



Annual Report / 11

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The European Group for Blood and Marrow Transplantation (EBMT)

is a not-profit organisation that was established in 1974 in order to allow scientists and physicians involved in clinical bone marrow transplantation to share their experience and develop co-operative studies. The EBMT is devoted to the promotion of all aspects associated with the transplantation of haematopoietic stem cells from all donor sources and donor types including basic and clinical research, education, standardisation, quality control, and accreditation for transplant procedures.

The organisation is represented and led by the EBMT Board which consists of the following members: President, President-Elect, Secretary, Treasurer, Chairpersons of the Working Parties, the President of the EBMT Nurses Group and the President of the forthcoming annual EBMT meeting.

OUR MISSION

is to foster excellence in science in order to further improve the outcomes of Stem Cell Transplantation and inform all concerned parties including patients and their families, about the development in the field.

OUR VISION

Increase the level of science across the organization with a view to advancing clinical practice;

Improve the governance structure for effective and accountable implementation of the Mission;

Maximize the resources to potentiate the activities of the Society.

EBMT at a glance

4,042

members based in 545 transplant centres in 58 countries worldwide

3

Prospective Clinical Trials underway and 2 trials were closed to accrual in 2011

4,301

participants from 81 countries attended EBMT 2011

130

current retrospective studies

37

publications in peer-reviewed journals

30,685

transplants were registered in the EBMT Registry during 2011

2,340

copies of the ESH-EBMT handbook distributed in 2011

33,362

HSCTs submitted to the Activity Survey

12

educational events



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It is our pleasure to introduce this Annual Report and present our achievements for 2011. Looking back at the past year, we are pleased to report that the EBMT Strategic Plan 2011-2013 is on track and a number of important milestones were taken in the areas of science, education, governance and resources.

During this first year of our Strategic Plan, much attention has been devoted to the further improvement of the EBMT's corporate governance and accountability, aiming to promote effective decision making. A new framework for governance has been endorsed by the Board, leading to two distinct legal entities: the Association and the Foundation and another important decision was adopted concerning the separation, for legal and fiscal reasons, of the entities of the EBMT and JACIE. We also concentrated our efforts to consolidate the organisational structure and planning tools in order to take our decisions under better control, transparency and accountability.

In the area of science, the EBMT has been committed to the completion of Clinical Trials (CT) and the CT Office has been reinforced. In addition, an independent CT Committee has been constituted in order to support the Board and to guarantee scientific relevance, operational feasibility, statistical support and financial sustainability.

Another major strand of the Strategic Plan has been to upgrade the Registry System with state-of-the-art software designed to meet future data collection and retrieval needs. The project focuses on four general objectives to: increase the scope and quality of the data available for research; improve efficiency of data collection; provide a user-friendly tool and enhance collaborations. We have been gathering requirements for the Registry upgrade to create an alliance with partners interested in collaborating with us; significant emphasis will be placed on this activity during 2012.

Regarding our organisational structure, the Registry Unit has been centralised in the London office; the distribution of study coordinators among the Working Parties has been revised and the Leiden and Paris Data Offices now manage several Working Party studies.

An important educational activity was the first Three-Working-Party Educational Meeting, hosted in, and organised by, Barcelona, as a pilot project to demonstrate the linking of different scientific areas in one meeting and to encourage local initiatives. This was a great success and will be repeated in the future within other Working Parties.

We also focused our efforts upon improving our communication and information sharing with our Members and other stakeholders by updating our communication tools and launching a new website. From feedback received, we feel our primary aims of ensuring that the new website has ease of use and most importantly is informative about our activities, have been met.

Despite challenging economic conditions ahead, 2012 is going to be a key year in which to continue implementing our Strategic Plan and consolidating the activities that have been launched already.

To conclude, we would like to express our appreciation to the Board and the Board of Councillors for their valuable support, to the EBMT staff who continue to show great professionalism and patience in the face of many changes and challenges and of course, to all of you, whom as Members, have contributed so much to our Society.

Alejandro Madrigal
EBMT President



Highlights of 2012 Strategic Plan by the EBMT Executive Director

2011 was a year dedicated to preparing the organisation for the challenges of the new Strategic Plan, mentioned by the EBMT President in his letter. 2012 will be a key year to launch most of the strategic activities of our Plan and consolidate those already launched.

We will concentrate our efforts on the following issues:

SCIENCE:

1. Develop a scientific policy and identify groups of excellence.
2. Launch New Clinical Trials proposals.
3. Assess technical solution for the Registry upgrade and assure its funding.

GOVERNANCE:

4. Update the new Bylaws and Statutes.
5. Constitute the new governance Platforms including the Board of the Association and Scientific Board.
6. Establish JACIE as an independent organisation.
7. Reorganise the Data Offices in Paris and Leiden.
8. Consolidate the Educational and Events Unit in Barcelona.
9. Improve transparency and accountability mechanisms, increase control to decrease risk and improve efficiency with the final aim to have unqualified opinion from the Auditors.

RESOURCES:

10. Balance Financial Budget 2012.
11. Develop and implement the EBMT Communication Policy with the Communication Working Group and continue to update the main communication tools.
12. Develop a PR plan for the 40th EBMT Anniversary in Milan 2015.
13. Develop a Fundraising Working Group with the objectives to work on three items: strengthen our relationship with our Members, increase the participation of our Sponsors in our projects and investigate new fundraising strategies.
14. The JACIE Office to directly manage between 30 and 40 inspections per annum and between 30-35 initial applications and reaccreditation requests.

Andreu Gusi
EBMT Executive Director



1990-2010: An overview from the EBMT Transplant Activity Survey

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The EBMT Transplant Activity Survey data office in Basel has been collecting information on the numbers of transplants performed in European countries for 21 years. It has amassed data on almost 37,600 HSCT during that time. 135,179 allogeneic HSCT (33%) and 240,769 (64%) were reported. Main indications were leukaemia's (33%; 78% allogeneic), lymphoproliferative disorders (50%; 91% autologous), solid tumours (11%; 97% autologous), non malignant disorders (5%; 92% allogeneic) and others (1%). Donor type was 66% HLA identical sibling, 6% other family relative, < 1% twin and 37% unrelated. Important trends have been observed, such as the change in use of bone marrow stem cells to peripheral blood stem cells and cord blood, the increased use of unrelated donors now being more frequent than HLA identical sibling donors in recent years and the decline in treatment of choice for CML. For autologous HSCT the same change in stem cell source from bone marrow to peripheral blood can be seen but much earlier and faster than with allogeneic HSCT and the sharp rise and fall in the numbers of solid tumours being treated with a transplant. The total number of patients receiving a HSCT has increased from 4,200 to over 30,000 annually from 1990 to 2010. Of the 376,000 patients transplanted approximately 45% are long term survivors requiring follow up.

In the 2010 survey data a record 30,012 patients were submitted from 634 teams in 46 countries. Furthermore, there were 2,022 re-transplants (959 allogeneic/1,063 autologous) and 1,328 multiple transplants (110 allogeneic/1,218 autologous), bringing the total to 33,362 HSCT procedures, 13,345 allogeneic (40%) and 20,017 autologous (60%) performed in 2010.

The EBMT activity survey office contributes to the WBMT data collection and the data processing for this survey is currently done in the EBMT activity survey office. Over a two-year period; 2006-2008,

146,808 transplants (45% allogeneic and 55% autologous) were reported worldwide from 1,411 centres in 72 countries (www.WBMT.org). In addition we have started together with Termis-EU, EULAR, ISCT-EU and ICERS-EU a cellular therapy survey. Done annually since 2008, information was collected on the use of cells such as mesenchymal stromal cells to combat graft versus host disease or for other indications and the use of haematopoietic stem cells for other purposes than to regenerate haematopoiesis, in particular for projects in regenerative medicine. In the 2010 combined EBMT activity and cellular therapy survey, 1,270 procedures were reported; 766 autologous and 504 allogeneic. 59% of the allogeneic therapies were for GvHD treatment or prevention or HSC graft enhancement. The main indication for an autologous cellular therapy was cardiovascular (39%) or musculoskeletal (39%) disorders.

