

Netherlands-Amsterdam: Ceiling Increase — Efficacy and Safety studies on Medicines
OJ S 248/2020 21/12/2020
Contract award 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: NL1 Noord-Nederland

Postal code: 1008 BA

Country: Netherlands

E-mail: PASS.Tender@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.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

Ceiling Increase — 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

The purpose of this procurement procedure is to increase the ceiling of multiple framework contracts with reopening of competition in 4 different lots awarded following open procedure EMA/2017/09/PE.

The subject of the framework contract are 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.

II.1.6. Information about lots

This contract is divided into lots: yes

II.1.7. Total value of the procurement

Value excluding VAT: 7 500 000,00 EUR

II.2. Description

II.2.1. Title

Use of Innovative Methods to Optimise the Utility of Sparse Data to Support Benefit/Risk Assessment

Lot No: 1

II.2.2. Additional CPV code(s)

73210000 Research consultancy services

II.2.3. Place of performance

NUTS code: NL1 Noord-Nederland

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: Technical merit / Weighting: 70 %

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

II.2. Description

II.2.1. Title

Qualitative Research

Lot No: 2

II.2.2. Additional CPV code(s)

73210000 Research consultancy services

II.2.3. Place of performance

NUTS code: NL1 Noord-Nederland

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: Technical merit / Weighting: 70 %

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

II.2. Description

II.2.1. Title

Pharmacoepidemiology Research – Rapid Descriptive Studies

Lot No: 3

II.2.2. Additional CPV code(s)

73210000 Research consultancy services

II.2.3. Place of performance

NUTS code: NL1 Noord-Nederland

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: Technical merit / Weighting: 70 %

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

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: NL1 Noord-Nederland

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: Technical merit / Weighting: 70 %
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

Section IV: Procedure

IV.1. Description

IV.1.1. Type of procedure

Award of a contract without prior publication of a call for competition in the Official Journal of the European Union in the cases listed below

- New works/services, constituting a repetition of existing works/services and ordered in accordance with the strict conditions stated in the directive

Explanation:

The use of this procedure was foreseen in the technical specifications EMA/2017/09/PE, and was concluded during the performance of the original contracts and during the 3 years following the conclusion of the original contracts.

Legal basis: Article 11.1(e) of Annex I to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union.

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/2018/16/PE

Lot No: 1

Title:

Use of Innovative Methods to Optimise the Utility of Sparse Data to Support Benefit/Risk Assessment

A contract/lot is awarded: yes

V.2. Award of contract

V.2.1. Date of conclusion of the contract

08/10/2020

V.2.2. Information about tenders

Number of tenders received: 2

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

V.2.3. Name and address of the contractor

Official name: Hasselt University

Town: Hasselt

NUTS code: BE221 Arr. Hasselt

Country: Belgium

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Katholieke Universiteit Leuven

Town: Leuven

NUTS code: BE242 Arr. Leuven

Country: Belgium

The contractor is an SME: no

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

Initial estimated total value of the contract/lot: 400 000,00 EUR

Total value of the contract/lot: 600 000,00 EUR

V.2.5. Information about subcontracting

Section V: Award of contract

Contract No: EMA/2018/17/PE

Lot No: 1

Title:

Use of Innovative Methods to Optimise the Utility of Sparse data to Support Benefit/Risk Assessment

A contract/lot is awarded: yes

V.2. Award of contract

V.2.1. Date of conclusion of the contract

22/09/2020

V.2.2.

Information about tenders

Number of tenders received: 2

The contract has been awarded to a group of economic operators: no

V.2.3. Name and address of the contractor

Official name: University of Dundee

Town: Dundee

NUTS code: UKM Scotland

Country: United Kingdom

The contractor is an SME: no

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

Initial estimated total value of the contract/lot: 400 000,00 EUR

Total value of the contract/lot: 600 000,00 EUR

V.2.5. Information about subcontracting**Section V: Award of contract**

Contract No: EMA/2018/18/PE

Lot No: 2

Title:

Qualitative Research

A contract/lot is awarded: yes

V.2. Award of contract**V.2.1. Date of conclusion of the contract**

12/11/2020

V.2.2. Information about tenders

Number of tenders received: 3

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

V.2.3. Name and address of the contractor

Official name: Universiteit Utrecht

Town: Utrecht

NUTS code: NL31 Utrecht

Country: Netherlands

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: University Medical Center Utrecht

