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Award

ACT2 Study

THE UNIVERSITY OF BIRMINGHAM

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Notice identifier: 2025/S 000-039471

Procurement identifier (OCID): ocds-h6vhtk-055e22

Published 14 July 2025, 9:40am

Scope

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, previously contracted GMP manufacturers are 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 Newcastle Advanced Therapies Facility has the unique requirements to deliver the project within the financial and time restrictions facing the project.

Contract 1

Supplier

- Newcastle Hospitals NHS Foundation Trust (Newcastle Advanced Therapies)

Contract value

- £515,318.12 excluding VAT
- £618,381.74 including VAT

Above the relevant threshold

Earliest date the contract will be signed

22 July 2025

Contract dates (estimated)

- 31 July 2025 to 1 August 2026
- 1 year, 2 days

Main procurement category

Services

CPV classifications

- 85141000 - Services provided by medical personnel

Contract locations

- UK - United Kingdom

Participation

Particular suitability

Small and medium-sized enterprises (SME)

Other information

Conflicts assessment prepared/revised

Yes

Procedure

Procedure type

Direct award

Direct award justification

Extreme and unavoidable urgency

Our decision to exclusively source the Newcastle Advanced Therapies Facility (NATF) to manufacture the chondrocyte therapy is founded on several irrefutable factors.

The Newcastle facility has a track-record in academic and commercial translational cell-therapy partnerships including DPFS funded programmes. They have successfully completed technical transfer and validation, compiled validation data and authored IMPDs for the successful submission and approval by the MHRA of several autologous and allogeneic products with some resulting in Phase I/II clinical trials. (EudraCT 2023-000020-11, EudraCT 2014-001476-63).

The funding requirements and the current project status require the manufacturer to be in a position to commence manufacture within 4 months. Consequently, the project requires a dedicated clean room for the project, which NATF are able to provide with immediate effect. The NATF laboratory has been working with us on the project for the last 6 months in order to satisfy our Quality control testing for the project. NATF are therefore familiar with the project and the manufacture process. They are the only facility we are aware of that can provide, within the restricted budget, the GMP grade flow cytometry and Karyotype assay requirements. With regards to the additional QC testing requirements, the Newcastle team have close relationships underpinned with valid technical agreements with several contract laboratories and have worked with them to validate all the tests required for ACT2. QC test validation work undertaken to date is also directly transferrable (and does not require repeating), e.g. our mycoplasma product work-up with Mycoplasma Experience (also used by the Newcastle facility). This provides the researchers with the opportunity to rapidly transfer and implement manufacturing protocols, ensuring, 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.

Supplier

Newcastle Hospitals NHS Foundation Trust (Newcastle Advanced Therapies)

- NHS Organisation Data Service: 86101

FREEMAN ROAD

Newcastle Upon Tyne

NE7 7DN

United Kingdom

Email: accounts.receivable@nuth.nhs.uk

Region: UKC22 - Tyneside

Small or medium-sized enterprise (SME): No

Voluntary, community or social enterprise (VCSE): No

Contract 1

Contracting authority

THE UNIVERSITY OF BIRMINGHAM

- Companies House: RC000645
- Public Procurement Organisation Number: PHCQ-3464-LVTM

Edgbaston

Birmingham

B15 2TT

United Kingdom

Email: procurement@bham.ac.uk

Website: <http://www.birmingham.ac.uk>

Region: UKG31 - Birmingham

Organisation type: Public authority - sub-central government