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Tender

## **(NU/1782) Supply and Installation of a Clinical Data Management System and a Randomisation System**

Newcastle University

F02: Contract notice

Notice identifier: 2022/S 000-025618

Procurement identifier (OCID): ocds-h6vhtk-0367f4

Published 13 September 2022, 11:28am

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

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

Newcastle University

Newcastle University, Procurement Services, Kingsgate

Newcastle

NE1 7RU

#### **Contact**

Dr Emma Barksby

#### **Email**

[emma.barksby@ncl.ac.uk](mailto:emma.barksby@ncl.ac.uk)

#### **Telephone**

+44 1912086298

**Country**

United Kingdom

**Region code**

UKC22 - Tyneside

**Internet address(es)**

Main address

<https://www.ncl.ac.uk>

Buyer's address

<https://www.ncl.ac.uk>

**I.3) Communication**

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

<https://procontract.due-north.com/>

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

<https://procontract.due-north.com/>

**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**

(NU/1782) Supply and Installation of a Clinical Data Management System and a Randomisation System

Reference number

DN629737

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

- 48810000 - Information systems

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

Supplies

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

Newcastle Clinical Trials Unit (NCTU) is a UKCRC Registered CTU that works in collaboration with investigators to design and deliver clinical trials and studies answering important clinical questions, whose findings bring substantial impact to patients and the NHS; it has a portfolio across many clinical disciplines and from different funders (public, commercial, and charitable). There are currently over 40 active interventional trials with a total funding value in excess of £30m, these include international trials and a growing portfolio of trials with adaptive designs. Most of the portfolio are regulated by the Medicines for Healthcare Products Regulatory Agency (MHRA).

NCTU works in a demanding and constantly evolving ethical, legal, regulatory and scientific landscape, across multiple countries. We seek opportunities for faster, more efficient, cost effective, and better research. NCTU requires systems that ensure robust trial design are conducted in line with MHRA and other legislated regulatory requirements that stand up to international scrutiny. The system(s) must be suitable for use in academic trials units and ensure they operate in a way which is compliant with applicable legislation. The systems should combine excellent functionality with customisability that will also require the set-up time of trials to be minimised without impacting on staff time needed to develop, test, and deploy trials and studies within the system. Staff move between locations to work, including from NHS Trusts and from home, and thus secure access from any location is needed to both build and manage the systems.

The scope is for the supply, implementation and support for a Clinical Data Management System and Randomisation System to be used by all members of the NCTU, and by trial teams across multiple clinical sites, nationally and globally. The requirements are for established cloud-based, off the shelf solutions which are in use within clinical trial environments. The systems must be accessed via a web-based interface. The systems must have different user profiles to support the setting up, management and data removal for statistical analysis.

This tender process is divided two lots. Suppliers may submit a bid for one of the lots or both lots. Each Lot will be assessed separately. Lot 1 - Clinical Data Management System and Lot 2 – Randomisation System.

### **II.1.5) Estimated total value**

Value excluding VAT: £3,750,000

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

This contract is divided into lots: Yes

Tenders may be submitted for all lots

## **II.2) Description**

### **II.2.1) Title**

Lot 1 Clinical Data Management System

Lot No

1

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

- 48600000 - Database and operating software package

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

NUTS codes

- UKC22 - Tyneside

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

Newcastle Clinical Trials Unit (NCTU) is a UKCRC Registered CTU that works in collaboration with investigators to design and deliver clinical trials and studies answering important clinical questions, whose findings bring substantial impact to patients and the NHS; it has a portfolio across many clinical disciplines and from different funders (public, commercial, and charitable). There are currently over 40 active interventional trials with a total funding value in excess of £30m, these include international trials and a growing portfolio of trials with adaptive designs. Most of the portfolio are regulated by the Medicines for Healthcare Products Regulatory Agency (MHRA).

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

Price is not the only award criterion and all criteria are stated only in the procurement documents

### **II.2.6) Estimated value**

Value excluding VAT: £2,000,000

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

## **system**

Duration in months

60

This contract is subject to renewal

Yes

Description of renewals

The initial contract term shall be for 5 years from the go-live date with an option to extend the contract for an additional 5 years, or for periods of 2 years thereafter. The total number of years for live running before a full re-tender exercise is undertaken shall not exceed 15 years. The justification for the length of contract is length of time for the clinical trials and the difficulty of extracting the data from live trials.

### **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

## **II.2) Description**

### **II.2.1) Title**

Lot 2 Randomisation System

Lot No

2

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

- 48600000 - Database and operating software package

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

NUTS codes

- UKC22 - Tyneside

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

Newcastle Clinical Trials Unit (NCTU) is a UKCRC Registered CTU that works in collaboration with investigators to design and deliver clinical trials and studies answering important clinical questions, whose findings bring substantial impact to patients and the NHS; it has a portfolio across many clinical disciplines and from different funders (public, commercial, and charitable). There are currently over 40 active interventional trials with a total funding value in excess of £30m, these include international trials and a growing portfolio of trials with adaptive designs. Most of the portfolio are regulated by the Medicines for Healthcare Products Regulatory Agency (MHRA).

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This tender process is divided into two lots. Suppliers may submit a bid for one of the lots or both lots. Each Lot will be assessed separately. Lot 1 - Clinical Data Management System and Lot 2 – Randomisation System.

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

Price is not the only award criterion and all criteria are stated only in the procurement documents

### **II.2.6) Estimated value**

Value excluding VAT: £1,750,000

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

Duration in months

60

This contract is subject to renewal

Yes

Description of renewals

The initial contract term shall be for 5 years from the go-live date with an option to extend the contract for an additional 5 years, or for periods of 2 years thereafter. The total number of years for live running before a full re-tender exercise is undertaken shall not exceed 15 years. The justification for the length of contract is length of time for the clinical trials and the difficulty of extracting the data from live trials.

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Options: Yes

Description of options

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### **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

17 October 2022

Local time

12:00pm

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

English

#### **IV.2.6) Minimum time frame during which the tenderer must maintain the tender**

Duration in months: 3 (from the date stated for receipt of tender)

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

Date

17 October 2022

Local time

2:00pm

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## Section VI. Complementary information

### VI.1) Information about recurrence

This is a recurrent procurement: No

### VI.4) Procedures for review

#### VI.4.1) Review body

Newcastle University

Newcastle upon Tyne

Country

United Kingdom

Internet address

<https://www.ncl.ac.uk>

#### VI.4.3) Review procedure

Precise information on deadline(s) for review procedures

Newcastle University will incorporate a minimum 10 calendar day standstill period at the point information on the award of the contract is communicated to tenderers. This period allows unsuccessful tenderers to seek further debriefing before the contract is entered into. Applicants have 2 working days from notification of the award decision to request additional debriefing and 4 / 4 that information has to be provided a minimum of 3 working days before expiry of the standstill period. Such additional information should be requested from the address referred to in part 1.1 above. If an appeal regarding the award of a contract has not been successfully resolved, the Public Contracts Regulations 2015 provide for aggrieved parties who have been harmed or are at risk of harm by a breach of the rules to take action in the High Court (England, Wales and Northern Ireland). Any such action must be brought promptly. Where a contract has not been entered into the Court may order the setting aside of the award decision or order the authority to amend any document and may award damages. If the contract has been entered into the Court may only award damages