Town: Utrecht

NUTS code: NL31 Utrecht

Country: Netherlands

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Dpt. Biomedical, Dental Sciences, Morphofunctional Imaging (BIOMORF)

University Messina

Town: Messina
NUTS code: ITG1 Sicilia
Country: Italy
The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
Town: Madrid
NUTS code: ES3 Comunidad de Madrid
Country: Spain
The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Fundació Institut Català de Farmacologia (FICF)
Town: Barcelona
NUTS code: ES51 Catalunya
Country: Spain
The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: London School of Hygiene and Tropical Medicine (LSHTM)
Town: London
NUTS code: UKI London
Country: United Kingdom
The contractor is an SME: no

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

Initial estimated total value of the contract/lot: 600 000,00 EUR
Total value of the contract/lot: 900 000,00 EUR

V.2.5. Information about subcontracting

Section V: Award of contract

Contract No: EMA/2018/19/PE

Lot No: 2

Title:

Qualitative Research

A contract/lot is awarded: yes

V.2. Award of contract

V.2.1. Date of conclusion of the contract

22/09/2020

V.2.2. Information about tenders

Number of tenders received: 3

The contract has been awarded to a group of economic operators: no

V.2.3. Name and address of the contractor

Official name: IQVIA Ltd

Town: Reading
NUTS code: UKJ1 Berkshire, Buckinghamshire and Oxfordshire
Country: United Kingdom
The contractor is an SME: no

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

Initial estimated total value of the contract/lot: 600 000,00 EUR
Total value of the contract/lot: 900 000,00 EUR

V.2.5. Information about subcontracting

Section V: Award of contract

Contract No: EMA/2018/20/PE

Lot No: 2

Title:

Qualitative Research

A contract/lot is awarded: yes

V.2. Award of contract

V.2.1. Date of conclusion of the contract

23/10/2020

V.2.2. Information about tenders

Number of tenders received: 3

The contract has been awarded to a group of economic operators: no

V.2.3. Name and address of the contractor

Official name: Icon Clinical Research Ltd

Town: Dublin

NUTS code: IE0 Ireland

Country: Ireland

The contractor is an SME: no

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

Initial estimated total value of the contract/lot: 600 000,00 EUR
Total value of the contract/lot: 900 000,00 EUR

V.2.5. Information about subcontracting

Section V: Award of contract

Contract No: EMA/2018/21/PE

Lot No: 3

Title:

Pharmacoepidemiology Research – Rapid Descriptive Studies

A contract/lot is awarded: yes

V.2. Award of contract

V.2.1. Date of conclusion of the contract

08/10/2020

V.2.2. Information about tenders

Number of tenders received: 3

The contract has been awarded to a group of economic operators: no

V.2.3. Name and address of the contractor

Official name: Erasmus University Medical Center

Town: Rotterdam

NUTS code: NL4 Zuid-Nederland

Country: Netherlands

The contractor is an SME: no

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

Initial estimated total value of the contract/lot: 1 000 000,00 EUR

Total value of the contract/lot: 1 500 000,00 EUR

V.2.5. Information about subcontracting

Section V: Award of contract

Contract No: EMA/2018/22/PE

Lot No: 3

Title:

Pharmacoepidemiology Research – Rapid Descriptive Studies

A contract/lot is awarded: yes

V.2. Award of contract

V.2.1. Date of conclusion of the contract

22/09/2020

V.2.2. Information about tenders

Number of tenders received: 3

The contract has been awarded to a group of economic operators: no

V.2.3. Name and address of the contractor

Official name: IQVIA Ltd

Town: Reading

NUTS code: UKJ1 Berkshire, Buckinghamshire and Oxfordshire

Country: United Kingdom

The contractor is an SME: no

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

Initial estimated total value of the contract/lot: 1 000 000,00 EUR

Total value of the contract/lot: 1 500 000,00 EUR

V.2.5. Information about subcontracting

Section V: Award of contract

Contract No: EMA/2018/23/PE

Lot No: 3

Title:

Pharmacoepidemiology Research – Rapid Descriptive Studies

A contract/lot is awarded: yes

V.2. Award of contract

V.2.1. Date of conclusion of the contract

12/11/2020

V.2.2. Information about tenders

Number of tenders received: 3

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

V.2.3. Name and address of the contractor

Official name: Universiteit Utrecht

Town: Utrecht

NUTS code: NL31 Utrecht

Country: Netherlands

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: University Medical Center Utrecht

