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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): ocds-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](mailto: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

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## **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

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## 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

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## **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](http://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

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## **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