IDTA**”), or International Data Transfer Agreement Addendum to the European Commission’s SCCs (the “**Addendum**”), as published by the Information Commissioner’s office from time to time, as well as any additional measures;
 - (iii) the Data Subject has enforceable rights and effective legal remedies;
 - (iv) the transferring Party complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the non-transferring Party in meeting its obligations); and
 - (v) the transferring Party complies with any reasonable instructions notified to it in advance by the non-transferring Party with respect to the processing of the Personal Data; and
- (k) where the Personal Data is subject to EU GDPR, not transfer such Personal Data outside of the EU unless the prior written consent of the non-transferring Party has been obtained and the following conditions are fulfilled:
 - (i) the transfer is in accordance with Article 45 of the EU GDPR; or
 - (ii) the transferring Party has provided appropriate safeguards in relation to the transfer in accordance with Article 46 of the EU GDPR as determined by the non-transferring Party which could include relevant parties entering into Standard Contractual Clauses in the European Commission’s decision



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

2021/914/EU or such updated version of such Standard Contractual Clauses as are published by the European Commission from time to time as well as any additional measures;

- (iii) the Data Subject has enforceable rights and effective legal remedies;
- (iv) the transferring Party complies with its obligations under the EU GDPR by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the non-transferring Party in meeting its obligations); and
- (v) the transferring Party complies with any reasonable instructions notified to it in advance by the non-transferring Party with respect to the Processing of the Personal Data.

2.2 Each Joint Controller shall use its reasonable endeavours to assist the other Controller to comply with any obligations under applicable Data Protection Legislation and shall not perform its obligations under this Annex in such a way as to cause the other Joint Controller to breach any of its obligations under applicable Data Protection Legislation to the extent it is aware, or ought reasonably to have been aware, that the same would be a breach of such obligations.

3. Data Protection Breach

3.1 Without prejudice to Paragraph 3.2 of this *Part B – Joint Controller Agreement of Annex 1 – Processing Personal Data*, each Party shall notify the other Party promptly and without undue delay, and in any event within 48 hours, upon becoming aware of any Personal Data Breach or circumstances that are likely to give rise to a Personal Data Breach, providing the other Party and its advisors with:

- (a) sufficient information and in a timescale which allows the other Party to meet any obligations to report a Personal Data Breach under the Data Protection Legislation;
- (b) all reasonable assistance, including:
 - (i) co-operation with the other Party and the Information Commissioner investigating the Personal Data Breach and its cause, containing and recovering the compromised Personal Data and compliance with the applicable guidance;
 - (ii) co-operation with the other Party including using such reasonable endeavours as are directed by the Buyer to assist in the investigation, mitigation and remediation of a Personal Data Breach;
 - (iii) co-ordination with the other Party regarding the management of public relations and public statements relating to the Personal Data Breach; and/or
 - (iv) providing the other Party and to the extent instructed by the other Party to do so, and/or the Information Commissioner investigating the Personal Data Breach, with complete information relating to the Personal Data Breach, including, without limitation, the information set out in Paragraph 3.2 of this



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

Part B – Joint Controller Agreement of Annex 1 – Processing Personal Data;.

3.2 Each Party shall use all reasonable endeavours to restore, re-constitute and/or reconstruct any Personal Data where it has lost, damaged, destroyed, altered or corrupted as a result of a Personal Data Breach as if it was that Party's own data at its own cost with all possible speed and shall provide the other Party with all reasonable assistance in respect of any such Personal Data Breach, including providing the other Party, as soon as possible and within 48 hours of the Personal Data Breach relating to the Personal Data Breach, in particular:

- (a) the nature of the Personal Data Breach;
- (b) the nature of Personal Data affected;
- (c) the categories and number of Data Subjects concerned;
- (d) the name and contact details of the Party's Data Protection Officer or other relevant contact from whom more information may be obtained;
- (e) measures taken or proposed to be taken to address the Personal Data Breach; and
- (f) a description of the likely consequences of the Personal Data Breach.

4. Audit

4.1 The Supplier shall permit:

- (a) the Buyer, or a third-party auditor acting under the Buyer's direction, to conduct, at the Buyer's cost, data privacy and security audits, assessments and inspections concerning the Supplier's data security and privacy procedures relating to Personal Data, its compliance with this of this *Part B – Joint Controller Agreement of Annex 1 – Processing Personal Data*; and the Data Protection Legislation; and/or
- (b) the Buyer, or a third-party auditor acting under the Buyer's direction, access to premises at which the Personal Data is accessible or at which it is able to inspect any relevant records, including the record maintained under Article 30 UK GDPR by the Supplier so far as relevant to the Contract, and procedures, including premises under the control of any third party appointed by the Supplier to assist in the provision of the Deliverables.

4.2 The Buyer may, in its sole discretion, require the Supplier to provide evidence of the Supplier's compliance with Paragraph 4.1 of this *Part B – Joint Controller Agreement of Annex 1 – Processing Personal Data* in lieu of conducting such an audit, assessment or inspection.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

5. Impact Assessments

The Parties shall:

- 5.1 provide all reasonable assistance to each other to prepare any Data Protection Impact Assessment as may be required (including provision of detailed information and assessments in relation to processing operations, risks and measures); and
- 5.2 maintain full and complete records of all processing carried out in respect of the Personal Data in connection with the Contract, in accordance with the terms of Article 30 UK GDPR.

6. ICO Guidance

The Parties agree to take account of any non-mandatory guidance issued by the Information Commissioner or any other regulatory authority. The Buyer may on not less than thirty (30) Working Days' notice to the Supplier amend the Contract to ensure that it complies with any guidance issued by the Information Commissioner and/or any relevant Central Government Body.

7. Liabilities for Data Protection Breach

- 7.1 If financial penalties are imposed by the Information Commissioner on either the Buyer or the Supplier for a Personal Data Breach ("**Financial Penalties**") then the following shall occur:
 - (a) if in the view of the Information Commissioner, the Buyer is responsible for the Personal Data Breach, in that it is caused as a result of the actions or inaction of the Buyer, its employees, agents, contractors (other than the Supplier) or systems and procedures controlled by the Buyer, then the Buyer shall be responsible for the payment of such Financial Penalties. In this case, the Buyer will conduct an internal audit and engage at its reasonable cost when necessary, an independent third party to conduct an audit of any such Personal Data Breach. The Supplier shall provide to the Buyer and its third party investigators and auditors, on request and at the Supplier's reasonable cost, full cooperation and access to conduct a thorough audit of such Personal Data Breach;
 - (b) if in the view of the Information Commissioner, the Supplier is responsible for the Personal Data Breach, in that it is not a Personal Data Breach that the Buyer is responsible for, then the Supplier shall be responsible for the payment of these Financial Penalties. The Supplier will provide to the Buyer and its auditors, on request and at the Supplier's sole cost, full cooperation and access to conduct a thorough audit of such Personal Data Breach; or
 - (c) if no view as to responsibility is expressed by the Information Commissioner, then the Buyer and the Supplier shall work together to investigate the relevant Personal Data Breach and allocate responsibility for any Financial Penalties as outlined above, or by agreement to split any Financial Penalties equally if no responsibility for the Personal Data Breach can be apportioned. In the event that the Parties do not agree such apportionment then such Dispute shall be



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

referred to the Dispute Resolution Procedure set out in clause 37 of the Conditions (Resolving disputes).

- 7.2 If either the Buyer or the Supplier is the defendant in a legal claim brought before a court of competent jurisdiction ("**Court**") by a third party in respect of a Personal Data Breach, then unless the Parties otherwise agree, the Party that is determined by the final decision of the court to be responsible for the Personal Data Breach shall be liable for the losses arising from such Personal Data Breach. Where both Parties are liable, the liability will be apportioned between the Parties in accordance with the decision of the Court.
- 7.3 In respect of any losses, cost claims or expenses incurred by either Party as a result of a Personal Data Breach (the "**Claim Losses**"):
- (a) if the Buyer is responsible for the relevant Personal Data Breach, then the Buyer shall be responsible for the Claim Losses;
 - (b) if the Supplier is responsible for the relevant Personal Data Breach, then the Supplier shall be responsible for the Claim Losses: and
 - (c) if responsibility for the relevant Personal Data Breach is unclear, then the Buyer and the Supplier shall be responsible for the Claim Losses equally.
- 7.4 Nothing in either Paragraph 7.2 or Paragraph 7.3 of this *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data* shall preclude the Buyer and the Supplier reaching any other agreement, including by way of compromise with a third party complainant or claimant, as to the apportionment of financial responsibility for any Claim Losses as a result of a Personal Data Breach, having regard to all the circumstances of the Personal Data Breach and the legal and financial obligations of the Buyer.

8. Termination

If the Supplier is in material default under any of its obligations under this of this *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data*;, the Buyer shall be entitled to terminate the Contract by issuing a termination notice to the Supplier in accordance with clause 11 of the Conditions (Ending the contract).

9. Sub-Processing

In respect of any processing of Personal Data performed by a third party on behalf of a Party, that Party shall:

- 9.1 carry out adequate due diligence on such third party to ensure that it is capable of providing the level of protection for the Personal Data as is required by the Contract, and provide evidence of such due diligence to the other Party where reasonably requested; and
- 9.2 ensure that a suitable agreement is in place with the third party as required under applicable Data Protection Legislation.



10. Data Retention

The Parties agree to erase Personal Data from any computers, storage devices and storage media that are to be retained as soon as practicable after it has ceased to be necessary for them to retain such Personal Data under applicable Data Protection Legislation and their privacy policy (save to the extent (and for the limited period) that such information needs to be retained by the Party for statutory compliance purposes or as otherwise required by the Contract), and taking all further actions as may be necessary to ensure its compliance with Data Protection Legislation and its privacy policy.



C. Part C – Independent Controllers

1. Independent Controller Provisions

- 1.1 With respect to Personal Data provided by one Party to another Party for which each Party acts as Controller but which is not under the Joint Control of the Parties, each Party undertakes to comply with the applicable Data Protection Legislation in respect of their processing of such Personal Data as Controller.
- 1.2 Each Party shall process the Personal Data in compliance with its obligations under the Data Protection Legislation and not do anything to cause the other Party to be in breach of it.
- 1.3 Where a Party has provided Personal Data to the other Party in accordance with Paragraph 1.1 of this Part C – *Independent Controllers* of Annex 1 – *Processing Personal Data* above, the recipient of the Personal Data will provide all such relevant documents and information relating to its data protection policies and procedures as the other Party may reasonably require.
- 1.4 The Parties shall be responsible for their own compliance with Articles 13 and 14 UK GDPR in respect of the processing of Personal Data for the purposes of the Contract.
- 1.5 The Parties shall only provide Personal Data to each other:
 - (a) to the extent necessary to perform their respective obligations under the Contract;
 - (b) in compliance with the Data Protection Legislation (including by ensuring all required data privacy information has been given to affected Data Subjects to meet the requirements of Articles 13 and 14 of the UK GDPR); and
 - (c) where it has recorded it in Part A - *Authorised Processing Template* of Annex 1 – *Processing Personal Data*.
- 1.6 Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, each Party shall, with respect to its processing of Personal Data as Independent Controller, implement and maintain appropriate technical and organisational measures to ensure a level of security appropriate to that risk, including, as appropriate, the measures referred to in Article 32(1)(a), (b), (c) and (d) of the UK GDPR, and the measures shall, at a minimum, comply with the requirements of the Data Protection Legislation, including Article 32 of the UK GDPR.
- 1.7 A Party processing Personal Data for the purposes of the Contract shall maintain a record of its processing activities in accordance with Article 30 UK GDPR and shall make the record available to the other Party upon reasonable request.
- 1.8 Where a Party receives a request by any Data Subject to exercise any of their rights under the Data Protection Legislation in relation to the Personal Data provided to it by the other Party pursuant to the Contract ("**Request Recipient**");



