# Table of Contents

**Message from the President** 2
**About the European Society for Blood and Marrow Transplantation** 3
**EBMT structure** 4
**Staff organisational chart** 5
**EBMT membership** 6
**New EBMT website** 8
**Legal and regulatory activities** 9

## SCIENCE

The scientific activity report 11
- Severe Aplastic Anaemia Working Party (SAAWP) 12
- Autoimmune Diseases Working Party (ADWP) 14
- Acute Leukaemia Working Party (ALWP) 16
- Cellular Therapy & Immunobiology Working Party (CTIWP) 18
- Infectious Diseases Working Party (IDWP) 20
- Inborn Errors Working Party (IEWP) 22
- Lymphoma Working Party (LWP) 24
- Paediatric Diseases Working Party (PDWP) 26
- Chronic Malignancies Working Party (CMWP) 28
- Transplant Complications Working Party (CQLWP) 30

**Publications** 32
**EBMT Transplant Activity Survey 2017** 39
**The EBMT Registry** 42
**EMA’s qualification opinion on Cellular therapy module of the EBMT Registry** 44

## EDUCATION

EBMT 44th Annual Meeting 47
**Awards** 50
**Educational events** 52
**The new EBMT Handbook** 53

## PATIENT CARE

EBMT Nurses Group 55
**JACIE** 58

**Financial Report and Highlights 2018** 62
**EBMT Corporate Sponsors** 66
In my first year as EBMT President, I am delighted and honoured to present the EBMT Activity Report summarising the remarkable achievements of our society in 2018.

On the following pages you can review the scientific and educational activities and productivity of our ten working parties within the last 12 months as evidenced by numerous publications in highly ranked peer-reviewed journals and by cutting-edge educational events. Taken together, these reflect the EBMT’s vital role in advancing the field of stem cell transplantation and cellular therapies.

In 2018, the EBMT paved the way for the increasing need for up-to-date education for all involved healthcare providers starting with the launch of the online EBMT Nurses Textbook and the release of the new EBMT Handbook. The process for developing an e-learning platform has already started and will be available in 2019.

The requirements and challenges of the complex regulatory environment in our daily life have mandated continued progress in ensuring that the EBMT adheres to the highest professional and regulatory standards. By upgrading the safety and quality systems in the Clinical Trials Office in Leiden and by implementing a data protection and quality management coordinator in the Executive Office in Barcelona, the EBMT assures that personal data are protected properly in accordance with EU law and that clinical trials are performed according to high-level standards (i.e. Good clinical practice GCP).

Special thanks go to the numerous staff members and volunteers who were, throughout 2018, continuously involved in the new MACRO Registry Upgrade project. The new EBMT Registry, as the backbone of most of our scientific activities, will be launched in 2019. It will provide a robustly benchmarked system and support user-friendly documentation of transplant data and data from the new Cellular and Gene Therapy form.

In 2018, the EBMT decided to make patients voices more audible and founded a Patient, Family and Donor Committee to promote patient advocacy groups for stem cell transplantation and cellular therapies around the globe. Thanks to the very active and dedicated committee members, a new more appealing format of the Patient, Family and Donor Day will be presented at the EBMT’s 45th Annual Meeting in Frankfurt, March 24–27 2019.

Probably the most important therapeutic advancement in the treatment of blood cancer in 2018 was the development of CAR-T cells and immune effector cells, which was confirmed by the EMA’s approval for commercial CAR-T cell products, i.e. Kymriah and Yescarta, in August 2018. Because of our leading historical and pioneering role in the development of haematopoietic cell transplantation, the EBMT is pivotally positioned to play a leading role in the rapidly developing field of innovative cellular and gene therapies manufactured from haematopoietic tissues. The EBMT is, therefore, ideally placed to accelerate the translation of basic scientific advances into the clinic and integrate academic and commercial aspects into the development of somatic cell therapy and gene therapy products. EBMT staff and members were involved early by attending the EMA CAR-T cell therapy Registries Workshop and applied for a positive opinion for the EBMT Registry to collect CAR-T cell safety and outcome data (see page 44). In our CAR-T cell and immune effector cell strategy, a new Cellular and Gene Therapy form was implemented after harmonisation with CIBMTR; it includes the requirements of the EMA and the needs of the pharmaceutical industry for the upcoming post-authorisation safety studies (PASS). The EBMT has and will further provide educational tools and events focusing on specific issues related to the administration of CAR-T cells and other advanced therapy medicinal products, such as the 1st European CAR-T Cell Meeting in collaboration with the European Hematology Association (EHA), held in Paris in February 2019. Due to our experience with the JACIE accreditation process for transplant activities, which provides high quality in processing and applying cellular products as well as in patient care in haematopoietic stem cell transplantation, the EBMT will work on a specific set of standards that will cover the administration of immune effector cells, which would also be applicable outside the context of classical transplantation centres.

2018 was a year of remarkable progress on many fronts, and I would therefore like to express my sincere gratitude to all those who contributed to the fabulous activities of our society, including everyone who reported data and patient outcomes to the EBMT Registry.

Please continue your commitment to the EBMT in 2019 and enjoy reading the Activity Report for 2018.
The EBMT is a not-for-profit medical and scientific organisation established in 1974.

It is dedicated to fighting life-threatening blood cancers and diseases and improving patients’ lives.

EBMT members—more than 4,500 physicians, nurses, scientists and other healthcare professionals—participate in a unique collaborative network of peers involved in haematopoietic stem cell transplantation (HSCT) and cellular therapy research. Membership encompasses more than 550 centres from over 60 countries, that perform or are involved in HSCT.

The EBMT holds a central role in performing cooperative studies and disseminating state-of-the-art knowledge: the aim is to increase survival rates and enhance the quality of life of patients with life-threatening blood cancers and diseases.
Board

1. Executive Committee, President
Nicolaus Kröger
University Hospital Eppendorf
Hamburg, Germany

2. Executive Committee, Secretary
Rafael Duarte
Hospital Universitario Puerta de Hierro
Madrid, Spain

3. Executive Committee, Treasurer
Jürgen Kuball
University Medical Centre
Utrecht, The Netherlands

4. Scientific Council Chair with Research and Sciences Portfolio
Mohamad Mohty
Hospital Saint Antoine
Paris, France

5. Scientific Council Vice-Chair with Research and Sciences Portfolio
Christian Chabannon
Institut Paoli Calmettes
Marseille, France

6. Scientific Council Representative with the Registry Portfolio
John Snowden
Sheffield Teaching Hospitals NHS Trust
Sheffield, UK

7. Scientific Council Representative with the Education Portfolio
Grzegorz W. Basak
Medical University of Warsaw
Warsaw, Poland

8. Nurse Group President
John Murray
Christie NHS Trust Hospital
Manchester, UK

9. EBMT 2019 Annual Meeting Co-President
Peter Rader & Thierry Klineber
Klinikum der Johann-Wolfgang Goethe Universität
Frankfurt, Germany

10. Severe Aplastic Anaemia
Régis Peffault de Latour
Hospital Saint Louis
Paris, France

11. Autoimmune Diseases
John Snowden
Sheffield Teaching Hospitals NHS Trust
Sheffield, UK

12. Acute Leukaemia
Mohamad Mohty
Hospital Saint Antoine
Paris, France

13. Cellular Therapy & Immunobiology
Christian Chabannon
Institut Paoli Calmettes
Marseille, France

14. Infectious Diseases
Jan Styczynski
University Hospital, Collegium Medicum UMK
Bydgoszcz, Poland

15. Inborn Errors
Agjan Lambrichts
Leiden University Hospital
Leiden, The Netherlands

16. Lymphoma
Silvia Montalto
St. Bartholomew’s and The Royal London NHS Trust
London, UK

17. Paediatric Diseases
Selim Corbacoglu
Children’s Hospital Regensburg
Regensburg, Germany

18. Chronic Malignancies
Ibrahim Yakoub-Agha
Lille Hospital
Lille, France

19. Transplant Complications
Grzegorz W. Basak
Medical University of Warsaw
Warsaw, Poland

20. Nuclear Accident
Ray Powles
Cancer Center London
London, UK

21. Statistical
Simona Iacobelli
Hospital Saint Antoine
Paris, France

22. JACIE
John Snowden
Sheffield Teaching Hospitals NHS Trust
Sheffield, UK

23. Donor Outcomes
Joerg Halter
University Hospital of Basel
Basel, Switzerland

24. Registry
Per Lyngman
Karolinska University Hospital
Stockholm, Sweden

25. Global
Norbert-Claude Gorin
Hospital Saint Antoine
Paris, France

26. Legal & Regulatory Affairs (LRAC)
Christian Chabannon
Institut Paoli Calmettes
Marseille, France

27. Pharmacist
Tiene Bauters
Paediatric Clinic Prinses Elisabeth
Gent, Belgium

28. Patient, Family and Donor
Bregje Verhoeven
Hematoon patient organisation
Utrecht, The Netherlands

Scientific Council - Working Parties

Committees
EBMT membership

The members belong to a unique collaborative network of peers involved in haematopoietic stem cell transplantation and cellular therapy research. They all have a common goal, and that is to enhance the quality of life of patients with life-threatening blood cancers and diseases.

Our members are listed according to their role within their team. They are comprised of the following distribution of roles:

- **Physicians**: 2,898
- **Nurses**: 826
- **Data Managers**: 645
- **Laboratory Technicians**: 162
- **Quality Managers**: 270
- **Other**: 160

Our members can be classified as centre members (full or associate); individual or provisional members.

**FULL centres reporting***: 518
**INDIVIDUAL members**: 125
**ASSOCIATE centres**: 53
**PROVISIONAL members (including centres and individuals)****: 25

* Commit to submitting data on all patients treated in their centres
** New members which are pending approval at the General Assembly Meeting during the upcoming EBMT Annual Meeting.

**Total Members**: 4,961
**Total Centers**: 583

18 centres and 13 individual members joined the EBMT in 2018

Source: ProMISe December 31, 2018

EBMT
TOP 10 COUNTRIES IN TERMS OF NUMBER OF CENTRES PARTICIPATING IN THE EBMT

France 51
Spain 46
Turkey 42
Italy 84
Switzerland 13
Poland 20
Belgium 16
Netherlands 15
UK 54

Our 583 centre members are located in 63 different countries

BECOME A MEMBER

Centres or independent persons that are active in the field of transplantation & cellular therapy related to any kind of haematopoietic stem cell, or any other organisation involved in the care of donors and recipients of HSCT, can become a member of the EBMT.

Members’ rights, obligations, and fees are dependent upon the category of membership to which they pertain. Visit our website to get more details about each of the categories.

www.ebmt.org | membership@ebmt.org
The new EBMT website went live on the 12th of March 2018 and was presented at the EBMT booth during the Annual Meeting in Lisbon.

We wanted to make our new website more user-centred to better serve our scientific community and welcome newcomers interested in the field of Bone Marrow Transplantation and Cellular Therapy. The new site enables users to learn more about the EBMT, share best practices and information, get involved in an active research project or submit a new study.

The responsive web design makes the new website look good on all devices (i.e. desktops, tablets and smartphones). Visitors to the website can see impactful changes such as a new modern design, improved navigation and search functions that significantly enhance their experience.

Also new is the full integration of the JACIE Accreditation site as a section within the main EBMT site. Of particular note is the updated section for patients and donors that contains useful information about the Registry, accredited centres, publications, research projects and patient associations that are relevant for this special target audience.

The EBMT Annual Meeting site was launched in September 2018 and is also now fully integrated within the main site (https://www.ebmt.org/annual-meeting).

The preparation of the new website required months of hard work from the many parties involved in the process. The EBMT site has a wealth of information and resources that are beneficial to data and quality managers, physicians, nurses, scientists and other healthcare professionals. This information is now well structured and organised, with consistent site navigation that directs the users, through smart topic filters, to the content that is most relevant to them.

The website is a work in progress. In 2019, there will be integration with the membership part of MACRO (the upcoming new Registry platform) with the objective to streamline the administrative functions and reduce most of the administrative work with regards to the management of memberships. It will also allow for personalisation of the site and the setting of access levels for sensitive information about studies and other internal Working Party topics. New features will be included such as the ‘My EBMT’ dashboard – where an EBMT member will be able to view the membership list, select his or her fields of interest, pay online, consult the status of payments and so on. So stay tuned!
Legal and regulatory activities

The EBMT was very active in 2018 with regard to regulatory activities. The most significant efforts were dedicated to EBMT’s request, presented in October 2017, to the European Medicines Agency (EMA) for qualification of the cellular therapy module of the EBMT Registry as suitable for performing pharmacoepidemiological studies for regulatory purposes, concerning CAR-T cell therapy for haematological malignancies. Major progress was made when EMA published their draft opinion in June 2018. The qualification opinion was released on February 28, 2019 (see page 44).

This achievement came on the back of months of engagement with EMA including two meetings in February when EBMT had a face-to-face meeting with the EMA in London followed two days later by the EMA CAR T-cell therapy registries workshop which included a much wider group of stakeholders.

