

Netherlands-Amsterdam: Quality, Efficacy and Safety Studies on Medicines

OJ S 50/2021 12/03/2021

Contract notice

Services

Legal Basis:

Regulation (EU, Euratom) No 2018/1046

Section I: Contracting authority

I.1. Name and addresses

Official name: European Medicines Agency

Postal address: PO Box 71010

Town: Amsterdam

NUTS code: NL329 Groot-Amsterdam

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=7933>

Additional information can be obtained from the abovementioned address

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**

Quality, Efficacy and Safety Studies on Medicines

Reference number: EMA/2020/46/TDA

II.1.2. Main CPV code

73000000 Research and development services and related consultancy services

II.1.3. Type of contract

Services

II.1.4. Short description

Performance of pre- and post-authorisation quality, efficacy and safety research on medicines to generate data and information to support regulatory decision-making in the human and veterinary medicines regulatory domain.

II.1.5. Estimated total value

Value excluding VAT: 33 000 000,00 EUR

II.1.6. Information about lots

This contract is divided into lots: yes

Tenders may be submitted for all lots

II.2. Description

II.2.1. Title

Pre-clinical Research

Lot No: 1

II.2.2. Additional CPV code(s)

73210000 Research consultancy services

II.2.3. Place of performance

NUTS code: NL329 Groot-Amsterdam

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

II.2.4. Description of the procurement

See internet address provided in section I.3).

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: 3 000 000,00 EUR

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

Duration in months: 48

This contract is subject to renewal: 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

II.2.14. Additional information

See internet address provided in section I.3).

II.2. Description

II.2.1. Title

Veterinary Studies

Lot No: 2

II.2.2. Additional CPV code(s)

73210000 Research consultancy services

II.2.3. Place of performance

NUTS code: NL329 Groot-Amsterdam

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

II.2.4. Description of the procurement

See internet address provided in section I.3).

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: 3 000 000,00 EUR

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

Duration in months: 48

This contract is subject to renewal: 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

II.2.14. Additional information

See internet address provided in section I.3).

II.2. Description**II.2.1. Title**

Statistical Research

Lot No: 3

II.2.2. Additional CPV code(s)

73210000 Research consultancy services

II.2.3. Place of performance

NUTS code: NL329 Groot-Amsterdam

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

II.2.4. Description of the procurement

See internet address provided in section I.3).

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: 3 000 000,00 EUR

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

Duration in months: 48

This contract is subject to renewal: 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

II.2.14. Additional information

See internet address provided in section I.3).

II.2. Description

II.2.1. Title

Qualitative Research

Lot No: 4

II.2.2. Additional CPV code(s)

73210000 Research consultancy services

II.2.3. Place of performance

NUTS code: NL329 Groot-Amsterdam

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

II.2.4. Description of the procurement

See internet address provided in section I.3).

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: 2 000 000,00 EUR

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

Duration in months: 48

This contract is subject to renewal: 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

II.2.14. Additional information

See internet address provided in section I.3).

II.2. Description

II.2.1. Title

Pharmacoepidemiological Research
Lot No: 5

II.2.2. Additional CPV code(s)

73210000 Research consultancy services

II.2.3. Place of performance

NUTS code: NL329 Groot-Amsterdam
Main site or place of performance: Contractor's premises.

II.2.4. Description of the procurement

See internet address provided in section I.3).

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: 19 000 000,00 EUR

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

Duration in months: 48
This contract is subject to renewal: 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

II.2.14. Additional information

See internet address provided in section I.3).

II.2. Description

II.2.1. Title

Quality of Medicines
Lot No: 6

II.2.2. Additional CPV code(s)

73210000 Research consultancy services

II.2.3. Place of performance

NUTS code: NL329 Groot-Amsterdam
Main site or place of performance: Contractor's premises.

II.2.4. Description of the procurement

See internet address provided in section I.3).

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: 3 000 000,00 EUR

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

Duration in months: 48

This contract is subject to renewal: 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

II.2.14. Additional information

See internet address provided in section I.3).

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: 10

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: 15/04/2021 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: 16/04/2021 Local time: 14:00

Place:

European Medicines Agency, 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: yes

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 Niedergrünewald

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

05/03/2021