

United Kingdom-Birmingham: Medical specialist services

OJ S 237/2018 08/12/2018

Contract notice

Services

Legal Basis:

Directive 2014/24/EU

Section I: Contracting authority

I.1. Name and addresses

Official name: University of Birmingham

Postal address: Edgbaston Park Road

Town: Birmingham

NUTS code: UKG31 Birmingham

Postal code: B152TT

Country: United Kingdom

Contact person: Susanna Ting

E-mail: s.y.ting@bham.ac.uk

Telephone: +44 12145389

Internet address(es):

Main address: <https://in-tendhost.co.uk/universityofbirmingham.aspx/Home>

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: <https://in-tendhost.co.uk/universityofbirmingham.aspx/Home>

Additional information can be obtained from the abovementioned address

Tenders or requests to participate must be submitted electronically via: <https://in-tendhost.co.uk/universityofbirmingham.aspx/Home>

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

Dynamic Purchasing System for the Provision of Clinical Trials Services

Reference number: FRAM429/18

II.1.2. Main CPV code

85121200 Medical specialist services

II.1.3.

Type of contract

Services

II.1.4. Short description

The University of Birmingham has a requirement for provision of clinical trials for various services and is seeking to appoint a number of suppliers under the following lots:

- lot 1 — distribution,
- lot 2 — labelling and distribution of finished product,
- lot 3 — packaging, labelling and dispensing of unlicensed product,
- lot 4 — import of unlicensed product from outside of the European Union,
- lot 5 — manufacture (package, label) and distribute certain Investigational Medicinal Products (IMPs), including placebos.

The University intends to implement a Dynamic Purchasing System (DPS) to deliver these requirements. This requires the release of procurement documents at the same time as publication of the OJEU notice which comprise the following:

- Dynamic Purchasing System instructions,
- Supplier's Questionnaire (SQ) — must be completed and return,
- UoB clinical terms and conditions.

II.1.5. Estimated total value

Value excluding VAT: 2 500 000,00 GBP

II.1.6. Information about lots

This contract is divided into lots: yes
Tenders may be submitted for all lots

II.2. Description

II.2.1. Title

Distribution
Lot No: 1

II.2.2. Additional CPV code(s)

33600000 Pharmaceutical products

II.2.3. Place of performance

NUTS code: UKG31 Birmingham
Main site or place of performance: University of Birmingham.

II.2.4. Description of the procurement

Lot 1: Distribution.

The University has a requirement to distribute certain Investigational Medicinal Products (IMPs) for clinical trials.

Information on supply chain:

The sponsor shall retain overall regulatory responsibility in its capacity as the sponsor of the clinical trial pursuant and under to the regulations.

Under a separate agreement, the study sponsor will contract with the Marketing Authorisation Holder (MAH) or other third party (the "Supplier") for the supply of finished product.

It is anticipated that the finished product will be shipped from the supplier to the tenderer, under appropriate temperature/shipping conditions, on a regular basis (anticipated to be once or twice a year) during the study.

No further packaging or manufacture is required.

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

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

Duration in months: 60

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

II.2.14. Additional information

II.2. Description

II.2.1. Title

Labelling and Distribution of Finished Product

Lot No: 2

II.2.2. Additional CPV code(s)

33600000 Pharmaceutical products

II.2.3. Place of performance

NUTS code: UKG31 Birmingham

Main site or place of performance: University of Birmingham.

II.2.4. Description of the procurement

Lot 2: Labelling and Distribution of Finished Product.

The university has a requirement to label (manufacture) and distribute certain Investigational Medicinal Products (IMPs) for clinical trials.

Information on supply chain:

The sponsor shall retain overall regulatory responsibility in its capacity as the sponsor of the clinical trial pursuant and under to the regulations.

Under a separate agreement, the study sponsors will contract with the Marketing Authorisation Holder (MAH) or other third party (the "Supplier") for the supply of finished product that requires additional labelling in accordance with Annex 13 requirements.

It is anticipated that the finished product will be shipped from the supplier to the tenderer, under appropriate temperature/shipping conditions, on a regular basis (anticipated to be once or twice a year) during the study.

No further packaging or manufacture is required.

