THE EBMT REGISTRY

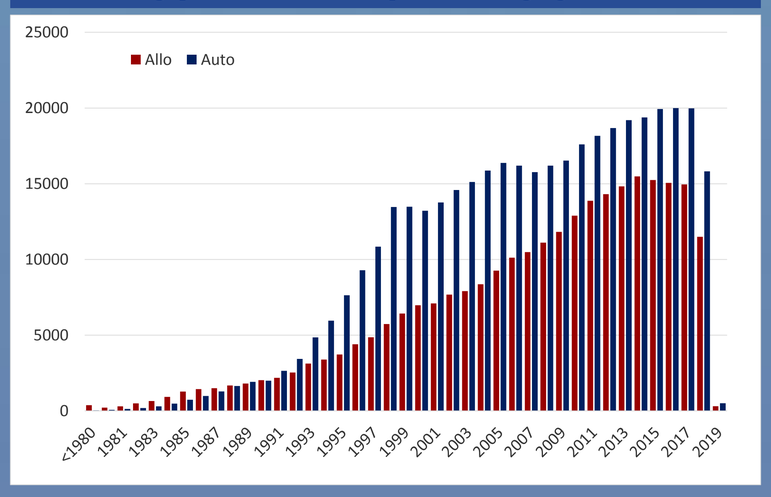
European Society for Blood and Marrow Transplantation

Current Data & News

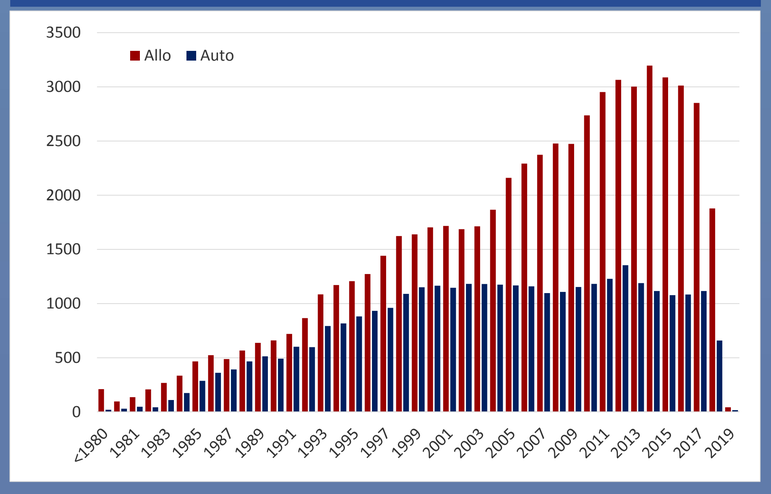
EBMT Registry Overview

Disease	Patients	Transplants
Acute leukaemias: AML	91,456	100,516
Acute leukaemias: ALL	50,147	54,165
Acute leukaemias: other/unknown	3,323	3,686
Chronic leukaemias: CML	22,092	23,809
Chronic leukaemias: CLL	6,957	7,650
Chronic leukaemias: other/unknown	1,075	1,179
Lymphomas: NHL	109,628	121,872
Lymphomas: Hodgkins	36,534	42,439
Lymphomas: other/unknown	1,709	1,829
Multiple myeloma/Plasma cell disorders	133,397	179,594
Solid tumours	43,896	59,910
Myelodysplastic/myeloproliferative	34,788	38,929
Aplastic anaemias	13,702	15,126
Primary immune deficiency	6,403	7,195
Inborn errors: other / unspecified	2,603	2,932
Histiocytic	1,530	1,680
Autoimmune diseases	2,851	2,911
Haemoglobinopathies	6,840	7,200
Other/unknown	250	292
Total	569,181	672,914

Type of transplant by year

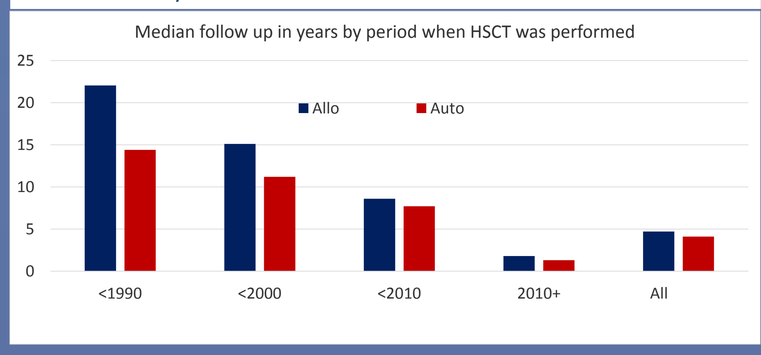


Paediatric transplants by year



Follow up

Long term follow up is essential for research. It helps us understand what can benefit or harm a patient, not only around the time of treatment but years after the event.

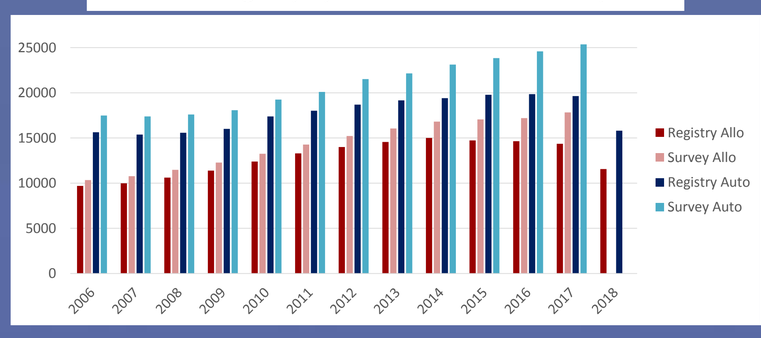


Registration Completeness

We aim to obtain 100% HSCT registrations from our members. However, a comparison with the Activity Survey which is conducted independently from the Registry shows that this is not the case. The trend towards less registrations being submitted to the EBMT Registry is worrying as it can introduce biases in the registry studies.

