

CONTRACT FOR SERVICES

Provision of consultancy services by Transforming Care Limited to the Medicines and Healthcare products Regulatory Agency to model a proposed Innovative Devices Access Pathway (Value Proposition)

9th March 2023



SCHEDULE

Agreement dated:	9 th March 2023
Agreement number:	2023/03/09/MHRA
Between:	
'Client':	Medicines and Healthcare products Regulatory Agency
and 'Consultancy':	Transforming Care Limited
Client Address:	10 S Colonnade Canary Wharf London E14 4PU
Commencement date:	Monday 13 th March 2023
Expected completion date:	Friday 26 th May 2023
Fixed price for this contract is (excluding VAT):	£94,350 plus out of pocket expenses (capped at 5%)
The estimated period of time per week for services to be provided:	Director, 4 - 5 days per week (by exception, remote working) Senior Manager, 3 -4 days per week (by exception, remote working)
Invoicing frequency:	Monthly
Payment terms:	30 days in advance
Nature of consultancy services:	Provision of advisory services to model the proposed Innovative Devices Access Pathway (IDAP). Key outputs and timeline as per the attached proposal.
Assumptions/Exclusions:	<ul style="list-style-type: none">• Provision of strategic direction, specifically from the Sponsor. This should include, but not be limited to, the proactive management and ownership of risks and issues and making decisions in a timely manner.• There will be clear lines of reporting and provision of calendar dates/submission deadlines for governance meetings where outputs will need presenting for validation and approval.• All key workshops will be agreed during the 'mobilisation' stage. This recognises the need to build in ample lead time to maximise attendance at workshops and meetings.• Where stakeholders are required to undertake specific activities they do so within the agreed timescales, e.g. provide information/data, feedback on deliverables.• We will apply an approach of reasonable endeavours to issue all preparatory documentation/reports for workshops/meetings at least 48 hours in advance.• Immediate access to key background information.• Availability of key staff to be involved in the process, in line with the agreed plan. <u>Any slippage to the overall plan due to availability issues will incur additional charges.</u>

- Team accommodation to enable us to work in an integrated way with your team on site (as required). This will include access to meeting rooms.

Facilities/Equipment provided:

By Client: Access to desks at client site and meeting room facilities

By Consultancy: Laptops and other relevant mobile technology to enable the effective provision of services

Notice Period for early Termination:

By Client: Two weeks

By Consultancy: Two weeks

SIGNATURES

For and on behalf of Transforming Care Limited

Signature: 

Designation: Director

Date: 09/03/23

For and on behalf of the Medicines and Healthcare products Regulatory Agency

Signature:

Designation: Date:

THIS CONSULTANCY AGREEMENT made on 9th March 2023

AGREEMENT NUMBER: 2023/03/09/MHRA

BETWEEN

- (1) Transforming Care Limited (“the Consultancy”), Mansion House, Manchester Road, WA14 4RW.
- (2) The Medicines and Healthcare products Regulatory Agency (“the Client”), 10 S Colonnade, Canary Wharf London E14 4PU.

WHEREAS

- (A) The Consultancy carries on the business of the provision of consultancy services relating to the services (“the Consultancy Services”) specified in the attached Contract Schedule (“the Schedule”).
- (B) The Client has requested the Consultancy and the Consultancy has agreed with the Client, to provide the Consultancy Services on the terms and subject to the conditions of this agreement (“the Agreement”).

IT IS AGREED as follows:-

1 INTERPRETATION AND DEFINITIONS

- 1.1 Unless the context otherwise requires, references to the singular include the plural and references to the masculine include the feminine, and vice versa.
- 1.2 The headings contained in the Agreement are for convenience only and do not affect their interpretation.

“**Client**” means the person, firm or corporate body together with any subsidiary or associated company as defined by the Companies Act 2006 requiring the services of the Consultancy and identified in the Schedule.

2 CONSULTANCY

- 2.1 The Consultancy's obligation to provide the Consultancy Services shall be performed by one or more employees of the Consultancy as the Consultancy may consider appropriate (“the Staff”), subject to the Client being reasonably satisfied that the Staff has the required skills, qualifications and resources to provide the Consultancy Services to the required standard.
- 2.2 The Consultancy has the right, at its own expense, to enlist additional or substitute Staff in the performance of the Consultancy Services or may, sub-contract all or part of the Consultancy Services, provided that the consultancy provides details, whenever practical, of the proposed substitute or sub-contractor ahead of the planned substitution and subject to the Client being reasonably satisfied that such additional Staff or any such sub-contractor has the required skills, qualifications, resources and personnel to provide the Consultancy Services to the required standard.
- 2.3 Where the Consultancy provides a substitute or sub-contracts all or part of the Consultancy Services pursuant to clause 2.2 above, the Consultancy shall be responsible for paying the substitute or sub-contractor and shall ensure that any agreement between the Consultancy and any such substitute or sub-contractor shall contain obligations which correspond to the obligations of the Consultancy under the terms of this Agreement and the Consultancy shall remain responsible for the acts or omissions of any such substitute or sub-contractor.