These surveys continue to provide invaluable information for health technology assessment, trends in indications and transplant technology and also show the strength of the EBMT community where open discussions and transparency have a long lived tradition. We will carry this spirit into the age of modern cellular therapy.

Helen Baldomero

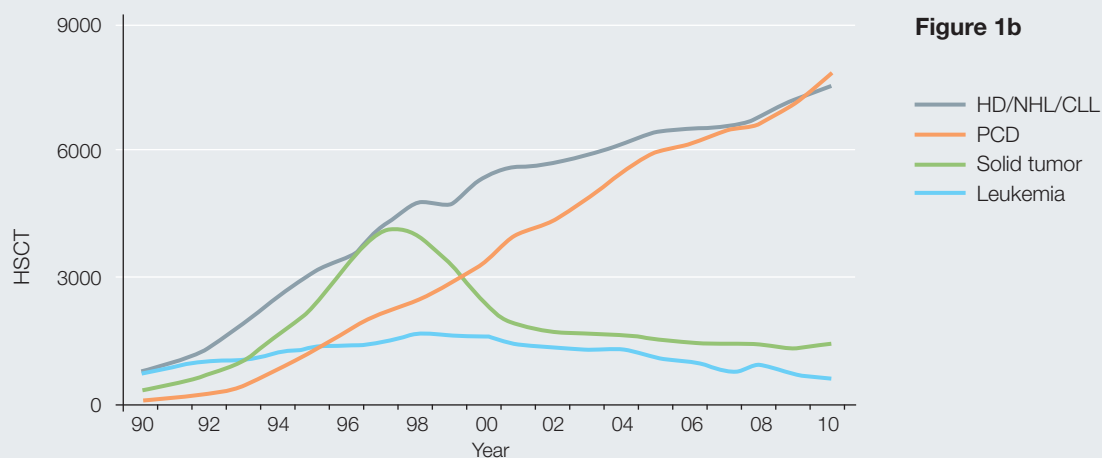
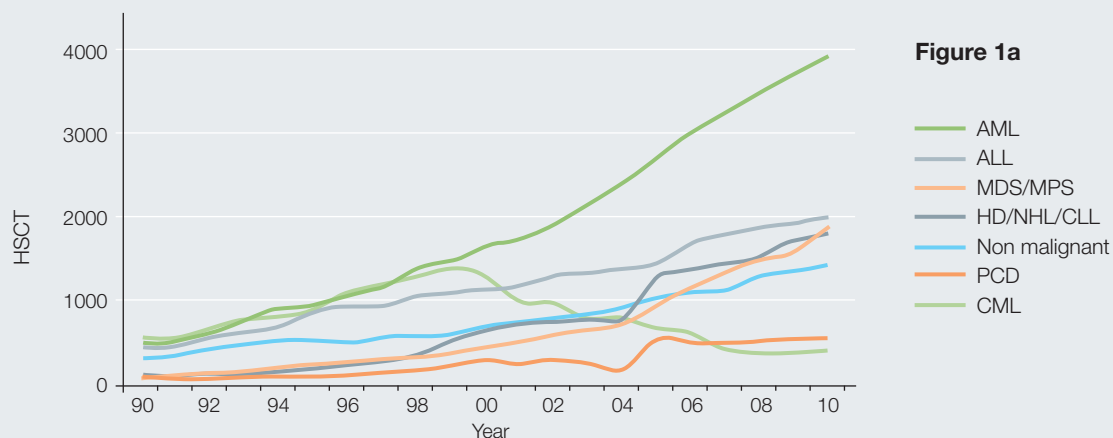
EBMT Activity Survey Data Office, Basel, Switzerland

Jakob Passweg

EBMT Activity Survey Data Office, Basel, Switzerland

	2010 Data							1990-2010 Data		
	HLA identical sibling	Other family	Twin	Unrelated	ALLO total	AUTO total	TOTAL	ALLO total	AUTO total	TOTAL
LEUKEMIAS	3,430	372	20	4,863	8,685	670	9,355	98,108	27,031	125,139
Acute Myeloid Leukemia	1,664	188	9	2,085	3,946	516	4,462	39,364	16,341	55,705
Acute Lymphoblastic Leukemia	818	105	2	1,082	2,007	86	2,093	24,792	5,605	30,397
Chronic Myeloid Leukemia	178	9	1	228	416	1	417	17,061	2,142	19,203
Myelodysplastic syndromes/ Myeloproliferative neoplasm	632	61	7	1,209	1,909	20	1,929	13,711	654	14,365
Chronic Lymphatic Leukemia	138	9	1	259	407	47	454	3,180	2,289	5,469
Lymphoid Neoplasias	828	90	13	1,046	1,977	15,385	17,362	17,625	171,674	189,299
Plasma Cell Disorders	250	10	8	298	566	7,835	8,401	5,676	75,618	81,294
Lymphomas	578	80	5	748	1,411	7,550	8,961	11,949	96,056	108,005
SOLID TUMORS	23	36	0	22	81	1,504	1,585	1,354	39,716	41,070
NON MALIGNANT DISORDERS	725	151	4	569	1,449	160	1,609	16,457	1,496	17,953
Bone Marrow Failure	357	36	4	279	676	1	677	7,338	15	7,353
Hemoglobinopathies	242	41	0	29	312	-	312	3,733	6	3,739
Primary Immune Deficiencies	99	58	0	174	331	9	340	3,000	44	3,044
Inherited Disorders	18	13	0	79	110	2	112	2,249	26	2,275
Auto Immune Disease	9	3	0	8	20	148	168	137	1,405	1,542
OTHERS	31	3	0	50	84	17	101	1,635	852	2,487
TOTAL	5,037	652	37	6,550	12,276	17,736	30,012	135,179	240,769	375,948

Table 1: Total cumulative number of patients transplanted in 2010 and during the period 1990-2010 for different indications



AML: Acute Myeloid Leukaemia, ALL: Acute Lymphoblastic Leukaemia MDS/MPS: Myelodysplastic syndromes/ Myeloproliferative Neoplasm, HD/NHL/CLL: Hodgkin's disease, Non Hodgkin's Lymphoma, Chronic Lymphatic Leukaemia, PCD: Plasma Cell Disorders, CML: Chronic Myeloid Leukaemia

Figure 1: Trends from 1990 to 2010 in allogeneic (fig1a) and autologous (Fig 1b) transplants separately for different disease categories



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Data overview

At time of writing, the database contains a total of 348,184 patients and 408,495 transplants. During 2011, 30,685 transplants were registered, 74% directly by the transplanting centres and the rest by a mixture of national registry and EBMT staff.

Registry centralisation

Centralisation of all Registry tasks in London was successfully achieved by the end of August 2011. The three data management staff in Paris were replaced with three data managers in London; this was accompanied by a small reorganisation in London leading to Shelley Hewerdine becoming the new Data Management Lead. This is the first time since the EBMT started collecting data that all tasks related to maintaining a central data repository are taking place under one roof. We believe this will result in increased efficiency and we are very pleased with the team we have put together.

Centralisation has come at the price of losing a very dedicated member of staff, Virginie Chesnel. Virginie had been with the EBMT since 1996 and had led the Data Office in Paris on behalf of the Registry for many years. The good news is that Virginie will be joining the EBMT data management groups as representative of SCETIDE, where she is currently employed.

Registry upgrade

During 2011, with the essential collaboration of Study coordinators from all Working Parties, the Registry wrote a fairly complete version of the requirements document. The Registry engaged in meetings with a series of stakeholders (national registries, donor registries,

Eurocord Registry), presented the preliminary project to the Advisory Board and EBMT Board and engaged in informal meetings with IT experts from WMDA, CIBMTR and NMDP to discuss general approaches.

The Board agreed to fund a project coordinator to support the Registry head in finalising the documentation and initialising the search for funding, as this has not been tackled until now.