In other areas, on 29-30 January, EBMT was represented at the DG SANTÉ (EU Commission, Public Health) meeting on data registries for Substances of Human Origin (SoHO) in Brussels presenting on the Registry and participating in wider discussions including sustainability, quality and data protection matters.

In March, EBMT was invited by the Council of Europe to a two-day event in Strasbourg under the title “Technical Meeting on National and EU-level tissue and cell activity data collection and reporting” under the auspices of the Directorate for the Quality of Medicines & HealthCare (EDQM).

In July, EBMT attended the EU-organised meeting under the title “The way forward for HTA (Health Technology Assessment) cooperation – the views of stakeholders”. In a time of breakthrough but expensive new therapies, health technology assessment requirements have to be taken into account in terms of getting access for patients to these treatments.

In November, EBMT responded to the public consultation by the EU Commission on their targeted stakeholder consultation on the draft Guidelines on Good Clinical Practice for Advanced Therapy Medicinal Products.

EBMT is also in the process of applying to EMA under their initiative for the involvement of healthcare professionals’ organisations in the activities of the Agency. This process is expected to close in the first half of 2019.

EBMT is registered in the EU Transparency Registry under identification number 65292023103-09.

EBMT is also a partner in the Common representation of Substances of Human Origin’s (SoHO) (CoRe SoHO) along with the European Eye Bank Association, the European Blood Alliance and the European Association of Tissues Banks.
The Scientific activity report

11
Severe Aplastic Anaemia Working Party (SAAWP)

12
Autoimmune Diseases Working Party (ADWP)

14
Acute Leukaemia Working Party (ALWP)

16
Cellular Therapy & Immunobiology Working Party (CTIWP)

18
Infectious Diseases Working Party (IDWP)

20
Inborn Errors Working Party (IEWP)

22
Lymphoma Working Party (LWP)

24
Paediatric Diseases Working Party (PDWP)

26
Chronic Malignancies Working Party (CMWP)

28
Transplant Complications Working Party (CQLWP)

30

Publications

32
EBMT Transplant Activity Survey 2017

39
The EBMT Registry

42
EMA's qualification opinion on Cellular therapy module of the EBMT Registry

44
The Scientific activity reports

2018 was a most vibrant and exciting year, with many wonderful scientific achievements, and new opportunities. As the chairman of the scientific council of the society, it is a great honour for me to present the impressive scientific productivity of the EBMT, thanks to the contributions of all our members. Announcing and writing about these new studies is always a source of pride, mainly for two reasons. Firstly, because of the enormous satisfaction of offering the transplant community new evidence relevant to clinical practice, and secondly, because it is the most tangible evidence that the society is fulfilling its role and goals. I strongly believe that the positive energy and ‘can-do’ attitude of EBMT members have taken our society a long way.

Over the last 12 months, the focus of the different working parties remained unwavering on delivering cutting-edge practical data and transplant guidelines, mainly based on the real-life experience gathered within the amazing EBMT Registry, as well as on the optimal management of transplant patients, especially with the advent of numerous targeted therapies which are being used before and after transplantation. The haplo-identical transplant approach continues to be an ever-evolving strategy that has been experiencing an impressive boom, particularly in acute leukaemia. It is already proving to be a valid transplant modality with outcomes being similar to those achieved with other stem cell sources and donors. At the same time, the EBMT Registry continues to be a timeless gateway to investigating the role of stem cell transplantation in rare disease entities or complications. Building on this background, the new Cellular Therapy module of the EBMT Registry became a reality in 2018 (see page 44). Such a new and modern module dedicated to all the novel innovative therapies represents a great success and a turning point for our strategy.

Besides the scientific publications, the EBMT has delivered in 2018 a record number of educational activities and events. The educational activities of the EBMT have been taken to new heights, in terms of both participation and scientific content. The EBMT’s comprehensive educational portfolio covers the needs of both the youngest researchers and the most experienced ones and brings together top scientists from all over the globe to exchange ideas, allowing for more effective care and practice-changing discoveries. The launch of the new version of the EBMT Handbook can be considered as one of the highlights of 2018. This handbook is available for free download.

All the above achievements highlight the expanding global influence of the EBMT. The success of the EBMT is due to the effort and hard work of its members. The society would like to encourage newly emerging talent and support their ideas. We want to show our confidence in the upcoming generations and for them to take an active role in the transformations we are witnessing in the field. More than half of the researchers who took the lead in recent EBMT studies were less than 35 years old! Whether it is your first research project or your 50th, there is always something new to explore in the EBMT Registry. The EBMT working parties are the best umbrella to achieve a rewarding and useful clinical research experience in the constantly evolving field of stem cell transplantation and cellular therapy. Please join us and spread the word.

Mohamad Mohty
Chairman of the ALWP of the EBMT
Chairman of the scientific council of the EBMT
Severe Aplastic Anaemia
Working Party
(SAAWP)

MAJOR ACHIEVEMENTS

PROGRESSION OF TWO PROSPECTIVE RANDOMISED CLINICAL TRIALS:

1. RACE trial compares standard immunosuppressive therapy (ATG+CsA) plus Eltrombopag vs Standard IST alone in patients with severe aplastic anaemia. This is an EBMT study supported financially by Novartis, Pfizer and Alexion. 182 patients have been randomised so far out of 200 expected, in 28 EBMT sites open for recruitment. An anticipated last patient is expected in February/March 2019.

2. EMAA study compares CsA plus Placebo vs CsA plus Eltrombopag in patients with moderate aplastic anaemia. This study is sponsored by the University of Ulm and supported financially by Novartis. 16 EBMT centres from 6 countries (Germany, Italy, France, The Netherlands, Switzerland and the UK) have recruited patients. German centres have been opened and 31 patients have been enrolled up to early December.

DATA QUALITY INITIATIVE

This initiative aims at improving the quality and follow-up data of patients receiving HSCT and the number of registration and the quality of data of those undergoing exclusive Immunosuppressive (IS) treatment. Until now, patients were selected between 2005 and 2014.

In October 2018, the SAAWP had received the completed files from 69 centres for a total of 1,418 patients (1,173 with acquired bone marrow failure and 245 with constitutional disorders).

PRINCIPAL RESEARCH STUDIES


5. Patient-reported symptom monitoring in aplastic anaemia and paroxysmal nocturnal hemoglobinuria. PI: B. Drexler.
KEY PUBLICATIONS


3. Transplant outcome for patients with acquired aplastic anaemia over the age of 40: has the outcome improved? Giammarco S et al., Blood.


5. Allogeneic Hematopoietic Cell Transplantation in Patients Aged 50 Years or Older with Severe Aplastic Anaemia. Rice C et al., Biol Blood Marrow Transplant.

MAJOR EDUCATIONAL COURSES

Joint Educational Meeting of the Autoimmune Diseases and Aplastic Anaemia Working Parties – 15-17 November 2018 in Florence, Italy.
Autoimmune Diseases
Working Party
(ADWP)

MAJOR ACHIEVEMENTS

Autoimmune diseases (ADs) are now the fastest growing indication for HSCT, and the ADWP has central role in bringing together transplant and disease specialist communities. In 2018, the ADWP continued to expand the evidence-base and support best practice with registry-based studies and guidelines. The AD section of the EBMT Registry is now the largest database of its kind worldwide with almost 3,000 transplants and 2018 has been the most active year to date. Special consideration has been given to current EBMT Registry developments to accommodate the future needs of multispecialty interactions for comprehensive and sustainable long-term data collection in patients with ADs receiving HSCT and other cell therapies. The ADWP also remains actively involved with prospective clinical trials, securing funding (96000 euros) to support long-term data collection and analysis in ASTIClite, a UK NIHR randomised controlled clinical trial of autologous HSCT versus standard of care in Crohn’s disease.

Education also continued to be central to global ADWP activities. In November, the ADWP educational meeting, organised jointly in Florence with the SAWP, attracted the greatest number of delegates ever (over 170), reflecting growing interest in the field. Special workshop sessions in MS, systemic sclerosis and Crohn’s disease evaluated the evidence-base, basic science and new clinical trial activity across Europe and beyond. The ADWP has been also engaged in the broader EBMT educational strategy, including the e-learning portal, the EBMT Curriculum and the EBMT Handbook.

‘Implementation science’ is now increasingly important to define how to best deliver HSCT in the context of biological and other modern therapies for ADs. The future depends on quality of outcomes and health economics. Along with disease specialist societies, the ADWP is working closely with JACIE, other EBMT Working Parties, the EBMT Nurses Group and Patient, Family & Donor Committee to assure best practice and clinical quality.

PRINCIPAL RESEARCH STUDIES

1. Allogeneic HSCT for Autoimmune Diseases (ADWP with PDWP/IEWP collaboration). Analyzed and manuscript in preparation.


5. Comparison of Cyclo+ATG vs BEAM+ATG conditioning regimens in autologous HSCT for Multiple Sclerosis.

6. Late complications after autologous HSCT for autoimmune diseases: a retrospective survey from the ADWP and TCWP.
7. Retrospective studies of autologous HSCT for:
   a. Polymyositis-Dermatomyositis
   b. Behçet’s Disease
   c. Rare neurological autoimmune diseases
   d. Immune cytopenias

8. Viral reactivations following HSCT for autoimmune disease: a retrospective EBMT survey.

9. Guidelines and recommendations for:
   a. Neurological diseases
   b. Paediatric autoimmune diseases (ADWP with IEWP/PWP collaboration)

10. ASTIClite: Via the ADWP, the EBMT secured funding (96000 euros) to support the data collection and analysis of the long-term follow-up study in this UK NIHR randomised controlled clinical trial of autologous HSCT versus standard of care in Crohn’s disease.

KEY PUBLICATIONS


5. Autologous haematopoietic stem cell transplantation (aHSCT) for severe resistant autoimmune and inflammatory diseases - a guide for the generalist. Snowden JA et al., Clinical Medicine.

MAJOR EDUCATIONAL COURSES


3. Other international educational events: European Crohn’s and Colitis Organisation (ECCO) Congress; BSBMT Annual Scientific Meeting; EBMT Highlights (Saudi Arabia and India); EBMT International Transplant Course; Myelin Meeting.
Acute Leukaemia Working Party (ALWP)

MAJOR ACHIEVEMENTS

The number of HSCT procedures for patients with acute leukaemia is continuously growing as reflected by the growing content of our Registry. According to recently published studies by the ALWP, it is accompanied by improving results, due to both lower risk of relapse and decreased non-relapse mortality. This spectacular progress is possible thanks to many factors, including rapidly developing pharmacological therapies, which allow higher proportion of patients entering HSCT in high quality remission. Some drugs may be used for either prophylactic or pre-emptive treatment after HSCT, increasing the chance to maintain remission. On the other hand, almost all patients being in need of allogeneic HSCT (including those with refractory disease) may be offered such treatment thanks to the growing number of haplo-identical donors. Finally, the HSCT procedure has become safer due to the development of new reduced-toxicity conditioning regimens and post-transplant supportive care protocols.

In 2018, the ALWP performed several studies tackling some of these hot topics. The impact of ATG, a backbone for GVHD prophylaxis, has been investigated in different settings, with some positive results, of importance in daily practice. The use of bone marrow versus mobilised peripheral blood stem cells in haplo-identical transplants incorporating post-transplant cyclophosphamide remains a matter of debate. Post-transplant cyclophosphamide continues actually to generate a lot of enthusiasm, including in the non-haplo settings where it may have nullified the detrimental effect of HLA-mismatch. Refinement of the different conditioning regimens has been another focus of several studies, especially in the context of high risk and refractory disease. Furthermore, measurable residual disease is gaining a lot of interest as it can strongly predict outcome in different transplant approaches. Finally, post-remission strategies for the prevention of relapse following allogeneic transplantation are increasingly used with convincing efficacy.

The list of the ALWP achievements is huge, because this is a very exciting area of investigation, as reflected by the number of scientific publications and meeting abstracts. Also, the ALWP is very proud of the educational events organised annually in various European countries. Our activities are possible thanks to all EBMT members who report their data voluntarily.

PRINCIPAL RESEARCH STUDIES

1. Analysis of donor characteristics, timing, doses and schedule of post-transplant cyclophosphamide and immunosuppressive therapy post T-replete haploidentical transplantation.

2. The role of measurable residual disease (MRD) in different transplant settings for acute leukaemia.

3. Pharmacological agents to treat and prevent relapse post HSCT for acute leukaemia.

4. Design of integrated pre-transplant scores for refining outcomes (e.g. novel conditioning score).
KEY PUBLICATIONS

1. Anti-thymocyte globulin improves survival free from relapse and graft-versus-host disease after allogeneic peripheral blood stem cell transplantation in patients with Philadelphia-negative acute lymphoblastic leukemia: An analysis by the Acute Leukemia Working Party of the EBMT. Czerw T et al., Cancer.


