Protas – Procurement of technical consultancy to co-develop requirements specification for an integrated clinical trials management platform.

Request for proposal (RfP)

Summary

- Protas is a new organisation to improve the process of developing and testing new medicines. Its objective is to make the way that new medicines are tested more efficient and more cost effective.
- As part of its offering to customers in the life sciences sector it will develop a trials management platform that integrates the end-to-end process from trial design to data analysis and reporting.
- Once Protas has defined its specification for the trials management platform, it will undertake a procurement process to identify an infrastructure provider to produce (and operate) the IT platform on behalf of Protas. The IT platform will need to be configurable, modular, scaleable and re-useable.
- The purpose of this RfP exercise is to appoint a technical consultancy to assist Protas in developing and refining Protas's specification for the design and technical architecture for the IT platform. The deliverable will be a detailed technical requirements specification for the IT platform for use in the subsequent procurement process for an infrastructure provider.
- The technical consultancy should have relevant expertise in the design and technical architecture of comparable systems, the ability to incorporate existing systems and applications as well as undertaking specific coding development, expertise in data ingress and egress, communications networks, cloud strategy, security and data standards for health data and the ability to define the interoperability of the different off-the-shelf components.
- Details of the process for selecting a technical consultancy to support Protas in this phase of work are included in this document.

1. Protas – background information (https://protas.co.uk/)

Protas has been established to address the problem of too few innovative interventions becoming available for common conditions (such as cardio-metabolic diseases, as well as the common cancers, degenerative conditions and drug-resistant infections) by seeking to substantially reduce the costs of large clinical outcome trials, while increasing their efficiency, quality and reliability.

Protas is a made up partly of personnel from Oxford University's Nuffield Department of Public Health (NDPH) and NDPH's Clinical Trial Service Unit (CTSU), the latter of which has a long track record in conducting efficient, reliable and cost-effective clinical trials. Protas itself has been established as a not-for-profit company to develop the infrastructure needed to support the design and delivery of more and more frequent randomized trials. As part of this, Protas will develop a modular, scalable and re-useable IT platform to enable multiple treatments for common conditions to be assessed.

The improved economics and efficiency should assist pharmaceutical (and other life sciences) organisations to develop and test a greater number of agents, particularly for common chronic conditions.

2. Protas's requirement for a flexible, modular IT platform

There are a large number of organisations who currently contract with life sciences companies to run clinical trials on their behalf. However, commonly, each new trial involves either the configuration of pre-existing systems with limited functionality and interoperability or the development of new IT individually aligned to the particular trial protocol. This is a time consuming and expensive process. Where clinical trial management systems do exist, they typically require a trial to adjust to the constraints of the IT that underpins them and involve significant configuration of the IT before recruitment for the trial can begin (often because the end-to-end process of the trial requires the use of several functional modules with limited functional integration, other than data transfer capability). This serves to delay the start of the trial and increases cost.

Protas's offering to its customers will be based around a new, efficient, integrated cloud-based IT platform to underpin the conduct of properly designed randomized trials (useable for all sizes of trial). It will cover the end-to-end trial process (including interaction with national health data systems enabling more efficient recruitment) that will improve quality and reduce cost (see Figure 1).