Data Sharing

SCETIDE (Stem Cell Transplantation for Immuno-deficiencies)

In line with the Registry policy of facilitating data submission by transplant centres, the EBMT Registry is providing access to SCETIDE to see data of centres who want to submit their data also to this organisation. This is done under the auspices of the Inborn Errors Working Party.

Eurocord / AGNIS project

The Registry has continued its collaboration with Eurocord Registry and the CIBMTR, supporting the above project, which was initiated on the 1st January 2010. A new member of staff, supported by the CIBMTR, started to work in the Registry office in October. The aim is for electronic data exchange between Eurocord Registry and the EBMT on one side, and CIBMTR on the other. The Head of the EBMT Registry, M.C. Ruiz de Elvira is supervising the project from the EBMT perspective.

Anna Sureda
EBMT Secretary

Carmen Ruiz de Elvira
Head of the EBMT Registry



The scientific activity reports

Severe Aplastic Anaemia Working Party (SAAWP) - Chair: Judith Marsh

Introduction: The Severe Aplastic Anaemia Working Party (SAAWP) reports on AA and other rare acquired and inherited bone marrow failure disorders. The AA database is the only "disease specific" database within the EBMT as data are not only collected on patients receiving transplant but also other forms of therapy, including immunosuppressive therapy.

Major scientific achievements: The prospective clinical trial of rabbit ATG (Thymoglobulin) NCT00471848 was completed in 2011 and the manuscript is about to be submitted.

An oral presentation was given at the Annual 2011 American Society for Haematology (ASH) meeting: de Latour, Long-Term Outcome After Matched Allogeneic Hematopoietic Stem Cell Transplantation for Fanconi Anemia (Blood 2011; 118: 325) and three poster presentations.

The most relevant activities in 2011: The Joint Educational Meeting of SAA, Late Effect and Autoimmune Diseases WPs, 3-6th November 2011 held in Barcelona.

The complete treatment algorithm for SAA which was placed on the EBMT website last year has been accepted as an invited document to be published as a special issue of the journal Bone Marrow Transplantation.

Important objectives for 2012: to promote further international collaborations with, for example, Centre for Blood and Marrow Transplantation Research (CIBMTR); to organise a second joint education meeting of SAA, Late Effects and Autoimmune Diseases WPs for 2012; to explore the option of a new clinical trial of Eltrombopag in refractory aplastic anaemia.

Expenses: € 35,800

Sponsors: Genzyme Therapeutics

Number of educational activities: 1

Number of publications: 2

Number of studies: 19 retrospective studies (RS) in progress, and 1 clinical trials (CT)

Autoimmune Diseases Working Party (ADWP) - Chair: Dominique Farge Bancel

Introduction: During 2011, the EBMT ADWP members have developed their clinical and research collaborative programs and networks with European Autoimmune Diseases Specialists for treating scleroderma (SSc) and lupus (SLE) (EULAR), Inflammatory Bowel's diseases (ECCO), Multiple Sclerosis (MS) (ECTRIMS) and initiated a CIBMTR/EBMT retrospective study on MS Long Term Outcomes.

Major scientific achievements: Over 1300 HSCT in the largest data base so far worldwide. ASTIMS and ASTIS EBMT prospective trials completed early follow up and first publications are expected in 2012. The ASTIC trial completed recruitment of 46 patients. Update of the European Guidelines for HSCT in ADs.

The most relevant activities in 2011: 3 publications illustrating our educational and research activities in the field. A joint educational meeting with Late Effects and Aplastic Anaemia.

Important objectives for 2012: 2 EBMT non interventional studies for MS and SSc. Development of a prospective Phase III trial with America (MS). Complete the EBMT-CIBMTR retrospective study for collect data of the 5 new retrospective studies.

2 business meetings and 1 combined educational meeting with the IWP.

Expenses: € 30,400

Sponsors: EBMT, Paris VII University (FP7)

Number of educational activities: 2

Other relevant activities: 6 abstracts presentation (6); CIBMTR meeting (1), EBMT Paris 2011 (3), COSTEM (1), Eurocord-WCB (1), EBMT-ESH HSCT Handbook: HSCT for severe autoimmune diseases

Number of publications: 3

Number of studies: 2 NIS, 6 RS and 3 CT

Acute Leukaemia Working Party (ALWP) - Chair: Mohamad Mohty

Transplant activity for acute leukaemia continues to increase worldwide. In the ALWP registry, there are currently more than 80,000 transplant procedures reported for Acute myeloid leukaemia (AML) and Acute lymphoblastic leukaemia (ALL) (auto and allo-SCT).

The ALWP's objectives are: (a) to organise high-level accredited educational activities pertinent to acute leukaemia (latest symposiums: Nantes in 2008, Barcelona in 2009, Milan in 2010 and Warsaw in 2011); (b) to design and support prospective clinical trials in the field of acute leukaemia across member centres (the elderly AML randomised trial is currently recruiting patients: ClinicalTrials.gov, Identifier: NCT00766779; more than 80 patients registered thus far; a non-interventional study on the use of 5-Azacytidine will be launched in 2012); (c) to generate high-quality retrospective studies addressing different issues related to acute leukaemia management and therapy; (d) to increase the quality of data pertinent to Stem Cell Transplantation for acute leukaemia within the EBMT registry; and (e) to generate guidelines pertinent to the management of acute leukaemia.

Currently, the ALWP's activities are organised and structured within 6 subcommittees (SC) focused on specific fields of interest: Autologous SCT SC, Immunotherapy SC, Alternative donors SC, RIC SC, Molecular markers SC and the Developing centres SC.

Expenses: € 19,500

Sponsors: -

Number of educational activities: 1 in Warsaw and several educational lectures on behalf of the ALWP at different meetings.

Other relevant activities: 2 business meetings and 11 oral communications (EBMT 2011 and ASH 2011).

Number of publications: 8

Number of studies: 13 abstracts submitted to EBMT 2012; 6 studies submitted for publication in 2011 and 8 are being finalized prior to submission.

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Chronic Leukaemia Working Party (CLWP) - Chair: Theo de Witte

Introduction: The CLWP consists of five subcommittees, each of them chaired by a subcommittee chairman. The chairmen form the core of the CLWP together with the collaborators of the CLWP Data Office in Leiden, and the CLWP associated statisticians. The CLWP has a close cooperation with several Working Parties of the EBMT, several European LeukemiaNet Work Packages, and with the International Bone Marrow Transplant Registry (IBMTR). Through new initiatives with external funding for retrospective and prospective non-interventional studies resources became available to contract new highly qualified collaborators within the Leiden Data Office.

Major scientific achievements: The MMVAR trial on treatment of Multiple Myeloma (MM) patients relapsed after autoSCT, has been closed and the manuscript has been submitted and accepted for publication in JCO. The prospective Chronic Lymphocytic Leukemia (CLL) auto trial has been published in Blood. The non-interventional prospective study (NIS) on DMSO toxicity has been successfully completed, presented and analysed; the manuscript is in its final stage.

The most relevant activities in 2011: The CLWP is a pioneer within the EBMT on non-interventional prospective studies and developed a format which has been implemented in all WPs of the EBMT. The non-interventional prospective studies are an ideal platform to attract new unrestricted funding for the Registries within the EBMT. This will facilitate the collection of data with better and more precise specifications, more elaborate sampling frame and less missing values in the EBMT data base. Considering that 10 non-interventional studies have been running in 2011 and patient accruals are successful, proves that these studies are very interesting for the participating centers and from a scientific point of view. A variety of retrospective analyses have been performed resulting in 9 publications in transplantation related journals annually. Approximately 8 data requests have been developed and sent to the EBMT centres, resulting in 10-12 presentations at congresses.

Important objectives for 2012: The funded Quality of Life analysis of the CLL auto trial has been completed and is in manuscript phase: abstract to EBMT 2012. The final collection of follow up/missing data for the NMAM2000 trial has been completed, and submission of the second manuscript is expected in 2012. The DMSO toxicity NIS is in manuscript phase and publication is expected in 2012. The outcome of the GVHD prophylaxis and treatment survey has been accepted for publication in BMT. The NIS on second generation TKI in CML is expected to reach 270m patients by the end of the year. The NIS on T-PLL will be closed and a manuscript will be prepared as soon 50 allogeneic transplants are reached.

