|  |
| --- |
| 1. **Dated**:  2023
2. UK BIOBANK LIMITED
3. [*THE SUPPLIER*]
 |
| **Agreement**  |
| relating to the supply, installation and support of an automated large-scale ultra-low temperature biological sample archive  |



CONTENTS

**Clause** **Page**

SECTION A – PRELIMINARIES 3

‎1 DEFINITIONS AND INTERPRETATION 3

‎2 DUE DILIGENCE 4

‎3 WARRANTIES 4

SECTION B – THE SERVICES 6

‎4 TERM 6

‎5 SERVICES 7

‎6 INSTALLATION AND TESTING 10

‎7 PERFORMANCE INDICATORS 11

‎8 EQUIPMENT AND MAINTENANCE 12

SECTION C – FINANCIAL AND CONTRACT GOVERNANCE 13

‎9 FINANCIAL 13

‎10 RECORDS AND AUDITS 13

‎11 CHANGE 14

SECTION D – SUPPLIER PERSONNEL AND SUPPLY CHAIN 15

‎12 SUPPLIER PERSONNEL 15

‎13 SUPPLY CHAIN RIGHTS AND PROTECTIONS 17

SECTION E – INTELLECTUAL PROPERTY, DATA AND CONFIDENTIALITY 17

‎14 INTELLECTUAL PROPERTY RIGHTS 17

‎15 RIGHTS GRANTED BY THE SUPPLIER 18

‎16 LICENCES GRANTED BY UK BIOBANK 19

‎17 IPRs INDEMNITY 20

‎18 UK BIOBANK DATA AND SECURITY REQUIREMENTS AND SERVICE CONTINUITY PLANS 20

‎19 CONFIDENTIALITY 22

‎20 DATA PROTECTION 24

‎21 PUBLICITY AND BRANDING 24

SECTION F – LIABILITY, INDEMNITIES AND INSURANCE 24

‎22 LIMITATIONS ON LIABILITY 24

SECTION G – REMEDIES AND RELIEF 26

‎23 RECTIFICATION PLAN PROCESS 26

‎24 UK BIOBANK CAUSE 27

‎25 FORCE MAJEURE 28

SECTION H – TERMINATION AND EXIT MANAGEMENT 28

‎26 TERMINATION RIGHTS 28

‎27 CONSEQUENCES OF EXPIRY OR TERMINATION 29

SECTION I – MISCELLANEOUS AND GOVERNING LAW 30

‎28 ASSIGNMENT AND NOVATION 30

‎29 WAIVER AND CUMULATIVE REMEDIES 30

‎30 RELATIONSHIP OF THE PARTIES 30

‎31 PREVENTION OF FRAUD AND BRIBERY 30

‎32 ENTIRE AGREEMENT 31

‎33 THIRD PARTY RIGHTS 31

‎34 NOTICES 31

‎35 DISPUTES 32

‎36 GOVERNING LAW AND JURISDICTION 33

Schedules

‎1 Definitions 35

‎2 Specification and Supplier Solution 56

‎3 Performance Levels 57

‎4 UK Biobank Responsibilities 69

‎5 Project Plan 70

‎6 Testing Procedures 74

‎7 Charging and Invoicing 84

‎8 Exit Management 91

‎9 Processing Personal Data 98

‎10 Staff Transfer 104

**THIS AGREEMENT** is made on 2023

**BETWEEN**

1. **UK BIOBANK LIMITED** a company registered in England and Wales under company number 04978912 whose registered office is at Units 1 & 2 Spectrum Way, Adswood, Stockport, Cheshire, SK3 0SA (“**UK Biobank**”); and
2. [***NAME OF THE SUPPLIER***] a company registered in [*England and Wales*] under company number [       ] whose registered office is at [               ] (“**Supplier**”)
3. (each a “**Party**” and together the “**Parties**”).
4. **INTRODUCTION**
5. UK Biobank holds a large-scale biomedical database and research resource containing genetic, lifestyle and health information from half a million UK participants. This is globally accessible to approved researchers who are undertaking health-related research that is in the public interest. UK Biobank is responsible for the safe preservation, and scientific exploitation, of the biological samples.
6. UK Biobank wishes to procure the supply, installation and support of an automated large-scale ultra-low temperature biological sample archive to replace its existing archive.
7. On [INSERT DATA] UK Biobank advertised in the UK Government’s Find a Tender Service (reference [INSERT REFERENCE NUMBER]), inviting prospective suppliers to submit proposals for the provision of a managed cold store system for biological samples.
8. The Supplier is a leading provider of automated large-scale ultra-low temperature biological sample archives and related services and has experience in the supply, installation and ongoing support thereof.
9. The Parties have agreed to contract with each other in accordance with the terms and conditions set out below.
10. **IT IS AGREED** as follows:

section a – preliminaries

1. **OPERATIVE PROVISIONS**
2. DEFINITIONS AND INTERPRETATION
	1. In this Agreement, unless otherwise provided or the context otherwise requires, capitalised expressions shall have the meanings set out in Schedule 1 (Definitions) or the relevant Schedule in which that capitalised expression appears.
	2. In this Agreement, unless the context otherwise requires:
		1. the singular includes the plural and vice versa;
		2. reference to a gender includes the other gender and the neuter;
		3. references to a person include an individual, company, body corporate, corporation, unincorporated association, firm, partnership or other legal entity;
		4. a reference to any Law includes a reference to that Law as amended, extended, consolidated or re-enacted from time to time;
		5. the words “**including**”, “**other**”, “**in particular**”, “**for example**” and similar words shall not limit the generality of the preceding words and shall be construed as if they were immediately followed by the words “without limitation”;
		6. the headings are for ease of reference only and shall not affect the interpretation or construction of this Agreement; and
		7. references to clauses and Schedules are references to the clauses and schedules of this Agreement and references in any Schedule to Paragraphs, Parts and Annexes are, unless otherwise provided, references to the paragraphs, parts and annexes of the Schedule or the Part of the Schedule in which the references appear.
	3. If there is any conflict between the clauses, the Schedules and/or any Annexes to the Schedules, the conflict shall be resolved in accordance with the following order of precedence:
		1. the clauses and Schedule 1 *(*Definitions);
		2. Part A of Schedule 2 (Specification and Supplier Solution), Schedule 3 (Performance Levels) and their respective Annexes;
		3. any other Schedules and their Annexes (other than Part B of Schedule 2 (Specification and Supplier Solution) and its Annexes (if any)); and
		4. Part B of Schedule 2 (Specification and Supplier Solution) and its Annexes (if any).
	4. The Schedules and their Annexes form part of this Agreement.
3. DUE DILIGENCE
	1. The Supplier acknowledges that:
		1. it has made its own enquiries to satisfy itself as far as is reasonably practicable as to the accuracy and adequacy of the Due Diligence Information;
		2. it has raised all relevant due diligence questions with UK Biobank prior to the Effective Date; and
		3. it has entered into this Agreement in reliance on its own due diligence alone.
	2. The Supplier shall not be excused from the performance of any of its obligations under this Agreement on the grounds of, nor shall the Supplier be entitled to recover any additional costs or charges arising as a result of:
		1. any unsuitable aspects of the Operating Environment, save in respect of any aspect that the Supplier had no reasonable opportunity to verify the suitability of prior to the Effective Date;
		2. any misinterpretation of UK Biobank Requirements; and/or
		3. any failure by the Supplier to satisfy itself as far as is reasonably practicable as to the accuracy and/or adequacy of the Due Diligence Information.
4. WARRANTIES
	1. UK Biobank represents and warrants that:
		1. there are no actions, suits or proceedings or regulatory investigations before any court or administrative body or arbitration tribunal pending or, to its knowledge, threatened against it that might affect its ability to perform its obligations under this Agreement; and
		2. its obligations under this Agreement constitute its legal, valid and binding obligations, enforceable in accordance with their respective terms subject to applicable bankruptcy, reorganisation, insolvency, moratorium or similar Laws affecting creditors’ rights generally and subject, as to enforceability, to equitable principles of general application (regardless of whether enforcement is sought in a proceeding in equity or law).
	2. The Supplier represents, warrants and undertakes that:
		1. there are no actions, suits or proceedings or regulatory investigations before any court or administrative body or arbitration tribunal pending or, to its knowledge, threatened against it or any of its Affiliates that might affect its ability to perform its obligations under this Agreement;
		2. its obligations under this Agreement constitute its legal, valid and binding obligations, enforceable in accordance with their respective terms subject to applicable bankruptcy, reorganisation, insolvency, moratorium or similar Laws affecting creditors’ rights generally and subject, as to enforceability, to equitable principles of general application (regardless of whether enforcement is sought in a proceeding in equity or law);
		3. all written statements and representations in any written submissions made by the Supplier as part of the procurement process, including its response to UK Biobank’s selection questionnaire and invitation to tender, its tender and any other documents submitted remain true and accurate except to the extent that such statements and representations have been superseded or varied by this Agreement; and
		4. it has and will continue to have for the duration of the Term all necessary rights in and to the Software, the Project Specific IPRs, the Third Party IPRs, the Supplier Background IPRs and any other materials made available by the Supplier (and/or any Sub-contractor) to UK Biobank which are necessary for the performance of the Supplier’s obligations under this Agreement and/or the receipt of the Services by UK Biobank and the use of the same by UK Biobank as provided for by this Agreement shall not infringe any Intellectual Property Rights.
	3. Without prejudice to clauses ‎5.7 to ‎5.9 (Supplier acknowledgements and covenants) and any other rights and remedies of UK Biobank howsoever arising, the Supplier represents, warrants and undertakes to UK Biobank that:
		1. it has exercised professional skill and judgement, in accordance with Good Industry Practice, in selecting the Archive as suitable for meeting the UK Biobank Requirements; and
		2. the Archive shall for the Term:
			1. provide the functionality set out in, and perform in all material respects in accordance with, the relevant specifications contained in:
				1. the Specification;
				2. the Supplier Solution; and
				3. the Documentation;
			2. interface with the UK Biobank System as set out in the Specification and the Supplier Solution;
			3. be free from material design and programming errors; and
			4. not infringe any Intellectual Property Rights.

section b – the services

1. TERM
	1. This Agreement shall:
		1. come into force on the Effective Date, save for clauses ‎‎1 (Definitions and Interpretation), ‎3.1 and ‎3.2 (Warranties), ‎4 (Term), ‎5.11 (Service Connection Requirements), ‎‎19 (Confidentiality), ‎‎‎21 (Publicity and Branding), ‎‎22 (Limitations on Liability), ‎‎29 (Waiver and Cumulative Remedies), ‎‎30 (Relationship of the Parties), ‎‎‎32 (Entire Agreement), ‎‎33 (Third Party Rights), ‎34 (Notices), ‎‎35 (Disputes) and ‎‎36 (Governing Law and Jurisdiction), which shall be binding and enforceable as between the Parties from the date on which this Agreement is signed by both Parties; and
		2. unless terminated at an earlier date by operation of Law or in accordance with clause ‎26 (Termination Rights), terminate:
			1. at the end of the Initial Term; or
			2. if UK Biobank elects to extend the Initial Term by giving the Supplier at least six (6) months’ notice in writing before the end of the Initial Term, at the end of the Extension Period; or
			3. if UK Biobank elects to extend any Extension Period by giving the Supplier at least six (6) months’ notice in writing before the end of the then current Extension Period, at the end of the final such Extension Period

provided that the Term may not exceed the period from the Effective Date to the Support Service Commencement Date plus fifteen (15) years.

1. [[1]](#footnote-1)**[Condition Precedent**
	1. Save for the clauses referenced in clause ‎4.1, this Agreement is conditional upon the receipt of cleared funding for the Archive and the Services by UK Biobank from UKRI sufficient to enable UK Biobank to fulfil its obligations under this Agreement (the “**Condition Precedent**”). UK Biobank may in its sole discretion at any time agree to waive compliance with the Condition Precedent by giving the Supplier notice in writing.
	2. UK Biobank shall use its reasonable endeavours to satisfy, or procure the satisfaction of, the Condition Precedent as soon as reasonably practicable. In the event that the Condition Precedent is not satisfied within six (6) months after the date of this Agreement, or within such other period as the Parties may agree in writing from time to time, then unless the Condition Precedent is waived by UK Biobank in accordance with clause ‎4.2:
		1. this Agreement shall automatically cease and shall not come into effect; and
		2. neither Party shall have any obligation to pay any compensation to the other Party as a result of such cessation.
	3. UK Biobank shall:
		1. keep the Supplier informed from time to time of its progress in satisfying the Condition Precedent and of any circumstances which are likely to result in the Condition Precedent not being satisfied by the date set out in clause ‎‎4.3; and
		2. notify the Supplier in writing upon satisfaction of the Condition Precedent.
	4. Where the Condition Precedent is satisfied, or waived by UK Biobank in accordance with clause ‎‎4.2, after [INSERT DATE 6 MONTHS AFTER DATE OF RECEIPT OF TENDER SUBMISSIONS] the Milestone Payments shall, upon satisfaction or waiver of the Condition Precedent after such date, be subject to Indexation in accordance with the applicable provisions of paragraph ‎0 of Part B of Schedule 7 (Charges and Invoicing).]
2. SERVICES
3. **Standard of Services**
	1. The Supplier shall provide:
		1. the Archive in accordance with the time scales set out in the Project Plan;
		2. the Installation Services from (and including) the Installation Services Commencement Date; and
		3. the Support Services from (and including) the relevant Support Service Commencement Date.
	2. The Supplier shall ensure that the Archive and the Services:
		1. comply in all respects with the Specification; and
		2. are supplied in accordance with the Supplier Solution and the provisions of this Agreement.
	3. The Supplier shall perform its obligations under this Agreement in accordance with:
		1. all applicable Law;
		2. Good Industry Practice; and
		3. the Standards.
4. **Optional Deliverables**
	1. UK Biobank may require the Supplier to provide the Optional Deliverables at any time prior to the third anniversary of the Support Service Commencement Date by giving notice to the Supplier in writing. The Supplier acknowledges that UK Biobank is not obliged to take any Optional Deliverables from the Supplier and that nothing shall prevent UK Biobank from receiving services that are the same as or similar to the Optional Deliverables from any third party.
	2. If a Change Request is submitted, the Supplier shall, as part of the Change Request Information provided by the Supplier in relation to such Change Request, provide details of the impact (if any) that the proposed Change will have on the relevant Optional Deliverables.
	3. Following receipt of UK Biobank’s notice pursuant to clause ‎5.4:
		1. the Parties shall document the inclusion of the relevant Optional Deliverables within the Archive and Services (as applicable) in accordance with the Change Control Procedure, modified to reflect the fact that the terms and conditions on which the Supplier shall provide the relevant Optional Deliverables have (save to the extent expressly set out in this Agreement) already been agreed;
		2. the Supplier shall implement and Test the relevant Optional Deliverables in accordance with the Optional Deliverables Project Plan;
		3. any additional charges for the Optional Deliverables shall be incorporated in the Charges as specified in paragraph ‎3 of Part B of Schedule 7 (Charges and Invoicing), subject to Indexation in accordance with the applicable provisions of paragraph ‎0 of Part B of Schedule 7 (Charges and Invoicing); and
		4. the Supplier shall, from the date agreed in the Optional Deliverables Project Plan (or, if later, the date of Achievement of any Milestones associated with the commencement of the relevant Optional Deliverables (if any)), provide the relevant Optional Deliverables to meet or exceed the applicable Target Performance Level in respect of all Performance Indicators.
5. **Supplier acknowledgements and covenants**
	1. The Supplier acknowledges that UK Biobank has entered into this Agreement in reliance upon the Supplier’s expertise in selecting and supplying the Archive, the Deliverables and the Services to meet UK Biobank Requirements.
	2. The Supplier shall:
		1. at all times allocate sufficient resources with the appropriate technical expertise to supply the Archive and Deliverables, and to provide the Services, in accordance with this Agreement;
		2. save to the extent that obtaining and maintaining the same are UK Biobank Responsibilities, obtain, and maintain throughout the duration of this Agreement, all the consents, approvals, licences and permissions (statutory, regulatory contractual or otherwise) it may require and which are necessary for the provision of the Services;
		3. minimise any disruption to the Archive, the Services, the Operating Environment and/or UK Biobank’s operations when carrying out its obligations under this Agreement; and
		4. co-operate with the Other Suppliers and provide reasonable information (including any Documentation), advice and assistance in connection with the Archive and the Services to any Other Supplier to enable such Other Supplier to create and maintain technical or organisational interfaces with therewith and, on the expiry or termination of this Agreement for any reason, to enable the timely transition of the Archive and Services (or any of them) to UK Biobank and/or to any Replacement Supplier;
		5. ensure that:
			1. it provides such advisory, error correction, bug fix and other support services (including the provision of New Releases and Updates) in respect of the Software as are necessary to ensure that the Archive continues to comply with the warranty set out in clause ‎3.3.2 (Warranties) and to meet and comply with the UK Biobank Requirements and provides such managed and other support services as are referred to in Schedule 2 (Specification and Supplier Solution) and Schedule 3 (Performance Levels), including as to patching, compliance with relevant industry standards and to remain within manufacturer support as set out in the Specification;
			2. it applies all New Releases and Updates that it makes available to its customers generally to the Archive in a timely manner and at no additional charge;
			3. the release of any new Software or upgrade to any Software (including any New Release or Update) complies with the interface requirements in the Specification and (except in relation to new Software or upgrades which are released to address Malicious Software or to comply with the security requirements of the Specification) shall notify UK Biobank promptly in advance of any such release and in any event not less than three (3) months before any such release; and
			4. all Software including Updates and New Releases used by or on behalf of the Supplier are currently supported versions of that Software and comply with the warranty set out in clause ‎3.3.2 (Warranties);
	3. Without prejudice to any other rights and remedies of UK Biobank howsoever arising, the Supplier shall remedy any breach of its obligations in clause ‎5.8 as soon as reasonably practicable after having become aware of the breach or being notified of the breach by UK Biobank.
6. **Access to UK Biobank Premises**
	1. Where UK Biobank grants access to and/or use of any of the UK Biobank Premises (or any part thereof), such access and/or use is subject to the following:
		1. no tenancy or other right of occupation will be created in relation to such access and/or use by the Supplier or any Sub-contractor;
		2. the Supplier shall comply with, and not do or omit to do anything that would cause UK Biobank to be in breach of, the terms of any UK Biobank licence, lease or other property agreement relating to occupation of, access to and/or use of the relevant UK Biobank Premises, provided that UK Biobank has provided the Supplier with a copy of the same;
		3. the Supplier shall comply with, and not do or omit to do anything that would cause UK Biobank to be in breach of, the terms and conditions of any planning consent or approvals relating to the relevant UK Biobank Premises;
		4. any such access and/or use is on a non-exclusive basis;
		5. the Supplier will (and will procure that its Sub-contractors will) only use the same to perform the Services in accordance with the terms of this Agreement and not for any other purpose whatsoever;
		6. the Supplier will not allow anyone else to use or occupy the same apart from the relevant Supplier Personnel;
		7. the Supplier will (and will procure that all Supplier Personnel will) comply with all of UK Biobank’s policies and any other policies and standards that are relevant to the performance of the Services and any other on site regulations (including security rules and safety requirements) specified by UK Biobank or for personnel working at UK Biobank Premises. UK Biobank will, on request, from time to time provide the Supplier with a copy of such policies and standards. The Supplier will be responsible for ensuring that it has requested and obtained copies of such policies;
		8. UK Biobank shall be entitled to deny entry to, or require the removal of any Supplier Personnel from, UK Biobank Premises at any time upon any reasonable grounds and the Supplier shall ensure prompt compliance by applicable Supplier Personnel; and
		9. the Supplier will comply with any reasonable requirements of or instructions that may be given by UK Biobank (including any request to leave immediately any UK Biobank Premises).

**Service Connection Requirements and Integration of the Archive with the Facility**

* 1. Within thirty (30) following the date on which this Agreement is signed by both Parties, the Supplier shall provide to UK Biobank a document setting out in detail all points of service connection required between the Archive and the Facility and their location and specification, including electricity, network, liquid nitrogen feed and exhaust, compressed air, any other piped gases, chilled water, condensate and mains water supply, drainage, information on heat loading to the Sample Hall from the Archive in kW and any other service connection requirements or physical characteristics that the Developer, in the reasonable opinion of the Supplier, will need to be aware of to support successful integration of the Archive with the Facility (“**Service Connection Requirements”**). The Service Connection Requirements must not be materially different to those provided by the Supplier in its tendered response to question B2.1 of the ITT.
	2. In order to facilitate the successful integration of the Archive with the Facility the Supplier shall:
		1. be responsible for identifying promptly to UK Biobank and the Developer, and resolving, any issues or concerns that may impact successful integration; and
		2. attend regular meetings with the Supplier and Developer (and any Other Suppliers as reasonably required), including UK Biobank’s monthly steering group for the overall project, as necessary to support timely communication of progress, risk management and successful integration of the Archive and Facility.
1. INSTALLATION AND TESTING
2. **Project Plan and Delays**
	1. The Parties shall comply with the provisions of Schedule 5 (Project Plan)in relation to the agreement and maintenance of the Detailed Project Plan.[[2]](#footnote-2)
	2. The Parties shall comply with the Project Plan and the Supplier shall ensure that each Milestone is Achieved on or before its Milestone Date.
	3. If the Supplier becomes aware that there is, or there is reasonably likely to be, a Delay:
		1. it shall in any event:
			1. notify UK Biobank in accordance with clause ‎23.1 (Rectification Plan Process); and
			2. use all reasonable endeavours to eliminate or mitigate the consequences of any Delay or anticipated Delay;
		2. it shall, where applicable, comply with the Rectification Plan Process in order to address the impact of the Delay or anticipated Delay;
		3. to the extent that the Delay would not have occurred but for a UK Biobank Cause, the provisions of clause ‎24 (UK Biobank Cause) shall apply; and
		4. to the extent that the Delay is directly caused by a Force Majeure Event, the provisions of clause ‎25 (Force Majeure) shall apply.

**UK Biobank Delay and Works Delay Change**

* 1. UK Biobank may at any time at its discretion delay the Milestone Dates and / or any other element of the Project Plan by notice in writing to the Supplier by a period of up to six (6) months on a one-off basis (**“UK Biobank Delay”**).
	2. In the event of a Works Delay, UK Biobank may submit a request to the Supplier to amend the Milestone Dates and / or any other element of the Project Plan in accordance with the Change Control Procedure (**“Works Delay Change”**), but subject to the provisions of clause ‎6.7.
	3. The Parties agree each to use reasonable endeavours to mitigate, to the extent reasonably possible, the impact of a UK Biobank Delay and all Works Delays on the Milestone Dates, the Project Plan and the performance of the Services and provision of the Goods.
	4. Provided that the periods of any UK Biobank Delay and all Works Delays do not exceed in aggregate six (6) months in duration, the Supplier shall not be entitled to any increase in the Charges as a consequence of any UK Biobank or Works Delay Change. Where the period of any UK Biobank Delay and all Works Delays cumulatively exceed in aggregate six (6) months in duration any Milestone Payments not yet due shall be subject to Indexation in accordance with the applicable provisions of paragraph ‎0 of Part B of Schedule 7 (Charges and Invoicing).

**Testing and Achievement of Milestones**

* 1. The Parties shall comply with the provisions of Schedule 6 (Testing Procedures) in relation to the testing and other procedures to determine whether a Milestone or Test has been Achieved.
1. PERFORMANCE INDICATORS
	1. The Supplier shall:
		1. provide the Support Services in such a manner so as to meet or exceed the Target Performance Level for each Key Performance Indicator from the Milestone Date for the OQ Milestone; and
		2. comply with the provisions of Schedule 3 (Performance Levels) in relation to the monitoring and reporting on its performance against the Key Performance Indicators.
2. **Performance Failures**
	1. If in any Service Period a Material KPI Failure occurs, the Supplier shall comply with the Rectification Plan Process.
	2. If in any Service Period an Unacceptable KPI Failure occurs, UK Biobank shall be entitled to withhold and retain as compensation for the Unacceptable KPI Failure a sum equal to any Service Charges which would otherwise have been due to the Supplier in respect of that Service Period, provided that the operation of this clause ‎7.3 shall be without prejudice to any right which UK Biobank may have to terminate this Agreement and/or to claim damages from the Supplier as a result of such Unacceptable KPI Failure.
3. **Transition**
	1. During the Transition the Supplier shall:
		1. provide all reasonable necessary assistance to UK Biobank and UK Biobank’s applicable Other Supplier; and
		2. ensure that an appropriate level of on-site support is available during the loading process,

as is necessary for Transition to proceed smoothly and efficiently, to minimise the period during which Samples are unavailable to UK Biobank and Users for research purposes and to ensure that UK Biobank get the best efficiency out of the Archive, including complying with all specific obligations in this regard as set out the Specification.

