

NHSBT strategic planning to address inequalities on the provision of apheresis treatments

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Cell, Apheresis and Gene Therapies Strategy 2022/27

The strategy is set in the context of the NHSBT vision and mission

The NHSBT Vision is a world where every patient receives the donation they need

The NHSBT Mission (that will enable us to realise the vision) is to
save and improve even more lives

This inspires and motivates us every day.

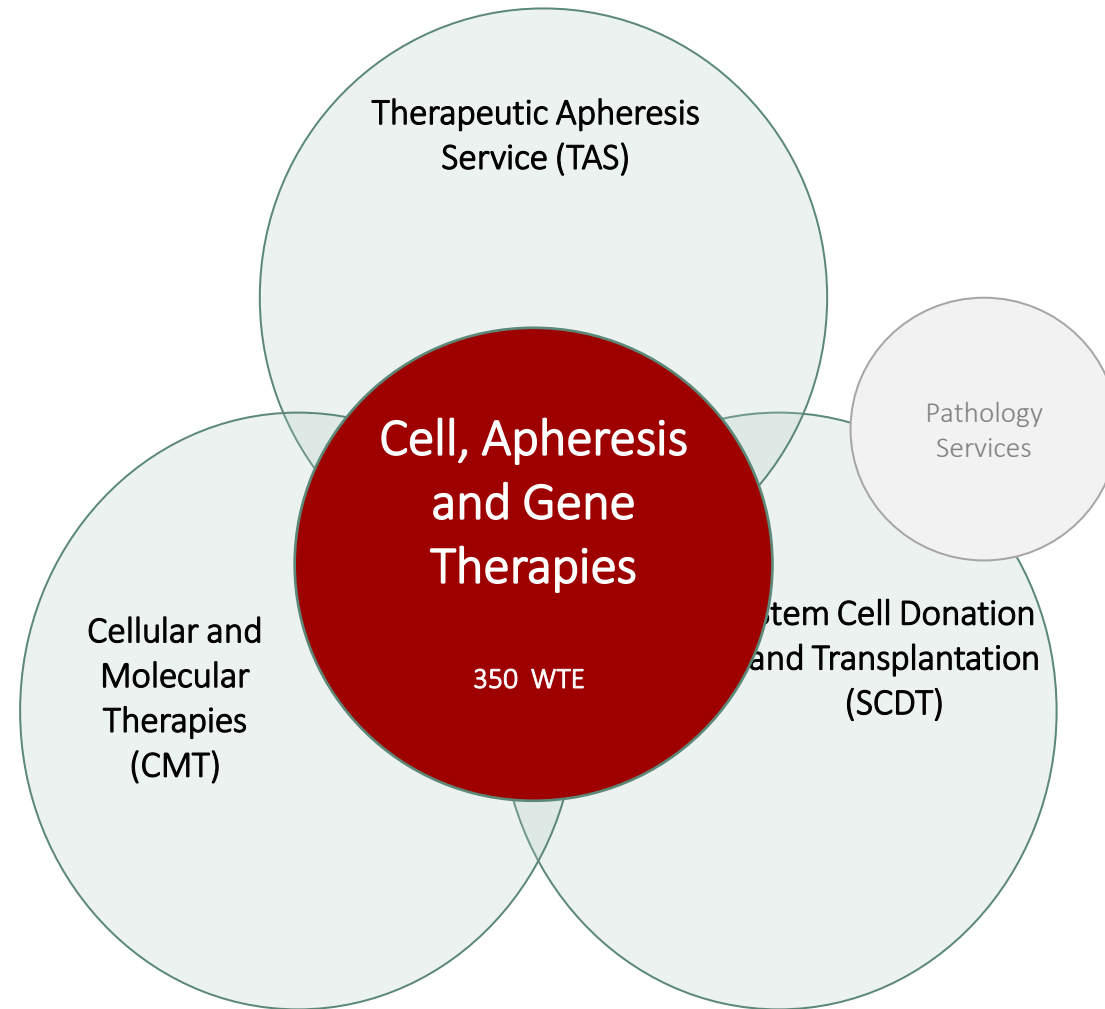
Achieving this will require significant change to what we do and how we work across every area of the Cell, Apheresis and Gene therapies (CAGT) functions.