MAJOR EDUCATIONAL COURSES


Cellular Therapy and Immunobiology Working Party (CTIWP)

MAJOR ACHIEVEMENTS

The CTIWP develops activities focussed on clinical and biological monitoring of existing cellular therapies (mostly allogeneic hematopoietic cell transplantation), regardless of transplant indications. The CTIWP also explores ways to accelerate access to innovative somatic cell therapy medicinal products or gene therapies manufactured from hematopoietic cells: these include drug products engineered from hematopoietic stem cells, immune effector cells and mesenchymal stem cells, whether developed as investigational drugs or in the context of the hospital exemption by academic facilities, or developed and marketed by the industry.

2018 saw a burning actuality with the first approval of two autologous CAR-T Cells in Europe. CTIWP members invest a considerable amount of time to fully define conditions that are necessary to efficiently master interactions between hospitals and industry for the supply chain, to provide educational tools and organisational support to all categories of healthcare practitioners that are involved in delivery and administration of these innovative therapies, some of which produce impressive disease responses and clinical side-effects, and to organise long-term follow-up of treated patients as mandated by FDA and EMA. As part of these efforts, CTIWP members played an important role in designing an additional form that complements existing forms in the EBMT Registry: this Cellular and Gene Therapy form allows EBMT centers to register patients treated with all kind of advanced cell therapy medicinal products, whether adding, substituting or bridging to conventional cell transplant. In addition, CTIWP members work together to gain a comprehensive knowledge of ongoing activities in Europe in this field, and network complementary expertise and knowledge.

PRINCIPAL RESEARCH STUDIES


4. Results of cord blood transplantations (A Ruggeri et al, Hematopoietic Stem Cells & Eurocord Subcommittee).

KEY PUBLICATIONS

1. Immune monitoring in allogeneic hematopoietic stem cell transplant recipients: a survey from the EBMT-CTIWP. Greco R et al., Bone Marrow Transplant.


4. Beneficial role of CD8+ T-cell reconstitution after HLA-haploidentical stem cell transplantation for high-risk acute leukaemias: results from a clinico-biological EBMT registry study mostly in the T cell-depleted setting. Bondanza A et al., *Bone Marrow Transplant*.

5. Handling, processing and disposal of stem cell products in Europe: A survey by the cellular therapy and immunobiology working party of the European Society for Blood and Marrow Transplantation. Holbro A et al., *Cytotherapy*.

**MAJOR EDUCATIONAL COURSES**


2. The CTIWP Scientific Session at the EBMT Annual Meeting including the delivery of the Jon van Rood Award to E Velardi and Dr A Galleu – 20 March 2018 in Lisbon, Portugal.

Infectious Diseases Working Party (IDWP)

MAJOR ACHIEVEMENTS

The mission of IDWP is to share the experience and develop cooperative studies to increase education in the field of diagnosis, prophylaxis and treatment of infectious complications in HSCT patients.


IDWP recent achievements were published in Clinical Infectious Diseases, Journal of Antimicrobial Chemotherapy, Bone Marrow Transplantation and Reviews in Medical Virology.

PRINCIPAL RESEARCH STUDIES

ONGOING RETROSPECTIVE PROJECTS:

1. Causes of deaths after HSCT.
2. Infections with legionellosis, toxoplasmosis, tuberculosis, nocardiosis, JCV, HEV after HSCT.
3. Role of CMV, EBV, ADV, JCV, HHV6, HHV8 and HIV on outcomes of HSCT.

ONGOING PROSPECTIVE NON-INTERVENTIONAL PROJECTS:

4. HHV6 infections after HSCT.
5. The incidence of gram-negative bacteremia, risk factors and resistance to antibiotics.
6. Impact of pre-existing invasive aspergillosis on allo-HSCT outcome.
7. Risk factors and outcome of pneumocystis pneumonia (PcP) infection in HSCT.
8. Treatment approach for patients with HCV infection and who underwent HSCT.
9. Anti-infective prophylaxis and antibiotic use in patients undergoing HSCT.
10. Infections of CNS after HSCT.
11. Impact of candidemia on transplant outcome.
KEY PUBLICATIONS


MAJOR EDUCATIONAL COURSES

1. 11th Paediatric Diseases, Infectious Diseases, Inborn Errors Working Parties and 6th Paediatric Nurses Group Meeting – 7-9 June 2018 in Verona, Italy.

Major Achievements

The IEWP can look back at a very interesting and productive year with many events in which IEWP has presented its activities. IEWP actively participated in the EBMT International Transplant Course in Barcelona with presentations on HSCT in primary immune disorders (PID) (A. Lankester) and hemoglobinopathies (J. de la Fuente). The 3rd thymus workshop (14 September in London) was organised in collaboration with the ESID clinical working party, and attended by a group of international experts in preclinical and clinical research.

The 4th Inborn Errors Working Party Annual Conference was organised in Leiden with special attention to the 50th anniversary of the first successful SCT in a SCID patient in Europe. On the first educational day, a series of international experts presented excellent overviews on developments in the field of SCT and gene therapy in SCID and non-SCID PID, SCID newborn screening, and long term outcome after SCT. The second and third day included sessions on various aspects of stem cell therapies and SCT indications in PID, hemoglobinopathies and inherited metabolic diseases, and reports on ongoing IEWP studies were presented.

During the ESID annual meeting, a very well attended IEWP session was fully dedicated to current management of chronic granulomatous disease patients including conventional treatment (S. Holland), SCT (T. Güngör) and gene therapy (C. Booth) followed by a panel discussion on CGD cases.

In 2018, six excellent manuscripts on IEWP studies were published. For 2019, IEWP has the ambition to further extend its study activities in collaboration with ESID, SCETIDE, PIDTC and other partners.

Principal Research Studies

1. Allogeneic HSCT in children and adults with chronic granulomatous disease.
8. HSCT for Erythropoietic Porphyria: EBMT-CIBMTR study.
9. HSCT in Inherited Metabolic Diseases with focus on immune cytopenia: IEWP-Eurocord study.
10. HSCT in LAL-Wolman’s disease.
11. HSCT in patients with IFNg receptor deficiencies.
KEY PUBLICATIONS


4. Early and late outcomes after cord blood transplantation for pediatric patients with inherited leukodystrophies. van den Broek BTA et al., Blood Adv.


MAJOR EDUCATIONAL COURSES

1. 11th Paediatric Diseases, Infectious Diseases, Inborn Errors Working Parties and 6th Paediatric Nurses Group Meeting – 7-9 June 2018 in Verona, Italy.


4. IEWP session “treatment of CGD in 2018 and beyond” during the annual meeting of the European Society for Immunodeficiencies (ESID) – 24-27 October 2018 in Lisbon, Portugal.
Lymphoma Working Party (LWP)

MAJOR ACHIEVEMENTS

It is a pleasure to report that we have had another successful and very active year in the LWP. This group comprises physicians from across Europe along with a nursing and a newly incorporated patient representative. We have an active trials portfolio currently comprising 31 studies. The trial portfolio is managed through fortnightly teleconferences. Over the last year we have published 10 papers and presented 17 papers (8 oral presentations and 9 poster presentations) at international scientific meetings. Additionally we have conducted a number of successful collaborative projects with the CIBMTR Lymphoma Working Committee.

We are also actively involved in educational activities, the highlight of which is the annual LWP educational course this year hosted in Palma de Mallorca, Spain attracting over 90 participants. The 2019 course will be held in Bristol UK on the 18th-19th September 2019. We also contribute to the EBMT Annual Meeting educational program with lectures and debates and have additionally contributed several chapters to the new EBMT Handbook.

PRINCIPAL RESEARCH STUDIES

1. Durable benefit of rituximab maintenance post-autograft in patients with relapsed follicular lymphoma: 12-year follow-up of the EBMT Lymphoma Working Party Lym1 trial long term follow up of the EBMT LYM-1 trial. Pettengell, R.

2. Efficacy of donor lymphocyte infusions for the treatment of relapse post allogeneic transplant for lymphoid malignancies. Robinson S.


4. Haploidentical stem cell transplantation for DLBCL. A joint study of the LWP EBMT and CIBMTR LWC. Dreger P and Hamadami M.

KEY PUBLICATIONS


4. High-Dose Therapy and Autologous Stem Cell Transplantation in Marginal Zone
Lymphomas: A Retrospective Study by the EBMT Lymphoma Working Party and FIL-GITMO. Avivi I et al., *Br J Haematol*.


**MAJOR EDUCATIONAL COURSES**

MAJOR ACHIEVEMENTS

In September 2018, after the extraordinary Chair elections, Selim Corbacioglu has been denominated as the new PDWP Chair, taking over from Peter Bader. Josu de la Fuente became Co-Chair and Katharina Kleinschmidt Secretary. The structure of the WP has been reorganised, with the introduction of specific subcommittees and the inauguration of the group of young investigators (WiPis).

The focus of the PDWP this year was on the educational level with the organisation of three educational courses/events:

1. The continuation of the “PDWP Supportive Care Workshop”, initiated in 2017: Part 2 was held in January in Milano, Part 3 in Frankfurt in October. The objective was the elaboration of consensus position papers on supportive care measures in paediatric HSCT, like ward isolation and sterility policy, peri- and post-transplant food handling and vaccination.

2. In June 2018, the joint PDWP, IDWP, IEWP and Paediatric Nurses Group Meeting was held in Verona, Italy. All important and most discussed topics were addressed such as the different methods of T-cell depletion versus post-transplant cyclophosphamide in haploidentical transplantation as well as new approaches in CAR T-cell therapy in relapsed leukaemia. Much space was dedicated to case presentations by younger colleagues; a trend which will be intensified in the upcoming years: a dedicated subcommittee (WiPis) has been created to give maximum support to young investigators, for active participation in conferences and educational events.

One major mission of the PDWP is to continuously improve the quality of registry-based data. Currently, more then 20 PDWP studies are under evaluation or already ongoing (see below for most relevant studies).

Collaborative international prospective trials are a major focus of the WP and will be intensified in the upcoming years.

PRINCIPAL RESEARCH STUDIES


2. Haematopoietic stem cell transplantation for sickle cell disease. An analysis on behalf of Eurocord, PDWP of EBMT, CIBMTR, USP and Ruby Hall Clinic.

3. Late effects after haematopoietic stem cell transplantation in patients with HLH.

4. The optimal alternative donor for ALL or AML: comparison between T-cell depleted haplo-HSCT and UCBT.

5. HSCT in children and adolescents with Non Hodgkin Lymphoma.

6. The use of TPO agonist post paediatric HSCT.

**KEY PUBLICATIONS**


2. Therapeutic Drug Monitoring of Busulfan for the Management of Pediatric Patients: Cross-Validation of Methods and Long-Term Performance. Choong E et al., *Ther Drug Monit*.


**MAJOR EDUCATIONAL COURSES**

1. 11th Paediatric Diseases, Infectious Diseases, Inborn Errors Working Parties and 6th Paediatric Nurses Group Meeting – 7-9 June 2018 in Verona, Italy.

2. PDWP Supportive Care Workshop Part 2 in Milano, Italy.

3. PDWP Supportive Care Workshop Part 3 in Frankfurt, Germany.
Chronic Malignancies
Working Party
(CMWP)

MAJOR ACHIEVEMENTS

The CMWP had a strong year with publications covering all aspects of stem cell transplantation. In March 2018, I. Yakoub-Agha (Lille) was elected as CMWP Chair and P. Hayden (Dublin) became Secretary. They have continued to build on the achievements of the previous Chair, N. Kröger (Hamburg), the current EBMT President, who had completed a highly productive four-year term.

The CMWP is a unique Working Party in spanning several groups of diseases. Reflecting this range of activities, the internal organisation was rearranged resulting in six subcommittees: (1) Myelodysplasia including CMML (2) Plasma Cell Diseases (3) Ph. Neg Myeloproliferative Disorders (4) CML (5) CLL and (6) Practice Harmonisation and Guidelines. This last committee will focus on producing practical clinically relevant guidelines for haematologists in the field of HSCT.

CMML has been more clearly defined as a distinct entity in recent decades and the WP has been fortunate to have F. Onida (Milan) joined M. Robin (Paris) and C. Scheid (Cologne) as an MDS subcommittee vice-chair with expertise in this uncommon disorder. After a very successful term, L. Garderet handed over the chair of the Plasma Cell Disease subcommittee to S. Schönland (Heidelberg) who has been joined by M. Beksic (Ankara) as vice-chair. The new Ph. Neg MPN subcommittee is chaired by D. McLornan (London) and co-chaired by T. Czerw (Gliwice) and JC Hernandez Bolud (Valencia). Finally, we welcomed O. Tourniac (Clermont-Ferrand) as the new chair of the CLL subcommittee with M. van Gelder (Amsterdam) remaining as vice-chair. Y. Chalandon (Geneva) continues as chair of the CML subcommittee.

The first Business and Educational Meeting took place in Dublin in January 2018. A productive Friday session was followed by an educational symposium on “Perspectives in the treatment of myeloma and other plasma cell disorders” on Saturday morning. We were fortunate to be joined by P. Hari of the CIBMTR and plans were laid for future collaborative projects. The rapid advances in the field of immunotherapy across a range of haematological malignancies were reviewed in Lille in September where an education session focussed on CAR T cell therapy in chronic haematological malignancies followed a well-attended business meeting.

