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Tender

Lotted Term Framework for the management and manufacture of research drugs including over-labelling, storage and distribution to trial sites, and associated trial monitoring services

University of Dundee

F02: Contract notice

Notice identifier: 2023/S 000-028044

Procurement identifier (OCID): ocds-h6vhtk-040307

Published 22 September 2023, 12:59pm

The closing date and time has been changed to:

27 November 2023, 12:00pm

See the [change notice](#).

Section I: Contracting authority

I.1) Name and addresses

University of Dundee

Procurement, 3rd Floor, Tower Building, Nethergate

Dundee

DD1 4HN

Contact

Mary Kirkpatrick

Email

m.y.kirkpatrick@dundee.ac.uk

Telephone

+44 1382386684

Country

United Kingdom

NUTS code

UKM71 - Angus and Dundee City

Internet address(es)

Main address

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

Buyer's address

https://www.publiccontractsscotland.gov.uk/search/Search_AuthProfile.aspx?ID=AA00105

I.2) Information about joint procurement

The contract is awarded by a central purchasing body

I.3) Communication

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

www.publiccontractsscotland.gov.uk

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

www.publiccontractsscotland.gov.uk

Electronic communication requires the use of tools and devices that are not generally available. Unrestricted and full direct access to these tools and devices is possible, free of charge, at

www.publiccontractsscotland.gov.uk

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Education

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

Lotted Term Framework for the management and manufacture of research drugs including over-labelling, storage and distribution to trial sites, and associated trial monitoring services

Reference number

UoD-LAB432-TC-2023

II.1.2) Main CPV code

- 73110000 - Research services

II.1.3) Type of contract

Services

II.1.4) Short description

This Lotted Term Framework is required in order to provide a quick route to market for smaller clinical trials being conducted by Tayside Clinical Trials Unit (TCTU) in respect of the management and manufacture of research drugs, including (as necessary) over-labelling, storage and distribution , and trial monitoring services

II.1.5) Estimated total value

Value excluding VAT: £1,000,000

II.1.6) Information about lots

This contract is divided into lots: Yes

Tenders may be submitted for maximum number of lots
7

II.2) Description

II.2.1) Title

Storage of Research Drugs

Lot No

3

II.2.2) Additional CPV code(s)

- 63120000 - Storage and warehousing services

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

Main site or place of performance

Dependent on on the location of the appointed service provider(s) and clinical trial location

II.2.4) Description of the procurement

Lot 3 of the Framework - Storage

II.2.5) Award criteria

Quality criterion - Name: Project Management & Communication / Weighting: 8

Quality criterion - Name: Storage Facility Size and Location / Weighting: 8

Quality criterion - Name: Temperature Control / Weighting: 8

Quality criterion - Name: Experience of Servicing Similar Contracts / Weighting: 8

Quality criterion - Name: Audit Control and Record Keeping / Weighting: 4

Quality criterion - Name: Business Continuity/Disaster Recovery Plan / Weighting: 4

Price - Weighting: 60

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

Duration in months

24

This contract is subject to renewal

Yes

Description of renewals

2 x 12 month extensions, subject to satisfactory performance and ongoing need.

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

II.2) Description

II.2.1) Title

QP Release

Lot No

6

II.2.2) Additional CPV code(s)

- 73110000 - Research services

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

Main site or place of performance

Dundee but could have sites all over the UK and potentially overseas dependent on the trial.

II.2.4) Description of the procurement

Lotted Term Framework for the management and manufacture of research drugs including over-labelling, storage and distribution to trial sites, and trial monitoring services

II.2.5) Award criteria

Quality criterion - Name: Project Management & Communication / Weighting: 8

Quality criterion - Name: Proposed Methodology for QP release / Weighting: 8

Quality criterion - Name: Experience of servicing similar contracts / Weighting: 8

Quality criterion - Name: Audit Control and Record Keeping / Weighting: 8

Quality criterion - Name: Business Continuity /Disaster Recovery Plan / Weighting: 8

Price - Weighting: 60

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

Duration in months

24

This contract is subject to renewal

Yes

Description of renewals

2 x 12 months subject to satisfactory performance and ongoing need.