Medicines & Healthcare products Regulatory Agency

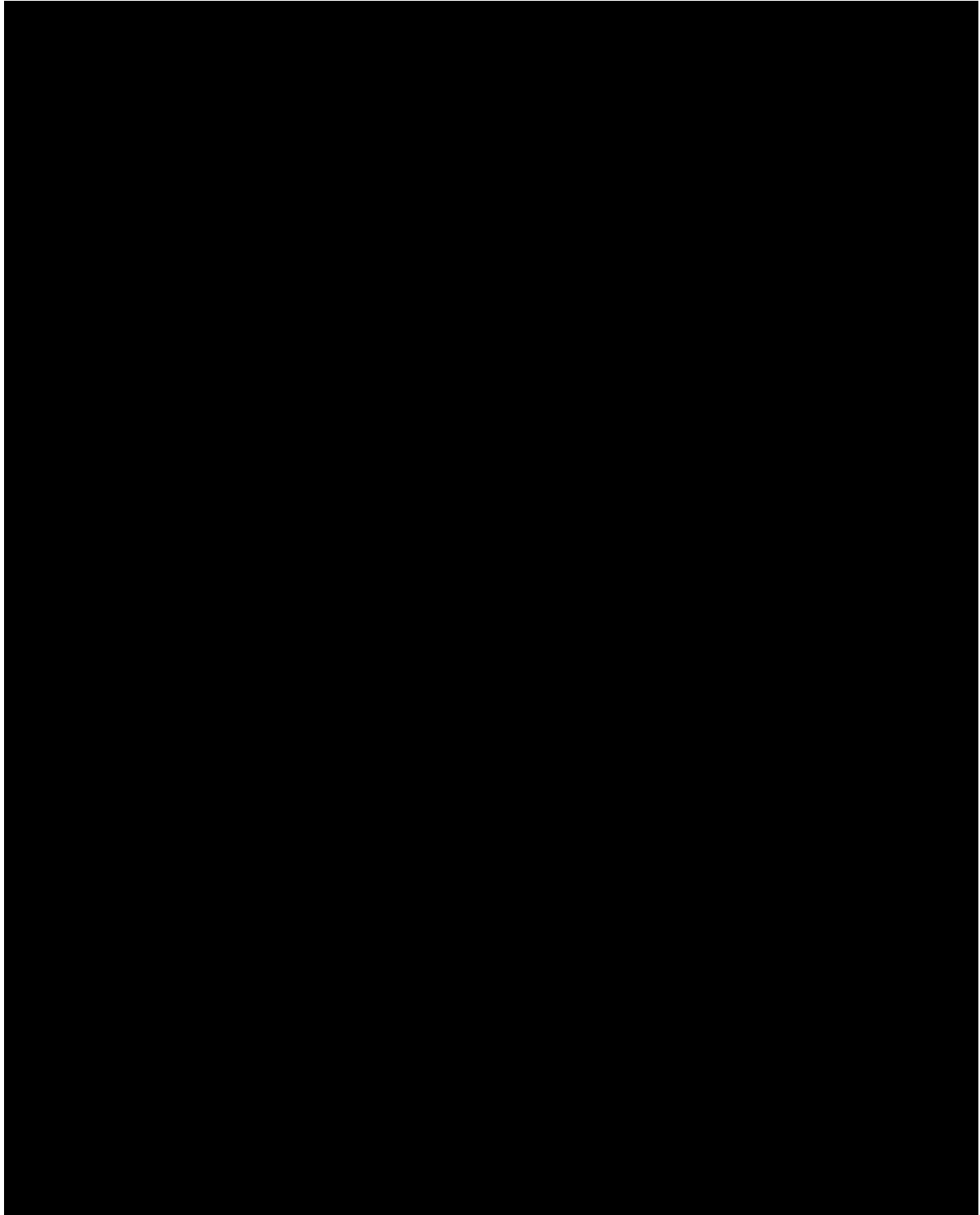
Crown Copyright 2022

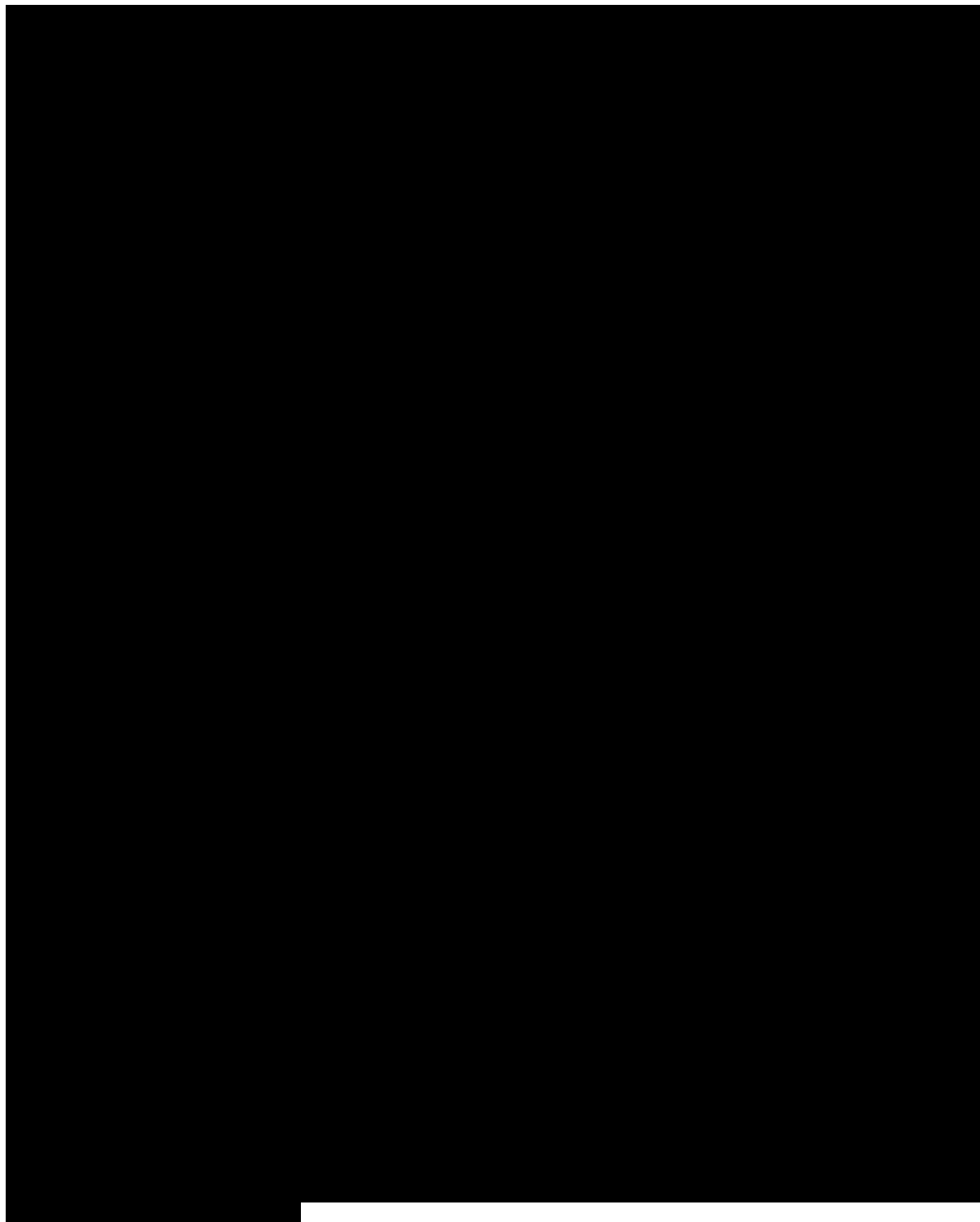
- (a) the other Party shall provide any information and/or assistance as reasonably requested by the Request Recipient to help it respond to the request or correspondence, at the cost of the Request Recipient; or
 - (b) where the request or correspondence is directed to the other Party and/or relates to that other Party's processing of the Personal Data, the Request Recipient will:
 - (i) promptly, and in any event within five (5) Working Days of receipt of the request or correspondence, inform the other Party that it has received the same and shall forward such request or correspondence to the other Party; and
 - (ii) provide any information and/or assistance as reasonably requested by the other Party to help it respond to the request or correspondence in the timeframes specified by Data Protection Legislation.
- 1.9 Each Party shall promptly notify the other Party upon it becoming aware of any Personal Data Breach relating to Personal Data provided by the other Party pursuant to the Contract and shall:
- (a) do all such things as reasonably necessary to assist the other Party in mitigating the effects of the Personal Data Breach;
 - (b) implement any measures necessary to restore the security of any compromised Personal Data;
 - (c) work with the other Party to make any required notifications to the Information Commissioner's office or any other regulatory authority and affected Data Subjects in accordance with the Data Protection Legislation (including the timeframes set out therein); and
 - (d) not do anything which may damage the reputation of the other Party or that Party's relationship with the relevant Data Subjects, save as required by Law.
- 1.10 Personal Data provided by one Party to the other Party may be used exclusively to exercise rights and obligations under the Contract as specified in Part A - *Authorised Processing Template* of Annex 1 – *Processing Personal Data*.
- 1.11 Personal Data shall not be retained or processed for longer than is necessary to perform each Party's respective obligations under the Contract which is specified in Part A - *Authorised Processing Template* of Annex 1 – *Processing Personal Data*.
- 1.12 Notwithstanding the general application of clauses 14.9(a) to 14.9(q) of the Conditions to Personal Data, where the Supplier is required to exercise its regulatory and/or legal obligations in respect of Personal Data, it shall act as an Independent Controller of Personal Data in accordance with Paragraphs 1.1 to 1.12 of this Part C – *Independent Controllers* of Annex 1 – *Processing Personal Data*.

This page is left blank.



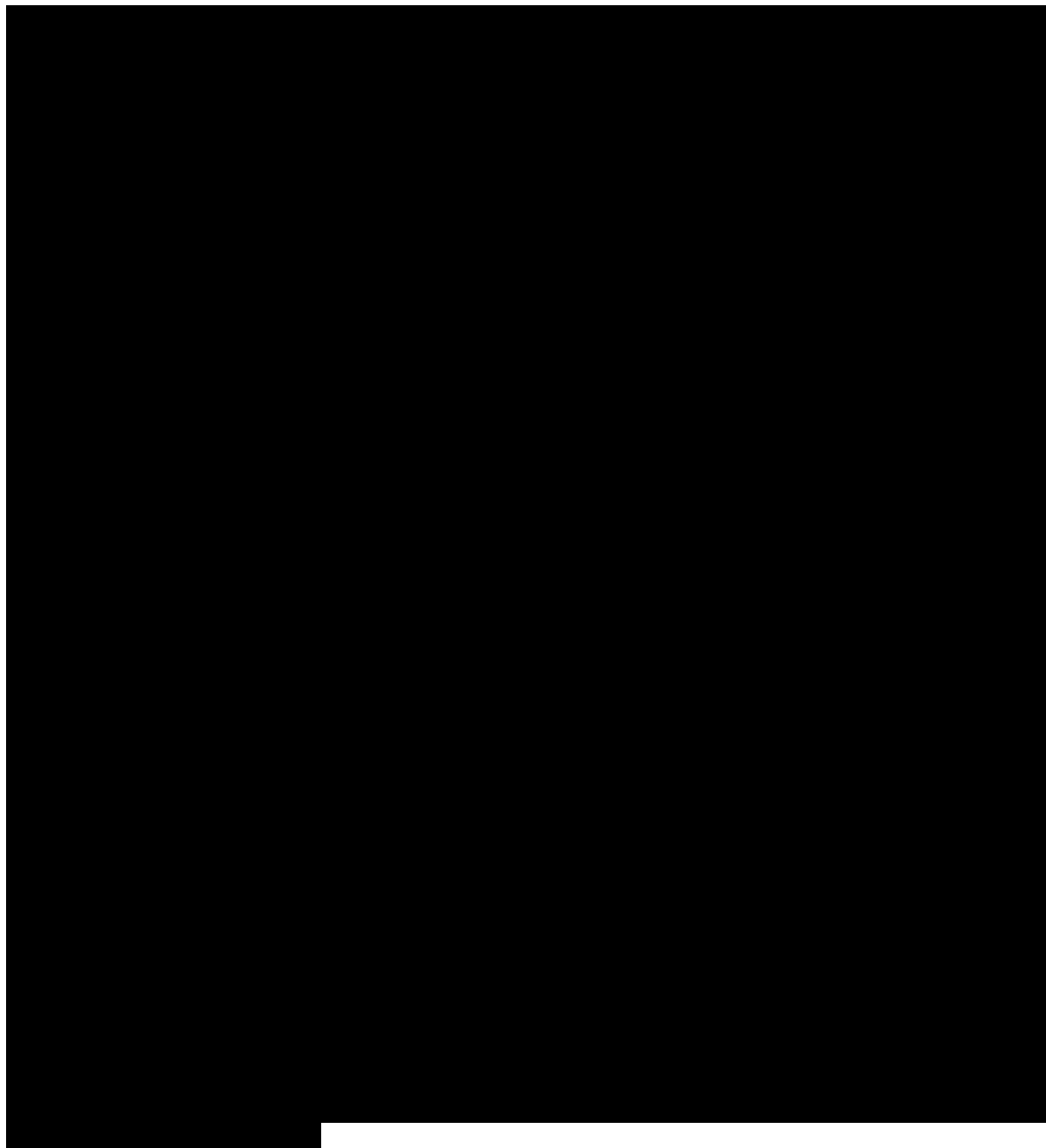
III. [Annex 2 – Specification] As submitted by supplier under Tender C180693







