Specifications: Improving Resilience - Stem Cell Registry

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1. PURPOSE
	1. The two aims of this procurement are:
2. Increase the number of UK donors providing stem cell transplants for UK patients to improve resilience and sustainability of the UK stem cell supply
3. Increase the diversity of the donor pool to reduce health inequalities facing ethnic minority patients.
	1. This will support three of DHSC’s strategic objectives:
* Improve, healthcare outcomes by providing high-quality and sustainable care at the right time in the right place and by improving infrastructure and transforming technology
* Improve healthcare outcomes through a well-supported workforce
* Improve, protect and level up the nation’s health, including through reducing health disparities
	1. The DHSC independent advisory body, the UK Stem Cell Strategic Forum (UKSCSF), published their report – a10-year vision for stem cell transplant and cellular therapies – on 15 July 2022. The report focused on the future of stem cell transplantation and implications for development of advanced cell and gene therapies in the UK. It is noted in the Report that UK stem dell donor to UK patient provision is now only 30%, raising questions about the resilience and sustainability of an independent UK stem cell supply.
	2. To ensure the sustainability and resilience of the UK stem cell supply the Report recommends a 45% share for UK-to-UK provision. The Report also recommends prioritising funding the recruitment of stem cell donors from ethnic minority communities to address existing health inequalities. Ethnic minority patients are only 37% likely to find a good match from an unrelated stem cell donor, compared to 71% for patients of European descent (data from Anthony Nolan).
	3. The DHSC Stem Cell Programme has previously supported the development of the *UK Aligned Stem Cell Registry* and the *Anthony Nolan and NHS Cord Blood Bank*. The current priority for the Programme is increasing resilience of the UK stem cell supply and addressing health inequalities. Currently Anthony Nolan are funded through the Programme to recruit from members of the public and NHSBT are funded to recruit from its blood donor registry.
1. BACKGROUND
	1. For patients with blood cancer (such as leukaemia, lymphoma, and myeloma*)* and other blood disorders, stem cell transplantation provides a life-saving treatment when other options are unavailable or have been exhausted. A stem cell transplant allows donor immune cells to kill blood cancer cells, while also providing replacement blood cells following chemotherapy and possibly radiotherapy. These transplanted cells are taken up into the bone marrow where they can produce healthy blood cells.
2. THE REQUIREMENTS
	1. The Department of Health and Social Care wish to appoint a Supplier to recruit donors, take buccal swabs for genotyping, conduct laboratory analysis and genotyping and add the genotyped donors to the aligned UK Stem Cell Registry.
	2. The recruitment should target young donors under 30 who are more likely to be chosen to donate as they give the best clinical outcomes and ethnic minority donors from members of the public.
	3. Recruitment must include obtaining informed consent from members of the public with evidence retained for audit purposes. This will include evidence of the ability to explain what the genotyping process is, what information will be stored and what it will be used for. Examples of the proposed documentation/online information to be provided to prospective donors will be required.
	4. Obtaining, storing and making available personal information to the appropriate people and organisations in the stem cell healthcare system will be in accordance with the latest data protection regulations as detailed below in 15.8.
	5. Recruited donors will undertake a buccal swab and swabs will be used to genotype the donor to a standard compatible with the aligned UK Stem Cell Registry.
	6. Information on those recruited will need to be organised and made available to allow clinicians to be able to make an informed decision on whether the donor is the best match available as part of the aligned UK Stem Cell Registry.
	7. Service User Survey - The Supplier will conduct anonymised surveys with recruited donors to assess both Service satisfaction and trends in relation to uptake of the Service. The survey will assess donors’ and clinician’s satisfaction with the Service provided.
	8. Appoint a key point of contact for all the matter related to the contract.
3. QUALITY STANDARDS
	1. The supplier will be accredited to the World Marrow Donor Association or willing to work towards this to ensure that recruited donors can be assessed as potential matches for patients in other healthcare systems.
	2. The recruitment will be required to be carried out in accordance with the relevant Council of Europe guidelines. For example, donation in the UK is performed on an altruistic basis and so stem cell donors do not receive payment for joining the registry or for donating.

**Publication title:** [Guide to the quality and safety of tissues and cells for human application](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffreepub.edqm.eu%2Fpublications%2FAUTOPUB_17%2Fdetail&data=05%7C01%7Cjonathan.graves%40dhsc.gov.uk%7Cf54b36837d0748f3558a08da6f269ce9%7C61278c3091a84c318c1fef4de8973a1c%7C1%7C0%7C637944508869683248%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=tCcHsVCutWu5JNV1uvwyJTEFp%2Fs3FMek2RnxhUSWi6A%3D&reserved=0)

*Guide to the quality and safety of tissues and cells for human application. 4th edition*
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**Publication title:** [Safety, quality and ethical matters related to the use of organs, tissues and cells of human origin](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffreepub.edqm.eu%2Fpublications%2FAUTOPUB_15%2Fdetail&data=05%7C01%7Cjonathan.graves%40dhsc.gov.uk%7Cf54b36837d0748f3558a08da6f269ce9%7C61278c3091a84c318c1fef4de8973a1c%7C1%7C0%7C637944508869683248%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=%2Fx1HshcT3pVepgbYRAHhV77e9dT%2F20M6Lqw5%2FpMm4sU%3D&reserved=0)