- 2.4 The Consultancy shall take all reasonable steps to avoid any unplanned changes of Staff assigned to the performance of the Consultancy Services but if the Consultancy is unable for any reason to perform the Consultancy Services the Consultancy should inform the Client on the first day of unavailability and in such case shall provide a substitute subject to the provisions of clause 2.2.
- 2.5 In the event that the Consultancy is unable to supply either the original personnel or acceptable substitutes or sub-contractors then the Client is entitled to cancel this Agreement forthwith.
- 2.6 The Schedule shall specify the Client, the fee payable by the Client and such disbursements as may be agreed and any other relevant information.
- 2.7 Save as otherwise stated in this Agreement, the Client acknowledges and accepts that the Consultancy is in business on its own account and the Consultancy shall be entitled to seek, apply for, accept and perform contracts to supply its services to any third party during the term of this Agreement provided that this in no way compromises or is to the detriment to the performance of the Consultancy Services.

3 THE CONTRACT

- 3.1 This Agreement constitutes the contract between the Client and the Consultancy and governs the performance of the Consultancy Services by the Consultancy for the Client.
- 3.2 The Consultancy shall not be required to provide any advice and assistance in addition to the Consultancy Services and any requests to provide such additional advice and assistance shall be subject to the prior approval of the Consultancy and agreement between the Consultancy and the Client as to the level of fees payable for such additional advice and assistance. In the event that such additional advice and assistance is agreed, the Consultancy must notify the Client of the terms upon which such services will be provided including details of any new fee arrangements in order that the fee arrangement between the Consultancy and Client as set out in the Schedule may be adjusted accordingly.
- 3.3 No variation or alteration of these terms shall be valid unless approved by the Client and the Consultancy in writing except where changes to the Consultancy Services are necessary to comply with applicable safety and other statutory requirements, in which case the Consultancy may make such necessary changes without prior notification to the Client.

4 UNDERTAKING OF THE CONSULTANCY

- 4.1 The Consultancy warrants to the Client that by entering into and performing its obligations under this Agreement it will not thereby be in breach of any obligation which it owes to any third party.
- 4.2 The Consultancy warrants to the Client that it's Staff and any substitutes or sub-contractors will carry out the Consultancy Services with reasonable skill and care and as far as possible in accordance with the terms of this Agreement and any other timetables or other targets agreed.

5 TRAINING

- 5.1 The Consultancy warrants to the Client that it's Staff and any substitutes and sub-contractors used in accordance with the terms of this contract have the necessary skills and qualifications to perform the Consultancy Services. The costs for any training needed in order to gain such qualifications and skills shall be at the Consultancy's or Staff's own expense.

6 CONSULTANCY'S OBLIGATION

- 6.1 The Consultancy agrees on its own part and on behalf of its Staff and any substitutes and subcontractors used in accordance with the terms of this contract as follows:-
- 6.1.1 Not to engage in any conduct detrimental to the interests of the Client which includes any conduct tending to bring the Client into disrepute or which results in the loss of custom or business.
 - 6.1.2 To comply with any statutory rules or regulations including but not limited to those relating to health and safety, together with such procedures of the Client as the Client notifies the Consultancy and/or its Staff and any substitutes and sub-contractors that it is essential that the Consultancy and its Staff and any substitutes and sub-contractors comply with to properly perform the Services (including for example where the Services are to be performed at the premises of the Client the health and safety policy and security arrangements) during the performance of the Consultancy Services. Subject to the rules and regulations which the Client notifies the Consultancy and/or its Staff and any substitutes and sub-contractors that it is essential that the Consultancy and its Staff and any substitutes and sub-contractors comply with the Consultancy and its Staff, and any substitutes and sub-contractors shall not be bound by the policies and procedures which an employee of the Client would be bound by.
 - 6.1.3 To furnish the Client with any progress reports as may be requested from time to time.
 - 6.1.4 To notify the Client forthwith in writing if it should become insolvent, dissolved or subject to a winding up petition.

7 EQUIPMENT

- 7.1 The Consultancy shall provide at its own cost, subject to any agreement to the contrary specified in the Schedule, all such necessary equipment as is reasonable for the satisfactory performance by the Staff and any substitutes and sub-contractors of the Consultancy Services.
- 7.2 Any computer equipment and associated software which it provides to its staff or to the Client in relation to its provision of services is free from any virus.
- 7.3 If as a matter of convenience, the consultancy is provided with equipment by the Client or Client for the purposes of an Assignment, the Consultancy shall be responsible for ensuring that they preserve the security and condition of such equipment. If and to the extent that any equipment is lost while in the Consultancy's possession, the Consultancy shall be responsible for the cost of any necessary repairs or replacement.