1. EQUIPMENT AND MAINTENANCE
2. **Supplier Equipment**
	1. All the Supplier’s property, including Supplier Equipment, shall remain at all times at the sole risk and responsibility of the Supplier.
3. **Maintenance**
	1. The Supplier shall develop and maintain and agree with UK Biobank a rolling schedule of planned, preventative maintenance to the Archive in accordance with the requirements set out in the Specification (in particular sections 7.1.3.3 and 7.1.3.13) (**“Maintenance Schedule”**). Any updates or changes to the same shall be agreed with the UK Biobank Representative prior to the same being implemented. The Supplier shall only undertake such planned, preventative maintenance (which shall be known as **“Permitted Maintenance”**) in accordance with the Maintenance Schedule.
4. **Supply of Goods**
	1. Where, as part of provision of the Archive and/or the Services, the Supplier is to sell goods or equipment (**“Goods”**) to UK Biobank:
		1. the relevant Goods shall be as set out in Schedule 2 (Specification and Supplier Solution);
		2. the Supplier shall supply, install and Test the Goods in accordance with the Specification and Supplier Solution and the other provisions of this Agreement;
		3. the Supplier shall ensure that the Goods are free from material defects in design, materials and workmanship and remain so for 12 months after delivery;
		4. if following inspection or Testing UK Biobank considers that the Goods do not conform with Schedule 2 (Specification and Supplier Solution), UK Biobank shall inform the Supplier and the Supplier shall, without prejudice to any other provisions of this Agreement that may also apply, immediately take such remedial action as is necessary to ensure compliance;
		5. without prejudice to any other rights or remedies of UK Biobank and subject to clause ‎8.3.6 below:
			1. subject to clause ‎8.3.7 below, risk in the Goods shall pass to UK Biobank at the time of delivery at the applicable UK Biobank Premises; and
			2. ownership of the Goods shall pass to UK Biobank at the time of payment;
		6. the Supplier shall provide, promptly replenish and maintain on UK Biobank Premises (unless otherwise specified by UK Biobank) at such secure location as UK Biobank shall specify from time to time such minimum stock of spare parts for the Archive as are specified in the Specification and Supplier Solution for use by the Supplier in the provision of the Support Services (**“Spares”**). The price of the Spares shall be included with the Service Charges and:
			1. subject to clause ‎8.3.7 below, risk in the Spares shall pass to UK Biobank at the time of delivery to the secure location at the applicable UK Biobank Premises as specified above; and
			2. ownership of the Spares shall pass to UK Biobank when incorporated by the Supplier into the Archive, or upon termination or expiry of this Agreement if not so incorporated at that time; and
		7. notwithstanding the provisions of clauses ‎8.3.5.1 and ‎8.3.6.1, the Supplier shall take good care of the Goods and Spares when in its possession or control and shall be responsible for any loss of or damage to the same arising from its or the Supplier Personnel’s negligence or any Supplier breach of this Agreement.

section c – FINANCIAL AND CONTRACT GOVERNANCE

1. FINANCIAL
2. **Charges and Invoicing**
	1. In consideration of the Supplier carrying out its obligations under this Agreement UK Biobank shall pay the Charges to the Supplier in accordance with the pricing and payment profile and the invoicing procedure specified in Schedule 7 (Charges and Invoicing).
	2. Except as otherwise provided, each Party shall each bear its own costs and expenses incurred in respect of compliance with its obligations under this Agreement.
3. **VAT**
	1. The Charges are stated exclusive of VAT, which shall be added at the prevailing rate as applicable and paid by UK Biobank following delivery of a valid VAT invoice.
4. RECORDS AND AUDITS
	1. The Supplier shall maintain complete and accurate reports, documents and records in relation to the Archive and the provision of the Services and make available to UK Biobank upon request a summary of the same.
	2. UK Biobank may conduct an audit to verify compliance by the Supplier with its obligations under this Agreement and/or in order to comply with a requirement of a Regulatory Authority. Except where:
		1. an audit is imposed on UK Biobank by a Regulatory Authority; or
		2. UK Biobank has reasonable grounds for believing that the Supplier has not complied with its obligations under this Agreement,

UK Biobank may not conduct an audit of the Supplier more than once in any Contract Year.

* 1. The Supplier shall (and shall procure that its Sub-contractors shall) on demand provide UK Biobank (and/or its agents or representatives) with all reasonable co-operation and assistance in relation to each audit, including:
		1. all information requested by UK Biobank within the permitted scope of the audit;
		2. reasonable access to any Sites controlled by the Supplier (and any Sub-contractor) and to any equipment used (whether exclusively or non-exclusively) in the performance of the Services; and
		3. access to Supplier Personnel.
	2. UK Biobank shall during each audit comply with the standard security, sites, systems and facilities operating procedures of the Supplier and use its reasonable endeavours to ensure that the conduct of each audit does not unreasonably disrupt the Supplier or delay the provision of the Services.
	3. UK Biobank shall provide at least fifteen (15) Working Days’ notice of its intention to conduct an audit, unless the audit is a matter of urgency in which case it shall provide as much notice as is reasonably practicable.
1. CHANGE
2. **Change Control Procedure**
	1. Unless otherwise stated in this Agreement, any Change shall be made only in accordance with this clause ‎11.
	2. The Parties shall deal with Change as follows:
		1. either Party may at any time request a Change by giving notice in writing to the other Party identifying the proposed Change (“Change Request”);
		2. the UK Biobank Representative shall have the right to request amendments to a Change Request, approve it or reject it in the manner set out in clause ‎11.4;
		3. the Supplier shall have the right to reject a Change Request solely in the manner set out in clause ‎11.5; and
		4. in any preparation of a Change Request or Change Request Information, unless otherwise agreed in writing, each Party will be liable for their own costs.
	3. The Supplier shall (in good faith) submit to UK Biobank in writing, within ten (10) Working Days (or such longer period as may be agreed) of receipt of a written Change Request from UK Biobank Representative (or at the same time as any written Change Request that the Supplier may submit):
		1. a full written quotation including a detailed breakdown and such supporting evidence of its costs and resources as UK Biobank shall reasonably require for such Change;
		2. particulars of any changes which would be required to UK Biobank Requirements and the Supplier Solution in order to implement the proposed Change;
		3. particulars of the other changes (if any) which would be required to this Agreement in order to implement the proposed Change; and
		4. the full cost and risk implications for UK Biobank that would result from the Change, including any proposed amendment to the Charges, provided that any such amendment to the Charges must be reasonable and proportionate in the circumstances and comply with the principles set out in Schedule 7 (Charging and Invoicing),

(together, **“Change Request Information”**), but subject always, where applicable, to clause ‎6.6‎6.7 (UK Biobank Delay and Works Delay Change).

* 1. Upon receipt of the Change Request Information:
		1. UK Biobank may elect, subject to clause ‎11.6, to approve the proposed contract change, in which case this Agreement will be amended accordingly and the Parties shall forthwith complete and sign a change control notice in such form as UK Biobank Representative shall reasonably require recording the Change that shall include the Change Request Information; or
		2. UK Biobank Representative may, in his or her reasonable discretion, reject the Change, in which case he shall notify the Supplier of the rejection; or
		3. where UK Biobank Representative reasonably considers that the Supplier has not complied with clause ‎11.3, he or she may require the Supplier to resubmit the Change Request Information, in which event the Supplier shall make such modifications as are necessary to comply with clause ‎11.3 and resubmit the same to UK Biobank Representative within five (5) Working Days of UK Biobank Representative’s request and the provisions of this clause ‎11.4 shall apply thereto.
	2. If following receipt of a Change Request from UK Biobank the Supplier reasonably believes that:
		1. the proposed Change would:
			1. materially and adversely affect the risks to the health and safety of any person; and/or
			2. require the Services to be performed in a way that infringes any Law; and/or
		2. the proposed Change is technically impossible to implement and neither the Supplier Solution nor the Specification state that the Supplier has the technical capacity and flexibility required to implement the proposed Change,

then the Supplier shall be entitled to reject the proposed Change, provided that it notifies UK Biobank within five (5) Working Days of receipt of the applicable Change Request of its reasons for doing so and substantiates the same to the reasonable satisfaction of the UK Biobank Representative.

* 1. Until such time as any Change is formally accepted in accordance with clause ‎11.4.1 and the applicable change control notice has been signed by a representative of each Party having the necessary authority, the same shall not be binding on the Parties and the Supplier will, unless otherwise agreed in writing, continue to perform and be paid as if no Change had been required.
1. **Change in Law**
	1. The Supplier shall neither be relieved of its obligations to supply the Archive and the Services in accordance with the terms and conditions of this Agreement nor be entitled to an increase in the Charges as the result of Change in Law.

section d – SUPPLIER personnel and supply chain

1. SUPPLIER PERSONNEL
	1. The Supplier shall:
		1. ensure that all Supplier Personnel:
			1. are appropriately qualified, trained and experienced to provide the Services with all reasonable skill, care and diligence;
			2. are vetted in accordance with Good Industry Practice and, where applicable, the security requirements set out in Schedule 2 (Specification and Supplier Solution); and
			3. comply with all reasonable security and other requirements of UK Biobank concerning conduct at UK Biobank Premises;
		2. be liable at all times for all acts or omissions of Supplier Personnel, so that any act or omission of a member of any Supplier Personnel which results in a Default under this Agreement shall be a Default by the Supplier;
		3. use all reasonable endeavours to minimise the number of changes in Supplier Personnel;
		4. replace (temporarily or permanently, as appropriate) any Supplier Personnel as soon as practicable if any Supplier Personnel have been removed or are unavailable for any reason whatsoever; and
		5. bear the programme familiarisation and other costs associated with any replacement of any Supplier Personnel.
	2. The Supplier’s key personnel listed in Part B of Schedule 2 (Specification and Supplier Solution) shall carry out the Services (including the key roles so specified) unless otherwise agreed in writing with UK Biobank Representative (whose agreement shall not be unreasonably withheld or delayed), which shall be the **“Key Personnel”** and **“Key Roles”** respectively for the purposes of this Agreement.
	3. The Supplier shall not remove or replace any Key Personnel unless:
		1. requested to do so by UK Biobank;
		2. the person concerned resigns, retires or dies or is on maternity leave, paternity leave or shared parental leave, or long-term sick leave;
		3. the person’s employment or contractual arrangement with the Supplier or a Sub-contractor is terminated; or
		4. the Supplier obtains UK Biobank’s prior written consent (such consent not to be unreasonably withheld or delayed).
	4. The Supplier shall ensure that any replacement for a Key Role:
		1. has a level of qualifications and experience appropriate to the relevant Key Role;
		2. is fully competent to carry out the tasks assigned to the Key Personnel whom he or she has replaced; and
		3. is agreed with UK Biobank pursuant to the provisions of clause ‎12.5.
	5. The Supplier shall:
		1. provide to UK Biobank a CV that includes details of the competencies, qualifications and experience appropriate to the relevant Key Role of all candidates to replace a Key Role;
		2. upon request from UK Biobank, permit UK Biobank to interview any candidate to replace a Key Role;
		3. take account of any reasonable representations that may be made by UK Biobank in respect of any such candidates and their suitability to be Key Personnel; and
		4. agree the replacement Key Personnel with UK Biobank prior to their appointment to a Key Role.
	6. UK Biobank Representative shall be entitled on written notice to request that the Supplier terminate immediately any person’s involvement with the provision of the Services when in the reasonable opinion of UK Biobank Representative it considers it undesirable for them to continue. The Supplier shall if so requested by UK Biobank Representative as soon as reasonably practicable replace any person so removed with a suitable person to be agreed by UK Biobank Representative.
2. **Representatives**
	1. Each Party shall have a representative for the duration of this Agreement who shall have the authority to act on behalf of their respective Party on the matters set out in, or in connection with, this Agreement.
	2. Each Party shall notify the other of the identity of its initial Representative within five (5) Working Days of the Effective Date.
	3. Either Party may, by written notice to the other Party, revoke or amend the authority of their Representative or appoint a new Representative.
3. **Staff Transfer**
	1. The Parties shall comply with the provisions of Schedule 10 (Staff Transfer) in respect of the application of the Employment Regulations.
4. SUPPLY CHAIN RIGHTS AND PROTECTIONS
5. **Appointment of Key Sub-contractors**
	1. Where the Supplier wishes to enter into a Key Sub-contract or replace a Key Sub-contractor, it must obtain the prior written consent of UK Biobank, such consent not to be unreasonably withheld or delayed.
	2. UK Biobank consents to the appointment of the Key Sub-contractors listed in Part B of Schedule 2 (Specification and Supplier Solution).
6. **Key Sub-contractors**
	1. Except where UK Biobank has given its prior written consent, the Supplier shall ensure that each Key Sub-contract shall include:
		1. provisions which will enable the Supplier to discharge its obligations under this Agreement;
		2. provisions to ensure that the Supplier is able to assign, novate or otherwise transfer to UK Biobank or any Replacement Supplier all of its rights and obligations under such Key Sub-contract without restriction (including any need to obtain and consent or approval) or payment by UK Biobank; and
		3. obligations no less onerous on the Key Sub-contractor than those imposed on the Supplier under this Agreement in respect of data protection requirements set out in clauses ‎18 (UK Biobank Data and Security Requirements) and ‎20 (Data Protection) and Schedule 9 (Processing Personal Data).
7. **Retention of Legal Obligations**
	1. Notwithstanding the Supplier’s right to sub-contract pursuant to this clause ‎13 , the Supplier shall remain responsible for all acts and omissions of its Sub-contractors and the acts and omissions of those employed or engaged by the Sub-contractors as if they were its own.

**Data processing supply chain**

* 1. The provisions of this clause ‎13 are subject to clause ‎20 (Protection of Personal Data) in respect of any sub-contracts relating to Personal Data Processing.

section E – intellectual property, data and confidentiality

1. INTELLECTUAL PROPERTY RIGHTS
	1. Except as expressly set out in this Agreement:
		1. UK Biobank shall not acquire any right, title or interest in or to the Intellectual Property Rights of the Supplier or its licensors, namely:
			1. the Specially Written Software;
			2. the Project Specific IPRs;
			3. the Supplier Software;
			4. the Third Party Software;
			5. the Third Party IPRs; and
			6. the Supplier Background IPRs; and
		2. the Supplier shall not acquire any right, title or interest in or to the Intellectual Property Rights of UK Biobank or its licensors, including:
			1. UK Biobank Software;
			2. UK Biobank Data; and
			3. UK Biobank Background IPRs.
	2. Where either Party acquires, by operation of law, title to Intellectual Property Rights that is inconsistent with the allocation of title set out in clause ‎14.1, it shall assign in writing such Intellectual Property Rights as it has acquired to the other Party on the request of the other Party (whenever made).
	3. Neither Party shall have any right to use any of the other Party’s names, logos or trade marks on any of its products or services without the other Party’s prior written consent, provided that each Party shall be entitled to use the same without the need for such consent to the extent reasonably necessary in order to perform its obligations under, and exercise its rights as contemplated by, this Agreement.
2. RIGHTS GRANTED BY THE SUPPLIER

**Software as a Service**

* 1. The Parties agree that where, in respect of any specific Software, it is agreed between the Parties that such Software is to be provided by way of Software as a Service and it is specified as such in Part B of Schedule 2 (Specification and Supplier Solution), UK Biobank acknowledges that, as a consequence:
		1. it will not be provided with a physical copy of the Software; and
		2. use of the Software is restricted to use by way of Software as a Service,

and the provisions of this clause ‎15 shall be construed accordingly.

* 1. The Supplier agrees to provide UK Biobank with all software keys, access codes and / or other login requirements as necessary to access and use Software provided by way of Software as a Service and to provide an accessible copy of all other Software in Object Code.
	2. All rights required to be granted under this clause ‎15 shall be granted with effect from, or procured to take effect from, the Installation Services Commencement Date, or date of creation of the applicable software or Intellectual Property Right, if later.
1. **Software, Project Specific IPRs and Background IPRs**
	1. The Supplier hereby grants to UK Biobank, or shall procure the grant to UK Biobank of, a perpetual, irrevocable, royalty-free, non-exclusive right to access and use (including but not limited to the right to load, execute, store, transmit, display and copy (for the purposes of archiving, backing-up, loading, execution, storage, transmission or display) and (in respect of the Specially Written Software and Project Specific IPRs only) modify, adapt, enhance, reverse compile, decode and translate) the Software, the Project Specific IPRs and the Background IPRs for any purpose relating to use or receipt of the Services (or substantially equivalent services) or to use or maintenance of the Archive (or a substantially equivalent system).
	2. UK Biobank may permit a third party to exercise the rights granted under clause ‎15.4 (Software, Project Specific IPRs and Background IPRs) on terms no broader than those granted to UK Biobank, for purposes relating to the exercise of UK Biobank’s business or function and provided that such third party shall be under a contractual obligation to UK Biobank to comply with confidentiality obligations that are broadly equivalent to those of UK Biobank pursuant to clause ‎19 (Confidentiality).
2. **Third Party COTS Software**
	1. If the Supplier cannot obtain for UK Biobank a licence in respect of any Third Party COTS Software in accordance with the licence terms set out in clauses ‎15.4 and ‎15.5 (Software, Project Specific IPRs and Background IPRs), the Supplier shall prior to incorporating the same into the Archive:
		1. notify UK Biobank; and
		2. procure the grant direct by the owner or an authorised licensor thereof to UK Biobank of a right to access and use the Third Party COTS Software for the Term on terms no less favourable than those on which such software is usually made commercially available by the Supplier or the relevant third party, provided that, except where UK Biobank has given its prior written consent, the Supplier shall ensure that such terms permit access to and use of the Third Party COTS Software for any purpose relating to use or receipt of the Services and the Archive.
3. LICENCES GRANTED BY UK BIOBANK
	1. UK Biobank hereby grants to the Supplier a royalty-free, non-exclusive, non-transferable licence during the Term to use UK Biobank Software, UK Biobank Background IPRs and UK Biobank Data solely to the extent necessary for performing the Services in accordance with this Agreement, including (but not limited to) the right to grant sub-licences to Sub-contractors provided that:
		1. any relevant Sub-contractor has entered into a confidentiality undertaking with the Supplier on the same terms as set out in clause ‎19 (Confidentiality); and
		2. the Supplier shall not, without UK Biobank’s prior written consent, use the licensed materials for any other purpose or for the benefit of any person other than UK Biobank.
	2. In the event of the termination or expiry of this Agreement, the licence granted pursuant to clause ‎16.1 and any sub-licence granted by the Supplier in accordance with clause ‎16.1 shall terminate automatically on the date of such termination or expiry and the Supplier shall:
		1. immediately cease all use of UK Biobank Software, UK Biobank Background IPRs and UK Biobank Data (as the case may be);
		2. at the discretion of UK Biobank, return or destroy documents and other tangible materials that contain any of UK Biobank Software, UK Biobank Background IPRs and UK Biobank Data, or, at the direction of UK Biobank Representative, send the same to the Replacement Supplier, provided that if UK Biobank has not made an election within six (6) months of the termination of the licence, the Supplier may destroy the documents and other tangible materials that contain any of UK Biobank Software, UK Biobank Background IPRs and UK Biobank Data (as the case may be); and
		3. ensure, so far as reasonably practicable, that any UK Biobank Software, UK Biobank Background IPRs and UK Biobank Data that are held in electronic, digital or other machine-readable form ceases to be readily accessible from any Supplier computer, word processor, voicemail system or any other Supplier device containing such UK Biobank Software, UK Biobank Background IPRs and/or UK Biobank Data.
4. IPRs INDEMNITY
	1. The Supplier shall at all times, during and after the Term, on written demand indemnify UK Biobank, and keep UK Biobank indemnified, against all Losses incurred by, awarded against or agreed to be paid by UK Biobank arising from an IPRs Claim.
	2. If UK Biobank receives notice of any IPRs Claim, UK Biobank shall give notice in writing to the Supplier as soon as reasonably practicable and provide to the Supplier such reasonable information, cooperation and assistance in respect of the IPRs Claim as the Supplier may reasonably request, provided that the Supplier reimburses to UK Biobank its reasonable costs incurred in connection with the same.
	3. If the Supplier is unable to procure for UK Biobank the right to continue using the relevant item which is subject to the IPRs Claim (or to replace or modify the relevant item with non-infringing substitutes or equivalent functionality acceptable to UK Biobank, acting reasonably) within twenty (20) Working Days of UK Biobank’s notice under clause ‎17.2, then:
		1. UK Biobank may terminate this Agreement (if subsisting) with immediate effect by written notice to the Supplier; and
		2. without prejudice to the indemnity set out in clause ‎17.1, the Supplier shall be liable for all reasonable and unavoidable costs of the substitute items and/or services including the additional costs of procuring, implementing and maintaining the substitute items.
5. UK BIOBANK DATA AND SECURITY REQUIREMENTS AND SERVICE CONTINUITY PLANS
	1. The Supplier shall not delete or remove any proprietary notices contained within or relating to UK Biobank Data.
	2. The Supplier shall not store, copy, disclose, or use UK Biobank Data except as necessary for the performance by the Supplier of its obligations under this Agreement or as otherwise expressly authorised in writing by UK Biobank.
	3. To the extent that UK Biobank Data is held and/or processed (which includes any Processing) by the Supplier, the Supplier shall supply that UK Biobank Data to UK Biobank as requested by UK Biobank in the format specified in Schedule 2 (Specification and Supplier Solution).
	4. The Supplier shall preserve the integrity of UK Biobank Data and prevent the corruption or loss of UK Biobank Data at all times that the relevant UK Biobank Data is under its control or the control of any Sub-contractor.
	5. If UK Biobank Data is corrupted, lost or sufficiently degraded so as to be unusable, UK Biobank may to the extent that the same is as a result of the Supplier’s Default:
		1. require the Supplier (at the Supplier’s expense) to restore or procure the restoration of UK Biobank Data as soon as practicable but not later than five (5) Working Days from the date of receipt of UK Biobank’s notice; and/or
		2. itself restore or procure the restoration of UK Biobank Data, and shall be repaid by the Supplier any reasonable expenses incurred in doing so.
	6. If at any time the Supplier suspects or has reason to believe that UK Biobank Data has or may become corrupted, lost or sufficiently degraded in any way for any reason, then the Supplier shall notify UK Biobank immediately and inform UK Biobank of the remedial action the Supplier proposes to take.
	7. The Supplier shall comply with the information security requirements set out in Parts A and B of Schedule 2 (Specification and Supplier Solution).

**Malicious Software**

* 1. The Supplier shall, as an enduring obligation throughout the Term, use the latest versions of anti-virus definitions and software available from an industry accepted anti-virus software vendor (unless otherwise agreed in writing between the Parties) to check for, contain the spread of, and minimise the impact of Malicious Software in the IT Environment (or as otherwise agreed by the Parties).
	2. Notwithstanding clause ‎18.8, if Malicious Software is found, the Parties shall cooperate to reduce the effect of the Malicious Software and, particularly if Malicious Software causes loss of operational efficiency or loss or corruption of UK Biobank Data, assist each other to mitigate any Losses and to restore the Services to their desired operating efficiency.
	3. Any cost arising out of the actions of the Parties taken in compliance with the provisions of clause ‎18.9 shall be borne by the Parties as follows:
		1. by the Supplier where the Malicious Software originates from the Software supplied by the Supplier (except where UK Biobank has waived the obligation set out in clause ‎18.8), or UK Biobank Data (whilst UK Biobank Data was under the control of the Supplier) unless, in the latter case, the Supplier can demonstrate that such Malicious Software was present and not quarantined or otherwise identified by UK Biobank when provided to the Supplier; and
		2. otherwise by UK Biobank.
1. **Service Continuity Plan**
	1. The Supplier shall, not less than forty (40) Working Days prior to the Milestone Date for the OQ Milestone, prepare and deliver to UK Biobank, for UK Biobank’s written approval, a plan which shall detail the processes and arrangements that the Supplier shall follow to:
		1. ensure continuity of the operation of the Archive and the Services in accordance with the Specification and the Target Performance Levels and the business processes and operations supported by the Archive and the Services following any Incident or any failure or disruption of any element of the Archive or the Services (including where caused by a Force Majeure Event or an Insolvency Event of the Supplier or any Key Sub-contractor); and
		2. the preservation and safety of the Samples, and the recovery of the Archive and the Services, in the event of a Disaster.
	2. The Service Continuity Plan shall be designed so as to ensure that:
		1. the Archive and the Services are provided in accordance with this Agreement at all times during and after the invocation of the Service Continuity Plan;
		2. the adverse impact of any Incident or Disaster; Archive or Service failure; an Insolvency Event of the Supplier or any Key Sub-contractor; or disruption on the operations of UK Biobank, is minimal as far as reasonably possible;
		3. it complies with the relevant provisions of ISO/IEC 22301 (or equivalent internationally recognised standard) and all other industry standards from time to time in force; and
		4. there is a process for the management of disaster recovery testing detailed in the Service Continuity Plan.
	3. Following receipt of the draft Service Continuity Plan from the Supplier, UK Biobank shall:
		1. review and comment on the draft Service Continuity Plan as soon as reasonably practicable; and
		2. acting reasonably, notify the Supplier in writing that it approves or rejects the draft Service Continuity Plan no later than twenty (20) Working Days after the date on which the draft Service Continuity Plan is first delivered to UK Biobank.
	4. If UK Biobank rejects the draft Service Continuity Plan:
		1. UK Biobank shall inform the Supplier in writing of its reasons for its rejection; and
		2. the Supplier shall then revise the draft Service Continuity Plan (taking reasonable account of UK Biobank’s comments) and shall re-submit a revised draft Service Continuity Plan to UK Biobank for UK Biobank’s approval within ten (10) Working Days of the date of UK Biobank’s notice of rejection. The provisions of clause ‎18.13 and this clause ‎18.14 shall apply again to any resubmitted draft Service Continuity Plan, provided that either Party may refer any disputed matters for resolution through the Dispute Resolution Procedure at any time.
	5. Approval of the draft Service Continuity Plan by UK Biobank in accordance with the foregoing process is a pre-requisite for Achievement of the OQ Milestone.
	6. The Supplier shall review and update the Service Continuity Plan on a regular basis and as a minimum once every twelve (12) months. The Supplier shall submit any updated Service Continuity Plan to UK Biobank for approval in accordance with the same process as set out in clauses ‎18.13 and ‎18.14.
	7. In the event of a Disaster, an Incident or any other circumstance referred to in clause ‎18.11.1, the Supplier will immediately implement the Service Continuity Plan. The Supplier will continue to perform those of its obligations which are not affected by the Disaster, Incident or other circumstance in accordance with the provisions of this Agreement.
2. CONFIDENTIALITY
	1. For the purposes of this clause ‎19, the term “**Disclosing Party**” shall mean a Party which discloses or makes available directly or indirectly its Confidential Information and “**Recipient**” shall mean the Party which receives or obtains directly or indirectly Confidential Information.
	2. Except to the extent set out in this clause ‎19 or where disclosure is expressly permitted elsewhere in this Agreement, the Recipient shall:
		1. treat the Disclosing Party’s Confidential Information as confidential and keep it in secure custody (which is appropriate depending upon the form in which such materials are stored and the nature of the Confidential Information contained in those materials);
		2. not disclose the Disclosing Party’s Confidential Information except as set out expressly in this Agreement or to any other person without obtaining the owner’s prior written consent;
		3. not use or exploit the Disclosing Party’s Confidential Information in any way except for the purposes anticipated under this Agreement; and
		4. immediately notify the Disclosing Party if it suspects or becomes aware of any unauthorised access, copying, use or disclosure in any form of any of the Disclosing Party’s Confidential Information.
	3. The Recipient shall be entitled to disclose the Confidential Information of the Disclosing Party where:
		1. the Recipient is required to disclose the Confidential Information by Law; or
		2. the need for such disclosure arises out of or in connection with:
			1. any legal challenge or potential legal challenge against UK Biobank arising out of or in connection with this Agreement; or
			2. the conduct of a Regulatory Authority review in respect of this Agreement; or
	4. If the Recipient is required by Law to make a disclosure of Confidential Information, the Recipient shall as soon as reasonably practicable and to the extent permitted by Law notify the Disclosing Party of the full circumstances of the required disclosure including the relevant Law and/or regulatory body requiring such disclosure and the Confidential Information to which such disclosure would apply.
	5. The Supplier may disclose the Confidential Information of UK Biobank on a confidential basis only to:
		1. Supplier Personnel who are directly involved in the provision of the Services and need to know the Confidential Information to enable performance of the Supplier’s obligations under this Agreement;
		2. its auditors; and
		3. its professional advisers for the purposes of obtaining advice in relation to this Agreement.

