

**Belgium-Brussels: Supporting Regulatory Acceptance of IMI Results**  
**OJ S 232/2020 27/11/2020**  
**Contract award notice**  
**Services**

**Legal Basis:**

Directive 2014/24/EU

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**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](mailto:procurement@imi.europa.eu)

**Internet address(es):**

Main address: <http://www.imi.europa.eu/>

**I.4. Type of the contracting authority**

European institution/agency or international organisation

**I.5. Main activity**

Health

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**Section II: Object**

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

**II.1.1. Title**

Supporting Regulatory Acceptance of IMI Results

Reference number: IMI.2020.HV.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 use a framework service contract to provide a central support system that will capitalise on project results generated by increasing or securing their impact and sustainability through adoption into regulatory agency guidelines or standard practice.

**II.1.6. Information about lots**

This contract is divided into lots: no

#### **II.1.7. Total value of the procurement**

Value excluding VAT: 250 000,00 EUR

#### **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**

Quality criterion - Name: Rationale and strategy / Weighting: 28

Quality criterion - Name: Timetable / Weighting: 21

Quality criterion - Name: Organisation of work, expertise and composition and functioning of the proposed team / Weighting: 21

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:  
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**

### **Section IV: Procedure**

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#### **IV.1. Description**

##### **IV.1.1. Type of procedure**

Competitive procedure with negotiation

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

##### **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 248-611295](#)

### **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**

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**Contract No:** IMI.2020.FWC.071

A contract/lot is awarded: yes

### **V.2. Award of contract**

#### **V.2.1. Date of conclusion of the contract**

30/10/2020

#### **V.2.2. Information about tenders**

Number of tenders received: 1

Number of tenders received from SMEs: 1

Number of tenders received from tenderers from other EU Member States: 1

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

#### **V.2.3. Name and address of the contractor**

Official name: Critical Path Institute, Ltd

National registration number: 3599762DH

Postal address: 33 Sir John Rogerson's

Town: Dublin

NUTS code: IE Éire / Ireland

Country: Ireland

Internet address: <https://c-path.org/contact/>

The contractor is an SME: yes

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

Initial estimated total value of the contract/lot: 250 000,00 EUR

Total value of the contract/lot: 250 000,00 EUR

#### **V.2.5. Information about subcontracting**

The contract is likely to be subcontracted Value or proportion likely to be subcontracted to third parties Value excluding VAT: 200 000,00 EUR Proportion: 80 % Short description of the part of the contract to be subcontracted:

The lead contractor intends to subcontract various implementation tasks to GCH Pharma Consulting Ltd, and to regulatory experts from the C-Path Main Office.

## **Section VI: Complementary information**

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### **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 Niedergrünwald

Town: Luxembourg

Postal code: 2925

Country: Luxembourg

E-mail: [generalcourt.registry@curia.europa.eu](mailto: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**

20/11/2020