8 METHOD OF PERFORMING SERVICES

- 8.1 The Consultancy's Staff are professionals who will use their own initiative as to the manner in which the Services are delivered provided that in doing so the Consultancy shall co-operate with the Client and comply with all reasonable and lawful instructions of the Client.
- 8.2 The Consultancy may provide the Consultancy Services at such times and on such days as the Consultancy shall decide but shall ensure that Services are provided at such times as are necessary for the proper performance of the Consultancy Services.
- 8.3 The relationship between the parties is between independent companies acting at arm's length and nothing contained in this Agreement shall be construed as constituting or establishing any partnership or joint venture or relationship of employer and employee between the parties or their personnel.

- 8.4 Where the proper performance of the Consultancy Services are dependent on the completion of tasks or services by third parties (including employees of the Client but excluding any substitute or sub-contractor of the Consultancy), the Consultancy shall have no liability to the Client for any delay, non or partial performance of the Consultancy Services arising from the delay or non or partial performance of such tasks by third parties.
- 8.5 The Consultancy may provide the Consultancy Services from such locations as are appropriate in the Consultancy's judgment. When necessary the Client will provide the Consultancy with appropriate access to the client's facilities as is necessary for the effective conduct of the Consultancy Services

9 EXPENSES

- 9.1 Expenses incurred by the Consultancy in undertaking of the consulting services will align with the Client's internal policy.

10 INVOICING

- 10.1 Upon completion of the Consultancy Services or as may be agreed and specified in the Schedule the Consultancy shall deliver to the Client its invoice for the amount due from the Client to the Consultancy giving a detailed breakdown showing the work performed. The Consultancy's invoice should bear the Consultancy's name, company registration number, VAT number and should state any VAT due on the invoice.
- 10.2 The Consultancy shall obtain the signature of an authorised representative of the Client as verification of execution of the Consultancy Services.
- 10.3 The Client shall not be obliged to pay any fees to the Consultancy unless an invoice has been properly submitted by the Consultancy in accordance with sub-clause 9.1 of this Agreement and until the Client has verified the execution of the Consultancy Services.

11 FEES

- 11.1 Subject to the receipt of the Consultancy's invoice in accordance with clause 9 above and verification by the Client of execution of the Consultancy Services in accordance with sub-clause 9.3 above, the Consultancy will receive payment from the Client for the Consultancy Services in accordance with the fee specified in the Schedule, plus VAT to be shown separately where appropriate.
- 11.2 The Consultancy shall be responsible for any PAYE Income Tax and National Insurance Contributions and any other taxes and deductions payable in respect of its Staff in respect of the Consultancy Services.
- 11.3 All payments will be made to the Consultancy within 30 days. If payments are not received within 30 days of receipt of invoice, a late payment fee of 1.5% will be applied to each month the payment is not received and the Consultancy reserves the right to withdraw from further work.
- 11.4 If the Consultancy shall be unable for any reason to provide the Consultancy Services to the Client, no fee shall be payable by the Client during any period that the Consultancy Services are not provided.
- 11.5 Notwithstanding the provisions of the proviso to clause 8.2, the Consultancy will be able to suspend the provision of the Consultancy Services on up to 20 days per annum per each Staff (or pro rata where the Consultancy Services are for less than one year). The Consultancy shall be responsible to pay the Staff all sums due in respect of those days upon which the Consultancy Services provided are suspended pursuant to the Working Time Regulations 1998 or otherwise.

12 OBLIGATIONS OF THE CLIENT

- 12.1 Throughout the term of this Agreement the Client shall pay the Consultancy the agreed fee in accordance with clause 10.1 above.
- 12.2 The Client shall furnish the Consultancy with sufficient information about the Consultancy Services in order for the Consultancy to arrange for the Consultancy Services to be carried out.
- 12.3 The Client will advise the Consultancy of any health & safety information or advice which may affect the Consultancy's Staff during the performance of the Consultancy Services.

13 TERM OF THE AGREEMENT

- 13.1 This Agreement shall commence in accordance with the Schedule and shall either (as specified in the Schedule) continue until completion of the Consultancy Services to the reasonable satisfaction of the Client or the termination date as specified in the Schedule, at which time this Agreement shall expire automatically, or the contract be terminated early by the Client or Consultancy upon giving the required notice as set out in the Contract Schedule.
- 13.2 Notwithstanding sub-clause 12.1 of this Agreement, the Client may at any time with two weeks' notice instruct the Consultancy to cease work on the Consultancy Services, or at any time without notice and without liability require the Consultancy to cease work on the Consultancy Services, where:
 - 13.2.1 The Consultancy (or its substitutes and sub-contractors) has committed any serious or persistent breach of any of its obligations under this Agreement;
 - 13.2.2 The Client reasonably believes that the Consultancy (or its substitutes and sub-contractors) has not observed any condition of confidentiality applicable to the Consultancy from time to time; or
 - 13.2.3 The Consultancy (or its substitutes and sub-contractors) proves, in the reasonable opinion of the Client, unsatisfactory to the Client including while performing the Consultancy Services acting in breach of any statutory obligations or acting in breach of such procedures of the Client as the Client notifies the Consultancy and/or its Staff that it is essential that the Consultancy and its Staff comply with to properly perform the Services;
 - 13.2.4 If performance of the Consultancy Services is prevented by the incapacity of the Staff and the Consultancy is unable to provide a replacement member of Staff or a suitable substitute or sub-contractor pursuant to the provisions of clause 2.2.
 - 13.2.5 The Consultancy becomes insolvent, dissolved or subject to a winding up petition;
 - 13.2.6 Any member of the Consultancy (or its substitutes and sub-contractors) is guilty of any fraud, dishonesty or serious misconduct.

