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Planning

Electronic Investigator Site File system (eISF) - Medical Research

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

F01: Prior information notice

Prior information only

Notice identifier: 2023/S 000-016662

Procurement identifier (OCID): ocds-h6vhtk-03d5a9

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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

Additional information can be obtained from 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

Ministry or any other national or federal authority

I.5) Main activity

Health

Section II: Object**II.1) Scope of the procurement****II.1.1) Title**

Electronic Investigator Site File system (eISF) - Medical Research

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 requirement is to provide an electronic Investigator Site File system (eISF) for the digitisation, administration, storage, management and approval of research documentation. The solution will require access for around 600-1000 end users, this isn't expected to be concurrent.

II.1.5) Estimated total value

Value excluding VAT: £100,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKC2 - Northumberland and Tyne and Wear

II.2.4) Description of the procurement

To procure a digital site file for medical research carried out at a UK Hospital for the digitisation, administration, storage, management and approval of research documentation.

II.3) Estimated date of publication of contract notice

5 June 2023

Section IV. Procedure

IV.1) Description

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: No

Section VI. Complementary information

VI.3) Additional information

To procure a digital site file for medical research carried out at a UK Hospital for the digitisation, administration, storage, management, and approval of research documentation.

Additional information

The Hospital maintains vast numbers 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 Hospital wishes to implement a fully electronic site file for each study that eliminates the use of paper documents, reduces the amount of staff time spent on printing and saves the cost of using an off-site storage facility to archive the documents of studies that have closed. The system must be an off the shelf software package provided as a cloud-based service that is already in use in a research environment and comply with FDA Part 11 requirements for electronic signatures. All data must be held in either the UK or the European Economic Area.

Requirements from Supplier

Confirm with the authority of their interest in the contract by the 14th of July 2023.

It is envisaged that a restricted tender process will be undertaken. This likely to take place during the months of August through to October.

Suppliers will be requested to respond to a specification as part of the tendering process.