Preparations for a new Data Quality Initiative (mini-MED B for CLL) will be finished soon and the request will be sent out early 2012. It is expected that 5 or 6 studies may be done with this data. Funding has been raised.

The accrual of the RICMAC trial (N=102) has improved and will be continued during 2012, unless an interim statistical analysis will lead to the advice to stop accrual. The NIS on iron Toxicity is running well (N=144) and will reach its target (200 patients) in 2012.

Expenses: € 11,400

Sponsors: Johnson&Johnson, Pierre Fabre, Novartis, Astellas Poland, Genzyme

Number of educational activities: 8 (EBMT, ESH, EHA)

Other relevant activities: 12 abstract presentations, 8 poster presentation (EBMT, ASH)

Number of publications: 8

Number of studies: 10 ongoing, 3 in preparation, 1 closed NIS

20 ongoing, 7 in preparation, 15 in manuscript phase RS

6 ongoing, 3 in preparation, 6 closed CT

Immunobiology Working Party (IWP) - Chair: Andrea Velardi

Introduction: In 2011 the IWP strengthened its key role in translating basic science into clinical applications.

Major scientific achievements: The IWP held its own very well attended session and another in conjunction with the International Cell Therapy and Experimental Hematology Societies at the 2011 EBMT Annual Meeting in Paris. In addition, the IWP organised an entire day of scientific sessions during the World Cord Blood Congress III (Rome, 27-29 Oct. 2011).

The IWP Scientific Committee selected the winner of the Jon van Rood Award for excellence in transplantation immunology/immunogenetics. The award was presented during the IWP Session of the 2011 EBMT Annual Meeting in Paris.

The IWP collaborated with the International Histocompatibility Working Group (IHWG) in a large scale international investigation on the role of DPB1 matching in unrelated donor transplantation (Lancet Oncology, 2012, in press). Collaboration is continuing by providing the IHWG with open access to the EBMT database.

The most relevant activities in 2011: With the newly allocated Study Coordinator and Statistician, the IWP designed three new studies:

1. A retrospective study on the role of parent/child and haploidentical sibling immune interactions (IPA/NIMA vs NIPA/IMA mismatching in GvH and HvG directions) on clinical outcomes of haploidentical transplantation. Principle Investigator: JJ van Rood.
2. The identification of T cell-related and NK cell-related immunological biomarkers predicting clinical outcome after haploidentical transplantation. Principle Investigators: C Bonini, A Bondanza.
3. A non-interventional perspective study on the role of donor vs recipient NK cell alloreactivity in haploidentical transplantation. Principal Investigator: A Velardi. All three studies are being conducted in collaboration with the Acute Leukemia Working Party Alternative Donor Sub-committee, F Ciceri and the Paediatric Diseases Working Party, C. Peters. All are being started as of February 2012.

Important objectives for 2012: To complete the retrospective studies listed above; To finalise arrangements, design and set-up of the following studies:

1. A retrospective study on the synergism between minor (H-Y) and major (HLA-DP) histocompatibility antigens in unrelated donor transplantation (PIs: M Stern and E Spierings).
2. A non-interventional perspective study on the role of non-HLA genetics in susceptibility to invasive aspergillosis in allogeneic hematopoietic transplantation (PI: L. Romani).
3. A non-interventional perspective study on thymic output after allogeneic hematopoietic transplantation (PI: A Toubert).

Expenses: € 13,300

Sponsors: -

Number of educational activities: 2

Number of publications: -

Number of studies: 3 NIS, 3 RS

Infectious Diseases Working Party (IDWP) - Chair: Simone Cesaro

Introduction: The IDWP aims to improve the diagnosis and management of infectious complications in patients who underwent stem cell transplantation. This goal is achieved through retrospective and prospective studies, educational activities, and the development of guidelines. Since the foundation in 1992, IDWP contributed significantly to the clinical research in the field of pre-emptive therapy for cytomegalovirus, epidemiology of post-transplant pneumococcal infection, epidemiology of respiratory virus infection, pneumococcal vaccination, epidemiology and therapy of adenovirus and BK virus infections, prophylaxis and therapy of fungal infections. IDWP is also partner of ECIL initiatives contributing to elaborate the European guidelines for management of infectious complications in leukaemia and transplant patients, and of IDSA for guidelines on vaccinations.

IDWP members met twice a year to present and discuss the annual scientific activity. Since 1998, the fall meeting is accompanied by a 2-day training course where juniors and young haematologists from different European countries have a full-immersion on infectious complications after hematopoietic stem cell transplantation and can actively interact with speakers. The active participation is encouraged by sending teaching clinical cases.

Major scientific achievements: Overall, 3 full papers has been published in 2011.

The most relevant activities in 2011: The IDWP training course was held in Prague and in 2012 is scheduled in Wurzburg (Germany). IDWP or its representatives were invited as speakers during 2011 in educational meeting at ASBMT Tandem Meeting and ESCMID. Another important appointment for 2011 was the participation to ECIL 4 that dealt for the first time with important topics such as bacteria drug resistance, paediatric fungal infections, respiratory virus infections as well updating previous topics.

Important objectives for 2012: Several publications are due for 2012 such as the virological response to cidofovir in patient with BK-virus associated haemorrhagic cystitis, the analysis of a prospective survey on neurological complications, the impact of CMV serostatus of recipient/donor pair in the outcome of the transplant,

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and the results of a retrospective study on the use of rituximab for EBV-PTLD. The planned scientific activity for 2012 comprises 2 non-interventional studies, 8 retrospective studies, ongoing or to be started, and 1 prospective study.

Expenses: € 10,700

Sponsors: -

Number of educational activities: 7

Other relevant activities: Official Partner of ECIL 4 initiative and IDSA committee for vaccination guidelines in SCT patients

Number of publications: 3

Number of studies: 2 NIS, 8 RS

Inborn Errors Working Party (IEWP) - Chair: Bobby Gaspar

Introduction: The IEWP is dedicated to the improvement of outcome of transplantation for inborn errors of metabolism including severe congenital immunodeficiencies and metabolic diseases. We aim to do this through exchange of ideas and transplant data, international collaborative retrospective studies, development of transplant guidelines and education of transplant physicians worldwide.

Major scientific achievements: Numerous IEWP publications over the last 20 years have been essential for defining the indication for transplant in inborn errors and shaping the way transplants for these conditions are undertaken. The activities and publications of IEWP have become an essential source of information for transplant physicians dealing with these rare and difficult diseases.

The most relevant activities in 2011: Retrospective data on a number of conditions were published including outcome of XLP1 and a collaborative retrospective study on the outcome of transplantation for Wiskott Aldrich syndrome. The IEWP is also PI on a major EU FP7 grant 'CELL-PID' and will help promote the educational and training opportunities of the network. The IEWP also completed and made available its "Guidelines" document for transplantation of severe immunodeficiencies. This is now freely available on the EBMT website.

Important objectives for 2012: We will aim to produce further high impact retrospective studies (2 are already in the process of being published). We will also increase collaborative working with other consortia dedicated to improve transplant outcome for inborn errors, including the first IEWP education session at the Paediatric Diseases Working Party.

Expenses: € 16,700

Sponsors: Medacs, Pierre-Fabre, Orphan Europe

Number of educational activities: 1

Number of publications: 2

Number of studies: 7 RS ongoing

Lymphoma Working Party (LWP) - Chair: Peter Dreger

Introduction: The EBMT LWP takes care of scientific and educational activities related to transplantations for lymphoma, which represents the largest single entity in the EBMT with over 100,000 registered transplantations to date. The LWP runs 6 scientific subcommittees, i.e. Hodgkin's lymphoma (Chairperson M Trneny), Indolent lymphoma (S Montoto), T cell lymphoma (N Schmitz), Aggressive B cell lymphoma (H Schouten), Mantle cell lymphoma (Olivier Hermine), and Education (Anna Sureda).

