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Planning

eCTD Solution

MHRA

F01: Prior information notice

Prior information only

Notice identifier: 2022/S 000-027041

Procurement identifier (OCID): ocids-h6vhtk-036bcc

Published 27 September 2022, 12:42pm

Section I: Contracting authority

I.1) Name and addresses

MHRA

10 South Colonnade

London

E14 4PU

Contact

Purchasing

Email

purchasing@mhra.gov.uk

Telephone

+44 2030806000

Country

United Kingdom

Region code

UK - United Kingdom

Internet address(es)

Main address

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

Buyer's address

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

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

National or federal Agency/Office

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

eCTD Solution

II.1.2) Main CPV code

- 72261000 - Software support services

II.1.3) Type of contract

Services

II.1.4) Short description

MHRA is embarking on the development of a next generation Regulatory Management System (RMS) that will replace multiple legacy systems with converged technology platforms to support the agency regulation of medicinal products and medical devices.

In order to support medicinal regulatory management, one component of the new platform identified is a technology solution to facilitate the management of information using the eCTD format (ICH electronic Common Technical Document).

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.2) Additional CPV code(s)

- 72261000 - Software support services
- 72261000 - Software support services

II.2.3) Place of performance

NUTS codes

- UKI - London

II.2.4) Description of the procurement

In preparing for the required activities, MHRA wishes to ensure that its plans are

supported appropriately by supply-side core skills and experience. The procurement procedure selected is: competitive procedure with negotiation (CPN).

This prior information notice (PIN) is a signal of future intentions to the marketplace regarding the procurement of an eCTD Solution.

This PIN is not a call for competition.

By publishing this PIN, the MHRA may shorten the time limit for the receipt of initial tenders to 10 days.

This contract is not divided into lots.

It is envisioned that up to 60 additional months will be available as renewals, this will be confirmed in the contract notice.

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

Estimated date of publication of contract notice 01/11/2022.

II.3) Estimated date of publication of contract notice

1 November 2022

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: Yes

Section VI. Complementary information

VI.3) Additional information

Please indicate your interest by registering in advance at <https://health-family.force.com/s/Welcome>, this is the address at which the procurement documents will be available for unrestricted and full direct access, free of charge.

The contracting authority is not a centralised purchasing body, and no other form of joint procurement is or may be involved.

Estimated nature and quantity or value of supplies: Industry specific software package, Software support services; £5,000,000.00

Please contact purchasing@mhra.gov.uk and quote "Procurement Project Ref: eCTD Solution" for further information.

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Please Note: Full Award Criteria will be published in the Contract Notice and Opportunity notice.