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A Pilot Project to Evaluate the Benefit of Additional Support in Haematopoietic Cell Transplant (HCT) Research Data Management on Behalf of Anthony Nolan and BSBMTCT

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ABSTRACT

Background: The participation of transplant centres in research studies that request detailed follow-up data on included patients can be challenging due to the amount of time centre Data Managers have to complete additional requests. The Research Data Manager (RDM) Pilot Project was designed to support Anthony Nolan's longitudinal Patient/Donor project and provide real-world evidence of the benefit of additional and dedicated data management resources in transplant centres.

Objectives:: For Anthony Nolan to continue advancing the field of donor selection, up-to-date and accurate follow-up data is needed. This 12-month pilot project aimed to demonstrate how on-the-ground support could improve access to outcome data.

Study Design: Following RDM placements at two participating centres, we reviewed the data quality and quantity collected, thus ensuring the methods used remain effective and are likely to result in successful and continuous data improvement. The cohort covered a broad timespan and included historical patient records, posing challenges in availability of prior data and long-term follow-up of discharged patients.

Results: Following the placements, over 400 patients now have the most up-to-date and complete patient clinical outcome data available within the EBMT/BSBMTCT registry database for any group to study, reducing the burden on these centres to complete research data requests for these individuals.

Trial Registration: The authors have confirmed clinical trial registration is not needed for this submission

1 | Introduction

The registration of unrelated donor (UD) haematopoietic cell transplants (HCTs) and collection of post-transplant follow-up data is vital for supporting clinical care as well as research projects that improve patient experience, care and outcomes.

Patient HCT data from UK transplant centres (TCs) is collected by the British Society of Blood and Marrow Transplantation and Cellular Therapy (BSBMTCT) Registry and is submitted through the EBMT data platform to which BSBMTCT has shared access and controllership.

Participation in research studies by BSBMTCT TCs, including our project, has been hindered due to a lack of DM resources to routinely complete EBMT data collection forms and study data requests, as well as verifying previous data entry, often requested on top of existing workloads. In addition, the lack of DM resources