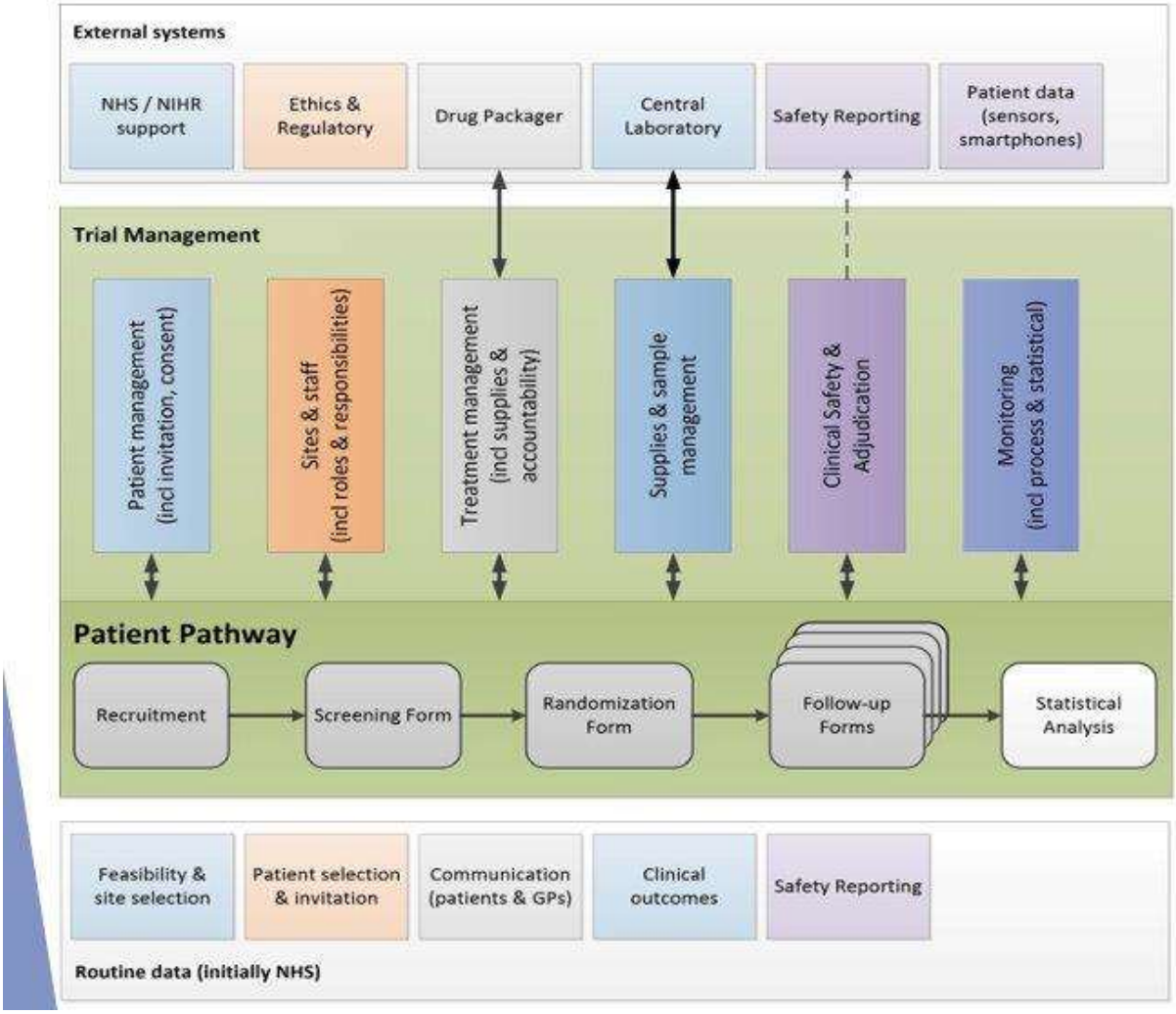

Figure 1: high level schematic showing the process scope, systems and data for a generic trial process (this example represents the process in the UK with data provided by the NHS but the description is broadly applicable internationally). NIHR – National Institutes for Health Research.

The platform will be configurable, scaleable, modular and re-usable for different trials; flexible to enable a range of trial designs and types to be supported; and developed using (as necessary) APIs and open-source, modern coding languages and health data standards so that, where integration and configuration is required, this can be achieved quickly and easily.

Currently, available systems also suffer from expensive (but not always effective), monitoring strategies (e.g., source document checking, frequent site visits) that are used by most pharmaceutical companies and CROs. Detectability (including being able to measure performance against objective quality metrics) should instead be built into the design of the platform (rather than just seeking to pick up post-event problems). Protas's objective is that its systems should be developed on a quality-by-design principle to ensure that all the required data are collected (i.e. items cannot be missed, consistency enhanced, and extra data are sought when required) and to ensure compliance with the study protocol

(e.g. in-built eligibility checks and prompts when particular actions – such as safety checks or treatment changes – are required). It should also include full integration of the study treatment supply logistics, pharmacovigilance requirements, and quality management activities (particularly developing an efficient process for centralised trial monitoring).

3. Current and short-term work – Protas's requirements for an IT platform specification

A functional and technical architecture requirements specification (the Specification) will need to be developed at a level of detail sufficient to form the basis of a subsequent procurement for an infrastructure provider to build, test and implement the Protas IT platform.

Current activity within Protas is focussing on defining the detail of the processes outlined in Figure 1 (comprising process and data flows, entity relationships, state machines and non-functional and cross-functional requirements). However, Protas seeks to engage an experienced technical consultancy to assist with the development of the Specification alongside Protas's internal team of programmers and business analysts (see section 4 – high level architecture).

The Specification will be for 'version one' of the IT platform which a subsequent infrastructure provider will develop and deliver; this version one of the IT platform will have all the necessary functionality and features to enable Protas to begin supporting its first trials (which should be assumed to be a relatively large-scale randomised trial for common chronic and acute conditions both with potential long-term follow up of patients).

The Protas IT platform will be developed against a number of principles outlined below. These are, of course, relevant to the subsequent infrastructure provider procurement, but should be reflected in the response to this RfP by interested technical consultancies and will need to be included (as applicable) in the final Specification:

- If functional elements of the overall IT platform are readily and reliably available off-the-shelf, they should be used in preference to in-house developed code (unless there is a good reason to the contrary). Protas will use IaaS and SaaS approaches as a default.
- Protas has no current intention of building a large in-house team of programmers/technicians to develop and maintain the systems and architecture. Nevertheless, it will retain appropriate in-house skills such as a CIO, a small team of business analysts and some software developers, who will co-ordinate and supervise the development of the IT platform.
- The platform architecture should also be such that it can be readily maintained, upgraded, amended and/or enhanced.
- A recognition that Protas is subject to the Public Contracts Regulations 2015 (as amended) (PCR) in undertaking the IT platform procurement and therefore (1) the Specification will need to comply with the requirements of PCR; and (2) Protas will need to consider whether any relevant information prepared in the context of this RfP process and/or in developing the

Specification needs to be shared as part of the subsequent IT platform procurement and take such other appropriate measures as it sees fit in order to ensure the IT platform procurement is not distorted by activities undertaken during this phase of work.

4. High level architecture

A level one technical architecture is shown in Figure 2. The requirement for the technical consultancy is to define all elements of the technical architecture including hardware, software, data ingress and egress, communications networks, cloud strategy and security and define the interoperability of the different off-the-shelf components. Where appropriate, reference should be made to relevant data standards and ontologies for health data and clinical trial data[1] to ensure efficient data transfer and use before the trial begins, during any audit activities, and during the analysis and reporting phase. The technical consultancy will identify where bespoke code needs to be developed and where potential functional elements - not listed here – may be required.

