

Section I: Contracting authority

one.1) Name and addressesI.1) Name and addresses

Department of Health and Social Care 39 Victoria Street London SW1H 0EU

Email

ccsinbox@dhsc.gov.uk

Country

United Kingdom

NUTS code

UKI32 - Westminster

Internet address(es)

Main address

https://www.gov.uk/government/organisations/department-of-health-and-social-care

Buyer's address

https://www.gov.uk/government/organisations/department-of-health-and-social-care

I.3) Communication

Additional information can be obtained from the above-mentioned address

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



https://health-family.force.com/s/Welcome

I.4) Type of the contracting authority

Ministry or any other national or federal authority

I.5) Main activity

Health

Section two: Object Section II: Object

II.1) Scope of the procurement

II.1.1) Title

DHSC NHS Human Leucocyte Antigen Typing – Advanced Rapid High Resolution Typing

II.1.2) Main CPV code

85145000 - Services provided by medical laboratories

II.1.3) Type of contract

Services

II.1.4) Short description

This work is being led by the Histocompatibility and Immunogenetics (H+I) Subgroup, established under the Department's fixed-term Implementation Steering group for Organ Utilisation (ISOU). The ISOU has been established to drive the delivery of the 12 recommendations set out in the Organ Utilisation Group's (OUG) report 'Honouring the gift of donation: utilising organs for transplant'. The H+I Subgroup will produce



recommendations to Ministers on the H&I service for solid organ transplantation.

This request for information/early market engagement is seeking supplier views on the provision of HLA typing assays that can produce a HLA type to the 2nd field (minimum) within a 4-5 hour period. The assay meeting all relevant regulatory and quality assurance requirements - should be implementable within a 5 year time frame, and the group would require the supplier to already have current experience with the HLA typing setting given the complex nature of this testing.

II.1.6) Information about lots

This contract is divided into lots: No

two.2) DescriptionII.2) Description

II.2.2) Additional CPV code(s)

- 85145000 Services provided by medical laboratories
- 85148000 Medical analysis services
- 85111800 Pathology services
- 85111810 Blood analysis services

II.2.3) Place of performance

NUTS codes

UKI32 – Westminster

II.2.4) Description of the procurement

This early request for information/market engagement exercise is being made publicly available to any organisations which have expertise in the provision of HLA typing assays for the purposes of clinical use in organ transplantation.

The purpose of the exercise is to inform the Implementation Steering Group for Organ Utilisation (ISOU) Histocompatibility & Immunogenetics Sub-



Group about the future direction and capabilities of assays which produce a high resolution HLA type of organ donors for transplantation purposes. This information will then be used to form recommendations within the ISOU framework and guide the future direction of HLA typing of organ donors in the UK.

This exercise seeks to engage with the market to enable the ISOU subgroup to:

Primary Requirement:

1. Understand the commercial assays capable of rapidly producing a type for HLA-A,B,C,DRB1/3/4/5, DQB1, DQA1, DPB1, DPA1 with a resolution of 2nd field (minimum). Currently the timeframe allocated for deceased donor typing is set at 4 hours, however this timeframe may be slightly relaxed in future, if for example a slightly longer timeframe produces a higher resolution type or clinically relevant information extending beyond the HLA loci is obtained.

The ISOU subgroup seeks to understand the assays and technologies which are currently available or will be brought to market in timeframe of 5 years which can fulfil the above remit.

Secondary Requirements:

- Availability of IT solutions for direct transfer of donor HLA typing results, including the use of Histoimmunogenetics Markup Language (HML) where appropriate, which would support the primary requirement.
- 3. Demonstrate compliance with in vitro diagnostic medical devices regulations (IVDR) for typing assays and software as required.
- 4. Indicate if typing beyond the HLA loci is being considered / developed with the capabilities of assays designed for rapid high resolution HLA typing. e.g. inclusion of HNA or MICA typing.

II.2.5) Process of engagement

OFFICIAL-SENSITIVE



Once you have registered using the link below we will contact you with a time slot and link for an online meeting on the **Friday 5**th **July 2024.** During this meeting you will have 35 minutes to present your company's offering in this space followed by 25 minutes of questions from the H&I sub group members. The information you provide will then be used to form recommendations within the ISOU framework and guide the future direction of HLA typing of organ donors in the UK.

Registration link: <u>C253996 Future of Technology within Histocompatibility</u> and <u>Immunogenetics (office.com)</u>

Please register your interest no later than 17:00 Friday 31st May 2024.