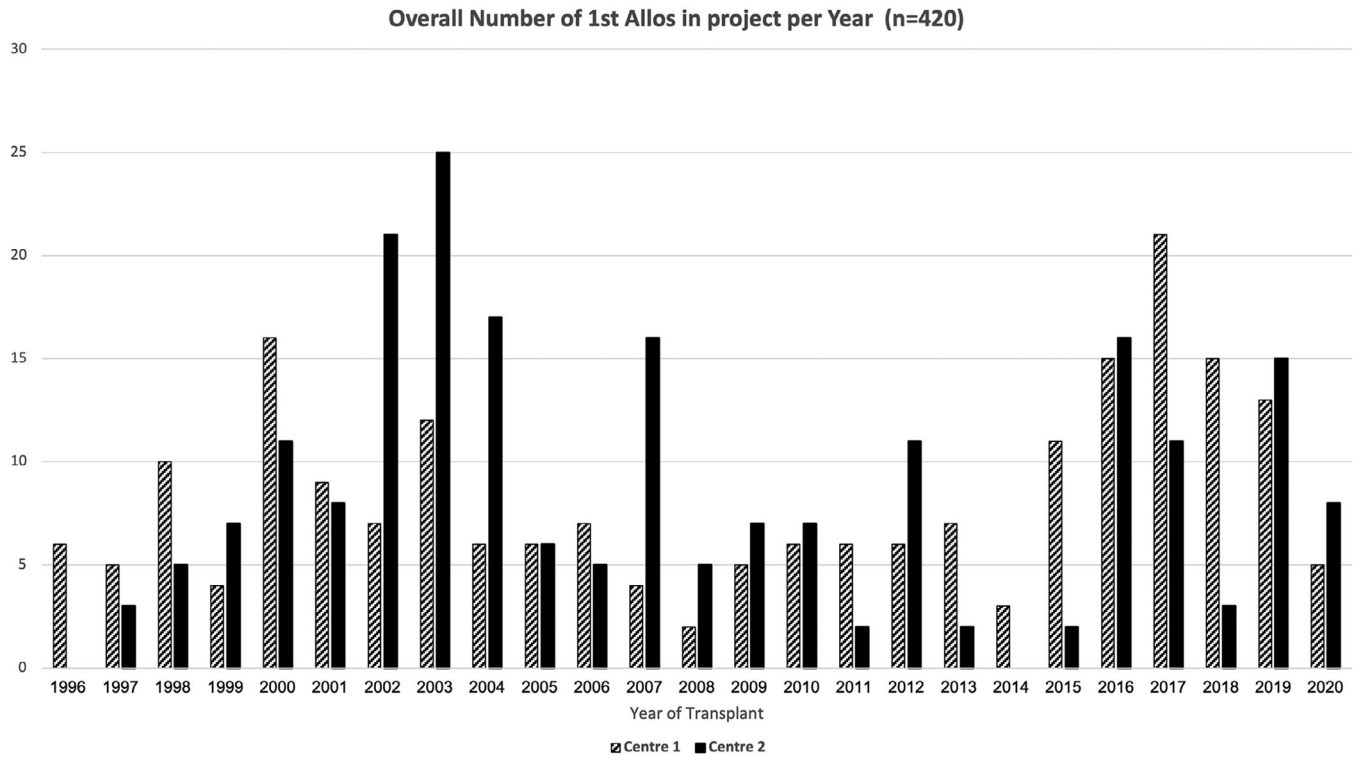

FIGURE 1 | Number of allografts at each participating centre that were part of the target enrichment project, meeting our inclusion criteria given in the methods section. Seven patients were excluded from the original cohort of 214 patients from Centre 1 due to consent issues or multiple allografts, while a further seven patients were excluded from the original cohort of 220 patients at Centre 2 due to multiple allografts and one transplant cancelled due to patient condition.

within TCs has meant that historical transplants are not updated with long-term follow-up data in a timely manner, or at all, as registration of new and more complex cases must be prioritised.

A DM survey highlighted the lack of dedicated HCT DMs in every TC, resulting in juggling EBMT data reporting with other tasks, and barriers for DMs accessing comprehensive training, induction and ongoing support from the clinical team [1, 2].

To address resource concerns, a 1-year pilot project was set up by Anthony Nolan Research Institute (ANRI) in 2021 to evaluate how additional, on-the-ground support from a dedicated Research Data Manager (RDM) could improve access to outcome data for research studies. Additional aims included supporting DMs with data audits, transitioning to new systems and increasing cross-centre communications between DMs.

2 | Methods

2.1 | Centre Selection

Four centres involved in Anthony Nolan's Graft Identification Advisory Service (GIAS) were asked for their interest in participating in the pilot, with two TCs agreeing to participate. EBMT transplant activity surveys pre-COVID indicated these centres performed 151 and 83 allografts, respectively in 2019 [3]. A selection of these were included in our cohort criteria as shown in Figure 1. Placements lasted approximately 6 months at each TC.

2.2 | Cohort Inclusion Criteria

The patients included in this targeted data enrichment project were part of ANRI's patient/donor project [4–8], a longitudinal study started in 1996 to determine how genetic and non-genetic clinical factors impact on the outcome of UD-HCT. Preliminary inclusion criteria were: (1) first allogeneic HCT with a UK donor; (2) HCT dates between 01/01/1996 and 31/12/2020; and (3) genomic DNA samples available for the patient and their respective UD.

Each centre's cohort was similarly sized but differently composed (Figure 1), with a higher number of recent transplants in Centre 1 and higher number of historical transplants in Centre 2. Final cohort sizes changed following review of the patient data, with exclusion due to lack of consent to share data or unknown previous allograft.

2.3 | RDM Training

The RDM required induction and systems training at each centre when beginning each placement, benefiting from existing knowledge of the EBMT Registry system and working knowledge of the data being collected. BSBMT Registry staff provided support where required.

Temporary honorary contracts were set up at both centres to allow the RDM to access local systems and work closely with a main BMT DM at each centre. Each centre nominated a host

manager to assist with induction and authorise relevant training and access.

2.3.1 | Centre 1—Placement Organisation and Logistics

The RDM worked with two DMs and one quality manager (QM) during the placement. The electronic patient record (EPR) systems in use were Epic (since 2019) and a local Filemaker Pro (Claris, Cupertino, USA) database for Day 0 HCT data.

A BMT module in Epic was in development; however, DMs could access some laboratory results and clinical documents dating back to 2010. These data had to be extracted manually from scanned documents, as no database containing post-transplant data was available. A legacy system used pre-Epic was no longer accessible. Multiple data sources had to be used to find stem cell laboratory data, diagnostics and medications.