PRINCIPAL RESEARCH STUDIES

1. Phase III: Vidaza vs allogeneic SCT in patients 55 to 69 years (N. Kröger, U. Platzbecker).
2. EMN RIC Allo Trial.
3. Retrospective comparison between RIC and MAC for MF.
4. Risk factors and outcomes after unrelated cord blood transplantation (UCBT) for patients with Chronic Myeloid Leukemia (CML): a collaborative study from the CMWP and Eurocord (H de Lavallade).
KEY PUBLICATIONS


2. HLA-Mismatched Donors in Patients with Myelodysplastic Syndrome: An EBMT Registry Analysis. Robin M et al., Biol Blood Marrow Transplant.

3. Melphalan 140 mg/m2 or 200 mg/m2 for autologous transplantation in myeloma: results from the Collaboration to Collect Autologous Transplant Outcomes in Lymphoma and Myeloma (CALM) study. A report by the EBMT Chronic Malignancies Working Party. Auner HW et al., Haematologica.

4. Outcome of patients with Myelofibrosis relapsing after allogeneic stem cell transplant: a retrospective study by the Chronic Malignancies Working Party of EBMT. McLornan DP et al., Br J Haematol.


MAJOR EDUCATIONAL COURSES


Educational symposium on “Perspectives in the treatment of myeloma & plasma cell disorders”.


Educational symposium on “CAR T Cell Therapy in Chronic Haematological Malignancies”.

Impact factor
(Chronic Malignancies)

2014 2015 2016 2017 2018
Oral Presentations 44 53 16 12 13
Poster Presentations 14 12 16 14 17
International Educational Events 4 2 4 2 2
Transplant Complications Working Party (TCWP)

MAJOR ACHIEVEMENTS

2018 has been a successful year for the TCWP in terms of both, education and research. The working party, chaired by G. Basak and supported by Z. Peric (Secretary), A. Harrington (Data Manager) and C. Peczynsky (Statistician), appointed new chairs of the three subcommittees: C. Koenecke for the Regimen-related toxicities and supportive care subcommittee, O. Penack for the Graft-versus-host disease subcommittee and H. Schoemans for the Late complications subcommittee as well as C. Eeltink for the Nurse Lead.

During this year, we have developed operating procedures for processing new studies and we continuously encourage EBMT members to join our working party with new proposals. We currently manage approximately 35 studies and we have successfully published 13 manuscripts this year. The TCWP has established strong links with late effects and quality of life subcommittee of the CIBMTR which resulted in very important consensus manuscripts on neurocognitive dysfunction, ocular graft-versus-host-disease and non-GVHD ocular complications. Moreover, together with the CIBMTR and National Institutes of Health, TCWP has recently published a position statement manuscript on the standardised GVHD assessment. The TCWP meets twice each year and conducts additional monthly teleconferences in order to follow the evolution of studies.

Finally, TCWP is strongly committed to educational activities. In November we organised a very dynamic educational course joined with the 4th Chronic GVHD symposium in Zagreb, Croatia. This meeting hosted a strong international faculty and gathered over 150 participants from 25 countries making it the most successful TCWP educational course so far.

PRINCIPAL RESEARCH STUDIES

1. EASIX score to predict outcomes of allo-HSCT (O. Penack, T. Luft) – validation and further investigation of new and easy score based on LDH, platelets and creatinine.


4. Association of socioeconomic factors with survival of patients who experience severe classic acute graft versus host disease after allogeneic stem cell transplantation (A. Frankiewicz, S. Giebel).

5. Survival after acute graft-versus-host disease over time: big data analysis (H. Greinix, N. Kröger) - retrospective analysis of outcomes of >113,000 patients with aGVHD st II-IV transplanted in years 1990-2015.
KEY PUBLICATIONS


2. European experience and risk factor analysis of donor cell-derived leukaemias/MDS following haematopoietic cell transplantation. Engel N et al., Leukemia.


MAJOR EDUCATIONAL COURSES

1. 4th International cGvHD Symposium & Transplant Complications Working Party Educational Meeting – 8-10 November 2018 in Zagreb, Croatia.
<table>
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<tr>
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<td>A survey on incidence and management of adenovirus infection after allogeneic HSCT.</td>
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<td>Accuracy and usability of the eGVHD app in assessing the severity of graft-versus-host disease at the 2017 EBMT annual congress.</td>
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<td>Allogeneic Hematopoietic Cell Transplantation in Patients Aged 50 Years or Older with Severe Aplastic Anemia.</td>
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<td>Allogeneic stem cell transplantation following relapse post autologous stem cell transplantation in adult patients with acute myeloid leukemia: A retrospective analysis of 537 patients from the Acute Leukemia Working Party of the EBMT.</td>
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<td>Allogeneic Stem Cell Transplantation for Myelodysplastic Syndrome Patients with a 5q Deletion.</td>
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<td>Allogeneic hematopoietic stem cell transplantation for relapsed follicular lymphoma: A combined analysis on behalf of the Lymphoma Working Party of the EBMT and the Lymphoma Committee of the CIBMTR.</td>
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<td>AlloHSCT for inv(3)(q21;q26)/t(3;3)(q21;q26) AML: a report from the acute leukemia working party of the European society for blood and marrow transplantation.</td>
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<td>Anti-thymocyte globulin improves survival free from relapse and graft-versus-host disease after allogeneic peripheral blood stem cell transplantation in patients with Philadelphia-negative acute lymphoblastic leukemia: An analysis by the Acute Leukemia Working Party of the EBMT.</td>
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<td>Autologous haematopoietic stem cell transplantation (ahSCT) for severe resistant autoimmune and inflammatory diseases - a guide for the generalist.</td>
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<td>Autologous stem cell transplantation for primary mediastinal B-cell lymphoma: long-term outcome and role of post-transplant radiotherapy. A report of the European Society for Blood and Marrow Transplantation.</td>
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<td>Biol Blood Marrow Transplant.</td>
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<td>Acute Lymphoblastic Leukemia: An Expert Opinion from the European</td>
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<td>Therapy-Related Acute Myeloid Leukemia with Prior Solid Tumor; a</td>
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<td>30087463</td>
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<td>The Perspective of an Interdisciplinary Working Group.</td>
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<td>van den Broek BTA</td>
<td>Blood Adv.</td>
<td>29344584</td>
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<td>Family mismatched allogeneic stem cell transplantation for Myelofibrosis: Report from the Chronic Malignancies Working Party of EBMT.</td>
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<td>29079323</td>
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<td>Handling, processing and disposal of stem cell products in Europe: A survey by the cellular therapy and immunobiology working party of the European Society for Blood and Marrow Transplantation.</td>
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<td>Haploidentical transplantation is associated with better overall survival when compared to single cord blood transplantation: an EBMT-Eurocord study of acute leukemia patients conditioned with thiopeta, busulfan, and fludarabine.</td>
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<td>J Hematol Oncol.</td>
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<td>Haploidentical versus unrelated allogeneic stem cell transplantation for relapsed/refractory acute myeloid leukemia: A report of 1578 patients from the Acute Leukemia Working Party of EBMT.</td>
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<td>Hematopoietic stem cell transplantation for adults with Philadelphia chromosome-negative acute lymphoblastic leukemia in first remission: a position statement of the European Working Group for Adult Acute Lymphoblastic Leukemia (EWALL) and the Acute Leukemia Working Party of the European Society for Blood and Marrow Transplantation (EBMT).</td>
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<td>High-dose therapy and autologous stem cell transplantation in marginal zone lymphomas: a retrospective study by the EBMT Lymphoma Working Party and FIL-GITMO.</td>
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<td>High-dose therapy with BEAC conditioning compared to BEAM conditioning prior to autologous stem cell transplantation for non-Hodgkin lymphoma: no differences in toxicity or outcome. A matched-control study of the EBMT-Lymphoma Working Party</td>
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<td>HLA-Mismatched Donors in Patients with Myelodysplastic Syndrome: An EBMT Registry Analysis.</td>
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<td>Ibrutinib for bridging to allogeneic hematopoietic cell transplantation in patients with chronic lymphocytic leukemia or mantle cell lymphoma: a study by the EBMT Chronic Malignancies and Lymphoma Working Parties</td>
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<td>Immune monitoring in allogeneic hematopoietic stem cell transplant recipients: a survey from the EBMT-CTIWP.</td>
<td>Greco R</td>
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<td>Impact of antithymocyte globulin doses in reduced intensity conditioning before allogeneic transplantation from matched sibling donor for patients with acute myeloid leukemia: a report from the acute leukemia working party of European group of Bone Marrow Transplantation.</td>
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<td>Impact of extramedullary disease in patients with newly diagnosed multiple myeloma undergoing autologous stem cell transplantation: a study from the Chronic Malignancies Working Party of the EBMT.</td>
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<td>Incidence of Second Primary Malignancies after Autologous Transplantation for Multiple Myeloma in the Era of Novel Agents.</td>
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</tr>
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<td>Is the use of unrelated donor transplantation leveling off in Europe? The 2016 European Society for Blood and Marrow Transplant activity survey report.</td>
<td>Passweg JR</td>
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</tr>
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<td>J Allergy Clin Immunol.</td>
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<td>Bone Marrow Transplant.</td>
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<tr>
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<td>Outcomes of Haploidentical Transplantation in Patients with Relapsed Multiple Myeloma: An EBMT/CIBMTR Report.</td>
<td>Sahebi F</td>
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<td>30243581</td>
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<td>Outcomes of hematopoietic stem cell transplantation from unmanipulated haploidentical versus matched sibling donor in patients with acute myeloid leukemia in first complete remission with intermediate or high-risk cytogenetics: a study from the Acute Leukemia Working Party of the European Society for Blood and Marrow Transplantation.</td>
<td>Salvatore D</td>
<td>Haematologica.</td>
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<td>Post-remission strategies for the prevention of relapse following allogeneic hematopoietic cell transplantation for high-risk acute myeloid leukemia: expert review from the Acute Leukemia Working Party of the European Society for Blood and Marrow Transplantation.</td>
<td>Lee CJ</td>
<td>Bone Marrow Transplant.</td>
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<td>Post-transplant cyclophosphamide for graft-versus-host disease prophylaxis in HLA matched sibling or matched unrelated donor transplant for patients with acute leukemia, on behalf of ALWP-EBMT.</td>
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<td>J Hematol Oncol.</td>
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<td>Prevention and treatment of relapse after stem cell transplantation by cellular therapies.</td>
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<td>Prophylactic donor lymphocyte infusion after allogeneic stem cell transplantation in acute leukaemia - a matched pair analysis by the Acute Leukaemia Working Party of EBMT.</td>
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<td>Protective environment for hematopoietic cell transplant (HSCT) recipients: The Infectious Diseases Working Party EBMT analysis of global recommendations on healthcare facilities.</td>
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<td>29535381</td>
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<td>Recommendations from the European Society for Blood and Marrow Transplantation (EBMT) for a curriculum in hematopoietic cell transplantation.</td>
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<td>Reduced Relapse Incidence with FLAMSA-RIC Compared with Busulfan/Fludarabine for Acute Myelogenous Leukemia Patients in First or Second Complete Remission: A Study from the Acute Leukemia Working Party of the European Society for Blood and Marrow Transplantation.</td>
<td>Heinicke T</td>
<td>Biol Blood Marrow Transplant.</td>
<td>30009981</td>
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<td>Refined graft-versus-host disease/relapse-free survival in transplant from HLA-identical related or unrelated donors in acute myeloid leukaemia.</td>
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<td>Relapse and survival after transplantation for complex karyotype acute myeloid leukemia: A report from the Acute Leukemia Working Party of the European Society for Blood and Marrow Transplantation and the University of Texas MD Anderson Cancer Center.</td>
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<td>Cancer.</td>
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<td>Related donor transplants: has posttransplantation cyclophosphamide nullified the detrimental effect of HLA mismatch?</td>
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<td>Risk factors affecting outcome of unrelated cord blood transplantation for children with familial haemophagocytic lymphohistiocytosis.</td>
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<td>Second Hematopoietic Stem Cell Transplantation for Post-TransplantationRelapsed Acute Leukemia in Children: A Retrospective EBMT-PDWP Study.</td>
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<td>Secondary malignancies after high-dose chemotherapy in germ cell tumor patients: a 34-year retrospective study of the European Society for Blood and Marrow Transplantation (EBMT).</td>
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<td>Single Dose Daily Fractionated Is Not Inferior To Twice A Day Fractionated Total Body Irradiation Prior To Allogeneic Stem Cell Transplantation For Acute Leukemia: A Useful Practice Simplification Resulting From The Sarasin Study.</td>
<td>Belkacemi Y</td>
<td>Int J Radiat Oncol Biol Phys.</td>
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<td>Solid organ transplantation after haematopoietic stem cell transplantation in childhood: a multicentric retrospective survey.</td>
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<td>T-cell-depleted haploidentical stem cell transplantation results improve with time in adults with acute leukemia: A study from the Acute Leukemia Working Party of the European Society of Blood and Marrow Transplantation (EBMT).</td>
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<td>Cancer.</td>
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<td>The effect of NIMA matching in adult unrelated mismatched hematopoietic stem cell transplantation - a joint study of the Acute Leukemia Working Party of the EBMT and the CIBMTR.</td>
<td>Pingel J</td>
<td>Bone Marrow Transplant.</td>
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<td>The eGVHD App has the potential to improve the accuracy of graft versus host disease assessment: a multicenter randomized controlled trial.</td>
<td>Schoemans HM</td>
<td>Haematologica.</td>
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<td>The European Society for Blood and Marrow Transplantation (EBMT) Consensus Guidelines for the Detection and Treatment of Donor-specific Anti-HLA Antibodies (DSA) in Haploidentical Hematopoietic Cell Transplantation.</td>
<td>Ciurea SO</td>
<td>Bone Marrow Transplant.</td>
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<td>Therapeutic Drug Monitoring of Busulfan for the Management of Pediatric Patients: Cross-Validation of Methods and Long-Term Performance.</td>
<td>Choong E</td>
<td>Ther Drug Monit.</td>
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<tr>
<td>Thiotepa, busulfan and fludarabine compared to busulfan and cyclophosphamide as conditioning regimen for allogeneic stem cell transplant from matched siblings and unrelated donors for acute myeloid leukemia.</td>
<td>Saraceni F</td>
<td>Am J Hematol.</td>
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<td>Thiotepa-busulfan-fludarabine compared to busulfan-fludarabine for sibling and unrelated donor transplant in acute myeloid leukemia in first remission.</td>
<td>Saraceni F</td>
<td>Oncotarget.</td>
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<td>Transplant outcome for patients with acquired aplastic anemia over the age of 40: has the outcome improved?</td>
<td>Giannarco S</td>
<td>Blood.</td>
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<td>Transplant Outcomes for Secondary Acute Myeloid Leukemia: Acute Leukemia Working Party of the European Society for Blood and Bone Marrow Transplantation Study.</td>
<td>Sengsayadeth S</td>
<td>Biol Blood Marrow Transplant.</td>
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<td>Transplant results in adults with Fanconi anaemia.</td>
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<td>Br J Haematol.</td>
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<td>Unmanipulated haploidential in comparison with matched unrelated donor stem cell transplantation in patients 60 years and older with acute myeloid leukemia: a comparative study on behalf of the ALWP of the EBMT.</td>
<td>Santoro N</td>
<td>J Hematol Oncol.</td>
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<td>Peric Z</td>
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<td>29515252</td>
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In 2017, 683 teams reported 45,418 transplants in 41,100 patients (first transplant) to the annual activity survey. Of these, 18,281 HCT (40%) were allogeneic and 27,137 (60%) autologous (Table 1). When compared with 2016, the total number of transplants increased by 4.1% (3.6% allogeneic HCT and 4.4% autologous HCT). In addition, there were 4,318 second or subsequent transplants, 1,126 being allogeneic, mainly to treat relapse or graft failure and 3,192 autologous, the majority of which were part of multiple transplant procedures such as either tandem procedures, or as salvage autologous transplants for plasma cell disorders.

