

Collaborative Working Project Executive Summary

Project title	The British Society of Bone Marrow Transplantation and Cellular Therapy (BSBMTCT) - Evolution requirements of the UK Data Registry Design
Partner organisation/s	British Society of Blood and Marrow Transplantation and Cellular Therapy c/o Guy's Hospital, Great Maze Pond London. SE1 9RT United Kingdom Sanofi 410 Thames Valley Drive, Reading, Berks, RG6 1PT
Project rationale	The UK possesses valuable Hematopoietic Stem Cell Transplantation (HSCT) and cellular therapy data assets, including the BSBMTCT Registry, NHS Blood and Transplant datasets, Anthony Nolan donor datasets, Deutsche Knochenmarkspenderdatei (DKMS) datasets, Welsh Bone Marrow Donor Registry (WBMDR), national cancer datasets, disease-specific registries and emerging cellular therapy datasets. These data assets, however, remain fragmented and largely operate in parallel. This ecosystem, including the BSBMTCT registry, which tracks stem cell transplants and cellular therapies across the UK and Republic of Ireland, requires modernisation to meet evolving clinical needs and support the growing pipeline of novel therapies. The system currently lacks linkage and integration of clinical data with patient outcomes and places a heavy manual burden on the organisation. BSBMTCT is scoping and developing a new bespoke registry in partnership with the UK Stem Cell Strategic Forum, aligned with government initiatives on federated data platforms. BSBMTCT has requested Sanofi's support as a strategic partner to provide funding, project management support, and input on pharmaceutical industry data needs. This is a registry design and facilitation exercise only. It does not involve the collection, recording or analysis of individual patient data, and does not constitute research. All patient data remains under the governance and control of BSBMTCT and the NHS.

Project period	Starting Q3 2026 18-month project (12-month implementation and 6-month lead time for recruitment)
Project objectives	This 18-month project aims to deliver a fully developed registry proposition and business case that enables BSBMTCT and the NHS to make an informed decision on commissioning a new bespoke registry. Specifically, this means producing: • Requirements Specification — A detailed, stakeholder-validated set of functional and capability requirements for the new registry • Data Framework — Defined scope of data to be collected, including clinical data, PROMs/PREMs, supply chain, and demographic data • Vision & Value Proposition — A compelling narrative articulating the case for the new registry • Implementation Roadmap — A phased plan for how the registry would be built and deployed • Investment Case — A costs and benefits analysis to support funding decisions • Governance Model — Recommendations on how the registry should be governed and delivered Outcomes for Patients: • Improved quality and completeness of registry data leading to better-informed clinical decisions and improved care pathways. • Routine collection of Patient-Reported Outcomes (PROMs) and Patient-Reported Experience Measures (PREMs), giving patients a voice in their care. • Enhanced ability to track long-term patient outcomes, supporting improvements in quality-of-life post-transplant and post-cellular therapy BSBMTCT / NHS: • A clearly defined vision and business case for a new bespoke UK registry that meets the needs of all stakeholders. • Improved data quality and completeness through standardised collection processes and enhanced interoperability with NHS Electronic Patient Record (EPR) systems, including compliance with Health Level 7 Fast Healthcare Interoperability Resource Standards (HL7 FHIR). • Linkage with other data sets providing whole pathway visibility.

	• Increased capability to deliver actionable insights from registry data to support clinical guidelines, service design and research priorities. • A Secure Data Environment (SDE) that meets the needs of researchers in academia and industry. • Strengthened capacity of the BSBMTCT Registry team through automation and investment, reducing the burden of manual data re-verification. • A sustainable funding model for the registry, including ethical monetisation of data assets. • Improved ability to support clinical trials and research, including prospective studies, and a streamlined research data access process. • Enhanced national benchmarking and commissioner reporting capabilities. • Mitigation of the risk of data fragmentation as new cell therapies come to market. Sanofi: • Greater understanding of registry design best practices and the needs of transplant centres and the wider HSCT and cellular therapy stakeholder community. • Positioning as a trusted collaborative partner supporting the development of patient-centred NHS data infrastructure. • Improved reputation with relevant NHS organisations, BSBMTCT, UKSCSF and the broader clinical community as a constructive and responsible industry partner. • As Sanofi produces a medicine indicated in Chronic Graft versus Host Disease, improvements in the quality of registry data and care pathways may support appropriate evidence-based use of treatments in line with national and local clinical guidance. The total expected direct & indirect costs of this collaborative working project are approximately £219,400. Proportions: NHS 69%, Sanofi 31%.
Contact details	David Reynolds – Chief Executive BSBMTCT gst-tr.bsbmtregistry@nhs.net Paul Naish – Head of Market Access, Sanofi GB-MarketAccess@sanofi.com