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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

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

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

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

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