IV. [Annex 3 – Charges] As submitted by supplier under Tender C180693





Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

A. Part A: Buyer ownership with limited Supplier rights to exploit New IPR for the purposes of the current Contract

10. Intellectual Property Rights (IPRs)

- 10.1 Each Party keeps ownership of its own Existing IPRs. The Supplier gives the Buyer a non-exclusive, perpetual, royalty-free, irrevocable, transferable worldwide licence to use, change and sub-license the Supplier's Existing IPR to enable the Buyer and its sub-licensees to both:
- (a) receive and use the Deliverables; and
 - (b) use the New IPR.
- 10.2 Any New IPR created under the Contract is owned by the Buyer. The Buyer gives the Supplier a licence to use any Existing IPRs and the New IPR for the purpose of fulfilling its obligations during the Term.
- 10.3 Where a Party acquires ownership of intellectual property rights incorrectly under this Contract it must do everything reasonably necessary to complete a transfer assigning them in writing to the other Party on request and at its own cost.
- 10.4 Neither Party has the right to use the other Party's intellectual property rights, including any use of the other Party's names, logos or trademarks, except as provided in clause 10 or otherwise agreed in writing.
- 10.5 If any claim is made against the Buyer for actual or alleged infringement of a third party's intellectual property arising out of, or in connection with, the supply or use of the Deliverables (an "**IPR Claim**"), then the Supplier indemnifies the Buyer against all losses, damages, costs or expenses (including professional fees and fines) incurred as a result of the IPR Claim.
- 10.6 If an IPR Claim is made or anticipated the Supplier must at its own expense and the Buyer's sole option, either:
- (a) obtain for the Buyer the rights in clauses 10.1 and 10.2 without infringing any third party intellectual property rights; and
 - (b) replace or modify the relevant item with substitutes that don't infringe intellectual property rights without adversely affecting the functionality or performance of the Deliverables.
- 10.7 The Supplier shall not use in the Delivery of the Deliverables any Third Party IPR unless it has notified the Buyer that the owner or an authorised licensor of the relevant Third Party IPR will grant a direct licence to the Buyer for the Third Party IPR and that licence has been granted. The Buyer, in its absolute discretion, shall have 10 Working Days following the Supplier's notification to reject the grant of the licence. If the Supplier cannot obtain for the Buyer a licence in respect of any Third Party IPR, for whatever reason, the Supplier shall:
- (a) notify the Buyer in writing; and



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (b) use the relevant Third Party IPR only if the Buyer has provided authorisation in writing, with reference to the acts authorised and the specific intellectual property rights involved.
- 10.8 In spite of any other provisions of the Contract and for the avoidance of doubt, award of this Contract by the Buyer and the ordering of any Deliverable under it does not constitute an authorisation by the Crown under Sections 55 and 56 of the Patents Act 1977, Section 12 of the Registered Designs Act 1949 or Sections 240 – 243 of the Copyright, Designs and Patents Act 1988.
- 10.9 Subject to clause 10.11, the Supplier agrees that the Buyer may at its sole discretion publish under Open Licence all or part of the New IPR Items and the Supplier warrants that the New IPR Items are suitable for release under Open Licence.
- 10.10 The Supplier will supply any or all New IPR Items in a format suitable for publication under Open Licence ("**the Open Licence Publication Material**") within 30 days of written request from the Buyer ("**Buyer Open Licence Request**").
- 10.11 The Supplier may within 15 days of a Buyer Open Licence Request under clause 10.10 request in writing that the Buyer excludes all or part of:
 - (a) the New IPR; or
 - (b) Supplier Existing IPR or Third Party IPR that would otherwise be included in the Open Licence Publication Material supplied to the Buyer pursuant to clause 10.10from Open Licence publication.
- 10.12 Any decision to approve any such request from the Supplier pursuant to clause 10.11 shall be at the Buyer's sole discretion, not to be unreasonably withheld, delayed or conditioned.
- 10.13 Subject to clause 12, the Buyer will not be liable in the event that any Supplier Existing IPR or Third Party IPR is included in the Open Licence Publication Material published by the Buyer.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

Part B: Supplier ownership of New IPR with Buyer rights for the current Contract and broader public sector functions

10. Intellectual Property Rights (IPRs)

- 10.1 Each Party keeps ownership of its own Existing IPRs. The Supplier gives the Buyer a non-exclusive, perpetual, royalty-free, irrevocable, transferable worldwide licence to use, change and sub-license the Supplier's Existing IPR to enable the Buyer and its sub-licensees to both:
- (a) receive and use the Deliverables; and
 - (b) use the New IPR.
- 10.2 Any New IPR created under the Contract is owned by the Supplier. The Buyer gives the Supplier a licence to use any Existing IPRs for the purpose of fulfilling its obligations during the Term.
- 10.3 Where a Party acquires ownership of intellectual property rights incorrectly under this Contract it must do everything reasonably necessary to complete a transfer assigning them in writing to the other Party on request and at its own cost.
- 10.4 Neither Party has the right to use the other Party's intellectual property rights, including any use of the other Party's names, logos or trademarks, except as provided in clause 10 or otherwise agreed in writing.
- 10.5 The Supplier hereby grants the Buyer a non-exclusive, perpetual, royalty-free, irrevocable, transferable, worldwide licence to use, change and sub-license any New IPR which is reasonably required by the Buyer to enable it to use and receive the Deliverables or for any purpose relating to the exercise of the Buyer's (or, if the Buyer is a Public Sector Body, any other Public Sector Body's) business or function. For the purposes of this clause 10.5 "**Public Sector Body**" means a formally established organisation that is (at least in part) publicly funded to deliver a public or government service.
- 10.6 If any claim is made against the Buyer for actual or alleged infringement of a third party's intellectual property arising out of, or in connection with, the supply or use of the Deliverables (an "**IPR Claim**"), then the Supplier indemnifies the Buyer against all losses, damages, costs or expenses (including professional fees and fines) incurred as a result of the IPR Claim.
- 10.7 If an IPR Claim is made or anticipated the Supplier must at its own expense and the Buyer's sole option, either:
- (a) obtain for the Buyer the rights in clauses 10.1 and 10.2 without infringing any third party intellectual property rights; and
 - (b) replace or modify the relevant item with substitutes that don't infringe intellectual property rights without adversely affecting the functionality or performance of the Deliverables.
- 10.8 The Supplier shall not use in the Delivery of the Deliverables any Third Party IPR unless it has notified the Buyer that the owner or an authorised licensor of the



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

relevant Third Party IPR will grant a direct licence to the Buyer for the Third Party IPR and that licence has been granted. The Buyer, in its absolute discretion, shall have 10 Working Days following the Supplier's notification to reject the grant of the licence. If the Supplier cannot obtain for the Buyer a licence in respect of any Third Party IPR, for whatever reason, the Supplier shall:

- (a) notify the Buyer in writing; and
- (b) use the relevant Third Party IPR only if the Buyer has provided authorisation in writing, with reference to the acts authorised and the specific intellectual property rights involved.

- 10.9 In spite of any other provisions of the Contract and for the avoidance of doubt, award of this Contract by the Buyer and the ordering of any Deliverable under it does not constitute an authorisation by the Crown under Sections 55 and 56 of the Patents Act 1977, Section 12 of the Registered Designs Act 1949 or Sections 240 – 243 of the Copyright, Designs and Patents Act 1988.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

V. Short form Terms (“Conditions”)

1. Definitions used in the Contract

In this Contract, unless the context otherwise requires, the following words shall have the following meanings:

“Affiliates”	in relation to a body corporate, any other entity which directly or indirectly Controls (in either of the senses defined in sections 450 and 1124 of the Corporation Tax Act 2010 and “Controlled” shall be construed accordingly), is Controlled by, or is under direct or indirect common Control of that body corporate from time to time;
“Audit”	<p>the Buyer’s right to:</p> <ul style="list-style-type: none">(a) verify the accuracy of the Charges and any other amounts payable by the Buyer under the Contract (including proposed or actual variations to them in accordance with the Contract);(b) verify the costs of the Supplier (including the costs of all Subcontractors and any third party suppliers) in connection with the provision of the Deliverables;(c) verify the Supplier’s and each Subcontractor’s compliance with the applicable Law;(d) identify or investigate actual or suspected breach of clauses 4 to 35, impropriety or accounting mistakes or any breach or threatened breach of security and in these circumstances the Buyer shall have no obligation to inform the Supplier of the purpose or objective of its investigations;(e) identify or investigate any circumstances which may impact upon the financial stability of the Supplier and/or any Subcontractors or their ability to provide the Deliverables;(f) obtain such information as is necessary to fulfil the Buyer’s obligations to supply information for parliamentary, ministerial, judicial or administrative purposes including the supply of information to the Comptroller and Auditor General;(g) review any books of account and the internal contract management accounts kept by the Supplier in connection with the Contract;



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

	<p>(h) carry out the Buyer's internal and statutory audits and to prepare, examine and/or certify the Buyer's annual and interim reports and accounts;</p> <p>(i) enable the National Audit Office to carry out an examination pursuant to Section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Buyer has used its resources;</p>
"Buyer"	the person named as Buyer in the Order Form. Where the Buyer is a Crown Body the Supplier shall be treated as contracting with the Crown as a whole;
"Buyer Cause"	any breach of the obligations of the Buyer or any other default, act, omission, negligence or statement of the Buyer, of its employees, servants, agents in connection with or in relation to the subject-matter of the Contract and in respect of which the Buyer is liable to the Supplier;
"Central Government Body"	<p>a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics:</p> <p>(a) Government Department;</p> <p>(b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal);</p> <p>(c) Non-Ministerial Department; or</p> <p>(d) Executive Agency;</p>
"Charges"	the charges for the Deliverables as specified in the Order Form;
"Claim"	any claim which it appears that the Buyer is, or may become, entitled to indemnification under this Contract;
"Compliance Officer"	the person(s) appointed by the Supplier who is responsible for ensuring that the Supplier complies with its legal obligations;
"Conditions"	means these short form terms and conditions of contract;
"Confidential Information"	all information, whether written or oral (however recorded), provided by the disclosing Party to the receiving Party and which (i) is known by the receiving Party to be confidential; (ii) is marked as or stated to be confidential; or (iii) ought reasonably to be considered by the receiving Party to be



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

	confidential;
"Conflict of Interest"	a conflict between the financial or personal duties of the Supplier or the Supplier Staff and the duties owed to the Buyer under the Contract, in the reasonable opinion of the Buyer;
"Contract"	the contract between (i) the Buyer and (ii) the Supplier which is created by the Supplier's counter signing the Order Form and includes the cover letter (if used), Order Form, these Conditions and the Annexes;
"Controller"	has the meaning given to it in the UK GDPR or the EU GDPR as the context requires;
"Crown Body"	the government of the United Kingdom (including the Northern Ireland Assembly and Executive Committee, the Scottish Government and the National Assembly for Wales), including, but not limited to, government ministers and government departments and particular bodies, persons, commissions or agencies from time to time carrying out functions on its behalf;
"Data Loss Event"	any event that results, or may result, in unauthorised access to Personal Data held by the Processor under this Contract, and/or actual or potential loss and/or destruction of Personal Data in breach of this Contract, including any Personal Data Breach;
"Data Protection Impact Assessment"	an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data;
"Data Protection Legislation"	(a) the UK GDPR, (b) the DPA 2018; (c) all applicable Law about the processing of personal data and privacy and guidance issued by the Information Commissioner and other regulatory authority; and (d) (to the extent that it applies) the EU GDPR (and in the event of conflict, the UK GDPR shall apply);
"Data Protection Liability Cap"	has the meaning given to it in row 13 of the Order Form;
"Data Protection Officer"	has the meaning given to it in the UK GDPR or the EU GDPR as the context requires;
"Data Subject"	has the meaning given to it in the UK GDPR or the EU GDPR as the context requires;
"Data Subject Access Request"	a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