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

II.2) Description

II.2.1) Title

Manufacture of Trial Drugs

Lot No

1

II.2.2) Additional CPV code(s)

- 33600000 - Pharmaceutical products

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

Main site or place of performance

Could be anywhere in UK or overseas depending on clinical trial

II.2.4) Description of the procurement

Supply and/or Manufacture of Clinical Trial drugs on a project by project basis (service provider(s) will be appointed via Mini Competition under the relevant Lot of the Framework)

II.2.5) Award criteria

Quality criterion - Name: 1. Project Management & Communication / Weighting: 8

Quality criterion - Name: 2. Randomisation & Drug Management / Weighting: 8

Quality criterion - Name: 3. Manufacture of IMP/Placebo / Weighting: 8

Quality criterion - Name: 4. Audit Control & Record Keeping / Weighting: 4

Quality criterion - Name: 5. Experience of Servicing Similar Contracts / Weighting: 8

Quality criterion - Name: 6. Business Continuity/Disaster Recovery Plan / Weighting: 4

Price - Weighting: 60

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

Duration in months

24

This contract is subject to renewal

Yes

Description of renewals

Option to extend framework for 2 x 12 months after initial 2 year term, subject to satisfactory performance and ongoing need.

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

II.2) Description

II.2.1) Title

Over-labelling Services (Labelling & Secondary Packaging)

Lot No

2

II.2.2) Additional CPV code(s)

- 79824000 - Printing and distribution services

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

Main site or place of performance

Determined on a project by project basis.

II.2.4) Description of the procurement

Provision of Over-labelling Services (Labelling & Secondary Packaging) in support of smaller clinical trials being conducted by Tayside Clinical Trials Unit (TCTU), University of Dundee.

II.2.5) Award criteria

Quality criterion - Name: Project Management & Communication / Weighting: 8

Quality criterion - Name: Proposed Labelling Methodology for IMP and Placebo / Weighting: 8

Quality criterion - Name: Proposed methodology for secondary packaging of Trial drug / Weighting: 8

Quality criterion - Name: Experience of Servicing Similar Contracts / Weighting: 8

Quality criterion - Name: Audit Control and Record Keeping / Weighting: 4

Quality criterion - Name: Business Continuity/Disaster Recovery Plan / Weighting: 4

Price - Weighting: 60

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

Duration in months

24

This contract is subject to renewal

Yes

Description of renewals

2 x 12 months, subject to satisfactory performance by the appointed service provider(s) and ongoing need.

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

II.2) Description

II.2.1) Title

Distribution of Trial Drugs and Placebos to UK and/or international sites

Lot No

4

II.2.2) Additional CPV code(s)

- 600000000 - Transport services (excl. Waste transport)

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

Main site or place of performance

Dundee, but trial sites could be anywhere in the UK and potentially overseas.

II.2.4) Description of the procurement

This Lot relates to the distribution of Clinical Trial Drugs to participating UK and/or international trial sites.

II.2.5) Award criteria

Quality criterion - Name: Project Management & Communication / Weighting: 8

Quality criterion - Name: Available Fleet for distribution of trial drugs to UK and/or international trial sites. / Weighting: 8

Quality criterion - Name: Audit Control and Record Keeping / Weighting: 8

Quality criterion - Name: Experience of Servicing Similar Contracts / Weighting: 8

Quality criterion - Name: Business Continuity/Disaster Recovery Plan / Weighting: 8

Price - Weighting: 60

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

Duration in months

24

This contract is subject to renewal

Yes

Description of renewals

2 x 12 months, subject to satisfactory performance and ongoing need by the University.

II.2.10) Information about variants

Variants will be accepted: No

II.2.11) Information about options

Options: Yes

Description of options

2 x 12 months, subject to satisfactory performance and ongoing need by the University.