AND the provisions of this clause 12.3 shall equally apply to any party performing the Consultancy's obligations as provided for in clause 2.

- 13.3 Upon completion or termination of the Consultancy Services the Client shall be under no obligation to offer the Consultancy further work, nor shall the Consultancy be under any obligation to accept any offer of work made by the Client.
- 13.4 Notwithstanding sub-clause 12.1 of this Agreement the Consultancy may terminate the contract if the Client has committed any serious or persistent breach of any of its obligations under this Agreement or in the event that the Client becomes insolvent, dissolved or subject to a winding up petition.

- 13.5 Without affecting any other right or remedy available to it, either party may terminate this agreement with immediate effect by giving written notice to the other party if:
- 13.5.1 the other party fails to pay any amount due under this agreement on the due date for payment and remains in default not less than 30 days after being notified in writing to make such payment;
 - 13.5.2 the other party commits a material breach of any term of this agreement which breach is irremediable or (if such breach is remediable) fails to remedy that breach within a period of 30 days after being notified in writing to do so;
 - 13.5.3 the other party repeatedly breaches any of the terms of this agreement in such a manner as to reasonably justify the opinion that its conduct is inconsistent with it having the intention or ability to give effect to the terms of this agreement;
 - 13.5.4 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 being a company is deemed unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986;
 - 13.5.5 the other party commences negotiations with all or any class of its creditors with a view to rescheduling any of its debts, or makes a proposal for or enters into any compromise or arrangement with its creditors other than (being a company) 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;
 - 13.5.6 a petition is filed, a notice is given, a resolution is passed, or an order is made, for or in connection with the winding up of that other party (being a company) 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;
 - 13.5.7 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 given or if an administrator is appointed, over the other party (being a company);
 - 13.5.8 the holder of a qualifying floating charge over the assets of that other party (being a company) has become entitled to appoint or has appointed an administrative receiver;
 - 13.5.9 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;
 - 13.5.10 a creditor or encumbrancer of the other party attaches or takes possession of, or a distress, execution, sequestration 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 14 days;
 - 13.5.11 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 in clauses 12.5.4 to clause 12.5.9 (inclusive);
 - 13.5.12 the other party suspends or ceases, or threatens to suspend or cease, carrying on all or a substantial part of its business.

14 INTELLECTUAL PROPERTY

14.1 The Consultancy hereby assigns to the Client all existing and future Intellectual Property Rights in the Works and the Inventions and all materials embodying these rights to the fullest extent permitted by law. Insofar as they do not vest automatically by operation of law or under this agreement, the Consultancy holds legal title in these rights and inventions on trust for the Client.

The Consultancy undertakes:

- (a) to notify to the Client in writing full details of any Inventions promptly on their creation;
- (b) to keep confidential details of all Inventions;
- (c) whenever requested to do so by the Client and in any event on the termination of the Engagement, promptly to deliver to the Client all correspondence, documents, papers and records on all media (and all copies or abstracts of them), recording or relating to any part of the Works and the process of their creation which are in his possession, custody or power;
- (d) not to register nor attempt to register any of the Intellectual Property Rights in the Works, nor any of the Inventions, unless requested to do so by the Client; and
- (e) to do all acts necessary to confirm that absolute title in all Intellectual Property Rights in the Works and the Inventions has passed, or will pass, to the Client.

The Consultancy warrants to the Client that:

- (a) he has not given and will not give permission to any third party to use any of the Works or the Inventions, nor any of the Intellectual Property Rights in the Works;
- (b) he is unaware of any use by any third party of any of the Works or Intellectual Property Rights in the Works; and
- (c) the use of the Works or the Intellectual Property Rights in the Works by the Client will not infringe the rights of any third party.

14.2 The Consultancy agrees to indemnify the Client and keep it indemnified at all times against all or any costs, claims, damages or expenses incurred by the Client, or for which the Client may become liable, with respect to any intellectual property infringement claim or other claim relating to the Works or Inventions supplied by the Consultancy to the Client during the course of providing the Services. The Consultancy shall maintain adequate liability insurance coverage and ensure that the Client's interest is noted on the policy, and shall supply a copy of the policy to the Client on request. The Client may at its option satisfy this indemnity (in whole or in part) by way of deduction from any payments due to the Consultancy.

