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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](mailto: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

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## **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
- l. 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

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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: 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

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## **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](mailto:procurement@noecpc.nhs.uk)

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<https://www.noecpc.nhs.uk>