Award

Glo-BNHL Central Review of Imaging and Clinical Data

THE UNIVERSITY OF BIRMINGHAM

F15: Voluntary ex ante transparency notice
Notice identifier: 2025/S 000-001970
Procurement identifier (OCID): ocds-h6vhtk-04d4e5
Published 21 January 2025, 9:30am

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

UK Register of Learning Providers (UKPRN number)

10006840

Internet address(es)

Main address

www.bham.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 Central Review of Imaging and Clinical Data

Reference number

SC13334/24

II.1.2) Main CPV code

- 85150000 - Medical imaging 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 central review of imaging and clinical data, 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: £685,056.07

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKG - West Midlands (England)

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 central review of imaging and clinical data, therefore a suitable third-party vendor must be engaged for this critical work.

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

- No tenders or no suitable tenders/requests to participate in response to open procedure

Explanation:

Glo-BNHL

A Global Study of Novel Agents in Paediatric and Adolescent Relapsed and Refractory B-

cell Non-Hodgkin Lymphoma

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 central review of imaging and clinical data, therefore a suitable third-party vendor must be engaged for this critical work.

The preferred vendor for central review of imaging and clinical data is Medidata. Medidata have been selected because:

? None of the vendors who applied through the open tender process were successful (Medidata did not apply)

? Medidata already operate the Glo-BNHL Electronic Data Capture (EDC) system which will allow for seamless integration of the central review with the rest of the trial data

? They have experience in the relevant disease group, B-cell Non-Hodgkin's Lymphoma (B-NHL)

? They have access to a CRF library for B-NHL and to industry partner CRF libraries

? They are able to deliver a live global central review system within 6-8 weeks

? They are able to demonstrate compliance with regulations across all global regions

? They are able to implement major trial protocol amendments (e.g. new treatment arms) without requiring temporary closures of existing live aspects of the database

? They can provide visibility on all imaging activity, including access to DICOM files/images, videos, imaging data and metadata

? They are able to review and mask Patient Health Information (PHI)

? They offer single sign-on and EDC unification

? They can provide regulatory compliant digital storage and archival

? They provide upload check to sites and raise data queries

? They can allow real-time, read-only access to UoB and can work with any third party imaging specialist to carry out the review

? They perform data reconciliation between imaging and the EDC

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 Medidata the right choice for this trial:

1. Experience working with CRCTU

o Medidata are familiar with our way of working and the Glo-BNHL study; existing Glo-BNHL EDC protocols and documentation can be quickly adapted, thereby saving time and providing greater value for money

o There is no lag time associated with familiarising the Medidata team with the study

o Sites will not be required to work with multiple providers and will instead use the Medidata system they are familiar with

o We have an established relationship with Medidata and they have already demonstrated their ability to deliver, therefore risk is mitigated by working with them again

2. There is an existing MSA between Medidata and UoB

o Having an MSA in place significantly speeds up the process of contracting with Medidata and means we will not delay the progress of the trial, benefiting the patients waiting for novel treatments

o We can begin working with Medidata upon execution of a Work Order, significantly reducing the timelines for opening the study as well as reducing the burden on the University support services

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

13 December 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

Medidata Solutions International Ltd

London

Country

United Kingdom

NUTS code

- UKI3 - Inner London – West

Companies House

09639306

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: £685,056.07

Section VI. Complementary information

VI.3) Additional information

A Global Study of Novel Agents in Paediatric and Adolescent Relapsed and Refractory B-cell Non-Hodgkin Lymphoma

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 central review of imaging and clinical data, therefore a suitable third-party vendor must be engaged for this critical work.

Medidata have been selected because:

? None of the vendors who applied through the open tender process were successful

? Medidata already operate the Glo-BNHL Electronic Data Capture (EDC) system which will allow for seamless integration of the central review with the rest of the trial data

? They have experience in the relevant disease group, B-cell Non-Hodgkin's Lymphoma (B-NHL)

? They have access to a CRF library for B-NHL and to industry partner CRF libraries

? They are able to deliver a live global central review system within 6-8 weeks

? They are able to demonstrate compliance with regulations across all global regions

? They are able to implement major trial protocol amendments (e.g. new treatment arms) without requiring temporary closures of existing live aspects of the database

? They can provide visibility on all imaging activity, including access to DICOM files/images, videos, imaging data and metadata

? They are able to review and mask Patient Health Information (PHI)

