

Belgium-Brussels: Supporting Regulatory Acceptance of IMI Results

OJ S 202/2019 18/10/2019

Contract notice

Services

Legal Basis:

Regulation (EU, Euratom) No 2018/1046

Section I: Contracting authority

I.1. Name and addresses

Official name: Innovative Medicines Initiative 2 Joint Undertaking

Postal address: IMI2 JU — TO 56 1049

Town: Brussels

NUTS code: BE10 Région de Bruxelles-Capitale/ Brussels Hoofdstedelijk Gewest

Postal code: 1060

Country: Belgium

Contact person: Procurement team

E-mail: procurement@imi.europa.eu**Internet address(es):**Main address: <http://www.imi.europa.eu/>**I.3. Communication**The procurement documents are available for unrestricted and full direct access, free of charge, at: <https://www.imi.europa.eu/work-for-us/procurement>

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

Health

Section II: Object

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

Supporting Regulatory Acceptance of IMI Results

Reference number: IMI.2019.OP.01

II.1.2. Main CPV code

85000000 Health and social work services

II.1.3. Type of contract

Services

II.1.4. Short description

The Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) intends to establish a framework service contract to provide a central support system which will capitalise on project

results generated by increasing or securing their impact and sustainability through adoption into regulatory agency guidelines or standard practice.

II.1.5. Estimated total value

Value excluding VAT: 250 000,00 EUR

II.1.6. Information about lots

This contract is divided into lots: no

II.2. Description

II.2.3. Place of performance

NUTS code: BE1 Région de Bruxelles-Capitale/Brussels Hoofdstedelijk Gewest

II.2.4. Description of the procurement

The objective of the initiative is to ensure that the key results generated by IMI projects are acceptable in a research and development (R&D) context (non-clinical or clinical studies), and are therefore implemented in the regulatory practices.

The results include novel biomarkers, endpoints, outcomes, tools/methodologies, recommendations that would support development of regulatory guidance documents. This may cover different disease areas or axes of research as per the IMI Strategic Research Agenda.

The contractor will be expected to:

- identify and prioritise the relevant project results,
- identify information/data gaps that need to be addressed to complete the submission,
- support preparation of files to be submitted to the EMA and FDA, and preliminary engagement with the agencies,
- implement process, quality criteria to be replicated across all projects, etc. to secure efficiency, consistency and quality.

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: 250 000,00 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 framework contract will be signed for an initial period of 2 years, and shall be renewable up to 2 times, for a 1-year period, for a total maximum duration of 4 years, under the same conditions.

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: yes

Identification of the project: The Innovative Medicines Initiative 2 Joint Undertaking operates with Horizon 2020 funds, the EU's framework programme for research and innovation.

II.2.14. Additional information

For additional information, please see procurement documents at the following URL address:
<https://www.imi.europa.eu/work-for-us/procurement>

Section III: Legal, economic, financial and technical information

III.1. Conditions for participation

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

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 a single operator

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: [2019/S 070-163862](#)

IV.2.2. Time limit for receipt of tenders or requests to participate

Date: 06/12/2019 Local time: 17:00

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

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

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

Duration in months: 4 (from the date stated for receipt of tender)

IV.2.7. Conditions for opening of tenders

Date: 16/12/2019 Local time: 10:00

Place:

IMI2 JU Headquarters, in Brussels.

Information about authorised persons and opening procedure: Maximum two representatives per participating tenderer may attend the opening session. Tenderers are requested to inform the IMI2 JU of their intention to attend, at least 5 working days prior to the opening session.

Section VI: Complementary information

VI.1. Information about recurrence

This is a recurrent procurement: no

VI.3. Additional information

VI.4. Procedures for review

VI.4.1. Review body

Official name: General Court of the European Union

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.5. Date of dispatch of this notice

11/10/2019