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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
- 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

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>