

President Annual Activity Report for 2019

Nicolaus Kröger, EBMT President



EBMT

European Society
for Blood and Marrow
Transplantation

Achievements in 2019 at a glance

SCIENCE

- **> 250** ongoing projects
- **138** publications in peer-reviewed journals
- **100** oral presentations at international meetings
- **17,767** allografts and **23,179** autografts reported to the Registry
- **337 CAR-T cells** treated patients registered in the Registry
- Collaboration with Novartis
- **701** centres reported **47,468** transplants in **42,901** patients from **50** countries to the Transplant Activity Survey 2018

EDUCATION

- **EBMT 45th Annual Meeting** in Frankfurt with **5,640** delegates from **94** countries
- **EBMT-EHA 1st European CAR T Cell Meeting** in Paris with 680 attendees
- **14 EBMT educational events**
- **New EBMT e-learning platform and webinars**

PATIENT CARE

JACIE

- **101** received applications; 43 applications included IEC in the scope of the accreditation process
- **71** performed inspections
- **78** awarded accreditations
- Kicked-off process to prepare the **8th Edition** of the FACT-JACIE standards

NURSES GROUP

- Educational meetings
- Medical Working Party Nurses
- Collaborative research projects

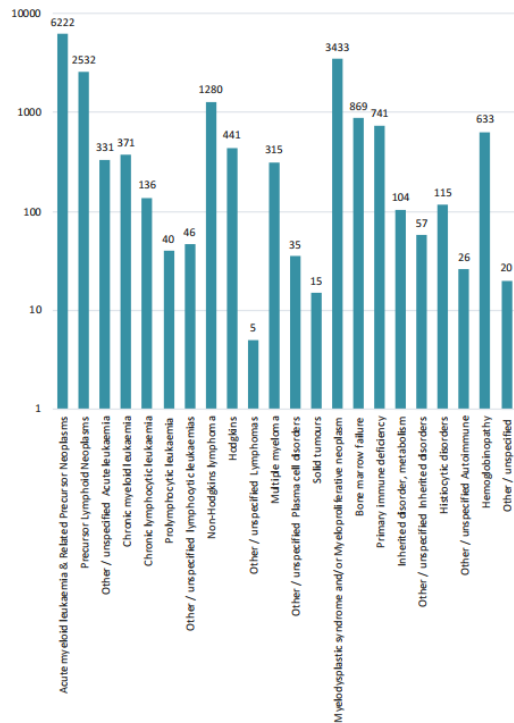


SCIENCE

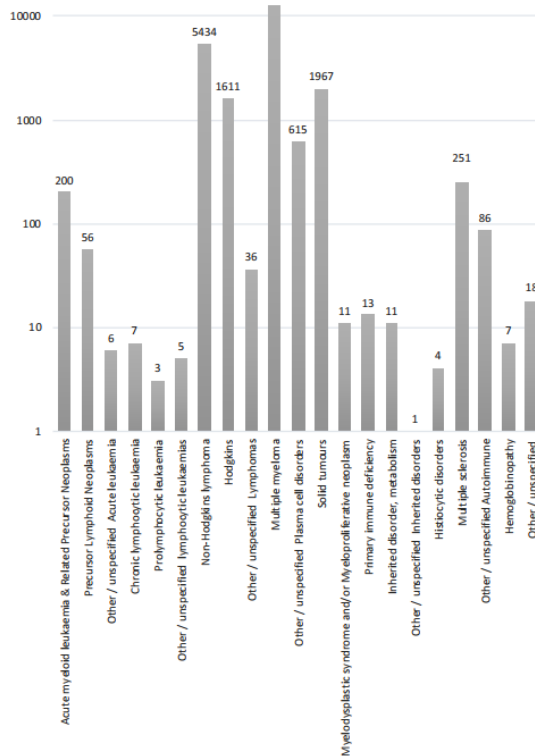


The EBMT Registry

Allografts



Autografts

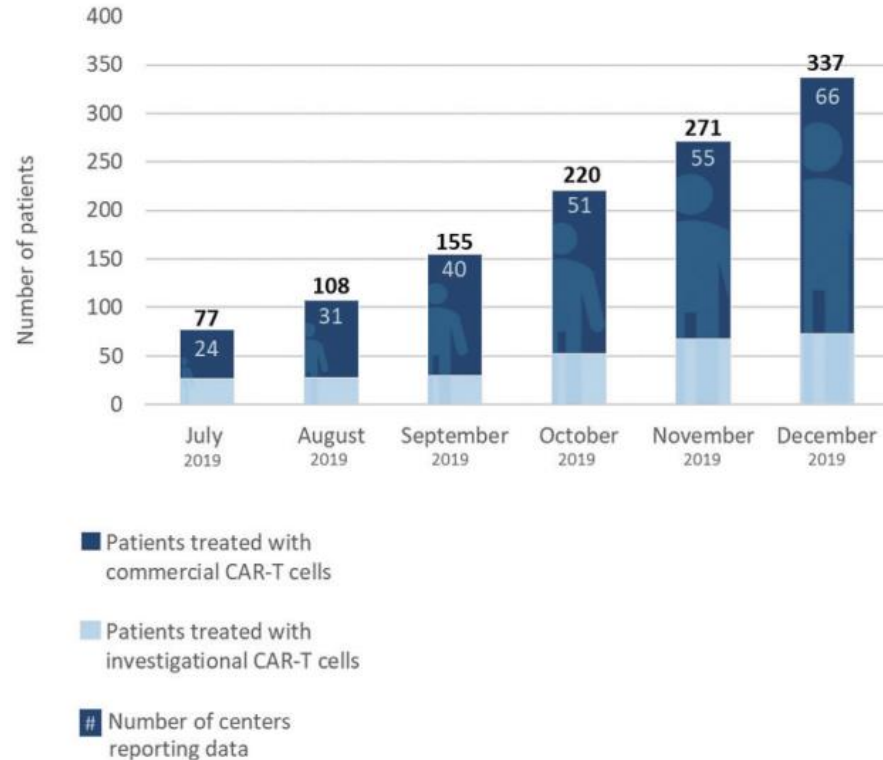


• By the end of 2019, the entire Registry included at least 709,000 transplant registrations in total.

• 17,767 allografts and 23,179 autografts were registered in 2019.

New registrations for cell therapy

Number of CAR-T cell treated patients registered in the EBMT Registry



The Registry has actively encouraged centres to report on all cases involved in the treatment of patients using a CAR-T product whether commercial or investigational.

This graph (left) illustrates the steady growth of new reported cases into the EBMT Registry during 2019 and the reflected number of centres.

All centres should continue to complete the current Cellular Therapy Form outlined in ProMISe on a timely basis to create an accurate patient representation.