2.3.2 | Centre 2—Placement Organisation and Logistics

The RDM induction consisted of 2 weeks on-site with the host manager. The RDM also worked with one main DM and a QM. The EPR system in use was Allscripts Sunrise, housing all HCT data since 2004, apart from stem cell laboratory data.

Again, no local database containing all BMT data was available. For both centres, data reports could be run in the EBMT Registry system, once data had been manually gathered from their local system and registered there.

2.4 | Historical Patient Records

Historical records were defined as those not available electronically: 69 patients transplanted prior to 2010 in Centre 1, and 80 patients transplanted prior to 2004 in Centre 2. All Centre 2 patients had a transplant protocol summary in Sunrise.

Historical records were requested from the TC archives. In Centre 2, 47% of historical records were not retained, since the requirement to store records for 30 years came into effect from November 2005.

To manage the broad timespan, the RDM started with the most recent patients to familiarize with the systems. Historical records were also requested at an early stage to check availability.

2.5 | Data Included in the Study

Patient outcome data were recorded in the EBMT/BSBMTCT registry, and data completion was measured using data points on the corresponding forms. The project primarily covered MED-A data (minimum essential data) that were routinely collected by EBMT/BSBMTCT. See Table S1 for further reference. A small proportion of variables lay within the optional MED-B dataset, usually submitted only for patients in research studies. (Since 2023, the MED-A and B datasets have been revised and renamed Core and Extended data)

To maximise the benefit to the TCs, the RDM opted to collect as much MED-AB data as possible for our cohort. This enabled the most complete data available within the EBMT Registry for any group to study, reducing the burden on these TCs to complete research data requests for these individuals.

2.6 | Primary Care Data

A key issue in obtaining good-quality data for research is the capacity to maintain continuous follow-up on all surviving HCT patients. To access long-term follow-up data for discharged patients, the RDM used the NHS England Spine portal to find their most recent medical centre. The portal displayed date of death; however, cause of death was not listed. A second tool, NHS Service Finder, allows users with a registered NHS email to access non-public emails for individual clinics, a timesaving resource that not all DMs were aware of. Although requesting patient summaries from clinics involved multiple emails, the email response rate was 85% after reminders. There appeared to be restricted access to full patient summary care records.

2.7 | London Care Record

In June 2022, the London Care Record was integrated into Sunrise, enabling patient data sharing within Primary and Secondary Care for London-based patients. If recent data were available via this resource, basic follow-up information could be obtained, bypassing the NHS tools mentioned above. An equivalent resource was subsequently introduced within Epic at Centre 1. This is now available more widely.

3 | Results

Through centres' historical records, local systems and primary care data, the RDM was able to significantly improve data accuracy and completeness. Variability in data availability was seen between centres, depending on the time period and, as expected, the inclusion of certain patients in prior studies (Table 1). Centre 2 had a greater number of patients with up-to-date MED-A and follow-up data, but fewer patients with MED-B data recorded in the EBMT Registry than Centre 1.

3.1 | Improving Data Completeness

When comparing results in Table 1, we discovered differences in centre practice and interpretation of EBMT guidelines, resulting in Disease Status being recorded differently in each centre.

Improvements in data completion are highlighted in Table 1. Patient blood group became 100% complete for our full cohort. Most patients did not have ethnicity recorded in detail; however, this could be completed in many cases, leaving less than 15% as unknown. The number of CD34+ cells infused remained a challenge to collect in both centres due to data being stored by separate teams and systems. In Centre 1, 58% could be completed, but 75% of Centre 2 patients still had this item missing.

TABLE 1 | Overview of the updated data for Centre 1 and 2.