14.3 The Consultancy waives any moral rights in the Works to which he is now or may at any future time be entitled under Chapter IV of the Copyright Designs and Patents Act 1988 or any similar provisions of law in any jurisdiction, including (but without limitation) the right to be identified, the right of integrity and the right against false attribution, and agrees not to institute, support, maintain or permit any action or claim to the effect that any treatment, exploitation or use of such Works or other materials infringes the Consultancy's moral rights.

14.4 The Consultancy acknowledges that, except as provided by law, no further fees or compensation other than those provided for in this agreement are due or may become due to the Consultancy in respect of the performance of his obligations under this clause 13.

- 14.5 The Consultancy undertakes, at the expense of the Client, at any time either during or after the Engagement, to execute all documents, make all applications, give all assistance and do all acts and things as may, in the opinion of the Client, be necessary or desirable to vest the Intellectual Property Rights in, and to register them in, the name of the Client and to defend the Client against claims that works embodying Intellectual Property Rights or Inventions infringe third party rights, and otherwise to protect and maintain the Intellectual Property Rights in the Works and the Inventions.
- 14.6 The Consultancy irrevocably appoints the Client to be his attorney in his name and on his behalf to execute documents, use the Consultancy's name and do all things which are necessary or desirable for the Client to obtain for itself or its nominee the full benefit of this clause. A certificate in writing, signed by any director or the secretary of the Client, that any instrument or act falls within the authority conferred by this agreement shall be conclusive evidence that such is the case so far as any third party is concerned.

15 CONFIDENTIALITY

- 15.1 In order to protect the confidentiality and trade secrets of any Client and without prejudice to every other duty to keep secret all information given to it or gained in confidence the Consultancy agrees on its own part and on behalf of its Staff and any substitutes and sub-contractors used in accordance with the terms of this contract as follows:-
- 15.1.1 Not at any time whether during or after the performance of the Consultancy Services (unless expressly so authorised by the Client as a necessary part of the performance of its duties) to disclose to any person or to make use of any of the trade secrets or confidential information of the Client;
- 15.1.2 To deliver up to the Client (as directed) at the end of the Assignment all documents and other materials belonging to the Client (and all copies) which are in its possession including documents and other materials created by it or the Staff during the course of the Assignment;
- 15.1.3 Not at any time to make any copy, abstract, summary or précis of the whole or any part of any document or other material belonging to the Client except when required to do so in the course of its duties under the Assignment in which event any such item shall belong to the Client.
- 15.2 The Consultancy shall procure and ensure that the provisions of this clause 14 shall also apply to any subcontractor performing the Consultancy's obligations provided for in clause 2.

16 RELATIONSHIP BETWEEN THE CLIENT AND CONSULTANCY

- 16.1 The Consultancy acknowledges to the Client that there is no intention on the part of the Consultancy, its staff, substitutes or sub-contractors or the Client to create an employment relationship between any of those parties and that the responsibility of complying with all statutory and legal requirements relating to the Staff of the Consultancy (including but not limited to the payment of taxation, maternity payments and statutory sick pay) shall fall upon and be discharged wholly and exclusively by the Consultancy. In the event that any person should seek to establish any liability or obligation upon the Client on the grounds that the staff are an employee of the Client, the Consultancy shall upon demand indemnify the Client and keep them indemnified in respect of any such liability or obligation and any related costs expenses or other losses which the Client shall incur.
- 16.2 The Client is under no obligation to offer work to the Consultancy and the Consultancy is under no obligation to accept any work that may be offered by the Client. Neither party wishes to create or imply any mutuality of obligation between themselves either in the course of, or between, any performance of Service under the Agreement.

17 NOTICES

- 17.1 All notices which are required to be given hereunder shall be in writing and shall be sent to the registered office from time to time of the party upon whom the notice is to be served. Any such notice may be delivered personally or by first class prepaid post or facsimile transmission and shall be deemed to have been served if by hand when delivered, if by first class post 48 hours and if by facsimile transmission when dispatched.