	Protection Legislation to access their Personal Data;
"Date of Delivery"	that date by which the Deliverables must be Delivered to the Buyer, as specified in the Order Form;
"Deliver"	hand over of the Deliverables to the Buyer at the address and on the date specified in the Order Form, which shall include unloading and any other specific arrangements agreed in accordance with clause 4.2. " Delivered " and " Delivery " shall be construed accordingly;
"Deliverables"	means the Goods and/or Services to be supplied under the Contract as set out in the Order Form;
"DPA 2018"	the Data Protection Act 2018;
"EU"	the European Union;
"EU GDPR"	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) as it has effect in EU law;
"Existing IPR"	any and all intellectual property rights that are owned by or licensed to either Party and which have been developed independently of the Contract (whether prior to the date of the Contract or otherwise);
"Expiry Date"	the date for expiry of the Contract as set out in the Order Form;
"FOIA"	the Freedom of Information Act 2000 together with any guidance and/or codes of practice issued by the Information Commissioner or relevant Government department in relation to such legislation;
"Force Majeure Event"	<p>any event, circumstance, matter or cause affecting the performance by either the Buyer or the Supplier of its obligations arising from:</p> <ul style="list-style-type: none">(a) acts, events, omissions, happenings or non-happenings beyond the reasonable control of the Party seeking to claim relief in respect of a Force Majeure Event (the "Affected Party") which prevent or materially delay the Affected Party from performing its obligations under the Contract;(b) riots, civil commotion, war or armed conflict, acts of terrorism, nuclear, biological or chemical warfare;



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

	<p>(c) acts of a Crown Body, local government or regulatory bodies;</p> <p>(d) fire, flood or any disaster; or</p> <p>(e) an industrial dispute affecting a third party for which a substitute third party is not reasonably available</p> <p>but excluding:</p> <p>(i) any industrial dispute relating to the Supplier, the Supplier Staff (including any subsets of them) or any other failure in the Supplier or the Subcontractor's supply chain;</p> <p>(ii) any event, occurrence, circumstance, matter or cause which is attributable to the wilful act, neglect or failure to take reasonable precautions against it by the Party concerned; and</p> <p>(iii) any failure of delay caused by a lack of funds,</p> <p>and which is not attributable to any wilful act, neglect or failure to take reasonable preventative action by that Party;</p>
"Goods"	the goods to be supplied by the Supplier to the Buyer under the Contract;
"Good Industry Practice"	standards, practices, methods and procedures conforming to the Law and the exercise of the degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged within the relevant industry or business sector;
"Government Data"	(a) the data, text, drawings, diagrams, images or sounds (together with any database made up of any of these) which are embodied in any electronic, magnetic, optical or tangible media, including any of the Buyer's confidential information, and which: (i) are supplied to the Supplier by or on behalf of the Buyer; or (ii) the Supplier is required to generate, process, store or transmit pursuant to the Contract; or (b) any Personal Data for which the Buyer is the Controller;
"Independent Controller"	a party which is Controller of the same Personal Data as the other Party and there is no element of joint control with regards to that Personal Data;



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

"Information"	has the meaning given under section 84 of the FOIA;
"Information Commissioner"	the UK's independent authority which deals with ensuring information relating to rights in the public interest and data privacy for individuals is met, whilst promoting openness by public bodies;
"Insolvency Event"	in respect of a person: <ul style="list-style-type: none">(a) if that person is insolvent;(b) where that person is a company, LLP or a partnership, if an order is made or a resolution is passed for the winding up of the person (other than voluntarily for the purpose of solvent amalgamation or reconstruction);(c) if an administrator or administrative receiver is appointed in respect of the whole or any part of the person's assets or business;(d) if the person makes any composition with its creditors; or(e) takes or suffers any similar or analogous action to any of the actions detailed in this definition as a result of debt in any jurisdiction;
"IP Completion Day"	has the meaning given to it in the European Union (Withdrawal Agreement) Act 2020;
"Joint Controller Agreement"	the agreement (if any) entered into between the Buyer and the Supplier substantially in the form set out in <i>Part B – Joint Controller Agreement</i> of Annex 1 – <i>Processing Personal Data</i> ;
"Joint Controllers"	Where two or more Controllers jointly determine the purposes and means of processing;
"Key Staff"	any persons specified as such in the Order Form or otherwise notified as such by the Buyer to the Supplier in writing, following agreement to the same by the Supplier;
"Law"	any law, subordinate legislation within the meaning of section 21(1) of the Interpretation Act 1978, bye-law, right within the meaning of the European Union (Withdrawal) Act 2018 as amended by European Union (Withdrawal Agreement) Act 2020, regulation, order, regulatory policy, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements of any



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

	regulatory body with which the Supplier is bound to comply;
"Month"	a calendar month and " Monthly " shall be interpreted accordingly;
"National Insurance"	contributions required by the Social Security Contributions and Benefits Act 1992 and made in accordance with the Social Security (Contributions) Regulations 2001 (SI 2001/1004);
"New IPR"	all and intellectual property rights in any materials created or developed by or on behalf of the Supplier pursuant to the Contract but shall not include the Supplier's Existing IPR;
"New IPR Items"	means a deliverable, document, product or other item within which New IPR subsists;
"Open Licence"	means any material that is published for use, with rights to access and modify, by any person for free, under a generally recognised open licence including Open Government Licence as set out at http://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/ and the Open Standards Principles documented at https://www.gov.uk/government/publications/open-standards-principles/open-standards-principles ;
"Order Form"	the order form signed by the Buyer and the Supplier printed above these Conditions;
"Party"	the Supplier or the Buyer (as appropriate) and " Parties " shall mean both of them;
"Personal Data"	has the meaning given to it in the UK GDPR or the EU GDPR as the context requires;
"Personal Data Breach"	has the meaning given to it in the UK GDPR or the EU GDPR as the context requires and includes any breach of Data Protection Legislation relevant to Personal Data processed pursuant to the Contract;
"Prescribed Person"	a legal adviser, an MP or an appropriate body which a whistle-blower may make a disclosure to as detailed in 'Whistleblowing: list of prescribed people and bodies', 24 November 2016, available online at: https://www.gov.uk/government/publications/blowing-the-whistle-list-of-prescribed-people-and-bodies--2/whistleblowing-list-of-prescribed-people-and-bodies as updated from time to time;
"Processor"	has the meaning given to it in the UK GDPR or the EU



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

	GDPR as the context requires;
"Processor Personnel"	all directors, officers, employees, agents, consultants and suppliers of the Processor and/or of any Subprocessor engaged in the performance of its obligations under the Contract;
"Protective Measures"	<p>technical and organisational measures which must take account of:</p> <ul style="list-style-type: none">(a) the nature of the data to be protected;(b) harm that might result from Data Loss Event;(c) state of technological development;(d) the cost of implementing any measures; <p>including pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of the such measures adopted by it;</p>
"Purchase Order Number" or "PO Number"	the Buyer's unique number relating to the order for Deliverables to be supplied by the Supplier to the Buyer in accordance with the Contract;
"Rectification Plan"	<p>the Supplier's plan (or revised plan) to rectify its material default which shall include:</p> <ul style="list-style-type: none">(a) full details of the material default that has occurred, including a root cause analysis;(b) the actual or anticipated effect of the material default; and(c) the steps which the Supplier proposes to take to rectify the material default (if applicable) and to prevent such material default from recurring, including timescales for such steps and for the rectification of the material default (where applicable);
"Regulations"	the Public Contracts Regulations 2015 and/or the Public Contracts (Scotland) Regulations 2015 (as the context requires) as amended from time to time;
"Request For Information"	has the meaning set out in the FOIA or the Environmental Information Regulations 2004 as relevant (where the meaning set out for the term "request" shall apply);



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

"Services"	the services to be supplied by the Supplier to the Buyer under the Contract;
"Specification"	the specification for the Deliverables to be supplied by the Supplier to the Buyer (including as to quantity, description and quality) as specified in the Order Form;
"Staff Vetting Procedures"	vetting procedures that accord with Good Industry Practice or, where applicable, the Buyer's procedures or policies for the vetting of personnel as specified in the Order Form or provided to the Supplier in writing following agreement to the same by the Supplier from time to time;
"Start Date"	the start date of the Contract set out in the Order Form;
"Sub-Contract"	any contract or agreement (or proposed contract or agreement), other than the Contract, pursuant to which a third party: (a) provides the Deliverables (or any part of them); (b) provides facilities or services necessary for the provision of the Deliverables (or any part of them); and/or (c) is responsible for the management, direction or control of the provision of the Deliverables (or any part of them);
"Subcontractor"	any person other than the Supplier, who is a party to a Sub-Contract and the servants or agents of that person;
"Subprocessor"	any third party appointed to process Personal Data on behalf of the Processor related to the Contract;
"Supplier"	the person named as Supplier in the Order Form;
"Supplier Staff"	all directors, officers, employees, agents, consultants and contractors of the Supplier and/or of any Subcontractor of the Supplier engaged in the performance of the Supplier's obligations under the Contract;
"Transparency Information"	In relation to Contracts with a value above the relevant threshold set out in Part 2 of the Regulations only, the content of the Contract, including any changes to this Contract agreed from time to time, as well as any information relating to the Deliverables and performance pursuant to the Contract required to be published by the Buyer to comply with its transparency obligations, including those set out in Public Procurement Policy Note 09/21



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

	(update to legal and policy requirements to publish procurement information on Contracts Finder) (https://www.gov.uk/government/publications/ppn-0921-requirements-to-publish-on-contracts-finder) and Public Procurement Policy Note 01/17 (update to transparency principles) where applicable (https://www.gov.uk/government/publications/procurement-policy-note-0117-update-to-transparency-principles) except for: (a) any information which is exempt from disclosure in accordance with the provisions of the FOIA, which shall be determined by the Buyer; and (b) Confidential Information;
"Term"	the period from the Start Date to the Expiry Date as such period may be extended in accordance with clause 11.2 or terminated in accordance with the Contract;
"Third Party IPR"	intellectual property rights owned by a third party which is or will be used by the Supplier for the purpose of providing the Deliverables;
"UK GDPR"	has the meaning as set out in section 3(10) of the DPA 2018, supplemented by section 205(4);
"VAT"	value added tax in accordance with the provisions of the Value Added Tax Act 1994;
"Worker"	any one of the Supplier Staff which the Buyer, in its reasonable opinion, considers is an individual to which Procurement Policy Note 08/15 (Tax Arrangements of Public Appointees) (https://www.gov.uk/government/publications/procurement-policy-note-0815-tax-arrangements-of-appointees) applies in respect of the Deliverables; and
"Working Day"	a day (other than a Saturday or Sunday) on which banks are open for business in the City of London.

2. Understanding the Contract

In the Contract, unless the context otherwise requires:

- 2.1 references to numbered clauses are references to the relevant clause in these Conditions;
- 2.2 any obligation on any Party not to do or omit to do anything shall include an obligation not to allow that thing to be done or omitted to be done;



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- 2.3 the headings in this Contract are for information only and do not affect the interpretation of the Contract;
- 2.4 references to "writing" include printing, display on a screen and electronic transmission and other modes of representing or reproducing words in a visible form;
- 2.5 the singular includes the plural and vice versa;
- 2.6 a reference to any Law includes a reference to that Law as amended, extended, consolidated or re-enacted from time to time and to any legislation or byelaw made under that Law;
- 2.7 the word "including", "for example" and similar words shall be understood as if they were immediately followed by the words "without limitation";
- 2.8 any reference which, immediately before IP Completion Day (or such later date when relevant EU law ceases to have effect pursuant to section 1A of the European Union (Withdrawal) Act 2018), is a reference to (as it has effect from time to time):
 - (a) any EU regulation, EU decision, EU tertiary legislation or provision of the EEA agreement ("**EU References**") which is to form part of domestic law by application of section 3 of the European Union (Withdrawal) Act 2018 and which shall be read on and after IP Completion Day as a reference to the EU References as they form part of domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 as modified by domestic law from time to time; and
 - (b) any EU institution or EU authority or other such EU body shall be read on and after IP Completion Day as a reference to the UK institution, authority or body to which its functions were transferred.