Where the Supplier discloses Confidential Information of UK Biobank pursuant to this clause ‎19.5, it shall remain responsible at all times for compliance with the confidentiality obligations set out in this Agreement by the persons to whom disclosure has been made.

* 1. UK Biobank may disclose the Confidential Information of the Supplier:
		1. on a confidential basis to any Regulatory Authority for any proper purpose of UK Biobank or of the relevant Regulatory Authority;
		2. on a confidential basis to a professional adviser, consultant, supplier or other person engaged by any of the entities described in clause ‎19.6.1 (including any benchmarking organisation) for any purpose relating to or connected with this Agreement;
		3. on a confidential basis for the purpose of the exercise of its rights under this Agreement; and
		4. on a confidential basis to a proposed Successor Body in connection with any assignment, novation or disposal of any of its rights, obligations or liabilities under this Agreement,

and for the purposes of the foregoing, references to disclosure on a confidential basis shall mean disclosure subject to a confidentiality agreement or arrangement containing terms no less stringent than those placed on UK Biobank under this clause ‎19.

* 1. Nothing in this clause ‎19 shall prevent a Recipient from using any techniques, ideas or know-how gained during the performance of this Agreement in the course of its normal business to the extent that this use does not result in a disclosure of the Disclosing Party’s Confidential Information or an infringement of Intellectual Property Rights.
	2. Any disclosure by the Supplier in accordance with this clause ‎19 must be undertaken in compliance with clause ‎20 (Data Protection).
1. DATA PROTECTION
	1. UK Biobank consider that the Samples do not, at the date of signing this Agreement, constitute Personal Data. To the extent that either Party will process Personal Data in respect of which the other Party is the data controller in connection with this Agreement, the provisions of Schedule 9 (Processing Personal Data) shall apply.
2. PUBLICITY AND BRANDING
	1. The Supplier shall not:
		1. make any press announcements or publicise this Agreement or its contents in any way;
		2. use UK Biobank’s name, brand or logo in any promotion or marketing or announcement of orders; or
		3. disclose that UK Biobank is a customer or client of the Supplier,

without the prior written consent of UK Biobank, which shall not be unreasonably withheld or delayed.

* 1. Each Party acknowledges to the other that nothing in this Agreement either expressly or by implication constitutes an endorsement of any products or services of the other Party and each Party agrees not to conduct itself in such a way as to imply or express any such approval or endorsement.

section F – liability, indemnities and insurance

1. LIMITATIONS ON LIABILITY
2. **Unlimited liability**
	1. Neither Party limits its liability for:
		1. death or personal injury caused by its negligence, or that of its employees, agents or Sub-contractors (as applicable);
		2. fraud or fraudulent misrepresentation by it or its employees;
		3. breach of any obligation as to title implied by section 12 of the Sale of Goods Act 1979 or section 2 of the Supply of Goods and Services Act 1982; or
		4. any liability to the extent it cannot be limited or excluded by Law.
3. **Financial and other limits**
	1. Subject to clause ‎22.1 (Unlimited Liability), clause ‎22.5 (Consequential losses) the Supplier’s aggregate liability in respect of all Losses incurred by UK Biobank under or in connection with this Agreement as a result of Defaults by the Supplier shall in no event exceed £20 million.
	2. Subject to clauses ‎22.1 (Unlimited Liability) and clause ‎22.5 (Consequential Losses) and without prejudice to UK Biobank’s obligation to pay the Charges as and when they fall due for payment:
		1. UK Biobank’s aggregate liability in respect of any claim by the Supplier against UK Biobank of infringement or alleged infringement of any Supplier owned IPRs (excluding any IPRs Claims the subject of clause ‎17 (IPRs Indemnity)) shall be in no event exceed £10 million; and
		2. UK Biobank’s aggregate liability in respect of all other Losses incurred by the Supplier under or in connection with this Agreement as a result of Defaults of UK Biobank shall in no event exceed:
			1. in relation to Defaults occurring in the first Contract Year, an amount equal to the Notional Average Annual Service Charges;
			2. in relation to Defaults occurring during any subsequent Contract Year, an amount in respect of that Contract Year equal to the Notional Average Annual Service Charges, subject to Indexation annually with effect from the commencement of the second Contract Year; and
			3. in relation to Defaults occurring after the end of the Term, an amount equal to the total Service Charges paid and/or due to be paid in connection with this Agreement in the twelve (12) month period immediately prior to the last day of the Term.
	3. For the avoidance of doubt:
		1. any liability of a Party which falls within clause ‎22.1 will not be taken into account in assessing whether the financial limits in clauses ‎22.2 or ‎22.3 (as applicable) have been reached;
		2. the financial limits in clauses ‎22.3.1 and ‎22.3.2 are separate not cumulative and any liability of UK Biobank which falls within one of those clauses shall not be taken into account in assessing whether the financial limits in the other such clauses have been reached.
4. **Consequential Losses**
	1. Subject to clauses ‎22.1 (Unlimited Liability), neither Party shall be liable to the other Party for:
		1. any indirect, special or consequential Loss; or
		2. any loss of profits, turnover, business opportunities or damage to goodwill (in each case whether direct or indirect).
5. **Mitigation**
	1. Each Party shall use all reasonable endeavours to mitigate any loss or damage suffered arising out of or in connection with this Agreement.
6. **Insurance**
	1. The Supplier will, at its own cost, purchase and maintain insurance policies during the Term which will provide cover in respect of the Services and the performance of the Supplier’s obligations under this Agreement, including, as a minimum, the Required Insurances.
	2. The Supplier undertakes that the Required Insurances will be purchased and maintained:
		1. on terms no less favourable than those generally available to a prudent contractor in respect of risks insured in the international insurance market from time to time; and
		2. with insurers who are of good financial standing in the United Kingdom insurance market, appropriately regulated and of good repute in the United Kingdom insurance market.
	3. The Supplier undertakes in relation to each of the Required Insurances:
		1. to comply with all requirements of the relevant insurance policies; and
		2. not by act or omission cause the Required Insurances to become void or voidable or prejudice any person’s entitlement under them.
	4. Neither failure to comply, nor full compliance with, the insurance provisions of this Agreement will limit or relieve the Supplier of its other liabilities and obligations under this Agreement.

section G – remedies and relief

1. RECTIFICATION PLAN PROCESS
	1. In the event that:
		1. there is, or is reasonably likely to be, a Delay; and/or
		2. in any Service Period there has been a Material KPI Failure; and/or
		3. the Supplier commits a material Default that is capable of remedy (and for these purposes a material Default may be a single material Default or a number of Defaults or repeated Defaults (whether of the same or different obligations and regardless of whether such Defaults are remedied) which taken together constitute a material Default),

(each a “**Notifiable Default**”), the Supplier shall notify UK Biobank of the Notifiable Default as soon as practicable but in any event within five (5) Working Days of becoming aware of the Notifiable Default, detailing the actual or anticipated effect of the Notifiable Default and, unless the Notifiable Default also constitutes a Rectification Plan Failure or other Supplier Termination Event, UK Biobank may not terminate this Agreement in whole or in part on the grounds of the Notifiable Default without first following the Rectification Plan Process.

1. **Notification**
	1. If:
		1. the Supplier notifies UK Biobank pursuant to clause ‎23.1 that a Notifiable Default has occurred; or
		2. UK Biobank notifies the Supplier that it considers that a Notifiable Default has occurred (setting out sufficient detail so that it is reasonably clear what the Supplier has to rectify),

then, unless the Notifiable Default also constitutes a Supplier Termination Event and UK Biobank serves a Termination Notice or the provisions of clause ‎24 (UK Biobank Cause) apply, the Supplier shall comply with the Rectification Plan Process.

* 1. The “**Rectification Plan Process**” shall be as set out in clauses ‎23.4 (Submission of the draft Rectification Plan) to ‎23.8 (Agreement of the Rectification Plan).
1. **Submission of the draft Rectification Plan**
	1. The Supplier shall submit a draft Rectification Plan to UK Biobank for it to review as soon as possible and in any event within ten (10) Working Days (or such other period as may be agreed between the Parties) after the original notification pursuant to clause ‎23.2 (Notification).
	2. The draft Rectification Plan shall set out:
		1. full details of the Notifiable Default that has occurred, including a root cause analysis;
		2. the actual or anticipated effect of the Notifiable Default; and
		3. the steps which the Supplier proposes to take to rectify the Notifiable Default (if applicable) and to prevent such Notifiable Default from recurring, including timescales for such steps and for the rectification of the Notifiable Default (where applicable).
	3. The Supplier shall promptly provide to UK Biobank any further documentation that UK Biobank reasonably requires to assess the Supplier’s root cause analysis. If the Parties do not agree on the root cause set out in the draft Rectification Plan the Dispute shall be determined in accordance with clause ‎35 (Disputes).

**Agreement of the Rectification Plan**

* 1. UK Biobank shall notify the Supplier whether it consents to the draft Rectification Plan as soon as reasonably practicable. If UK Biobank rejects the draft Rectification Plan, UK Biobank shall give reasons for its decision and the Supplier shall take the reasons into account in the preparation of a revised Rectification Plan. The Supplier shall submit the revised draft of the Rectification Plan to UK Biobank for review within five (5) Working Days (or such other period as agreed between the Parties) of UK Biobank’s notice rejecting the first draft.
	2. If UK Biobank consents to the Rectification Plan:
		1. the Supplier shall immediately start work on the actions set out in the Rectification Plan; and
		2. UK Biobank may no longer terminate this Agreement in whole or in part on the grounds of the relevant Notifiable Default.
1. UK BIOBANK CAUSE
	1. Notwithstanding any other provision of this Agreement, if the Supplier has failed to:
		1. Achieve a Milestone by its Milestone Date or there is any other Delay;
		2. provide the Support Services in accordance with the Target Performance Levels; and/or
		3. comply with its obligations under this Agreement,

(each a “**Supplier Non-Performance**”) and can demonstrate that the Supplier Non-Performance would not have occurred but for a UK Biobank Cause, then (subject to the Supplier fulfilling its obligations in clause ‎24.2):

* + 1. the Supplier shall not be treated as being in breach of this Agreement to the extent the Supplier can demonstrate that the Supplier Non-Performance was caused by UK Biobank Cause;
		2. the applicable Milestone Date (if any) and any other relevant dates set out in the Project Plan shall be postponed by a period equal to the period of Delay that the Supplier can demonstrate was caused by UK Biobank Cause;
		3. the Supplier shall not be entitled to withhold and retain any compensation for Unacceptable KPI Failure pursuant to clause ‎7.3 (Performance Failures); and
		4. UK Biobank shall not be entitled to exercise any other rights that may arise as a result of that Supplier Non-Performance.
	1. In order to claim any of the rights and/or relief referred to in clause ‎24.1, the Supplier shall as soon as reasonably practicable (and in any event within ten (10) Working Days) after becoming aware that an UK Biobank Cause has caused, or is reasonably likely to cause, a Supplier Non-Performance, give UK Biobank notice setting out details of:
		1. the Supplier Non-Performance;
		2. UK Biobank Cause and its effect, or likely effect, on the Supplier’s ability to meet its obligations under this Agreement;
		3. any steps which UK Biobank can take to eliminate or mitigate the consequences and impact of such UK Biobank Cause; and
		4. the relief claimed by the Supplier.
	2. The Supplier shall use all reasonable endeavours to eliminate or mitigate the consequences and impact of an UK Biobank Cause, including the duration and consequences of any Delay or anticipated Delay.
1. FORCE MAJEURE
	1. Subject to the remaining provisions of this clause ‎25 (and, in relation to the Supplier, subject to its compliance with its Service Continuity Plan), a Party may claim relief under this clause ‎25 from liability for failure to meet its obligations under this Agreement for as long as and only to the extent that the performance of those obligations is directly affected by a Force Majeure Event.
	2. If the Supplier is the Affected Party, it shall not be entitled to claim relief under this clause ‎25 to the extent that consequences of the relevant Force Majeure Event:
		1. are capable of being mitigated by any of the Services and / or compliance with the Service Continuity Plan, but the Supplier has failed to do so; and/or
		2. should have been foreseen and prevented or avoided by a prudent provider of services similar to the Services, operating to the standards required by this Agreement.
	3. The Parties shall at all times following the occurrence of a Force Majeure Event and during its subsistence use their respective reasonable endeavours to prevent and mitigate the effects of the Force Majeure Event. Where the Supplier is the Affected Party, it shall take all steps in accordance with Good Industry Practice to overcome or minimise the consequences of the Force Majeure Event.

section H – termination and exit management

1. TERMINATION RIGHTS
2. **Termination by UK Biobank**
	1. UK Biobank may terminate this Agreement by issuing a Termination Notice to the Supplier:
		1. if a Supplier Termination Event occurs;
		2. if a Force Majeure Event endures for a continuous period of more than ninety (90) days; or
		3. if the Agreement has been amended to the extent that the Public Contracts Regulations require a new procurement procedure,

and this Agreement shall terminate on the date specified in the Termination Notice.

1. **Termination by the Supplier**
	1. The Supplier may terminate this Agreement by issuing a Termination Notice to UK Biobank:
		1. if UK Biobank fails to pay an undisputed sum due to the Supplier under this Agreement which in aggregate exceeds a sum equivalent to not less than two months’ Service Charges as then applicable (or prior to the Support Service Commencement Date a sum equivalent to not less than one sixth of the Notional Average Annual Service Charges as then applicable) and such amount remains outstanding sixty (60) Working Days after the receipt by UK Biobank of a notice of non-payment from the Supplier and this Agreement or the relevant Services (as the case may be) shall then terminate on the date specified in the Termination Notice (which shall not be less than twenty (20) Working Days from the date of the issue of the Termination Notice);
		2. if UK Biobank commits a material breach of the terms of clause ‎15 (Rights Granted by the Supplier) which, if the breach is capable of remedy, is not remedied within twenty (20) Working Days after the Supplier gives UK Biobank written notice specifying the breach and requiring its remedy; or
		3. if a Force Majeure Event endures for a continuous period of more than ninety (90) days.
2. CONSEQUENCES OF EXPIRY OR TERMINATION
3. **General Provisions on Expiry or Termination**
	1. The provisions of clauses ‎6.1 (Project Plan and Delays), ‎9.3 (Financial), ‎10 (Records and Audits), ‎12.10 (Staff Transfer), ‎14 (Intellectual Property Rights), ‎15 (Rights Granted by the Supplier), ‎17.1 (IPRs Indemnity), ‎19 (Confidentiality), ‎20 (Data Protection), ‎22 (Limitations on Liability), ‎27 (Consequences of Expiry or Termination), ‎32 (Entire Agreement), ‎33 (Third Party Rights), ‎35 (Disputes) and ‎36 (Governing Law and Jurisdiction), and the provisions of Schedules 1 (Definitions), 7 (Charges and Invoicing), 8 (Exit Management) and 9 (Processing Personal Data) shall survive the termination or expiry of this Agreement.
4. **Exit Management**
	1. The Supplier shall comply with the provisions of Schedule 8 (Exit Management) and any current Exit Plan in relation to the orderly transition of the Services to UK Biobank or a Replacement Supplier.
5. **Payments by UK Biobank**
	1. If this Agreement is terminated (in part or in whole) by UK Biobank or the Term expires, the only payments that UK Biobank shall be required to make as a result of such termination (whether by way of compensation or otherwise) are:
		1. payments in respect of any Assets in accordance with Schedule 8 (Exit Management); and
		2. payments in respect of unpaid Charges for Services received up until the Termination Date.
6. **Payments by the Supplier**
	1. In the event of termination or expiry of this Agreement, the Supplier shall repay to UK Biobank all Charges it has been paid in advance in respect of Services not provided by the Supplier as at the date of expiry or termination.
	2. If this Agreement is terminated (in whole or in part) by UK Biobank pursuant to clause ‎26.1.1 (Termination by UK Biobank) prior to Achievement of the PQ Milestone, UK Biobank may at any time on or within twelve (12) months of the issue of the relevant Termination Notice by issue to the Supplier of written notice require the Supplier to repay to UK Biobank an amount equal to the aggregate Milestone Payments already paid to the Supplier less a reasonable amount to reflect any Deliverables that UK Biobank wishes to retain (taking into account the Supplier’s costs of providing that Deliverable and the benefit derived by UK Biobank).

section I – miscellaneous and governing law

1. ASSIGNMENT AND NOVATION
	1. UK Biobank shall not assign charge or transfer this Agreement or any of its rights under it without the prior written consent of the Supplier (such consent not to be unreasonably withheld or delayed), provided that the Supplier’s consent shall not be required where it is between UK Biobank and its direct or indirect holding companies and its direct or indirect subsidiaries (within the meaning of s1159 Companies Act 2006) (“**Successor Body**”).
	2. The Supplier shall not assign charge or transfer this Agreement or any of its rights under it without the prior written consent of UK Biobank (such consent not to be unreasonably withheld or delayed). Any assignment, charge or transfer of this Agreement or any of the Supplier’s rights under it by the Supplier will comply with the provisions of clause ‎20.
2. WAIVER AND CUMULATIVE REMEDIES
	1. The failure or delay by any Party to enforce at any time or for any period any of the terms or conditions of this Agreement shall not be a waiver of them or of the right at any time subsequently to enforce all terms and conditions of this Agreement.
	2. Unless otherwise provided in this Agreement, rights and remedies under this Agreement are cumulative and do not exclude any rights or remedies provided by law, in equity or otherwise.
3. RELATIONSHIP OF THE PARTIES

Except as expressly provided otherwise in this Agreement, nothing in this Agreement, nor any actions taken by the Parties pursuant to this Agreement, shall create a partnership, joint venture or relationship of employer and employee or principal and agent between the Parties, or authorise either Party to make representations or enter into any commitments for or on behalf of any other Party.

1. PREVENTION OF FRAUD AND BRIBERY

**General**

* 1. The Supplier shall comply with all applicable anti-bribery, anti-corruption and anti-slavery legislation including the Bribery Act 2010 and Modern Slavery Act 2015.

**Bribery Act Compliance**

* 1. The Supplier shall maintain and enforce its own policies and procedures, including adequate procedures under the Bribery Act 2010, to ensure compliance with all applicable anti-bribery and anti-corruption legislation. Adequate procedures shall be determined in accordance with section 7(2) of the Bribery Act 2010 (and any guidance issued under section 9 of the Act).
	2. The Supplier shall use reasonable endeavours to ensure that all persons associated with the Supplier (as defined by section 8 of the Bribery Act 2010) including any subcontractors and suppliers comply with this clause.

**Modern Slavery Act Requirements**

* 1. The Supplier shall implement due diligence procedures for its own suppliers, subcontractors and other participants in its supply chains, to ensure that there is no slavery or human trafficking in its supply chains.
	2. The Supplier shall use reasonable endeavours not to purchase any raw materials, resources or products from any country that has been sourced from producers or manufacturers using forced labour in its operations or practice.
1. ENTIRE AGREEMENT
	1. This Agreement constitutes the entire agreement between the Parties in respect of its subject matter and supersedes and extinguishes all prior negotiations, arrangements, understanding, course of dealings or agreements made between the Parties in relation to its subject matter, whether written or oral.
	2. Neither Party has been given, nor entered into this Agreement in reliance on, any warranty, statement, promise or representation other than those expressly set out in this Agreement.
	3. Nothing in this clause ‎32 shall exclude any liability in respect of misrepresentations made fraudulently.
2. THIRD PARTY RIGHTS
	1. A person who is not a Party to this Agreement has no right under the CRTPA to enforce any term of this Agreement but this does not affect any right or remedy of any person which exists or is available otherwise than pursuant to that Act.
3. NOTICES
	1. Any notices sent under this Agreement must be in writing.
	2. Subject to clause ‎34.4, the following table sets out the method by which notices may be served under this Agreement and the respective deemed time and proof of service:

|  |  |  |
| --- | --- | --- |
| **Manner of Delivery** | **Deemed time of service** | **Proof of service** |
| Email | 9.00am on the first Working Day after sending | Dispatched as a pdf attachment to an email to the correct email address without any error message. |

* 1. Notices shall be sent to the addresses set out below or at such other address as the relevant Party may give notice to the other Party for the purpose of service of notices under this Agreement:

|  |  |  |
| --- | --- | --- |
|  | **Supplier** | **UK Biobank** |
| 1. **Contact**
 |  | Jonathan Sellors |
| 1. **Address**
 |  | Units 1 & 2 Spectrum Way, Adswood, Stockport, Cheshire, SK3 0SA |
| 1. **Email**
 |  | notices@ukbiobank.ac.uk |

* 1. The following notices may only be served as an attachment to an email if the original notice is then sent to the recipient by personal delivery or recorded delivery in the manner set out in the table below:
		1. notices issued by the Supplier pursuant to clause ‎26.2 (Termination by the Supplier);
		2. Termination Notices; and
		3. Dispute Notices.

|  |  |  |
| --- | --- | --- |
| **Manner of Delivery** | **Deemed time of service** | **Proof of service** |
| Personal delivery | On delivery, provided delivery is between 9.00am and 5.00pm on a Working Day. Otherwise, delivery will occur at 9.00am on the next Working Day. | Properly addressed and delivered as evidenced by signature of a delivery receipt. |
| Prepaid, Royal Mail Signed for 1st Class or other prepaid, next Working Day service providing proof of delivery. | At the time recorded by the delivery service, provided that delivery is between 9.00am and 5.00pm on a Working Day. Otherwise, delivery will occur at 9.00am on the same Working Day (if delivery before 9.00am) or on the next Working Day (if after 5.00pm). | Properly addressed prepaid and delivered as evidenced by signature of a delivery receipt. |

* 1. Failure to send any original notice by personal delivery or recorded delivery in accordance with clause ‎34.4 shall invalidate the service of the related e-mail transmission. The deemed time of delivery of such notice shall be the deemed time of delivery of the original notice sent by personal delivery or Royal Mail Signed For™ 1st Class delivery (as set out in the table in clause ‎34.2) or, if earlier, the time of response or acknowledgement by the other Party to the email attaching the notice.
	2. This clause ‎33.1 does not apply to the service of any proceedings or other documents in any legal action or, where applicable, any arbitration or other method of dispute resolution (other than the service of a Dispute Notice under clause ‎35.1.1 (Disputes)).
1. DISPUTES
	1. Subject to clauses ‎35.3 and 35.5, neither Party may commence proceedings in relation to a Dispute that arises out of or in connection with this Agreement (including in relation to any non-contractual obligations) unless that Party has:
		1. served a written notice (a “Dispute Notice”) on the other Party notifying it of the relevant Dispute; or
		2. already received a Dispute Notice from the other Party in relation to the same Dispute.
	2. Following service of the Dispute Notice in relation to a Dispute, each Party will respectively procure that such Dispute will be referred for resolution to legal counsel for the time of each Party. Those representatives will meet at the earliest convenient time and in any event within seven (7) days of the date of service of the relevant Dispute Notice and will negotiate in good faith and in order to resolve the Dispute.
	3. If a Dispute has not been resolved within seven (7) days of the date of service of the relevant Dispute Notice each party will respectively procure that such Dispute be referred for resolution to the Deputy Chief Executives (or equivalent) for the time being of each Party. Those representatives will meet at the earliest convenient time and in any event within fourteen (14) days of the date of service of the relevant Dispute Notice and will negotiate in good faith and in order to resolve the Dispute.
	4. If a Dispute is not resolved within fourteen (14) days of service of the relevant Dispute Notice either Party may commence proceedings in accordance with clause ‎36 or, if both Parties agree in writing to do so, the Parties will attempt to settle the Dispute by mediation in accordance with the CEDR Model Mediation Procedure in each case irrespective of whether clauses ‎35.2 and ‎35.3 have been complied with. The provisions of this clause ‎35.4 are without prejudice to any right that either Party may have to damages in respect of any breach by the other Party of clauses ‎35.2 and ‎35.3. Either Party may withdraw from mediation at any time.
	5. Notwithstanding the provisions of clause ‎35.1 to ‎35.4, where Part II of the Housing Grants, Construction and Regeneration Act 1996 (as amended) applies, either Party may refer any Dispute arising under this Agreement to adjudication. The adjudication procedures and the agreement for the appointment of an adjudicator shall be as set out in the Scheme for Construction Contracts current at the date of reference, subject to the provisions of this clause. The nominating body shall be the Technology and Construction Solicitors’ Association or any successor organisation. As soon as possible after reaching their decision, the adjudicator will provide each Party with a copy of their decision, supported by their reasons. The adjudication and all matters arising in the course of the adjudication, must be kept confidential by the Parties, except as may be properly required for the purpose of obtaining legal or professional advice or for the purpose of any subsequent proceedings. In any reference to adjudication, each Party will bear its own costs.
	6. Nothing in this clause ‎35 will prevent or delay either Party from:
		1. seeking orders for specific performance, interim or final injunctive relief;
		2. exercising any rights it has to terminate this Agreement; or
		3. commencing any proceedings where this is necessary to avoid any loss of a claim due to the rules on limitation of actions.
2. GOVERNING LAW AND JURISDICTION
	1. This Agreement and any issues, disputes or claims (whether contractual or non‑contractual) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the laws of England and Wales.
	2. Subject to clause ‎35 (Disputes), the Parties agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (whether contractual or non-contractual) that arises out of or in connection with this Agreement or its subject matter or formation.