18 LIABILITY

- 18.1 The Consultancy shall be liable for any loss, damage or injury to any party, resulting from the acts or omissions of the Consultancy or its Staff (including substitute or replacement Staff) or from the acts or omission of any sub-contractor to whom the Consultancy sub-contracts the performance of the Consultancy Services whether or not such act or omission constitutes a breach of this Agreement and the Consultancy shall indemnify and keep indemnified any such party including, without limitation to the foregoing, the Client against any such loss, damage or injury provided that the total aggregate liability of the Consultancy shall not exceed in the case of liability covered by professional indemnity insurance £1,000,000.
- 18.2 The Consultancy shall ensure the provision of adequate insurance to cover the risk of a claim against the Consultancy (or its Staff or any sub-contractor) whether pursuant to the terms of this Agreement (including clause 19.1) or otherwise (including without limitation Employer's Liability Insurance, Public Liability Insurance and any other suitable policies of insurance such as Professional Indemnity insurance in respect of the Consultancy and its Staff or any sub-contractor).
- 18.3 The Consultancy shall be liable for any defects arising as a result of the provision of the Consultancy Services and the Consultancy shall rectify at its own cost such notified defects as may be capable of remedy.
- 18.4 The Consultancy acknowledges that the Staff provided is not an Agency Worker as defined under the Agency Worker Regulations 2010 and that the Agency Worker Regulations 2010 do not apply in relation to this Agreement. The Consultancy shall indemnify and keep indemnified the Client against any losses the Client may suffer as a result of any claim made by or on behalf of any of the Staff under the Agency Worker Regulations 2010.

19 HEALTH AND SAFETY AND OTHER POLICIES

- 19.1 The Consultancy shall comply with the Client's policies on social media, use of information and communication systems, anti-harassment and bullying, no smoking and substance misuse.

20 DATA PROTECTION

- 20.1 The Consultant shall procure that the Individual consents to the Client holding and processing data relating to him for legal, personnel, administrative and management purposes and in particular to the processing of any "special categories of personal data" (as defined in the Data Protection Legislation) and criminal records data relating to the Individual including, as appropriate:
- 20.1.1 the Individual's racial or ethnic origin or religious or similar beliefs in order to monitor compliance with equal opportunities legislation;
- 20.1.2 information relating to any criminal proceedings in which the Individual has been involved for insurance purposes and in order to comply with legal requirements and obligations to third parties; and any other special categories of personal data to be processed as set out in the Specification.

- 20.2 The Consultant consents (and shall procure that the Individual consents) to the Client making such information available to those who provide products or services to the Client such as advisers, grant providers, regulatory authorities, governmental or quasi-governmental organisations and potential purchasers of the Client or any part of its business.
- 20.3 The Consultant shall comply, and shall procure that the Individual shall comply, with the Client's data protection policy and relevant obligations under the data protection legislation and associated codes of practice when processing personal data relating to any employee, worker, customer, Client supplier or agent of the Client.
- 20.4 The parties acknowledge that for the purposes of the Data Protection Legislation, the Client is the data controller and the Consultant is the data processor (where Data Controller and Data Processor have the meanings as defined in the Data Protection Legislation) for any data collected by or provided to the Consultant in accordance with this Contract and that the attached Data Processing Schedule constitutes the data processing instructions and includes the scope, nature and purpose of processing by the Consultant, the duration of the processing and the types of personal data and categories of Data Subject.
- 20.5 In relation to any data for which the Consultant is acting as Data Processor on behalf of the Client, the Consultant shall:
- 20.5.1 Notify the Client immediately if it considers that any of the Client's instructions infringe the Data Protection Legislation.
- 20.5.2 Provide all reasonable assistance to the Client in the preparation of any Data Protection Impact Assessment prior to commencing any processing. Such assistance may, at the discretion of the Client, include: a) a systematic description of the envisaged processing operations and the purpose of the processing; b) an assessment of the necessity and proportionality of the processing operations in relation to the Services; c) an assessment of the risks to the rights and freedoms of Data Subjects; and d) the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.
- 20.5.3 Process that Personal Data only in accordance with the Data Protection Schedule unless the Consultant is required to do otherwise by Law. If it is so required the Consultant shall promptly notify the Client before processing the Personal Data unless prohibited by Law;
- 20.5.4 Ensure that it has in place Protective Measures, which are appropriate to protect against 10 a Data Loss Event, which the Client may reasonably reject (but failure to reject shall not amount to approval by the Client of the adequacy of the Protective Measures) having taken account of the: a) nature of the data to be protected; b) harm that might result from a Data Loss Event; c) state of technological development; and d) cost of implementing any measures;
- 20.5.5 Ensure that the Consultant Staff or the Individual do not process Personal Data except in accordance with this Agreement (and in particular the Data Processing Schedule)
- 20.5.6 Ensure it takes all reasonable steps to ensure the reliability and integrity of any personnel or staff who have access to the Personal Data and ensure that they: a) are aware of and comply with the Consultant's duties under this clause; b) are subject to appropriate confidentiality undertakings with the Consultant or any Subprocessor; c) 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 Client or as otherwise permitted by this Agreement; and d) have undergone adequate training in the use, care, protection and handling of Personal Data; and
- 20.5.7 Not transfer Personal Data outside of the EU unless the prior written consent of the Client has been obtained and the following conditions are fulfilled: a) the Client or the Consultant has provided appropriate safeguards in relation to the transfer (whether in accordance with GDPR Article 46 or Law Enforcement Directive Article 37) as determined by the Client; b) the Data Subject has enforceable rights and effective legal remedies; c) the Consultant complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Client in meeting its obligations); and d) the Consultant complies with any reasonable

instructions notified to it in advance by the Client with respect to the processing of the Personal Data;

