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Tender

# **Digital Site File Application**

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

F02: Contract notice

Notice identifier: 2023/S 000-029693

Procurement identifier (OCID): ocds-h6vhtk-0408fd

Published 9 October 2023, 1:38pm

## **Section I: Contracting authority**

## I.1) Name and addresses

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital, Freeman Road, High Heaton

Newcastle-upon-Tyne

NE7 7DN

#### Contact

Ewan Bond

#### **Email**

ewan.bond@nhs.net

#### **Telephone**

+44 1912138916

### Country

**United Kingdom** 

Region code

UKC22 - Tyneside

Internet address(es)

Main address

https://www.newcastle-hospitals.nhs.uk

Buyer's address

https://www.newcastle-hospitals.nhs.uk

### I.3) Communication

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

https://health-family.force.com/s/Welcome

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

https://health-family.force.com/s/Welcome

Tenders or requests to participate must be submitted to the above-mentioned address

Electronic communication requires the use of tools and devices that are not generally available. Unrestricted and full direct access to these tools and devices is possible, free of charge, at

https://health-family.force.com/s/Welcome

## I.4) Type of the contracting authority

Body governed by public law

## I.5) Main activity

Health

## **Section II: Object**

### II.1) Scope of the procurement

### II.1.1) Title

Digital Site File Application

#### II.1.2) Main CPV code

48000000 - Software package and information systems

#### II.1.3) Type of contract

Supplies

#### II.1.4) Short description

The Clinical Research Directorate of the Newcastle upon Tyne NHS Foundation Trust currently maintains a large number of paper site files relating to study governance. Each site file contains documents such as study protocols, ethics regulatory approvals, delegation logs, training logs, consent forms and email correspondence. Each study will have between three and ten large lever arch site files and there are currently 1,400 studies in progress.

Many of the above documents are dynamic and version-controlled and paper copies of all changes must be retained for audit purposes. After study closure the files are sent to an off-site storage facility for periods ranging from five to 25 years depending on the nature of the study.

The Directorate wishes to implement a fully electronic site file for each study that will vastly reduce the use of paper documents, reduce the amount of staff time spent on printing and filing and eliminate the requirement to use an off-site storage facility to archive the documents of studies that have closed.

The system must have the facility to:

- a. Store and version-control documents
- b. Allow electronic signature of documents
- c. Be accessed and viewed remotely by non-trust employees with appropriate access controls
- d. Be aligned with Good Clinical Practice (GCP) expectations around controls, security, training and validation (Section 10.5.3 in the Grey Guide)
- e. Comply with Medicines & Healthcare products Regulatory Agency (MRHA) regulatory

#### requirements

- f. Create an audit trail for all activities in the system.
- g. Create a comprehensive folder structure with sub-folders to facilitate storage and easy retrieval of documents
- h. Be configurable to organisational requirements
- j. Have search functionality for the location of documents with multiple options including pdf
- j. Exchange regulatory and source documentation with Sponsor/CTU
- k. Manage study timelines via alerts e.g. submission of annual reports
- I. Manage "live documents" e.g. amendment logs, delegation logs, AE/SAE logs

#### II.1.6) Information about lots

This contract is divided into lots: No

### II.2) Description

#### II.2.3) Place of performance

**NUTS** codes

• UKC22 - Tyneside

Main site or place of performance

NE3 3HD

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

To procure a Digital Site File

#### II.2.5) Award criteria

Quality criterion - Name: Social Value / Weighting: 10

Quality criterion - Name: Specification / Weighting: 70

Cost criterion - Name: Commercial / Weighting: 20

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

Duration in months

60

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: No

## IV.2) Administrative information

### IV.2.2) Time limit for receipt of tenders or requests to participate

Date

10 November 2023

Local time

5:00pm

#### 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

Tender must be valid until: 28 February 2024

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

Date

9 October 2023

Local time

2:00pm

# **Section VI. Complementary information**

## VI.1) Information about recurrence

This is a recurrent procurement: Yes

Estimated timing for further notices to be published: January 2028

## VI.4) Procedures for review

VI.4.1) Review body

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Regent Point

**NEWCASTLE UPON TYNE** 

NE7 7DN

Email

procurement@noecpc.nhs.uk

Country

**United Kingdom** 

Internet address

https://www.noecpc.nhs.uk