**SIGNED BY** or on behalf of the Parties on the date stated at the beginning of this Agreement.

[Signed as a deed by )

**UK BIOBANK LIMITED** )

acting by two directors or )

one director and its secretary )

Signature of director

Signature of director/secretary]

[Signed as a deed by )

**[NAME OF COMPANY]** )

acting by two directors or )

one director and its secretary )

Signature of director

Signature of director/secretary]

1. schedule

Definitions

1. Unless otherwise provided or the context otherwise requires the following expressions shall have the meanings set out below.

|  |  |
| --- | --- |
| 1. “**Achieve**”
 | * 1. in respect of a Test, to successfully pass a Test in accordance with the provisions of Schedule 6 (Testing Procedure); and
	2. in respect of a Milestone, the issue of a Milestone Achievement Certificate in respect of that Milestone in accordance with the provisions of Schedule 6 (Testing Procedures),
1. and “**Achieved**” and “**Achievement**” shall be construed accordingly;
 |
| 1. **“Affected Party”**
 | 1. the Party seeking to claim relief in respect of a Force Majeure Event;
 |
| 1. **“Affiliate”**
 | 1. in relation to a body corporate, any other entity which directly or indirectly Controls, is Controlled by, or is under direct or indirect common Control with, that body corporate from time to time;
 |
| 1. **“Archive”**
 | the automated large-scale ultra-low temperature biological sample archive incorporating the Supplier IT System that is to be provided, configured, implemented, integrated and supported by the Supplier under this Agreement, as set out in UK Biobank Requirements and the Supplier Solution; |
| 1. **“Assets”**
 | 1. all assets and rights used by the Supplier to provide the Services in accordance with this Agreement but excluding UK Biobank Assets;
 |
| 1. **“Background IPRs”**
 | 1. Supplier Background IPRs and Third Party IPRs;
 |
| 1. **“Change”**
 | 1. any change to this Agreement;
 |
| 1. **“Change Control Procedure”**
 | 1. the procedure set out in clause ‎11 (Change);
 |
| 1. **“Change in Law”**
 | 1. any change in Law which impacts on the performance of the Services which comes into force after the Effective Date;
 |
| 1. **“Change Request”**
 | 1. has the meaning given in clause ‎11.2.1 (Change);
 |
| 1. **“Change Request Information”**
 | 1. has the meaning given in clause ‎11.3 (Change);
 |
| 1. **“Charges”**
 | 1. the charges for the provision of the Services and access to and use of the Archive set out in or otherwise calculated in accordance with Schedule 7 (Charges and Invoicing), including (unless otherwise specified) any Milestone Payments and Service Charges;
 |
| 1. **[“Condition Precedent”**
 | has the meaning given in clause ‎4.2;] |
| 1. **“Confidential Information”**
 | * 1. Information, including all Personal Data, which (however it is conveyed) is provided by the Disclosing Party pursuant to or in anticipation of this Agreement that relates to:
		1. the Disclosing Party Group; or
		2. the operations, business, affairs, developments, intellectual property rights, trade secrets, know-how and/or personnel of the Disclosing Party Group;
	2. other Information provided by the Disclosing Party pursuant to or in anticipation of this Agreement that is clearly designated as being confidential or equivalent or that ought reasonably to be considered to be confidential (whether or not it is so marked) which comes (or has come) to the Recipient’s attention or into the Recipient’s possession in connection with this Agreement;
	3. discussions, negotiations, and correspondence between the Disclosing Party or any of its directors, officers, employees, consultants or professional advisers and the Recipient or any of its directors, officers, employees, consultants and professional advisers in connection with this Agreement and all matters arising therefrom; and
	4. Information derived from any of the above,
1. but not including any Information which:
	* 1. was in the possession of the Recipient without obligation of confidentiality prior to its disclosure by the Disclosing Party;
		2. the Recipient obtained on a non-confidential basis from a third party who is not, to the Recipient’s knowledge or belief, bound by a confidentiality agreement with the Disclosing Party or otherwise prohibited from disclosing the information to the Recipient;
		3. was already generally available and in the public domain at the time of disclosure otherwise than by a breach of this Agreement or breach of a duty of confidentiality;
		4. was independently developed without access to the Confidential Information; or
		5. relates to the Supplier’s performance under this Agreement;
 |
| 1. **“Contract Year”**
 | * 1. a period of twelve (12) months commencing on the Effective Date; or
	2. thereafter a period of twelve (12) months commencing on each anniversary of the Effective Date,
1. provided that the final Contract Year shall end on the expiry or termination of the Term;
 |
| 1. **“Control”**
 | 1. the possession by person, directly or indirectly, of the power to direct or cause the direction of the management and policies of the other person (whether through the ownership of voting shares, by contract or otherwise) and “**Controls**” and “**Controlled**” shall be interpreted accordingly;
 |
| 1. **“Controller”**
 | 1. has the meaning given in the UK GDPR or the EU GDPR as the context requires;
 |
| 1. **“CRTPA”**
 | 1. the Contracts (Rights of Third Parties) Act 1999;
 |
| 1. **“Data Loss Event”**
 | 1. any event that results, or may result, in unauthorised access to Personal Data held by the Supplier under this Agreement, and/or actual or potential loss and/or destruction of Personal Data in breach of this Agreement, including any Personal Data Breach;
 |
| 1. **“Data Protection Impact Assessment”**
 | 1. an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data;
 |
| 1. **“Data Protection Laws”**
 | * 1. the UK GDPR;
	2. the DPA 2018 to the extent that it relates to processing of personal data and privacy;
	3. all applicable Law about the processing of personal data and privacy; and
	4. (to the extent that it applies) the EU GDPR;
 |
| 1. **“Data Subject”**
 | has the meaning given to it in the UK GDPR or the EU GDPR as the context requires; |
| 1. **“Data Subject Request”**
 | a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Laws to their Personal Data; |
| 1. **“Default”**
 | 1. any breach of the obligations of the relevant Party (including abandonment of this Agreement in breach of its terms, repudiatory breach or breach of a fundamental term) or any other default, act, omission, negligence or statement:
	1. in the case of UK Biobank, of its employees, servants, agents; or
	2. in the case of the Supplier, of its Sub-contractors or any Supplier Personnel,
2. in connection with or in relation to the subject matter of this Agreement and in respect of which such Party is liable to the other;
 |
| 1. **“Delay”**
 | * 1. a delay in the Achievement of a Milestone by its Milestone Date; or
	2. a delay in the design, development, testing or installation of a Deliverable by the relevant date set out in the Project Plan;
 |
| 1. **“Deliverable”**
 | 1. an item or feature (including all components of the Archive) delivered or to be delivered by the Supplier at or before a Milestone Date or at any other stage during the performance of this Agreement;
 |
| 1. **“Detailed Project Plan”**
 | 1. the plan developed and revised from time to time in accordance with Paragraphs 3 and 4 of Schedule 5 (Project Plan);
 |
| 1. **“Developer”**
 | 1. has the meaning given in the Specification;
 |
| 1. **“Disaster”**
 | 1. the occurrence of one or more events which, either separately or cumulatively, mean that the Archive or the Services, or a material part of the Archive or Services, will be unavailable for handling of Samples for a period of greater than seven (7) days, or which is reasonably anticipated will mean that the Archive or the Services or a material part of the Archive or the Services will be unavailable for that period, or an inability to rectify a breach of the KPI Service Threshold in respect of KPI1 (Climate) leading to exposure of the Samples to temperatures of higher than or equal to minus 60 degrees for any period of more than 8 hours;
 |
| 1. **“Disclosing Party”**
 | 1. has the meaning given in clause ‎19.1 (Confidentiality);
 |
| 1. **“Disclosing Party Group”**
 | * 1. where the Disclosing Party is the Supplier, the Supplier and any Affiliates of the Supplier; and
	2. where the Disclosing Party is UK Biobank, UK Biobank and any with which UK Biobank or the Supplier interacts in connection with this Agreement;
 |
| 1. **“Dispute”**
 | 1. any dispute, difference or question of interpretation arising out of or in connection with this Agreement, including any dispute, difference or question of interpretation relating to the Services or any matter where this Agreement directs the Parties to resolve an issue by reference to the Dispute Resolution Procedure;
 |
| 1. **“Dispute Notice”**
 | 1. has the meaning given in clause ‎35.1.1 (Disputes);
 |
| 1. **“Dispute Resolution Procedure”**
 | 1. the dispute resolution procedure set out in clause ‎35 (Disputes);
 |
| 1. **“Documentation”**
 | 1. descriptions of the Services and the Archive, relevant design and development information, technical specifications of all functionality including those not included in standard manuals (such as those that modify system performance and access levels), configuration details, test scripts, user manuals, operating manuals, process definitions and procedures, and all such other documentation as:
	1. is required to be supplied by the Supplier to UK Biobank under this Agreement;
	2. would reasonably be required by a competent third party capable of Good Industry Practice contracted by UK Biobank to develop, configure, build, deploy, run, maintain, upgrade and test the individual systems that provide Services;
	3. is required by the Supplier in order to provide the Services; and/or
	4. has been or shall be generated for the purpose of providing the Services;
 |
| 1. **“DPA 2018”**
 | 1. the Data Protection Act 2018;
 |
| 1. **“Due Diligence Information”**
 | 1. any information supplied to the Supplier by or on behalf of UK Biobank prior to the Effective Date;
 |
| 1. **“EEA”**
 | 1. European Economic Area;
 |
| 1. **“Effective Date”**
 | 1. the later of:
	1. the date on which this Agreement is signed by both Parties; and
	2. the date on which the Condition Precedent has been satisfied or waived in accordance with clause ‎4.2 (Condition Precedent);;
 |
| 1. **“Employment Regulations”**
 | 1. the Transfer of Undertakings (Protection of Employment) Regulations 2006 (SI 2006/246) as amended or replaced;
 |
| 1. **“EU GDPR”**
 | 1. 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;
 |
| 1. **“Exit Management”**
 | 1. services, activities, processes and procedures to ensure a smooth and orderly transition of all or part of the Services from the Supplier to UK Biobank and/or a Replacement Supplier, as set out or referred to in Schedule 8 (Exit Management);
 |
| 1. **“Exit Plan”**
 | 1. the plan produced and updated by the Supplier during the Term in accordance with clause ‎27.2 (Exit Management) and Schedule 8 (Exit Management);
 |
| 1. **“Extension Period”**
 | 1. a period extending the Term from the end of the Initial Term or any prior Extension Period, as applicable, as may be specified in the notice given by UK Biobank pursuant to clause ‎4.1.2.2 or ‎4.1.2.3 (Term), as applicable, provided that:
	1. each such period must be for a minimum of period of twelve (12) months; and
	2. the total of all such periods may not exceed ten (10) years in aggregate;
 |
| 1. **“Facility”**
 | 1. has the meaning given in the Specification;
 |
| 1. **“Factory Acceptance Test” or “FAT”**
 | 1. the Testing process described as such in the Annex 1 of Schedule 6 (Testing Procedures);
 |
| 1. **“Force Majeure Event”**
 | 1. any event outside the reasonable control of either Party affecting its performance of its obligations under this Agreement arising from acts, events, omissions, happenings or non-happenings beyond its reasonable control and which are not attributable to any wilful act, neglect or failure to take reasonable preventative action by that Party, including acts of God, riots, war or armed conflict, acts of terrorism, fire, flood, storm or earthquake, or disaster, but excluding:
	1. any industrial dispute relating to the Supplier or the Supplier Personnel; and
	2. any other failure in the Supplier’s or a Sub-contractor’s supply chain;
 |
| 1. **“Good Industry Practice”**
 | 1. at any time the exercise of that degree of care, skill, diligence, prudence, efficiency, foresight and timeliness which would be reasonably expected at such time from a leading and expert supplier of services similar to the Services to a customer like UK Biobank, such supplier seeking to comply with its contractual obligations in full and complying with applicable Laws;
 |
| 1. **“Goods”**
 | 1. has the meaning given in clause ‎8.3;
 |
| 1. **“Incident”**
 | 1. any unplanned interruption which significantly impairs the ability of the Supplier to supply the Archive and/or perform the Services (in whole or in part) in accordance with this Agreement;
 |
| **“Indexation”** | the adjustment of an amount or sum in accordance with Paragraph ‎0 of Part C of Schedule 7 (Charging and Invoicing); |
| 1. **“Information”**
 | 1. all information of whatever nature, however conveyed and in whatever form, including in writing, orally, by demonstration, electronically and in a tangible, visual or machine-readable medium (including CD-ROM, magnetic and digital form);
 |
| 1. **“Initial Term”**
 | 1. the period from and including the Effective Date until and including the fifth (5th) anniversary of the Support Service Commencement Date;
 |
| 1. **“Insolvency Event”**
 | * 1. the other Party suspends, or threatens to suspend, payment of its debts, or is unable to pay its debts as they fall due or admits inability to pay its debts, or is deemed unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986;
	2. the other Party commences negotiations with one or more of its creditors (using a voluntary arrangement, scheme of arrangement or otherwise) with a view to rescheduling any of its debts, or makes a proposal for or enters into any compromise or arrangement with one or more of its creditors or takes any step to obtain a moratorium pursuant to Section 1A and Schedule A1 of the Insolvency Act 1986 other than for the sole purpose of a scheme for a solvent amalgamation of that other Party with one or more other companies or the solvent reconstruction of that other Party;
	3. a person becomes entitled to appoint a receiver over the assets of the other Party or a receiver is appointed over the assets of the other Party;
	4. a creditor or encumbrancer of the other Party attaches or takes possession of, or a distress, execution or other such process is levied or enforced on or sued against, the whole or any part of the other Party's assets and such attachment or process is not discharged within fourteen (14) days;
	5. the other Party suspends or ceases, or threatens to suspend or cease, carrying on all or a substantial part of its business;
	6. a petition is presented (which is not dismissed within fourteen (14) days of its service), a notice is given, a resolution is passed, or an order is made, for or in connection with the winding up of the other Party other than for the sole purpose of a scheme for a solvent amalgamation of that other Party with one or more other companies or the solvent reconstruction of that other Party;
	7. an application is made to court, or an order is made, for the appointment of an administrator, or if a notice of intention to appoint an administrator is filed at Court or given or if an administrator is appointed, over the other Party; or
	8. any event occurs, or proceeding is taken, with respect to the other Party in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events mentioned above;
 |
| 1. **“Installation Qualification” or “IQ”**
 | the Testing process described as such in the Annex 1 of Schedule 6 (Testing Procedures); |
| 1. **“Installation Services”**
 | 1. the installation services described as such in the Specification;
 |
| 1. **“Installation Services Commencement Date”**
 | 1. the date on which the Supplier is to commence provision of the Installation Services, being [INSERT DATE];
 |
| 1. **“Intellectual Property Rights”** or **“IPRs”**
 | * 1. copyright, rights related to or affording protection similar to copyright, rights in databases, patents and rights in inventions, semi-conductor topography rights, trade marks, rights in Internet domain names and website addresses and other rights in trade names, designs, Know-How, trade secrets and other rights in Confidential Information;
	2. applications for registration, and the right to apply for registration, for any of the rights listed at (a) that are capable of being registered in any country or jurisdiction; and
	3. all other rights having equivalent or similar effect in any country or jurisdiction;
 |
| 1. **“IPRs Claim”**
 | 1. any claim against UK Biobank of infringement or alleged infringement (including the defence of such infringement or alleged infringement) of any Relevant IPRs save for any such claim to the extent that it is caused by any use by or on behalf of that UK Biobank of any Relevant IPRs, or the use of UK Biobank Software by or on behalf of the Supplier, in either case in combination with any item not supplied or recommended by the Supplier pursuant to this Agreement or for a purpose not reasonably to be inferred from the Specification or the provisions of this Agreement;
 |
| 1. **“IT Environment”**
 | 1. UK Biobank System and the Supplier System;
 |
| 1. **“ITT”**
 | 1. UK Biobank’s Invitation to Tender (ITT) for an Automated Large-Scale Ultra-Low Temperature Biological Sample Archive (Procurement Reference Number: UKBB017);
 |
| 1. **“Key Performance Indicator”**
 | 1. the key performance indicators set out in Schedule 3 (Performance Levels);
 |
| 1. **“Key Personnel”**
 | 1. those persons appointed by the Supplier to fulfil the Key Roles, being the persons listed in Part B of Schedule 2 (Specification and Supplier Solution) against each Key Role as at the Effective Date or as amended from time to time in accordance with clause ‎12.3 (Supplier Personnel);
 |
| 1. **“Key Roles”**
 | 1. the on-site engineering support and project manager roles identified in the Specification, the Supplier Representative and any role described as a Key Role in Schedule 2 (Specification and Supplier Solution);
 |
| 1. **“Key Sub-contract”**
 | 1. each Sub-contract with a Key Sub-contractor;
 |
| 1. **“Key Sub-contractor”**
 | * 1. [INSERT]; and
	2. any other Sub-contractor:
		1. which, in the opinion of UK Biobank, performs (or would perform if appointed) a critical role in the provision of all or any part of the Services; and/or
		2. with a Sub-contract with a contract value which at the time of appointment exceeds (or would exceed if appointed) 25% of the aggregate Charges forecast to be payable in connection with this Agreement;
 |
| 1. **“Know-How”**
 | 1. all ideas, concepts, schemes, information, knowledge, techniques, methodology, and anything else in the nature of know how relating to the Services but excluding know how already in the other Party’s possession before this Agreement;
 |
| 1. **“KPI Failure”**
 | 1. a failure to meet the Target Performance Level in respect of a Key Performance Indicator;
 |
| 1. **“KPI Service Threshold”**
 | 1. shall be as set out against the relevant Key Performance Indicator in Schedule 3 (Performance Levels);
 |
| 1. **“Laboratory System”**
 | 1. has the meaning given in the Specification;
 |
| 1. **“Law”**
 | 1. any law, statute, subordinate legislation within the meaning of section 21(1) of the Interpretation Act 1978, bye-law, enforceable right within the meaning of section 2 of the European Communities Act 1972, regulation, order, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements of any regulatory body with which the Supplier is bound to comply;
 |
| 1. **“Losses”**
 | 1. losses, liabilities, damages, costs and expenses (including legal fees on a solicitor/client basis) and disbursements and costs of investigation, litigation, settlement, judgment interest and penalties whether arising in contract, tort (including negligence), breach of statutory duty or otherwise;
 |
| 1. **“Malicious Software”**
 | 1. any software program or code intended to destroy, interfere with, corrupt, or cause undesired effects on program files, data or other information, executable code or application software macros, whether or not its operation is immediate or delayed, and whether the malicious software is introduced wilfully, negligently or without knowledge of its existence;
 |
| 1. **“Material KPI Failure”**
 | * 1. a failure by the Supplier to meet a KPI Service Threshold; or
	2. as otherwise set out against the relevant Key Performance Indicator in Schedule 3 (Performance Levels);
 |
| 1. **“Milestone”**
 | 1. an event or task described in the Project Plan (or in respect of the Optional Deliverables, the Optional Deliverables Project Plan) which, if applicable, shall be completed by the relevant Milestone Date;
 |
| 1. **“Milestone Achievement Certificate”**
 | 1. the certificate to be granted by UK Biobank when the Supplier has Achieved a Milestone, which shall be in substantially the same form as that set out in Schedule 6 (Testing Procedures);
 |
| 1. **“Milestone Date”**
 | 1. the target date set out against the relevant Milestone in the Project Plan (or in respect of the Optional Deliverables, the Optional Deliverables Project Plan) by which the Milestone must be Achieved;
 |
| 1. **“Milestone Payment”**
 | 1. a payment identified in Schedule 7 (Charges and Invoicing) to be made following the issue of a Milestone Achievement Certificate;
 |
| 1. **“New Releases”**
 | 1. an item produced primarily to extend, alter or improve the Software and/or any Deliverable by providing additional functionality or performance enhancement (whether or not defects in the Software and/or Deliverable are also corrected) while still retaining the original designated purpose of that item, including standard upgrades, new versions and new releases of the Software and/or a Deliverable and any other product enhancements;
 |
| 1. **“Non-trivial Customer Base”**
 | 1. a significant customer base with respect to the date of first release and the relevant market but excluding Affiliates and other entities related to the licensor;
 |
| 1. **“Notifiable Default”**
 | 1. shall have the meaning given in clause ‎23.1 (Rectification Plan Process);
 |
| 1. **“Notional Average Annual Service Charges”**
 | 1. the average of annual Service Charges payable by UK Biobank during the first five (5) years following the Support Service Commencement Date, as set out in Schedule 7 (Charging and Invoicing);
 |
| **“Object Code”** | software and/or data in machine-readable, compiled object code form; |
| 1. **“Operating Environment”**
 | 1. UK Biobank System and the Sites;
 |
| 1. **“Operational Qualification” or “OQ”**
 | 1. the Testing process described as such in the Annex 1 of Schedule 6 (Testing Procedures);
 |
| 1. **“Optional Deliverables”**
 | 1. the goods and services described as such in Schedule 2 (Specification and Supplier Solution), which are to be provided by the Supplier if required by UK Biobank in accordance with clause ‎5.4 (Optional Deliverables);
 |
| 1. **“Optional Deliverables Project Plan”**
 | 1. the project plan to effect the Optional Deliverables agreed between the Parties prior to the Effective Date or, if not agreed prior to the Effective Date, to be developed by the Supplier and approved by UK Biobank pursuant to clause ‎5.6.1 (Optional Deliverables);
 |
| 1. **“OQ Milestone”**
 | 1. the Milestone linked to successful completion of Operational Qualification, set out in the Project Plan;
 |
| 1. **“Other Supplier”**
 | 1. any supplier to UK Biobank (other than the Supplier) which is notified to the Supplier from time to time and/or of which the Supplier should have been aware;
 |
| 1. **“Outline Project Plan”**
 | 1. the outline plan set out at Annex 1 of Schedule 5 (Project Plan);
 |
| 1. **“Parties”** and **“Party”**
 | 1. UK Biobank and/or the Supplier, as the context requires;
 |
| 1. “**Pay Less Notice**”
 | 1. a notice in writing specifying the sum that UK Biobank considers is due to the Supplier at the date that this notice is served (which may be zero) and the basis upon which that sum has been calculated;
 |
| 1. **“Personal Data”**
 | 1. has the meaning given in the UK GDPR or the EU GDPR as the context requires;
 |
| 1. **“Personal Data Breach”**
 | 1. has the meaning given in the UK GDPR or the EU GDPR as the context requires;
 |
| 1. **“Performance Failure”**
 | 1. a KPI Failure;
 |
| 1. **“Performance Qualification ” or “PQ”**
 | 1. the Testing process described as such in the Annex 1 of Schedule 6 (Testing Procedures);
 |
| 1. **“Permitted Maintenance”**
 | 1. has the meaning given in clause ‎8.2 (Maintenance);
 |
| 1. **“PQ Milestone”**
 | 1. the Milestone linked to successful completion of Performance Qualification, set out in the Project Plan;
 |
| 1. **“Processor”**
 | 1. has the meaning given to it under the UK GDPR or the EU GDPR as the context requires;
 |
| 1. **“Processor Personnel”**
 | 1. all directors, officers, employees, agents, consultants and suppliers of the Processor and/or of any Sub-processor engaged in the performance of its obligations under this Agreement;
 |
| 1. **“Project Plan”**
 | 1. the Outline Project Plan or (if and when approved by UK Biobank pursuant to Paragraph 3 of Schedule 5 (Project Plan)) the Detailed Project Plan as updated in accordance with Paragraph 4 of Schedule 5 (Project Plan) from time to time;
 |
| 1. **“Project Specific IPRs”**
 | * 1. Intellectual Property Rights in items created by the Supplier (or by a third party on behalf of the Supplier) specifically for the purposes of this Agreement and updates and amendments of these items including (but not limited to) database schema; and/or
	2. Intellectual Property Rights arising as a result of the performance of the Supplier's obligations under this Agreement;

