

United Kingdom-London: Efficacy and Safety Studies on Medicines
OJ S 44/2019 04/03/2019
Contract award notice
Services

Legal Basis:

Directive 2014/24/EU

Section I: Contracting authority

I.1. Name and addresses

Official name: European Medicines Agency

Postal address: 30 Churchill Place

Town: London

NUTS code: UK14 Inner London - East

Postal code: E14 5EU

Country: United Kingdom

E-mail: pass.tender@ema.europa.eu

Internet address(es):

Main address: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000259.jsp&mid=WC0b01ac0580029487

Address of the buyer profile: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000259.jsp&mid=WC0b01ac0580029487

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

Efficacy and Safety Studies on Medicines

Reference number: EMA/2017/09/PE

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

Post-authorisation effectiveness and pharmacoepidemiology studies to generate data and information to support regulatory decision-making. Research may also focus on the effectiveness of regulatory measures taken and on the impact of relevant legislation. The range of research topics is limited to those with high public health relevance and with a European impact. The scope of the funding covers both nationally and centrally authorised products, including vaccines. The results obtained from this research will subsequently be

assessed by the responsible Agency Committee regarding the need for regulatory action and further research may subsequently also be conducted to measure the effectiveness of regulatory actions taken.

The research may concern four different lots, with a maximum of five framework contracts for lots 1, 2 and 3 and a maximum of eight framework contracts for lot 4.

II.1.6. Information about lots

This contract is divided into lots: yes

II.1.7. Total value of the procurement

Value excluding VAT: 5 000 000,00 EUR

II.2. Description

II.2.1. Title

Pharmacoepidemiology Research - Association Studies, Including Pregnancy and Breastfeeding Research

Lot No: 4

II.2.2. Additional CPV code(s)

73210000 Research consultancy services

II.2.3. Place of performance

NUTS code: UKI4 Inner London - East

II.2.4. Description of the procurement

For full description please see section 3.2 of the technical specifications (procurement documents).

II.2.5. Award criteria

Quality criterion - Name: Case study / Weighting: 30

Quality criterion - Name: Research Team and Tasks / Weighting: 20

Quality criterion - Name: Project management and communication / Weighting: 20

Price - Weighting: 30

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

Please note that a maximum of eight framework contracts is foreseen for lot 4.

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

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.2.1. Previous publication concerning this procedure

Notice number in the OJ S: [2017/S 240-497343](#)

IV.2.8. Information about termination of dynamic purchasing system

IV.2.9. Information about termination of call for competition in the form of a prior information notice

Section V: Award of contract

Contract No: EMA/2018/27/PE

Lot No: 4

Title:

Pharmacoepidemiology Research - Association Studies, Including Pregnancy and Breastfeeding Research

A contract/lot is awarded: yes

V.2. Award of contract

V.2.1. Date of conclusion of the contract

15/02/2019

V.2.2. Information about tenders

Number of tenders received: 8

The contract has been awarded to a group of economic operators: yes

V.2.3. Name and address of the contractor

Official name: University of Ulster

Town: Coleraine

NUTS code: UKN Northern Ireland

Country: United Kingdom

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Dipartimento di Scienze Mediche – Università Degli Studi Di Ferrara

Town: Ferrara

NUTS code: IT Italia

Country: Italy

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Consiglio Nazionale Delle Ricerche – Institute of Clinical Physiology

Town: Roma

NUTS code: IT Italia

Country: Italy

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Swansea University
Town: Swansea
NUTS code: UKL Wales
Country: United Kingdom
The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: University Hospital Center of Toulouse
Town: Toulouse
NUTS code: FR France
Country: France
The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: University of Bath
Town: Bath
NUTS code: UK United Kingdom
Country: United Kingdom
The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Hospital Lillebaelt, Region Syddanmark
Town: Vejle
NUTS code: DK Danmark
Country: Denmark
The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Stichting ENTIS (European Network Teratology Information Services)
Foundation
Town: s'-Hertogenbosch
NUTS code: NL Nederland
Country: Netherlands
The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Otto-von-Guericke-Universitaet Magdeburg, Medical faculty
Town: Magdeburg
NUTS code: DE Deutschland
Country: Germany
The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Fundación Para el Fomento de la Investigación Sanitaria Y Biomédica de la Comunitat Valenciana
Town: Valencia
NUTS code: ES España
Country: Spain
The contractor is an SME: no

V.2.4. Information on value of the contract/lot

Initial estimated total value of the contract/lot: 3 000 000,00 EUR

Total value of the contract/lot: 3 000 000,00 EUR

V.2.5. Information about subcontracting

Section VI: Complementary information

VI.3. Additional information

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:

You may submit any observations concerning the award procedure to the contracting authority indicated under heading I.1.

If you believe that there was maladministration, you may lodge a complaint to the European Ombudsman within 2 years of the date when you became aware of the facts on which the complaint is based (see <http://www.ombudsman.europa.eu>). Such complaint does not have as an effect either to suspend the time limit to launch an appeal or to open a new period for lodging an appeal.

Within 2 months of the notification of the award decision you may lodge an appeal to the body referred to in VI.4.1.

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

Official name: European Medicines Agency

Postal address: 30 Churchill Place

Town: London

Postal code: E14 5EU

Country: United Kingdom

E-mail: info@ema.europa.eu

Telephone: +44 2036606000

Fax: +44 2036605555

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

VI.5. Date of dispatch of this notice

25/02/2019