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Contract

Protas Unified Clinical Trials Management Platform

QUALITY BY RANDOMIZATION LIMITED

F03: Contract award notice

Notice identifier: 2023/S 000-000570

Procurement identifier (OCID): ocds-h6vhtk-0335c4

Published 9 January 2023, 3:32pm

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

Region code

UKD - North West (England)

Companies House

13073677

Internet address(es)

Main address

www.protas.co.uk

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.1.6) Information about lots

This contract is divided into lots: No

II.1.7) Total value of the procurement (excluding VAT)

Value excluding VAT: £29,310,190.21

II.2) Description

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

Quality criterion - Name: Functional requirements / Weighting: 40

Quality criterion - Name: Non-functional requirements / Weighting: 25

Quality criterion - Name: Implementation aspects / Weighting: 35

Price - Weighting: Set out in tender documents

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

Price is not the only award criterion and all criteria are stated only 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: No

IV.2) Administrative information

IV.2.1) Previous publication concerning this procedure

Notice number: [2022/S 000-012071](#)

IV.2.9) Information about termination of call for competition in the form of a prior information notice

The contracting authority will not award any further contracts based on the above prior information notice

Section V. Award of contract

A contract/lot is awarded: Yes

V.2) Award of contract

V.2.1) Date of conclusion of the contract

23 December 2022

V.2.2) Information about tenders

Number of tenders received: 3

The contract has been awarded to a group of economic operators: No

V.2.3) Name and address of the contractor

Slalom Consulting Limited

London

Country

United Kingdom

NUTS code

- UK - United Kingdom

Companies House

08874662

The contractor is an SME

No

V.2.4) Information on value of contract/lot (excluding VAT)

Total value of the contract/lot: £29,310,190.21

Section VI. Complementary information

VI.4) Procedures for review

VI.4.1) Review body

High Court of England & Wales

The Strand

London

Country

United Kingdom