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Tender

## **Investigational Medicinal Product (IMP) & Placebo Manufacture - IM Woman Trial**

London School of Hygiene & Tropical Medicine

F02: Contract notice

Notice identifier: 2021/S 000-029090

Procurement identifier (OCID): ocds-h6vhtk-02f911

Published 22 November 2021, 6:10pm

### **Section I: Contracting authority**

#### **I.1) Name and addresses**

London School of Hygiene & Tropical Medicine

Keppel Street,

London

WC1E 7HT

#### **Contact**

Paul Pester

#### **Email**

[paul.pesther@lshtm.ac.uk](mailto:paul.pesther@lshtm.ac.uk)

#### **Telephone**

+44 02079272471

#### **Country**

United Kingdom

**NUTS code**

UKI31 - Camden and City of London

**National registration number**

RC000330

**Internet address(es)**

Main address

<http://www.lshtm.ac.uk>

Buyer's address

<https://uk.eu-supply.com/ctm/Company/CompanyInformation/Index/104519>

**I.3) Communication**

The procurement documents are available for unrestricted and full direct access, free of charge, at

[https://uk.eu-supply.com/app/rfq/rwlenrance\\_s.asp?PID=40736&B=LSHTM](https://uk.eu-supply.com/app/rfq/rwlenrance_s.asp?PID=40736&B=LSHTM)

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

[https://uk.eu-supply.com/app/rfq/rwlenrance\\_s.asp?PID=40736&B=LSHTM](https://uk.eu-supply.com/app/rfq/rwlenrance_s.asp?PID=40736&B=LSHTM)

Tenders or requests to participate must be submitted to the above-mentioned address

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

Body governed by public law

**I.5) Main activity**

Health

## **Section II: Object**

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

#### **II.1.1) Title**

Investigational Medicinal Product (IMP) & Placebo Manufacture - IM Woman Trial

Reference number

LSHTM-2021-29

#### **II.1.2) Main CPV code**

- 33600000 - Pharmaceutical products

#### **II.1.3) Type of contract**

Supplies

#### **II.1.4) Short description**

Manufacturing and packing of IMP for the IM Woman Trial due to commence in March 2023.

Three arms include experimental treatment (IM TXA), reference treatment/active control (IV TXA), and placebo control (0.9% sodium chloride solution).

Treatment Kit Boxes required for 4 campaigns with approximately 10,000 patient packs per campaign. Recruitment period is 24 months - campaign approximately once every 6 months.

#### **II.1.5) Estimated total value**

Value excluding VAT: £975,000

#### **II.1.6) Information about lots**

This contract is divided into lots: No

### **II.2) Description**

#### **II.2.2) Additional CPV code(s)**

- 33141310 - Syringes

- 33141320 - Medical needles
- 33621000 - Medicinal products for the blood and blood-forming organs
- 33621200 - Antihemorrhagics
- 33698000 - Clinical products
- 39299100 - Glass ampoules
- 44617100 - Cartons
- 79920000 - Packaging and related services

### **II.2.3) Place of performance**

NUTS codes

- UKI31 - Camden and City of London

Main site or place of performance

LSHTM - Keppel Street, London WC1A 7HT

### **II.2.4) Description of the procurement**

Manufacturing and packing of IMP for the IM Woman Trial due to commence in March 2023.

A randomised, triple-blind, three-arm, non-inferiority trial to assess the efficacy and safety of intramuscular tranexamic acid compared to intravenous tranexamic acid and placebo in women having vaginal and caesarean section births.

Three arms include experimental treatment (IM TXA), reference treatment/active control (IV TXA), and placebo control (0.9% sodium chloride solution).

Treatment Kit Boxes required for 4 campaigns with approximately 10,000 patient packs per campaign. Recruitment period is 24 months - campaign approximately once every 6 months.

### **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: £975,000

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

Duration in months

25

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

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**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

GMP and MHRA certification

**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

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## **Section IV. Procedure**

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

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

Open procedure

#### **IV.1.8) Information about the Government Procurement Agreement (GPA)**

The procurement is covered by the Government Procurement Agreement: Yes

### **IV.2) Administrative information**

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

Date

5 January 2022

Local time

1:00pm

#### **IV.2.4) Languages in which tenders or requests to participate may be submitted**

English

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

Tender must be valid until: 5 April 2022

#### **IV.2.7) Conditions for opening of tenders**

Date

5 January 2022

Local time

1:00pm

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## **Section VI. Complementary information**

### **VI.1) Information about recurrence**

This is a recurrent procurement: No

### **VI.4) Procedures for review**

#### **VI.4.1) Review body**

The Royal Courts of Justice

The Strand

London

WC2A 2LL

Country

United Kingdom

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

London School of Hygiene & Tropical Medicine

Keppel Street

London

WC1E 7HT

Email

[procurement@lshtm.ac.uk](mailto:procurement@lshtm.ac.uk)

Country

United Kingdom