? They offer single sign-on and EDC unification

? They can provide regulatory compliant digital storage and archival

? They provide upload check to sites and raise data queries

? They can allow real-time, read-only access to UoB and can work with any third party imaging specialist to carry out the review

? They perform data reconciliation between imaging and the EDC

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 Medidata the right choice for this trial:

1. Experience working with CRCTU

o Medidata are familiar with our way of working and the Glo-BNHL study; existing Glo-BNHL EDC protocols and documentation can be quickly adapted, thereby saving time and providing greater value for money

o There is no lag time associated with familiarising the Medidata team with the study

o Sites will not be required to work with multiple providers and will instead use the Medidata system they are familiar with

o We have an established relationship with Medidata and they have already demonstrated their ability to deliver, therefore risk is mitigated by working with them again

2. There is an existing MSA between Medidata and UoB

o Having an MSA in place significantly speeds up the process of contracting with Medidata and means we will not delay the progress of the trial, benefiting the patients waiting for novel treatments

o We can begin working with Medidata upon execution of a Work Order, significantly reducing the timelines for opening the study as well as reducing the burden on the University support services

Criteria for vendor:

? Able to conduct independent central review of cross-sectional imaging by CT or MRI, of

PET-CT scans, and of bone marrow aspirate, bone marrow trephine and lumbar puncture pathology reports for a global, multi-centre clinical trial

? Provide evidence of previous relevant experience of conducting independent central review of cross-sectional imaging by CT or MRI, of PET-CT scans, and of bone marrow aspirate, bone marrow trephine and lumbar puncture pathology reports, with patient and site numbers similar to those of Glo-BNHL, in similar geographical locations

? Collaborate with the Sponsor (University of Birmingham) to develop the necessary documentation and procedures for this project

? Able to begin work immediately

? Able to translate site manuals/documents into the languages of the countries specified (UK, Europe (Austria, Belgium, France, Germany, Italy, Netherlands, Sweden, Norway, Denmark, Finland, Poland, Spain), USA, Canada, Australia, New Zealand and Israel)

? Able to work to the International Pediatric Non-Hodgkin Lymphoma Response criteria

? Provide evidence of having worked to the International Pediatric Non-Hodgkin Lymphoma Response criteria before

? Able to receive data electronically

? Can anonymise data

? Can operate 2+1 read design

? Able to detail how readers are selected and utilised for individual projects

? Able to review the patient numbers and time points as detailed in the protocol

? Able to batch read in the pattern detailed in the protocol

? Able to complete a batch read within 2 weeks of receipt of all required data

? Allow the Sponsor (University of Birmingham) to regularly export raw data (e.g. after batch reads)

? Perform full data transfer to the Sponsor (University of Birmingham) to allow interim and final analysis

? Complete closeout activities in a timely manner

? Archive data

? Be prepared to work with UoB College IT department to ensure that they are compatible with the local network to facilitate security and transfer of data to other computers and storage solutions

? Assign a dedicated company representative with whom the Sponsor (University of Birmingham) can make contact if required

? Respond to technical queries from sites in a timely manner

? Detail methods to resolve any issues with sites accessing the portal in the event that firewalls block access

? Have examples of excellent customer service, and how customer satisfaction is ensured

? Operate to ICH E6 guidelines

? Demonstrate how data queries are handled

? Allow the Sponsor (University of Birmingham) to have visibility of site data and data queries

? Demonstrate how data queries that are not resolved by sites in a timely manner are escalated

? Support the study until LPLV in December 2027 for Treatment Arm I & Treatment Arm II

? Able to support the study beyond this date for an estimated 7 years in total

? Host an Investigator meeting as part of the set-up process

? Support the Sponsor (University of Birmingham) during the set-up process and throughout the project

? Provide support to users from 45 sites internationally (estimate 40% North America and 60% RoW)

? Train and support 2 staff from each site, plus 2 staff from the Sponsor (University of Birmingham)

? Train site staff in use of the system and assess site staff competency

? Have a sustainability and environmental policy and goals

? Provide a breakdown of costs for the specific items to be supplied excluding VAT for the base price of the system including any optional items to meet the requirements of the specification

? Provide a breakdown of costs for the specific items excluding VAT for any additional desirable/optional services that you wish to recommend over and above those required to meet the specification

? Proven expertise in oncology trials, particularly rare disease trials

? Proven expertise in paediatric trials

? Proven expertise in global trials

? 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

VI.4) Procedures for review

VI.4.1) Review body

University of Birmingham

Edgbaston

Country

United Kingdom