Make sure you report all transplants

Number of transplants reported to the Activity Survey and EBMT Registry by centres known in both systems



European Medicines Agency (EMA) and Cell Therapies

Positive Qualification Opinion – EMA

In July 2018 EMA has released its draft positive qualification opinion on using the EBMT Registry to monitor long-term safety and efficacy of Chimeric antigen receptor (CAR) T-cell therapies. The Committee for Medicinal Products for Human Use (CHMP) considers that the cellular therapy module of the EBMT Registry may be used as a data source for regulatory purposes in the context of CAR-T cell therapies authorised for haematological malignancies.

The publication of the draft EMA opinion has driven a sharp increase in interest among pharmaceutical companies in collaborating with EBMT to collect long-term safety data for Chimeric Antigen Receptor (CAR) T-cell therapy and Immune Effector Cells.

EBMT will effectively be a key collaborator in rolling out these novel therapies by supporting post-authorisation follow-up and supplying data to facilitate risk-benefit evaluations.

Register your patients' data with the Cellular Therapy MED-A form

The Cell Therapy Registry (CTR) aims to collect data on the administration and long-term follow-up of somatic cell therapy medicinal products and gene therapy medicinal products engineered from human hematopoietic cells at large, including but not limited to Chimeric Antigen Receptor (CAR) T-cell therapy and other Immune Effector Cells (IEC), whether industry or academia-manufactured.

The Cell Therapy form has been capturing a large amount of the items that were recently defined as "must have" by the European Medicines Agency (EMA) during negotiations that led EBMT to apply for its registry regulatory qualification.

Since many CAR T-cell and IEC therapies are now increasingly used in clinical practice, data managers from centres and national registries are requested to use the current Cellular Therapy MED-A form, implemented in ProMISe, to register the above mentioned cell/gene therapy treatments. The form can be found in the Data Collection section of the EBMT website www.ebmt.org.

During the last year, the EBMT has further worked on the Cell Therapy Med-A, with the end result of creating a new, upcoming Cellular and Gene Therapy Form. It incorporates the remaining "must have" items required by EMA. This new form is being implemented in MACRO, the new registry system that will go live in coming weeks. The data that have been registered using the current Cell Therapy Med-A form will be migrated to MACRO during the normal data migration process, and the transferred registrations can then be completed using the new Cellular and Gene Therapy Form.

MACRO Progress

The Registry Upgrade project is coming closer to go-live. The exact launch date will be announced after this EBMT Annual Meeting.

Thorough Data Entry testing has been carried out by representatives in the Registry team, EBMT study offices, National Registries and a small number of member centres. We would like to thank all the beta testers for their help with this important part of the project.

The Data Retrieval function needed more development to ensure it meets the needs of EBMT users running reports. Due to this, we postponed our Train the Trainer session and this took place on 11-12 February 2019. We are pleased to announce the Centre training plans below.

Data Migration tests are being carried out and centres are starting to receive queries regarding records with inconsistent dates or status, which will be problematic when migrating the data to the new system, if they are not corrected. We appreciate your cooperation with this.

Centre Training

Plans for MACRO training are now under way:

Face-to-face training for transplant centres is planned to take place over the next few months. Sessions will concentrate on the user interface and Data Entry. This will be in the form of:

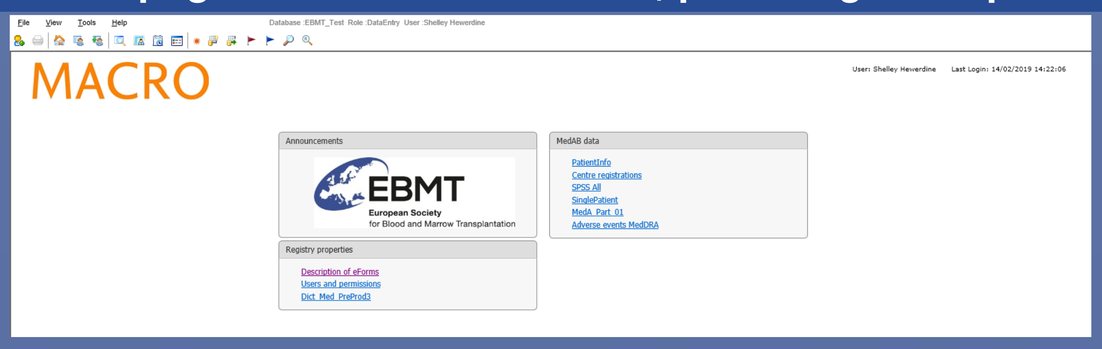
1. Training organised by National Registries for their centres
2. Group training for centres from a given country/region
3. Group training sessions at EBMT 2019 Frankfurt

Information on MACRO training organised by the EBMT will be available on www.ebmt.org – Registry – Registry Education & Training. We are grateful to our colleagues so far in Ghent, Antalya, Madrid, London, Stockholm, Warsaw, Athens and Helsinki who have planned, or are helping to plan group training venues.

Centres within National Registries will be contacted directly by their society regarding MACRO training.

Please contact us on registryhelpdesk@ebmt.org if you have any questions.

Home page with announcements; pre-designed reports



Patient Index to look up records