3. How the Contract works

- 3.1 The Order Form is an offer by the Buyer to purchase the Deliverables subject to and in accordance with the terms and conditions of the Contract.
- 3.2 The Supplier is deemed to accept the offer in the Order Form when the Buyer receives a copy of the Order Form signed by the Supplier.
- 3.3 The Supplier warrants and represents that its tender (if any) and all statements made and documents submitted as part of the procurement of Deliverables are and remain true and accurate.

4. What needs to be delivered

4.1 All Deliverables

- (a) The Supplier must provide Deliverables: (i) in accordance with the Specification, the tender in Annex 4 – Supplier Tender (where applicable) and the Contract; (ii) using reasonable skill and care; (iii) using Good Industry Practice; (iv) using its own policies, processes and internal quality control measures as long as they don't conflict with the Contract; (v) on the dates agreed; and (vi) that comply with all Law.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (b) The Supplier must provide Deliverables with a warranty of at least 90 days (or longer where the Supplier offers a longer warranty period to its Buyers) from Delivery against all obvious defects.

4.2 **Goods clauses**

- (a) All Goods delivered must be new, or as new if recycled, unused and of recent origin.
- (b) All manufacturer warranties covering the Goods must be assignable to the Buyer on request and for free.
- (c) The Supplier transfers ownership of the Goods on completion of Delivery (including off-loading and stacking) or payment for those Goods, whichever is earlier.
- (d) Risk in the Goods transfers to the Buyer on Delivery, but remains with the Supplier if the Buyer notices damage following Delivery and lets the Supplier know within 3 Working Days of Delivery.
- (e) The Supplier warrants that it has full and unrestricted ownership of the Goods at the time of transfer of ownership.
- (f) Supplier shall use reasonable endeavours to meet any agreed time period for delivery or Installation of the Goods. Deviations from any planned delivery date must be agreed with the Agency.
- (g) The Supplier must provide sufficient packaging for the Goods to reach the point of Delivery safely and undamaged.
- (h) All deliveries must have a delivery note attached that specifies the order number, type and quantity of Goods.
- (i) The Supplier must provide all tools, information and instructions the Buyer needs to make use of the Goods.
- (j) The Supplier will notify the Buyer of any request that Goods are returned to it or the manufacturer after the discovery of safety issues or defects that might endanger health or hinder performance and shall indemnify the Buyer against the costs arising as a result of any such request.
- (k) The Buyer can cancel any order or part order of Goods which has not been Delivered. If the Buyer gives less than 14 days' notice then it will pay the Supplier's reasonable and proven costs already incurred on the cancelled order as long as the Supplier takes all reasonable endeavours to minimise these costs.
- (l) The Supplier must at its own cost repair, replace, refund or substitute (at the Buyer's option and request) any Goods that the Buyer rejects because they don't conform with clause 4.2. If the Supplier doesn't do this it will pay the Buyer's costs including repair or re-supply by a third party.
- (m) The Buyer will not be liable for any actions, claims, costs and expenses incurred by the Supplier or any third party during Delivery of the Goods unless and to



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

the extent that it is caused by negligence or other wrongful act of the Buyer or its servant or agent. If the Buyer suffers or incurs any damage or injury (whether fatal or otherwise) occurring in the course of Delivery or installation then the Supplier shall indemnify the Buyer from any losses, charges, costs or expenses which arise as a result of or in connection with such damage or injury where it is attributable to any act or omission of the Supplier or any of its Subcontractors or Supplier Staff.

4.3 Services clauses

- (a) Late Delivery of the Services will be a default of the Contract.
- (b) The Supplier must co-operate with the Buyer and third party suppliers on all aspects connected with the delivery of the Services and ensure that Supplier Staff comply with any reasonable instructions including the security requirements (where any such requirements have been provided).
- (c) The Buyer must provide the Supplier with reasonable access to its premises at reasonable times for the purpose of supplying the Services
- (d) The Supplier must at its own risk and expense provide all equipment required to deliver the Services. Any equipment provided by the Buyer to the Supplier for supplying the Services remains the property of the Buyer and is to be returned to the Buyer on expiry or termination of the Contract.
- (e) The Supplier must allocate sufficient resources and appropriate expertise to the Contract.
- (f) The Supplier must take all reasonable care to ensure performance does not disrupt the Buyer's operations, employees or other contractors.
- (g) On completion of the Services, the Supplier is responsible for leaving the Buyer's premises in a clean, safe and tidy condition and making good any damage that it has caused to the Buyer's premises or property, other than fair wear and tear.
- (h) The Supplier must ensure all Services, and anything used to deliver the Services, are of good quality and free from defects.
- (i) The Buyer is entitled to withhold payment for partially or undelivered Services, but doing so does not stop it from using its other rights under the Contract.

5. Pricing and payments

- 5.1 In exchange for the Deliverables, the Supplier must invoice the Buyer for the charges in the Order Form.
- 5.2 All Charges:
 - (a) exclude VAT, which is payable on provision of a valid VAT invoice; and
 - (b) include all costs and expenses connected with the supply of Deliverables.
- 5.3 The Buyer must pay the Supplier the charges within 30 days of receipt by the Buyer of a valid, undisputed invoice, in cleared funds to the Supplier's account stated in the invoice or in the Order Form.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- 5.4 A Supplier invoice is only valid if it:
- (a) includes all appropriate references including the Purchase Order Number and other details reasonably requested by the Buyer; and
 - (b) includes a detailed breakdown of Deliverables which have been delivered.
- 5.5 If there is a dispute between the Parties as to the amount invoiced, the Buyer shall pay the undisputed amount. The Supplier shall not suspend the provision of the Deliverables unless the Supplier is entitled to terminate the Contract for a failure to pay undisputed sums in accordance with clause 11.6. Any disputed amounts shall be resolved through the dispute resolution procedure detailed in clause 37.
- 5.6 The Buyer may retain or set-off payment of any amount owed to it by the Supplier under this Contract or any other agreement between the Supplier and the Buyer if notice and reasons are provided.
- 5.7 The Supplier must ensure that all Subcontractors are paid, in full, within 30 days of receipt of a valid, undisputed invoice. If this doesn't happen, the Buyer can publish the details of the late payment or non-payment.
- 6. The Buyer's obligations to the Supplier**
- 6.1 If Supplier fails to comply with the Contract as a result of a Buyer Cause:
- (a) the Buyer cannot terminate the Contract under clause 11;
 - (b) the Supplier is entitled to reasonable and proven additional expenses and to relief from liability under this Contract;
 - (c) the Supplier is entitled to additional time needed to deliver the Deliverables; and
 - (d) the Supplier cannot suspend the ongoing supply of Deliverables.
- 6.2 Clause 6.1 only applies if the Supplier:
- (a) gives notice to the Buyer within 10 Working Days of becoming aware;
 - (b) demonstrates that the failure only happened because of the Buyer Cause; and
 - (c) mitigated the impact of the Buyer Cause.
- 7. Record keeping and reporting**
- 7.1 The Supplier must ensure that suitably qualified representatives attend progress meetings with the Buyer and provide progress reports when specified in the Order Form.
- 7.2 The Supplier must keep and maintain full and accurate records and accounts on everything to do with the Contract for 7 years after the date of expiry or termination of the Contract and in accordance with the UK GDPR or the EU GDPR as the context requires.
- 7.3 The Supplier must allow any auditor appointed by the Buyer access to its premises to verify all contract accounts and records of everything to do with the Contract and provide copies for the Audit.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- 7.4 During an Audit, the Supplier must provide information to the auditor and reasonable co-operation at their request.
- 7.5 The Parties will bear their own costs when an Audit is undertaken unless the Audit identifies a material default by the Supplier, in which case the Supplier will repay the Buyer's reasonable costs in connection with the Audit.
- 7.6 If the Supplier is not providing any of the Deliverables, or is unable to provide them, it must immediately:
- (a) tell the Buyer and give reasons;
 - (b) propose corrective action; and
 - (c) provide a deadline for completing the corrective action.
- 7.7 If the Buyer, acting reasonably, is concerned as to the financial stability of the Supplier such that it may impact on the continued performance of the Contract then the Buyer may:
- (a) require that the Supplier provide to the Buyer (for its approval) a plan setting out how the Supplier will ensure continued performance of the Contract and the Supplier will make changes to such plan as reasonably required by the Buyer and once it is agreed then the Supplier shall act in accordance with such plan and report to the Buyer on demand; and
 - (b) if the Supplier fails to provide a plan or fails to agree any changes which are requested by the Buyer or fails to implement or provide updates on progress with the plan, terminate the Contract immediately for material breach (or on such date as the Buyer notifies).
- 7.8 If there is a material default, the Supplier must notify the Buyer within 3 Working Days of the Supplier becoming aware of the material default. The Buyer may request that the Supplier provide a Rectification Plan within 10 Working Days of the Buyer's request alongside any additional documentation that the Buyer requires. Once such Rectification Plan is agreed between the Parties (without the Buyer limiting its rights) the Supplier must immediately start work on the actions in the Rectification Plan at its own cost.
- 8. Supplier Staff**
- 8.1 The Supplier Staff involved in the performance of the Contract must:
- (a) be appropriately trained and qualified;
 - (b) be vetted in accordance with the Staff Vetting Procedures; and
 - (c) comply with all conduct requirements when on the Buyer's premises.
- 8.2 Where the Buyer decides one of the Supplier's Staff isn't suitable to work on the Contract, the Supplier must replace them with a suitably qualified alternative.
- 8.3 If requested, the Supplier must replace any person whose acts or omissions have caused the Supplier to breach clause 29.1 to 29.3 .



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- 8.4 The Supplier must provide a list of Supplier Staff needing to access the Buyer's premises and say why access is required.
- 8.5 The Supplier indemnifies the Buyer against all claims brought by any person employed or engaged by the Supplier caused by an act or omission of the Supplier or any Supplier Staff.
- 8.6 The Supplier shall use those persons nominated (if any) as Key Staff in the Order Form or otherwise notified as such by the Buyer to the Supplier in writing, following agreement to the same by the Supplier to provide the Deliverables and shall not remove or replace any of them unless:
- (a) requested to do so by the Buyer or the Buyer approves such removal or replacement (not to be unreasonably withheld or delayed);
 - (b) the person concerned resigns, retires or dies or is on parental or long-term sick leave; or
 - (c) the person's employment or contractual arrangement with the Supplier or any Subcontractor is terminated for material breach of contract by the employee.
- 8.7 The Supplier shall ensure that no person who discloses that he/she has a conviction that is relevant to the nature of the Contract, relevant to the work of the Buyer, or is of a type otherwise advised by the Buyer (each such conviction a "**Relevant Conviction**"), or is found by the Supplier to have a Relevant Conviction (whether as a result of a police check, a disclosure and barring service check or otherwise) is employed or engaged in the provision of any part of the Deliverables.