*Safety, quality and ethical matters related to the use of organs, tissues and cells of human origin. Council of Europe conventions, recommendations, resolutions and reports. 3rd edition*
[download link](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffreepub.edqm.eu%2Fdownload%2Ftoken%2F85fb8354256813d3c1ac225d7525a2723faa7cca%2F&data=05%7C01%7Cjonathan.graves%40dhsc.gov.uk%7Cf54b36837d0748f3558a08da6f269ce9%7C61278c3091a84c318c1fef4de8973a1c%7C1%7C0%7C637944508869683248%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=8obszWn84BgR%2B06B13%2FaOsy4dWV9v5A4mK5xJXngIEM%3D&reserved=0)

1. DELIVERABLES/OUTCOMES/OUTPUTS
	1. List of deliverables and outputs:
* Recruitment of donor(s)
* Provide adequate information to donor(s) so they can have an informed decision.
* Undertake any clinical activity required to input the donor(s) data into the aligned UK Stem Cell registry: buccal swabs for genotyping, laboratory analysis
* Processing of donor(s) data adequately to allow clinicians to determine a good match.
* Quarterly reports that summarise the activities undertaken during that period and achievement of KPIs.
* Annual review report that summarise all year activities as well as Lessons Learnt and Service Improvements.
* Maintain the functionality to allow clinicians access to the potential donor’s information to determine if they are a suitable match for 10 years.

1. AUTHORITY RESPONSIBILITIES
	1. Appoint a contract manager that will attend meetings and be the main point of contact for any issues arising from the service.
	2. Arrange and attend quarterly and annual meetings for review of the service.
2. CONTRACTOR RESPONSIBILITIES
	1. Appoint a Contract Manager to oversee the work and liaise with/report as DHSC requires to DHSC’s Contract Manager.
	2. Provide the Department with timely and ongoing evaluation and quality assurance information relating to the programme
	3. Attend quarterly meetings and provide quarterly reports which include updates on costs to review progress and discuss the service, as required by the Department.
	4. Provide Business Continuity and Contingency Plan and Exit plan in accordance with the contract
	5. Facilitate to the Authority any required information for the completion of the Data Protection Impact Assessment.
	6. Attend a post contract review with the Department to review whether the objectives of the contract were met, to review the benefits achieved and to identify any lessons learnt for future projects; and
	7. Liaise with the DHSC representative/ contract manager as may be applicable given the nature and the extent of services required.
3. **YEARLY KPIs**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **KPI Number** | **Quality Key Performance Indicators** | **Good (=Target)** | **Approaching Target** | **Requires Improvement** | **Inadequacy** | **Reporting Frequency** |
| 1 | Number of male donors recruited under 30 (no ethnic minority)  | TBC |  |  |  | Quarterly |
| 2 | Number of donors recruited from ethnic minority groups under the age of 40 | TBC |  |  |  | Quarterly |
| 3 | Survey User Satisfaction completed by all Donors | 100% | 90% | <90-80% | <80% | Quarterly |
| 4 | Reports provided on time | 100% | 90% | <90-80% | <80% | Quarterly |
| 5 | Data breaches reported immediately | 100% | 99% | <99-98% | <98% | Within 2 hours of breach coming to the attention of provider |

1. CONTRACT PERIOD
	1. The contract period is from 1st January 2023 to 31 March 2025 with the option to extend for a further period or periods of 6 months.
2. BUDGET
	1. The budget assigned to this contract is specified below. Availability of funds for Period 2 and beyond are subject to annual business planning and confirmation from DHSC Finance team.

|  |  |  |
| --- | --- | --- |
| Period | £ (excluding VAT) | £ (including VAT) |
| 1. 1st January 2023 – 31st March 2023
 | £83,333.33 | £100,000 |
| 1. 1st April 2023 – 31st March 2024
 | £333,333.33 | £400,000 |
| 1. 1st April 2024 – 31st March 2025
 | £333,333.33 | £400,000 |
| 1st April 2025 – 31st August 2025 | Contingent extension at no cost to allow for possible delays |
| **TOTAL** | **£750,000** | **£900,000** |

1. **PAYMENT SCHEDULE**
	1. Payments will be made quarterly upon receipt of invoice and review of quarterly reports.

|  |  |
| --- | --- |
| Payment Period 1 | £ excluding VAT |
| 30th June 2023 | £83,333.33 |
| Payment Period 2 | £ excluding VAT |
| 30th June 2023 | £83,333.33 |
| 30th September 2023 | £83,333.33 |
| 31st December 20223 | £83,333.33 |
| 31st March 2024 | £83,333.33 |
| Payment Period 3 | £ excluding VAT |
| 30th June 2024 | £83,333.33 |
| 30th September 2024 | £83,333.33 |
| 31st December 20224 | £83,333.33 |
| 31st March 2025 | £83,333.33 |

1. CONTRACT MONITORING
	1. During the first 2 months of the contract, meetings are likely to take place fortnightly. Thereafter, meetings will take place:
	* Initial Meeting: Introduction of the Meeting; request of Business Continuity Plan and Exit plan; DPIA discussion.
	* Quarterly: review will focus on Key Performance Indicators and risk management.
	* Annual: review will focus on Final KPIs, Risk Management, Lesson learnt and Service Improvements.
	1. Two weeks prior to each quarterly meeting the Contractor will issue reports that reflect KPIs achievement.