We must be ambitious on behalf of the patients who rely on our critical products and services.

Therefore, this strategy sets out our **overall ambition in CAGT** to...

Grow and deliver a resilient cell, apheresis and gene therapy service to address health inequalities
and save and improve even more lives

The Cell, Apheresis and Gene Therapies Strategy



This strategy will set the direction for NHSBT's Cell, Apheresis and Gene Therapies (CAGT) services. It aligns CAGT's vision with the NHSBT strategy and the 2022 UK Stem Cell Strategic Forum (UKSCSF) report.

* GIA = Grant in Aid funding provided by the Department of Health & Social Care

Key Drivers of Change

- Health Inequalities – disparate access to standard and novel therapies
- Rapid growth in ATMP development – particularly relevant for priority patient groups
- Alignment with government priorities – timely contribution to UK Life Sciences Vision
- Fragmented national infrastructure – both physical and in relation to data collection/access
- Skilled workforce capacity – current shortages predicted to become more acute over next 5 years



**Grow and
diversify our
donor base**



**Modernise
our
operations**



**Drive
innovation**



**Collaborate
with partners**



**Invest in
people and
culture**

NHSBT's globally unique national infrastructure

Donor ID

NHSBT manages the British Bone Marrow Registry (BBMR) and Cord Blood Bank (CBB)

380,000 stem cell donors and 19,000 cord blood units for potential life-saving transplant

Tissue Typing

6 Histocompatibility & Immunogenetics laboratories part of Pathology Services, a key dependency

20,000 donors typed for CAGT (along with typing services for NHS patients)

Cell collection

9 regional Therapeutic Apheresis Service units

12,000 procedures provided to 2,400 patients and donors; supporting 5 ATMP clinical trials and delivery of 3 licensed ATMPs

Cell processing, freezing and storage

6 Cellular and Molecular Therapies laboratories
4 with MHRA licence to manufacture ATMP; cryogenic storage facilities supported by an ultra-low cold supply chain

1,800 life-saving stem cell transplants
Supporting 13 ATMP clinical trials and delivery of 3 licensed ATMPs