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

For detailed information, please see attached tender documents.

II.2) Description

II.2.1) Title

Importation of Research Drugs

Lot No

5

II.2.2) Additional CPV code(s)

- 79824000 - Printing and distribution services

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

Main site or place of performance

Based in Dundee but could have Clinical Trial Sites across the UK and/or abroad.

II.2.4) Description of the procurement

Lotted Term Framework for the Management and manufacture of Research Drugs.

II.2.5) Award criteria

Quality criterion - Name: Project Management & Communication / Weighting: 8

Quality criterion - Name: Proposed Methodology for over-labelling importation of

Research Drugs importa / Weighting: 8

Quality criterion - Name: Experience of Servicing similar contracts / Weighting: 8

Quality criterion - Name: Audit Control and Record Keeping / Weighting: 8

Quality criterion - Name: Continuity/Disaster Recovery Plan / Weighting: 8

Price - Weighting: 60

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

Duration in months

24

This contract is subject to renewal

Yes

Description of renewals

2 x 12 month extension(s), subject to satisfactory performance an ongoing need.

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

II.2) Description

II.2.1) Title

Trial Monitoring Services

Lot No

7

II.2.2) Additional CPV code(s)

- 73110000 - Research services

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

Main site or place of performance

Based in Dundee but trials could be anywhere in the UK and/or overseas.

II.2.4) Description of the procurement

Lot 7 relates to Trial Monitoring Services for any Clinical trials that may require them.

II.2.5) Award criteria

Quality criterion - Name: Project Management & Communication / Weighting: 8

Quality criterion - Name: Preparation of Plan of Activity to Deliver Sponsor Monitoring Plan / Weighting: 8

Quality criterion - Name: Audit Control & Record Keeping / Weighting: 8

Quality criterion - Name: Experience of Servicing Similar Contracts / Weighting: 8

Quality criterion - Name: Business Continuity/Disaster Recovery Plan / Weighting: 8

Price - Weighting: 60

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

Duration in months

24

This contract is subject to renewal

Yes

Description of renewals

2 x 12 month extensions after initial 2 year term, subject to satisfactory performance and ongoing need.

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

MHRA Certificate of GMP Compliance of a Manufacturer/Manufacturer's Authorisation - IMP with named Qualified Person (QP).

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

III.2) Conditions related to the contract

III.2.2) Contract performance conditions

As detailed in tender 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 several operators

Envisaged maximum number of participants to the framework agreement: 21

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

Originally published as:

Date

27 October 2023

Local time

12:00pm

Changed to:

Date

27 November 2023

Local time

12:00pm

See the [change notice](#).

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: 30 November 2023

IV.2.7) Conditions for opening of tenders

Date

27 October 2023

Local time

12:00pm

Place

Electronically

Information about authorised persons and opening procedure

Mary Kirkpatrick, Category Manager, duly authorised.

Section VI. Complementary information

VI.1) Information about recurrence

This is a recurrent procurement: No

VI.2) Information about electronic workflows

Electronic ordering will be used

Electronic invoicing will be accepted

Electronic payment will be used

VI.3) Additional information

NOTE: To register your interest in this notice and obtain any additional information please

visit the Public Contracts Scotland Web Site at

https://www.publiccontractsscotland.gov.uk/Search/Search_Switch.aspx?ID=740555.

The buyer has indicated that it will accept electronic responses to this notice via the Postbox facility. A user guide is available at

https://www.publiccontractsscotland.gov.uk/sitehelp/help_guides.aspx.

Suppliers are advised to allow adequate time for uploading documents and to dispatch the electronic response well in advance of the closing time to avoid any last minute problems.

(SC Ref:740555)

Download the ESPD document here:

https://www.publiccontractsscotland.gov.uk/ESPD/ESPD_Download.aspx?id=740555

VI.4) Procedures for review

VI.4.1) Review body

Dundee Sheriff Court

Bell Street

Dundee

Country

United Kingdom