Major scientific achievements: Several retrospective registry studies with significant scientific impact in the field of lymphoma treatment. From 2008 to 2011, the LWP has published 25 studies with a mean Impact Factor of > 10.

The most relevant activities in 2011: Comprise the conduction, completion, or preparation of 35 retrospective or prospective non-interventional studies (involving 26 Principal Investigators from 12 countries), the publication of 4 scientific papers, and the 7th Annual LWP Educational Course in Bordeaux, France. Finally, the launch of the "EBMT Follicular Lymphoma Transplant Consensus" coordinated by Silvia Montoto promises to become a major hallmark for the EBMT's reputation for setting transplant guidelines.

2011 began tragic because the LWP's Study Coordinator Jian-Jian Luan, who was considered as the "heart" of the LWP, had a fatal accident during an alpine hiking tour. This was not only a serious loss of a good friend, an extremely competent colleague, and a very sympathetic human being, but also a major drawback for all LWP study activities. We were lucky, however, to find a competent new Study Coordinator in the person of Hervé Finel who started on April 1 in the Paris office and has taken over rapidly all the professional skills a professional EBMT Study Coordinator needs to have.

Important objectives for 2012: In Jian-Jian's spirit, however, we hope that we can achieve most of the planned objectives: continue the numerous studies mentioned, attract and launch important new ones, publish most of the 11 scientific manuscripts planned for release in 2012, finalize the EBMT FL transplant consensus, and perform the 8th LWP Educational Course (October 18-19, Bucharest, Local Organizer A Tanase) even more successfully than before. Moreover, we are looking forward to the 1st presentation of the Jian-Jian Luan Award for Lymphoma Transplant research during the LWP session at the EBMT Annual Meeting in Geneva.

Expenses: € 37,400

Sponsors: Genzyme-Sanofi, Riemser

Number of educational activities: 1 (7th Annual LWP Educational Course in Bordeaux, France)

Other relevant activities: 4 Oral presentations at important meetings (Lugano 3, ASH 1)

Number of publications: 4

Number of studies: 32 RS, 3 NIS

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Paediatric Diseases Working Party (PDWP) - Chair: Christina Peters

Introduction: The PDWP is dedicated to support research and education to improve the availability, safety, and efficacy of haematopoietic stem cell transplantation and other cellular therapeutics for children and adolescents. We engage and promote active co-operation with all EBMT Working Parties treating children and adolescents in an effort to meet the total needs of the full spectrum of paediatric HSCT patients.

The most relevant activities in 2011: The third training course for paediatricians and paediatric nurses on HSCT in children and adolescents was an interactive educational EBMT course from 31st May to 3rd June 2011 in Genova. 80 physicians and 40 nurses participated. Participants presenting selected abstracts were awarded with grants covering registration and housing.

To update and harmonize treatment standards for children and adolescents with red cell disorders, the PDWP organised an expert workshop in Vienna from 22nd to 23rd September 2011. A consensus manuscript on indication, timing and HSCT procedures for patients with sickle cell disease and thalassaemia was elaborated and is prepared for publication.

From 15th to 16th December 2011 a specific JACIE-training for paediatric centres was held in Barcelona. The workshop was fully booked and will probably be repeated.

The collaboration with the European Medicines Evaluation Agency (EMA) and the implementation of a network for paediatric research at EMA (EnprEMA) was continued. PDWP became 1st category member of this network. Three business meetings were held in 2011 to discuss projects, strategies and work plans for the next working period.

Important objectives for 2012: Initiate the ALL SCTped study: prospective, randomized, open multicenter multinational study for allogeneic HSCT in children and adolescents with ALL;

PDWP Meeting in Prague (7th to 9th June 2012): Scientific course for physicians and nurses in cooperation with the IE WP;

Expert Workshop for congenital and acquired bone marrow failure syndromes: September 2012, Vienna;

Strategy meeting of the International SCT consortium (BBMT, COG, EBMT, IBMTR and others): September 2012.

Expenses: € 13,700

Sponsors: SIRP, St. Anna Cancer Research Institute, Amomed, Medac, Novartis, Sobi

Number of educational activities: 3

Number of publications: 3

Number of studies: 5 and 12 planned studies

Solid Tumours Working Party (STWP) - Chair: Marco Bregni

Introduction: Numbers of transplants for solid tumours are stable in the last 10 years. Most frequent indications for auto are tumours of young adults (relapsed germ cell tumors, Ewing's family tumors) and tumours that are not cured by conventional treatment (e.g., triple-negative breast cancer; advanced ovarian cancer). Indications for allograft in renal cancer are decreasing due to the introduction of molecularly targeted therapies; allograft in other adult solid tumours is developmental.

Major scientific achievements: In 2011, the two meta-analyses on the effects of autologous transplant in adjuvant and metastatic breast cancer (in cooperation with the MD Anderson Cancer Center) have been published in the Journal of Clinical Oncology, and have fueled the debate on major cancer journals on the benefit of autologous transplant in selected breast cancer subtypes (e.g., triple-negative tumors).

The most relevant activities in 2011: the cooperation with the international cooperative group on the prospective randomized Phase III study on autograft vs conventional dose therapy for relapsed/resistant germ cell tumors as a second line treatment (TIGER study) is continuing. A request to the CT2-EBMT for EBMT being the sponsor of the EU study has been forwarded. Funding for the Italian national part of the study has been approved. Educational activities have been: the 4th ATST meeting, and the joint STWP business meeting/3rd Meeting of the Haploidentical Transplant in Solid Tumor Group.

Important objectives for 2012: We will focus on cell therapy and immunotherapy of solid tumors: allograft should be considered a platform for further cell manipulations, provided that a non-toxic and feasible conditioning can be used; autograft should concentrate on lymphoablative protocols and reinfusion of T cells as autologous adoptive immunotherapy.

Expenses: € 20,500

Sponsors: Novartis, Fresenius, Kirin, Roche, Biorep, Coronado, Pierre Fabre supported the ATST Meeting

Number of educational activities: 2

Other relevant activities: 9 abstracts presentations to international meetings (ASCO 2011, EBMT 2011)

Number of publications: 5

Number of ongoing studies: 8 RS, 1 CT

Late Effects Working Party (LEWP) - Chair: André Tichelli

Introduction: The aim of the LEWP is to assess malignant and non-malignant late effects, general health status and quality of life in long-term survivors after HSCT, to provide guidelines for screening and prevention of late complications, and to coordinate education in the field of long term survivorship.

Major scientific achievements: A number of retrospective studies/papers have been achieved, and their manuscript submitted for publication. On invitation by the guest editor of Seminars of Hematology for a special number on late effects after allogeneic HSCT, a review on cardiovascular complications has been published on behalf of the LEWP.

Furthermore, there are two studies that are presently submitted for publications:

1. *Predictors of sperm recovery in males after allogeneic HSCT. A survey of the Late Effects Working Party of the EBMT*, from Alicia Rovó et al.
2. *Increase of suicidal and accidental deaths after Hematopoietic Stem Cell Transplantation: from the Late Effects Working Party of the EBMT*, from André Tichelli et al.

Three further manuscripts are soon ready for submission: a retrospective analysis on secondary tumors after HSCT, an update from the previous EULEP/EBMT study published in 1999; a study on the incidence and risk factors of chronic GVHD after unrelated cord blood transplant (Joint Study with EUROCORD), and a study on Current Practice in Growth Hormone Treatment in Children and Adolescents after HSCT (Joint Study with Paediatric WP).

The Most relevant activities in 2011: The greatest success of the LEWP in 2011 was certainly the Joint Educational Meeting organized together with two other WPs (SAA-WP; AID-WP). It was a kind of première, since



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the whole planning, organization and realization has been performed from the beginning together with the Education and events coordinator of the EBMT (Dan Wilde) and the EBMT Education Committee Chair (Tamás Masszi). According to the participant reports, it was a scientific success; economically, the event proved self-sufficiency. With this pilot approach, we proved that it is possible and advantageous to coordinate an educational meeting with the central EBMT Office. This support was of particular importance since these three WPs have low chance to get substantial support from companies (minimally drug driven WPs).

