Award

Metabolite Analyser Equipment for the use in the manufacture of gene therapy drugs/treatments for research and development, education/teaching and training.

UNIVERSITY OF SHEFFIELD

F15: Voluntary ex ante transparency notice
Notice identifier: 2022/S 000-001797
Procurement identifier (OCID): ocds-h6vhtk-030d9e
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Section I: Contracting authority/entity

I.1) Name and addresses

UNIVERSITY OF SHEFFIELD

Western Bank

SHEFFIELD

S102TN

Contact

Jamie Shaw

Email

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Telephone

+44 1142221516

Country

United Kingdom

NUTS code

UKE32 - Sheffield

Internet address(es)

Main address

https://sheffield.ac.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

Metabolite Analyser Equipment for the use in the manufacture of gene therapy drugs/treatments for research and development, education/teaching and training.

II.1.2) Main CPV code

- 38434540 - Biomedical equipment

II.1.3) Type of contract

Supplies

II.1.4) Short description

The University of Sheffield (UoS) is establishing a new 'Gene Therapy Innovation Manufacturing Centre' (GTIMC) to advance scientific discoveries into life-changing treatments for patients with life threatening diseases. The Sheffield GTIMC will be one of three cutting edge hubs in the UK dedicated to advancing the clinical development of new genetic treatments. This facility is due to open in the Summer of 2022 and further details can be found at the following link: -

https://www.sheffield.ac.uk/news/new-gene-therapy-innovation-centre-advance-scientific-discoveries-life-changing-treatments

The UoS requires metabolite analyser systems, in order to undertake this co-ordinated work in parallel to other UK site - NHS Blood and Transplant (Bristol) working on identical methods and processes. To ensure the consistency of the science and comparability of the process development and results, the same equipment needs to be purchased as the other hub at NHSBT. GTIMC and NHSBT Hubs will use the same manufacturing platform being tech transferred from Cell and Gene Therapy Catapult.

II.1.6) Information about lots

This contract is divided into lots: No

II.1.7) Total value of the procurement (excluding VAT)

Value excluding VAT: £320,000

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKE32 - Sheffield

Main site or place of performance

Gene Therapy Innovation and Manufacturing Centre, Faculty of Medicine Dentistry of Health, The University of Sheffield

II.2.4) Description of the procurement

In order to assist with the tech transfer from Catapult the following item is being purchased asap:

1 x Bioflex 2

Between 2022 and 2027 the following items may be purchased:-

2 x Bioflex 2

The above equipment will be used to furnish one research and development lab and two clean rooms.

Installation, commissioning, consumables, training and annual support/maintenance/calibration may be incorporated for between 3 and 5 years as part of the purchase.

II.2.11) Information about options

Options: No

II.2.14) Additional information

Regulation 32 of PCR 2015 is being applied as in 32. (2) (b) (ii) and 32. (5) (a).

No contract will be entered into until after a 10-calendar day period from the submission of the VEAT notice date.

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Negotiated without a prior call for competition

- The products involved are manufactured purely for the purpose of research, experiment, study or development
- The works, supplies or services can be provided only by a particular economic operator for the following reason:
    - absence of competition for technical reasons

Explanation:

The University of Sheffield signed an agreement with Cell and Gene Therapy Catapult (CGT Catapult) to tech transfer the Catapult AAV (Adeno-Associated Virus) manufacturing platform to Gene Therapy Innovation and Manufacturing Centre' (GTIMC). This task is one of the milestones under the funding award supporting the establishment of the GTIMC in Sheffield. The milestone must be completed within 12 months of the start of the GTIMC Project, i.e. by end July 2022. Any delay in the tech transfer will also impact on the milestone related to MHRA accreditation of GTIMC due by end Q4 2022.

Using exactly the same equipment as the set up at Cell and Gene Therapy Catapult facilities will minimise delays and reduce time/avoid the need for optimisation of manufacturing protocols at GTIMC and allow us timely and within budget achievement of tech transfer milestones, optimisation using non generic equipment may introduce inconsistent results and invalidate the process which as a result would delay process, characterisation and final production processes.

The GTIMC and University of Sheffield will jointly acquire a technology license from CGT Catapult to be able to use their AAV manufacturing platform. This platform was established and optimised based on the processes developed using the proposed list of equipment.

The list of equipment (as set out herein) and the estimated timescales we plan to purchase was included in our proposal to the MRC/LifeArc to secure funding for the establishment of GTIMC in Sheffield. The subsequent Grant Offer includes the specific brands/models of equipment set out herein.

A single source is therefore proposed to formalise the solution provided by Nova

Biomedical for the following reasons: -

This equipment has been identified and is currently used by CGT Catapult and therefore to not use the same equipment would invalidate the Tech Transfer processes and agreements.

Furthermore, this specific equipment and supplier was identified by CGT Catapult as the optimum type to produce the results and treatments for the better advancement of the process, deviation from this would require significant lengthy additional optimisation which would significantly delay the process and miss funding milestones and therefore minimise delays and reduce time/avoid the need for optimisation of manufacturing protocols at GTIMC and allow us timely and within budget achievement of tech transfer milestones, optimisation using different equipment may introduce inconsistent results and invalidate the process which as a result would delay process, characterisation and final production processes.

Finally, the equipment set out herein will purely for the purpose of research, experiment, study or development within the University and no commercial licence will be held during the lifespan of this equipment. The prime functions of the GTIMC hub is to accelerate translational of gene therapy programs and clinical trials for rare monogenic diseases.

To increase the U.K. capacity for GMP clinical vector manufacturing using the catapult process to allow for expansion of U.K. skills and training within the GTIMC space and increase partnerships with other academia which will create a fertile ecosystem for innovation and research excellence in this field across academia.

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

The procurement is covered by the Government Procurement Agreement: Yes

Section V. Award of contract/concession

A contract/lot is awarded: Yes

V.2) Award of contract/concession

V.2.1) Date of conclusion of the contract

21 January 2022

V.2.2) Information about tenders

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

V.2.3) Name and address of the contractor/concessionaire

Nova Biomedical

Runcorn

Country

United Kingdom

NUTS code

- UKD63 - Cheshire West and Chester

The contractor/concessionaire is an SME

No

V.2.4) Information on value of contract/lot/concession (excluding VAT)

Initial estimated total value of the contract/lot/concession: £320,000

Total value of the contract/lot/concession: £320,000

Section VI. Complementary information

VI.4) Procedures for review

VI.4.1) Review body

High Court of England, Wales and Northern Ireland

London

Country

United Kingdom