	Centre 1			Centre 2		
	No. of transplants with missing data		Unknown/not evaluated	No. of transplants with missing data		Unknown/not evaluated
Data items	**Start**	**End**	**End**	**Start**	**End**	**End**
Full MED-A missing	4	0	0	0	0	0
Patient blood group	63	0	0	22	0	0
Patient ethnicity (further specified)	206	0	17[a]	147	0	19[b]
Main cause death	1	0	10	1	0	16
Reduced intensity conditioning	15	0	0	3	0	1
Other cell therapy/DLI Y/N	18	0	1	67	0	8
Best response	8	0	41	2	2	23
Chemo	6	1	0	12	1	0
Doses	16	4	0	61	2	1
GvHD prevention drugs	16	3	0	11	0	1
Stem cell source (donor) BM/PB	1	0	0	1	0	0
Donor blood group	68	0	0	29	0	0
Number of CD34 positive cells infused	123	0	52	204	154	1
Comorbidity at HSCT	21	0	5	127	0	30
Patient weight at HSCT	91	9	2	138	2	11
Patient height at HSCT	97	14	3	139	2	22
Neutrophil recovery	4	0	2	0	0	1
Engraftment date	8	0	1	3	0	1
Overall chimerism	121	4	136[c]	212	1	69[c]
aGvHD grade	7	0	7	2	0	17
aGvHD date onset	50	12	3	62	1	18
Infections by D100 Y/N	122	0	4	205	0	22
Other complications by D100 Y/N	113	0	0	234	0	60
Disease status at transplant	12	0	3	17	0	0
WBC at diagnosis	183	89	21	194	62	74
Cytogenetics at diagnosis[d]	165	69	27	133	19	24
Last assessment data						
aGvHD	98	0	20	103	0	31
cGvHD	8	0	7	52	0	20
Infections	150	0	15	200	0	34
Other complications	151	0	18	207	0	60
Secondary malignancy Y/N	26	0	9	86	0	24
Additional disease treatment Y/N	29	0	7	62	0	15
Relapse	20	0	8	60	0	17
Last disease status	114	0	49	153	0	94
Conception	29	0	22	179	0	15

(Continues)

TABLE 1 | (Continued)

Data items	Centre 1			Centre 2		
	No. of transplants with missing data		Unknown/not evaluated	No. of transplants with missing data		Unknown/not evaluated
	Start	End	End	Start	End	End
Survival status	0	0	0	1	0	0
Patients lost to follow-up	28	9[e]	0	22	3[f]	0

Note: At Centre 2, reasons patients were lost to follow-up were: Moved overseas, $n = 2$; no longer registered in NHS, $n = 1$.

[a]For Centre 1, the ethnicities of 17 patients were not known (i.e., the data were not captured within patient records). Seventy-two patient ethnicities could not be further specified within the ProMISe database based on available data from patient records, for example, we just have 'White,' 'Black,' 'Asian,' etc., without any further detail.

[b]For Centre 2, the ethnicities of 19 patients were not known. Forty patient ethnicities could not be further specified within the ProMISe database based on available data from patient records, as detailed above.

[c]Chimerism: many results are 'not evaluated' due to the type of disease, or tests not done within 100 days.

[d]Cytogenetic data were not available on all patients as this was not a feature of their disease.

[e]At Centre 1, reasons patients were lost to follow-up were: No reply from last known GP, $n = 3$; GP refused to give information, $n = 1$; no contact with GP since 2015, $n = 1$; moved overseas, $n = 4$.

[f]At Centre 2, reasons patients were lost to follow-up were: Moved overseas, $n = 2$; No longer registered in NHS, $n = 1$.

Regarding treatments, 849 and 769 drug records were added for Centres 1 and 2, respectively, affecting 170 and 182 patients at each site. Most were additional treatments pre- or post-transplant. As this data was mainly recorded in the optional data forms, it would be unlikely that this information would have been captured otherwise.

Overall, clinical outcome data reporting was greatly improved (Table 1). Relapse status was verified in all follow-up records and updated where necessary. Of all patients with acute GvHD reported at the start, 27% had the onset date missing. By the end of the pilot, this reduced to 3%. The aGvHD onset date had never been noted for 21 patients (5% overall) therefore, those remained unknown.

In Centre 1, 33 patients eligible for follow-up had a pre-2019 date last reported to EBMT/BSBMTCT. This reduced to 7 patients by the end of placement. Similarly, in 2022 at Centre 2, 62 patients had a pre-2020 follow up reported, reduced to 9 patients by placement end. Improvements were also made in the rate of lost-to-follow-up patients. Table 1 indicates that 13.5% (Centre 1) and 10.3% (Centre 2) were recorded as lost-to-follow-up. The RDM reduced this to 4.4% and 1.4% on placement completion.

TABLE 2 | Examples of amended data for Centre 1 and 2.

Data items	Number of records changed	
	Centre 1	Centre 2
Main cause of death	13[a]	26[a]
New drug records added	849[b]	769[c]
Drug records recoded	17	14
Source of stem cells (BM, PB)	4	7
Acute GvHD max grade	53[a]	88[a]
Chronic GvHD status	112[a,d]	162[a,e]
Relapse status post HCT	40[a,f]	58[a,g]
Main diagnosis classification	2	6
Main diagnosis date	31	16

[a]Includes updating records previously coded as 'unknown'.