9. Rights and protection

- 9.1 The Supplier warrants and represents that:
- (a) it has full capacity and authority to enter into and to perform the Contract;
 - (b) the Contract is executed by its authorised representative;
 - (c) it is a legally valid and existing organisation incorporated in the place it was formed;
 - (d) there are no known legal or regulatory actions or investigations before any court, administrative body or arbitration tribunal pending or threatened against it or its affiliates that might affect its ability to perform the Contract;
 - (e) all necessary rights, authorisations, licences and consents (including in relation to IPRs) are in place to enable the Supplier to perform its obligations under the Contract and the Buyer to receive the Deliverables;
 - (f) it doesn't have any contractual obligations which are likely to have a material adverse effect on its ability to perform the Contract; and
 - (g) it is not impacted by an Insolvency Event.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- 9.2 The warranties and representations in clause 3.3 and clause 9.1 are repeated each time the Supplier provides Deliverables under the Contract.
- 9.3 The Supplier indemnifies the Buyer against each of the following:
- (a) wilful misconduct of the Supplier, any of its Subcontractor and/or Supplier Staff that impacts the Contract; and
 - (b) non-payment by the Supplier of any tax or National Insurance.
- 9.4 If the Supplier becomes aware of a representation or warranty made in relation to the Contract that becomes untrue or misleading, it must immediately notify the Buyer.
- 9.5 All third party warranties and indemnities covering the Deliverables must be assigned for the Buyer's benefit by the Supplier.
- 10. Intellectual Property Rights (IPRs)**
- 10.1 Each Party keeps ownership of its own Existing IPRs. The Supplier gives the Buyer a non-exclusive, perpetual, royalty-free, irrevocable, transferable worldwide licence to use, change and sub-license the Supplier's Existing IPR to enable the Buyer and its sub-licensees to both:
- (a) receive and use the Deliverables; and
 - (b) use the New IPR.
- 10.2 Any New IPR created under the Contract is owned by the Buyer. The Buyer gives the Supplier a licence to use any Existing IPRs and the New IPR which the Supplier reasonably requires for the purpose of fulfilling its obligations during the Term or using or exploiting the New IPR developed under the Contract.
- 10.3 Where a Party acquires ownership of intellectual property rights incorrectly under this Contract it must do everything reasonably necessary to complete a transfer assigning them in writing to the other Party on request and at its own cost.
- 10.4 Neither Party has the right to use the other Party's intellectual property rights, including any use of the other Party's names, logos or trademarks, except as provided in clause 10 or otherwise agreed in writing.
- 10.5 If any claim is made against the Buyer for actual or alleged infringement of a third party's intellectual property arising out of, or in connection with, the supply or use of the Deliverables (an "**IPR Claim**"), then the Supplier indemnifies the Buyer against all losses, damages, costs or expenses (including professional fees and fines) incurred as a result of the IPR Claim.
- 10.6 If an IPR Claim is made or anticipated the Supplier must at its own expense and the Buyer's sole option, either:
- (a) obtain for the Buyer the rights in clauses 10.1 and 10.2 without infringing any third party intellectual property rights; and
 - (b) replace or modify the relevant item with substitutes that don't infringe intellectual property rights without adversely affecting the functionality or performance of the Deliverables.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

10.7 The Supplier shall not use in the Delivery of the Deliverables any Third Party IPR unless it has notified the Buyer that the owner or an authorised licensor of the relevant Third Party IPR will grant a direct licence to the Buyer for the Third Party IPR and that licence has been granted. The Buyer, in its absolute discretion, shall have 10 Working Days following the Supplier's notification to reject the grant of the licence. If the Supplier cannot obtain for the Buyer a licence in respect of any Third Party IPR, for whatever reason, the Supplier shall:

- (a) notify the Buyer in writing; and
- (b) use the relevant Third Party IPR only if the Buyer has provided authorisation in writing, with reference to the acts authorised and the specific intellectual property rights involved.

10.8 In spite of any other provisions of the Contract and for the avoidance of doubt, award of this Contract by the Buyer and the ordering of any Deliverable under it does not constitute an authorisation by the Crown under Sections 55 and 56 of the Patents Act 1977, Section 12 of the Registered Designs Act 1949 or Sections 240 – 243 of the Copyright, Designs and Patents Act 1988.

11. Ending the contract

11.1 The Contract takes effect on the Start Date and ends on the earlier of the Expiry Date or termination of the Contract, or earlier if required by Law.

11.2 The Buyer can extend the Contract where set out in the Order Form in accordance with the terms in the Order Form.

11.3 Ending the Contract without a reason

The Buyer has the right to terminate the Contract at any time without reason or liability by giving the Supplier not less than 90 days' written notice, and if it's terminated clause 11.5(a)(ii) to 11.5(a)(viii) applies.

11.4 When the Buyer can end the Contract

(a) If any of the following events happen, the Buyer has the right to immediately terminate its Contract by issuing a termination notice in writing to the Supplier:

- (i) there's a Supplier Insolvency Event;
- (ii) if the Supplier repeatedly breaches the Contract in a way to reasonably justify the opinion that its conduct is inconsistent with it having the intention or ability to give effect to the terms and conditions of the Contract;
- (iii) the Supplier is in material breach of any obligation which is capable of remedy, and that breach is not remedied within 30 days of the Supplier receiving notice specifying the breach and requiring it to be remedied;
- (iv) there's a change of control (within the meaning of section 450 of the Corporation Tax Act 2010) of the Supplier which isn't pre-approved by the Buyer in writing;



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (v) the Buyer discovers that the Supplier was in one of the situations in 57 (1) or 57(2) of the Regulations at the time the Contract was awarded;
 - (vi) the Supplier or its affiliates embarrass or bring the Buyer into disrepute or diminish the public trust in them; or
 - (vii) the Supplier fails to comply with its legal obligations in the fields of environmental, social, equality or employment Law when providing the Deliverables.
- (b) The Buyer also has the right to terminate the Contract in accordance with clauses 7.7(b), 21.3, 29.4(b), 34.3 and Paragraph 8 of *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data* (if used).
- (c) If any of the events in 73(1) (a) or (b) of the Regulations happen, the Buyer has the right to immediately terminate the Contract and clause 11.5(a)(ii) to 11.5(a)(viii) applies.

11.5 What happens if the Contract ends (Buyer termination)

- (a) Where the Buyer terminates the Contract under clause 11.4(a), 7.7(b), 29.4(b), or Paragraph 8 of *Part B – Joint Controller Agreement* of Annex 1 – *Processing Personal Data* (if used), all of the following apply:
- (i) the Supplier is responsible for the Buyer's reasonable costs of procuring replacement Deliverables for the rest of the term of the Contract;
 - (ii) the Buyer's payment obligations under the terminated Contract stop immediately;
 - (iii) accumulated rights of the Parties are not affected;
 - (iv) the Supplier must promptly delete or return the Government Data except where required to retain copies by Law;
 - (v) the Supplier must promptly return any of the Buyer's property provided under the Contract;
 - (vi) the Supplier must, at no cost to the Buyer, give all reasonable assistance to the Buyer and any incoming supplier and co-operate fully in the handover and re-procurement;
 - (vii) the Supplier must repay to the Buyer all the Charges that it has been paid in advance for Deliverables that it has not provided as at the date of termination or expiry; and
 - (viii) the following clauses survive the termination of the Contract: 4.2(j), 7, 8.5, 10, 12, 14, 15, 16, 19, 20, 37 and 38 and any clauses which are expressly or by implication intended to continue.

11.6 When the Supplier can end the Contract and what happens when the contract ends (Buyer and Supplier termination)

- (a) The Supplier can issue a reminder notice if the Buyer does not pay an undisputed invoice on time. The Supplier can terminate the Contract if the



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

Buyer fails to pay an undisputed invoiced sum due and worth over 10% of the total Contract value or £1,000, whichever is the lower, within 30 days of the date of the reminder notice.

- (b) Where the Buyer terminates the Contract in accordance with clause 11.3 or the Supplier terminates the Contract under clause 11.6(a) or 24.4:

- (i) the Buyer must promptly pay all outstanding charges incurred by the Supplier;
- (ii) the Buyer must pay the Supplier reasonable committed and unavoidable losses as long as the Supplier provides a fully itemised and costed schedule with evidence - the maximum value of this payment is limited to the total sum payable to the Supplier if the Contract had not been terminated; and

(iii) clauses 11.5(a)(ii) to 11.5(a)(viii) apply.

- (c) The Supplier also has the right to terminate the Contract in accordance with Clauses 21.3 and 24.4.

11.7 Partially ending and suspending the Contract

- (a) Where the Buyer has the right to terminate the Contract it can terminate or suspend (for any period), all or part of it. If the Buyer suspends the Contract it can provide the Deliverables itself or buy them from a third party.
- (b) The Buyer can only partially terminate or suspend the Contract if the remaining parts of it can still be used to effectively deliver the intended purpose.
- (c) The Parties must agree (in accordance with clause 26) any necessary variation required by clause 11.7, but the Supplier may not either:
 - (i) reject the variation; or
 - (ii) increase the Charges, except where the right to partial termination is under clause 11.3.
- (d) The Buyer can still use other rights available, or subsequently available to it if it acts on its rights under clause 11.7.

12. How much you can be held responsible for

12.1 Each Party's total aggregate liability under or in connection with the Contract (whether in tort, contract or otherwise) is no more than 125% of the Charges paid or payable to the Supplier.

12.2 No Party is liable to the other for:

- (a) any indirect losses; and/or
- (b) loss of profits, turnover, savings, business opportunities or damage to goodwill (in each case whether direct or indirect).

12.3 In spite of clause 12.1, neither Party limits or excludes any of the following:



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (a) its liability for death or personal injury caused by its negligence, or that of its employees, agents or Subcontractors;
 - (b) its liability for bribery or fraud or fraudulent misrepresentation by it or its employees; or
 - (c) any liability that cannot be excluded or limited by Law.
- 12.4 In spite of clause 12.1, the Supplier does not limit or exclude its liability for any indemnity given under clauses 8.5, 9.3(b), 10.5, or 33.2(b).
- 12.5 Notwithstanding clause 12.1, but subject to clauses 12.1 and 12.3, the Supplier's total aggregate liability under clause 14.7(e) shall not exceed the Data Protection Liability Cap.
- 12.6 Each Party must use all reasonable endeavours to mitigate any loss or damage which it suffers under or in connection with the Contract, including any indemnities.
- 12.7 If more than one Supplier is party to the Contract, each Supplier Party is fully responsible for both their own liabilities and the liabilities of the other Suppliers.
- 13. Obeying the Law**
- 13.1 The Supplier must, in connection with provision of the Deliverables:
 - (a) comply and procure that its Subcontractors comply with the Supplier Code of Conduct:
(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779660/20190220-Supplier_Code_of_Conduct.pdf) as such Code of Conduct may be updated from time to time, and such other sustainability requirements as set out in the Order Form;
 - (b) comply with the provisions of the Official Secrets Acts 1911 to 1989 and section 182 of the Finance Act 1989;
 - (c) support the Buyer in fulfilling its Public Sector Equality duty under section 149 of the Equality Act 2010;
 - (d) comply with the model contract terms contained in Example 1 of Annex C of the guidance to PPN 05/19 (Tackling Modern Slavery in Government Supply Chains) shall apply to the Contract, as such clauses may be amended or updated from time to time; and
 - (e) meet the applicable Government Buying Standards applicable to Deliverables which can be found online at:
<https://www.gov.uk/government/collections/sustainable-procurement-the-government-buying-standards-gbs>.
- 13.2 The Supplier indemnifies the Buyer against any costs resulting from any default by the Supplier relating to any applicable Law to do with the Contract.
- 13.3 The Supplier must appoint a Compliance Officer who must be responsible for ensuring that the Supplier complies with Law, clause 13.1 and clauses 28 to 35.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

14. Data Protection

- 14.1 The Supplier must not remove any ownership or security notices in or relating to the Government Data.
- 14.2 The Supplier must make accessible back-ups of all Government Data, stored in an agreed off-site location and send the Buyer copies every 6 Months.
- 14.3 The Supplier must ensure that any Supplier system holding any Government Data, including back-up data, is a secure system that complies with the security requirements specified in writing by the Buyer (where any such requirements have been provided).
- 14.4 If at any time the Supplier suspects or has reason to believe that the Government Data is corrupted, lost or sufficiently degraded, then the Supplier must immediately notify the Buyer and suggest remedial action.
- 14.5 If the Government Data is corrupted, lost or sufficiently degraded so as to be unusable the Buyer may either or both:
 - (a) tell the Supplier to restore or get restored Government Data as soon as practical but no later than 5 Working Days from the date that the Buyer receives notice, or the Supplier finds out about the issue, whichever is earlier; and/or
 - (b) restore the Government Data itself or using a third party.
- 14.6 The Supplier must pay each Party's reasonable costs of complying with clause 14.5 unless the Buyer is at fault.
- 14.7 The Supplier:
 - (a) must provide the Buyer with all Government Data in an agreed open format within 10 Working Days of a written request;
 - (b) must have documented processes to guarantee prompt availability of Government Data if the Supplier stops trading;
 - (c) must securely destroy all storage media that has held Government Data at the end of life of that media using Good Industry Practice;
 - (d) securely erase all Government Data and any copies it holds when asked to do so by the Buyer unless required by Law to retain it; and
 - (e) indemnifies the Buyer against any and all losses incurred if the Supplier breaches clause 14 or any Data Protection Legislation.
- 14.8 The Parties acknowledge that for the purposes of the Data Protection Legislation, the nature of the activity carried out by each of them in relation to their respective obligations under the Contract dictates the status of each party under the DPA 2018. A Party may act as:
 - (a) "Controller" in respect of the other Party who is "Processor";
 - (b) "Processor" in respect of the other Party who is "Controller";
 - (c) "Joint Controller" with the other Party;



- (d) “Independent Controller” of the Personal Data where the other Party is also “Controller”,

in respect of certain Personal Data under the Contract and shall specify in Part A - *Authorised Processing Template* of Annex 1 – *Processing Personal Data* which scenario they think shall apply in each situation.