The total number of patients transplanted under the age of 18 in both dedicated and joint adult-paediatric units was 5,056 (3,725 allogeneic and 1,331 autologous). This is an increase of 7.8% (5.1% allogeneic, 16.2% autologous) when compared to 2016.

Main indications for HCT were myeloid malignancies (AML, CML, MDS or MD/MPN overlap and MPN); 10,147 (25% of total; 96% of which were allogeneic); lymphoid malignancies (ALL, CLL, HL, NHL and PCD); 26,488 (64%; 19% allogeneic); solid tumors: 1,607 (4%; 2% allogeneic); non-malignant disorders: 2,667 (7%; 81% allogeneic) and others: 191 (0.5%).

Figure 1 shows the distribution of disease indications for allogeneic (Figure 1a) and autologous (Figure 1b) HCT as a pie graph. In Figure 1a, AML is the most frequent indication (39%), of these 56% were for patients in CR1, 29% for patients with more advanced disease and 15% for patients with transformed AML, either therapy-related or from MDS/MPN. The number of patients has increased 3.6-fold over a twenty-year period from 4,751 in 1997 to 17,155 in 2017. During this time, the decline in HCT for CML from 25.3% to 1.9% can be clearly observed. Whereas AML, MDS and MPN have increased substantially during this period, the proportion of ALL transplants has decreased only slightly.

In Figure 1b, the most frequent indication is for plasma cell disorders (53%). The number of patients has increased 2-fold over a twenty-year period, from 12,199 in 1997 to 23,945 in 2017 with myeloma being the dominant indication; increasing from 18% to 53% during this time. Proportions of HCTs for Hodgkin and Non-Hodgkin lymphoma have remained stable. Autologous HCT for AML has decreased from 13% to 1.72%. Already well described is the change in autologous HCT for solid tumor where the decrease in use of this technology in breast cancer has decreased to 0.1%.

**CELLULAR THERAPY USE**

Table 2 shows cell therapies performed in EBMT centers in 2017. 2,825 patients received donor lymphocyte infusions. The majority of DLI’s were given for relapse (1,284) and graft enhancement (661). Other reasons being for residual disease (422) and ‘per protocol’ (458). 1,202 patients received other forms of cell therapy, most commonly mesenchymal stromal cells (n=557; 91% allogeneic), mainly to treat graft versus host disease. Expanded / selected T lymphocytes (n=179; 100% allogeneic) and genetically modified T cells (n=151; 50% allogeneic) were the second most frequently reported cell therapy. The area with the highest growth is genetically modified T-cells. The main indications for cell therapies (excluding DLI) being GvHD or graft enhancement (n=688; 95% allogeneic), malignancy (n=253; 50% allogeneic), infections (n=124; 100% allogeneic), autoimmune disease (n=61; 43% allogeneic) and genetic disease (n=14; 7% allogeneic).

The annual activity survey of the EBMT reflects current activity and trends in the field of transplant technology. It is valuable for the dissemination of the most recent information on indications, donor and stem cell usage, which can ultimately be beneficial in health care planning.

Helen Baldomero, Jakob R Passweg
EBMT Activity Survey Office, Hematology, Department of Medicine, University Hospital, Basel, Switzerland

**The EBMT activity survey report 2017: a focus on allogeneic HCT for nonmalignant indications and on the use of non-HCT cell therapies**

Helen Baldomero, Jakob R Passweg
EBMT Activity Survey Office, Hematology, Department of Medicine, University Hospital, Basel, Switzerland

**Abstract**

Diseases of the hematopoietic system (DHS) are a major cause of morbidity and mortality around the world. Due to advances in basic and clinical research, the treatment options for patients with DHS are rapidly expanding.HLA-matched related donors are currently the standard of care for patients with malignant hematologic diseases. However, the availability of related donors is limited, especially in cases of unrelated patients. In recent years, the field of cellular therapies has seen significant advancements, particularly the use of allogeneic hematopoietic stem cell transplantation (HSCT) for the treatment of fatal hematologic disorders. The EBMT activity survey report 2017 highlights the increasing trend in the use of allogeneic HSCT for the treatment of non-HSCT cell therapies across various disease indications, including metabolic, immunological, infectious, and neoplastic conditions. The report also underscores the importance of interdisciplinary cooperation in the development and delivery of innovative cellular therapies, emphasizing the need for continued research and collaboration among hematologists, oncologists, immunologists, and other relevant medical professionals. The EBMT activity survey provides valuable insights into the current landscape of cellular therapies and sets the stage for future advancements in the field. This report further emphasizes the significance of the EBMT Activity Survey Office in disseminating the latest information and trends in hematopoietic stem cell transplantation, which can ultimately contribute to better health care planning and patient outcomes.
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<td>Cord</td>
<td>33</td>
<td>99</td>
</tr>
<tr>
<td>All</td>
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<tr>
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<td>1420</td>
<td>27137</td>
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<tr>
<td>PBPC</td>
<td>4411</td>
<td>45418</td>
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<tr>
<td>Cord</td>
<td>33</td>
<td>99</td>
</tr>
<tr>
<td>Only</td>
<td>212</td>
<td>211</td>
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<tr>
<td>PBPC</td>
<td>212</td>
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<tr>
<td>Cord</td>
<td>212</td>
<td>211</td>
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**Ref:** Passweg et al. Bone Marrow Transplantation February 2019
Table 2:
NUMBERS OF CELL THERAPIES IN EUROPE 2017 BY INDICATION, DONOR TYPE AND CELL SOURCE.

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>DLI</th>
<th>MSC</th>
<th>NK cells</th>
<th>Selected expanded T cells or CIK</th>
<th>Regulatory T cells (TREGS)</th>
<th>Genetically modified T cells</th>
<th>Dendritic cells</th>
<th>Expanded CD34+ cells</th>
<th>Genetically modified CD34+ cells</th>
<th>Other</th>
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<tr>
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<td>13</td>
<td>13</td>
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<td>13</td>
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<tr>
<td>Graft enhancement</td>
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<td>1</td>
<td>14</td>
<td>5</td>
<td>57</td>
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<td>19</td>
<td>6</td>
<td>27</td>
<td>0</td>
<td>179</td>
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<td>2</td>
<td>2</td>
<td>2</td>
<td>4</td>
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<td>Malignancy</td>
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<td>24</td>
<td>8</td>
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<td>Regenerative medicine</td>
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<td>1</td>
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<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>11</td>
</tr>
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<td>48</td>
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<td>0</td>
<td>179</td>
<td>0</td>
<td>65</td>
<td>8</td>
<td>73</td>
</tr>
</tbody>
</table>

Figure 1:
RELATIVE PROPORTION OF DISEASE INDICATIONS FOR HCT IN EUROPE 2017.

Fig 1a: RELATIVE PROPORTION OF ALLOGENEIC HCT

Fig 1b: RELATIVE PROPORTION OF AUTOLOGOUS HCT

Abbreviations:
HCT; hematopoietic stem cell transplant, AML; acute myeloid leukemia, ALL; acute lymphoblastic leukemia, CML; chronic myeloid leukemia, MDS or MDS/MPN overlap; myelodysplastic or myelodysplastic/myeloproliferative neoplasm, MPN; myeloproliferative neoplasm, CLL; chronic lymphocytic leukemia, PCD; plasma cell disorders, MM; multiple myeloma, HL; Hodgkin lymphoma, NHL; Non-Hodgkin lymphoma, SAA; severe aplastic anemia, CR1; 1st. complete remission, DLI; donor lymphocyte infusion, MSC; mesenchymal stromal cells.
During 2018 the EBMT Registry received a draft positive qualification opinion from the European Medicines Agency (EMA) regarding its Cellular Therapy module. The qualification opinion was released on February 28, 2019 (see page 44). In addition, the data collection form (MED-A) for Cellular Therapy has undergone further review during the year. More detail is included below.

At the Registry we are continuing to work with Elsevier, our chosen supplier for the New Registry System. The solution named MACRO is due to replace ProMiSe and go live in the first half of 2019. Please see below for more information on the progress and plan.

By the end of 2018, the entire Registry included at least 666,000 transplant registrations in total. New registrations (allografts) entered during 2018 increased by approximately 10% on the previous year. We include the charts below.

NEW REGISTRATIONS

17,256 allografts and 23,397 autografts were registered during 2018. This includes mainly recent transplants, but also some transplants performed during earlier years.
POSITIVE QUALIFICATION OPINION - EMA

In the summer of 2018, EMA issued the first two marketing authorisations for CAR T-cells medicines in the European Union. Among the conditions imposed by EMA is the utilisation of a patient registry as part of the risk management measures for these two new medicines in order to monitor long-term safety and efficacy.

The EBMT had already formally engaged with the European Medicines Agency (EMA) regarding the EBMT Registry and this led to the publication by EMA in July 2018 of their draft positive qualification opinion on the cellular therapy module of the EBMT Registry for public consultation. The qualification opinion was released on February 28, 2019 (see page 44). 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.

CELL THERAPY

During the last year, the EBMT has further worked on the Cell Therapy Med-A, resulting in the creation of a new Cellular and Gene Therapy Form. This will incorporate the remaining “must have” items required by EMA.

The new form is being implemented in MACRO, the upcoming new registry system that will go live in 2019. The data that have been registered using the current Cell Therapy Med-A form in ProMISe 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.

Competent authorities will require manufacturers to perform long-term (15 years) follow-up of recipients which implies collecting significant amounts of clinical data. With this requirement in mind, the EBMT has been working with commercial CAR-T manufacturers to review and validate the Cell Therapy form. This form is expected to be fully implemented shortly. CAR T teams and clinical departments will be key to collecting the data on their patients, both at the time of treatment and subsequent follow-up.

