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Award

## **GLO-BNHL: A Global Study of Novel Agents in Paediatric and Adolescent Relapsed and Refractory B-cell non-Hodgkin Lymphoma.**

THE UNIVERSITY OF BIRMINGHAM

F15: Voluntary ex ante transparency notice

Notice identifier: 2022/S 000-018410

Procurement identifier (OCID): ocds-h6vhtk-034e92

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### **Section I: Contracting authority/entity**

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

THE UNIVERSITY OF BIRMINGHAM

Chancellors Close

BIRMINGHAM

B152TT

#### **Contact**

Karen Aird

#### **Email**

[k.aird@bham.ac.uk](mailto:k.aird@bham.ac.uk)

#### **Telephone**

+44 1214158491

**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**

GLO-BNHL: A Global Study of Novel Agents in Paediatric and Adolescent Relapsed and Refractory B-cell non-Hodgkin Lymphoma.

Reference number

SC10895/22

**II.1.2) Main CPV code**

- 48611000 - Database software package

**II.1.3) Type of contract**

Supplies

**II.1.4) Short description**

The GLO-BNHL trial (sponsored by the University of Birmingham) is a platform study which is funded by industry collaborators and Cancer Research UK. The trial is required to have a suitably compliant clinical trial database (electronic data capture (EDC) system) that is active and ready for use by September 2022. Funding is provided to support the trial to be compliant with additional regulations (International Conference on Harmonization, the Food and Drug Administration (FDA) and European Medicines Agency (EMA) standards - specifically 21 CFR Part 11 guidance.

#### **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: £587,644.28

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

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

- 48610000 - Database systems
- 48620000 - Operating systems

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

NUTS codes

- UKG - West Midlands (England)

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

The GLO-BNHL trial (sponsored by the University of Birmingham) is a platform study which is funded by industry collaborators and Cancer Research UK. The trial is required to have a suitably compliant clinical trial database (electronic data capture (EDC) system) that is active and ready for use by September 2022. Funding is provided to support the trial to be compliant with additional regulations (International Conference on Harmonization, the Food and Drug Administration (FDA) and European Medicines Agency (EMA) standards - specifically 21 CFR Part 11 guidance.

#### **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:

Medidata Rave are an established provider of electronic remote data capture (eRDC) systems. The company has a track record of delivering clinical trial databases to 21 CFR Part 11 standards. Additionally, Medidata has undergone a detailed audit of their systems by the University of Birmingham and have successfully passed inspections by regulatory health authorities.

The industry collaborator use Medidata Rave as their database provider and as such house a Case Report Form (CRF) Library within the platform which will be used for this trial. This library is not accessible elsewhere. In addition, regular transfers of data to the industry collaborator will be required which require the same eRDC system for ease of transfer. Additionally, drug supply will be managed within the system and Medidata have established relationships with the industry partners preferred drug distributor.

The following are detailed reasons for the selection of Medidata as a vendor to provide an EDC system GLO-BNHL:

- Experience in relevant disease group
- Access to CRF library for the disease area
- Access to industry partner CRF libraries
- The same eRDC system as the funder (industry collaborator) to enable ease of data transfer
- Able to deliver a live clinical trial database for the study by September 2022
- Successfully passed a regulatory inspection and audit by the University of Birmingham
- Able to demonstrate compliance with regulations across all global regions

- Able to implement major trial protocol amendments (new treatment arms) without requiring temporarily closures or existing live aspects of the database.
- Able to manage a treatment management system with direct access to drug distributor systems

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

The procurement is covered by the Government Procurement Agreement: No

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### **Section V. Award of contract/concession**

#### **Contract No**

SC10895/22

#### **Title**

GLO-BNHL: A Global Study of Novel Agents in Paediatric and Adolescent Relapsed and Refractory B-cell non-Hodgkin Lymphoma.

A contract/lot is awarded: Yes

#### **V.2) Award of contract/concession**

##### **V.2.1) Date of conclusion of the contract**

30 June 2022

##### **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**

Medidata Solutions International Limited

London

Country

United Kingdom

NUTS code

- UKI - London

The contractor/concessionaire is an SME

No

#### **V.2.4) Information on value of contract/lot/concession (excluding VAT)**

Initial estimated total value of the contract/lot/concession: £587,644.28

Total value of the contract/lot/concession: £587,644.28

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## **Section VI. Complementary information**

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

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

University of Birmingham

Birmingham

Country

United Kingdom