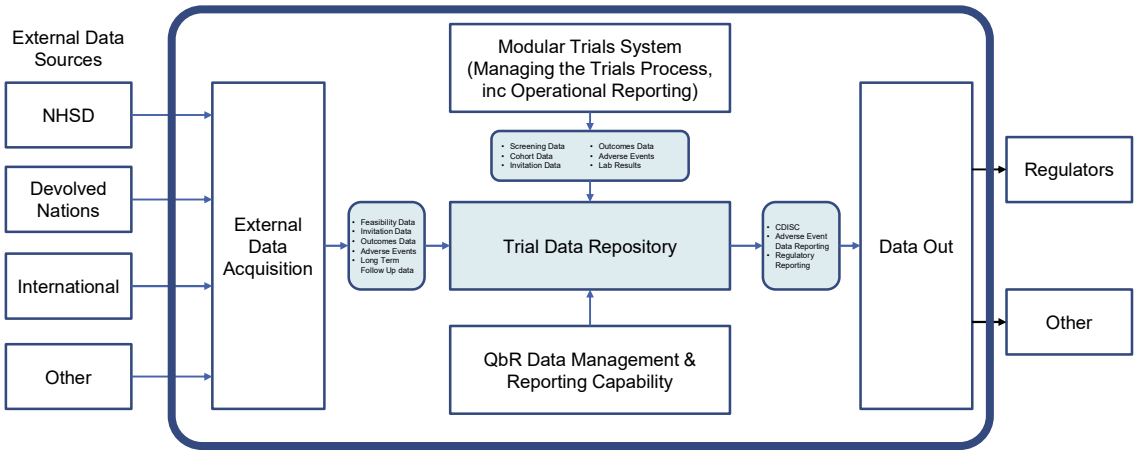

Figure 2: High level architecture required for the Protas trials management platform. (NHSD – NHS-Digital, CDISC – Clinical Data Interchange Standards Consortium [https://www.cdisc.org/]). The data types shown in the blue-shaded squares are given as examples not as an exhaustive list.

The technical Specification to be developed by the technical consultancy needs to be fully generic and neutral as regards any particular technology, proprietary architecture, software or cloud provider. If off-the-shelf software from particular providers is recommended to provide particular functionality, plausible alternatives should (where available) also need to be considered and the merits of each listed.

1 Different data standards in healthcare and clinical trials will create integration challenges and need to be addressed. Health data tends to use HL7 & similar standards and ICD/SNOMED terminologies. Clinical trials have to use CDISC standards and MedDRA terminologies (at least for reporting to regulators).

5. Protas's requirements for a technical consultancy

Interested technical consultancies responding to this RfP will need to demonstrate the appropriate design and technical expertise and will also need to demonstrate as part of this RfP that it has expertise in health data and data standards, experience of the clinical trial environment and having worked successfully with academic (or comparable) groups on previous similar assignments.

As highlighted above, this phase of work will be undertaken based on a clear understanding that the contract to build and implement the IT platform will go through a formal public procurement procedure. In order to plan for a scenario where the technical consultancy wishes to bid for or participate in a bid team as part of that IT platform procurement, the selected technical consultancy will be required to ringfence the team that works on this phase of work alongside Protas from other colleagues within the technical consultancy's organisation, together with implementing appropriate information barriers to ensure that information is only accessible by Protas and the relevant technical consultancy team members supporting Protas.
The proposed start state for the work is immediately on completion of the tender and it is required that the work will take no longer than 2 months.

6. Budget

Protas has allocated a maximum budget of £100K for this work. However, interested technical consultancies should not consider this as a target estimated value and should ensure that they submit proposals to deliver the services required in the most cost effective and efficient method, whether based on daily rates or other relevant metrics.

7. Tender process to appoint a technical consultancy

This process is not a procurement procedure subject to PCR but Protas will undertake a tender process in line with good procurement practice as follows:

- This document may be sent to potential respondents but will also be made public through the Protas website (https://protas.co.uk/).
- The process will run from 14.00 BST on 30th July to 17.00 BST on 30th August – no responses to this RfP will be accepted after this time.
- Interested parties can ask questions or seek clarification during this period – answers will be provided where possible and also published on our website and will therefore be available to other interested parties, other than where they are properly identified as (and considered by Protas to be) confidential. Questions should be sent in the first instance to tim.peakman1857@gmail.com.
- No responses will be reviewed by Protas before the deadline set out above.

- Responses are required to be submitted by email to tim.peakman1857@gmail.com. Any responses submitted via any other means shall not be evaluated by Protas.
- Please limit your main response (excluding to appendices and cvs) to 30 pages or fewer. Interested parties must ensure that responses to each of the criteria and questions set out in Appendix A are included in their submission and are concise and relevant. If cvs of key staff are included they should be no more than a page in length, and that no additional information, marketing material, etc is included. A short covering letter can also be included but is not a requirement.
- The criteria for the award of the technical consultancy contract are set out in Appendix A to this RfP. This includes details of the Pass/Fail criteria relating to the relevant mandatory/discretionary exclusion grounds and the interested party's technical ability and experience, for which interested parties must achieve a "Pass". For the avoidance of doubt, any interested party which achieves a "Fail" in any of these criteria will be excluded from this RfP process.
- Those interested parties who pass all Pass/Fail criteria, will then have their Quality and Price submissions evaluated in full. The contract will be awarded on the basis of the most economically advantageous tender as per the scored criteria and weightings set out in Appendix A.
- Protas may seek further clarification from interested parties following receipt of responses.
- Protas's current expectation is that contract award will be made within two weeks of the deadline for submitting responses.
- The contractual terms are set out (which are intended to be balanced and reasonable and will not be subject to negotiation). Interested parties are asked to review these carefully before submitting their responses, as it will be a condition of contract award that the successful technical consultancy will enter into these contractual terms and tenders are therefore assumed to be submitted on this basis.
- Protas does not guarantee to make an award to any interested party following receipt of a response to this RfP.
- Protas undertakes to provide summary feedback to unsuccessful interested parties as quickly as possible. Response times will depend on the number of responses to this request for proposal but we will try to provide feedback within three weeks of the response submission date.
- Further terms and conditions for participation in this procurement are set out in Appendix B to this RfP.