[b]Multiple drug records per patient can be added. These amendments were made to 170 patients at Centre 1.

[c]As b. Amendments were made to 182 patients at Centre 2.

[d]Multiple assessment records per patient can be added. These amendments were made to 72 patients at Centre 1.

[e]As d. Amendments were made to 66 patients at Centre 2.

[f]As d. Amendments were made to 26 patients at Centre 1.

[g]As d. Amendments were made to 43 patients at Centre 2.

3.2 | Verification of Existing Data

In addition to missing data, previously reported data within the EBMT registry was verified and amended where necessary (Table 2).

Day 0 data was amended in a small number of cases, for example main diagnosis or cell source. Historical data for Centre 1 had been converted and imported to the EBMT Registry in the early 2000s; therefore, some estimated diagnosis dates could be updated.

Many amendments to follow-up data involved updating assessments previously coded as 'unknown,' however, data was retrospectively found in historical records. Examples include the relapse status, aGvHD grade and incidence of cGvHD (Table 2).

3.3 | Additional TC Support

The RDM supported the Centre DMs in additional tasks. At Centre 1, the DMs and RDM shared the workload for a research study, including 40 lymphoma patients: a good example of time-consuming data gathering where additional support from a dedicated RDM made this study feasible.

During Placement 2, the RDM assisted with data checks for outcome reports, including missing cytogenetics data in national registry outcomes analysis. This covered 391 patients, transplanted 2016–2020, with 3 months to collect and register the missing cytogenetics data. The task was shared between the main DM and RDM and involved checking the more complex cases with clinicians. This improved cytogenetics data can now be reused in research studies. The importance of completed cytogenetic data to determine disease risk factors is highlighted in the EBMT benchmarking project [9, 10].

The RDM was able to transfer primary care access knowledge to DMs in the second placement, demonstrating the benefit of having team members working across sites with the specific aim to improve patient data reporting. The RDM helped DMs in both centres with data reports in the EBMT Registry system, identifying groups of patients with specific characteristics or missing data.

Following on from the pilot, 420 patients now have the most up-to-date and complete data available within the EBMT registry database for any group to study. An additional 142 patients (34% of the full cohort) can now be included in research studies from the ANRI patient/donor project.

Currently, the patient/donor project requires ultra-high resolution (UHR) HLA typing data for six HLA loci (HLA-A, -B, -C, -DRB1, -DQB1 and -DPB1) as the minimum for inclusion into further analyses. From our first publication on the importance of typing and matching patients and donors at this level, 134 of 891 included patients were from Centre 1 and 2, had complete typing, and were included in the analysis [7].

4 | Conclusions

The results of this pilot demonstrate that the availability of additional and dedicated DM resources does improve data completion and accuracy. However, as highlighted in previous BSBMTCT surveys, many DMs are not working full-time on the reporting and completion of EBMT data due to conflicting departmental priorities.

This is a challenge not only faced within the UK; similar issues have been raised by other national registries [11, 12]. Improved access to training and resources were also highlighted as key solutions in the strategy for more effective data acquisition by the Austrian Registry [13].

4.1 | Induction and Training of DMs

In response to the training challenges cited in DM surveys, BSBMTCT has provided fully funded annual DM dedicated training days since 2017. Their DM Induction manual launched in March 2023, as a step towards standardising training among BSBMTCT centres. This provides e-learning opportunities through certified modules. More standardised DM job descriptions and banding are also being considered, as this varies across centres.

With the new EBMT data platform in August 2023, EBMT created certified e-learning modules covering data entry and filtering, which must be passed before access is granted. Initial training sessions on the data extraction tool were released in September 2024. Due to limited functionality, data quality checks have not been optimal during the first 2 years of the new EBMT registry; however, improvements are in progress.

Following the EBMT 2024 Annual Meeting, Catherine Grundy, DM at Nottingham University Hospital, volunteered to set up a network for DMs to share information and meet online regularly. During the bi-monthly meetings, educational presentations are given by experienced colleagues working in the field.

4.2 | Handling MED-AB Data

Day 0 data were often not registered within the 7-day guideline, and casework continues to build when DM resources are stretched. Common to most TCs, the MED-B data were only occasionally recorded at both centres due to time constraints and patient caseload.