- 20.5.8 At the written direction of the Client, delete or return Personal Data (and any copies of it) to the Client on termination of the Contract unless the Consultant is required by Law to retain the Personal Data.
- 20.5.9 Shall notify the Client immediately if it: a) receives a Data Subject Access Request (or purported Data Subject Access Request); b) receives a request to rectify, block or erase any Personal Data; c) receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation; d) receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data processed under this Contract 11 e) 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 f) becomes aware of a Data Loss Event.
- 20.5.10 The Consultant's obligation to notify under clause 19.5.9 shall include the provision of further information to the Client in phases as details become available.
- 20.5.11 Taking into account the nature of the processing, the Consultant shall provide the Client with full assistance in relation to either Party's obligations under Data Protection Legislation and any complaint, communication or request made under such legislation (and insofar as possible within the timescales reasonably required by the Client) including by promptly providing: a) full details and copies of the complaint, communication or request; b) such assistance as is reasonably requested by the Client to enable the Client to comply with a Data Subject Access Request within the relevant timescales set out in the Data Protection Legislation; c) the Client, at its request, with any Personal Data it holds in relation to a Data Subject; d) assistance as requested by the Client following any Data Loss Event; e) assistance as requested by the Client with respect to any request from the Information Commissioner's Office, or any consultation by the Client with the Information Commissioner's Office.
- 20.5.12 The Consultant shall maintain complete and accurate records and information to demonstrate its compliance with this clause 19.5.
- 20.5.13 The Consultant shall allow for audits of its Data Processing activity by the Client or the Client's designated auditor.
- 20.5.14 The Consultant shall designate a Data Protection Officer if required by the Data Protection Legislation.
- 20.5.15 Before allowing any Sub-processor to process any Personal Data related to this Contract, the Consultant must: a) notify the Client in writing of the intended Sub-processor and processing; b) obtain the written consent of the Client; c) enter into a written agreement with the Sub-processor which give effect to the terms set out in this clause 19.5 such that they apply to the Sub-processor; and d) provide the Client with such information regarding the Sub-processor as the Client may reasonably require.
- 20.5.16 The Consultant shall remain fully liable for all acts or omissions of any Sub-processor.
- 20.5.17 The Client may, at any time on not less than 30 Working Days' notice, revise any part of this clause 19.5 by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to this Contract).
- 20.5.18 The Parties agree to take account of any guidance issued by the Information Commissioner's Office. The Client may on not less than 30 Working Days' notice to the Contractor amend this Contract to ensure that it complies with any guidance issued by the 12 Information Commissioner's Office.

21 FREEDOM OF INFORMATION

- 21.1 The Consultancy is aware that the Client is bound by the Freedom of Information and the Environmental Information Regulations, so the release of contract information to the public is also governed by such regulations. Disclosure of contractual information will be dependant on exemptions and the public interest test.
- 21.2 The Consultancy is aware that agreements or confidentiality clauses in contracts may be invalid to the extent that they may exceed the exemptions or public interest.
- 21.3 In accordance with the recommendation of Section 45 of the FOI Act, the Client will consult with the Consultant if their views would help to decide if contract related information is a) exempt or b) in the public interest. However, the Consultant is aware that it is the Client, not the Consultant, who will decide whether information should be disclosed.

22 ANTI-BRIBERY AND ANTI-CORRUPTION

- 22.1 The Consultancy shall:
- 22.1.1 comply and shall procure that it shall comply with all applicable laws, statutes and regulations relating to anti-bribery and anti-corruption, including but not limited to the Bribery Act 2010;
 - 22.1.2 comply and shall procure that it shall comply with the Clients' Anti-Bribery Policy, as the same may be updated from time to time;
 - 22.1.3 have and maintain in place throughout the Term its own policies and procedures, including but not limited to adequate procedures under the Bribery Act 2010, to ensure compliance with the Relevant Requirements and the Bribery Policy and will enforce them where appropriate;
 - 22.1.4 promptly report and shall procure that it shall promptly report to Client any request or demand for any undue financial or other advantage of any kind received by the Consultancy in connection with the performance of this Agreement; and
 - 22.1.5 ensure and shall procure that it shall ensure that all persons associated with the Consultancy or other persons who are performing services in connection with this Agreement comply with this clause 21.
- 22.2 For the purpose of this clause the meaning of adequate procedures and whether a person is associated with another person shall be determined in accordance with section 7(2) of the Bribery Act 2010 (and any guidance issued under section 9 of that Act) and section 8 of that Act respectively.

23 GOVERNING LAW AND JURISDICTION

- 23.1 This Agreement shall be construed in accordance with the laws of England & Wales and all disputes, claims or proceedings between the parties relating to the validity, construction or performance of this Agreement shall be subject to the exclusive jurisdiction of the Courts of England & Wales.