Appendix A - Criteria for Assessment of Responses

Responses to this request for proposal will be assessed according to the following criteria and weightings:

Criterion	Scoring/ Weighting	Sub-Criterion	Response Requirement	Scoring approach	Weighting
1. Exclusion Grounds	Pass/Fail	N/A	**a. Mandatory Exclusion Grounds** The detailed grounds for mandatory exclusion of an organisation are set out on this webpage, which should be referred to before completing these questions. Please indicate (yes/no) if, within the past five years you, your organisation, any person who is a member of its administrative, management or supervisory body, or any other person who has powers of representation, decision or control in the organisation been convicted anywhere in the world of any of the offences within the summary below and listed on the webpage. • Participation in a criminal organisation • Corruption • Fraud • Terrorist offences or offences linked to terrorist activities • Money laundering or terrorist financing • Child labour and other forms of trafficking in human beings If you have answered 'yes' in respect of any of the above, please provide further details, including (i) date of conviction, (ii) which of the grounds listed the conviction was for, (iii) reasons for conviction, and (iv) identity of who has been convicted. If any relevant documentation is available electronically, please provide the web address, issuing authority, and precise reference of the documents. If you have answered 'yes' in respect of any of the above, have measures been taken to demonstrate the reliability of the organisation despite the existence of a relevant ground for exclusion ('self-cleaning')? If yes, please explain these measures.	Pass/Fail – see Table A below	N/A

			b. Tax Specific Exclusion Grounds Has it been established (yes/no) for your organisation, by a judicial or administrative decision having final and binding effect in accordance with the legal provisions of any part of the UK or the legal provisions of the country in which the organisation is established (if outside the UK), that the organisation is in breach of obligations related to the payment of tax or social security contributions? If you have answered 'yes' in respect of the above, please provide further details. Please also confirm you have paid, or have entered into a binding arrangement with a view to paying, the outstanding sum including where applicable any accrued interest and/or fines. **c. Discretionary Exclusion Grounds** The detailed grounds for discretionary exclusion of an organisation are set out on this webpage, which should be referred to before completing these questions. Please indicate (yes/no) if, within the past three years, anywhere in the world any of the following situations have applied to you, your organisation or any other person who has powers of representation, decision or control in the organisation. • Breach of environmental obligations • Breach of social obligations • Breach of labour law obligations • Bankrupt or being the subject of insolvency or winding-up proceedings, where the organisation's assets are being administered by a liquidator or by the court, where it is in an arrangement with creditors, where its business activities are suspended or it is in any analogous situation arising from a similar procedure under the laws and regulations of any State • Guilty of grave professional misconduct • Entered into agreements with other economic operators aimed at distorting competition • Aware of any conflict of interest within the meaning of regulation 24 of the Public Contracts Regulations 2015 due to the participation in the procurement procedure		

			• Been involved in the preparation of the procurement procedure
			• Shown significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, a prior contract with a contracting entity, or a prior concession contract, which led to early termination of that prior contract, damages or other comparable sanctions
			• Where the organisation:
			  ○ is guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria; or
			  ○ has withheld such information or is not able to submit supporting documents required under regulation 59 of the Public Contracts Regulations 2015
			• The organisation has influenced the decision-making process of the contracting authority to obtain confidential information that may confer upon the organisation undue advantages in the procurement procedure, or to negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award.
			
			If you have answered 'yes' in respect of any of the above, have measures been taken to demonstrate the reliability of the organisation despite the existence of a relevant ground for exclusion ('self-cleaning')? If yes, please explain these measures.
			
			Note that where you are relying on a sub-contractor in order to satisfy the Technical Ability and Experience criteria, you can only do so where they will perform the services (or relevant part) for which their capacity has been relied upon and you must ensure that:
			
			(1) within your RfP response, you identify:
			• each sub-contractor
			
			• each sub-contractor's role in demonstrating the Technical Ability and Experience required
			
			• each sub-contractor's role in the performance of the services as part of your response to the Quality questions below; and		

			• submit evidence of a commitment from the relevant sub-contractor to your RfP response; and (2) each sub-contractor must separately complete the Exclusion Ground questions and achieves a "Pass".		
2. Technical Ability and Experience	Pass/Fail	N/A	Please briefly describe your relevant ability and experience in each of the following areas: • Successfully working with academic and/or comparable partners in the delivery of similar assignments; • Successfully delivering similar assignments (in environment which are comparably regulated) involving highly sensitive and confidential data; • Successfully integrating with a customer's in-house team on a remote basis in the delivery of similar assignments to programme; and • Successfully working on similar assignments in relation to the development of IT architecture for the management of highly regulated processes. Please provide short summary evidence with contact details (of up to three prior relevant assignments) to demonstrate your technical ability and experience.	Pass/Fail – see Table B below	N/A
3. Quality	85%	Team and Resources	Please describe the team structure that will work on this assignment and include a short Curriculum Vitae (CV) for the following individuals: ○ Your proposed Programme Manager for the delivery of this assignment if you are successfully appointed; and ○ Other individuals that you propose will have a significant role in the delivery of this assignment if you are successfully appointed.	Scored – see Table C below	15%
			Please describe your proposed approach to ensuring that a sufficient level of resourcing will be allocated to this assignment, particularly in view of the short timescales identified for delivery. To the extent that your proposed approach involves individuals other than those identified above working on the assignment, please identify these individuals and provide an explanation of their role.	Scored – see Table C below	15%