but shall not include the Supplier Background IPRs or the Specially Written Software; |
| 1. **“Protective Measures”**
 | appropriate technical and organisational measures designed to ensure compliance with obligations of the Parties arising under Data Protection Laws, which may include: 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; |
| 1. **“Public Contracts Regulations”**
 | 1. the Public Contracts Regulations 2015 (as amended from time to time);
 |
| 1. **“Recipient”**
 | 1. has the meaning given in clause ‎19.1 (Confidentiality);
 |
| 1. **“Rectification Plan”**
 | 1. a plan to address the impact of, and prevent the reoccurrence of, a Notifiable Default;
 |
| 1. **“Rectification Plan Failure”**
 | * 1. the Supplier failing to submit or resubmit a draft Rectification Plan to UK Biobank within the timescales specified in clauses ‎23.4 (Submission of the draft Rectification Plan) or ‎23.7 (Agreement of the Rectification Plan);
	2. UK Biobank, acting reasonably, rejecting a revised draft of the Rectification Plan submitted by the Supplier pursuant to clause ‎23.7 (Agreement of the Rectification Plan);
	3. the Supplier failing to rectify a material Default within the later of:
		1. thirty (30) Working Days of a notification made pursuant to clause ‎23.2 (Notification); and
		2. where the Parties have agreed a Rectification Plan in respect of that material Default and the Supplier can demonstrate that it is implementing the Rectification Plan in good faith, the date specified in the Rectification Plan by which the Supplier must rectify the material Default;
	4. a Material KPI Failure re-occurring in respect of the same Key Performance Indicator for the same (or substantially the same) root cause in any of the three (3) Service Periods subsequent to the Service Period in which the initial Material KPI Failure occurred;
	5. the Supplier not Achieving the OQ Milestone by the expiry of one hundred (100) days following its applicable Milestone Date; and/or
	6. following the successful implementation of a Rectification Plan, the same Notifiable Default recurring within a period of six (6) months for the same (or substantially the same) root cause as that of the original Notifiable Default;
 |
| 1. **“Rectification Plan Process”**
 | 1. the process set out in clauses ‎23.4 (Submission of the Rectification Plan) to ‎23.8 (Agreement of the Rectification Plan);
 |
| **“Regulatory Authorities”** | 1. all governmental, statutory or regulatory bodies and any other competent authorities or entities in any jurisdiction having responsibility for the regulation or governance of UK Biobank, the Supplier, this Agreement, the Services or the activities which are comprised in all or some of the Services or the use or application of the output from any part of the Services; and **“Regulatory Authority”** means any of them;
 |
| 1. **“Relevant IPRs”**
 | 1. IPRs used to provide the Services or the Archive or as otherwise provided and/or licensed by the Supplier (or to which the Supplier has provided access) to UK Biobank or a third party in the fulfilment of the Supplier’s obligations under this Agreement including IPRs in the Software, the Project Specific IPRs and the Background IPRs but excluding any IPRs in UK Biobank Software and UK Biobank Background IPRs;
 |
| 1. **“Replacement Services”**
 | 1. any services which are the same as or substantially similar to any of the Services and which UK Biobank receives in substitution for any of the Services following the expiry or termination of this Agreement, whether those services are provided by UK Biobank internally and/or by any third party;
 |
| 1. **“****Replacement Supplier”**
 | 1. any third party service provider of Replacement Services appointed by UK Biobank from time to time, including any sub-contractor thereof (or where UK Biobank is providing Replacement Services for its own account, UK Biobank);
 |
| 1. **“Representative”**
 | 1. the UK Biobank Representative and / or the Supplier Representative, as applicable
 |
| 1. **“Required Insurance”**
 | * 1. public liability insurance with a minimum per occurrence limit of indemnity of £20 million and a minimum aggregate limit of indemnity of £20 million;
	2. professional indemnity insurance with a minimum per occurrence limit of indemnity of £20 million and a minimum aggregate limit of indemnity of £20 million;
	3. product liability insurance with a minimum per occurrence limit of indemnity of £20 million and a minimum aggregate limit of indemnity of £20 million;
	4. employer’s (compulsory) liability insurance with a minimum per occurrence limit of indemnity of £5 million and a minimum aggregate limit of indemnity of £5 million; and
	5. either (i) cyber liability insurance (ii) network security and privacy liability (or equivalent) cover under professional indemnity insurance or (iii) equivalent insurance, in each case covering third party liability and first party loss resulting from cyber related risks including: theft of data, cyberattacks, ransomware, theft of intellectual property, and cost of dealing with regulatory investigations following a data security breach, with a minimum per occurrence limit of indemnity of £2 million and a minimum aggregate limit of indemnity of £2 million;
 |
| 1. **“Sample”**
 | 1. a UK Biobank cryopreserved biological sample; for the purposes of this Agreement, includes the labware used to contain it (a sample tube, held on a rack, or a sample held in a well on a plate);
 |
| 1. **“Sample Hall”**
 | 1. has the meaning given in the Specification;
 |
| 1. **“Sample Handling”**
 | 1. has the meaning given in the Specification;
 |
| 1. **“Scheme for Construction Contracts”**
 | 1. Part 1 of the Schedule to the Scheme for Construction Contracts (England and Wales) Regulations 1998 as amended by the Scheme for Construction Contracts (England and Wales) Regulations 1998 (Amendment) (England) Regulations 2011;
 |
| 1. **“Service Charges”**
 | 1. the periodic payments made in accordance with Schedule 7 (Charges and Invoicing) in respect of the supply of the Services;
 |
| 1. **“Service Continuity Plan”**
 | 1. the Supplier’s plan for its emergency response, back-up procedures and business continuity in the event of the occurrence of an Incident;
 |
| 1. **“Service Period”**
 | 1. a calendar month, save that:
	1. the first service period shall begin on the first Support Service Commencement Date and shall expire at the end of the calendar month in which the first Support Service Commencement Date falls; and
	2. the final service period shall commence on the first day of the calendar month in which the Term expires or terminates and shall end on the expiry or termination of the Term;
 |
| 1. **“Services”**
 | 1. any and all of the services to be provided by the Supplier under this Agreement, including provision of the Archive, the Installation Services, the Support Services and any other services set out in Schedule 2 (Specification and Supplier Solution);
 |
| 1. **“Specification”**
 | 1. the specification and services description set out in Schedule 2 (Specification and Supplier Solution);
 |
| 1. **“Site Acceptance Test” or “SAT”**
 | 1. IQ, OQ and / or PQ, as applicable in the context;
 |
| 1. **“Sites”**
 | 1. any premises (including UK Biobank Premises, the Supplier’s premises or third party premises):
	1. from, to or at which:
		1. the Archive is to be installed;
		2. any Services are (or are to be) provided; or
		3. the Supplier manages, organises or otherwise directs the provision or the use of the Services; or
	2. where:
		1. any part of the Supplier System is situated; or
		2. any physical interface with UK Biobank System takes place;
 |
| 1. **“Software”**
 | 1. Specially Written Software, Supplier Software and Third Party Software;
 |
| 1. **“Software as a Service”**
 | 1. Software which is provided to the market as a service rather than as a tangible good and usually made available over the internet;
 |
| 1. **“Spares”**
 | 1. has the meaning given in clause ‎8.3.6;
 |
| 1. **“Specially Written Software”**
 | 1. any software (including database software, linking instructions, test scripts, compilation instructions and test instructions) created by the Supplier (or by a Sub-contractor or other third party on behalf of the Supplier) specifically for the purposes of this Agreement, including any modifications or enhancements to UK Biobank Software, Supplier Software or Third Party Software created specifically for the purposes of this Agreement;
 |
| 1. **“Standards”**
 | 1. the standards, policies and/or procedures identified in Schedule 2 (Specification and Supplier Solution);
 |
| 1. **“Sub-contract”**
 | 1. any contract or agreement (or proposed contract or agreement) between the Supplier (or a Sub-contractor) and any third party whereby that third party agrees to provide to the Supplier (or the Sub-contractor) all or any part of the Services or facilities or services which are material for the provision of the Services or any part thereof or necessary for the management, direction or control of the Services or any part thereof;
 |
| 1. **“Sub-contractor”**
 | 1. any third party with whom:
	1. the Supplier enters into a Sub-contract; or
	2. a third party under (a) above enters into a Sub-contract,
2. or the servants or agents of that third party;
 |
| 1. **“Sub-processor”**
 | 1. any third party appointed to process Personal Data on behalf of the Processor related to this Agreement;
 |
| 1. **“Successor Body”**
 | 1. has the meaning given in clause ‎28.1 (Assignment and Novation);
 |
| 1. **“Supplier Background IPRs”**
 | * 1. Intellectual Property Rights owned by the Supplier before the Effective Date, for example those subsisting in the Supplier's standard development tools, program components or standard code used in computer programming or in physical or electronic media containing the Supplier's Know-How or generic business methodologies; and/or
	2. Intellectual Property Rights created by the Supplier independently of this Agreement,
1. which in each case is or will be used before or during the Term for designing, testing implementing or providing the Services but excluding Intellectual Property Rights owned by the Supplier subsisting in the Supplier Software;
 |
| 1. **“Supplier Equipment”**
 | 1. the hardware, computer and telecoms devices and equipment used by the Supplier or its Sub-contractors (but not hired, leased or loaned from UK Biobank) for the provision of the Services;
 |
| 1. **“Supplier IT System”**
 | 1. the information technology system (all hardware, software (including the Software) and management components required to support the operation and management of the Archive as required to be provided by the Supplier in accordance with the Specification;
 |
| 1. **“Supplier Non-Performance”**
 | 1. has the meaning given in clause ‎24 (UK Biobank Cause);
 |
| 1. **“Supplier Personnel”**
 | 1. all directors, officers, employees, agents, consultants and contractors of the Supplier and/or of any Sub-contractor engaged in the performance of the Supplier’s obligations under this Agreement;
 |
| 1. **“Supplier Representative”**
 | 1. the representative appointed by the Supplier pursuant to clause ‎12.8 (Representatives);
 |
| 1. **“Supplier Software”**
 | 1. software which is proprietary to the Supplier (or an Affiliate of the Supplier) and which is or will be used by the Supplier for the purposes of providing the Services, including the software specified as such in Part B of Schedule 2 (Specification and Supplier Solution);
 |
| 1. **“Supplier Solution”**
 | 1. the Supplier's solution for the Services set out in Part B of Schedule 2 (Specification and Supplier Solution);
 |
| 1. **“Supplier System”**
 | 1. the information and communications technology system used by the Supplier in implementing and performing the Services including the Archive, the Software, the Supplier Equipment, configuration and management utilities, calibration and testing tools and related cabling (but excluding UK Biobank System);
 |
| 1. **“Supplier Termination Event”**
 | * 1. the Supplier committing a material Default which is irremediable;
	2. a Rectification Plan Failure;
	3. where a right of termination is expressly reserved in this Agreement, including pursuant to clause ‎17 (IPRs Indemnity);
	4. the Supplier committing a Default under any of the following clauses:
		1. clause ‎19 (Confidentiality); and/or
		2. clause ‎20 (Data Protection); and/or
		3. Schedule 9 (Processing Personal Data);
	5. an Insolvency Event occurring in respect of the Supplier; or
	6. UK Biobank has become aware that the Supplier should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations from the procurement procedure leading to the award of this Agreement;
 |
| 1. **“Support Service Commencement Date”**
 | 1. in relation to an Support Service, the later of:
	1. the date identified in the Project Plan upon which the Support Service is to commence; and
	2. the date upon which the Supplier Achieves the OQ Milestone;
 |
| 1. **“Support Services”**
 | 1. the support services described as such in the Specification;
 |
| 1. **“Support Services Year”**
 | * 1. a period of twelve (12) months commencing on the Support Service Commencement Date; or
	2. thereafter a period of twelve (12) months commencing on each anniversary of the Support Service Commencement Date,
1. provided that the final Support Services Year shall end on the expiry or termination of the Term;
 |
| 1. **“Target Performance Level”**
 | 1. the minimum level of performance for a Performance Indicator which is required by UK Biobank, as set out against the relevant Performance Indicator in Schedule 3 (Performance Levels);
 |
| 1. **“Term”**
 | 1. the period commencing on the Effective Date and ending on the expiry of the Initial Term or (where UK Biobank exercises its rights pursuant to clause ‎4.1.2.2 or ‎4.1.2.3) any Extension Period or on earlier termination of this Agreement;
 |
| 1. “**Termination Assistance Notice**”
 | 1. has the meaning given in Schedule 8 (Exit Management);
 |
| 1. **“Termination Date”**
 | 1. the date set out in a Termination Notice on which this Agreement (or a part of it as the case may be) is to terminate;
 |
| 1. **“Termination Notice”**
 | 1. a written notice of termination given by one Party to the other, notifying the Party receiving the notice of the intention of the Party giving the notice to terminate this Agreement on a specified date and setting out the grounds for termination;
 |
| 1. “**Termination Services**”
 | 1. the services and activities to be performed by the Supplier pursuant to the Exit Plan, including any services as reasonably specified by UK Biobankpursuant to the Termination Assistance Notice or otherwise;
 |
| 1. **“Tests” and “Testing”**
 | 1. any tests required to be carried out under this Agreement, as further described in Schedule 6 (Testing Procedures) and “**Tested**” shall be construed accordingly;
 |
| 1. **“Third Party COTS Software”**
 | 1. Third Party Software that:
	1. the relevant third party makes generally available commercially prior to the date of this Agreement (whether by way of sale, lease or licence) on standard terms which are not typically negotiated by the Supplier save as to price; and
	2. has a Non-trivial Customer Base,
2. including where indicated as such in Part B of Schedule 2 (Specification and Supplier Solution);
 |
| 1. **“Third Party IPRs”**
 | 1. Intellectual Property Rights owned by a third party but excluding Intellectual Property Rights owned by the third party subsisting in any Third Party Software;
 |
| 1. **“Third Party Software”**
 | 1. software which is proprietary to any third party (other than an Affiliate of the Supplier) which in any case is, will be or is proposed to be used by the Supplier for the purposes of providing the Services, including the software specified as such in Part B of Schedule 2 (Specification and Supplier Solution);
 |
| 1. **“Transition”**
 | 1. the transition from the current cold store system to the new Archive by UK Biobank and its preferred transition supplier to include extraction and transfer of Samples;
 |
| 1. **“UK Biobank Assets”**
 | 1. UK Biobank Materials, UK Biobank infrastructure and any other data, software, assets, equipment or other property owned by and/or licensed or leased to UK Biobank and which is or may be used in connection with the provision or receipt of the Services;
 |
| 1. **“UK Biobank Background IPRs”**
 | * 1. IPRs owned by UK Biobank before the Effective Date, including IPRs contained in any of UK Biobank's Know-How, documentation, processes and procedures; and/or
	2. IPRs created by UK Biobank independently of this Agreement
1. but excluding IPRs owned by UK Biobank subsisting in UK Biobank Software;
 |
| 1. **“UK Biobank Cause”**
 | 1. any breach by UK Biobank of any of UK Biobank Responsibilities, except to the extent that such breach is:
	1. the result of any act or omission by UK Biobank to which the Supplier has given its prior consent; or
	2. caused by the Supplier, any Sub-contractor or any Supplier Personnel;
 |
| 1. **“UK Biobank Data”**
 | * 1. 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, and which are:
		1. supplied to the Supplier by or on behalf of UK Biobank; and/or
		2. which the Supplier is required to generate, process, store or transmit pursuant to this Agreement; and/or
	2. data which is Processed and/or generated by Users, including their results data and relevant derived variables, which they are required to return to UK Biobank; and/or
	3. any Personal Data for which UK Biobank is the Controller;
 |
| 1. **“UK Biobank Delay”**
 | has the meaning given in clause ‎6.4 (UK Biobank Delay and Works Delay Change); |
| 1. **“UK Biobank Materials”**
 | 1. UK Biobank Data together with any materials, documentation, information, programs and codes supplied by UK Biobank to the Supplier, the IPRs in which:
	1. are owned or used by or on behalf of UK Biobank; and
	2. are or may be used in connection with the provision or receipt of the Services,
2. but excluding any Project Specific IPRs, Specially Written Software, Supplier Software, Third Party Software and Documentation relating to Supplier Software or Third Party Software;
 |
| 1. **“UK Biobank Premises”**
 | 1. premises owned, controlled or occupied by UK Biobank and/or any which are made available for use by the Supplier or its Sub-contractors for provision of the Services (or any of them);
 |
| 1. **“UK Biobank Representative”**
 | 1. the representative appointed by UK Biobank pursuant to clause ‎12.8 (Representatives);
 |
| 1. **“UK Biobank Requirements”**
 | 1. the requirements of UK Biobank set out in Schedules 2 (Specification and Supplier Solution), 3 (Performance Levels) and 8 (Exit Management);
 |
| 1. **“UK Biobank Responsibilities”**
 | 1. the responsibilities of UK Biobank specified in this Agreement including any set out in Schedule 4 (UK Biobank Responsibilities);
 |
| 1. **“****UK Biobank Software”**
 | 1. software which is owned by or licensed to UK Biobank (other than under or pursuant to this Agreement) and which is or will be used by the Supplier for the purposes of providing the Services;
 |
| 1. **“UK Biobank System”**
 | 1. UK Biobank's computing environment (consisting of hardware, software and/or telecommunications networks or equipment) used by UK Biobank or the Supplier in connection with this Agreement which is owned by UK Biobank or licensed to it by a third party and which interfaces with the Archive and / or the Supplier System or which is necessary for UK Biobank to receive the Services, including the Laboratory System;
 |
| 1. **“UK GDPR”**
 | 1. has the meaning as set out in section 3(10) of the DPA 2018, supplemented by section 205(4) of the DPA 2018;
 |
| 1. **“UKRI”**
 | 1. UK Research and Innovation, a non-departmental public body sponsored by the Department for Science, Innovation and Technology;
 |
| 1. **“Unacceptable KPI Failure”**
 | 1. the Supplier failing to achieve the KPI Service Threshold in respect of any of the Key Performance Indicators that are measured in that Service Period;
 |
| 1. **“Updates”**
 | 1. in relation to any Software and/or any Deliverable means any patch, fix, release or version of such item which has been produced primarily to overcome defects or errors in, or to improve the operation of, that item;
 |
| 1. **“Users”**
 | 1. researchers authenticated by UK Biobank as entitled to use UK Biobank Data and who have entered into a material transfer agreement with UK Biobank;
 |
| 1. **“Working Day”**
 | 1. any day other than a Saturday, Sunday or public holiday in England and Wales;
 |
| 1. **“Works Delay”**
 | 1. a delay in the development and construction of the UK Biobank Premises where the Archive is to be installed or access to such UK Biobank Premises to enable installation of the Archive or performance of the Installation Services; and
 |
| 1. **“Works Delay Change”**
 | 1. has the meaning given in clause ‎6.5 (UK Biobank Delay and Works Delay Change).
 |

1. Schedule

Specification and Supplier Solution

**Part A – Specification**

**Part B – Supplier Solution**[[3]](#footnote-3)

* Supplier Solution (to include responses to all ITT questions);
* Maintenance Schedule;
* Security measures with regard to the protection of UK Biobank data (including any Personal Data);
* Key Personnel and Key Roles;
* Key Sub-contractors;
* Goods; and
* Software (Specially Written Software, Supplier Software and Third Party Software (including Third Party COTS Software).)
1. schedule

Performance Levels

1. **Definitions**

In this Schedule, the following definitions shall apply:

|  |  |
| --- | --- |
| **“Available”** | has the meaning given in paragraph ‎1.1 of Part II of Annex 1 to Schedule 3 (Performance Levels); |
| **“Archive Availability”** | has the meaning given in paragraph ‎1.2 of Part II of Annex 1 to Schedule 3 (Performance Levels); and |
| **“Maintenance Schedule”** | has the meaning given in clause ‎8.2; |
| **“Performance Monitoring Report”** | has the meaning given in paragraph ‎1.1 of Part B of Schedule 3 (Performance Levels); |
| **“Performance Review Meeting”** | the regular meetings between the Supplier and UK Biobank to manage and review the Supplier's performance under this Agreement; and |
| **“UKB Support Personnel”** | UK Biobank’s Head of Estates and Technical Services, and any other individual nominated by that person. |

**PART A**

**Performance Indicators**

1. **Performance Indicators**
	1. Annex 1 sets out the Key Performance Indicators which the Parties have agreed shall be used to measure the performance of the Services by the Supplier.
	2. The Supplier shall monitor its performance against each Performance Indicator and shall send UK Biobank a report detailing the level of service actually achieved in accordance with Part B.
2. **Permitted Maintenance**

The Supplier shall be allowed to book a maximum amount of time per Service Period as specified in the Specification (in particular sections 7.1.3.3 and 7.1.3.13) for Permitted Maintenance in any one Service Period which shall take place between the hours and on the day specified in the Maintenance Schedule unless otherwise agreed in writing with UK Biobank.

**PART B**

**Performance Monitoring**

1. **Performance Monitoring and Performance Review**
	1. Within five (5) Working Days of the end of each Service Period, the Supplier shall provide a report to the UK Biobank Representative which summarises the performance by the Supplier against each of the Performance Indicators as more particularly described in paragraph ‎1.2 (the “**Performance Monitoring Report**”).

**Performance Monitoring Report**

* 1. The Performance Monitoring Report shall be in such format as agreed between the Parties from time to time and contain, as a minimum, the following information:

**Information in respect of the Service Period just ended**

* + 1. for each Key Performance Indicator, the actual performance achieved over the Service Period, and that achieved over the previous three (3) Service Periods;
		2. a summary of all Performance Failures that occurred during the Service Period;
		3. whether any KPI Failure which occurred during the Service Period fell below the KPI Service Threshold;
		4. which Performance Failures remain outstanding and progress in resolving them;
		5. for any KPI Failures occurring during the Service Period, the cause of the relevant KPI Failure and the action being taken to reduce the likelihood of recurrence;
		6. the status of any outstanding Rectification Plan processes, including:
			1. whether or not a Rectification Plan has been agreed; and
			2. where a Rectification Plan has been agreed, a summary of the Supplier’s progress in implementing that Rectification Plan;
		7. the conduct and performance of any agreed periodic tests that have occurred, such as the annual failover test of the Service Continuity Plan;
		8. relevant particulars of any aspects of the Supplier’s performance which fail to meet the requirements of this Agreement;
		9. such other details as UK Biobank may reasonably require from time to time; and

**Information in respect of previous Service Periods**

* + 1. a rolling total of the number of Performance Failures that have occurred over the past six (6) Service Periods;
		2. the conduct and performance of any agreed periodic tests that have occurred in such Service Period such as the annual failover test of the Service Continuity Plan; and

**Information in respect of the next Quarter**

* + 1. any scheduled downtime for Permitted Maintenance that has been agreed between UK Biobank and the Supplier for the next Quarter.
1. **Performance Records**
	1. The Supplier shall keep appropriate documents and records (including help desk records, staff records, timesheets, training programmes, staff training records, goods received documentation, supplier accreditation records, complaints received etc) in relation to the Services being delivered. Without prejudice to the generality of the foregoing, the Supplier shall maintain accurate records of call histories for a minimum of twelve (12) months and provide prompt access to such records to UK Biobank upon UK Biobank's request. The records and documents of the Supplier shall be available for inspection by UK Biobank and/or its nominee at any time and UK Biobank and/or its nominee may make copies of any such records and documents.
	2. In addition to the requirement in paragraph ‎2.1 to maintain appropriate documents and records, the Supplier shall provide to UK Biobank such supporting documentation as UK Biobank may reasonably require in order to verify the level of the performance of the Supplier for any specified period.
	3. The Supplier shall ensure that the Performance Monitoring Report and any variations or amendments thereto, any reports and summaries produced in accordance with this Schedule and any other document or record reasonably required by UK Biobank are available to UK Biobank on-line and are capable of being printed.
2. **Performance Verification**

The UK Biobank reserves the right to verify Archive Availability and the Supplier’s performance under this Agreement against the Performance Indicators including by sending test processes through the Archive or otherwise.

**ANNEX 1**

**Key Performance Indicators**

**PART I: Key Performance Indicators**

The Key Performance Indicators that shall apply to the Services and the Archive shall be such of the indicators set out below as are set out below:

| **No.** | **Key Performance Indicator Title** | **Requirement** | **Severity Levels** | **Definition** | **Supplier Action Required** |
| --- | --- | --- | --- | --- | --- |
| 1 | Climate | Samples must be stored at a stable temperature of -80°C and humidity of ≤10 ppm | Target Performance Level | Sample storage temperature in every area maintained at -80°C Humidity in every Sample storage area maintained at ≤10 ppm | Performance Monitoring Report |
| KPI Failure 1 (Minor Failure) | Sample storage temperature in any area deviates beyond > -75°C or < -85°C for a period of between 2 and 8 hoursHumidity in any Sample storage area deviates to > 10 ppm for a period of between 2 and 8 hours | SMS and Email notification to UKB Support Personnel within 4 hoursContinuous monitoring by Supplier Personnel during period of temperature deviationPrompt diagnosis and resolution to prevent KPI Failure 2 (Major Failure). The time for resolution shall be such period as is reasonable and proportionate having regard to the nature of the failure and its criticality in maintaining the temperature and humidity regulation of the Archive as set out in the Specification, preserving the Samples and avoiding, as far as reasonably possible, the need to implement (automatically or otherwise) the Service Continuity Plan.Report to be included in next Performance Monitoring Report |
| KPI Failure 2 (Major Failure) | Sample storage temperature in any area deviates beyond > -75°C or < -85°C for a period of > 8 hoursAND/ORReaches a temperature of ≥ -70°C for any periodAND/ORMore than two KPI Failure 1 in three consecutive Service Periods | SMS and Email notification to UKB Support Personnel within 2 hoursContinuous monitoring by Supplier Personnel during period of temperature deviationPrompt diagnosis and resolution to prevent breaching the KPI Service Threshold (Critical Failure). The time for resolution shall be such period as is reasonable and proportionate having regard to the nature of the failure and its criticality in maintaining the temperature and humidity regulation of the Archive as set out in the Specification, preserving the Samples and avoiding, as far as reasonably possible, the need to implement (automatically or otherwise) the Service Continuity Plan.Deemed a Material KPI Failure such that a Rectification Plan must be developed and agreed with UK Biobank under provisions of clause 23 of this Agreement including root cause analysisReport to be included in next Performance Monitoring Report  |
| KPI Service Threshold (Critical Failure) | Sample storage temperature in any area deviates beyond > -70°C for a period of > 8 hoursAND/ORReaches a temperature of ≥ -60°C for any periodAND/ORArchive activates backup liquid-nitrogen coolingAND/ORMore than two KPI Failure 2 in three consecutive Service Periods | SMS and Email notification to UKB Support Personnel and notification to UK Biobank’s Business Continuity Plan Group by ‘WhatsApp’ within 1 hourContinuous monitoring by Supplier Personnel during period of temperature deviationPrompt diagnosis and resolution to prevent damage to Samples. The time for resolution shall be such period as is reasonable and proportionate having regard to the nature of the failure and its criticality in maintaining the temperature and humidity regulation of the Archive as set out in the Specification, preserving the Samples and avoiding, as far as reasonably possible, the need to implement (automatically or otherwise) the Service Continuity Plan.Deemed a Material KPI Failure such that a Rectification Plan must be developed and agreed with UK Biobank under provisions of clause 23 of this Agreement including root cause analysisDeemed an Unacceptable KPI Failure for the purposes of clause 7.3 of this Agreement.Report to be included in next Performance Monitoring Report  |
| 2 | Availability | Archive must be Available for Sample Handling to UKB’s specification for at least 95% of the time (see Part II paragraph ‎1) | Target Performance Level  | Archive Available for Sample Handling for ≥ 95% of time each Service Period, excluding agreed time for Permitted Maintenance | Performance Monitoring Report |
| KPI Failure 1 (Minor Failure) | Archive Available for Sample Handling for ≥ 90% and < 95% of time each Service Period, excluding agreed time for Permitted Maintenance | Diagnosis and resolution of the failure within two Service Periods following the Service Period in which the KPI Failure 1 occurred to prevent KPI Failure 2 (Major Failure)Report to be included in next Performance Monitoring Report |
| KPI Failure 2 (Major Failure) | Archive Available for Sample Handling for ≥ 80% and < 90% of time each Service Period, excluding agreed time for Permitted Maintenance More than two KPI Failure 1 in three consecutive Service Periods  | Diagnosis and resolution of the failure within the Service Period following the Service Period in which the KPI Failure 2 occurred to prevent a breach of the KPI Service Threshold (Critical Failure) Deemed a Material KPI Failure such that a Rectification Plan must be developed and agreed with UK Biobank under provisions of clause 23 of this Agreement including root cause analysisReport to be included in next Performance Monitoring Report  |
| KPI Service Threshold (Critical Failure) | Archive Available for Sample Handling for < 80% of time each Service Period, excluding agreed time for Permitted MaintenanceMore than two KPI Failure 2 in three consecutive Service Periods  | Diagnosis and resolution of the failure within the Service Period following the Service Period in which the KPI Service Threshold was breached to protect access to Samples Prompt diagnosis and resolution. The time for resolution shall be such period as is reasonable and proportionate having regard to the nature of the failure and its criticality in maintaining Sample Handling operations as set out in the Specification, protecting access to the Samples and avoiding, as far as reasonably possible, the need to implement (automatically or otherwise) the Service Continuity Plan.Deemed a Material KPI Failure such that a Rectification Plan must be developed and agreed with UK Biobank under provisions of clause 23 of this Agreement including root cause analysisDeemed an Unacceptable KPI Failure for the purposes of clause 7.3 of this Agreement.Report to be included in next Performance Monitoring Report  |
| 3 | Throughput | Archive must achieve hourly Sample Handling throughput as per Supplier Solution (i.e. Supplier response to Question B4.3 of the ITT against the four Sample Handling Tasks in Table C of the Specification) (see Part II paragraph ‎2) | Target Performance Level  | Archive Sample Handling Throughput measured in Labware movements per hour over the Service Period ≥ 95% of Supplier Solution | Performance Monitoring Report  |
| KPI Failure 1 (Minor) | Archive Sample Handling Throughput measured in Labware movements per hour over the Service Period ≥ 90% and < 95% of Supplier Solution  | Diagnosis and resolution of the failure within two Service Periods following the Service Period in which the KPI Failure 1 occurred to prevent KPI Failure 2 (Major Failure)Report to be included in next Performance Monitoring Report  |
| KPI Failure 2 (Major) | Archive Sample Handling Throughput measured in Labware movements per hour over the Service Period ≥ 80% and < 90% of Supplier SolutionMore than two KPI Failure 1 in the three consecutive Service Periods  | Diagnosis and resolution of the failure within the Service Period following the Service Period in which the KPI Failure 2 occurred to prevent a breach of the KPI Service Threshold (Critical Failure)Deemed a Material KPI Failure such that a Rectification Plan must be developed and agreed with UK Biobank under provisions of clause 23 of this Agreement including root cause analysisReport to be included in next Performance Monitoring Report  |
| KPI Service Threshold (Critical Failure) | Archive Sample Handling Throughput measured in Labware movements per hour over the Service Period < 80% of Supplier SolutionMore than two KPI Failure 2 in three consecutive Service Periods  | Prompt diagnosis and resolution. The time for resolution shall be such period as is reasonable and proportionate having regard to the nature of the failure and its criticality in maintaining Sample Handling operations as set out in the Specification, protecting access to the Samples and avoiding, as far as reasonably possible, the need to implement (automatically or otherwise) the Service Continuity Plan.Deemed a Material KPI Failure such that a Rectification Plan to be developed and agreed with UK Biobank under provisions of clause 23 of this Agreement including root cause analysisDeemed an Unacceptable KPI Failure for the purposes of clause 7.3 of this Agreement.Report to be included in next Performance Monitoring Report   |

**Part II: Definitions**

1. **Archive Availability**
	1. The Archive shall be Available for Sample Handling (and **“Available”** shall be interpreted accordingly) when:
		1. Temperature in every Sample Handling area is maintained at -20°C (+2/-5°C); AND
		2. the Archive (including for the avoidance of doubt Supplier IT System) is available to process all Sample Handling requests input by an Operator into the GUI, or sent programmatically, or triggered automatically.
	2. Archive Availability shall be measured as a percentage of the total time in a Service Period, in accordance with the following formula:

Archive Availability % = 

where:

MP = total number of hours within the relevant Service Period (on a 24 x 7 basis), excluding time agreed with UK Biobank for Permitted Maintenance; and

SD = total number of hours of Archive unavailability for Sample Handling, where the four criteria above are not met, excluding time agreed with UK Biobank for Permitted Maintenance in the relevant Service Period.

