

This is a published notice on the Find a Tender service: <https://www.find-tender.service.gov.uk/Notice/014694-2024>

Award

ACT2 Project

THE UNIVERSITY OF BIRMINGHAM

F15: Voluntary ex ante transparency notice

Notice identifier: 2024/S 000-014694

Procurement identifier (OCID): ocds-h6vhtk-0457fb

Published 8 May 2024, 2:12pm

Section I: Contracting authority/entity

I.1) Name and addresses

THE UNIVERSITY OF BIRMINGHAM

Edgbaston

BIRMINGHAM

B152TT

Contact

Kseniya Samsonik

Email

K.Samsonik@bham.ac.uk

Telephone

+44 1214146899

Country

United Kingdom

Region code

UKG31 - Birmingham

Companies House

RC000645

Internet address(es)

Main address

<https://www.birmingham.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**

ACT2 Project

II.1.2) Main CPV code

- 85121200 - Medical specialist services

II.1.3) Type of contract

Services

II.1.4) Short description

University of Birmingham (UoB) is the sponsor of ACT2 (Allogeneic Chondrocyte Therapy - A phase 2a study), an MRC funded project (MR/V027670/1). The study commenced in 2021 with the aim to develop and manufacture an allogeneic chondroprogenitor cell therapy from fresh osteochondral allografts in order to treat cartilage lesions in a single surgery. The study requires a manufacturing facility that can work with the research team to develop and validate the manufacturing process of the cell therapy product to a standard that can gain MHRA approval and thus enable the commencement of a Phase 2a human trial. Due to unforeseen circumstances UoB is no longer able to manufacture the cell therapy product and, thus an alternative manufacturing facility is required expeditiously.

The UoB team must operate within the restrictions placed upon them by the funder and the current project plan. In addition to this, the administrative burden as a consequence of BREXIT makes the use of a UK laboratory the only viable option. The OsCell Laboratory at The Robert Jones and Agnes Hunt Hospital (RJAHH) has the unique requirements to deliver the project within the financial and time restrictions facing the project.

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: £617,001.66

II.2) Description

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

II.2.4) Description of the procurement

Our decision to exclusively source the OsCell laboratory to manufacture the chondrocyte therapy is founded on several irrefutable factors. The OsCell Laboratory is the only GMP facility within the UK who currently manufacture a GMP compliant chondrocyte therapy for clinic use. It is the most experienced laboratory in the UK for the manufacture of chondrocytes, with a proven track record of chondrocyte manufacture since 1997. OsCell is the only GMP laboratory in the UK with the necessary experience of process development and the validation of new therapies for cartilage repair, as well as producing cells for use in a

clinical trial of a cell therapy for cartilage repair. RJAH and the OsCell Laboratory, together with Keele University, instigated and delivered the ACTIVE trial (ISRCTN48911177), which remains the largest clinical trial investigating a chondrocyte cell therapy in the world. In addition, the RJAH and OsCell Laboratory has just completed the ASCOT trial (ISRCTN98997175), a randomised controlled trial of autologous chondrocyte implantation vs. two mesenchymal stem cell (MSC) therapies, 1 of which was combined with chondrocytes. No other facility in the UK possesses the capability to furnish us with the complete suite of resources, knowledge, experience and support necessary to uphold the exceptional standards of research and innovation we strive to maintain.

The funding requirements and the current project status require the manufacturer to be in a position to commence manufacture within 2 months. The location of the OsCell laboratory is unique in that it is on the same site as the Keele University researchers involved in the study. This provides the researchers with the opportunity to closely interact with the facility to enable rapid knowledge transfer and ensure, as best as possible, that the future timelines of the project are met. It is anticipated that the manufacture protocols of the new therapy can be easily embedded within the facility and minimise the training requirements, hence facilitating a relatively early adoption. In addition, the close proximity will allow for optimised training and practice, negating the need for additional ethical and administrative approvals. The use of any other facility would result in significant delays, particularly regarding training and administration, which would threaten the project timelines. The nature of the OsCell Laboratory facility is also unique in that only 1 research project at a time is accepted by the facility, guaranteeing the project will receive the necessary priority that the current imposed timelines necessitate. The Qualified Person (QP) involved in the project for the last 14 months would remain in place, ensuring continuity. No other facility can provide a QP with prior knowledge of the project and experience of currently supervising the release of manufactured chondrocytes for clinical use in a UK facility.

II.2.11) Information about options

Options: No

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Award of a contract without prior publication of a call for competition in the cases listed below

- The procurement falls outside the scope of application of the regulations

Explanation:

Our decision to exclusively source the OsCell laboratory to manufacture the chondrocyte therapy is founded on several irrefutable factors. The OsCell Laboratory is the only GMP facility within the UK who currently manufacture a GMP compliant chondrocyte therapy for clinic use. It is the most experienced laboratory in the UK for the manufacture of chondrocytes, with a proven track record of chondrocyte manufacture since 1997. OsCell is the only GMP laboratory in the UK with the necessary experience of process development and the validation of new therapies for cartilage repair, as well as producing cells for use in a clinical trial of a cell therapy for cartilage repair. RJAH and the OsCell Laboratory, together with Keele University, instigated and delivered the ACTIVE trial (ISRCTN48911177), which remains the largest clinical trial investigating a chondrocyte cell therapy in the world. In addition, the RJAH and OsCell Laboratory has just completed the ASCOT trial (ISRCTN98997175), a randomised controlled trial of autologous chondrocyte implantation vs. two mesenchymal stem cell (MSC) therapies, 1 of which was combined with chondrocytes. No other facility in the UK possesses the capability to furnish us with the complete suite of resources, knowledge, experience and support necessary to uphold the exceptional standards of research and innovation we strive to maintain.

The funding requirements and the current project status require the manufacturer to be in a position to commence manufacture within 2 months. The location of the OsCell laboratory is unique in that it is on the same site as the Keele University researchers involved in the study. This provides the researchers with the opportunity to closely interact with the facility to enable rapid knowledge transfer and ensure, as best as possible, that the future timelines of the project are met. It is anticipated that the manufacture protocols of the new therapy can be easily embedded within the facility and minimise the training requirements, hence facilitating a relatively early adoption. In addition, the close proximity will allow for optimised training and practice, negating the need for additional ethical and administrative approvals. The use of any other facility would result in significant delays, particularly regarding training and administration, which would threaten the project timelines. The nature of the OsCell Laboratory facility is also unique in that only 1 research project at a time is accepted by the facility, guaranteeing the project will receive the necessary priority that the current imposed timelines necessitate. The Qualified Person (QP) involved in the project for the last 14 months would remain in place, ensuring continuity. No other facility can provide a QP with prior knowledge of the project and experience of currently supervising the release of manufactured chondrocytes for clinical use in a UK facility.

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

1 May 2024

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

Robert Jones and Agnes Hunt Orthopaedic Hospital

Arthritis Research Centre, Rjah Hospital

Oswestry

SY10 7AG

Country

United Kingdom

NUTS code

- UK - United Kingdom

Companies House

02992437

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: £617,001.66

Total value of the contract/lot/concession: £617,001.66

Section VI. Complementary information

VI.4) Procedures for review

VI.4.1) Review body

The University of Birmingham

Birmingham

Country

United Kingdom