New registrations for cell therapy

Countries reporting CAR-T cell treated patients
to the EBMT Registry

■ Reporting countries



Source: EBMT Registry, December 2019

The 2nd graph (left) represents a geographical approach in blue of all our reporting countries who are continually processing data into the EBMT Registry.

We look forward to welcoming more countries in 2020 as the number of CAR-T products on the market steadily increases.

EMA'S QUALIFICATION OPINION ON CELLULAR THERAPY MODULE OF EBMT REGISTRY

28th February 2019: EBMT Registry qualified as a suitable platform for the collection of data for post-authorisation safety study (PASS).



GOVERNANCE STRUCTURE CAR T COMMUNITY

In the context of the qualification opinion on the cellular therapy module of the EBMT registry and the growing clinical use of CAR-T cell and IEC therapies, the EBMT has set up a governance structure for the CAR-T Community (approved by the EBMT Board during the June 2019 Board Meeting in Hamburg).

The EBMT Legal and Regulatory Affairs Committee and the cellular Therapy and Immunobiology Working Party **engaged with different key stakeholders** such as national transplantation groups; clinical CAR-T centers; disease-oriented scientific societies; pharmaceutical companies; patient advocates; health technology assessment bodies; regulators - to present and discuss this structure.

The last **stakeholder meeting** took place during the 2nd European CAR T Cell Meeting to further discuss individual roles in the different work packages.

CELLULAR THERAPY MED-A FORM

The EBMT is in the process of finalising the Cellular Therapy Med-A Form which plans to be a **robust stand-alone document** reflecting on current standard of treatment across our Hospital community.

This important data collection form is to be the basis of all **PASS CAR-T Studies** and will eventually be implemented into our new MACRO Electronic Data Capture system replacing ProMISe.

Any patient data that has been registered using the current Cellular Therapy Med-A Form in ProMISe will be **migrated into MACRO** during our ongoing data migration process which is currently taking place at the London Registry Office as of Q4 2019.