		Methodology	Please explain your proposed methodology for the delivery of this assignment if you are successfully appointed. As a minimum, your methodology should describe your approach to the following issues in advising on and developing the specification: o Cloud technology, hardware and software relevant to the assignment; o Inter-operability issues and integration of off-the-shelf functional components; o Whole system security (internal and external to the firewall), including organisational policy and on-going operation; o Efficient data transfer and synchronisation; and o Functional requirements of the clinical trials process.	Scored – see Table C below	15%
			Please provide an outline programme for the delivery of the assignment, bearing in mind the short timescales identified for delivery. Your programme should set out the anticipated milestone dates in respect of the key deliverables.	Scored – see Table C below	15%
		Partnering	Please describe how, in delivering the assignment, you will work collaboratively with Protas, with a particular focus on how you will work with Protas's in-house executive lead and BA team on a remote basis.	Scored – see Table C below	12.5%
		Regulatory Compliance	Please describe how, in delivering the assignment, you will work within the relevant regulatory environment, data standards and data harmonisation initiatives for healthcare data and clinical trials data in the UK and internationally.	Scored – see Table C below	12.5%
4. Price	15%		Protas expects the successful bidder to provide certainty on cost and visibility of resources allocated as possible at the outset of the contract (and throughout), including e.g. by way of a fixed or maximum fee(s) for the entire task or for certain component tasks. For evaluation purposes, Protas will assess bidders' hourly/daily rates. Any fees (including fixed fees) which are agreed with the successful bidder during the contract will be based on the tendered rates.	Scored – see Table D below	15%

The Pass/Fail criteria or scoring methodologies relevant to the questions above are as follows:

Table A – Pass/Fail criteria for Exclusion Grounds

Pass	The relevant organisation has answered 'no' in respect of each exclusion ground OR the relevant organisation has answered 'yes' to a particular exclusion ground but Protas is satisfied that the relevant organisation has either demonstrated sufficient evidence of self-cleaning within the meaning of Regulation 57(13)-(17) of the Public Contracts Regulations 2015 or Protas is satisfied that Regulation 57(5), (6) or (7) apply (in each case as relevant to the exclusion ground)
Fail	The relevant organisation has answered 'yes' to a particular exclusion ground but has not provided evidence to demonstrate self-cleaning or Protas is not satisfied that the relevant organisation has demonstrated sufficient evidence of self-cleaning (within the meaning of Regulation 57(13)-(17) of the Public Contracts Regulations 2015) or Protas is not satisfied that Regulation 57(5), (6) or (7) apply (in each case as relevant to the exclusion ground)

Table B – Pass/Fail criteria for Technical Ability and Experience

Pass	Response demonstrates that the bidder has suitable relevant experience in all of the areas identified in delivering similar assignments.
Fail	Response fails to adequately demonstrates that the bidder has suitable relevant experience in all of the areas identified in delivering similar assignments.

Table C – Scoring methodology for Quality

Score	Description
0	Unacceptable – the response fundamentally fails to address the question and/or there is no confidence that any of the proposed approaches and methods will deliver the requirements of this assignment.
1	Weak - the response demonstrates an approach / method which is of poor quality and/or provides little confidence that the proposed approaches and methods will deliver the requirements of this assignment.
2	Adequate - the response demonstrates an approach / method which is of satisfactory quality and provides adequate confidence that the proposed approaches and methods will deliver the requirements of this assignment.
3	Good - the response demonstrates an approach / method which is of good quality and provides good confidence that the proposed approaches and methods will deliver the requirements of this assignment.

4	Excellent - the response demonstrates an approach / method which is of excellent quality and provides excellent confidence that the proposed approaches and methods will deliver the requirements of this assignment.

Table D – Scoring methodology for Price

Scoring Methodology
1. Each daily/hourly rate will be multiplied by the relevant weighting identified 2. The weighted daily/hourly rates will then be added together to create a total sub-weighted amount 3. The bidder with the lowest total sub-weighted amount will receive the full 15% allocated for the Price criterion 4. All other bidders will be scored relative to the lowest priced bidder using the following formula: *lowest total sub-weighted amount/bidder's total sub-weighted amount * 15%*

Appendix B – Conditions of the Procurement

General

Interested parties must comply and ensure that their response complies with the provisions set out in this RfP. Any response which fails to comply with the provisions of this RfP may be disqualified.

Protas reserves the right, at its sole discretion, to reject any interested party that fails to comply fully with the requirements of the process set out in this RfP, or which makes any misrepresentation in supplying any information requested.

All Bids shall be in English, and all prices should be quoted in Pounds Sterling.

All Bids submitted shall remain valid for acceptance by Protas for a period of three months from the submission date. Submission of a response shall be deemed to constitute acceptance of this requirement.

Interested parties acknowledge that notification of intended contract award does not constitute a binding agreement or contract unless and until a formal written contract or contracts have been executed, and agrees that, in the event of their selection as a successful technical consultancy, they will complete all necessary steps and execute all necessary documentation.

Eligibility

By submitting a response, the interested party warrants that, save as disclosed in writing to Protas, any information supplied by it remains true, and that the interested party has not, its directors have not, and other persons (if any) having powers of representation, decision or control of the interested party have not, been convicted of any of the offences listed in Appendix A (mandatory exclusion grounds) and that the other circumstances in Appendix A (discretionary exclusion grounds) do not apply.

If the interested party makes a misrepresentation in any part of its dealings with, or responses to, Protas such interested party will be disqualified.

Non-Collusion, Canvassing and Contact

Any interested party who, in connection with this procurement:

- enters into any agreement or arrangement with any other person with the aim of preventing responses being made or as to the fixing or adjusting of the amount of any response or the conditions on which any response is made;
- offers any inducement, fee or reward to any employee or officer of Protas or any person acting as an agent, consultant or adviser for Protas in connection with this procurement;
- informs any person other than Protas of the amount or the approximate amount of the response, except where the disclosure, in confidence, of the amount of the response was necessary to obtain quotations necessary for the preparation of the response for insurance or for professional advice required for the preparation of the response;
- causes or induces any person to enter into such an agreement or arrangement as is mentioned above or to provide information about the amount or the approximate amount of any rival response;
- commits any offence under the Bribery Act 2010 in connection with this procurement;
- offers or agrees to pay or give any sum of money, inducement or valuable consideration directly or indirectly to any person for doing or having done, causing or having caused to be done, any act or omission in relation to any other response or proposed response;
- canvasses or solicits any employee or officer of Protas or any person acting as an agent, consultant or adviser for Protas in connection with this procurement; or
- contacts any employee or officer of Protas about any aspect of this procurement, except as permitted by this RfP;

will be disqualified (without prejudice to any other civil remedies available to Protas and without prejudice to any criminal liability that such conduct by an interested party may attract).