One other relevant activity and success for the LEWP and the whole EBMT is the update of the "*Recommendations on screening and prevention of late effects after HSCT*" worked out first together with CIBMTR and ASBMT (2006). For the updated Recommendations, other BMT societies of the whole world have been invited to participate. The manuscript is ready and has been submitted. It will be published at the same time in four Journals worldwide at least, including Bone Marrow Transplantation and Biology of Blood and Marrow Transplantation.

Important objectives for 2012: In 2012 the Joint Educational will be repeated but this time in Budapest. In March 2012 will be the elections for the new chairperson for the LEWP. The other future plans will greatly depend on the elected chairperson.

Expenses: € 16,400

Sponsors: Novartis Switzerland, the Hematology Department of the University Hospital of Basel.

Number of educational activities: 1 Joint Educational Meeting; Education session at the Annual Meeting; 2 Business Working Party Meetings.

Other relevant activities: Update of the Recommended Screening and Preventive Practices for long-term Survivors after Hematopoietic Cell Transplantation.

Number of publications: 1

Number of studies: 2 NIS; 14 RS



Publications 2011 in peer-reviewed journals

WP	Title	First Listed Author	Journal	PMID
EBMT Activity Survey Office	The EBMT activity survey 2009: trends over the past 5 years.	Baldomero H	Bone Marrow Transplant.	21358689
EBMT Nurses Group	Patient information in stem cell transplantation from the perspective of health care professionals: A survey from the Nurses Group of the European Group for Blood and Marrow Transplantation.	Kirsch M	Bone Marrow Transplant.	22139070
SAAWP	A randomized controlled study in patients with newly diagnosed severe aplastic anemia receiving antithymocyte globulin (ATG), cyclosporine, with or without G-CSF: a study of the SAA Working Party of the European Group for Blood and Marrow Transplantation.	Tichelli A	Blood	21233311
SAAWP	Rabbit ATG for aplastic anaemia treatment: a backward step?	Dufour C	Lancet	21737135
ADWP	Secondary autoimmune diseases occurring after HSCT for an autoimmune disease: a retrospective study of the EBMT Autoimmune Disease Working Party.	Daikeler T	Blood	21596847
ADWP	Autologous HSCT in systemic sclerosis: a step forward.	Farge D	Lancet	21777973
ADWP	Haematopoietic SCT in severe autoimmune diseases: updated guidelines of the European Group for Blood and Marrow Transplantation.	Snowden JA	Bone Marrow Transplant.	22002489
ALWP	Factors predicting outcome after unrelated donor stem cell transplantation in primary refractory acute myeloid leukaemia.	Craddock C	Leukemia	21339758
ALWP	Allogeneic hematopoietic stem cell transplantation for isolated and leukemic myeloid sarcoma in adults: a report from the Acute Leukemia Working Party of the European group for Blood and Marrow Transplantation.	Chevallier P	Haematologica	21685467
ALWP/ Eurocord	Effect of donor-recipient HLA matching at HLA A, B, C, and DRB1 on outcomes after umbilical-cord blood transplantation for leukaemia and myelodysplastic syndrome: a retrospective analysis.	Eapen M	Lancet Oncol.	21982422

WP	Title	First Listed Author	Journal	PMID
ALWP	Reduced-intensity conditioning allogeneic hematopoietic cell transplantation in adults with acute myeloid leukemia.	Hamadani M	Cancer Control.	21976242
ALWP	Impact Of FLT3 Internal Tandem Duplication (FLT3/LTD) On The Outcome Of Related And Unrelated Hematopoietic Transplantation For Adult Acute Myeloid Leukemia In First Remission.	Brunet S	Journal Of Clinical Oncology	In press
ALWP	Treatment, Risk Factors and Outcome of Adults with relapsed AML after Reduced Intensity Conditioning for Allogeneic SCT.	Schmid C	Blood	In press
ALWP	Outcomes and Prognostic Factors of Adults with Acute Lymphoblastic Leukemia who Relapse after Allogeneic Hematopoietic Cell Transplantation. An analysis on behalf of the Acute Leukemia Working Party of EBMT.	Spyridonidis A	Leukemia	In press
ALWP	Growth factor-associated graft-versus-host disease and mortality 10 years after allogeneic bone marrow transplantation.	Olle Ringdén	British J Haematol	In press
CLWP	Unrelated cord blood transplantation in adults with myelodysplasia or secondary acute myeloblastic leukemia: a survey on behalf of Eurocord and CLWP of EBMT.	Robin M.	Leukemia	20882048
CLWP	Autologous hematopoietic stem cell transplantation in chronic lymphocytic leukemia: results of European intergroup randomized trial comparing autografting versus observation.	Michallet M.	Blood	21106985
CLWP	Allogeneic stem cell transplantation for myelodysplastic syndromes with bone marrow fibrosis.	Kröger N.	Haematologica	20971823
CLWP	Tandem autologous/reduced-intensity conditioning allogeneic stem-cell transplantation versus autologous transplantation in myeloma: long-term follow-up.	Björkstrand B.	J Clin Oncol.	21730266
CLWP	Allogeneic stem cell transplantation for myelodysplastic syndromes: critical for cure?	de Witte T.	Clin Lymphoma Myeloma Leuk.	22035747
CLWP	Current status of hematopoietic cell transplantation in the treatment of systemic amyloid light-chain amyloidosis.	Schönland SO.	Bone Marrow Transplant.	21785469
CLWP	Allogeneic stem cell transplantation for patients harboring T315I BCR-ABL mutated leukemias.	Nicolini FE.	Blood	21926354
CLWP	The European LeukemiaNet: achievements and perspectives.	Hehlmann R.	Haematologica	21048032
IDWP	Outcome of pandemic H1N1 infections in hematopoietic stem cell transplant recipients.	Ljungman P	Haematologica	21546495
IDWP	Voriconazole as secondary antifungal prophylaxis in stem cell transplant recipients.	Cordonnier C	Haematologica	21282716
IDWP	Long-term follow-up of HCV-infected hematopoietic SCT patients and effects of antiviral therapy.	Ljungman P	Bone Marrow Transplant.	22158388
IEWP	Long-term outcome and lineage-specific chimerism in 194 patients with Wiskott-Aldrich syndrome treated by hematopoietic cell transplantation in the period 1980-2009: an international collaborative study.	Moratto D	Blood	21659547
IEWP	X-linked lymphoproliferative disease due to SAP/SH2D1A deficiency: a multicenter study on the manifestations, management and outcome of the disease.	Booth C	Blood	20926771
LWP	High-Dose Therapy and Autologous Stem Cell Transplantation in First Relapse for Diffuse Large B Cell Lymphoma in the Rituximab Era: An Analysis Based on Data from the European Blood and Marrow Transplantation Registry.	Mounier N	Biol Blood Marrow Transplant.	22005647

