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Opportunity

Protas Unified Clinical Trials Management Platform

QUALITY BY RANDOMIZATION LIMITED

F02: Contract notice

Notice reference: 2022/S 000-012071

Published: 9 May 2022, 7:03pm

Section I: Contracting authority

I.1) Name and addresses

QUALITY BY RANDOMIZATION LIMITED

6 Stanley Street

SALFORD

M35GS

Email

procurement@protas.co.uk

Country

United Kingdom

NUTS code

UKD34 - Greater Manchester South West

Internet address(es)

Main address

<https://protas.co.uk/>

I.3) Communication

The procurement documents are available for unrestricted and full direct access, free of charge, at

<https://award.bravosolution.co.uk/protas/web/project/4cd04141-cd84-4dd6-84ba-8633653636ff/register>

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

<https://award.bravosolution.co.uk/protas/web/project/4cd04141-cd84-4dd6-84ba-8633653636ff/register>

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

Protas Unified Clinical Trials Management Platform

Reference number

PROT-UCTMP-01

II.1.2) Main CPV code

- 72200000 - Software programming and consultancy services

II.1.3) Type of contract

Services

II.1.4) Short description

Protas, a non-profit organisation, will facilitate the development of better treatments for common diseases and improve public health outcomes by combining smart randomized trial design with effective technology and collaborative partnerships with organisations undertaking clinical trials.

Protas seeks to engage a provider to design, develop, deploy, operate, and support a new, globally available, Unified Clinical Trials Management Platform (UCTMP). A more detailed description of the procurement is provided below. The full scope of the services required is provided in the tender documentation.

II.1.5) Estimated total value

Value excluding VAT: £30,000,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.2) Additional CPV code(s)

- 48180000 - Medical software package
- 48430000 - Inventory management software package
- 48460000 - Analytical, scientific, mathematical or forecasting software package
- 48600000 - Database and operating software package
- 48814200 - Patient-administration system
- 48814400 - Clinical information system
- 72210000 - Programming services of packaged software products
- 72220000 - Systems and technical consultancy services
- 72250000 - System and support services
- 72261000 - Software support services
- 72262000 - Software development services
- 72263000 - Software implementation services
- 72265000 - Software configuration services
- 72266000 - Software consultancy services
- 72267000 - Software maintenance and repair services
- 72316000 - Data analysis services
- 72317000 - Data storage services
- 72322000 - Data management services

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

II.2.4) Description of the procurement

Protas, a not-for-profit organisation, was formed in 2020 to transform the way clinical trials are run and to reduce the barriers to the discovery and licensing of new medicines. Large-scale randomized trials are powerful approaches to demonstrating the safety and efficacy of new medicines; the current Recovery trial used national datasets and large populations properly randomized to demonstrate the efficacy of dexamethasone in treating Covid in the most ill people as well as unequivocally demonstrating the lack of effect of hydroxyquinoline in the same patient group.

There is an opportunity for well-designed large-scale trials with randomization and clear outcomes to transform the cost of drug development. The excessive cost and complexity of the current clinical trial process has made development of new medicines (especially for common chronic conditions) a high-risk business. Phase 3 trials for drugs are very expensive (typically costing hundreds of millions of US Dollars and potentially over 1 billion US Dollars). As a consequence of the very high cost, too few participants may be recruited, or the trial may be run for too short a period to demonstrate the full effect of the treatment. As a result,

many pharmaceutical companies are re-directing their portfolios to treatments for rare diseases, the resultant lack of new treatments for common, chronic conditions will place a significant burden on healthcare systems and funders.

Well-designed trials, efficiently run can be completed typically a fraction of the average cost of a trial. To achieve this requires:

- Good design with focus on a few principal outcomes supported by follow up through health records;
- Efficient processes for running trials in as few locations as possible; and
- A unified IT system that supports data ingress, use and analysis, enables the entire process of running and monitoring the trial and complies with the regulatory and data use requirements of different national bodies.

Protas has the expertise and processes to deliver well-designed, efficiently run trials and now seeks to engage a provider to design, develop, deploy, operate, and support a new, globally available, highly configurable, first in class Unified Clinical Trials Management Platform (UCTMP). The functional and non-functional requirements of the future platform are articulated in the tender documentation. Once on contract, and through an Agile software development process, the chosen supplier will be required to define the individual implementation level requirements in collaboration with the Protas Product Team. Collaboration with the Protas Product Team will be further required during consecutive Agile sprints as platform functionality is iteratively designed, developed, and deployed in readiness for configuration for the first clinical trial. Continual verification and validation to regulatory standards will be required. As such, the contract covers development and concurrent operation and support of the platform as functionality is taken into use.

The future Protas UCTMP will be required to support all phases during the lifecycle of a typical clinical trial:

Phase 1 - Trial design.

Phase 2 - Prepare for delivery.

Phase 3 - Recruit to trial.

Phase 4 - Follow up.

Phase 5 - Close and analyse.

Phase 6 - Post-trial activities.

These phases are typical and provided as an illustration only. Clinical trial context is described in more detail in the draft Invitation to Participate in Dialogue (ITPD).