Town: Utrecht

NUTS code: NL31 Utrecht

Country: Netherlands

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Dpt. Biomedical, Dental Sciences, Morphofunctional Imaging (BIOMORF)
University Messina

Town: Messina

NUTS code: ITG1 Sicilia

Country: Italy

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Town: Madrid

NUTS code: ES3 Comunidad de Madrid

Country: Spain

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Fundació Institut Català de Farmacologia (FICF)

Town: Barcelona

NUTS code: ES51 Catalunya

Country: Spain

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: London School of Hygiene and Tropical Medicine (LSHTM)

Town: London

NUTS code: UKI London

Country: United Kingdom

The contractor is an SME: no

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

Initial estimated total value of the contract/lot: 1 000 000,00 EUR

Total value of the contract/lot: 1 500 000,00 EUR

V.2.5. Information about subcontracting

Section V: Award of contract

Contract No: EMA/2018/24/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

23/10/2020

V.2.2. Information about tenders

Number of tenders received: 6

The contract has been awarded to a group of economic operators: no

V.2.3. Name and address of the contractor

Official name: Aarhus University Hospital, Department of Clinical Epidemiology

Town: Aarhus

NUTS code: DK0 Danmark

Country: Denmark

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: 4 500 000,00 EUR

V.2.5. Information about subcontracting

Section V: Award of contract

Contract No: EMA/2018/25/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**

22/09/2020

V.2.2. Information about tenders

Number of tenders received: 6

The contract has been awarded to a group of economic operators: no

V.2.3. Name and address of the contractor

Official name: University of Dundee

Town: Dundee

NUTS code: UKM Scotland

Country: United Kingdom

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: 4 500 000,00 EUR

V.2.5. Information about subcontracting**Section V: Award of contract**

Contract No: EMA/2018/26/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**

22/09/2020

V.2.2. Information about tenders

Number of tenders received: 6

The contract has been awarded to a group of economic operators: no

V.2.3. Name and address of the contractor

Official name: RTI Health Solutions

Town: Barcelona

NUTS code: ES51 Cataluña

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: 4 500 000,00 EUR

V.2.5. Information about subcontracting**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**

23/10/2020

V.2.2. Information about tenders

Number of tenders received: 6

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: Rome

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: UKK1 Gloucestershire, Wiltshire and Bristol/Bath area
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: DEE Sachsen-Anhalt
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: ES52 Comunitat Valenciana
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: 4 500 000,00 EUR

V.2.5. Information about subcontracting**Section V: Award of contract**

Contract No: EMA/2018/28/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

12/11/2020

V.2.2. Information about tenders

Number of tenders received: 6

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

V.2.3. Name and address of the contractor

Official name: Universiteit Utrecht

Town: Utrecht

NUTS code: NL31 Utrecht

Country: Netherlands

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: University Medical Center Utrecht

Town: Utrecht

NUTS code: NL31 Utrecht

Country: Netherlands

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Dpt. Biomedical, Dental Sciences, Morphofunctional Imaging (BIOMORF)

University Messina

Town: Messina

NUTS code: ITG1 Sicilia

Country: Italy

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Fundació Institut Català de Farmacologia (FICF)

Town: Barcelona

NUTS code: ES51 Catalunya

Country: Spain

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: London School of Hygiene and Tropical Medicine (LSHTM)

Town: London

NUTS code: UKI London

Country: United Kingdom

The contractor is an SME: no

V.2.3. Name and address of the contractor

Official name: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Town: Madrid

NUTS code: ES3 Comunidad de Madrid

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: 4 500 000,00 EUR

V.2.5. Information about subcontracting**Section V: Award of contract**

Contract No: EMA/2018/29/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**

22/09/2020

V.2.2. Information about tenders

Number of tenders received: 6

The contract has been awarded to a group of economic operators: no

V.2.3. Name and address of the contractor

Official name: IQVIA Ltd

Town: Reading

NUTS code: UKJ1 Berkshire, Buckinghamshire and Oxfordshire

Country: United Kingdom

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: 4 500 000,00 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 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.4.4. 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

14/12/2020