14.9 Where one Party is Controller and the other Party its Processor

- (a) Where a Party is a Processor, it must only process Personal Data if authorised to do so in Part A - *Authorised Processing Template* of Annex 1 – *Processing Personal Data* by the Controller. Any further written instructions relating to the processing of Personal Data are incorporated into Part A - *Authorised Processing Template* of Annex 1 – *Processing Personal Data*.
- (b) The Processor must give all reasonable assistance to the Controller in the preparation of any Data Protection Impact Assessment before starting any processing, including:
- (i) a systematic description of the expected processing and its purpose;
 - (ii) the necessity and proportionality of the processing operations;
 - (iii) the risks to the rights and freedoms of Data Subjects; and
 - (iv) the intended measures to address the risks, including safeguards, security measures and mechanisms to protect Personal Data.
- (c) The Processor must notify the Controller immediately if it thinks the Controller's instructions breach the Data Protection Legislation.
- (d) The Processor must put in place appropriate Protective Measures to protect against a Data Loss Event which must be approved by the Controller.
- (e) If lawful to notify the Controller, the Processor must promptly notify the Controller if the Processor is otherwise required to process Personal Data by Law before processing it.
- (f) The Processor must use all reasonable endeavours to ensure the reliability and integrity of any Processor Personnel who have access to the Personal Data and ensure that they:
- (i) are aware of and comply with the Processor's duties under this clause 14;
 - (ii) are subject to appropriate confidentiality undertakings with the Processor or any Subprocessor;
 - (iii) are informed of the confidential nature of the Personal Data and do not provide any of the Personal Data to any third party unless directed in writing to do so by the Controller or as otherwise allowed by the Contract; and
 - (iv) have undergone adequate training in the use, care, protection and handling of Personal Data.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (g) Where the Personal Data is subject to UK GDPR, the Processor must not transfer Personal Data outside of the UK unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:
 - (i) the transfer is in accordance with Article 45 of the UK GDPR (or section 73 of DPA 2018); or
 - (ii) the Controller or the Processor has provided appropriate safeguards in relation to the transfer (whether in accordance with UK GDPR Article 46 or section 75 of the DPA 2018) as determined by the Controller which could include relevant parties entering into the International Data Transfer Agreement (the "**IDTA**"), or International Data Transfer Agreement Addendum to the European Commission's SCCs (the "**Addendum**"), as published by the Information Commissioner's Office from time to time as well as any additional measures determined by the Controller;
 - (iii) the Data Subject has enforceable rights and effective legal remedies when transferred;
 - (iv) the Processor meets its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred; and
 - (v) the Processor complies with the Controller's reasonable prior instructions about the processing of the Personal Data.
- (h) Where the Personal Data is subject to EU GDPR, the Processor must not transfer Personal Data outside of the EU unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:
 - (i) the transfer is in accordance with Article 45 of the EU GDPR; or
 - (i) the Controller or Processor has provided appropriate safeguards in relation to the transfer in accordance with Article 46 of the EU GDPR as determined by the Controller which could include relevant parties entering into Standard Contractual Clauses in the European Commission's decision 2021/914/EU or such updated version of such Standard Contractual Clauses as are published by the European Commission from time to time as well as any additional measures determined by the Controller;
 - (ii) the Data Subject has enforceable rights and effective legal remedies;
 - (iii) the Processor complies with its obligations under the EU GDPR by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Controller in meeting its obligations); and
 - (iv) the Processor complies with any reasonable instructions notified to it in advance by the Controller with respect to the processing of the Personal Data.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (j) The Processor must notify the Controller immediately if it:
 - (i) receives a Data Subject Access Request (or purported Data Subject Access Request);
 - (ii) receives a request to rectify, block or erase any Personal Data;
 - (iii) receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;
 - (iv) receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data processed under this Contract;
 - (v) receives a request from any third Party for disclosure of Personal Data where compliance with the request is required or claims to be required by Law; and
 - (vi) becomes aware of a Data Loss Event.
- (k) Any requirement to notify under clause (j) includes the provision of further information to the Controller in stages as details become available.
 - (i) The Processor must promptly provide the Controller with full assistance in relation to any Party's obligations under Data Protection Legislation and any complaint, communication or request made under clause (j). This includes giving the Controller:
 - (ii) full details and copies of the complaint, communication or request;
 - (iii) reasonably requested assistance so that it can comply with a Data Subject Access Request within the relevant timescales in the Data Protection Legislation;
 - (iv) any Personal Data it holds in relation to a Data Subject on request;
 - (v) assistance that it requests following any Data Loss Event; and
 - (vi) assistance that it requests relating to a consultation with, or request from, the Information Commissioner's Office or any other regulatory authority.
- (l) The Processor must maintain full, accurate records and information to show it complies with this clause 14. This requirement does not apply where the Processor employs fewer than 250 staff, unless either the Controller determines that the processing:
 - (i) is not occasional;
 - (ii) includes special categories of data as referred to in Article 9(1) of the UK GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the UK GDPR; or
 - (iii) is likely to result in a risk to the rights and freedoms of Data Subjects.
- (m) The Parties shall designate a Data Protection Officer if required by the Data Protection Legislation.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (n) Before allowing any Subprocessor to process any Personal Data, the Processor must:
 - (i) notify the Controller in writing of the intended Subprocessor and processing;
 - (ii) obtain the written consent of the Controller;
 - (iii) enter into a written contract with the Subprocessor so that this clause 14 applies to the Subprocessor; and
 - (iv) provide the Controller with any information about the Subprocessor that the Controller reasonably requires.
- (o) The Processor remains fully liable for all acts or omissions of any Subprocessor.
- (p) At any time the Buyer can, with 30 Working Days' notice to the Supplier, change this clause 14 to replace it with any applicable standard clauses (between the controller and processor) or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to the Contract).
- (q) The Parties agree to take account of any non-mandatory guidance issued by the Information Commissioner's Office or any other regulatory authority.

14.10 Joint Controllers of Personal Data

In the event that the Parties are Joint Controllers in respect of Personal Data under the Contract, the Parties shall implement paragraphs that are necessary to comply with UK GDPR Article 26 based on the terms set out in *Part B – Joint Controller Agreement of Annex 1 – Processing Personal Data*.

14.11 Independent Controllers of Personal Data

In the event that the Parties are Independent Controllers in respect of Personal Data under the Contract, the terms set out in *Part C – Independent Controllers of Annex 1 – Processing Personal Data* shall apply to this Contract.

15. What you must keep confidential

15.1 Each Party must:

- (a) keep all Confidential Information it receives confidential and secure;
- (b) not disclose, use or exploit the disclosing Party's Confidential Information without the disclosing Party's prior written consent, except for the purposes anticipated under the Contract; and
- (c) immediately notify the disclosing Party if it suspects unauthorised access, copying, use or disclosure of the Confidential Information.

15.2 In spite of clause 15.1, a Party may disclose Confidential Information which it receives from the disclosing Party in any of the following instances:

- (a) where disclosure is required by applicable Law, a regulatory body or a court with the relevant jurisdiction if the recipient Party notifies the disclosing Party of the



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

full circumstances, the affected Confidential Information and extent of the disclosure;

- (b) if the recipient Party already had the information without obligation of confidentiality before it was disclosed by the disclosing Party;
- (c) if the information was given to it by a third party without obligation of confidentiality;
- (d) if the information was in the public domain at the time of the disclosure;
- (e) if the information was independently developed without access to the disclosing Party's Confidential Information;
- (f) on a confidential basis, to its auditors or for the purposes of regulatory requirements;
- (g) on a confidential basis, to its professional advisers on a need-to-know basis; and
- (h) to the Serious Fraud Office where the recipient Party has reasonable grounds to believe that the disclosing Party is involved in activity that may be a criminal offence under the Bribery Act 2010.

15.3 The Supplier may disclose Confidential Information on a confidential basis to Supplier Staff on a need-to-know basis to allow the Supplier to meet its obligations under the Contract. The Supplier shall remain responsible at all times for compliance with the confidentiality obligations set out in this Contract by the persons to whom disclosure has been made.

15.4 The Buyer may disclose Confidential Information in any of the following cases:

- (a) on a confidential basis to the employees, agents, consultants and contractors of the Buyer;
- (b) on a confidential basis to any other Central Government Body, any successor body to a Central Government Body or any company that the Buyer transfers or proposes to transfer all or any part of its business to;
- (c) if the Buyer (acting reasonably) considers disclosure necessary or appropriate to carry out its public functions;
- (d) where requested by Parliament; and
- (e) under clauses 5.7 and 16.

15.5 For the purposes of clauses 15.2 to 15.4 references to disclosure on a confidential basis means disclosure under a confidentiality agreement or arrangement including terms as strict as those required in clause 15.

15.6 Transparency Information, and Information which is exempt from disclosure by clause 16 is not Confidential Information.

15.7 The Supplier must not make any press announcement or publicise the Contract or any part of it in any way, without the prior written consent of the Buyer and must take all reasonable endeavours to ensure that Supplier Staff do not either.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

16. When you can share information

- 16.1 The Supplier must tell the Buyer within 48 hours if it receives a Request For Information.
- 16.2 In accordance with a reasonable timetable and in any event within 5 Working Days of a request from the Buyer, the Supplier must give the Buyer full co-operation and information needed so the Buyer can:
- (a) comply with any FOIA request;
 - (b) comply with any Environmental Information Regulations (“EIR”) request;
 - (c) if the Contract has a value over the relevant threshold in Part 2 of the Regulations, comply with any of its obligations in relation to publishing Transparency Information.
- 16.3 To the extent that it is allowed and practical to do so, the Buyer will use reasonable endeavours to notify the Supplier of a Request For Information and may talk to the Supplier to help it decide whether to publish information under clause 16. However, the extent, content and format of the disclosure is the Buyer’s decision in its absolute discretion.

17. Insurance

The Supplier shall ensure it has adequate insurance cover for this Contract.

18. Invalid parts of the contract

If any part of the Contract is prohibited by Law or judged by a court to be unlawful, void or unenforceable, it must be read as if it was removed from the Contract as much as required and rendered ineffective as far as possible without affecting the rest of the Contract, whether it’s valid or enforceable.

19. No other terms apply

The provisions incorporated into the Contract are the entire agreement between the Parties. The Contract replaces all previous statements, or agreements whether written or oral. No other provisions apply.

20. Other people's rights in the contract

No third parties may use the Contracts (Rights of Third Parties) Act (“C RTPA”) to enforce any term of the Contract unless stated (referring to C RTPA) in the Contract. This does not affect third party rights and remedies that exist independently from C RTPA.

21. Circumstances beyond your control

- 21.1 Any Party affected by a Force Majeure Event is excused from performing its obligations under the Contract while the inability to perform continues, if it both:
- (a) provides written notice to the other Party; and
 - (b) uses all reasonable measures practical to reduce the impact of the Force Majeure Event.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

21.2 Any failure or delay by the Supplier to perform its obligations under the Contract that is due to a failure or delay by an agent, Subcontractor and/or Supplier Staff will only be considered a Force Majeure Event if that third party is itself prevented from complying with an obligation to the Supplier due to a Force Majeure Event.

21.3 Either Party can partially or fully terminate the Contract if the provision of the Deliverables is materially affected by a Force Majeure Event which lasts for 90 days continuously.

21.4 Where a Party terminates under clause 21.3:

- (a) each Party must cover its own losses; and
- (b) clause 11.5(a)(ii) to 11.5(a)(viii) applies.

22. Relationships created by the contract

The Contract does not create a partnership, joint venture or employment relationship. The Supplier must represent themselves accordingly and ensure others do so.

23. Giving up contract rights

A partial or full waiver or relaxation of the terms of the Contract is only valid if it is stated to be a waiver in writing to the other Party.

24. Transferring responsibilities

24.1 The Supplier cannot assign, novate or in any other way dispose of the Contract or any part of it without the Buyer's written consent.

24.2 The Buyer can assign, novate or transfer its Contract or any part of it to any Crown Body, public or private sector body which performs the functions of the Buyer.

24.3 When the Buyer uses its rights under clause 24.2 the Supplier must enter into a novation agreement in the form that the Buyer specifies.