24 ILLEGALITY

- 24.1 If any provision or term of this Agreement shall become or be declared illegal, invalid or unenforceable for any reason whatsoever including, but without limitation, by reason of the provisions of any legislation or other provisions having the force of law or by reason of any decision of any Court or other body or authority having jurisdiction over the parties of this Agreement such terms or provisions shall be divisible from this Agreement and shall be deemed to be deleted from this Agreement and the remainder of the provisions shall continue in full force and effect provided always that if any such

deletion substantially affects or alters the commercial basis of this Agreement the parties shall negotiate in good faith to amend the modify the provisions and terms of this Agreement as necessary or desirable in the circumstances.

25 ENTIRE AGREEMENT

- 25.1 This agreement constitutes the entire agreement between the parties and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter.
- 25.2 Each party acknowledges that in entering into this agreement it does not rely on, and shall have no remedies in respect of, any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this agreement.
- 25.3 Each party agrees that it shall have no claim for innocent or negligent misrepresentation or negligent misstatement based on any statement in this agreement.
- 25.4 Nothing in this clause shall limit or exclude any liability for fraud.

26 VARIATION

- 26.1 No variation of this agreement [or of any of the documents referred to in it] shall be effective unless it is in writing and signed by the parties (or their authorised representatives).

27 COUNTERPARTS

- 27.1 This agreement may be executed in any number of counterparts, each of which, when executed [and delivered], shall constitute a duplicate original, but all the counterparts shall together constitute the one agreement.

28 THIRD PARTY RIGHTS

- 28.1 Except as expressly provided elsewhere in this agreement, a person who is not a party to this agreement shall not have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this agreement. This does not affect any right or remedy of a third party which exists, or is available, apart from that Act.
- 28.2 The rights of the parties to terminate, rescind or agree any variation, waiver or settlement under this agreement are not subject to the consent of any other person.

29 DISPUTE RESOLUTION

- 29.1 The parties shall use their best efforts to resolve any dispute arising out of or relating to this contract through negotiations between senior executives of the parties, who have authority to settle the same, before resorting to any other means of resolution. To this effect, they shall consult and negotiate with each other in good faith and, recognising their mutual interests, attempt to reach a just and equitable solution satisfactory to all parties.
- 29.2 If the matter is not resolved by negotiation within 30 days of receipt of a written 'invitation to negotiate', the parties will attempt to resolve the dispute in good faith through an agreed Alternative Dispute Resolution (ADR) procedure, or in default of agreement, through an ADR procedure as

recommended to the parties by the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators.

29.3 If the matter has not been resolved by an ADR procedure within 60 days of the initiation of that procedure, or if any party will not participate in an ADR procedure, the dispute may be referred to arbitration by any party. The seat of the arbitration shall be England and Wales. The arbitration shall be governed by both the Arbitration Act 1996 and Rules as agreed between the parties. Should the parties be unable to agree on an arbitrator or arbitrators, or be unable to agree on the Rules for Arbitration, any party may, upon giving written notice to other parties, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators for the appointment of an Arbitrator or Arbitrators and for any decision on rules that may be necessary.

30 FORCE MAJEURE

30.1 The Consultancy shall not be liable for any breaches of its obligations under this Agreement resulting from causes beyond its reasonable control including but not limited to Acts of God, enemy, fire, flood, explosion or other catastrophe.

30.2 The Consultancy accepts that the Client shall not be liable for any breaches of its obligations to the Consultancy under its agreement with the Client resulting from causes beyond its reasonable control including but not limited to Acts of God, enemy, fire, flood, explosion or other catastrophe.

SIGNATURES

For and on behalf of Transforming Care Limited

Signature: 

Designation: Director

Date: 09/03/23

For and on behalf of the Medicines and Healthcare products Regulatory Agency

Signature: 

Designation: Deputy Director Innovative Devices

Date: 14/03/2023

SCHEDULE A – Data Processing

Description	Details
Subject matter of the processing	<p>The processing will inform the development of a model (Value Proposition) for the proposed Innovative Devices Access Pathway (IDAP). This will involve the processing of:</p> <ul style="list-style-type: none"> • Key organisational and partner information to inform the development of the pathway; • Non attributable feedback from key stakeholders to inform options development; • Data (costings) to inform the financial model.
Duration of the processing	A 11-week period (13 th March 2023 – 26 th May 2023)
Nature and purposes of the processing	<p>Analysis of information and data provided to develop pathway options and then model the preferred pathway to create a value proposition. To log non-attributable semi-structured interviews that have taken place.</p>
Type of Personal Data	Name, role and employer
Categories of Data Subject	Staff of the organisations that have been engaged with during the assignment
Plan for return and destruction of the data once the processing is complete	<p>Inclusion of outputs in the final deliverable. Raw data to removed off Consultant systems. Copy of the final deliverable to be kept by the Consultant on agreement by the Client.</p>