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Award

FaR-RMS Trial - Clinical trial database

UNIVERSITY OF BIRMINGHAM

F15: Voluntary ex ante transparency notice

Notice identifier: 2021/S 000-025023

Procurement identifier (OCID): ocids-h6vhtk-02e92d

Published 7 October 2021, 11:57am

Section I: Contracting authority/entity

I.1) Name and addresses

UNIVERSITY OF BIRMINGHAM

Edgbaston

BIRMINGHAM

B152TT

Contact

Paul Markham

Email

p.markham@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

FaR-RMS Trial - Clinical trial database

Reference number

SC9502/21

II.1.2) Main CPV code

- 72320000 - Database services
 - LA23 - For medical use

II.1.3) Type of contract

Services

II.1.4) Short description

The FaR-RMS trial (Sponsored by the University of Birmingham) is an Investigator Initiated Trial which is funded by Cancer Research UK and Bayer AG. The funding is contingent upon having a suitably compliant clinical trial database that is active and ready for use by the end of 2021. Funding is provided to support the trial to be compliant with additional regulations. The trial used an existing clinical trial database (also sourced externally) however upon review, the existing clinical trial database is not suitable for the revised scope of the trial. Therefore, a new clinical trial database that is regulatory compliant, is able to be delivered within a tight timeline and fall within budget is required.

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

- UKG - West Midlands (England)

Main site or place of performance

University of Birmingham,

Edgbaston,

Birmingham

Some work carried out at supplier premises:

Uppsala, Sweden

II.2.4) Description of the procurement

The FaR-RMS trial (Sponsored by the University of Birmingham) is an Investigator Initiated Trial which is funded by Cancer Research UK and Bayer AG. The funding is contingent upon having a suitably compliant clinical trial database that is active and ready for use by the end of 2021. Funding is provided to support the trial to be compliant with additional regulations. The trial used an existing clinical trial database (also sourced externally) however upon review, the existing clinical trial database is not suitable for the revised scope of the trial. Therefore, a new clinical trial database that is regulatory compliant, is able to be delivered within a tight timeline and fall within budget is required.

The preferred vendor for creating a clinical trial database for this trial is Viedoc TM. Viedoc TM 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 running clinical trials of this nature (international, paediatric oncology trials with multiple arms) and was independently recommended to the University of Birmingham. Additionally, Viedoc TM 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. Viedoc TM have confirmed their ability to deliver the clinical trial database in 2021 and within the budget. The detailed audit of Viedoc TM has also confirmed that it is compliant with the regulations and is therefore suitable for use in the FaR-RMS trial.

II.2.11) Information about options

Options: No

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Award of a contract without prior publication of a call for competition in the cases listed below

- The procurement falls outside the scope of application of the regulations

Explanation:

The preferred vendor for creating a clinical trial database for this trial is Viedoc TM. Viedoc TM 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 running clinical trials of this nature (international, paediatric oncology trials with multiple arms) and was independently recommended to the University of Birmingham. Additionally, Viedoc TM 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. Viedoc TM have confirmed their ability to deliver the clinical trial database in 2021 and within the budget. The detailed audit of Viedoc TM has also confirmed that it is compliant with the regulations and is therefore suitable for use in the FaR-RMS trial.

The following are detailed reasons for the selection of Viedoc TM as a vendor to provide a clinical trial database for FaR-RMS:

- Able to perform a 'rescue' mission and align an existing clinical database that is in use into a single database for the study
- Able to deliver a live clinical trial database for the study in 2021
- Qualified by the University of Birmingham as a regulatory compliant clinical trial 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

A contract/lot is awarded: Yes

V.2) Award of contract/concession

V.2.1) Date of conclusion of the contract

4 October 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

Viedoc Technologies AB

S:t Persgatan 6

Uppsala

75320

Country

Sweden

NUTS code

- SE - Sweden

Internet address

www.viedoc.com

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.3) Additional information

The standstill period for this VEAT notice will expire at midnight at the end of Monday 18th October 2021.

VI.4) Procedures for review

VI.4.1) Review body

The University of Birmingham

Edgbaston

Birmingham

B15 2TT

Country

United Kingdom