24.4 The Supplier can terminate the Contract novated under clause 24.2 to a private sector body that is experiencing an Insolvency Event.

24.5 The Supplier remains responsible for all acts and omissions of the Supplier Staff as if they were its own.

25. Supply Chain

25.1 The Supplier cannot sub-contract the Contract or any part of it without the Buyer's prior written consent. The Supplier shall provide the Buyer with the name of any Subcontractor the Supplier proposes to engage for the purposes of the Contract. The decision of the Buyer to consent or not will not be unreasonably withheld or delayed. If the Buyer does not communicate a decision to the Supplier within 10 Working Days of the request for consent then its consent will be deemed to have been given. The Buyer may reasonably withhold its consent to the appointment of a Subcontractor if it considers that:

- (a) the appointment of a proposed Subcontractor may prejudice the provision of the Deliverables or may be contrary to its interests;



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (b) the proposed Subcontractor is unreliable and/or has not provided reliable goods and or reasonable services to its other customers; and/or
 - (c) the proposed Subcontractor employs unfit persons.
- 25.2 If the Buyer asks the Supplier for details about Subcontractors, the Supplier must provide details of all such Subcontractors at all levels of the supply chain including:
 - (a) their name;
 - (b) the scope of their appointment; and
 - (c) the duration of their appointment.
- 25.3 The Supplier must exercise due skill and care when it selects and appoints Subcontractors.
- 25.4 The Supplier will ensure that all Sub-Contracts in the Supplier's supply chain entered into after the Start Date wholly or substantially for the purpose of performing or contributing to the performance of the whole or any part of this Contract contain provisions that:
 - (a) allow the Supplier to terminate the Sub-Contract if the Subcontractor fails to comply with its obligations in respect of environmental, social, equality or employment Law;
 - (b) require the Supplier to pay all Subcontractors in full, within 30 days of receiving a valid, undisputed invoice; and
 - (c) allow the Buyer to publish the details of the late payment or non-payment if this 30-day limit is exceeded.
- 25.5 The Supplier will take reasonable endeavours to ensure that all Sub-Contracts in the Supplier's supply chain entered into before the Start Date but made wholly or substantially for the purpose of performing or contributing to the performance of the whole or any part of this Contract contain provisions that:
 - (a) allow the Supplier to terminate the Sub-Contract if the Subcontractor fails to comply with its obligations in respect of environmental, social, equality or employment Law;
 - (b) require the Supplier to pay all Subcontractors in full, within 30 days of receiving a valid, undisputed invoice; and
 - (c) allow the Buyer to publish the details of the late payment or non-payment if this 30-day limit is exceeded.
- 25.6 At the Buyer's request, the Supplier must terminate any Sub-Contracts in any of the following events:
 - (a) there is a change of control within the meaning of Section 450 of the Corporation Tax Act 2010 of a Subcontractor which isn't pre-approved by the Buyer in writing;



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (b) the acts or omissions of the Subcontractor have caused or materially contributed to a right of termination under Clause 11.4;
- (c) a Subcontractor or its Affiliates embarrasses or brings into disrepute or diminishes the public trust in the Buyer;
- (d) the Subcontractor fails to comply with its obligations in respect of environmental, social, equality or employment Law; and/or
- (e) the Buyer has found grounds to exclude the Subcontractor in accordance with Regulation 57 of the Regulations.

25.7 The Supplier is responsible for all acts and omissions of its Subcontractors and those employed or engaged by them as if they were its own.

26. Changing the contract

Either Party can request a variation to the Contract which is only effective if agreed in writing and signed by both Parties. The Buyer is not required to accept a variation request made by the Supplier.

27. How to communicate about the contract

27.1 All notices under the Contract must be in writing and are considered effective on the Working Day of Delivery as long as they're delivered before 5:00pm on a Working Day. Otherwise the notice is effective on the next Working Day. An email is effective at 9am on the first Working Day after sending unless an error message is received.

27.2 Notices to the Buyer or Supplier must be sent to their address or email address in the Order Form.

27.3 This clause does not apply to the service of legal proceedings or any documents in any legal action, arbitration or dispute resolution.

28. Dealing with claims

28.1 If the Buyer becomes aware of any Claim, the Buyer must:

- (a) notify the Supplier as soon as reasonably practical becoming aware of a Claim;
- (b) at the Supplier's cost, allow the Supplier to conduct all negotiations and proceedings to do with a Claim;
- (c) at the Supplier's cost, give the Supplier reasonable assistance with the Claim if requested; and
- (d) not make admissions about the Claim without the prior written consent of the Supplier which cannot be unreasonably withheld or delayed.

28.2 The Supplier must:

- (a) consider and defend the Claim diligently and in a way that does not damage the Buyer's reputation; and
- (b) not settle or compromise any Claim without the Buyer's prior written consent which it must not unreasonably withhold or delay.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

29. Preventing fraud, bribery and corruption

29.1 The Supplier shall not:

- (a) commit any criminal offence referred to in 57(1) and 57(2) of the Regulations; or
- (b) offer, give, or agree to give anything, to any person (whether working for or engaged by the Buyer or any other public body) an inducement or reward for doing, refraining from doing, or for having done or refrained from doing, any act in relation to the obtaining or execution of the Contract or any other public function or for showing or refraining from showing favour or disfavour to any person in relation to the Contract or any other public function.

29.2 The Supplier shall take all reasonable endeavours (including creating, maintaining and enforcing adequate policies, procedures and records), in accordance with Good Industry Practice, to prevent any matters referred to in clause 29.1 and any fraud by the Supplier Staff and the Supplier (including its shareholders, members and directors) in connection with the Contract and shall notify the Buyer immediately if it has reason to suspect that any such matters have occurred or is occurring or is likely to occur.

29.3 If the Supplier notifies the Buyer as required by clause 29.2, the Supplier must respond promptly to their further enquiries, co-operate with any investigation and allow the Audit of any books, records and relevant documentation.

29.4 If the Supplier or the Supplier Staff engages in conduct prohibited by clause 29.1 or commits fraud in relation to the Contract or any other contract with the Crown (including the Buyer) the Buyer may:

- (a) require the Supplier to remove any Supplier Staff from providing the Deliverables if their acts or omissions have caused the default; and
- (b) immediately terminate the Contract.

30. Equality, diversity and human rights

30.1 The Supplier must follow all applicable employment and equality Law when they perform their obligations under the Contract, including:

- (a) protections against discrimination on the grounds of race, sex, gender reassignment, religion or belief, disability, sexual orientation, pregnancy, maternity, age or otherwise; and
- (b) any other requirements and instructions which the Buyer reasonably imposes related to equality Law.

30.2 The Supplier must use all reasonable endeavours, and inform the Buyer of the steps taken, to prevent anything that is considered to be unlawful discrimination by any court or tribunal, or the Equality and Human Rights Commission (or any successor organisation) when working on the Contract.

31. Health and safety

31.1 The Supplier must perform its obligations meeting the requirements of:



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (a) all applicable Law regarding health and safety; and
- (b) the Buyer's current health and safety policy while at the Buyer's premises, as provided to the Supplier.

31.2 The Supplier and the Buyer must as soon as possible notify the other of any health and safety incidents or material hazards they're aware of at the Buyer premises that relate to the performance of the Contract.

32. Environment and sustainability

32.1 In performing its obligations under the Contract, the Supplier shall, to the reasonable satisfaction of the Buyer:

- (a) meet, in all material respects, the requirements of all applicable Laws regarding the environment; and
- (b) comply with its obligations under the Buyer's current environmental policy, which the Buyer must provide.

32.2 The Supplier must ensure that Supplier Staff are aware of the Buyer's environmental policy.

33. Tax

33.1 The Supplier must not breach any tax or social security obligations and must enter into a binding agreement to pay any late contributions due, including where applicable, any interest or any fines. The Buyer cannot terminate the Contract where the Supplier has not paid a minor tax or social security contribution.

33.2 Where the Supplier or any Supplier Staff are liable to be taxed or to pay National Insurance contributions in the UK relating to payment received under the Contract, the Supplier must both:

- (a) comply with the Income Tax (Earnings and Pensions) Act 2003 and all other statutes and regulations relating to income tax, the Social Security Contributions and Benefits Act 1992 (including IR35) and National Insurance contributions; and
- (b) indemnify the Buyer against any Income Tax, National Insurance and social security contributions and any other liability, deduction, contribution, assessment or claim arising from or made during or after the Term in connection with the provision of the Deliverables by the Supplier or any of the Supplier Staff.

33.3 If any of the Supplier Staff are Workers who receive payment relating to the Deliverables, then the Supplier must ensure that its contract with the Worker contains requirements that:

- (a) the Buyer may, at any time during the term of the Contract, request that the Worker provides information which demonstrates they comply with clause 33.2, or why those requirements do not apply, the Buyer can specify the information the Worker must provide and the deadline for responding;



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- (b) the Worker's contract may be terminated at the Buyer's request if the Worker fails to provide the information requested by the Buyer within the time specified by the Buyer;
- (c) the Worker's contract may be terminated at the Buyer's request if the Worker provides information which the Buyer considers isn't good enough to demonstrate how it complies with clause 33.2 or confirms that the Worker is not complying with those requirements; and
- (d) the Buyer may supply any information they receive from the Worker to HMRC for revenue collection and management.

34. Conflict of interest

- 34.1 The Supplier must take action to ensure that neither the Supplier nor the Supplier Staff are placed in the position of an actual, potential or perceived Conflict of Interest.
- 34.2 The Supplier must promptly notify and provide details to the Buyer if an actual, potential or perceived Conflict of Interest happens or is expected to happen.
- 34.3 The Buyer will consider whether there are any appropriate measures that can be put in place to remedy an actual, perceived or potential Conflict of Interest. If, in the reasonable opinion of the Buyer, such measures do not or will not resolve an actual or potential conflict of interest, the Buyer may terminate the Contract immediately by giving notice in writing to the Supplier where there is or may be an actual or potential Conflict of Interest and clauses 11.5(a)(ii) to 11.5(a)(viii) shall apply.

35. Reporting a breach of the contract

- 35.1 As soon as it is aware of it the Supplier and Supplier Staff must report to the Buyer any actual or suspected breach of Law, clause 13.1, or clauses 28 to 34.
- 35.2 The Supplier must not retaliate against any of the Supplier Staff who in good faith reports a breach listed in clause 35.1 to the Buyer or a Prescribed Person.

36. Further Assurances

Each Party will, at the request and cost of the other Party, do all things which may be reasonably necessary to give effect to the meaning of this Contract.

37. Resolving disputes

- 37.1 If there is a dispute between the Parties, their senior representatives who have authority to settle the dispute will, within 28 days of a written request from the other Party, meet in good faith to resolve the dispute by commercial negotiation.
- 37.2 If the dispute is not resolved at that meeting, the Parties can attempt to settle it by mediation using the Centre for Effective Dispute Resolution ("CEDR") Model Mediation Procedure current at the time of the dispute. If the Parties cannot agree on a mediator, the mediator will be nominated by CEDR. If either Party does not wish to use, or continue to use mediation, or mediation does not resolve the dispute, the dispute must be resolved using clauses 37.3 to 37.5.



Medicines & Healthcare products Regulatory Agency

Crown Copyright 2022

- 37.3 Unless the Buyer refers the dispute to arbitration using clause 37.4, the Parties irrevocably agree that the courts of England and Wales have the exclusive jurisdiction to:
- (a) determine the dispute;
 - (b) grant interim remedies; and
 - (c) grant any other provisional or protective relief.
- 37.4 The Supplier agrees that the Buyer has the exclusive right to refer any dispute to be finally resolved by arbitration under the London Court of International Arbitration Rules current at the time of the dispute. There will be only one arbitrator. The seat or legal place of the arbitration will be London and the proceedings will be in English.
- 37.5 The Buyer has the right to refer a dispute to arbitration even if the Supplier has started or has attempted to start court proceedings under clause 37.3, unless the Buyer has agreed to the court proceedings or participated in them. Even if court proceedings have started, the Parties must do everything necessary to ensure that the court proceedings are stayed in favour of any arbitration proceedings if they are started under clause 37.4.
- 37.6 The Supplier cannot suspend the performance of the Contract during any dispute.
- 38. Which law applies**
- This Contract and any issues or disputes arising out of, or connected to it, are governed by English law.