Award

PARIS Trial Clinical Trials EDC system: A phase 2 study of PD-1 inhibition in Rheumatoid Arthritis, Ulcerative Colitis and Sjogrens syndrome

UNIVERSITY OF BIRMINGHAM

F15: Voluntary ex ante transparency notice
Notice identifier: 2021/S 000-030689
Procurement identifier (OCID): ocds-h6vhtk-02ff58
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Section I: Contracting authority/entity

I.1) Name and addresses

UNIVERSITY OF BIRMINGHAM

University of Birmingham

BIRMINGHAM

B152TT

Contact

Susanna Ting

Email

s.y.ting@bham.ac.uk

Country

United Kingdom

NUTS code

UKG31 - Birmingham

Internet address(es)

Main address

https://www.birmingham.ac.uk/index.aspx

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Education

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

PARIS Trial Clinical Trials EDC system: A phase 2 study of PD-1 inhibition in Rheumatoid Arthritis, Ulcerative Colitis and Sjogrens syndrome

Reference number

SC9830/21

II.1.2) Main CPV code

- 48613000 - Electronic data management (EDM)

II.1.3) Type of contract

Supplies

II.1.4) Short description

The PARIS trial (Sponsored by the University of Birmingham) is an Investigator Initiated Trial which is funded by an industry collaborator. The trial is required to have a suitably compliant clinical trial database (electronic data capture (EDC) system) that is active and ready for use by January 2022. Funding is provided to support the trial to be compliant with additional regulations (International Conference on Harmonization, the Food and Drug Administration (FDA) and European Medicines Agency (EMA) standards - specifically 21 CFR Part 11 guidance.

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: £500,000

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKG31 - Birmingham

II.2.4) Description of the procurement

The PARIS trial (Sponsored by the University of Birmingham) is an Investigator Initiated Trial which is funded by an industry collaborator. The trial is required to have a suitably compliant clinical trial database (electronic data capture (EDC) system) that is active and ready for use by January 2022. Funding is provided to support the trial to be compliant with additional regulations (International Conference on Harmonization, the Food and Drug Administration (FDA) and European Medicines Agency (EMA) standards - specifically 21 CFR Part 11 guidance.

II.2.11) Information about options

Options: No

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Negotiated without a prior call for competition

- The works, supplies or services can be provided only by a particular economic operator for the following reason:

  - absence of competition for technical reasons

Explanation:

The preferred vendor for creating an EDC system for this trial is Medidata (Rave). Medidata meets the criteria outlined below that are essential for delivering the clinical trial. The company has a track record of delivering clinical trials to registration standard with other academic organisations and industry partners running clinical trials of this nature and was independently recommended to the University of Birmingham. Additionally, Medidata is in the process of undergoing a detailed audit of their systems with the University of Birmingham. This is an essential requirement to perform prior to the set-up of an electronic clinical trial database when required for registration standard trials. Critically, Medidata have successfully passed inspections by regulatory health authorities. Regular transfers of data to the industry collaborator will be required and therefore we require the same EDC platform to be used for ease of transfer.

Medidata have confirmed their ability to deliver the clinical trial database in January 2022, within the budget and using Case Report Form (CRF) libraries held by the industry collaborator.

The following are detailed reasons for the selection of Medidata as a vendor to provide an EDC system PARIS:

• Experience in relevant disease group (Rheumatoid Arthritis, Ulcerative Colitis, Sjogren's Syndrome)

• Access to CRF library for the diseases listed above

• Access to industry partner CRF libraries

• The same EDC system as the funder (industry collaborator) to enable ease of data transfer

• Able to deliver a live clinical trial database for the study by January 2022

• Successfully passed a regulatory inspection and undergoing an audit by the University of Birmingham

• Able to demonstrate compliance with regulations across all global regions

• Able to implement major trial protocol amendments (new treatment arms) without requiring temporarily closures or existing live aspects of the database

• Fall under a maximum budget of £500,000 for the whole clinical trial database

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

The procurement is covered by the Government Procurement Agreement: Yes

Section V. Award of contract/concession

Contract No

SC9830/21

Title

PARIS Trial Clinical Trials EDC system: A phase 2 study of PD-1 inhibition in Rheumatoid Arthritis, Ulcerative Colitis and Sjogrens syndrome

A contract/lot is awarded: Yes

V.2) Award of contract/concession

V.2.1) Date of conclusion of the contract

9 December 2021

V.2.2) Information about tenders

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

V.2.3) Name and address of the contractor/concessionaire

Medidata Solutions International Limited

12 Hammersmith Grove, 9th Floor

London

W6 7AP

Country

United Kingdom

NUTS code

- UKI - London

The contractor/concessionaire is an SME

No

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

Total value of the contract/lot/concession: £500,000

Section VI. Complementary information

VI.4) Procedures for review

VI.4.1) Review body

The University of Birmingham

Birmingham

B152TT

Country

United Kingdom