Confidentiality and Announcements

This RfP is intended for the exclusive use of the interested party and is provided on the express understanding that this RfP and the information contained in it, or in connection with it, will be regarded and treated as strictly confidential. This RfP may not be reproduced in whole or in part nor furnished to any persons other than the interested party save for the purposes of:

- taking legal and/or professional advice in connection with completing a response; and/or

- obtaining the input from any other parties that will provide information relevant to their response, provided that in each case interested parties obtain from such parties prior to such disclosure, confidentiality undertakings of at least equivalent strength to the present requirements.

All responses received by Protas will be treated as confidential in their entirety and will not be disclosed to any other party. Protas may disclose detailed information relating to responses to its officers, employees, agents, consultants or advisers where required by the tender process.

Interested parties must not make, or permit any person to make, any public announcement concerning this procurement without the prior written consent of Protas (which shall not be unreasonably withheld) except as required by law or any governmental or regulatory authority).

Conflicts of Interests

In order to ensure a fair and competitive procurement process, Protas requires that all actual or potential conflicts of interests are resolved to Protas's satisfaction prior to the submission of responses. The concept of a conflict of interest includes any situation where relevant staff members, partners, advisers/ consultants, parent or group companies or any member of their proposed supply chain have, directly or indirectly, a financial, economic or other personal interest which might be perceived to compromise their impartiality and independence in the context of the procurement procedure.

Interested parties should be proactive in seeking to prevent, identify and remedy any actual or potential conflict of interest including checking (and monitoring) with members of its bid team, advisors and any member of their proposed supply chain. As soon as interested party becomes aware of an actual, potential or perceived conflict of interests, it should immediately notify Protas. This is also an ongoing obligation on the interested party. Notifications to Protas in this regard should provide details of such actual, potential or perceived conflict of interests.

Bidder Changes

Interested parties are subject to an ongoing obligation throughout the procurement to notify Protas of any changes to any of the information that they provide. This includes, but is not limited to, changes to the identity of supply chain members or the ownership or solvency of the interested party. Protas should be notified of any changes as soon as they become apparent.

Failure to notify Protas of any changes or to comply with any of these provisions may lead to an interested party being disqualified at the sole discretion of Protas.

Changes to the Procurement Process

Interested parties are reminded that Protas, at its sole discretion, reserves the right to vary this procurement process, or to suspend the process, at any time.

Protas reserves the right, at its sole discretion, to issue amendments or modifications to this RfP at any time before the submission date. These will be issued by e-mail and responses will be assumed to take account of any such modifications and amendments.

It shall be each interested party's sole responsibility to ensure that they have understood all of the requirements, instructions and information issued under this RfP.

Disclaimer

Protas reserves the right, at its sole discretion, to change the basis of, or the procedures (including the timetable) relating to, the procurement process, to reject any, or all, of the responses, not to invite an interested party to proceed further and not award contracts for the service.

Protas shall not be obliged to appoint any of the interested parties, and Protas reserve the right not to proceed with the procurement, or any part thereof, at any time.

Nothing in the RfP and supporting documentation is, nor shall be relied upon as, a promise or representation as to any decision by Protas in relation to this procurement.

The information contained in the RfP and supporting documentation is presented in good faith and does not purport to be comprehensive or to have been independently verified.

Neither Protas nor any of their employees, officers, consultants, agents or advisers make any representation or warranty as to, or accept any responsibility or liability (except in the case of fraud or fraudulent misrepresentation) in relation to, the adequacy, accuracy, reasonableness or completeness or information which has been, or which is subsequently, made available to any interested party in connection with this RfP, orally or in writing or in whatever media.

Interested parties must take their own steps to verify the accuracy of any information which they consider relevant and are not entitled to rely on any statement or representation made by Protas or any of their advisers.

The subject matter of this RfP shall only have contractual effect when it is contained in the express terms of an executed contract.

Disqualification of interested parties

Interested parties acting in contravention of the provisions set out in the RfP or any other information provided by Protas may, at Protas's sole discretion, be disqualified from further participation in this procurement (without prejudice to any other civil or legal remedies available and without prejudice to any criminal liability which such conduct by an interested party may attract).

Costs and Expenses

All interested parties shall be responsible for all costs incurred by them in connection with all stages of this procurement. Under no circumstances will Protas be liable for any costs or expenses incurred by an interested party arising directly or indirectly from the procurement process or termination or suspension thereof, including, without limitation, any changes or adjustments made to the procurement process or documentation or disqualification of an interested party.

Terms and conditions

Protas has prepared a short set of terms and conditions for the appointment. As set out above, these are not negotiable.

Terms and conditions of the technical consultancy

THIS AGREEMENT is made on 2021

BETWEEN

(1) **Quality by Randomization** of [ADDRESS] (the "**Customer**"); and

(2) [***NAME OF THE SUPPLIER***] a company registered in [*England and Wales*] under company number [ ] whose registered office is at [ ] (the "**Supplier**")

(each a "**Party**" and together the "**Parties**").

