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Tender

## **Provision of Clinical Trial Monitoring to the FaR-RMS Trial**

Tender for the Provision of Clinical Trial Monitoring to the FaR-RMS Trial

F02: Contract notice

Notice identifier: 2021/S 000-006675

Procurement identifier (OCID): ocds-h6vhtk-02a184

Published 31 March 2021, 2:30pm

### **Section I: Contracting authority**

#### **I.1) Name and addresses**

Tender for the Provision of Clinical Trial Monitoring to the FaR-RMS Trial

University of Birmingham

Edgbaston

B15 2TT

#### **Contact**

Peter Nobbs

#### **Email**

[P.K.G.Nobbs@bham.ac.uk](mailto:P.K.G.Nobbs@bham.ac.uk)

#### **Country**

United Kingdom

#### **NUTS code**

UKG31 - Birmingham

**Internet address(es)**

Main address

<http://www.birmingham.ac.uk>

**I.3) Communication**

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

<https://in-tendhost.co.uk/universityofbirmingham.aspx/Home>

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted to the above-mentioned address

**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**

Provision of Clinical Trial Monitoring to the FaR-RMS Trial

Reference number

SC9073/21

#### **II.1.2) Main CPV code**

- 73300000 - Design and execution of research and development

#### **II.1.3) Type of contract**

Services

#### **II.1.4) Short description**

The FaR-RMS trial The University of Birmingham Cancer Research Clinical Trials Unit are working on a collaboration with a large Pharmaceutical company to add a new arm to an existing study. The trial is a multicentre, randomised phase II trial evaluating the new therapy against a control arm in paediatric patients with relapsed/refractory rhabdomyosarcoma. Patients will receive therapy for up to 12 cycles (approx. 12 months) and will be followed-up for 5 years.

#### **II.1.6) Information about lots**

This contract is divided into lots: No

### **II.2) Description**

#### **II.2.2) Additional CPV code(s)**

- 48814400 - Clinical information system
- 33195000 - Patient-monitoring system

#### **II.2.3) Place of performance**

NUTS codes

- UKG31 - Birmingham

#### **II.2.4) Description of the procurement**

The University of Birmingham Cancer Research Clinical Trials Unit are working on a collaboration with a large Pharmaceutical company to add a new arm to an existing study. The trial is a multicentre, randomised phase II trial evaluating the new therapy against a control arm in paediatric patients with relapsed/refractory rhabdomyosarcoma. Patients will receive therapy for up to 12 cycles (approx. 12 months) and will be followed-up for 5 years.

#### **II.2.5) Award criteria**

Cost criterion - Name: Cost / Weighting: 15%

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

Duration in months

72

This contract is subject to renewal

No

#### **II.2.10) Information about variants**

Variants will be accepted: No

#### **II.2.11) Information about options**

Options: No

#### **II.2.13) Information about European Union Funds**

The procurement is related to a project and/or programme financed by European Union funds: No

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## **Section IV. Procedure**

### **IV.1) Description**

#### **IV.1.1) Type of procedure**

Open procedure

#### **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

30 April 2021

Local time

12:00pm

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

English

#### **IV.2.7) Conditions for opening of tenders**

Date

30 April 2021

Local time

12:00pm

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## **Section VI. Complementary information**

### **VI.1) Information about recurrence**

This is a recurrent procurement: No

### **VI.3) Additional information**

The proposed start date for recruitment is June 2021. We will require clinical trial monitoring services to perform on-site Source Data Verification (SDV) and monitoring of the conduct of the trial in participating sites in Europe, Canada and Asia Pacific.

Information on services required: The Sponsor (University of Birmingham) shall retain overall regulatory responsibility in its capacity as the Sponsor of the Clinical Trial pursuant and under to the Regulations. The Sponsor will enter into a separate agreement with the selected tenderer outlining the clinical trial monitoring requirements. It is anticipated that on-site monitoring services will be required at regular intervals during the recruitment and treatment stages of the trial. It is envisaged the first site will open to recruitment in Jun 2021 and monitoring the first monitoring visits will be performed in July/August 2021.

Monitoring Requirements The tenderer will work closely with the Sponsor team to effectively monitor the trial conduct at sites. The Sponsor team will perform Site Initiation visits and remote monitoring of sites and we are seeking tenderer to specifically perform the on-site visits and report the findings to the Sponsor team. Active Site Management (e.g., monitoring and reporting recruitment, provision of documents, general issues) is not required by the tenderer as this will be performed by the Sponsor team. However, the tenderer will be required to follow-up matters specifically related to the on-site monitoring visits that they have performed. A separate close-out visit is not required and where possible, close-out activities should be performed within the number of visits planned for sites (see table-below). The tenderer will have a one-to-one relationship with the Sponsor team to ensure the smooth and efficient running of the trial.

### **VI.4) Procedures for review**

#### **VI.4.1) Review body**

University of Birmingham

Edgbaston

B15 2TT

Country

United Kingdom