1. **Archive Throughput**
	1. Archive Throughput shall be measured against the Supplier’s tendered response to Question B4.3 of the ITT as to the time taken to execute the ‘typical’ daily UK Biobank throughput (as per Section 4.3 of the Specification) as returned by the Supplier and incorporated into the Supplier Solution.
	2. The time stated in the Supplier Solution for the following four tasks (Table C of the Specification) will be converted into the number of Labware movements per hour for each task:
		1. Loading 215 Racks to the Archive;
		2. Internal retrieval and return to storage of 372 Racks;
		3. Picking 6,054 Sample Tubes; and
		4. Unloading 66 Racks from the Archive.
	3. Over each Service Period, the Supplier shall measure, for each of these four Labware movements, the time expended and the number of Labware items moved, and convert these to a number of Labware movements per hour. Measurement should include the effect on time and number of movements of any need for manual operator intervention. The Monthly Performance Report will present these data for the Service Period compared with the time for each from Supplier Solution
	4. KPI performance will be based on combined performance across all four tasks. That is to say: the Target Performance Level consists of:
		1. Racks loaded per hour (actual) ≥ 95% of the Racks loaded per hour (Supplier Solution); **AND**
		2. Internal retrieval and return to storage of Racks per hour (actual) ≥ 95% of the Internal retrieval and return to storage of Racks per hour (Supplier Solution); **AND**
		3. Picking of Sample Tubes per hour (actual) ≥ 95% of Picking of Sample Tubes per hour (Supplier Solution); **AND**
		4. Racks unloaded per hour (actual) ≥ 95% of the Racks unloaded per hour (Supplier Solution).

If any Labware movement per hour metric falls beneath 95% of the corresponding value in the Supplier Solution, it shall represent a KPI Failure 1 (Minor Failure), unless it falls beneath 90%, when it shall represent a KPI Failure 2 (Major Failure). If any Labware movement per hour metric falls beneath 80%, it shall represent a breach of the KPI Service Threshold (Critical Failure). Reflecting UK Biobank’s balance of throughput needs across all four tasks, outperformance relative to the Supplier Solution on one metric will not compensate for underperformance on any other. The terms “Racks”, “Sample Tubes”, “Picking” and “Labware” shall have the meanings given in the Specification.

1. schedule

UK Biobank Responsibilities

1. UK Biobank shall:
2. perform those obligations of UK Biobank which are set out in the Clauses of this Agreement and the Paragraphs of the Schedules (except for Part B of Schedule 2 (Specification and Supplier Solution));
3. use its reasonable endeavours to provide the Supplier with access to appropriate members of the UK Biobank’s staff, as such access is reasonably requested by the Supplier in order for the Supplier to discharge its obligations throughout the Term and the Termination Assistance Period;
4. provide sufficient and suitably qualified staff to fulfil UK Biobank’s roles and duties under this Agreement as defined in the Project Plan;
5. use its reasonable endeavours to provide such documentation, data and/or other information that the Supplier reasonably requests that is necessary to perform its obligations under the terms of this Agreement provided that such documentation, data and/or information is available to UK Biobank and is authorised for release by UK Biobank;
6. procure for the Supplier such agreed access and use of UK Biobank Premises (as a licensee only) and facilities (including relevant IT systems) as is reasonably required for the Supplier to comply with its obligations under this Agreement, such access to be provided during UK Biobank’s normal working hours on each Working Day or as otherwise agreed by UK Biobank (such agreement not to be unreasonably withheld or delayed);
7. be responsible, through its logistics provider, for transfer of Samples from the current archive to the Sample Hall of the new Facility and shall be responsible for loading the Samples into the Archive;
8. keep the Supplier informed from time to time as to progress in relation to development and construction of the UK Biobank Premises where the Archive is to be installed and notify the Supplier as soon as reasonably practicable when UK Biobank becomes aware of any delay in the development of such premises which is likely to constitute a Works Delay;
9. attend (and procure that any Other Suppliers as reasonably required attend) regular meetings with the Supplier as necessary to facilitate the Supplier’s integration of the Archive with the Facility; and
10. invite the Supplier in timely manner to attend UK Biobank’s monthly steering group for the overall project, alongside (where available and appropriate) the Developer, their main construction contractor and Arcadis, UK Biobank’s project management and cost consultants, so as to support timely communication of progress, risk management and successful integration of the Archive and Facility.
11. schedule

Project Plan

1. **INTRODUCTION**
	1. This Schedule:
		1. defines the process for the preparation and implementation of the Outline Project Plan and Detailed Project Plan; and
		2. identifies the Milestones (and associated Deliverables) including the Milestones which trigger payment to the Supplier of the applicable Milestone Payments following the issue of the applicable Milestone Achievement Certificate.
2. **OUTLINE PROJECT PLAN**
	1. The Outline Project Plan is set out in Annex 1.
	2. Subject to the provisions of clause ‎6.4 (UK Biobank Delay and Works Delay Change), all changes to the Outline Project Plan shall be subject to the Change Control Procedure provided that the Supplier shall not attempt to postpone any of the Milestones using the Change Control Procedure or otherwise (except in accordance with clause ‎24 (*UK Biobank Cause*)).
3. **APPROVAL OF THE DETAILED PROJECT PLAN**
	1. The Supplier shall submit a draft of the Detailed Project Plan to UK Biobank for approval within ten (10) Working Days of the Effective Date.
	2. The Supplier shall ensure that the draft Detailed Project Plan:
		1. incorporates all of the Milestones and Milestone Dates set out in the Outline Project Plan;
		2. without prejudice to its obligation to meet all Milestone Dates, is structured and designed to ensure Achievement of the OQ Milestone by the Milestone Date for the OQ Milestone;
		3. includes (as a minimum) the Supplier's proposed timescales in respect of the following for each of the Milestones:
			1. the completion of any design documents;
			2. the completion of the build/configuration phase;
			3. the completion of any Testing to be undertaken in accordance with Schedule 6 (*Testing Procedures*); and
			4. training and roll-out activities; and
		4. clearly outlines all the steps required to implement the Milestones in conformity with UK Biobank Requirements;
		5. clearly outlines the required roles and responsibilities of both Parties, including staffing requirements; and
		6. is produced using a software tool as specified, or agreed by UK Biobank.
	3. Prior to the submission of the draft Detailed Project Plan to UK Biobank in accordance with Paragraph ‎3.1, UK Biobank shall have the right:
		1. to review any documentation produced by the Supplier in relation to the development of the Detailed Project Plan, including:
			1. details of the Supplier's intended approach to the Detailed Project Plan and its development;
			2. copies of any drafts of the Detailed Project Plan produced by the Supplier; and
			3. any other work in progress in relation to the Detailed Project Plan; and
		2. to require the Supplier to include any reasonable changes or provisions in the Detailed Project Plan.
	4. Following receipt of the draft Detailed Project Plan from the Supplier, UK Biobank shall:
		1. review and comment on the draft Detailed Project Plan as soon as reasonably practicable; and
		2. notify the Supplier in writing that it approves or rejects the draft Detailed Project Plan no later than five (5) Working Days after the date on which the draft Detailed Project Plan is first delivered to UK Biobank.
	5. If UK Biobank rejects the draft Detailed Project Plan:
		1. UK Biobank shall inform the Supplier in writing of its reasons for its rejection; and
		2. the Supplier shall then revise the draft Detailed Project Plan (taking reasonable account of UK Biobank's comments) and shall re-submit a revised draft Detailed Project Plan to UK Biobank for UK Biobank's approval within five (5) Working Days of the date of UK Biobank's notice of rejection. The provisions of [Paragraph](http://uk.practicallaw.com/0-202-4551?q=outsourcing#a372155) ‎3.4 and this [Paragraph](http://uk.practicallaw.com/0-202-4551?q=outsourcing#a410835) ‎3.5 shall apply again to any resubmitted draft Detailed Project Plan, provided that either Party may refer any disputed matters for resolution by the Dispute Resolution Procedure at any time.
	6. If UK Biobank approves the draft Detailed Project Plan, it shall replace the Outline Project Plan from the date of UK Biobank’s notice of approval.
4. **UPDATES TO AND MAINTENANCE OF THE DETAILED PROJECT PLAN**
	1. Following the approval of the Detailed Project Plan by UK Biobank:
		1. the Supplier shall submit a revised Detailed Project Plan to UK Biobank every 3 months starting 3 months from the Effective Date;
		2. without prejudice to Paragraph ‎4.1‎4.1.1, UK Biobank shall be entitled to request a revised Detailed Project Plan at any time by giving written notice to the Supplier and the Supplier shall submit a draft revised Detailed Project Plan to UK Biobank within ten (10) Working Days of receiving such a request from UK Biobank (or such longer period as the Parties may agree provided that any failure to agree such longer period shall be referred to the Dispute Resolution Procedure); and
		3. any revised Detailed Project Plan shall (subject to Paragraph ‎4.2) be submitted by the Supplier for approval in accordance with the procedure set out in Paragraph ‎3.
	2. Save for any amendments which are of a type identified and notified by UK Biobank (at UK Biobank's discretion) to the Supplier in writing as not requiring approval, and subject to clause ‎6.4 (UK Biobank Delay and Works Delay Change), any material amendments to the Detailed Project Plan shall be subject to the Change Control Procedure provided that:
		1. any amendments to elements of the Detailed Project Plan which are based on the contents of the Outline Project Plan shall be deemed to be material amendments; and
		2. in no circumstances shall the Supplier be entitled to alter or request an alteration to any Milestone Date except in accordance with clause ‎24 (*UK Biobank Cause*).
	3. Any proposed amendments to the Detailed Project Plan shall not come into force until they have been approved in writing by UK Biobank.

**ANNEX 1**

**OUTLINE PROJECT PLAN**[[4]](#footnote-4)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Milestone**[[5]](#footnote-5) | **Deliverables** | **Milestone Date** | **Milestone Payment associated?** |
| 1. | Effective Date | Agreement signed by both Parties | - | Y |
| 2. | Factory Acceptance Test successfully passed  | Test Certificate in respect of FAT (including all deliverables relating thereto) | [TBA] | Y |
| 3. | Installation of Archive at UK Biobank Premises commences | Written logistical arrangements including delivery schedules and working hours agreed with UK Biobank and Developer, including agreement of Construction Design and Management procedures with the Developer’s main construction contractor before access to the FacilityInstallation Services commence on site at the Facility | Effective Date plus 15 months | N |
| 4. | Site Acceptance Test - Installation Qualification successfully passed  | Test Certificate in respect of SAT – IQ (including all deliverables relating thereto) | Effective Date plus 20 months | Y |
| 5. | Site Acceptance Test - Operational Qualification successfully passed (OQ Milestone)  | Test Certificate in respect of SAT – OQ (including all deliverables relating thereto)Commencement of on-site engineering support as part of Support ServicesAgreed Service Continuity Plan | Effective Date plus 21 months | Y |
| 6. | Site Acceptance Test - Performance Qualification successfully passed (PQ Milestone) | Test Certificate in respect of SAT – PQ (including all deliverables relating thereto) | Effective Date plus 29 months | Y |

1. schedule

Testing Procedures

1. **Definitions**

In this Schedule, the following definitions shall apply:

|  |  |
| --- | --- |
| **“Component”** | any constituent parts of the Archive or Services; |
| **“Material Test Issue”** | a Test Issue of the Severity Level as specified by UK Biobank for the relevant Test Plan; |
| **“Severity Level”** | the level of severity of a Test Issue, criteria for which will be described in the relevant Test Plan]; |
| **“Test Certificate”** | a certificate issued by UK Biobank when a Deliverable has satisfied its relevant Test Success Criteria; |
| **“Test Issue”**  | any variance or non-conformity of a Deliverable from its requirements (such requirements to be set out in the relevant Test Success Criteria); |
| **“Test Issue Threshold”** | in relation to the Tests applicable to readiness of the Archive or any Services or completion of a Milestone, a maximum number of Test Issues of particular Severity Levels as specified by UK Biobank for the Test Plan concerned; |
| **“Test Issue Management Log”** | a log for the recording of Test Issues as described further in Paragraph ‎9; |
| **“Test Plan”** | a plan:* + - * 1. for the Testing of Deliverables; and
				2. setting out other agreed criteria related to the Achievement of Milestones

as described further in paragraph ‎5;  |
| **“Test Reports”** | the reports to be produced by the Supplier setting out the results of Tests; |
| **“Test Specification”** | the specification that sets out how Tests will demonstrate that the Test Success Criteria have been satisfied, as described in more detail in paragraph ‎7;  |
| **“Test Strategy”** | a strategy for the conduct of Testing as described further in paragraph ‎4;  |
| **“Test Success Criteria”** | in relation to a Test, the test success criteria for that Test as referred to in paragraph ‎6;  |
| **“Test Witness”** | any person appointed by UK Biobank pursuant to paragraph 10; |

1. **RISK**
	1. The issue of a Test Certificate, a Milestone Achievement Certificate and/or a conditional Milestone Achievement Certificate shall not:
		1. operate to transfer any risk that the relevant Deliverable or Milestone is complete or will meet and/or satisfy UK Biobank's requirements for that Deliverable or Milestone; or
		2. affect UK Biobank's right subsequently to reject:
			1. all or any element of the Deliverables to which a Test Certificate relates; or
			2. any Milestone to which a Milestone Achievement Certificate relates.
	2. Notwithstanding the issuing of any Milestone Achievement Certificate (including the Milestone Achievement Certificate in respect of UK Biobank to Proceed) or Test Certificate, the Supplier shall remain solely responsible for ensuring that:
		1. the Archive and Supplier Solution as designed, developed and configured is suitable for the delivery of the Services and meets UK Biobank Requirements;
		2. the Archive and Support Services are implemented in accordance with this Agreement; and
		3. each Target Performance Level is met from the Support Services Commencement Date.
2. **Testing Overview**
	1. All Tests conducted by the Supplier shall be conducted in accordance with the Test Strategy, the Test Plans and the Test Specifications and Testing shall include the Factory Acceptance Test and Site Acceptance Tests.
	2. The Supplier shall not submit any Deliverable for Testing:
		1. unless the Supplier is reasonably confident that it will satisfy the relevant Test Success Criteria;
		2. until UK Biobank has issued a Test Certificate in respect of any prior, dependent Deliverable(s) and Test(s); and
		3. until the Parties have agreed the Test Plan and the Test Specification relating to the relevant Deliverable(s) and Test(s).
	3. The Supplier shall submit each Deliverable for Testing or re-Testing by or before the date set out in the Project Plan for the commencement of Testing in respect of the relevant Deliverable.
	4. Prior to the issue of a Test Certificate, UK Biobank shall be entitled to review the relevant Test Reports and the Test Issue Management Log.
	5. Any Disputes between UK Biobank and the Supplier regarding Testing shall be referred to the Dispute Resolution Procedure with each Party using its reasonable endeavours to expedite such process.
3. **Test Strategy**
	1. The Supplier shall develop the Test Strategy in collaboration with UK Biobank as soon as practicable after the Effective Date but in any case, no later than thirty (30) Working Days (or such other period as the Parties may agree in writing) prior to the start date for the Factory Acceptance Tests (as specified in the Project Plan) for approval by UK Biobank.
	2. The Test Strategy shall include:
		1. an overview of how Testing will be conducted in accordance with the Project Plan and in compliance with Annex 1 of this Schedule, including Factory Acceptance Test and Site Acceptance Tests;
		2. the process to be used to capture and record Test results and the categorisation of Test Issues;
		3. the method for mapping the expected Test results to the Test Success Criteria;
		4. the procedure to be followed if a Deliverable fails to satisfy the Test Success Criteria or produces unexpected results, including a procedure for the resolution of Test Issues;
		5. the procedure to be followed to sign off each Test;
		6. the process for the production and maintenance of Test Reports and reporting, including templates for the Test Reports and the Test Issue Management Log, and a sample plan for the resolution of Test Issues;
		7. the names and contact details of UK Biobank's and the Supplier's Test representatives;
		8. a high-level identification of the resources required for Testing, including facilities, infrastructure, tools, personnel and UK Biobank and/or third-party involvement in the conduct of the Tests;
		9. the technical environments required to support the Tests; and
		10. the procedure for managing the configuration of the Test environments.
	3. UK Biobank shall not unreasonably withhold or delay its approval of the Test Strategy provided that the Supplier shall incorporate any reasonable requirements of UK Biobank in the Test Strategy.
4. **Test Plans**
	1. The Supplier shall develop Test Plans and submit these for the approval of UK Biobank as soon as practicable but in any case, no later than twenty (20) Working Days (or such other period as the Parties may agree in the Test Strategy or otherwise agree in writing) prior to the start date for the relevant Testing (as specified in the Project Plan) for approval by UK Biobank.
	2. Each Test Plan shall include as a minimum:
		1. the relevant Test definition and the purpose of the Test, the Milestone to which it relates, the requirements being Tested and, for each Test, definitions of Material Test Issue, Severity Levels and the Test Issue Threshold and the specific Test Success Criteria to be satisfied;
		2. a detailed procedure for the Tests to be carried out, including:
			1. the timetable for the Tests, including start/end dates;
			2. the Testing mechanism;
			3. the respective roles of each of UK Biobank and the Supplier in the Tests;
			4. dates and methods by which UK Biobank can inspect Test results or witness the Tests in order to establish that the Test Success Criteria have been met;
			5. the mechanism for ensuring the quality, completeness and relevance of the Tests;
			6. the format and an example of Test progress reports and the process with which UK Biobank accesses daily Test schedules;
			7. the process which UK Biobank will use to review Test Issues and the Supplier’s progress in resolving these in a timely basis;
			8. the Test schedule;
			9. the re-Test procedure, the timetable and the resources which would be required for re-Testing; and
			10. the process for escalating Test Issues from a re-Test situation to the taking of specific remedial action to resolve the Test Issue

and shall comply with the Test Strategy.

* 1. UK Biobank shall not unreasonably withhold or delay its approval of the Test Plans provided that the Supplier shall incorporate any reasonable requirements of UK Biobank in the Test Plans, including with regard to definitions of Material Test Issue, Severity Levels and the Test Issue Threshold and the specific Test Success Criteria to be satisfied.
1. **Test Success Criteria**

The Test Success Criteria for Tests shall be agreed between the Parties as part of the relevant Test Plan pursuant to paragraph ‎5.

1. **Test Specification**
	1. Following approval of the Test Plan, the Supplier shall develop the Test Specification for the relevant Deliverables as soon as reasonably practicable and in any event at least fifteen (15) Working Days (or such other period as the Parties may agree in the Test Strategy or otherwise agree in writing) prior to the start of the relevant Testing (as specified in the Project Plan) for approval by UK Biobank.
	2. Each Test Specification shall include as a minimum:
		1. the specification of the Test, including its source, scope, volume and management, a request (if applicable) for relevant Test inputs to be provided by UK Biobank and the extent to which it is equivalent to live operational inputs;
		2. the respective roles of each of UK Biobank and the Supplier in the Tests;
		3. a plan to make the resources available for Testing;
		4. Test scripts;
		5. Test pre-requisites and the mechanism for measuring them; and
		6. expected Test results including:
			1. a mechanism to be used to capture and record Test results; and
			2. a method to process the Test results to establish their content

and shall comply with the Test Strategy and relevant Test Plan.

* 1. UK Biobank shall not unreasonably withhold or delay its approval of the Test Specifications provided that the Supplier shall incorporate any reasonable requirements of UK Biobank in the Test Specifications.
1. **Testing**
	1. Before submitting any Deliverables for Testing the Supplier shall subject the relevant Deliverables to its own internal testing and quality control measures to ensure that the relevant Deliverables are ready for Testing.
	2. The Supplier shall manage the progress of Testing in accordance with the relevant Test Plan and shall, except where the relevant Test Plan or Test Specification identifies that UK Biobank are to carry part or all of a Test, carry out the Tests in accordance with the relevant Test Specification. Tests carried out by the Supplier may be witnessed by the Test Witnesses in accordance with paragraph ‎10. Tests carried out by UK Biobank shall be witnessed by the Supplier, except where the Parties have agreed in writing that such attendance is not necessary.
	3. The Supplier shall notify UK Biobank:
		1. in respect of FAT, at least twenty (20) Working Days; and
		2. in respect of SAT, at least ten (10) Working Days

(or, in respect of either, such other period as the Parties may agree in writing) in advance of the date, time and location of the relevant Tests and UK Biobank shall ensure that the Test Witnesses attend the Tests except where UK Biobank has specified in writing that such attendance is not necessary. Where Tests are to be carried out by UK Biobank, UK Biobank shall notify the Supplier at least ten (10) Working Days (or such other period as the Parties may agree in writing) in advance of the date, time and location of the relevant Tests and the Supplier shall ensure that appropriate Supplier Personnel attend the Tests, except where the Parties have agreed in writing that such attendance is not necessary.

