

Netherlands-Amsterdam: Strengthening the Use of Real-world Data in Drug Development – Metadata and Data Quality Framework

OJ S 78/2021 22/04/2021

Contract notice

Services

Legal Basis:

Directive 2014/24/EU

Section I: Contracting authority

I.1. Name and addresses

Official name: European Medicines Agency

Postal address: PO Box 71010

Town: Amsterdam

NUTS code: NL1 Noord-Nederland

Postal code: 1008 BA

Country: Netherlands

E-mail: procurement@ema.europa.eu**Internet address(es):**Main address: <https://www.ema.europa.eu/>Address of the buyer profile: <https://www.ema.europa.eu/en/about-us/procurement>**I.3. Communication**The procurement documents are available for unrestricted and full direct access, free of charge, at: <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8018>

Additional information can be obtained from the abovementioned address

Tenders or requests to participate must be submitted electronically via: <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8018>

Tenders or requests to participate must be submitted to the abovementioned address

I.4. Type of the contracting authority

European institution/agency or international organisation

I.5. Main activity

General public services

Section II: Object

II.1. Scope of the procurement**II.1.1. Title**

Strengthening the Use of Real-world Data in Drug Development – Metadata and Data Quality Framework

Reference number: EMA/2020/13/TDA

II.1.2. Main CPV code

72300000 Data services

II.1.3. Type of contract

Services

II.1.4. Short description

Strengthening the use of real-world data in drug development – metadata and data quality framework.

II.1.5. Estimated total value

Value excluding VAT: 1 000 000,00 EUR

II.1.6. Information about lots

This contract is divided into lots: no

II.2. Description

II.2.2. Additional CPV code(s)

72321000 Added-value database services, 72322000 Data management services

II.2.3. Place of performance

NUTS code: NL1 Noord-Nederland

Main site or place of performance: Contractor's premises.

II.2.4. Description of the procurement

The Agency aims to establish an EU catalogue of sources of real-world data, characterised by a common set of metadata and data quality measurements, along with establishing a data quality framework aimed to define the data quality standards required for the evidence generated to be used by the EU Regulatory Network for decision making.

II.2.5. Award criteria

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

II.2.6. Estimated value

Value excluding VAT: 1 000 000,00 EUR

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

Duration in months: 48

This contract is subject to renewal: yes

Description of renewals:

The contract will be concluded for an initial period of 2 years with the possibility of two renewals each of 1 year (maximum contract duration is 4 years).

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

II.2.14. Additional information

The estimated contract value is of EUR 1 000 000.00.

The Agency may use the negotiated procedure under point 11.1.e of Annex 1 to the General Financial Regulation to procure new services from the contractors up to a maximum of 50 % of the initial framework contract ceiling.

Section III: Legal, economic, financial and technical information

III.1. Conditions for participation

III.1.1. Suitability to pursue the professional activity, including requirements relating to enrolment on professional or trade registers

List and brief description of conditions:

See internet address provided in section I.3).

III.1.2. Economic and financial standing

Selection criteria as stated in the procurement documents

III.1.3. Technical and professional ability

Selection criteria as stated in the procurement documents

III.2. Conditions related to the contract

III.2.2. Contract performance conditions

See internet address provided in section I.3).

Section IV: Procedure

IV.1. Description

IV.1.1. Type of procedure

Open procedure

IV.1.3. Information about a framework agreement or a dynamic purchasing system

The procurement involves the establishment of a framework agreement

Framework agreement with several operators
Envisaged maximum number of participants to the framework agreement: 3

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: 26/05/2021 Local time: 12:00

IV.2.3. Estimated date of dispatch of invitations to tender or to participate to selected candidates

IV.2.4. Languages in which tenders or requests to participate may be submitted

English, Bulgarian, Danish, German, Greek, Estonian, Finnish, French, Irish, Croatian, Hungarian, Italian, Latvian, Lithuanian, Maltese, Dutch, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish, Swedish, Czech

IV.2.6. Minimum time frame during which the tenderer must maintain the tender

Duration in months: 9 (from the date stated for receipt of tender)

IV.2.7. Conditions for opening of tenders

Date: 27/05/2021 Local time: 10:00

Place:

European Medicines Agency, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands

Information about authorised persons and opening procedure: See internet address provided in section I.3).

Section VI: Complementary information

VI.1. Information about recurrence

This is a recurrent procurement: no

VI.3. Additional information

See internet address provided in section I.3).

VI.4. Procedures for review

VI.4.1. Review body

Official name: General Court

Postal address: rue du Fort Niedergrünwald

Town: Luxembourg

Postal code: 2925

Country: Luxembourg

E-mail: generalcourt.registry@curia.europa.eu

Telephone: +352 4303-1

Fax: +352 4303-2100

Internet address: <http://curia.europa.eu>

VI.4.3. Review procedure

Precise information on deadline(s) for review procedures:

See internet address provided in section I.3).

VI.4.4. Service from which information about the review procedure may be obtained

Official name: European Medicines Agency

Postal address: PO Box 71010

Town: Amsterdam

Postal code: 1008 BA

Country: Netherlands

E-mail: info@ema.europa.eu

Telephone: +31 88781600

Internet address: <https://www.ema.europa.eu>

VI.5. Date of dispatch of this notice

15/04/2021