PROJECT 2020: REGISTRY UPGRADE

As announced in the last report, Elsevier was appointed in February 2017 to work on the new registry system (MACRO). During 2018, comprehensive testing of Data Entry continued, alongside the initial testing of the new Data Retrieval function, following further customised development for EBMT. This led to some delays in the project timeline that had been planned.

In addition to EBMT staff, the pool of beta testers was increased and a number of National Registry staff and Centre data managers volunteered their time and gave important feedback. We are very grateful for their support.

END USER ENGAGEMENT

During 2018, presentations took place at the BSBMT Data Manager Training Days (UK) and at the EBMT Annual Meeting in Lisbon. During the EBMT congress we also provided taster sessions using MACRO in the computer room.

TRAINING

A Train the Trainer session took place in February 2019 in London, primarily aimed at National Registry staff who will be providing training to their centres, with support from the EBMT Registry. Group training sessions are already planned in Turkey, Spain and at the EBMT Annual Meeting in March 2019. Further regional sessions are being planned by other National Registries, and others will be planned for those centres outside of National Registries. Suggestions for host venues will be very welcome.

TIMELINE

We aim to go live as soon as possible after the centre training has started taking place, after the EBMT Annual Meeting in March. We will keep members informed of the next steps. We look forward to working together on the new Registry in 2019.

For any comments, suggestions or questions regarding the EBMT Registry please email registryhelpdesk@ebmt.org

Carmen Ruiz de Elvira
Head of the EBMT Registry
EMA’s qualification opinion on Cellular therapy module of the EBMT Registry

ON FEBRUARY 28, 2019, THE EBMT RECEIVED A REGULATORY QUALIFICATION FROM THE EUROPEAN MEDICINE AGENCY (EMA) ON THE USE OF ITS PATIENT REGISTRY TO SUPPORT NOVEL CAR T-CELL THERAPIES.

The EBMT Registry has been qualified by EMA as a suitable platform for the collection of data for post-authorisation safety studies. The registry is now considered suitable to perform pharmacoepidemiological studies for regulatory purposes, concerning Chimeric Antigen Receptor (CAR) T-cell therapy used in the treatment of haematological malignancies.

CAR T-cell immunotherapies are advanced therapy medicinal products (ATMPs) manufactured from human primary living cells procured by hospitals or blood banks. While clinical results of CART-cell products so far have been impressive, these highly personalised medicines can also have substantial adverse effects leading to severe complications in patients including death. Furthermore, some ATMPs may be considered as a once-in-a-lifetime treatment and long-term follow-up is needed to demonstrate the sustainability of efficacy. This is where registries such as EBMT become essential actors with a proven long-term follow-up of large cohorts of patients undergoing complex therapeutic procedures such as haematopoietic cell transplantation and immune effector cells.

The EBMT developed a specific Cellular and Gene Therapy Form to standardise registration of patients treated with cellular therapies such as CAR T-cells in Europe. Furthermore EBMT contributed to the EMA-facilitated consensus with regulators and industry on establishing the minimal dataset needed for long-term surveillance of patients receiving CAR T-cells.

The qualification opinion came as a result of extensive interaction with EMA starting in late 2016 when the EBMT first responded to the EMA’s Patient Registry Initiative and subsequently in the formal qualification opinion request process.

The EMA recognises the value of its registry and this recognition will lead to improved communication among the various stakeholders, including registry owners, regulators and marketing authorisation holders, giving confidence to users on the data collected and ultimately bring safe and effective therapies to the patients.

The EBMT acknowledges the important contributions of EBMT volunteers to this achievement: Chiara Bonini, Christian Chabannon, Jürgen Kuball, with the support of EBMT staff including Eoin McGrath, Carmen Ruiz de Elvira and Anja van Biezen.

The full qualification opinion report is available on www.ebmt.org and www.ema.europa.eu
## EDUCATION

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
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<tr>
<td>EBMT 44th Annual Meeting</td>
<td>47</td>
</tr>
<tr>
<td>Awards</td>
<td>50</td>
</tr>
<tr>
<td>Educational events</td>
<td>52</td>
</tr>
<tr>
<td>The new EBMT Handbook</td>
<td>53</td>
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</table>
EBMT 2018
44th ANNUAL MEETING
OF THE EUROPEAN
SOCIETY FOR BLOOD AND
Marrow Transplantation

Meeting of the Physicians
Meeting of the Nurses Group
Meeting of the Data Management Group
Patient, Family & Donor Day
Meeting of the Quality Management Group
Cell Therapy Day
Paediatric Day
Pharmacist Day
Psy Day

Attendance

5,261 delegates from 87 countries
Programme

1,213 abstracts submitted

192 oral presentations
971 posters presented
171 sessions
15 awards

Continent of origin of the speakers:

- North America: 6%
- Europe: 87%
- Middle East: 2%
- Africa: 0.2%
- Asia: 1%
- Australia / Oceania: 0.5%

364 speakers
**Sponsoring and Exhibition**

- **24** companies, associations or groups supported EBMT 2018
- **33** sponsored sessions (industry symposium, industrial theatre, How Do I...?)
- **51** exhibiting organisations in over **1,170 m2** exhibition area

**Digital Activities**

- **945** people sent **5,312** tweets to the Twitter wall generating **20,411,265** impressions and reaching **13,495,218** people
- **7,191** page views of the EBMT TV online (WebsEdge and YouTube)
- **3,627** mobile app downloads

**Networking Activities**

- **850** delegates attended the opening session and welcome reception
- **600** delegates attended the networking event in the Patio da Gale

Delegates gave the Annual Meeting a rating of **8 out of 10** (EBMT 18 delegates’ survey - 1,856 respondents)
Awards

VAN BEKKUM AWARD

The Van Bekkum Award for the best abstract submitted to the physician’s programme, sponsored by EBMT, was presented to Richard K. Burt (United States) for the abstract entitled: NON-MYELOABLATIVE HAEMATOPOIETIC STEM CELL TRANSPLANTATION VERSUS CONTINUED DISEASE MODIFYING THERAPIES (DMT) IN PATIENTS WITH HIGHLY ACTIVE RELAPSING REMITTING MULTIPLE SCLEROSIS (RRMS)

JIAN-JIAN LUAN AWARD

The Jian-Jian Luan Award for Lymphoma Transplant Research, sponsored by EBMT, was presented to Anne-Claire Mamez (Switzerland) for the abstract entitled: ALLOGENEIC STEM CELL TRANSPLANTATION FOR PERIPHERAL T-CELL LYMPHOMAS: A STUDY OF 284 PATIENTS FROM THE SOCIETE FRANCOPHONE DE GREFFE DE MOELLE ET DE THERAPIE CELLULAIRE

HONORARY MEMBERSHIP

Honorary Membership awarded to Enric Carreras (Spain), Dietrich Niethammer (Germany) (represented by Peter Bader) and Ray Powles (United Kingdom)

CLINICAL ACHIEVEMENTS

The Clinical Achievements Award awarded to Boris Afanasiev (Russian Federation)

JON VAN ROOD AWARD

The Jon van Rood Award for the best paper in the immunobiology of allogeneic hematopoietic transplantation, sponsored by EBMT, was presented to Antonio Galleu (United Kingdom) for the paper entitled: APOPTOSIS IN MESENCHYMYAL STROMAL CELLS INDUCES IN VIVO RECIPIENT-MEDIATED IMMUNOMODULATION and to Enrico Velardi (United States) for the paper entitled: PRODUCTION OF BMP4 BY ENDOTHELIAL CELLS IS CRUCIAL FOR ENDOGENOUS THYMIC REGENERATION

BASIC SCIENCE AWARD

The Basic Science Award, sponsored by Chimeric Antigen Receptors for Advanced Therapies (CARAT), was presented to Fermín Sánchez-Guijo (Spain) for the abstract entitled: THE INCORPORATION OF EXTRACELLULAR VESICLES FROM MESENCHYMAL STROMAL CELLS INTO HEMATOPOIETIC PROGENITORS INCREASE THEIR CLONOGENIC CAPACITY AND THEIR ENGRAFTMENT ABILITY
BEST YOUNG ABSTRACTS

The Best Young Abstract Awards for the best abstracts submitted for Oral and Poster presentations, sponsored by the EBMT, were presented to ten young investigators:

1. Mattia Algeri (Italy) 6. Hardikkumar Jetani (Germany)
2. Jon Badiola Gonzalez (Spain) 7. Nayoun Kim (Korea, Republic of)
3. Nico Gagelmann (Germany) 8. Marthe C.J. Roex (The Netherlands)
4. Federica Galaverna (Italy) 9. Serena Scala (Italy)
5. Mojibade Hassan (United States) 10. Anke Verlinden (Belgium)

BEST CHINESE ORAL & POSTER ABSTRACTS

The Best Chinese oral abstract Award was presented to Honghu Li (China) for the abstract entitled: PRIMITIVE NEUTROPHILS DERIVED IL6 POSITIVELY REGULATES EMBRYONIC HEMATOPOIETIC STEM CELL EMERGENCE

The Best Chinese poster abstract Award was presented to Zhao Wu (China) for the abstract entitled: POTENT ANTI-LEUKEMIA ACTIVITIES OF HUMANIZED CHIMERIC ANTIGEN RECEPTOR MODIFIED T(CAR-T) CELL THERAPY IN CHINESE PATIENTS WITH RELAPSED/REFRACTORY ACUTE LYMPHOBLAST LEUKEMIA

BEST LATIN AMERICAN ABSTRACTS

The Best Latin American Abstract Award was presented to Carmem Bonfim (Brazil) for the abstract entitled: EXCELLENT OUTCOME FOR 91 FANCONI ANEMIA PATIENTS UNDERGOING MATCHED RELATED TRANSPLANTS USING CYCLOPHOSPHAMIDE 60MG/KG IN CURITIBA, BRAZIL and to Monica Magdalena Rivera Franco (Mexico) for the abstract entitled: DONOR AND RECIPIENT HYPERCHOLESTEROLEMIA BEFORE ALLOGENIC STEM CELL TRANSPLANTATION ASSOCIATES WITH INCREASED INCIDENCE OF ACUTE GRAFT-VERSUS-HOST DISEASE

BEST latin AMERICAN ABSTRACTS

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LIFETIME ACHIEVEMENT AWARD IN ACUTE LEUKAEMIA

The EBMT Lifetime Achievement Award in Acute Leukaemia awarded to Eliane Gluckman

NATURE PUBLISHING POSTER AWARDS

The Best Clinical Poster Award, sponsored by Nature Publishing Group, was presented to Britta Eiz-Vesper (Germany) for her poster #A129 entitled: VIRUS-SPECIFIC T CELLS FROM STEM CELL, FAMILY AND THIRD PARTY T CELL DONORS: PATIENT MONITORING, DONOR SELECTION AND GMP-COMPLIANT MANUFACTURING

The Best Science Poster Award, sponsored by Nature Publishing Group, was presented to Lars Wallstabe (Germany) for his poster #A094 entitled: CAR-T CELLS TARGETING αVβ3 INTEGRIN CONFERS COMPLETE REMISSION OF EPITHELIAL CANCERS IN PRE-CLINICAL MODELS IN VIVO

NURSES GROUP AWARDS

Distinguished Merit Award to Jacqui Stringer (United Kingdom)

Best research abstract oral presentation to Jantina Kortleve-Kadijk (The Netherlands) for the abstract entitled: A CRITICAL APPRAISED TOPIC (CAT): WHAT IS THE NEED FOR HYDRATION AFTER AUTOLOGOUS STEM CELL TRANSPLANTATION?