* 1. UK Biobank may raise and close Test Issues during the Tests or Test witnessing process.
	2. The Supplier shall provide to UK Biobank in relation to each Test:
		1. a draft Test Report not less than two (2) Working Days (or such other period as the Parties may agree in writing) prior to the date on which the Test is planned to end; and
		2. the final Test Report within five (5) Working Days (or such other period as the Parties may agree in writing) of completion of Testing.
	3. Each Test Report shall provide a full report on the Testing conducted in respect of the relevant Deliverables, including:
		1. an overview of the Testing conducted;
		2. identification of the relevant Test Success Criteria that have been satisfied;
		3. identification of the relevant Test Success Criteria that have not been satisfied together with the Supplier’s explanation of why those criteria have not been met;
		4. the Tests that were not completed together with the Supplier’s explanation of why those Tests were not completed;
		5. the Test Success Criteria that were satisfied, not satisfied or which were not Tested, and any other relevant categories, in each case grouped by Severity Level in accordance with paragraph 9; and
		6. the specification for any hardware and software used throughout Testing and any changes that were applied to that hardware and/or software during Testing.
	4. Where UK Biobank carries out any part of a Test, the Supplier shall consult with UK Biobank in relation to the preparation of the relevant Test Report.
1. **Test issues**
	1. Where a Test Report identifies a Test Issue, the Parties shall agree the classification of the Test Issue using the criteria specified the relevant Test Plan and the Test Issue Management Log maintained by the Supplier shall log Test Issues reflecting the Severity Level allocated to each Test Issue.
	2. The Supplier shall be responsible for maintaining the Test Issue Management Log and for ensuring that its contents accurately represent the current status of each Test Issue at all relevant times. The Supplier shall make the Test Issue Management Log available to UK Biobank upon request.
	3. UK Biobank shall confirm the classification of any Test Issue unresolved at the end of a Test in consultation with the Supplier. If the Parties are unable to agree the classification of any unresolved Test Issue, the Dispute shall be dealt with in accordance with the Dispute Resolution Procedure with the Parties using reasonable endeavours to expedite the time scales entailed.
2. **Test Witnessing**
	1. Where Tests are being conducted primarily by the Supplier, UK Biobank may, in its sole discretion, require the attendance at any Test of one or more Test Witnesses selected by UK Biobank each of whom shall have appropriate skills to fulfil the role of a Test Witness.
	2. The Supplier shall give the Test Witnesses access to any documentation and Testing environments reasonably necessary and requested by the Test Witness to perform their role as a Test Witness in respect of the relevant Tests.
	3. The Test Witnesses:
		1. shall actively review the Test documentation;
		2. will attend and engage in the performance of the Tests on behalf of UK Biobank so as to enable UK Biobank to gain an informed view of whether a Test Issue may be closed or whether the relevant element of the Test should be re-Tested;
		3. except where UK Biobank is carrying out a part of the Test itself as per the relevant Test Plan or Test Specification, shall not be involved in the execution of any Test;
		4. shall be required to verify that the Supplier conducted the Tests in accordance with the Test Success Criteria and the relevant Test Plan and Test Specification;
		5. may produce and deliver their own, independent reports on Testing, which may be used by UK Biobank to assess whether the Tests have been Achieved;
		6. may raise Test Issues on the Test Issue Management Log in respect of any Testing; and
		7. may require the Supplier to demonstrate the modifications made to any defective Deliverable before a Test Issue is closed.
3. **Outcome of Testing**
	1. UK Biobank shall issue a Test Certificate when the Test is successfully passed by the Deliverables satisfying the Test Success Criteria in respect of that Test without any Test Issues.
	2. If the Deliverables (or any relevant part) do not satisfy the Test Success Criteria in respect of any Test, then UK Biobank shall notify the Supplier and:
		1. UK Biobank may issue a Test Certificate conditional upon the remediation of the Test Issues
		2. where the Parties agree that there is sufficient time, in accordance with the Project Plan, UK Biobank may extend the Test Plan by such reasonable period or periods as the Parties may reasonably agree and require the Supplier to rectify the cause of the Test Issue and resubmit the Deliverables (or the relevant part) to Testing; or
		3. where the failure to satisfy the Test Success Criteria results, or is likely to result, in a Delay, then without prejudice to UK Biobank’s other rights and remedies, such failure shall constitute a Notifiable Default for the purposes of clause ‎23.1 (Rectification Plan Process).
4. **Issue OF MILESTONE ACHIEVEMENT certificate**
	1. UK Biobank shall issue a Milestone Achievement Certificate as soon as is reasonably practicable following:
		1. the issuing by UK Biobank of Test Certificates and/or conditional Test Certificates in respect of all Deliverables related to the Milestone concerned; and
		2. performance by the Supplier to the reasonable satisfaction of UK Biobank of any other tasks identified in the Project Plan as associated with the Milestone concerned (which may include the submission of a Deliverable that is not due to be Tested, such as the production of Documentation).
	2. The grant of a Milestone Achievement Certificate shall entitle the Supplier to invoice for the Milestone Payment (if any) relating to that Milestone (when it becomes due) in accordance with Schedule 7 (Charging and Invoicing).
	3. If a Milestone is not Achieved by the date set out in the Project Plan UK Biobank shall promptly issue a report to the Supplier setting out:
		1. the applicable Test Issues; and
		2. any other reasons for its non-Achievement.
	4. If there are Test Issues but these do not exceed the Test Issues Threshold, then provided there are no Material Test Issues, UK Biobank shall issue the Milestone Achievement Certificate.
	5. If there is one or more Material Test Issue(s), UK Biobank may refuse to issue the Milestone Achievement Certificate and, without prejudice to UK Biobank’s other rights and remedies, such failure shall constitute a Notifiable Default for the purposes of clause ‎23.1 (Rectification Plan Process).
	6. If there are Test Issues which exceed the Test Issues Threshold but there are no Material Test Issues, UK Biobank may at its discretion (without waiving any rights in relation to the other options) choose to issue the Milestone Achievement Certificate conditional on the remediation of the Test Issues in accordance with an agreed Rectification Plan provided that any Rectification Plan shall be agreed before the issue of a conditional Milestone Achievement Certificate unless UK Biobank agrees otherwise (in which case the Supplier shall submit a Rectification Plan for approval by UK Biobank within seven (7) Working Days of receipt of UK Biobank’s report pursuant to paragraph ‎12.3).

**ANNEX 1**

**Overview of Factory Acceptance Tests and Site Acceptance Tests**

|  |  |  |  |
| --- | --- | --- | --- |
| **Testing stage** | **Definition** | **Purpose** | **Examples** |
| FAT | Series of tests undertaken at Supplier’s site with UK Biobank present to verify the UK Biobank Requirements have been met before the Archive installation begins. | * Opportunity for UK Biobank to see the Archive and gain assurance
* Opportunity for UK Biobank to identify any issues
* Decide if Archive is ready to ship
 | * Sample Handling area maintains a temperature no warmer than -20°C (+2/-5°C)
* Sample storage area maintains a temperature of -80°C (+/-5°C)
* A Rack can be loaded into the Archive and stored
* A tube can be picked from a Rack
* Physical size to Specification and suitable for installation
* Power consumption and chilled water requirements as per Specification
* Supplier IT System available for GUI to function
 |
| SAT – IQ | Series of tests undertaken at the Facility to confirm the Archive has been installed and configured as specified  | * Ensure the Archive has all the components expected
* Ensure the Archive has been configured to meet the UK Biobank Requirements
 | * Archive is not damaged
* Receipt of calibration certificates for probes (and other installed components)
* Physical size to Specification and installed as per design
* Connected to facility services
* Agreed documentation supplied
* Temperature for Sample Handling area set to -20°C
* Temperature for sample storage area set to -80°C
* Humidity set to <10ppm
* Energy meter is installed
* Temperature probes are installed
* Supplier IT System available for GUI and programmatic access
* Configured to accept ABGene 1.2ml, ABGene 0.65ml and FluidX Racks
* Background consolidation configuration set (rules that define what samples are allowed to be consolidated together)
* Alerts for temperature deviations are configured
 |
| SAT – OQ | Series of tests undertaken at the Facility to confirm the Archive meets the UK Biobank Requirements and is performing within the Supplier operating ranges | * Ensure the Archive is operating as expected
* Check the operating ranges are within Specification
 | * Humidity is <10ppm
* Sample Handling area maintains a temperature no warmer than -20°C (+2/-5°C)
* Sample storage area maintains a temperature of -80°C (+/-5°C)
* Alerts send when a temperature deviation occurs
* ABGene 1.2ml, ABGene 0.65ml, FluidX Racks can be loaded into the Archive
* Archive Inventory correctly updates on Sample Handling
* Supplier IT System available and UK Biobank accounts provisioned, and programmatic integration with UK Biobank Laboratory Systems successful
* Time taken to load a Rack is as per Specification
* Time taken to pick tubes is as per Specification
* Electricity and chilled water consumption of the Archive as per Specification
* Full test of resilience features to failure of electricity and chilled water supply, including activation of backup LN2 cooling and testing of LN2 consumption
* Supplier Service Continuity Plan approved
* Monthly performance reporting demonstrated
* Safety systems are operational
* CCTV and security measures are operational
* Agreed Spares available at UKB facility
* Archive noise generation is within Specification
 |
| SAT - PQ | Series of tests undertaken at the Facility to verify the ongoing performance of the Archive against the UK Biobank Requirements during normal operation | * Ensure UKB requirements can be met on an ongoing basis
* Ensure the components work together to achieve the UKB requirements
 | * Samples can be loaded and picked at the same time
* Initial load of Racks from existing archive is completed
* Sample Handling area maintains a temperature no warmer than -20°C (+2/-5°C) over a 6 month period
* Sample storage area maintains a temperature of -80°C (+/-5°C) over a 6 month period
* Work can be done overnight without UK Biobank intervention
* Tubes can be picked at the rate as per the Specification for a week
* Overall Sample Handling performance in line with the Specification including tube picking, rack loading/unloading and consolidation
* Monthly Performance Monitoring Report established
* Target Performance Levels for KPIs are achieved
* Archive Inventory accurate and synchronised with Laboratory Systems
 |

1. schedule

Charging and Invoicing

**PART A**

**Charging Mechanisms**

1. **Milestone Payments**
	1. On the Achievement of a Milestone the Supplier shall be entitled to invoice UK Biobank for the Milestone Payment associated with that Milestone as set out in the Annex to this Schedule.
	2. Each invoice relating to a Milestone Payment shall be supported by a Milestone Achievement Certificate.
	3. Except where:
		1. there are UK Biobank and Works Delays which exceed in aggregate six (6) months in duration, as provided for in clause ‎6.7 (UK Biobank Delay and Works Delay Change); or
		2. the Condition Precedent is not satisfied by [INSERT DATE 6 MONTHS AFTER DATE OF RECEIPT OF TENDER SUBMISSIONS], as provided in clause ‎4.5 (Condition Precedent)

Milestone Payments are not subject to Indexation.

1. **Service Charges**
	1. Each Service to which a Service Charge relates shall commence on the Achievement of the Milestone set out against that Service in the Annex to this Schedule and shall be for the amount as specified in the Annex to this Schedule, as applicable.
	2. Service Charges shall be invoiced by the Supplier for each Service Period in arrear in accordance with the requirements of Part C.
	3. If the relevant Service:
		1. commences on a day other than the first day of a month; and/or
		2. ends on a day other than the last day of a month,

the Service Charge for the relevant Service Period shall be pro-rated based on the proportion which the number of days in the month for which the Service is provided bears to the total number of days in that month.

* 1. An invoice for a Service Charge shall not be payable by UK Biobank unless all adjustments relating to the Service Charges for the immediately preceding Service Period have been agreed.
	2. Service Charges are subject to Indexation.

**PART B**

**Adjustments to the Charges**

1. **Changes To Charges**

Where the Parties agree that a change to the Services or any obligation of the Supplier under this Agreement requires a change to the Charges, such change shall be developed and agreed by the Parties in accordance with the applicable provisions of this Agreement and on the basis that the Supplier’s profit margin on such Charges shall be no greater than that applying to Charges using the same pricing mechanism as at the Effective Date.

1. **INDEXATION**
	1. Any amounts or sums in this Agreement which are expressed to be “subject to Indexation” shall be adjusted in accordance with the provisions of this paragraph ‎0 to reflect the effects of inflation.
	2. Subject to paragraph ‎2.3, where Indexation applies, the relevant adjustment shall be:
		1. in respect of Service Charges during the Initial Term, applied:
			1. in respect of the Support Services Year 1 Service Charges, on the Support Service Commencement Date (an “adjustment date”); and
			2. in respect of each of the Support Services Year 2 to Support Services Year 5 Service Charges, on the applicable anniversary of the Support Service Commencement Date at the start of the relevant Support Services Year (each such date an “adjustment date”) and

determined by multiplying the relevant amount or sum by the percentage increase in the Consumer Price Index between that published in respect of [October 2023][[6]](#footnote-6) and that last published before the relevant adjustment date;

* + 1. in respect of Service Charges during any Extension Periods, applied:
			1. in respect of the Support Services Year 6 Service Charges, on the anniversary of the Support Service Commencement Date at the start of that year (an “adjustment date”) and determined by multiplying the relevant amount or sum by the percentage increase in the Consumer Price Index between that published in respect of [October 2023][[7]](#footnote-7) and that last published before the relevant adjustment date; and
			2. in respect of subsequent Support Services Years’ Service Charges, on the applicable anniversary of the Support Service Commencement Date at the start of the relevant Support Services Year (each such date an “adjustment date”) and determined by multiplying the Services Charges for the previous Support Services Year by the annual percentage increase in the Consumer Price Index last published before the relevant adjustment date;
		2. in respect of the Notional Average Annual Service Charges, for the purposes of clause ‎22.3.2.2 (Financial and Other Limits), applied on the commencement of each Contract Year, starting from commencement of the second Contract Year (each such date an “adjustment date”) and determined by multiplying the relevant amount or sum by the annual percentage increase in the Consumer Price Index last published before the relevant adjustment date;
		3. [in respect of Milestone Payments where subject to Indexation as provided for in clause ‎4.5 (Condition Precedent), applied on the date that the Condition Precedent is satisfied (an “adjustment date”) and determined by multiplying the relevant amount or sum by the percentage increase in the Consumer Price Index between that published in respect of [INSERT MONTH THAT IS 6 MONTHS AFTER MONTH OF RECEIPT OF TENDER SUBMISSIONS]and that last published before the relevant adjustment date;]
		4. in respect of Charges for Optional Deliverables, applied on the date that UK Biobank gives notice pursuant to clause ‎5.4 (Optional Deliverables) (an “adjustment date”) and determined by multiplying the relevant amount or sum by the percentage increase in the Consumer Price Index between that published in respect of [October 2023][[8]](#footnote-8) and that last published before the relevant adjustment date; and
		5. in respect of Milestone Payments where subject to Indexation as provided for in clause ‎6.7 (UK Biobank Delay and Works Delay Change), applied on the date on which any UK Biobank and Works Delays exceed in aggregate six (6) months in duration (an “adjustment date”) and determined by the following formula:

RMP = MP x ((I x (D/365)+1)

Where:

RMP is the revised Milestone Payment;

MP is the applicable Milestone Payment prior to adjustment;

I is the annual percentage increase in the Consumer Price Index last published before the relevant adjustment date; and

D is the number of days delay in respect of the Milestone Date for the applicable Milestone to which the Milestone Payment relates in excess of six months.

Indexation shall be applied only in respect of any Milestone Payments not yet due at the adjustment date.

* 1. Where in respect of any of the adjustments referred to in paragraph ‎2.2 there is either no change or a percentage decrease in the Consumer Price Index in respect of the applicable period, the relevant amount or sum which is subject to Indexation shall remain unchanged.
	2. Except as set out in this paragraph ‎0, neither the Charges nor any other costs, expenses, fees or charges shall be adjusted to take account of any inflation, change to exchange rate, change to interest rate or any other factor or element which might otherwise increase the cost to the Supplier or Sub-contractors of the performance of their obligations.
1. **OPTIONAL DELIVERABLES**
	1. If UK Biobank gives notice pursuant to clause ‎5.4 (Optional Deliverables) that it requires the Supplier to provide any or all of the Optional Deliverables, the Milestone Payments for the relevant Optional Deliverables shall be calculated by reference to the pricing mechanism and relevant rates and prices for those Optional Deliverables set out in the Annex. The total Milestone Payment shall be split in the same proportions and be payable on the Achievement of equivalent Milestones as those applying to the original Archive and its installation, subject to any adjustment thereto agreed by the Parties in the Optional Deliverables Project Plan.
	2. Any amendment to the Service Charges for the provision of Support Services in respect of Optional Deliverables shall be agreed in accordance with the Change Control Procedure.

**PART C**

**Invoicing and Payment Terms**

1. **Supplier Invoices**
	1. The Supplier shall prepare and provide to UK Biobank for approval of the format a template invoice within ten (10) Working Days of the Effective Date which shall include, as a minimum, the details set out in paragraph ‎1.2 together with such other information as UK Biobank may reasonably require to assess whether the Charges that will be detailed therein are properly payable. If the template invoice is not approved by UK Biobank then the Supplier shall make such amendments as may be reasonably required by UK Biobank. If UK Biobank uses an e-invoicing system then the Supplier shall instead comply with the requirements of that system.
	2. The Supplier shall ensure that each invoice is submitted in the correct format for UK Biobank’s e-invoicing system, or that it contains the following information:
		1. the date of the invoice;
		2. a unique invoice number;
		3. the Service Period or other period(s) to which the relevant Charge(s) relate;
		4. the correct reference for this Agreement;
		5. the reference number of the purchase order to which it relates;
		6. the dates between which the Services subject of each of the Charges detailed on the invoice were performed;
		7. the pricing mechanism used to calculate the Charges (Fixed Price, Time and Materials etc);
		8. any payments due in respect of Achievement of a Milestone, including the Milestone Achievement Certificate number for each relevant Milestone;
		9. the total Charges gross and net of any applicable deductions and, separately, any VAT or other sales tax payable in respect of each of the same;
		10. details of deductions that shall apply to the Charges detailed on the invoice;
		11. the sum that the Supplier considers to be or have been due at the relevant payment due date and the basis on which that sum has been calculated, whether or not that sum is zero;
		12. reference to any reports required by UK Biobank in respect of the Services to which the Charges detailed on the invoice relate (or in the case of reports issued by the Supplier for validation by UK Biobank, then to any such reports as are validated by UK Biobank in respect of the Services);
		13. a contact name and telephone number of a responsible person in the Supplier's finance department in the event of administrative queries; and
		14. the banking details for payment to the Supplier via electronic transfer of funds (i.e. name and address of bank, sort code, account name and number).
	3. The Supplier shall issue a valid VAT invoice to UK Biobank in accordance with the requirements of Part A. The Supplier shall submit to UK Biobank an invoice setting out the Charges that the Supplier considers to be or have been due at the relevant payment due date and the basis on which that sum has been calculated, whether or not that sum is zero. .
	4. Sufficient information in writing to enable UK Biobank reasonably to assess whether the Charges and other sums due from UK Biobank detailed in the information are properly payable, including copies of any applicable Milestone Achievement Certificates or receipts, is required for each invoice.
	5. The Supplier shall submit all invoices via email to Purchasing@ukbiobank.ac.uk.
	6. All Supplier invoices shall be expressed in sterling or such other currency as shall be permitted by UK Biobank in writing.
	7. UK Biobank shall regard an invoice as valid only if it complies with the provisions of this Part C. Where any invoice does not conform to UK Biobank's requirements set out in this Part C, UK Biobank shall return the disputed invoice to the Supplier and the Supplier shall promptly issue a replacement invoice which shall comply with such requirements.
2. **Payment Terms**
	1. The due date:
		1. for each Milestone Payment will be the date of Achievement of the Milestone;
		2. for each payment of the Service Charges will be the last Working Day of each month,

or in each case, if later, the date when UK Biobank receives an invoice submitted by the Supplier and which complies with the requirements of paragraph 1. Any invoice that is incomplete or submitted prematurely will be resubmitted by the Supplier to comply with this Schedule 7.

* 1. The final date for payment will be thirty (30) days after the due date for the relevant payment (“**Final Date for Payment**”).
	2. No later than five (5) Working Days after each due date UK Biobank will consider and verify each invoice properly submitted to it in compliance with paragraph 1, and will notify the Supplier of the sum that UK Biobank considers to have been payable at the relevant due date and the basis on which the sum is calculated. If that is for less than the invoiced amount, within one (1) day of receipt of UK Biobank’s notice the Supplier will issue a valid VAT invoice for the amount stated in UK Biobank’s notice.
	3. Subject to paragraph ‎‎2.5, UK Biobank shall pay the Supplier the sum referred to in UK Biobank’s notice under paragraph 2.3 (or if UK Biobank has not served a notice under paragraph 2.3, the sum referred to in the Supplier’s invoice) (“**Notified Sum**”) on or before the Final Date for Payment of each payment.
	4. Not less than five (5) days before the Final Date for Payment (“**Prescribed Period**”), UK Biobank may give the Supplier a Pay Less Notice and UK Biobank will pay the sum stated in the Pay Less Notice. Within one (1) day of receipt of a Pay Less Notice the Supplier will issue a valid VAT invoice for the amount stated in the Pay Less Notice to UK Biobank.
	5. Notwithstanding paragraph 2.4 and paragraph 2.5, if the Supplier is subject to an Insolvency Event after the Prescribed Period, UK Biobank will not be required to pay the Supplier the Notified Sum on or before the Final Date for Payment.
	6. Unless the Parties agree otherwise in writing, all Supplier invoices shall be paid in sterling by electronic transfer of funds to the bank account that the Supplier has specified on its invoice.

**ANNEX**

[*To be populated from successful bidder’s pricing response*]

1. schedule

Exit Management

1. **Definitions**

In this Schedule, the following definitions shall apply:

|  |  |
| --- | --- |
| **“Exclusive Assets”** | those Assets used by the Supplier which are used exclusively in the provision of the Services, which shall include all Spares; |
| **“Exit Information”** | has the meaning given in paragraph ‎3.1 of Schedule 8 (Exit Management); |
| **“Exit Manager”** | the person appointed by each Party pursuant to paragraph ‎0 of Schedule 8 (Exit Management) for managing the Parties’ respective obligations under Schedule 8 (Exit Management); |
| **“Net Book Value”** | the net book value of the relevant Asset(s) calculated in accordance with the depreciation policy of the Supplier set out in the letter in the agreed form from the Supplier to UK Biobank of the same date as this Agreement; |
| **“Non‑Exclusive Assets”** | those Assets (if any) which are used by the Supplier in connection with the Services but which are also used by the Supplier for other purposes of material value; |
| **“Termination Assistance Period”** | has the meaning given in paragraph ‎5.1.3 of Schedule 8 (Exit Management); |
| **“Transferable Assets”** | those of the Exclusive Assets which are capable of legal transfer to UK Biobank, which shall include all Spares; |
| **“Transferable Contracts”** | the Sub-contracts, licences for Supplier Software, licences for Third Party Software or other agreements which are necessary to enable UK Biobank or any Replacement Supplier to perform the Services or the Replacement Services, including in relation to licences all relevant Documentation; |
| **“Transferring Contracts”** | has the meaning given in paragraph ‎6.2.3 of Schedule 8 (Exit Management). |

1. **EXIT MANAGER**

Each Party shall appoint a person for the purposes of managing the Parties' respective obligations under this Schedule and provide written notification of such appointment to the other Party within three (3) months of the Effective Date. The Supplier's Exit Manager shall be responsible for ensuring that the Supplier and its employees, agents and Sub-contractors comply with this Schedule. The Supplier shall ensure that its Exit Manager has the requisite authority to arrange and procure any resources of the Supplier as are reasonably necessary to enable the Supplier to comply with the requirements set out in this Schedule. The Parties' Exit Managers will liaise with one another in relation to all issues relevant to the termination of this Agreement and all matters connected with this Schedule and each Party's compliance with it.

1. **Obligations to assist on re-tendering of services**
	1. On reasonable notice at any point during the Term, the Supplier shall provide to UK Biobank and/or its potential Replacement Suppliers (subject to the potential Replacement Suppliers entering into reasonable written confidentiality undertakings), the following material and information in order to facilitate the preparation by UK Biobank of any invitation to tender and/or to facilitate any potential Replacement Suppliers undertaking due diligence:
		1. details of the Service(s);
		2. the information and artefacts referred to in paragraph 7.1.5 of the Specification;
		3. an inventory of UK Biobank Data in the Supplier's possession or control;
		4. to the extent permitted by applicable Law, all information relating to Services Employees required to be provided by the Supplier under this Agreement; and
		5. such other material and information as UK Biobank shall reasonably require,

(together, the “**Exit Information**”).

* 1. The Supplier acknowledges that UK Biobank may disclose the Supplier's Confidential Information to an actual or prospective Replacement Supplier or any third party whom UK Biobank is considering engaging to the extent that such disclosure is necessary in connection with such engagement (except that UK Biobank may not under this paragraph ‎3.2 disclose any Supplier’s Confidential Information which is information relating to the Supplier’s or its Sub-contractors’ prices or costs).
	2. The Exit Information shall be accurate and complete in all material respects and the level of detail to be provided by the Supplier shall be such as would be reasonably necessary to enable a third party to:
		1. prepare an informed offer for those Services; and
		2. not be disadvantaged in any subsequent procurement process compared to the Supplier (if the Supplier is invited to participate).
1. **Exit plan**
	1. The Supplier shall, no later than twenty (20) Working Days after the Effective Date, deliver to UK Biobank an Exit Plan which:
		1. sets out the Supplier's proposed methodology for achieving an orderly transition of the Services from the Supplier to UK Biobank and/or its Replacement Supplier on the expiry or termination of this Agreement;
		2. ensures the preservation and continued safety of the Samples;
		3. complies with the requirements set out in paragraph ‎4.3; and
		4. is otherwise reasonably satisfactory to UK Biobank.
	2. The Parties shall use reasonable endeavours to agree the contents of the Exit Plan. If the Parties are unable to agree the contents of the Exit Plan within twenty (20) Working Days of its submission, then such Dispute shall be resolved in accordance with the Dispute Resolution Procedure.
	3. The Exit Plan shall set out, as a minimum:
		1. the mechanism for dealing with exit, including transfer and cessation processes and provision for the supply by the Supplier of all such reasonable assistance as UK Biobank shall require to enable UK Biobank or its sub-contractors to provide the Services;
		2. how the Services will transfer to the Replacement Supplier and/or UK Biobank, including details of the processes, documentation, data transfer, systems migration, security and the segregation of UK Biobank's technology components from any technology components operated by the Supplier or its Sub-contractors (where applicable);
		3. how the Samples will be preserved and their continued safety maintained during any Services transfer or transfer to a replacement Archive;
		4. the scope of the Termination Services that may be required for the benefit of UK Biobank;
		5. a timetable and critical issues for providing the Termination Services; and
		6. any charges that would be payable for the provision of the Termination Services (which must be reasonable and proportionate and calculated in accordance with the principles set out in paragraph ‎1 of Part B of Schedule 7 (Charges and Invoicing)), together with a capped estimate of such charges and subject always to paragraph ‎7 below.
	4. The Supplier shall review and (if appropriate) update the Exit Plan on a basis consistent with the principles set out in this Schedule in the first month of each Contract Year (commencing with the second Contract Year) to reflect any changes in the Services that have occurred since the Exit Plan was last agreed. Following such update the Supplier shall submit the revised Exit Plan to UK Biobank for review and approval. If the Parties are unable to agree the contents of the revised Exit Plan within that twenty (20) Working Day period, such dispute shall be resolved in accordance with the Dispute Resolution Procedure.
2. **Termination Services**

**Notification of Requirements for Termination Services**

* 1. UK Biobank shall be entitled to require the provision of Termination Services at any time during the Term by giving written notice to the Supplier (a “**Termination Assistance Notice**”) at least three (3) months prior to the date of termination or expiry of this Agreement or as soon as reasonably practicable (but in any event, not later than one (1) month) following the service by either Party of a Termination Notice. The Termination Assistance Notice shall specify:
		1. the date from which Termination Services are required;
		2. the nature of the Termination Services required; and
		3. the period during which it is anticipated that Termination Services will be required, which shall continue no longer than twelve (12) months after the date that the Supplier ceases to provide the Services (“**Termination Assistance Period**”).
	2. UK Biobank shall have an option to extend the period of assistance beyond the period specified in the Termination Assistance Notice provided that such extension shall not extend for more than eighteen (18) months after the date the Supplier ceases to provide the Services and provided that it shall notify the Supplier to such effect no later than twenty (20) Working Days prior to the date on which the provision of Termination Services are otherwise due to expire. UK Biobank shall have the right to terminate its requirement for Termination Services by serving not less than twenty (20) Working Days' written notice upon the Supplier to such effect.