INTRODUCTION

(A) The Customer wishes to develop a trial management platform that integrates the process for testing new medicines from trial design to data analysis and reporting (an "**IT Platform**"). It intends to undertake a procurement process to identify a third-party provider that will develop and operate the IT Platform on the Customer's behalf.

(B) The Customer now wishes to appoint a supplier to provide some initial deliverables to assist the Customer define its requirements for the IT Platform.

(C) Following a procurement processes, the Customer has selected the Supplier and wishes to appoint the Supplier to provide the deliverables set out in and on the terms of this Agreement.

IT IS AGREED as follows:

OPERATIVE PROVISIONS

1. **DEFINITIONS**

1.1 In this Agreement, unless otherwise provided or the context otherwise requires, capitalised expressions shall have the meanings set out below:

"Affiliate"	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, and for this purpose "**Control**" means, in relation to a body corporate, the power (whether direct or indirect) to direct or cause the direction of its affairs, whether by means of holding shares, possessing voting power, exercising contractual powers or otherwise and "**Controlled**" will be construed accordingly;
"Deliverables"	means the technical design specification and parameters, including a description of the necessary components and applications within a defined IT architecture, of the IT Platform that the Supplier produces for the Customer pursuant to the RfP and this Agreement (and for the avoidance of doubt does not include any of the actual components of the IT platform);
"Intellectual Property Rights"	all intellectual and industrial property rights of any kind whatsoever including patents, supplementary protection certificates, rights in Know-How, registered trade marks, registered designs, utility models, unregistered design rights, unregistered trade marks, rights to prevent passing off or unfair competition and copyright (whether in

	drawings, plans, specifications, designs and computer software or otherwise), database rights, topography rights, any rights in any invention, discovery or process, and applications for and rights to apply for any of the foregoing, in each case in the United Kingdom and all other countries in the world and together with all renewals, extensions, continuations, divisions, reissues, re-examinations and substitutions;
"Know-How"	all ideas, concepts, schemes, information, knowledge, techniques, methodology, and anything else in the nature of know how relating to the Deliverables but excluding know how already in the other Party's possession before this Agreement.
"RfP"	the Request for Proposal published by the Customer on its website http://www.protas.co.uk .

2. **TERM**

This Agreement shall come into force on the date of this Agreement and will continue until the Deliverables have been completed in accordance with the terms of this Agreement.

3. **DELIVERABLES**

3.1 The Supplier will commence work on the delivery of the Deliverables on the date of this Agreement and will complete the Deliverables by two months from the date of this Agreement.

4. **CHARGES AND PAYMENT**

4.1 The charges payable for the Deliverables will be £[INSERT] (exclusive of VAT) (the "**Charges**").

4.2 The Supplier will be entitled to invoice the Customer for:

4.2.1 50% of the Charges on the date of this Agreement; and

4.2.2 the remaining 50% of the Charges on the receipt by the Customer of the Deliverables.

4.3 Each invoice will be payable by the Customer within thirty (30) days following the date on which the invoice is received by the Customer.

5. **INTELLECTUAL PROPERTY RIGHTS**

5.1 Save as set out in this clause 5, neither Party will receive any rights in respect of the pre-existing Intellectual Property Rights of the other Party.

5.2 The Customer will own the Intellectual Property Rights in the Deliverables and will be able to use the Deliverables for the purpose of an ITT Process (as set out in clause 9 below), without the requirement for any further licence, consent, permission or payment from either the Supplier or any third party.

5.3 The Supplier, with full title guarantee, hereby:

5.3.1 assigns to the Customer (by way of present assignment of the future copyright, design right and/or database right) all future copyright, design right and/or database right comprised in the Deliverables; and

5.3.2 agrees to assign to the Customer all other Intellectual Property Rights in the Deliverables, such assignment to take place immediately and automatically upon the creation of such Deliverables.

5.4 The Supplier will, at its own cost:

5.4.1 execute all such documents and do all such acts and things as the Customer may reasonably request from time to time in order to secure the full right, title and interest of the Customer in the Intellectual Property Rights in the Deliverables; and

5.4.2 procure the irrevocable waiver of all moral rights (and any broadly equivalent rights which may exist in any territory of the world) in the Deliverables.

6. CONFIDENTIALITY

6.1 For the purposes of this clause 6.1, "**Confidential Information**" means any information that relates to a Party (or any of its Affiliates or businesses) and which is disclosed to the other Party in connection with this Agreement, but excluding information that:

6.1.1 is at the relevant time in the public domain (other than by virtue of a breach of this clause 6);

6.1.2 was received by the other Party from a third party who did not acquire it in confidence; or

6.1.3 is developed by the other Party without any breach of this Agreement.

6.2 Each Party will, subject to clause 6.3:

6.2.1 only use the other Party's Confidential Information for the purpose of performing its obligations and exercising its rights under this Agreement;

6.2.2 keep the other Party's Confidential Information secret, safe and secure; and

6.2.3 not disclose the other Party's Confidential Information to any other person.

6.3 Each Party may disclose the other Party's Confidential Information:

6.3.1 to the extent required to publicise the Agreement;

6.3.2 to the extent required by law, by an order of a court of competent jurisdiction or by any securities exchange, listing authority, governmental or regulatory body to which that Party is subject or to which that Party submits; and

6.3.3 to those of its officers, directors, employees and professional advisers who need access to that Confidential Information so that it can perform its obligations and exercise its rights under this Agreement.

7. LIMITATIONS ON LIABILITY

7.1 Subject to clauses 7.2 and 7.3, each Party's maximum aggregate liability arising out of or in connection with this Agreement, whether in contract, tort (including negligence), misrepresentation or otherwise will be limited to an amount equal to one hundred per cent (100%) of the Charges paid, due or which would have been payable under this Agreement.

7.2 Subject to clause 7.3, neither Party shall be liable to the other Party for any indirect, special or consequential loss.