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WP	Title	First Listed Author	Journal	PMID
LWP	Autologous stem-cell transplantation in patients with mantle cell lymphoma beyond 65 years of age: a study from the European Group for Blood and Marrow Transplantation (EBMT).	Jantunen E	Ann Oncol.	21467125
LWP	The role of in vivo T-cell depletion on reduced-intensity conditioning allogeneic stem cell transplantation from HLA-identical siblings in patients with follicular lymphoma.	Delgado J	Leukemia	21183951
LWP	Allogeneic stem-cell transplantation as salvage therapy for patients with diffuse large B-cell non-Hodgkin's lymphoma relapsing after an autologous stem-cell transplantation: an analysis of the European Group for Blood and Marrow Transplantation Registry.	van Kampen RJ	J Clin Oncol.	21321299
PDWP	Risk of complications during hematopoietic stem cell collection in pediatric sibling donors: a prospective EBMT-PDWP study.	Styczynski J	Blood	22160619
PDWP	Treosulfan-based preparative regimens for allo-HSCT in childhood hematological malignancies: a retrospective study on behalf of the EBMT pediatric diseases working party.	Wachowiak J	Bone Marrow Transplant.	21297673
PDWP/ADWP	Haematopoietic Stem Cell Transplantation (HSCT) in severe autoimmune diseases: Updated Guidelines of the European Group for Blood and Marrow Transplantation (EBMT)	Snowden JA	Bone Marrow Transplant.	22002489
STWP	No improvement of survival with reduced-versus high-intensity conditioning for allogeneic stem cell transplants in Ewing tumor patients.	Thiel U	Ann Oncol.	21245159
STWP	High-dose chemotherapy with autologous stem-cell support as adjuvant therapy in breast cancer: overview of 15 randomized trials.	Berry DA	J Clin Oncol.	21768471
STWP	High-dose chemotherapy with autologous hematopoietic stem-cell transplantation in metastatic breast cancer: overview of six randomized trials.	Berry DA	J Clin Oncol.	21768454
STWP	Allogeneic stem cell transplantation for renal cell carcinoma.	Bregni M	Expert Rev Anticancer Ther.	21707287
STWP	Is adoptive T-cell therapy for solid tumors coming of age?	Pedrazzoli P	Bone Marrow Transplant.	21804611
LEWP	Cardiovascular complications in long-term survivors after allogeneic hematopoietic stem cell transplantation.	Rovó A	Semin Hematol.	22221782



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The EBMT maintains its commitment to perform high quality large academic prospective clinical trials, in order to improve patient care. To this end, during 2011, 2 new members of staff were appointed in the EBMT Clinical Trials Office (CTO) in London (Liz Clark, Clinical Trials Operations Manager and Benjamin Pelle, Clinical Trials Coordinator). The CTO has now almost completed the reorganisation and process improvement exercise, which was started in 2010. The CTO team has been working hard to develop new SOPs and to increase the competencies of staff members. This means that we are now ready to initiate new prospective clinical trials selected by the redesigned clinical trials committee (CT2-EBMT).

The Clinical Trials Office is ready to begin exciting new projects, despite the ongoing challenges to academic prospective clinical trials and low investment. External investment remains low because many of the potential therapeutic innovations that we investigate do not necessarily attract the pharmaceutical industry. This will continue to be a major challenge for us particularly in the current economic climate. For this reason, the CTO will strive to implement further efficiency savings and attempt to generate more external funding.

At the end of 2011, there were 3 prospective clinical trials underway and 2 trials were closed to accrual in 2011 (Dasatinib and Convince). There are 3 trials under analysis which should be published in 2012. Of particular highlight is the MMVAR trial, which will be published in the first half of 2012. The CTO made 2 publications in 2011 reporting the CLL and Flagship AA trials (Michallet M et al, Blood 2011; 117: 1516-21 and Tichelli A et al, Blood 2011; 117: 4434-41) and several oral and poster presentations at EBMT and ASH.

Trials open to recruitment

- **ASTIC** (Autologous Stem Cell Transplantation for Crohn's Disease)
- **RICMAC** (Dose-reduced Versus Standard Conditioning Followed by Allogeneic Stem Cell Transplantation in Patients with MDS (Myelodysplastic syndromes) or secondary AML. A randomized Phase III study)
- **HCT vs. CT elderly AML** (A Randomized Phase III study comparing conventional chemotherapy to low dose total body irradiation-based conditioning and hematopoietic cell transplantation from related and unrelated donors as consolidation therapy for older Patients with AML in first Complete Remission.)

Trials under analysis

- **MMVAR** (A Randomized controlled study of Velcade (Bortezomib) plus Thalidomide plus Dexamethasone compared to Thalidomide plus Dexamethasone for the treatment of myeloma patients progressing or relapsing after autologous transplantation (MMVAR))
- **RATGAA07** (Prospective Phase II Pilot study of Rabbit Antithymocyte globulin (ATG, Thymoglobuline®, Genzyme) with ciclosporin for Patients with Acquired Aplastic Anaemia and comparison with matched historical patients treated with horse ATG and ciclosporin.)
- **ASTIS** (High dose immunoablation and autologous haematopoietic stem cell transplantation versus monthly intravenous pulse therapy cyclophosphamide for the treatment of patients with severe systemic sclerosis.)

In October 2011 the new CT2-EBMT committee was opened (Chair: Prof Hermann Einsele) and six new



prospective clinical trial proposals were reviewed. It is expected that 2 or 3 of these trials will be sponsored by the EBMT in 2012, subject to adequate funding being achieved.

In summary, prospective clinical trials continue to be very important to the EBMT. However, they also continue to be highly challenging owing to the regulatory environment and current economic constraints. It is hoped that the CTO will be successful with the new prospective clinical trials that will be initiated in 2012 and that there will be improvements in and harmonisation of the requirements for academic clinical trials. In the meantime, the CTO will continue to implement efficiencies and to increase investment in our clinical trials. This should ensure our financial sustainability. 2012 is set to be an exciting year for the Clinical Trials Office.

Liz Clark
Clinical Trials Operations
Manager

Hermann Einsele
CT2-EBMT
Committee Chair



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EBMT ED is the educational arm of the EBMT. It works in conjunction with entities both within and without the organisation to offer members a range of educational opportunities. During 2011 the educational events listed in the table below were staged by, or received direct input from, the EBMT and its Working Parties and Nurses Group.

2011 also saw EBMT ED implement the first year of its three year strategic plan for the period 2011-13. The activities carried out sought to bring further cohesion across the range of EBMT educational initiatives and to increase interaction between the various actors involved.

A key event with regard to increasing cohesion was the educational meeting staged in Barcelona in November by three EBMT Working Parties and staff based in the EBMT Executive Office - the first collaboration of its

type. The event proved an important testing ground for communications channels, financial procedures and the ability of the organisation to successfully host medium-size events with limited outside assistance.

As concerns external actors, links with partner organisation ESH were further consolidated with the signing of a new agreement governing organisation of the 2011, 2012 and 2013 editions of the BMT Annual Training Course held jointly by the two entities. Preparation and editing of the latest edition of the acclaimed EBMT-ESH HSCT Handbook also advanced smoothly during 2011. The 6th edition will be published in time to be distributed to members at the EBMT Annual Congress 2012.

Tamàs Masszi
EBMT Education Committee Chair

Date	Event	Venue
31 Mar -1 Apr	4 th ATST Meeting: Autologous and Allogeneic Cell Therapy in Solid Tumors	Venice, Italy
8-11 May	15 th EBMT-ESH Annual Training Course	La Baule, France
31 May - 3 Jun	3 rd ESH-EBMT Training Course for Paediatricians and Paediatric Nurses on HSCT in Children and Adolescents	Genoa, Italy
22 Sep	EBMT Paediatric Diseases Working Party Red Cell Disorder Workshop	Baden, Austria
6-8 Oct	EBMT Inborn Errors Working Party Conference	Belgrade, Serbia
7-8 Oct	EBMT Chronic Leukemia Working Party Educational Meeting	Dresden, Germany
14-15 Oct	7 th EBMT Lymphoma Working Party Educational Course	Bordeaux, France
27-29 Oct	World Cord Blood Congress III	Rome, Italy
3-6 Nov	Joint Educational Meeting of the EBMT Severe Aplastic Anaemia, Late Effects and Autoimmune Diseases Working Parties	Barcelona, Spain
5 Nov	EBMT Nurses Group Haematological Study Day in cooperation with the Swiss EBMT National Nurses Group	Zürich, Switzerland
10-11 Nov	EBMT Solid Tumours Working Party Educational Meeting in conjunction with the Haploidentical Transplant in Pediatric Solid Tumors Group	Brescia, Italy
18-19 Nov	EBMT Acute Leukemia Working Party Business Meeting and Symposium on "HSCT for Adult Acute Lymphoblastic Leukemia. Current Practice and Future Perspectives"	Warsaw, Poland



Standards and Accreditation - improve quality and safety in cellular therapy

Since 2000, the Joint Accreditation Committee-ISCT & EBMT (JACIE), has received over 250 applications from centres in Europe and beyond and 229 inspections have been performed. Over 160 have achieved accreditation at least once with practically all centres requesting reaccreditation after the expiry of their initial accreditation. This achievement is all the more remarkable for being based on a voluntary programme delivered in the context of diverse regulations, languages and resources.