* 1. Location of contract management meetings: Authority or Provider site or Teams video call
1. **AUTHORITY REPRESENTATIVES AND CONTACT POINTS**

Name of Authority's Contract Representative(s): Kath Bainbridge (Manager) **Head of Genomic Science and Emerging Technologies**: kath.bainbridge@dhsc.gov.uk

Main point of contact: Jonathan Graves, Advanced Therapies Lead: jonathan.graves@dhsc.gov.uk

In their absence: Roya Ziaie Team Lead – Genomics Science and Emerging Technologies: roya.ziaie@dhsc.gov.uk

For escalation process: Gail Marzetti gail.marzetti@dhsc.gov.uk

For commercial issues: Julia Estruga Commercial Lead: Julia.estruga@dhsc.gov.uk

Data Protection Officer: Adam Grindrod Deputy Data Protection Officer,
Office of the DPO, ODPO@dhsc.gov.uk

1. DATA
	1. Provision of data within the Service should flow securely and in accordance with Data Protection regulations.

## **Security**

* 1. The Service Provider shall deliver the service in accordance with the HMG Security Policy Framework.

<https://www.gov.uk/government/publications/security-policy-framework>

* 1. The Service Provider shall have a Cyber Essentials Scheme Basic Certificate or equivalent at the commencement date of the contract. Cyber Essential Scheme requirements can be located at:

<https://www.ncsc.gov.uk/cyberessentials/overview>.

* 1. The Service Provider shall ensure that Customer’s and Service Users information and Data is secured in a manner that complies with the Government Security Classification Policy rating of OFFICIAL-SENSITIVE.

[May-2018\_Government-Security-Classifications-2.pdf (publishing.service.gov.uk)](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/715778/May-2018_Government-Security-Classifications-2.pdf)

* 1. The Service Provider shall ensure that the Government Security Classification Policy rating is also applied when information and Data is transmitted across all applicable networks and/or in line with the Authority’s requirements.
	2. The Service Provider shall, where required, have the capability to employ encryption to information / Data which shall be sent across a network or extracted by electronic means. The Supplier shall ensure that the level of encryption complies in full with the Government Security Classification Policy rating of OFFICIAL-SENSITIVE and/or in line with the Authority’ requirements.
	3. The Service Provider shall ensure that any suspected or actual security breaches are reported to the Customer’s representative immediately and depending on the impact of the breach, shall be included in monthly/quarterly performance reporting to the Authority.
	4. The Service provider shall comply with all relevant legislation, organisational and cross Government policy and guidelines in relation to Data and asset security.

## **Standards**

* 1. The Service provider shall provide secure solutions that comply with any restrictions or requirements arising out of Customer’s security policies. This shall include, but not be limited to:
		+ - Cyber Essentials Scheme Basic Certificate; or
			- NHS Data Security and Protection Toolkit; or
			- ISO 27001 Information Security Management as agreed;
	2. The service provider shall not charge a premium to Buyers for any additional standards and/or security compliance applicable to a Call Off contract, unless otherwise agreed in advance by Buyers.
1. **SOCIAL VALUE**

The DHSC follows the Social Value model created by the Government and that include 5 themes and 8 policy outcomes which flow from these themes, as follows:

* Theme 1 COVID-19 recovery: Help local communities to manage and recover from the impact of COVID-19
* Theme 2 Tackling economic inequality: Create new businesses, new jobs and new skills; Increase supply chain resilience and capacity
* Theme 3 Fighting climate change: Effective stewardship of the environment
* Theme 4 Equal opportunity: Reduce the disability employment gap; Tackle workforce inequality
* Theme 5 Wellbeing: Improve health and wellbeing; Improve community cohesion

This contract supports theme 4 Equal Opportunity- Tackle workforce inequality - MAC 6.1: Demonstrate action to identify and tackle inequality in employment, skills and pay in the contract workforce.

To this effect we will require A time-bound action plan informed by monitoring to ensure employers have a workforce that proportionately reflects the diversity of the communities in which they operate, at every level.

The metrics you will need to report on annual basis:

* Number of full-time equivalent (FTE) people from groups under-represented in the workforce employed under the contract, by UK region.
* Total percentage of people from groups under-represented in the workforce on **apprenticeship schemes** (Level 2, 3, and 4+) under the contract, as a proportion of the all people on apprenticeship schemes (Level 2, 3, and 4+) within the contract workforce, by UK region.
* Total percentage of people from groups under-represented in the workforce on **other training schemes** (Level 2, 3, and 4+) under the contract, as a proportion of the all people on other training schemes (Level 2, 3, and 4+) within the contract workforce, by UK region.
* Number of people from groups under-represented in the workforce on other training schemes (Level 2, 3, and 4+) under the contract, by UK region.