This study identified cases where transplants were not registered with EBMT, likely coinciding with DM staff shortages or project reallocation. In addition to the consent to treatment, centres must obtain explicit consent for EBMT data sharing, potentially hindering timely registration if not built into TC procedures.

One potential solution to data standardisation challenges would be implementing a BMT-specific module within the EPR systems. This has been explored by the paediatrics team at the Royal Marsden Hospital in their EBMT 2025 poster [14]. The module may be reproducible across centres to avoid duplicating effort. The use of templates has been demonstrated as an efficient data collection method by several centres in the UK and elsewhere. Institut Catala d'Oncologia-Hospitalet Barcelona has shown that completion of in-house templates designed by their clinical team improves accuracy and punctuality of the data [15].

Variation in capturing GvHD grading was noted, with DMs manually searching text in clinical notes. Without a template, many consultants record whether a patient's GvHD has 'improved' or 'worsened.' Centre 2 used a centre-developed clinic proforma to record the extent and site of cGvHD, which facilitated data gathering for those patients. This centre used a BMT scorecard containing GvHD information for evaluating patients and symptoms. The DM confirmed that clinical notes remained the main source for transcribing GvHD data to the EBMT registry because this was the most consistent and reliable. This finding corresponds with those of DMs in other countries, for example, the audit performed at Rigshospitalet in Copenhagen [16]. A BSBMTCT abstract highlighted improvements in GvHD data completeness since 2004, demonstrating centre efforts to improve GvHD data quality [17]. However, a quarter of the BSBMTCT DM survey respondents could not confirm established data collection processes in place to support GvHD data submissions, suggesting that additional support would be beneficial.

4.3 | Tracking Follow-Ups

For patients that have lost clinical contact with the centre, DMs must contact external clinics for updates. Centre 2 had good availability of follow-up data internally through its late effects clinic. Although these clinics are not available in all TCs, the number has recently been increasing, in recognition of their benefit on patient long-term welfare, and the diverse needs of such a unique patient population. From 2014 to 2019, improvements were seen in the number of NHS-based centres having a dedicated long-term follow-up clinic for allogeneic transplant recipients (52% vs. 33%) [18]. This will inevitably result in the improvement of detailed patient outcome data available to DMs.

The follow-up data acquisition is currently time-consuming, especially for external data. A BSBMTCT presentation illustrates trends in follow-up completeness, which is more up-to-date for recent transplants, prioritised over historical patients due to time constraints [19]. As access to primary care physician details has improved, many patients originally 'lost-to-follow-up' can now be tracked. Direct access to more detailed primary care records, external clinic letters and coroner reports would increase efficiency for DMs seeking follow-up data; however, there may be some patient consent constraints.

Our results clearly demonstrate the benefits of additional DM resources, providing much-needed support to existing teams, and helping to improve patient outcomes by facilitating detailed research studies. The previously acquired expertise in handling HCT patient data and the EBMT system was hugely beneficial. The RDM was able to ensure complete, accurate and up-to-date patient outcome data were available on this cohort of individuals, making the long-term goal of improving patient outcome data, a reality.

Author Contributions

S.H., G.J., J.L., H.Br., H.A., J.A.S., S.G.E.M. and N.P.M. designed the study. S.H., B.C., H.Bl., Y.V., V.P., T.S. and L.V. were responsible for data collection. S.H., J.L. and N.P.M. interpreted the data. S.H. performed the analysis. All authors critically reviewed and edited the manuscript and approved the final version.

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Ethics Statement

The Anthony Nolan Patient/Donor project commenced in 1996 and received ethical approval. A separate ethical approval was not sought for this initiative as it covered routine data collection being conducted by UK data managers in the HCT field.

Consent

Recipients and donors sign a consent form to participate in the patient/donor project. In January 2025, the project was evaluated by an external Research Review Board as part of both an internal review of projects and the Association of Medical Research Charities (AMRC) membership requirements, which included review by both patients and donors, as well as scientific and medical experts, and was given favourable opinions to continue in the long-term.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The content of datasets analysed during this study is available at https://www.ebmt.org/registry/ebmt-data-collection, but data are not publicly available for patient confidentiality reasons. The TCs involved in the study have access to their own data in the EBMT Registry database. All data analysed within this study are available within the BSBMTCT Registry. Access to anonymised data for any future studies is subject to study protocol approval via the BSBMTCT Clinical Trials Subcommittee and completion of their data sharing agreement.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.

Supporting File 1: jha270235-sup-0001-tableS1.docx.