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

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

Duration in months: 60

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

II.2.14. Additional information

II.2. Description

II.2.1. Title

Packaging, Labelling and Dispensing of Unlicensed Product
Lot No: 3

II.2.2. Additional CPV code(s)

33600000 Pharmaceutical products

II.2.3. Place of performance

NUTS code: UKG31 Birmingham

II.2.4. Description of the procurement

The university has a requirement to manufacturer (package, label) and distribute certain Investigational Medicinal Products (IMPs) for clinical trials.

Information on supply chain:

The sponsor shall retain overall regulatory responsibility in its capacity as the sponsor of the clinical trial pursuant and under to the regulations.

Under a separate agreement, the study sponsor will contract with the manufacturer or other third party (the "Supplier") for the supply of the unlicensed product that requires additional manufacturing steps (e.g. packaging and labelling) in accordance with Annex 13 requirements. It is anticipated that the finished product will be shipped from the supplier to the tenderer, under appropriate temperature/shipping conditions, on a regular basis (anticipated to be once or twice a year) during the study.

No further packaging or manufacture is required.

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

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

Duration in months: 60

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

II.2.14. Additional information

II.2. Description

II.2.1. Title

Import of Unlicensed Product from Outside of the European Union
Lot No: 4

II.2.2. Additional CPV code(s)

33600000 Pharmaceutical products

II.2.3. Place of performance

NUTS code: UKG31 Birmingham

II.2.4. Description of the procurement

The university has a requirement to manufacturer (package, label) and distribute certain unlicensed Investigational Medicinal Products (IMPs) for clinical trials.

Information on supply chain:

The sponsor shall retain overall regulatory responsibility in its capacity as the sponsor of the clinical trial pursuant and under to the regulations.

Under a separate agreement, the study sponsor will contract with the manufacturer or other third party (the "Supplier") for the supply of the unlicensed product from outside of the EU that requires additional manufacturing steps (e.g. packaging and labelling) in accordance with Annex 13 requirements.

It is anticipated that the finished product will be shipped from the supplier to the tenderer, under appropriate temperature/shipping conditions, on a regular basis (anticipated to be once or twice a year) during the study.

No further packaging or manufacture is required.

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

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

Duration in months: 60

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

II.2.14. Additional information

II.2. Description

II.2.1. Title

Manufacture (Package, Label) and Distribute Certain Investigational Medicinal Products (IMPs) Including Placebos

Lot No: 5

II.2.2. Additional CPV code(s)

33600000 Pharmaceutical products

II.2.3. Place of performance

NUTS code: UKG31 Birmingham

II.2.4. Description of the procurement

The university has a requirement to manufacture (package, label) and distribute certain Investigational Medicinal Products (IMPs) including placebos for clinical trials.

Information on supply chain:

The sponsor shall retain overall regulatory responsibility in its capacity as the sponsor of the clinical trial pursuant and under to the regulations.

Under a separate agreement, the study sponsor will contract with the manufacturer or other third party (the "Supplier") for the supply of the product and placebo that requires additional manufacturing steps (e.g. packaging and labelling) in accordance with Annex 13 requirements. It is anticipated that the finished product will be shipped from the supplier to the tenderer, under appropriate temperature/shipping conditions, on a regular basis (anticipated to be once or twice a year) during the study.

No further packaging or manufacture is required.

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

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

Duration in months: 60

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

II.2.14. Additional information

Section IV: Procedure

IV.1. Description

IV.1.1. Type of procedure

Restricted procedure

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

The procurement involves the setting up of a dynamic purchasing system

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: 07/12/2023 Local time: 12:00

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**

English

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

Duration in months: 60 (from the date stated for receipt of tender)

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

To create the DPS arrangement the first round of expression of interest/SQ submissions should be open for a period of 30 days, thereafter SQ submissions can be submitted at any time over the life of the DPS arrangement. See the document referenced as "SQ — UoB DPS Instructions" for further information on how the university intends to operate the DPS and various lots to potential suppliers. It should be noted that the university shall call-off specific competitions from this arrangement as and when required and may run multiple tender exercises from the arrangement if required.

VI.4. Procedures for review**VI.4.1. Review body**

Official name: University of Birmingham

Postal address: Edgbaston Park Road

Town: Birmingham

Postal code: B152TT

Country: United Kingdom

E-mail: procurement@bham.ac.uk

Telephone: +44 1214145389

VI.5.

Date of dispatch of this notice

06/12/2018