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Award

Glo-BNHL international clinical site monitoring

THE UNIVERSITY OF BIRMINGHAM

F15: Voluntary ex ante transparency notice

Notice identifier: 2024/S 000-000664

Procurement identifier (OCID): ocds-h6vhtk-042bb3

Published 9 January 2024, 3:08pm

Section I: Contracting authority/entity

I.1) Name and addresses

THE UNIVERSITY OF BIRMINGHAM

Edgbaston

BIRMINGHAM

B152TT

Contact

Kseniya Samsonik

Email

K.Samsonik@bham.ac.uk

Country

United Kingdom

Region code

UKG31 - Birmingham

Companies House

RC000645

Internet address(es)

Main address

www.birmingham.ac.uk

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

Glo-BNHL international clinical site monitoring

Reference number

SC12209/24

II.1.2) Main CPV code

- 73000000 - Research and development services and related consultancy services

II.1.3) Type of contract

Services

II.1.4) Short description

Glo-BNHL is an international multi-arm clinical trial developed in collaboration with a number of key childhood cancer research organisations, including Innovative Therapies

for Children with Cancer (ITCC) and the European Intergroup for Childhood NHL (EICNHL) in Europe, and the Children's Oncology Group (COG) in North America. The trial will be delivered globally with support from these organisations and in partnership with the C17 Council in Canada and the Australia and New Zealand Children's Haematology and Oncology Group (ANZCHOG). The trial is jointly funded by Cancer Research UK, Fight Kids Cancer and industry collaborators (currently ADC Therapeutics and Regeneron Pharmaceuticals). The funding provided is contingent upon the use of vendors with a track record of delivering clinical trials of this kind.

The Cancer Research UK Clinical Trials Unit (CRCTU) at the University of Birmingham is not able to perform monitoring on an international scale, therefore a suitable third-party vendor must be engaged for this critical work.

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: £3,400,000

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKG31 - Birmingham

II.2.4) Description of the procurement

Glo-BNHL is an international multi-arm clinical trial developed in collaboration with a number of key childhood cancer research organisations, including Innovative Therapies for Children with Cancer (ITCC) and the European Intergroup for Childhood NHL (EICNHL) in Europe, and the Children's Oncology Group (COG) in North America. The trial will be delivered globally with support from these organisations and in partnership with the C17 Council in Canada and the Australia and New Zealand Children's Haematology and Oncology Group (ANZCHOG). The trial is jointly funded by Cancer Research UK, Fight Kids Cancer and industry collaborators (currently ADC Therapeutics and Regeneron Pharmaceuticals). The funding provided is contingent upon the use of vendors with a track record of delivering clinical trials of this kind.

The Cancer Research UK Clinical Trials Unit (CRCTU) at the University of Birmingham is not able to perform monitoring on an international scale, therefore a suitable third-party vendor must be engaged for this critical work.

The preferred vendor for clinical site monitoring is Premier Research. Premier were selected in 2020 to work on the Far-RMS trial after going to tender because they most closely fulfilled our needs as detailed below:

? They are familiar with working with academic institutions of our kind, with over 85% of their client base being emerging sponsors and academic institutes

? They have extensive experience in haemato-oncology projects operating globally (194 projects to date)

? They have experience in the paediatric arena (261 studies over the past 5 years, 17 of those global, haemato-oncology studies)

? They have a specialised paediatric training programme to ensure staff understand the unique challenges of paediatric research

? They have expertise in global monitoring, having conducted studies in 75 countries worldwide and having 21 offices worldwide

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 clinical site monitoring is Premier Research.

? They are familiar with working with academic institutions of our kind, with over 85% of their client base being emerging sponsors and academic institutes

? They have extensive experience in haemato-oncology projects operating globally (194 projects to date)

? They have experience in the paediatric arena (261 studies over the past 5 years, 17 of those global, haemato-oncology studies)

? They have a specialised paediatric training programme to ensure staff understand the unique challenges of paediatric research

? They have expertise in global monitoring, having conducted studies in 75 countries worldwide and having 21 offices worldwide

When deciding upon a partner to work with us on Glo-BNHL, we felt the expertise detailed above, as well as the following other considerations, made Premier the right choice for this trial::

? Proven expertise in oncology trials, particularly rare disease trials

? Proven expertise in paediatric trials

? Proven expertise in global trials

? Ability to perform interim and follow-up site monitoring visits (and proven experience of doing so) in the following countries: UK, Europe (Austria, Belgium, France, Germany, Italy, Netherlands, NOPHO (Sweden, Norway, Denmark, Finland), Poland, Spain), USA, Canada, Australia, New Zealand and Israel

? Ability to perform interim and follow-up site monitoring visits across 45 sites

? Ability to support the volume of data that will be produced by 30 patients per treatment arm according to the treatment schedule outlined in the Glo-BNHL protocol

? Ability to work with the procedures and systems of the CRCTU at the University of Birmingham

? Ability to develop a monitoring plan in conjunction with the Glo-BNHL trial management team

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

The procurement is covered by the Government Procurement Agreement: No

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

9 January 2024

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

Premier Research Group Limited

Reading

Country

United Kingdom

NUTS code

- UKJ11 - Berkshire

Companies House

04671020

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: £0.01

Section VI. Complementary information

VI.4) Procedures for review

VI.4.1) Review body

University Of Birmingham

Edgbaston

Country

United Kingdom