**Termination Assistance Period**

* 1. Throughout the Termination Assistance Period, or such shorter period as UK Biobank may require, the Supplier shall:
		1. continue to provide the Services (as applicable) and, if required by UK Biobank pursuant to paragraph ‎5.1, provide the Termination Services;
		2. in addition to providing the Services and the Termination Services, provide to UK Biobank any reasonable assistance requested by UK Biobank to allow the Services to continue without interruption following the termination or expiry of this Agreement and to facilitate the orderly transfer of responsibility for and conduct of the Services to UK Biobank and/or its Replacement Supplier;
		3. use all reasonable endeavours to reallocate resources to provide such assistance as is referred to in paragraph ‎5.3.2 without additional costs to UK Biobank; and
		4. provide the Services and the Termination Services at no detriment to the Target Performance Levels.
	2. Without prejudice to the Supplier’s obligations under paragraph ‎5.3.3, if it is not possible for the Supplier to reallocate resources to provide such assistance as is referred to in paragraph ‎5.3.2 without additional costs to UK Biobank, any additional costs incurred by the Supplier in providing such reasonable assistance which is not already in the scope of the Termination Services or the Exit Plan shall be agreed between the Parties in accordance the principles set out paragraph ‎4.3.6.

**Termination Obligations**

* 1. The Supplier shall comply with all of its obligations contained in the Exit Plan.
	2. Upon termination or expiry (as the case may be) or at the end of the Termination Assistance Period (or earlier if this does not adversely affect the Supplier's performance of the Services and the Termination Services and its compliance with the other provisions of this Schedule), the Supplier shall:
		1. cease to use UK Biobank Data;
		2. provide UK Biobank and/or the Replacement Supplier with a complete and uncorrupted version of UK Biobank Data in electronic form (or such other format as reasonably required by UK Biobank);
		3. erase from any computers, storage devices and storage media that are to be retained by the Supplier after the end of the Termination Assistance Period all UK Biobank Data and promptly certify to UK Biobank that it has completed such deletion;
		4. return to UK Biobank such of the following as is in the Supplier's possession or control:
			1. all copies of UK Biobank Software and any other software licensed by UK Biobank to the Supplier under this Agreement;
			2. all materials created by the Supplier under this Agreement in which the IPRs are owned by UK Biobank;
			3. any parts of the IT Environment and any other equipment which belongs to UK Biobank; and
			4. any items that have been on-charged to UK Biobank, such as consumables; and
		5. vacate any UK Biobank Premises.
	3. Upon termination or expiry (as the case may be) or at the end of the Termination Assistance Period (or earlier if this does not adversely affect the Supplier's performance of the Services and the Termination Services and its compliance with the other provisions of this Schedule), each Party shall return to the other Party (or if requested, destroy or delete) all Confidential Information of the other Party and shall certify that it does not retain the other Party's Confidential Information save to the extent (and for the limited period) that such information needs to be retained by the Party in question for the purposes of providing or receiving any Services or Termination Services or for statutory compliance purposes.
	4. Except where this Agreement provides otherwise, all licences, leases and authorisations granted by UK Biobank to the Supplier in relation to the Services shall be terminated with effect from the end of the Termination Assistance Period.
1. **Assets, sub-contracts and software**
	1. Following notice of termination of this Agreement and during the Termination Assistance Period, the Supplier shall not, without UK Biobank's prior written consent:
		1. terminate, enter into or vary any Sub-contract except to the extent that such change does not or will not affect the provision of Services or the Charges;
		2. (subject to normal maintenance requirements) make material modifications to, or dispose of, any existing Assets or acquire any new Assets; or
		3. terminate, enter into or vary any licence for software in connection with the Archive or Services.
	2. UK Biobank shall provide written notice to the Supplier setting out:
		1. which, if any, of the Transferable Assets UK Biobank requires to be transferred to UK Biobank and/or the Replacement Supplier (“**Transferring Assets**”);
		2. which, if any, of:
			1. the Exclusive Assets that are not Transferable Assets; and
			2. the Non-Exclusive Assets,

UK Biobank and/or the Replacement Supplier requires the continued use of; and

* + 1. which, if any, of Transferable Contracts UK Biobank requires to be assigned or novated to UK Biobank and/or the Replacement Supplier (the “**Transferring Contracts**”),

in order for UK Biobank and/or its Replacement Supplier to receive and / or provide the Services or Replacement Services from the expiry of the Termination Assistance Period, or as UK Biobank may otherwise require. Where requested by UK Biobank and/or its Replacement Supplier, the Supplier shall provide all reasonable assistance to UK Biobank and/or its Replacement Supplier to enable it to determine which Transferable Assets and Transferable Contracts UK Biobank and/or its Replacement Supplier requires to provide the Services or Replacement Services.

* 1. With effect from the expiry of the Termination Assistance Period, the Supplier shall sell the Transferring Assets to UK Biobank and/or its nominated Replacement Supplier for a consideration equal to their Net Book Value, except where:
		1. a Termination Payment is payable by UK Biobank to the Supplier, in which case, payment for such Assets shall be included within the Termination Payment; or
		2. the cost of the Transferring Asset has been partially or fully paid for through the Charges at the time of expiry or termination of this Agreement, in which case UK Biobank shall pay the Supplier the Net Book Value of the Transferring Asset less the amount already paid through the Charges; or
		3. in respect of Spares which shall be transferred at zero cost.
	2. Risk in the Transferring Assets shall pass to UK Biobank or the Replacement Supplier (as appropriate) at the end of the Termination Assistance Period and title to the Transferring Assets shall pass to UK Biobank or the Replacement Supplier (as appropriate) on payment for the same.
	3. Where the Supplier is notified in accordance with paragraph ‎6.2.2 that UK Biobank and/or the Replacement Supplier requires continued use of any Exclusive Assets that are not Transferable Assets or any Non-Exclusive Assets, the Supplier shall as soon as reasonably practicable:
		1. procure a non-exclusive, perpetual, royalty-free licence (or licence on such other terms that have been agreed by UK Biobank) for UK Biobank and/or the Replacement Supplier to use such assets (with a right of sub-licence or assignment on the same terms); or failing which
		2. procure a suitable alternative to such assets and UK Biobank or the Replacement Supplier shall bear the reasonable proven costs of procuring the same.
	4. The Supplier shall as soon as reasonably practicable assign or procure the novation to UK Biobank and/or the Replacement Supplier of the Transferring Contracts. The Supplier shall execute such documents and provide such other assistance as UK Biobank reasonably requires to effect this novation or assignment.
	5. UK Biobank shall:
		1. accept assignments from the Supplier or join with the Supplier in procuring a novation of each Transferring Contract; and
		2. once a Transferring Contract is novated or assigned to UK Biobank and/or the Replacement Supplier, carry out, perform and discharge all the obligations and liabilities created by or arising under that Transferring Contract and exercise its rights arising under that Transferring Contract, or as applicable, procure that the Replacement Supplier does the same.
	6. The Supplier shall hold any Transferring Contracts on trust for UK Biobank until such time as the transfer of the relevant Transferring Contract to UK Biobank and/or the Replacement Supplier has been effected.
	7. The Supplier shall indemnify UK Biobank (and/or the Replacement Supplier, as applicable) against each loss, liability and cost arising out of any claims made by a counterparty to a Transferring Contract which is assigned or novated to UK Biobank (and/or Replacement Supplier) pursuant to paragraph ‎6.6 in relation to any matters arising prior to the date of assignment or novation of such Sub-contract.
1. **Charges**
	1. During the Termination Assistance Period (or for such shorter period as UK Biobank may require the Supplier to provide the Termination Services), UK Biobank shall pay the Charges to the Supplier in respect of the Termination Services in accordance with the rates set out in the Exit Plan (but shall not be required to pay costs in excess of the estimate set out in the Exit Plan without the prior agreement of UK Biobank). If the scope or timing of the Termination Services is changed and this results in a change to the costs of such Termination Services, the estimate may be varied by agreement between the Parties in accordance the principles set out paragraph ‎4.3.6.
	2. Except as otherwise expressly specified in this Agreement, the Supplier shall not make any charges for the services provided by the Supplier pursuant to, and UK Biobank shall not be obliged to pay for costs incurred by the Supplier in relation to its compliance with, this Schedule including the preparation and implementation of the Exit Plan and any activities mutually agreed between the Parties to carry on after the expiry of the Termination Assistance Period.
2. schedule

Processing Personal Data

1. The Parties acknowledge that for the purposes of the Data Protection Laws, the nature of the activity carried out by each of them in relation to their respective obligations under this Agreement will determine the status of each Party under the Data Protection Laws. A Party may act as:
	1. “**Controller**” (where the other Party acts as the “**Processor**”); or
	2. “**Processor**” (where the other Party acts as the “**Controller**”)

and the Parties shall set out in the Annex to this Schedule 9 (Processing Personal Data) which scenario or scenarios are intended to apply under this Agreement.

1. Where a Party is a Processor, the only processing that it is authorised to do is listed in Schedule 9 (Processing Personal Data) by the Controller and may not be determined by the Processor. The term “processing” and any associated terms are to be read in accordance with Article 4 of the UK GDPR and EU GDPR (as applicable).
2. The Processor shall notify the Controller immediately if it considers that any of the Controller’s instructions infringe the Data Protection Laws.
3. The Processor shall provide all reasonable assistance to the Controller in the preparation of any Data Protection Impact Assessment prior to commencing any processing. Such assistance may, at the discretion of the Controller, include:
	1. a systematic description of the envisaged processing operations and the purpose of the processing;
	2. an assessment of the necessity and proportionality of the processing operations in relation to the Services;
	3. an assessment of the risks to the rights and freedoms of Data Subjects; and
	4. the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.
4. The Processor shall, in relation to any Personal Data processed in connection with its obligations under this Agreement:
	1. process that Personal Data only in accordance with Schedule 9 (Processing Personal Data), unless the Processor is required to do otherwise by Law. If it is so required the Processor shall promptly notify UK Biobank before processing the Personal Data unless prohibited by Law;
	2. ensure that it has in place Protective Measures, including in the case of the Supplier the measures set out in clause ‎‎18 (UK Biobank Data and Security Requirements and Service Continuity), which the Controller may reasonably reject (but failure to reject shall not amount to approval by the Controller of the adequacy of the Protective Measures) having taken account of the:
		1. nature of the data to be protected;
		2. harm that might result from a Data Loss Event;
		3. state of technological development; and
		4. cost of implementing any measures;
	3. ensure that:
		1. the Processor Personnel do not process Personal Data except in accordance with this Agreement (and in particular the Annex to this Schedule 9 (Processing Personal Data));
		2. it takes all reasonable steps to ensure the reliability and integrity of any Processor Personnel who have access to the Personal Data and ensure that they:
			1. are aware of and comply with the Processor’s duties under this Schedule 9 (Processing Personal Data) and clauses ‎‎18 (UK Biobank Data and Security Requirements And Service Continuity Plans) and ‎‎19 (Confidentiality) and;
			2. are subject to appropriate confidentiality undertakings with the Processor or any Sub-processor;
			3. are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third party unless directed in writing to do so by the Controller or as otherwise permitted by this Agreement; and
			4. have undergone adequate training in the use, care, protection and handling of Personal Data;
	4. not transfer such Personal Data outside of the UK and/or the EEA unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:
		1. the destination country has been recognised as adequate by the UK government in accordance with Article 45 of the UK GDPR (or section 74A of DPA 2018) and/or the transfer is in accordance with Article 45 of the EU GDPR (where applicable); or
		2. the Controller and/or the Processor has provided appropriate safeguards in relation to the transfer (whether in accordance with Article 46 of the UK GDPR or DPA 2018 Section 75 and/or Article 46 of the EU GDPR (where applicable)) as determined by the Controller which could include relevant parties entering into:
			1. where the transfer is subject to UK GDPR:
5. the UK International Data Transfer Agreement as published by the Information Commissioner’s Office under section 119A(1) of the DPA 2018 from time to time; or
6. the European Commission’s Standard Contractual Clauses per decision 2021/914/EU or such updated version of such Standard Contractual Clauses as are published by the European Commission from time to time (“EU SCCs”), together with the UK International Data Transfer Agreement Addendum to the EU SCCs (the “Addendum”) as published by the Information Commissioner's Office from time to time; and/or
	* + 1. where the transfer is subject to EU GDPR, the EU SCCs, as well as any additional measures determined by the Controller being implemented by the importing party;
		1. the Data Subject has enforceable rights and effective legal remedies;
		2. the Processor complies with its obligations under the Data Protection Laws 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
		3. the Processor complies with any reasonable instructions notified to it in advance by the Controller with respect to the processing of the Personal Data; and
	1. at the written direction of the Controller, delete or return Personal Data (and any copies of it) to the Controller on termination of the Agreement unless the Processor is required by Law to retain the Personal Data.
7. Subject to paragraph ‎7, the Processor shall notify the Controller immediately if it:
	1. receives a Data Subject Request (or purported Data Subject Request);
	2. receives a request to rectify, block or erase any Personal Data;
	3. receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Laws;
	4. receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data processed under this Agreement;
	5. receives a request from any third Party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law; or
	6. becomes aware of a Data Loss Event.
8. The Processor’s obligation to notify under paragraph ‎‎6 shall include the provision of further information to the Controller in phases, as details become available.
9. Taking into account the nature of the processing, the Processor shall provide the Controller with reasonable assistance in relation to either Party's obligations under Data Protection Laws and any complaint, communication or request made under paragraph ‎‎6 (and insofar as possible within the timescales reasonably required by the Controller) including by promptly providing:
	1. the Controller with full details and copies of the complaint, communication or request;
	2. such assistance as is reasonably requested by the Controller to enable it to comply with a Data Subject Request within the relevant timescales set out in the Data Protection Laws;
	3. the Controller, at its request, with any Personal Data it holds in relation to a Data Subject;
	4. assistance as requested by the Controller following any Data Loss Event; and/or
	5. assistance as requested by the Controller with respect to any request from the Information Commissioner’s Office or any other regulatory authority, or any consultation by the Controller with the Information Commissioner's Office or any other regulatory authority.
10. The Processor shall maintain complete and accurate records and information to demonstrate its compliance with this Schedule 9 (Processing Personal Data). This requirement does not apply where the Processor employs fewer than 250 staff, unless:
	1. the Controller determines that the processing is not occasional;
	2. the Controller determines the processing 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
	3. the Controller determines that the processing is likely to result in a risk to the rights and freedoms of Data Subjects.
11. The Processor shall allow for audits of its Data Processing activity by the Controller or the Controller’s designated auditor.
12. The Parties shall designate a Data Protection Officer if required by the Data Protection Laws.
13. Before allowing any Sub-processor to process any Personal Data related to this Agreement, the Processor must:
	1. notify the Controller in writing of the intended Sub-processor and processing;
	2. obtain the written consent of the Controller;
	3. enter into a written agreement with the Sub-processor which gives effect to the terms set out in this Schedule 9 (Processing Personal Data) such that they apply to the Sub-processor; and
	4. provide the Controller with such information regarding the Sub-processor as the Controller may reasonably require.
14. The Processor shall remain fully liable for all acts or omissions of any of its Sub-processors.
15. The Parties agree to take account of any guidance issued by the Information Commissioner’s Office or any other regulatory authority. UK Biobank may on not less than thirty (30) Working Days’ notice to the Supplier amend this Agreement to ensure that it complies with any guidance issued by the Information Commissioner’s Office or any other regulatory authority.
16. **ANNEX**
17. This Annex shall be completed by the Controller, who may take account of the view of the Processor, however the final decision as to the content of this Schedule shall be with UK Biobank at its absolute discretion.
	1. The contact details of the UK Biobank’s Data Protection Officer are: [*Insert Contact details*]
	2. The contact details of the Supplier’s Data Protection Officer are: [*Insert Contact details*]
	3. The Processor shall comply with any further written instructions with respect to processing by the Controller.
	4. Any such further instructions shall be incorporated into this Schedule.

|  |  |
| --- | --- |
| 1. **Description**
 | 1. Details
 |
| 1. **Identity of Controller for each Category of Personal Data**
 | 1. UK Biobank is Controller and the Supplier is Processor
2. The Parties acknowledge that in accordance with this Schedule 9 (Processing Personal Data) and for the purposes of the Data Protection Legislation, UK Biobank is the Controller and the Supplier is the Processor of the following Personal Data:
3. *[Insert the scope of Personal Data for which the purposes and means of the processing by the Supplier is determined by UK Biobank]*
4. The Supplier is Controller and UK Biobank is Processor
5. The Parties acknowledge that for the purposes of the Data Protection Legislation, the Supplier is the Controller and UK Biobank is the Processor in accordance with this Schedule 9 (Processing Personal Data) of the following Personal Data:
6. *[Insert the scope of Personal Data for which the purposes and means of the processing by UK Biobank is determined by the Supplier]*
 |
| 1. **Duration of the processing**
 | 1. *[Clearly set out the duration of the processing including dates]*
 |
| 1. **Nature and purposes of the processing**
 | 1. *[Please be as specific as possible, but make sure that you cover all intended purposes.*
2. *The nature of the processing means any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of data (whether or not by automated means) etc.*
3. *The purpose might include: employment processing, statutory obligation, recruitment assessment etc]*
 |
| 1. **Type of Personal Data**
 | 1. *[Examples here include: name, address, date of birth, NI number, telephone number, pay, images, biometric data etc]*
 |
| 1. **Categories of Data Subject**
 | 1. *[Examples include: Staff (including volunteers, agents, and temporary workers), customers/ clients, suppliers, patients, students / pupils, members of the public, users of a particular website etc]*
 |
| 1. **Plan for return and destruction of the data once the processing is complete**
2. **UNLESS requirement under law to preserve that type of data**
 | 1. *[Describe how long the data will be retained for, how it be returned or destroyed]*
 |
| 1. **Locations at which the Supplier and/or its Sub-contractors process Personal Data under this Contract**
 | 1. *[Clearly identify each location]*
 |
| 1. **Protective Measures that the Supplier and, where applicable, its Sub-contractors have implemented to protect Personal Data processed under this Contract Agreement against a breach of security (insofar as that breach of security relates to data) or a Personal Data Breach**
 | 1. *[Please be as specific as possible]*
 |

1.
2. schedule

Staff Transfer

1. **DEFINITIONS**
	1. In this Schedule, the following definitions shall apply:

|  |  |
| --- | --- |
| 1. **“Relevant Transfer”**
 | 1. as defined in paragraph ‎2;
 |
| 1. **“Service Transfer”**
 | 1. as defined in paragraph ‎2;
 |
| 1. **“Service Transfer Date”**
 | 1. the date of a Service Transfer or, if more than one, the date of the relevant Service Transfer as the context requires;
 |
| 1. **“Staffing Information”**
 | 1. in relation to all persons identified on the Supplier’s Provisional Supplier Personnel List or Supplier’s Final Supplier Personnel List, as the case may be, such information as UK Biobank may reasonably request (subject to all applicable provisions of Data Protection Law), but including in an anonymised format:
	1. their ages, dates of commencement of employment or engagement and gender and place of work;
	2. details of whether they are employed, self‑employed contractors or consultants, agency workers or otherwise;
	3. the identity of the employer or relevant contracting party;
	4. their relevant contractual notice periods and any other terms relating to termination of employment, including redundancy procedures, and redundancy payments;
	5. their wages, salaries and profit sharing arrangements as applicable;
	6. details of other employment‑related benefits, including (without limitation) medical insurance, life assurance, pension or other retirement benefit schemes, share option schemes and company car schedules applicable to them;
	7. any outstanding or potential contractual, statutory or other liabilities in respect of such individuals (including in respect of personal injury claims);
	8. details of any such individuals on long term sickness absence, parental leave, maternity leave or other authorised long term absence;
	9. copies of all relevant documents and materials relating to such information, including copies of relevant contracts of employment (or relevant standard contracts if applied generally in respect of such employees); and
	10. any other “employee liability information” as such term is defined in regulation 11 of the Employment Regulations;
 |
| 1. **“Supplier’s Final Supplier Personnel List”**
 | 1. a list provided by the Supplier of all Supplier Personnel who will transfer under the Employment Regulations on the Service Transfer Date;
 |
| 1. **“Supplier’s Provisional Supplier Personnel List”**
 | 1. a list prepared and updated by the Supplier of all Supplier Personnel who are at the date of the list engaged in or wholly or mainly engaged in or assigned to the provision of the Services or any relevant part of the Services which it is envisaged as at the date of such list will no longer be provided by the Supplier; and
 |
| 1. **“Transferring Supplier Employees”**
 | 1. those employees of the Supplier and/or Sub‑contractors to whom the Employment Regulations will apply on the Service Transfer Date.
 |

1. **INTRODUCTION**
2. Termination or expiry of this Agreement or of the Services to which it relates may entail the transfer of the Services (or any part of the Services) from the Supplier (or any Sub-contractor) to a Replacement Supplier, where Replacement Services are to be provided (**“Service Transfer”**). Such change in the identity of the supplier of such services may constitute a transfer of employment (from the Supplier to a Replacement Supplier) to which the Employment Regulations apply (**“Relevant Transfer”**). The provisions of this Schedule are intended to regulate and help the Parties manage any such Service Transfer and potential consequential Relevant Transfer.
3. **PRE‑SERVICE TRANSFER OBLIGATIONS**
	1. The Supplier agrees that within twenty (20) Working Days of receipt of a written request of UK Biobank at any time (provided that UK Biobank shall only be entitled to make one such request in any six month period) it shall provide in a suitably anonymised format so as to comply with Data Protection Law, the Supplier’s Provisional Supplier Personnel List, together with the Staffing Information in relation to the Supplier’s Provisional Supplier Personnel List and it shall provide an updated Supplier’s Provisional Supplier Personnel List at such intervals as are reasonably requested by UK Biobank.
	2. At least twenty (20) Working Days prior to the Service Transfer Date, the Supplier shall provide to UK Biobank or at the direction of UK Biobank to any Replacement Supplier:
		1. the Supplier’s Final Supplier Personnel List, which shall identify which of the Supplier Personnel are Transferring Supplier Employees; and
		2. the Staffing Information in relation to the Supplier’s Final Supplier Personnel List (insofar as such information has not previously been provided).
	3. UK Biobank shall be permitted to use and disclose information provided by the Supplier under paragraphs ‎3.1 and ‎3.2 for the purpose of informing any prospective Replacement Supplier.
	4. The Supplier warrants that all information provided pursuant to paragraphs ‎3.1 and ‎3.2 shall be true, accurate and complete in all material respects at the time of providing the information.
	5. The Supplier shall provide, and shall procure that each Sub‑contractor shall provide, all reasonable cooperation and assistance to UK Biobank and any Replacement Supplier to ensure the smooth transfer of the Transferring Supplier Employees on the Service Transfer Date.
4. **EMPLOYMENT REGULATIONS EXIT PROVISIONS**
	1. UK Biobank and the Supplier agree that, as a result of the operation of the Employment Regulations, where a Relevant Transfer occurs, the contracts of employment between the Supplier and the Transferring Supplier Employees (except in relation to any contract terms disapplied through operation of regulation 10(2) of the Employment Regulations) will have effect on and from the Service Transfer Date as if originally made between the Replacement Supplier and each such Transferring Supplier Employee.
	2. The Supplier shall, and shall procure that each Sub‑contractor shall, comply with all its obligations in respect of the Transferring Supplier Employees arising under the Employment Regulations in respect of the period up to (and including) the Service Transfer Date and shall perform and discharge, and procure that each Sub‑contractor shall perform and discharge, all its obligations in respect of all the Transferring Supplier Employees arising in respect of the period up to (and including) the Service Transfer Date.
	3. The Supplier shall, and shall procure that each Sub‑contractor shall, promptly provide to UK Biobank and any Replacement Supplier, in writing such information as is necessary to enable UK Biobank and the Replacement Supplier to carry out their respective duties under regulation 13 of the Employment Regulations. UK Biobank shall procure that the Replacement Supplier shall promptly provide to the Supplier and each Sub‑contractor in writing such information as is necessary to enable the Supplier and each Sub‑contractor to carry out their respective duties under regulation 13 of the Employment Regulations.
	4. UK Biobank shall procure that the Replacement Supplier complies with all its obligations in respect of the Transferring Supplier Employees arising under the Employment Regulations in respect of the period after the Service Transfer Date and shall perform and discharge all its obligations in respect of all the Transferring Supplier Employees arising in respect of the period after the Service Transfer Date.
1. Note to bidders: Condition Precedent drafting only required if funding not in place at time of contract award / signing. [↑](#footnote-ref-1)
2. Note to bidders: Where a phased approach is proposed by the successful Supplier and accepted by UK Biobank, consequential changes may be required to the Project Plan, Testing and Milestone Payment provisions to split Milestones and related obligations between phases and to stagger the commencement of the Support Services and related Service Charges, on a proportionate basis. [↑](#footnote-ref-2)
3. Note to bidders: From the successful tenderer’s bid. [↑](#footnote-ref-3)
4. Note to bidders: To include here Supplier tendered response to question B6.1 of the ITT. [↑](#footnote-ref-4)
5. Note to bidders: Where a phased approach is proposed by the successful Supplier and accepted by UK Biobank, consequential changes may be required to the Project Plan to split Milestones and related obligations between phases, on a proportionate basis. [↑](#footnote-ref-5)
6. Note to bidders: Month of tender submission – adjust if delayed. [↑](#footnote-ref-6)
7. Note to bidders: Month of tender submission – adjust if delayed. [↑](#footnote-ref-7)
8. Note to bidders: Month of tender submission – adjust if delayed. [↑](#footnote-ref-8)