Best oral presentation to Joanne Ellis (United Kingdom) for the abstract ANALYSIS OF PARENT, STAFF AND WARD EXPERIENCE FOLLOWING THE IMPLEMENTATION OF A ROBUST, VALIDATED TEACHING TOOL FOR PARENTS OF CHILDREN WHO REQUIRE (HOME) PARENTERAL NUTRITION

Best paediatric oral presentation to Shohui Nakajima (Japan) for the abstract entitled: PREDICTORS OF PARENTAL PSYCHOLOGICAL DISTRESS DURING THE ACUTE PHASE OF PEDIATRIC HEMATOPOIETIC STEM CELL TRANSPLANTATION IN JAPAN: A MULTICENTER PROSPECTIVE LONGITUDINAL STUDY

Best poster to Teresa Solano (Spain) for the poster entitled: IMPLEMENTATION OF LATE-EFFECTS FOLLOW-UP NURSE CONSULTATION FOR ALLOGENIC HEMATOPOIETIC STEM CELL TRANSPLANTATION RECIPIENTS: HIGH INCIDENCE OF NUTRITIONAL, PSYCHOLOGICAL AND SEXUAL DYSFUNCTIONS

Best paediatric poster to Victoria Cassels (United Kingdom) for the poster entitled: STANDARDISING DISCHARGE INFORMATION FOR NURSES WORKING ON A PAEDIATRIC STEM CELL TRANSPLANT WARD

EDUCATION
## Educational events 2018

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<tr>
<th>Location</th>
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<td>Leiden, The Netherlands</td>
<td>18-20 January 2018</td>
<td><strong>CTIWP</strong> 2nd Cellular Therapy &amp; Immunobiology Scientific Symposium</td>
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<tr>
<td>Dublin, Ireland</td>
<td>26-27 January 2018</td>
<td>Chronic Malignancies Working Party Business &amp; Educational Meeting</td>
</tr>
<tr>
<td>Marseille, France</td>
<td>20-22 April 2018</td>
<td>Advances in Allogeneic Immunotherapy: where do we stand in 2018?</td>
</tr>
<tr>
<td>Barcelona, Spain</td>
<td>24-25 May 2018</td>
<td>Inspector Training Course</td>
</tr>
<tr>
<td>Verona, Italy</td>
<td>7-9 June 2018</td>
<td><strong>PDWP / IDWP / IEWP / NG</strong> 11th Paediatric Diseases, Infectious Diseases, Inborn Errors Parties and 6th Paediatric Nurses Group Meeting</td>
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<tr>
<td>Barcelona, Spain</td>
<td>7-9 September 2018</td>
<td><strong>EBMT</strong> 3rd EBMT International Transplant Course</td>
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<td>Lille, France</td>
<td>14-15 September 2018</td>
<td>Chronic Malignancies Working Party Business &amp; Educational Meeting</td>
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<tr>
<td>Palma de Mallorca, Spain</td>
<td>26-28 September 2018</td>
<td><strong>LWP</strong> 14th Edition of the Lymphoma Working Party Educational Course</td>
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<td>Montpellier, France</td>
<td>4-5 October 2018</td>
<td><strong>NG</strong> 10th EBMT Nurses International Study Day</td>
</tr>
<tr>
<td>London, UK</td>
<td>12 October 2018</td>
<td>Emerging Therapies - Let’s focus on CAR T Cell</td>
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<tr>
<td>London, UK</td>
<td>8-9 November 2018</td>
<td>Inspector Training Course</td>
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<tr>
<td>Zagreb, Croatia</td>
<td>8-10 November 2018</td>
<td><strong>TCWP</strong> 4th International cGvHD Symposium &amp; Transplant Complications Working Party Educational Meeting</td>
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<tr>
<td>Bellinzona, Italy</td>
<td>15 November 2018</td>
<td><strong>NG</strong> Swiss Nurses Working Group Study Day</td>
</tr>
<tr>
<td>Florence, Italy</td>
<td>15-17 November 2018</td>
<td><strong>ADWP / SAAWP</strong> Joint Educational Meeting of the Autoimmune Diseases and Aplastic Anaemia Working Parties</td>
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<tr>
<td>Krakow, Poland</td>
<td>16-17 November 2018</td>
<td><strong>ALWP</strong> Acute Leukaemia Working Party Scientific Meeting and Educational Symposium &quot;Advances in pre and post-transplant management of acute lymphoblastic leukaemia&quot;</td>
</tr>
<tr>
<td>Barcelona, Spain</td>
<td>22-23 November 2018</td>
<td>Inspector Training Course</td>
</tr>
<tr>
<td>Mumbai, India</td>
<td>December 2018</td>
<td><strong>NG</strong> 2nd training course for HSCT Nurses</td>
</tr>
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</table>

**Abbreviations:**
- ALWP: Acute Leukemia Working Party
- IEWP: Inborn Errors Working Party
- TCWP: Transplant Complications Working Party
- LWP: Lymphoma Working Party
- SAAWP: Severe Aplastic Anaemia Working Party
- IDWP: Infectious Diseases Working Party
- CMWP: Chronic Malignancies Working Party
- PDWP: Paediatric Diseases Working Party
- ADWP: Autoimmune Diseases Working Party
- CTIWP: Cellular Therapy and Immunobiology Working Party
- NG: Nurses Group
- JACIE: Joint Accreditation Committee of the European Bone Marrow Transplantation Network
The new EBMT Handbook

The EBMT Handbook Hematopoietic Stem Cell Transplantation and Cellular Therapies was released in a new format in January 2019. The project started in 2017 and was coordinated by Enric Carreras, one of the editors together with Carlo Dufour, Mohamad Mohty and Nicolaus Kröger.

This new formatted EBMT Handbook which follows the long tradition of the ESH-EBMT Handbook, addresses the latest developments and innovations in stem cell transplantation and cellular therapy. In 93 chapters written by 175 leading experts in the field, the book covers all types of stem cell and bone marrow transplantation, including haplo-identical stem cell and cord blood transplantation, but also indications for transplantation, the management of early and late complications as well as the new and rapidly evolving field of cellular therapies. Other important issues such as quality management and JACIE accreditation, stem cell collection, conditioning, donor selection, HLA typing, graft manipulation, ethical issues, psychological support, and quality of life are also properly addressed.

This book provides an unparalleled description of current practices to enhance readers’ knowledge and practice skills.

The book is downloadable in PDF and all participants of the EBMT 45th Annual Meeting will be able to get a free-hard copy.

The open-access and print edition (Springer Open) have been possible thanks to the generous unrestricted educational grant from the Fondation José Carreras pour la lutte contre la leucémie, Genève.

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PATIENT CARE
EBMT Nurses Group

Haematology and HSCT Nursing

EBMT Nurses Group (NG) is committed to patient care through education, research and international network collaboration.

The EBMT NG is one of the leading groups in the field of haematology and HSCT nursing. It is dedicated to improving the care of patients receiving HSCT and promoting excellence in and through evidence based practice. The NG’s mission is to enhance and value the nursing role all over the world, supporting and sharing knowledge through communication, advocacy, research, training and education.

Education

The nurses and allied health care professions programme at EBMT 2018 in Lisbon was a great success from the first session on Sunday 18th through to Wednesday 21st March and was our 34th nurses meeting. Over the 4 days of congress there were many stimulating and inspiring sessions, covering the many complications our patients face from diagnosis to their initial treatment and through and beyond the transplant process.

This year we had 2 satellite symposiums throughout the conference, supported by Jazz Pharmaceuticals and Mallinckrodt that were extremely well attended and gave good feedback.

Grants for 2018 were given to five nurses, these grants enable nurses to attend our Annual Meeting, travel to other EBMT centres and share excellent practice and generate ideas and improve working practices. The winners for 2018 were, M. Jafar, who received the educational grant, C. Lim, travel grant recipient, O. Niculita, the grant to attend the annual paediatric training day, C. Locca, the exchange grant winner and M. Achrekar was our outreach nurse from Mumbai India who attended the Annual Meeting. All have supplied fantastic feedback either within the EBMT NG newsletter or by oral presentation.

Paediatric Training Days

The 6th Paediatricians & Paediatric Nurses training course on HSCT in Children and Adolescents was held from 7th to 9th June in Verona, Italy, and was a great success with nurses across Europe attending. Details are within the PDWP update.

International Nurses Training Day and Second Research Nurses Day

Annually EBMT NG provides an autumn education meeting. 2018 saw the 10th training day and the 2nd research day. This year we were hosted in Montpellier and had a fantastic reception with a great turn out of local nurses. The 10th training day saw 71 nurses from across Europe join together to learn. As usual we offer a wide spread of topics, with talks on MDS, DLI, GvHD and care of the young adult, a cornucopia on offer that was a stimulating and thought provoking programme.

The second day saw the return of the research day, a new idea for 2017 that we repeated this year and has now become a permanent day in the calendar. There were 42 attendees with presentations aimed specifically at nurses. The research abstract and general abstract finalists talked through their winning pieces of work, giving hints and tips for future writers. A workshop in the afternoon made this a more practical day. Helping nurses turn an idea into a reality by developing their question using research methodology. This led to feedback of >90% satisfaction of a good meeting and people happy to attend again next year, a success.
MEDICAL WORKING PARTY NURSES

This role is now firmly established as a valuable resource in each of the medical working parties. The goal to develop collaborative nursing/medical projects for patient benefit continues to develop at pace. The roles have begun to adapt to the needs of the WP with many nurses taking more responsibility for education. We have 2 current vacancies. The nurses and their respective working parties are:

1. Infectious diseases WP - Iris Agreiter (Italy)
2. Lymphoma WP - Erik Aerts (Switzerland)
3. Acute leukaemia WP - Elisabeth Wallhult (Sweden)
4. Paediatric diseases WP - Eugenia Trigoso Arjona (Spain)
5. Severe Aplastic Anaemia WP – vacancy advertised
6. Autoimmune Diseases WP - Helen Jessop (UK)
7. Transplant Complications WP - Corien Eeltink (Netherlands)
8. Cellular therapy & Immunobiology WP – Rose Ellard (UK)
9. Chronic malignancy WP – vacancy advertised
10. Inborn errors WP – Hilda Mekelenkamp (Netherlands)

GLOBAL EDUCATIONAL COMMITTEE

The Global Educational Committee in collaboration with the EBMT NG, aims to coordinate and organise outreach meetings in cooperation with other non-profit associations with the same mission. Together they coordinate and provide a range of educational activities for nurses and allied health professionals within the field of Haematology and HSCT.

On the 14th and 15th December 2018 the GEC visited the ACTREC hospital in Mumbai, India to give a series of presentations focussed on JACIE Nursing specific standards. Approx. 220 nurses attended this educational program. Feedback was once again excellent and will be published in 2019.
NURSING RESEARCH COMMITTEE

We have had two publications this year in Bone Marrow Transplantation and there are several projects currently recruiting or about to be launched by the EBMT nurses research group.

S-FAST Collaboration with TCWP – Ethical approval has been given for several European countries and data collection continues.

Nutritional Surveys Collaboration with TCWP – Manuscript is currently being prepared and is due for submission spring 2019.

Survey on protective environment in HSCT settings collaboration with IDWP – Questionnaire designed due for release spring 2019.

CVC study on preferred insertion sites collaboration with IDWP – Study open and enrolling.

ATG survey – Looking at centre specific practices when treating patients with ATG, survey open and recruiting.

Infection Control questionnaire for LMIC; EBMT /WHO collaboration – Data collected and analysed, manuscript being written. An abstract has been written and accepted for Frankfurt annual conference.

Cutaneous cGvHD QoL questionnaire – Assess current position with regard to care of patient’s skin that has chronic GvHD and the impact of cutaneous cGvHD on morbidity / QoL in adult and paediatric population, study in development.

NG Paediatric committee Collaboration with PDWP – Safe Transfer from SCT unit to ICU: your experience, data has been collected and this is now closed and will be presented in Frankfurt with the PDWP.

Related donor care manuscript has been written and is currently under review.

Specialized Paediatric Palliative Care Services in European Paediatric Hematopoietic Stem Cell Transplant Centres, data has been collected and will be presented in Frankfurt.

Nurse competencies and patient outcomes in India Global Education Committee project – Data collected and currently being analysed.

PUBLICATIONS

1. Health-care professionals’ perspective on discussing sexual issues in adult patients after haematopoietic cell transplantation. Eeltink CM, Bone Marrow Transplant. 2018 Mar.


THE TEXTBOOK FOR NURSES

RELEASED: MARCH 2018

The EBMT nurses Group launched this ground breaking book in March 2018, the first of its kind. There have been approx. 150,000 downloads. This unique, comprehensive publication informs and guides readers through the myriad of difficulties associated with HSCT. This textbook, for adult and paediatric nurses paves a journey through the history of transplant nursing, including essential and progressive elements to help nurses improve their knowledge and benefit the patient experience, as well as a comprehensive introduction to research and auditing methods. A must have for all levels of HSCT nurse and other professionals specialising or wishing to specialise in this area.

The EBMT NG has a wealth of nurses dedicated to improving knowledge and sharing this with its members. It can be seen from the variety of activities generated in 2018 that this vibrant team is moving the nursing agenda forward and improving patient care.

John Murray
President EBMT Nurses Group
The Joint Accreditation Committee ISCT & EBMT (JACIE) was established in 1998. It promotes high-quality patient care and laboratory performance in the collection, processing and administration of cellular therapy through a profession-led, voluntary accreditation scheme.

JACIE works continuously with international partner organisations to develop and maintain standards for the provision of quality medical and laboratory practice in HSCT, performs on-site inspections, and accredits those programmes that demonstrate compliance with these standards. JACIE also provides training for inspectors and centres on the accreditation process.

Since 2000, 434 transplant programmes and facilities in 33 countries in Europe and beyond have applied to JACIE and 665 inspections (first-time and reaccreditation) have been performed. 320 applicants have achieved accreditation at least once with practically all centres repeating the process after completing the first accreditation cycle. There are over 300 registered inspectors, all volunteers drawn from the cellular therapy field.

2018 stands out for 2 significant events. The first joint JACIE-FACT inspection in Latin America was performed in November in Córdona, Argentina. A further 11 centres from the region have presented themselves to be accredited during 2019-2020. This is the first region in which the StepWise approach to accreditation is being tested. Secondly, several centres in England achieved accreditation for immune effector cell administration in conjunction with NHS England as part of their CAR-T cell therapy roll-out strategy. Both of these special initiatives impacted on the JACIE’s applications, inspections and accreditations activities in 2018.