Protas' main business will be running trials for customers, but it may elect to license the UCTMP to customers to use in trials they conduct themselves (or with another third party) and Protas may be involved in training such customers (and/or another third party) in the use of UCTMP. As such, Protas expects to have the commercial freedom to license use of the UCTMP to other parties. The precise requirements that a customer of Protas may need will depend on the logistics of running a particular trial and the provider may therefore be required to provide services to Protas which are in support of a service which Protas provides to a customer (although such support and the terms of such support would be equivalent and no more onerous to those involved in a trial which Protas might run itself).

The UCTMP requirement is described functionally by 22 feature groups each with listed features and supporting detail. Additionally, a list of non-functional requirements describes the overarching properties required. The full set of requirements are set out in the Statement of Work (SoW) provided as part of the tender documents.

II.2.5) Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

II.2.6) Estimated value

Value excluding VAT: £30,000,000

II.2.7) Duration of the contract, framework agreement or dynamic purchasing system

Duration in months

84

This contract is subject to renewal

Yes

Description of renewals

The contract will be for an initial duration of 36 months. Protas will have two options to extend the contract, each option for a period of 24 months, providing a maximum contract duration of 7 years.

II.2.9) Information about the limits on the number of candidates to be invited

Envisaged number of candidates: 3

II.2.10) Information about variants

Variants will be accepted: No

II.2.11) Information about options

Options: Yes

Description of options

The contract will be for an initial duration of 36 months. Protas will have two options to extend the contract, each option for a period of 24 months, providing a maximum contract duration of 7 years.

II.2.14) Additional information

A detailed timetable is provided in the procurement documents. A high-level summary is as follows:

11:00am (GMT) on 10th June 2022: Deadline for submission of supplier responses to Selection Questionnaire

1st July 2022: Estimated date of despatch of Invitations to Participate in Dialogue (ITPD)

11th July-26th August: 7-week dialogue period (expected dates)

9th September: Estimated date of despatch of Invitations to Submit Final Tender (ISFT)

16th November: Estimated date of Contract Award

Section III. Legal, economic, financial and technical information

III.1) Conditions for participation

III.1.2) Economic and financial standing

Selection criteria as stated in the procurement documents

III.1.3) Technical and professional ability

Selection criteria as stated in the procurement documents

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Competitive dialogue

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: Yes

IV.2) Administrative information

IV.2.2) Time limit for receipt of tenders or requests to participate

Date

10 June 2022

Local time

11:00am

IV.2.3) Estimated date of dispatch of invitations to tender or to participate to selected candidates

1 July 2022

IV.2.4) Languages in which tenders or requests to participate may be submitted

English

IV.2.6) Minimum time frame during which the tenderer must maintain the tender

Duration in months: 6 (from the date stated for receipt of tender)

Section VI. Complementary information

VI.1) Information about recurrence

This is a recurrent procurement: No

VI.3) Additional information

All interested suppliers are required to register into the Protas Platform Procurement Data Room where they can access the Selection Questionnaire (SQ) and all procurement documents. Access is provided for free and there is no barrier to entry. Suppliers wishing to raise clarification questions are welcome to do so via the data room by using the communications functionality therein.

The data room can be accessed via this URL address:

<https://award.bravosolution.co.uk/protas/web/project/4cd04141-cd84-4dd6-84ba-8633653636ff/register>

Groups of economic operators may participate in this contract opportunity and are not required to have a specific legal form in order to submit a tender or a request to participate. However, Protas requires that any contract awarded by Protas pursuant to this procurement process will be entered into with a single contracting party.

This Contract Notice is linked to the Prior Information Notice (PIN) titled 'Protas Clinical Trials Management Platform' published 2 December 2021 via the www.gov.uk/find-tender service. The direct link to the PIN is here Protas Clinical Trials Management Platform - Contracts Finder. The procurement documentation relating to this contract notice fully replaces the previously published Request for Information (RFI), which is now out of date.

The Protas website provides additional information related to this procurement. Recent press releases may be particularly relevant. See - Protas | News & Stories.

All communication regarding this procurement must be conducted via the Protas Platform Procurement Data Room. Suppliers corresponding with Protas about this procurement via email will be referred to the Protas Platform Procurement Data Room.

In order to submit a request to participate in this procurement, a supplier must complete the Selection Questionnaire (SQ) and upload it to the Protas Platform Procurement Data Room no later than 11.00am (GMT) on 10th June 2022. Suppliers who expect to submit an SQ response are invited to indicate their intention to submit in advance of the deadline to Protas via the data room. This will be interpreted as the supplier's expression of interest. Suppliers that do not express an interest are still fully entitled to submit an SQ response before the deadline.

Protas reserves the right to change without notice the procedure for awarding the contract, to reject all or any bids for the contract; to terminate discussions with any or all interested parties and/or to stop the process and not award a contract at any time without liability on its part. Protas also reserves the right to award a contract for only part of the advertised scope.

Protas shall not be liable for any costs or expenses incurred by any supplier in connection with the completion and return of the information requested in this contract notice, or in the completion or submission of any tender.

VI.4) Procedures for review

VI.4.1) Review body

High Court of England & Wales

The Strand

London

Country

United Kingdom