As competent authorities require a 15-year follow-up of recipients the staff at all our centres including data managers and clinical departments will be instrumental in **collating all the necessary patient data** both at the time of treatment and subsequent follow-up visits.

Registry upgrade

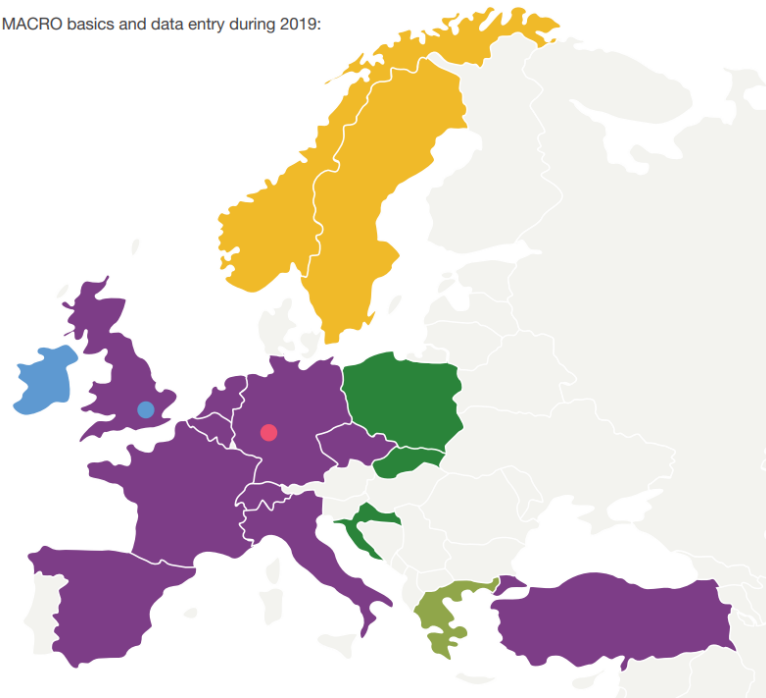
Substantial work has continued on this project during 2019 and in Q4 the production environment was made available allowing the **data transfer from ProMISe to MACRO** to begin. The full system validation is due to take place in 2020.

Since February 2019 the Registry has rolled out a **data entry training program** to EBMT staff and data managers in the National Registries and Centres.

Almost all affiliated national societies have been providing training to centres in their region and we are very grateful for their collaboration.

Around 600 users have been trained in MACRO basics and data entry during 2019:

- **EBMT registry:**
London, UK
- **EBMT Annual Meeting:**
Frankfurt, Germany
- **National society:**
Turkey
Spain
Belgium
UK
France
Czech Republic
Germany
Italy
Switzerland
The Netherlands
- **Medical University of Warsaw:**
Warsaw, Poland
- **Evangelismos Hospital:**
Athens, Greece
- **Karolinska Institute:**
Stockholm, Sweden



Registry resource

In 2019 the Registry has transitioned from the previous Head **Carmen Ruiz de Elvira** to **Debra Gordon** who joined EBMT Registry in November 2018. EBMT would like to thank Carmen for her exceptional contribution, dedication and commitment that she has shown to the organisation over the past 20 years and wishes her well in her future endeavours.

EBMT welcomes Debra as Head of Registry.

The Registry has also proceeded to **hire a new data manager** experienced in MACRO alongside the expansion of our IT department which now has greater technical expertise much needed for the challenges of MACRO and delivery of our upcoming Registry IT Projects.



Carmen Ruiz de Elvira



Debra Gordon

Collaboration with Novartis

Beginning of 2020, the EBMT announced a new collaboration with Novartis Pharmaceuticals to study the long-term outcomes of patients treated with CAR T therapies.

Under the terms of the collaboration, EBMT will collect treatment and long-term safety and efficacy data from patients treated with Kymriah® (tisagenlecleucel) in both approved indications in the EBMT registry for cellular therapy in the European regions.

Transplant Activity Survey

HEMATOPOIETIC CELL TRANSPLANTATION

In 2018, 701 centers reported 47,468 transplants in 42,901 patients (first transplant) from 50 countries to the annual activity survey.

CELLULAR THERAPIES

In the 2018, 1,325 patients in 28 countries received hematopoietic cellular therapies (excluding donor lymphocyte infusions).