7.3 Neither Party limits its liability for:

7.3.1 death or personal injury caused by its negligence, or that of its employees, agents or sub-contractors (as applicable);

7.3.2 fraud or fraudulent misrepresentation by it or its employees; or

7.3.3 any liability to the extent it cannot be limited or excluded by law.

8. **GENERAL**

8.1 Following expiry or termination of this Agreement, any provisions which expressly or impliedly continue to have effect after expiry or termination of this Agreement will continue in force.

8.2 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, and:

8.2.1 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; and

8.2.2 nothing in this clause 8.2 shall exclude any liability in respect of fraud or fraudulent misrepresentation.

8.3 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.

8.4 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.

8.5 No variation to this Agreement will be effective unless it is in writing and signed by a duly authorised representative on behalf of each of the Parties.

8.6 No term of this Agreement is intended by the Parties to be enforceable by a third party.

8.7 **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.**

8.8 The Supplier shall not assign, charge, subcontract or transfer this Agreement or any of its rights under it without the prior written consent of the Customer (such consent not to be unreasonably withheld or delayed).

9. **CONFLICTS OF INTEREST**

9.1 For the purposes of this **clause 9**, the following terms will have the meanings given to them below:

9.1.1 **"Bid Team" means any staff or agents of the Supplier or its Affiliates connected to the preparation of an ITT Response;**

9.1.2 **"Conflicted Personnel" means any staff or agents of the Supplier or its Affiliates who, because of the Supplier's relationship with the Customer under this Agreement, have or have had access to information which creates or may create an actual, potential or perceived conflict of interest;**

9.1.3 **"ITT Process" means any procurement process conducted by the Customer with regard to the supply of the IT Platform;**

9.1.4 "**ITT Response**" means the tender submitted or to be submitted by the Supplier or an Affiliate (or, where relevant, by an Other Bidder) in response to an **invitation to submit tenders issued by the Customer as part of an ITT Process;**

9.1.5 "**Other Bidder**" means any other bidder or potential bidder in the ITT Process that is not the Supplier or one of its Affiliates;

9.1.6 "**PCR**" the Public Contracts Regulations 2015 (as amended from time to time); and

9.1.7 "**Relevant Representatives**" means the officers, directors, employees, advisers and agents of the Supplier and its Affiliates.

9.2 **The Supplier:**

9.2.1 **shall take all appropriate steps to ensure that neither the Supplier nor its Affiliates or the Relevant Representatives are in a position where, in the reasonable opinion of the Customer, there is or may be an actual, potential or perceived conflict between the interests of the Supplier or its Affiliates or Relevant Representatives and the duties owed to the Customer under this Agreement or pursuant to an open and transparent ITT Process;**

9.2.2 **acknowledges and agrees that a conflict of interest may arise in situations where the Supplier or an Affiliate intends to take part in the ITT Process and, because of the Supplier's relationship with the Customer under this Agreement, the Supplier, its Affiliates and/or the Relevant Representatives have or have had access to information which could provide the Supplier and/or its Affiliates with an advantage or distort competition and create a risk that the Customer may be in breach of the principles of non-discrimination, transparency and equal treatment in the ITT Process; and**

9.2.3 **where there is or is likely to be a conflict of interest or the perception of a conflict of interest of any kind in relation to the ITT Process, shall comply with clause 9.3.**

9.3 **The Supplier will:**

9.3.1 **not assign any of the Conflicted Personnel to the Bid Team at any time;**

9.3.2 **ensure that no act or omission by itself, its staff, agents and/or Affiliates and in particular the Conflicted Personnel results in information of any kind or in any format and however so stored:**

9.3.2.1 **about this Agreement, its performance, operation and all matters connected or ancillary to it (including the Deliverables); and/or**

9.3.2.2 **which would or could in the opinion of the Customer confer an unfair advantage on the Supplier in relation to its participation in the ITT Process,**

becoming available to the Bid Team;

9.3.3 **ensure that appropriate information technology safeguards (such as, as appropriate, information barriers, encryption, password protection) are put in place to protect electronically held information from disclosure by the Conflicted Personnel to the Bid Team and vice versa; and**

9.3.4 **take such reasonable steps and execute such documents as may be reasonably requested by the Customer to minimise the risk of the distortion of competition and/or violation of the principles of transparency, non-discrimination and equal treatment.**

9.4 **Without prejudice to clauses 9.2 or 9.3, the Supplier will notify the Customer immediately of all perceived, potential and/or actual conflicts of interest that arise.**

9.5 **The Supplier acknowledges that the Customer is bound by the PCR, including regulation 24 on conflicts of interest, and that, to the extent deemed reasonably necessary by the Customer and subject to clause 6, information shared between the Customer and Supplier pursuant to this Agreement may be shared with Other Bidders in any ITT Process.**

10. **GOVERNING LAW AND JURISDICTION**

10.1 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by and construed in accordance with the laws of England and Wales.

10.2 Subject to clause 10.3, 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.

10.3 Either Party may seek interim injunctive relief or any other interim measure of protection in any court of competent jurisdiction

SCHEDULE 1 / THE DELIVERABLES

The Deliverables means:

- the technical design specification and parameters, including a description of the necessary components and applications within a defined IT architecture, of the IT Platform that the Supplier produces for the Customer pursuant to the RfP and this Agreement;

- In the form of a report which will enable the Customer to produce a specification which is suitable for conducting an ITT Process in accordance with clause 9 of this Agreement.

The Deliverables should, inter alia, include:

  - Specific reference to functions/components that will require customisation or configuration;

  - Specific reference to functions/components that are not available off the shelf;

  - Identification of necessary internal skills and resource that would Protas may need to provide for the build/test/implement phase.

The report will also include indicative timelines for the build/test/implement cycle for release one.