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Tender

Investigational Medicinial 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.pester@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/rfg/rwlentrance_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/rfg/rwlentrance 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 Medicinial 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 Antihaemorrhagics
- 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 vyaginal 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

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

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

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

Country

United Kingdom