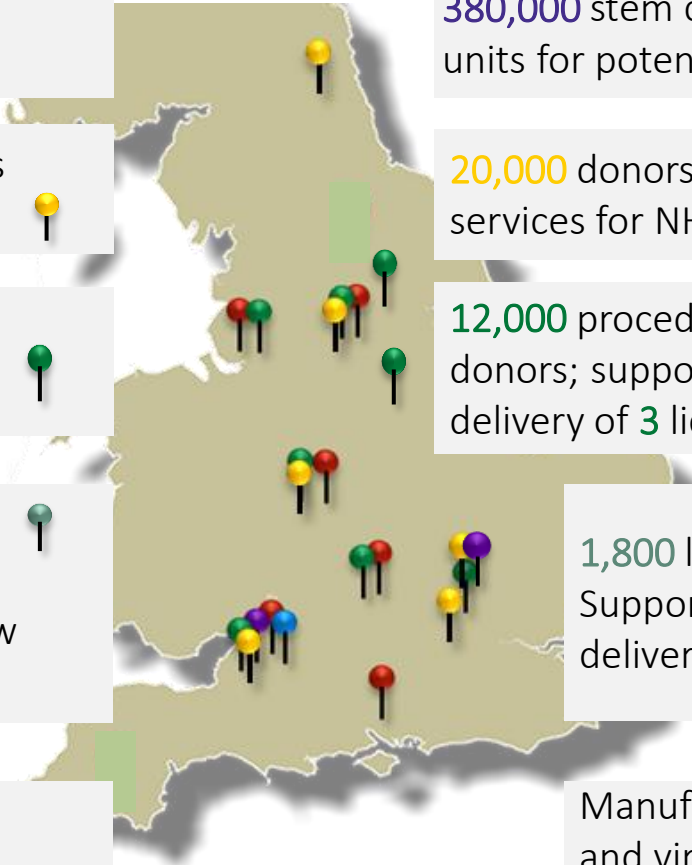
Genetic Modification

1 Clinical Biotechnology Centre (CBC)

Manufacturing GMP grade DNA plasmids and viral vectors; supporting 5 clinical trials

Clinical Trials

Clinical Trials Unit
Accelerated Clinical Trials Ltd (and previously IMPACT)



Drivers of growth in TAS

Increased demand for red cell and plasma exchange

Increased demand for automated red cell exchange to treat sickle cell patients, driven by the No One's Listening Report and the MedTech funding mandate.

Changes in IVIG (intravenous immunoglobulin) commissioning practices and supply chain issues have resulted in increased demand for plasma exchange services for patients with autoimmune neurological conditions.

Geographical gaps in service provision

TAS are establishing services in two areas we do not currently operate in, driven by geographical gaps in apheresis provision. TAS Bristol will provide a spoke plasma exchange service in the Southwest Peninsula. The new TAS Cambridge team will provide a red cell exchange service in East of England. In both locations, patients currently cannot access apheresis services and so receive alternative treatments or must travel. There is further opportunity to expand in the Southeast and Northeast.

Increasing demand for stem cell collection

All UK stem cell registries report difficulties in securing stem cell collection slots, and state that the lack of collection capacity adversely impacts provision of UK donors to both UK and overseas patients.

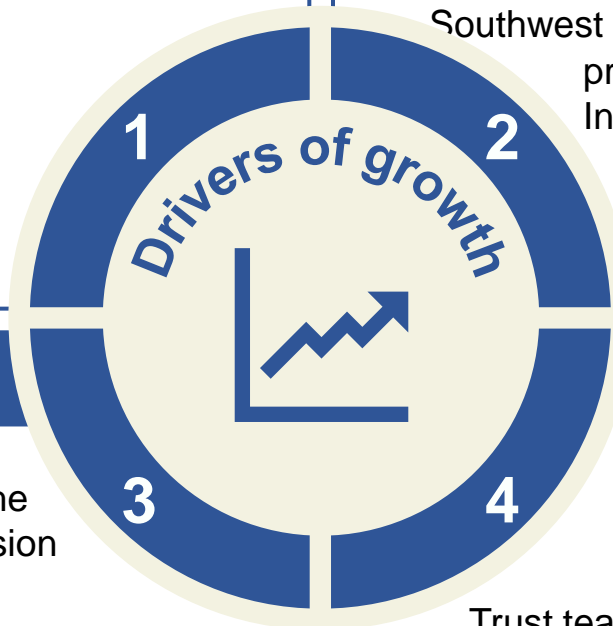
Demand for Advanced Therapy Medicinal Products (ATMPs), including CAR-T, is growing.

TAS are receiving increasing requests from researchers and biopharmaceutical companies for collection services for starting materials and clinical trials.