APPLICATIONS 2018

75 APPLICATIONS
(30 first-time and 45 reaccreditation) received

INSPECTIONS 2018

78 INSPECTIONS
(19 first-time and 59 reaccreditation)
51 ACCREDITATIONS
(9 first-time and 42 reaccreditation) awarded

The 7th edition of the FACT-JACIE Standards was published on 1 March 2018. This edition featured Immune Effector Cells, first developed in edition 6.1. These particular standards have sparked a lot of interest given the recent upsurge in CAR-T cellular therapy activity.

IMMUNE EFFECTOR CELLS (IEC)

In early 2018, the National Health Service of England incorporated JACIE accreditation for IEC administration into its criteria for designation of centres to administer CAR-T cell therapy. JACIE performed focussed inspections of 8 centres using a bespoke checklist for IECs between September and October with all of those centres achieving accreditation. Sincere thanks to all of the inspectors for their invaluable contribution to the success of this project.

EDUCATIONAL EVENTS

Three JACIE training courses were held during 2018 - two in Barcelona, (Spain) and another in London (United Kingdom) with 60 participants in total. Furthermore, a joint JACIE-FACT workshop was held at the AfBMT congress in Casablanca, Morocco. Finally, JACIE was represented at the International Congress on Stem Cell and Regenerative Medicine in Tehran, Iran.
JACIE EVENTS 2018

Casablanca, Morocco
19 April
AfBMT/WBMT congress

Casablanca, Morocco
22-23 November
Course

Barcelona, Spain
22-23 November
Course

Barcelona, Spain
24-25 May
Course

Brussels, Belgium
30 November
BHS Meeting

Antalya, Turkey
28 February
Turkish Hematology Society Meeting

Antalya, Turkey
28 November
International Congress on Stem Cell and Regenerative Medicine

Montpellier, France
21 November
SFGM-TC Congress

London, UK
8-9 November
Course

Tehran, Iran
28 November
International Congress on Stem Cell and Regenerative Medicine

Figure 2. JACIE Information Day in Antalya, Turkey
OTHER

The JACIE website has now been fully incorporated into the new EBMT website. The JACIE Twitter account @JACIE_EBMT has grown to 921 followers.

We would like to express our appreciation and admiration for the Inspectors, JACIE Committee Members, Accreditation, Standards and Quality Manager Committee members, other volunteers and the JACIE Office team for all their tremendous hard work, commitment and dedication.

John Snowden  
Chair, JACIE Committee

Eoin McGrath  
JACIE Operations Manager

Institutions awarded accreditation in 2018

Medical University of Vienna, Vienna, Austria; Cliniques Universitaires St Luc, Brussels, Belgium; Jessa Ziekenhuis, campus Virga Jesse, Hasselt, Belgium; AZ Turnhout vzw, Campus Sint-Elisabeth, Turnhout, Belgium; University Hospital Centre Zagreb, Zagreb, Croatia; Centre Hospitalier Lyon Sud (CHLS), Lyon, France; Institut d’Hématologie et d’Oncoologie Pédiatrique, IHOPe - Lyon, Lyon, France; Hôpitaux Universitaires Pitié Salpêtrière - Charles - Foix, Paris, France; Institut Gustave Roussy, Villejuif, France; Institut Gustave Roussy, Villejuif, France; Evangelisches Krankenhaus Essen-Werden, Essen, Germany; St Franziskus Hospital, Medizinische Klinik I, Flensburg, Germany; Univ. Hospital Regensburg, HSCT, Regensburg, Germany; University Medical Center Würzburg, Würzburg, Germany; University Medical Center Würzburg, Würzburg, Germany; MEDIAG Kft., Debrecen, Hungary; Azienda Ospedaliera Brotzu, Cagliari, Italy; Aorn Santobono Pausilipon, Napoli, Italy; Sanquin Research, Amsterdam, Netherlands; The Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital (NKI-AVL) Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands; Maastricht University Medical Center, Maastricht, Netherlands; University Medical Center Utrecht, Utrecht, Netherlands; University Medical Center Utrecht, Utrecht, Netherlands; Hospital Duran i Reynals, Institut Catalá d’Oncologia, Barcelona, Spain; Hospital Universitario Morales Meseguer, Murcia, Spain; Skane University Hospital, Lund, Sweden; University Hospital Berne Paediatric Haematology / Oncology, Berne, Switzerland; Hôpitaux Universitaires de Genève, Geneva, Switzerland; Birmingham Women’s and Children’s NHS Foundation Trust, Birmingham, United Kingdom; Queen Elizabeth Hospital, Birmingham, United Kingdom; Blackpool Victoria Hospital, Blackpool, United Kingdom; Bristol Royal Hospital for Children, Bristol, United Kingdom; Bristol Royal Hospital for Children, Bristol, United Kingdom; Royal Devon and Exeter NHS Foundation Trust, Exeter, United Kingdom; Hull and East Yorkshire Hospitals NHS Trust, Hull, United Kingdom; Great Ormond Street Hospital, London, United Kingdom; Great Ormond Street Hospital, London, United Kingdom; Imperial College Healthcare NHS Trust, London, United Kingdom; King’s College Hospital NHS Foundation Trust, London, United Kingdom; London Bridge Hospital, London, United Kingdom; University College London Hospitals NHS Foundation Trust, London, United Kingdom; Manchester University Hospitals NHS Foundation Trust, Manchester, United Kingdom; Manchester University Hospitals NHS Foundation Trust, Manchester, United Kingdom; The Christie NHS Foundation Trust, The Christie Clinic and The Christie NHS Foundation Trust, Manchester, United Kingdom; Norfolk and Norwich University Hospital NHS Foundation Trust, Norwich, United Kingdom; Nottingham University Hospitals NHS Trust, Nottingham, United Kingdom; Nottingham University Hospitals NHS Trust, Nottingham, United Kingdom; Poole Hospital NHS Foundation Trust, Poole, United Kingdom; NHS Blood and Transplant, Southampton, United Kingdom; The Wessex Blood and Marrow Transplant Program, Southampton, United Kingdom;

Full list available at www.ebmt.org/jacie-accredited-centres
Financial Report and Highlights 2018

For the 4th consecutive time, EBMT has obtained an “unqualified opinion”, this demonstrates that EBMT is maintaining its high standard of modern management, improving its financial stability and provides assurance that money is being spent and allocated according to our mission.

EBMT has closed for a 5th consecutive year with a positive result and continues to invest in its strategic goals in line with its mission.

During the last four years as EBMT Treasurer, the EBMT Board substantially changed the financial model, which allowed the creation of a continuous reserve of income for strategic projects. This permitted a one-third increase in staff positions but also augmented financial obligations (Figure 1). Therefore, at the very same time we increased our reserves from 2,267 k€ in 2014 to 5,260 k€ in 2018 to cover salary costs in case of any unexpected event.

Figure 1. Growth in (A) FTE Employees (B) Salary costs (C) Income
SPENDING OUR FINANCIAL RESOURCES ON OUR MISSIONS

Our increasing annual income has been mainly used to further work on our mission as well as to improve the executive structure of EBMT in order to keep pace with the growing organisation. The budget needed for management (i.e. board and executive office expenses), therefore, slightly increased from 8% to 10%, still resulting in an allocation of 90% to our main missions (i.e. studies, Registry, accreditation and education, including the Annual Meeting) (Figure 2 Financial highlights 2018). Thereby, EBMT remains a very efficient organisation when assessed by international rankings (A/ A+ in line with CharityWatch).

DEVELOPING A WELL-BALANCED STRATEGIC FINANCIAL ROADMAP FOR THE FUTURE

In 2018, the main challenge was to develop a well-balanced financial roadmap for the next four years in order to be able to cover all financial challenges in line with our ambitions but also to secure a strong backbone. To cover future financial challenges, we earmarked 300 k€ per year for the last few years. The EBMT Board decided to partially release such allocated reserves in 2019 (1,153 k€) to support our roadmap for the next few years which covers the following strategic topics:

1. IMPLEMENTING THE NEW EBMT REGISTRY (MACRO)

This project will be closed in 2019 and has the highest financial priority. Reserves have been earmarked to cover all expected costs. Also, additional reserves are being held for any unexpected expenses.

2. INTRODUCING THE “BENCHMARKING” CONCEPT

We have increased the JACIE fees to cover the “benchmarking project”, which will allow centres to know how their own clinical transplantation outcomes compare to the rest of Europe. For the very first time, this will give back the most valuable information to each reporting centre: How is the quality of our daily clinical care and can we learn from over-performers to improve clinical outcomes of all centres?

3. JACIE AND LOW TO MIDDLE-INCOME COUNTRIES

The Board decided to further reach out to countries outside Europe to implement JACIE as a quality system for transplantation centres. We will, therefore, financially support this initiative.

4. IMPLEMENTING THE CELLULAR THERAPY PROJECT AND PASS STUDIES

In receiving the qualification opinion from EMA on the cellular therapy module of the EBMT Registry in February 2019 (see page 44), the board decided to strengthen manpower further to support this initiative, which will collect post-market evidence for safety and efficacy of different commercial CAR T products. In addition, this registry tool will also be helpful for all researchers who are executing clinical studies with CAR T and other advanced therapy medicinal products (ATMPs) in order to gather more comprehensive data sets on efficacy and safety in this very exciting field.

5. INVESTING IN IT AND HUMAN RESOURCES TO ALLOW PROPER MANAGEMENT OF THE ORGANISATION

With a growing organisation, we need to increase the managerial infrastructure and modernise software tools in order to further strengthen the efficiency of the EBMT.

The Board decided to recruit a medical officer who will be dedicated to supporting all medical aspects within the organisation; this has been mainly handled by volunteers until now.

6. CONSOLIDATING THE EVENTS AND EDUCATIONAL UNIT

The in-housing process of the Annual Meeting has been a huge success in order to increase the EBMT’s positioning and visibility and to improve financial control as requested by auditors. We will further invest in this important aspect of our mission, and my compliments go to the Barcelona office.

7. IMPLEMENTING E-LEARNING TOOLS

We plan to invest in an e-learning platform, which will allow the community to further educate themselves. The recently published EBMT Handbook 2019 is an excellent example of the EBMT educational activities.
FINANCIAL CONCLUSION

The very positive financial development of the organisation during recent years has allowed EBMT to further build on its strategic goals and consolidate its structure. Current highlights include the website renewal, registry upgrade, cellular therapy registry, and the development of an EBMT-based benchmarking system which has been initiated in 2019 and will be further developed in the next few years. Despite all these substantial strategic key financial investments in 2018 for IT and staff, EBMT will be closing the year 2018 with a positive total result of 2,106 k€ (expenses of 8,956 k€ and a total income of 11,062 k€). A total of 500 k€ will be earmarked in line with the Board’s decisions for structural innovation (300 k€) and registry implementation (200 k€). For other running projects 582 k€ will be earmarked as well. The residual budget of 1,024 k€ will be returned to our reserves and used to further secure our key staff positions and main strategic projects in case of any unforeseen serious adverse financial event. Additionally, 1,153 k€ will be used in 2019 to strategically invest in the goals mentioned above.

It has been my very pleasure to serve EBMT during the last four years. I would like to express my appreciation for the finance team in the Leiden office, Bas Natkiel, Liesbeth Hoekstra, Seppie Öztürk for their hard work and dedication.

Jürgen Kuball
EBMT Treasurer
### SOURCE OF INCOME

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<tr>
<th>Source</th>
<th>Total</th>
<th>%</th>
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<tbody>
<tr>
<td>EBMT Members donations</td>
<td>€626,000</td>
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<td>Scientific Sponsors donations</td>
<td>€282,000</td>
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<td>Annual Meeting</td>
<td>€6,551,000</td>
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<td>Results from investments</td>
<td>-€44,000</td>
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<tr>
<td>Grants for Studies, Clinical Trials &amp; Education</td>
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<td>Accreditation (JACIE)</td>
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<td><strong>Total Income</strong></td>
<td><strong>€11,062,000</strong></td>
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### DESTINATION OF RESOURCES

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<td>EBMT Registry</td>
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<td>Annual Meeting</td>
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<td>Standards &amp; Accreditation (JACIE)</td>
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<td>Management and administration</td>
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<tr>
<td><strong>Total Expenditure</strong></td>
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### FINANCIAL OUTCOME

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<td><strong>Total Costs</strong></td>
<td><strong>€8,956,000</strong></td>
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<td><strong>Net Result</strong></td>
<td><strong>€1,024,000</strong></td>
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**Figure 2. Financial highlights 2018**

At the time of the report was printed (March 6, 2019), the audit process had not been completed yet.
The EBMT would like to thank the 22 corporate sponsors for their generous support in 2018.

**DIAMOND**

**RUBY**

**SAPPHIRE**

**SILVER**

**BRONZE**
Thank you to Professors Peter Bader and Thomas Klingebiel and their team from the Klinikum der Johann Wolfgang Goethe-Universität Frankfurt am Main, Germany, for providing the necessary permission and organising the photoshoot.