The EBMT activity survey on hematopoietic-cell transplantation and cellular therapy 2018: CAR-T's come into focus

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Abstract

Hematopoietic-cell transplantation (HCT) is widely used for acquired and congenital disorders of the hematopoietic system. Number of transplants performed in Europe and associated countries continues to rise with 47,468 HCT in 42,901 patients [19,630 allogeneic (41%) and 27,838 autologous (59%)] reported by 701 centers in 50 countries in 2018. Main indications were myeloid malignancies 10,679 (25%; 97% allogeneic), lymphoid malignancies 27,318 (64%; 20% allogeneic), solid tumors 1625 (4%; 2.9% allogeneic), and nonmalignant disorders 3063 (7%; 81% allogeneic). This year's analysis focuses on cellular therapies with the marked growth in CAR T-cell therapies from 151 in 2017 to 301 patients reported in 2018. Other cellular therapy numbers show less significant changes. Important trends in HCT include a 49% increase in allogeneic HCT for chronic phase CML (although transplant numbers remain low) and a 24% increase in aplastic anemia. In autologous HCT, there is an ongoing increase in autoimmune diseases (by 19%), predominantly due to activity in multiple sclerosis. This annual report reflects current activity and highlights important trends, useful for health care planning.

Figure 1b:

ABSOLUTE NUMBERS OF PATIENTS RECEIVING OTHER NON CAR-T CELLULAR THERAPIES

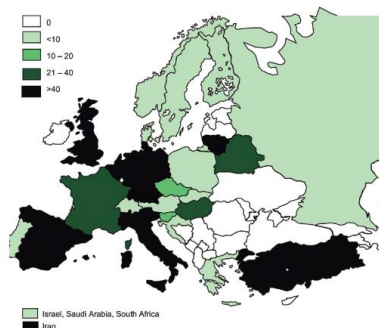
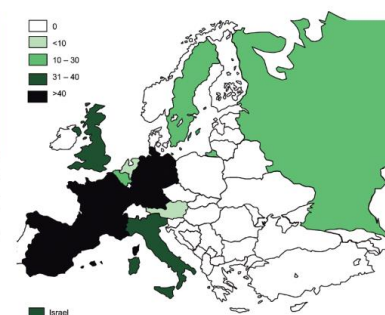


Figure 1a:

ABSOLUTE NUMBERS OF PATIENTS RECEIVING CAR-T CELLULAR THERAPIES





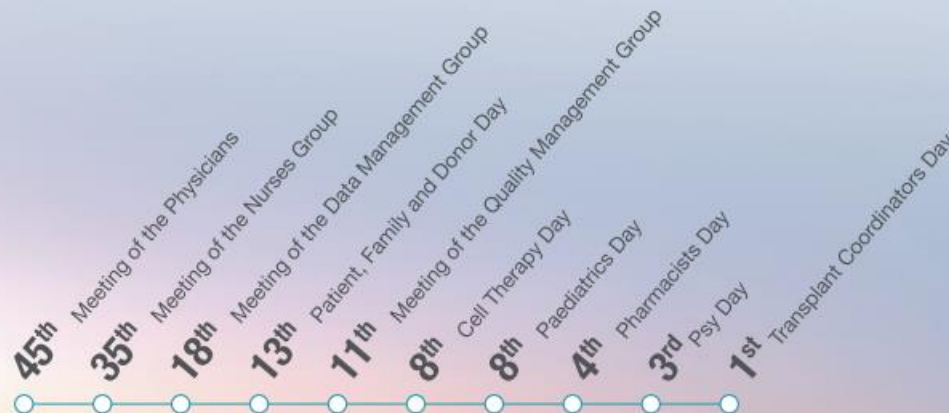
EDUCATION





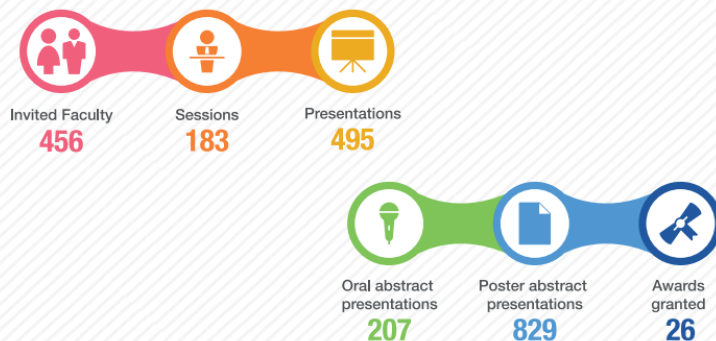
45th Annual Meeting
of the European Society for
Blood and Marrow Transplantation