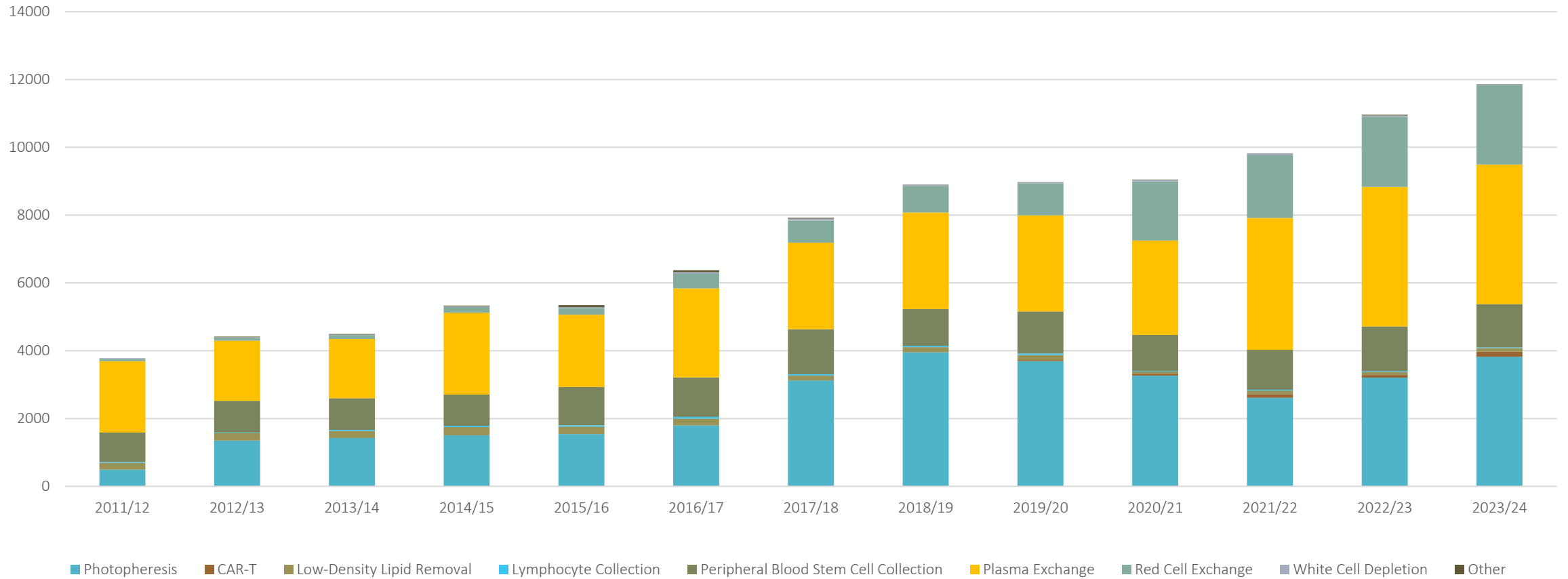
Lack of resilience in NHS services

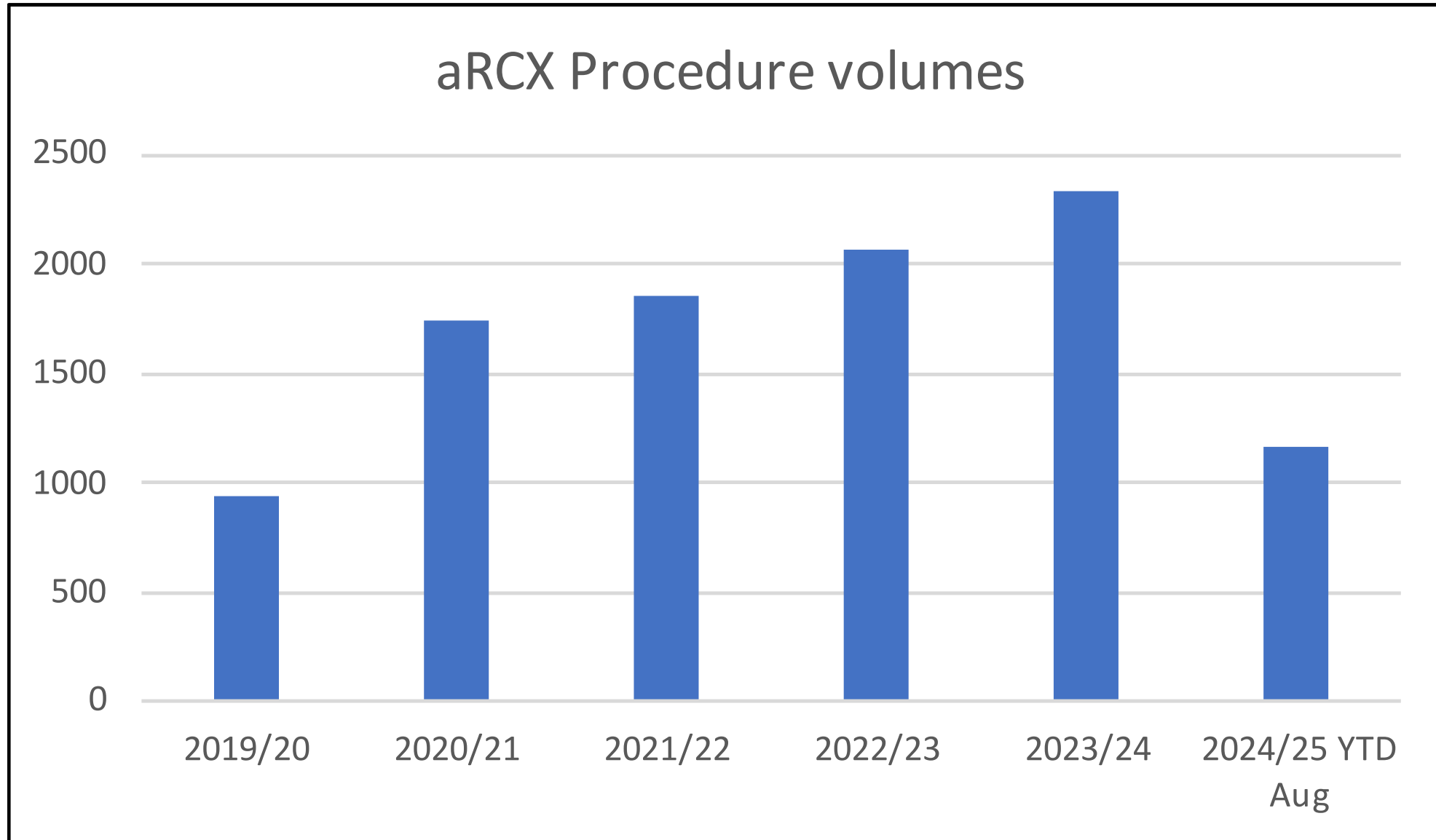
Where TAS do not provide services, NHS Trusts have their own apheresis teams.

Trust teams are often small, and therefore lack resilience in comparison to TAS, which has a large national team of Nurses. Trusts may also work in silo, for example neurology teams frequently struggle to access plasma exchange services run by Trust renal teams.



Demand for our services – 2011/12-2023/24





TAS Operations

TAS are one of the NHS's automated red cell exchange providers for patients with SCD (2339 aRCX procedures in 23/24) and are able to offer services to both adults and children which include not only access to routine aRCX, but are also able to mobilise our teams to offer the services at the patient bedside where required and provide urgent access to aRCX 24/7. This is a level of service many Trust's who themselves support patients with SCD are unable to match.

TAS Operations

- As a result Therapeutic Apheresis Services have been working in partnership with NHS Trusts, NHS England and Med Tech working group to improve access to aRCX, we plan to do this by:
 - Working with commissioners to ensure appropriate tariffs for aRCX procedures
 - Supporting existing customers expansion of aRCX services
 - Onboarding of new aRCX customers in existing regions and into new geographical regions.
 - Developing our workforce to better support patients living with SCD – New NHSBT / Trust shared medical roles responsible for the management of patients with SCD and new Advanced Clinical Nurse Practitioners able to support shared MDT review of care of SCD patients

Networking, Expansion, Modernisation

TAS digitally managed service

London Expansion

Genesis

Apheresis Working Group

UKFHD

Genetic testing for Sickle Cell Patients