24th–27th March 2019 · Frankfurt, Germany



More than 5,640
participants from 94
countries

1,068 submitted
abstracts

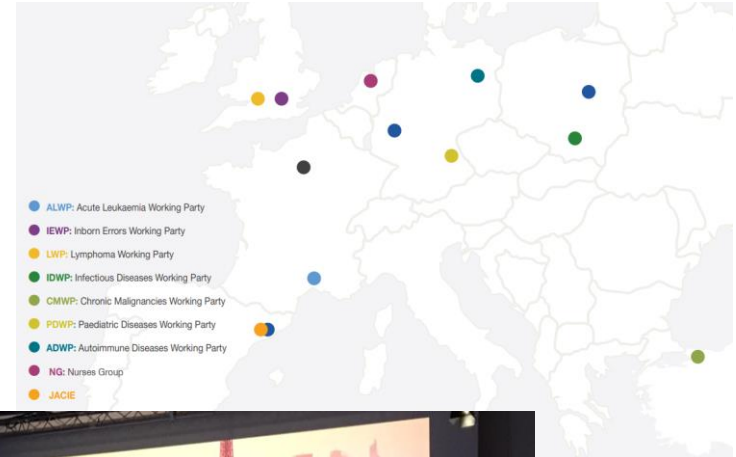


High educational productivity (1/2)

EDUCATIONAL EVENTS

14 cutting-edge educational events and courses in total organised by the Working Parties; Nurses Group and JACIE and attended by more than 2,100 participants in total.

- **1st European CAR T Cell Meeting** jointly organized by EBMT and EHA (14-16 Feb. 2019 in Paris – 680 attendees)
- **1st EBMT GVHD summit** (16-18 May 2019 in Warsaw – 234 attendees)
- **4th International Transplant Course** (6-8 September 2019 in Barcelona – 293 attendees)



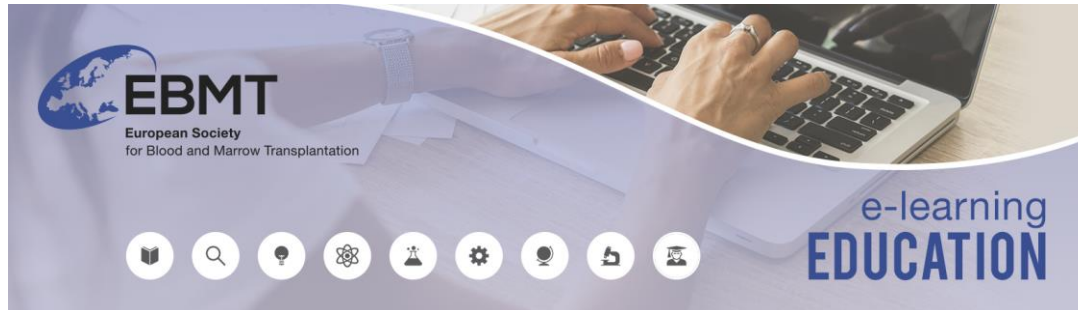
High educational productivity (2/2)

E-LEARNING PLATFORM

The process for developing an e-learning platform to further educate the EBMT community has started in 2018 and it will be launched during the EBMT 2020 Annual Meeting in Madrid.

The e-learning materials include:

Nurses e-course
Educational webinars
CAR-T cell e-course
JACIE Inspector course



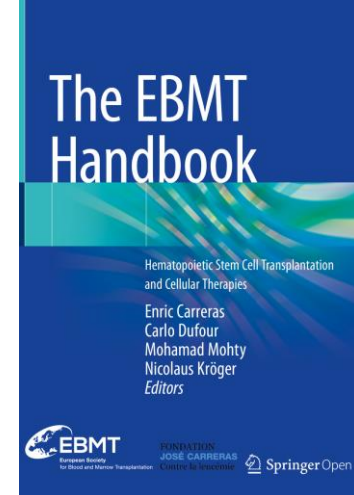
EBMT EXAM

The first edition of the EBMT Exam will be held on Sunday 30 August 2020 during the EBMT Annual Meeting.

The Exam has the aim to provide a personal qualification for physicians to assess their knowledge on the clinical aspects of Hematopoietic Stem Cell Transplantation and Cellular Therapies.

EBMT HANDBOOK

Release of the new EBMT Handbook in January 2019. The project started in 2017. The Handbook is composed of 93 chapters written by 175 leading experts in the field.





PATIENT CARE



EBMT Nurses Group (1/2)

PAEDIATRIC TRAINING DAYS

The Paediatricians and Paediatric Nurses held a training course in Regensburg on sickle cell disease on 16th and 17th May and this was a great success with nurses across Europe attending.

NURSES INTERNATIONAL STUDY DAY AND NURSES RESEARCH

2019 saw the 11th Nurses International Study Day and the 3rd Nurses Research Study hosted in Amsterdam. There was a wide spread of topics, with talks on chronic GvHD, endocrine dysfunction and care of the young adult, and thought-provoking programme.

JOINT EBMT EHA COLLABORATION

The joint EBMT EHA CAR-T Cell Meeting in Paris in January had a nurse's program which was well received and evaluated.

INTERNATIONAL TRAINING DAY

This is the first time that the Nurses Group has been invited along to the EBMT International Transplant Course. A well attended meeting held in Barcelona each October. The NG had a whole day and used it wisely to give presentations based on the JACIE competencies.

EBMT Nurses Group (2/2)

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.

GLOBAL EDUCATIONAL COMMITTEE

On the 1st and 2nd August the GEC visited Brasilia attending the LABMT annual meeting and giving 2 days of presentations. The GEC also visited Paraguay 2-3rd September and Argentina 30th October to 1st November and participated in the programs of education.

NURSING RESEARCH COMMITTEE

Publication in *Bone Marrow Transplantation* Polemeni et al.: “Haematopoietic cell transplant nurse coordinators’ perceptions of related donor care: a European survey from the EBMT Nurses Group.”

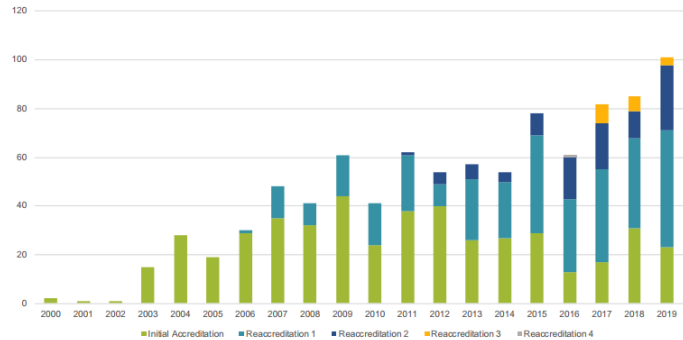
There are several projects currently recruiting or about to be launched by the EBMT nurses research group.



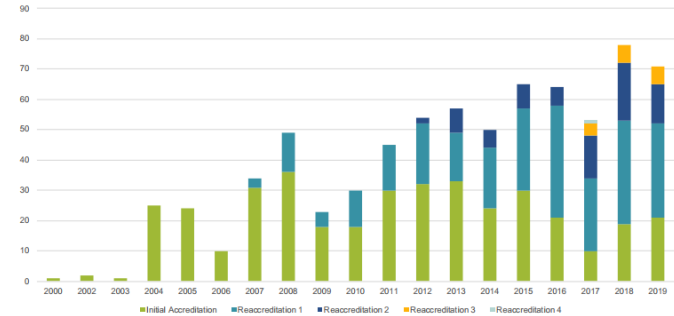
Highlights of the JACIE's activities



101 APPLICATIONS RECEIVED



71 INSPECTIONS PERFORMED

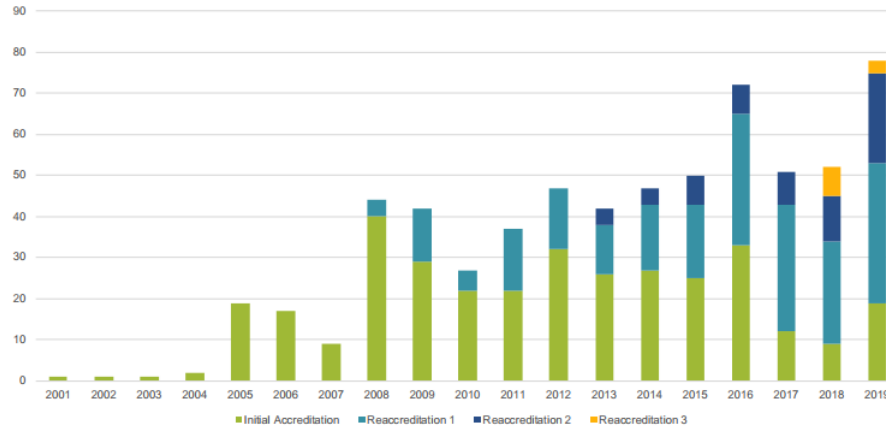


43 applications received in 2019 included Immune Effector Cells in the scope of the accreditation processes.

JACIE Accreditations

The full list of institutions awarded accreditation in 2019 is available at <https://www.ebmt.org/jacie-accredited-centres>

78 ACCREDITATION AWARDS



Educational events and Standards



EDUCATIONAL EVENTS

Two JACIE training courses were held during 2019, both in Barcelona with 38 participants in total from 17 countries while 6 other meetings and events were dedicated to or included accreditation. Furthermore, in September, a joint JACIE-FACT workshop was held at the WBMT/WHO meeting in Asunción, Paraguay.

8TH EDITION OF FACT-JACIE STANDARDS

The process to prepare the 8th edition of the FACT-JACIE Standards kicked-off in mid-2019. The sub-committees commenced their review during the last months of 2019 and will complete their work in early 2020. The first draft will be opened for public consultation in April 2020 during 3 months.

Other achievements

Restructuring the organigram

In 2019 we restructured the managerial infrastructure of the EBMT and organized it in **six departments**: (1) Science, (2) Registry, (3) Educational, (4) JACIE, (5) Support and (6) Business. Each department is led by a department head that together with the Executive Director form the EBMT management team.

Furthermore, we recruited a **Medical Officer** (Isabel Sánchez-Ortega) to support all medical aspects within the organization, a **HR Coordinator** (Áurea Villar) and **IT Coordinator** (Bernat Sifre) to better support our organization and mission.

Further implementation of the restructured organigram will continue in 2020 to strengthen the efficiency and mission goals of the EBMT.

Acknowledgments

Acknowledgments to the EBMT Scientific Council and President of the Nurses Group



Chair
Régis Pefaut de Latour

Severe Aplastic
Anaemia
Working Party
(SAAWP)



Chair
John Snowden

Autoimmune
Diseases
Working Party
(ADWP)



Chair
Mohamed Mohty

Acute
Leukaemia
Working Party
(ALWP)



Chair
Christian Chabannon

Cellular
Therapy and
Immunobiology
Working Party
(CTIWP)



Chair
Jan Styczynski

Infectious
Diseases
Working Party
(IDWP)



Chair
Arjan Lankester

Inborn
Errors
Working Party
(IEWP)



Chair
Silvia Montoto

Lymphoma
Working Party
(LWP)



Chair
Selim Corbacioglu

Paediatric
Diseases
Working Party
(PDWP)



Chair
Ibrahim Yakoub-Agha

Chronic
Malignancies
Working Party
(CMWP)



Chair
Grzegorz W. Basak

Transplant
Complications
Working Party
(TCWP)



John Murray
President of the Nurses
Group

Acknowledgments to the Executive Committee



Rafael Duarte
Secretary



Harry Dolstra
Treasurer



Andreu Gusi
Executive Director

Acknowledgments to the EBMT Staff Members



Acknowledgments to Rafael Duarte, EBMT 2020 Congress President and Anna Sureda, Scientific Chair



Postponement of the Annual Meeting 2020

Due to the Coronavirus COVID-19 outbreak, the EBMT had to postpone the 45th Annual Meeting in Madrid.

On 3 March 2020, the Spanish Minister of Health released an official statement suspending all congresses, conferences and seminars in Spain involving healthcare professionals. In accordance with this decision and the guidance provided by the health authorities, **EBMT has postponed its 46th Annual Meeting from 22 March to 25 March 2020 to 30 August to 2 September 2020**. The postponed conference will take place at the same venue, IFEMA, in Madrid, Spain.

EBMT would like to thank all of our members and supporters for their cooperation and understanding during this time. Despite this difficult situation, we appreciate your support and are working hard to ensure the postponed edition of the 46th Annual Meeting of EBMT is a success.



46th Annual
Meeting of the
European
Society
for Blood and
Marrow
Transplantation

30 August -
2 September 2020
Madrid, Spain



Thank you!