In 2011, 55 applications were received (32 first-time and 23 reaccreditation) and 43 inspections were performed. 37 accreditations (22 first-time and 15 reaccreditation) were awarded.

JACIE is now a regulatory requirement in 4 countries and is cited in various guidelines. More information is available at www.jacie.org/about/national-regulations.

The preparation of the 5th edition of the Standards continued with equal participation by representatives of both FACT and JACIE. A public consultation was opened from April to July 2011 and a final draft was approved by the respective Boards in December. The final release of the 5th edition is scheduled for 1 March 2012.

4 training courses for centres and inspectors were run on the initiative of national societies, groups or individuals with JACIE support or directly by JACIE. One Internal Audit training course was held in 2011 in collaboration with the Kerteza training company.

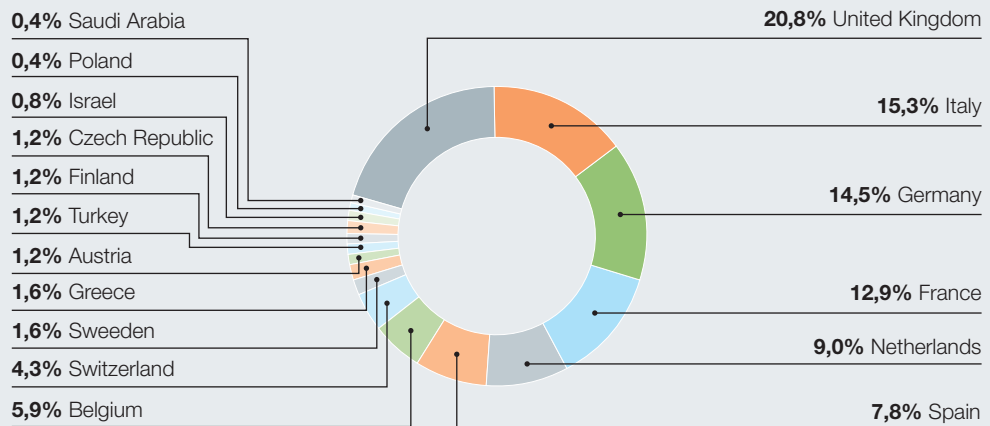
In terms of structure and organization, in October 2011, following a long period of assessment and discussion, the EBMT Board voted to separate JACIE from the EBMT for legal and fiscal reasons. The result will be an independent JACIE entity, probably established in Spain over the course of 2012.

In the JACIE team, Catherine Foggo departed on maternity leave in May and Antoni Aules was recruited to provide cover on a part-time basis. Catherine has since extended her leave up to June 2012 and Antoni's contract has been extended until then.

To conclude, I would like to express my appreciation and admiration for the inspectors, Board members and other volunteers for their amazing hard work, commitment and dedication.

Eoin McGrath
JACIE Executive Officer

% distribution of total initial applications by country



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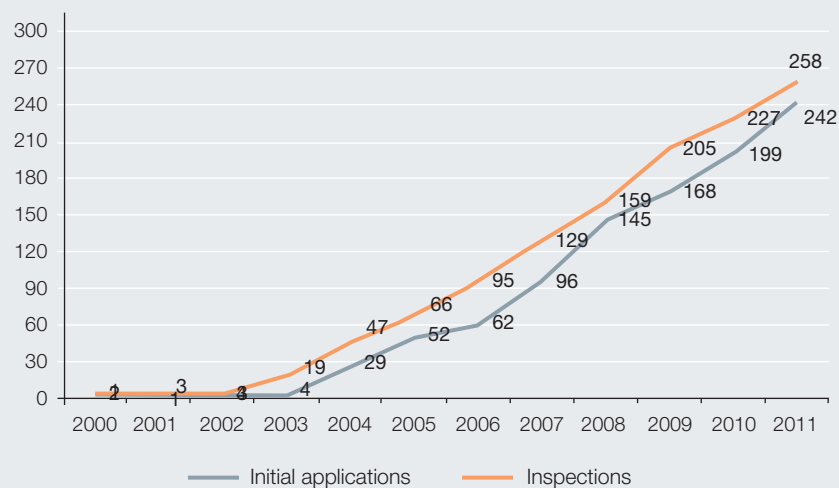
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Cumulative initial applications & all inspections



About JACIE

The Joint Accreditation Committee-ISCT (Europe) & EBMT was established in 1998 with the primary aim of promoting high quality patient care and laboratory performance in the collection, processing and administration of cellular therapy through voluntary accreditation based on standards developed by professionals working in the field. Accreditation is awarded following successful completion of a rigorous process including on-site inspection. JACIE in collaboration with the US-based Foundation for the Accreditation of Cel-

lular Therapy (FACT) develops standards for the provision of quality medical and laboratory practice in HSC transplantation. Accreditation in general is increasingly being used by regulators and other organisations as an independent, impartial, and transparent means of assessing the competence of healthcare providers and this also holds true for JACIE with regulators in a number of European countries including JACIE among the requirements for transplant programmes.



EBMT Nurses Group - improving patient care in Haematology and HSCT

The 27th Meeting of the Nurses Group

Nurses and other health care professional submitted 163 abstracts from 36 countries for the Annual Meeting. There were 652 participants from 40 countries, 13 of which were non-European countries. The EBMT-NG also participated in the 5th Patient and Family Day which was attended by 197 participants. The Nurses Group Board awarded its Distinguished Merit Award for the third time and this year's recipient was Peter van der Graaf (Netherlands) who has been active within the EBMT-NG since 1986.

Scientific Committee

Each year, the Scientific Committee plans and coordinates the Nurses programme, including the 7th Pre-Meeting Study Day which had 168 participants from 19 countries, and is one of the most important annual educational initiatives.

Research Committee

In 2011 the activities of the Research Committee have been focused on several studies including Late effects together with LEWP committee, Adherence and ITP. In December 2011 the Committee published:

Kirsch M., Crombez P., Calza S., Eeltink C., & Johansson E. Patient information in stem cell transplantation from the perspective of health care professionals: A survey from the Nurses Group of the European Group for Blood and Marrow Transplantation. Bone Marrow Transplantation, 47, 1-3.

The Research Committee is in the process of finalising an article regarding Adherence.

Communication and Networking Committee (CNC)

The CNC participated in the development of the new EBMT website and has been working on the continuous production and edition of the nursing content. The CNC has also been responsible for the content of the Nurses Group News that is part of the EBMT Newsletter.

Paediatric Committee

The Paediatric Committee has developed an active collaboration with the Paediatric Diseases Working Party (PDWP) and are also involved in the Scientific Committee. The third ESH-EBMT training course for paediatricians and paediatric nurses on HSCT for children and adolescents was held in Genoa, Italy. The course was addressed specifically to postgraduate/resident level young physicians and paediatric nurses.

The 3rd Meeting of the EBMT Paediatric Nurses together with the 8th Meeting of the EBMT Paediatric Diseases WP (PDWP) and Inborn Errors WP will be held in Prague, Czech Republic, 7-10 June 2012. Paediatric Committee members are developing an interesting program in accordance with PDWP program.

National Groups and Regional Forums

The Nurses Group works intensively with 9 National Groups and 3 Regional Forums - France being the latest country to join the National Group and the Eastern Mediterranean Blood and Marrow Transplantation group (EMBMT) as a Regional Forum - on several projects on a regional, national and international scale. The expansion into different countries is one of the



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goals of the EBMT NG Board. There is an annual meeting with National Group Chairs held in Zurich to discuss the future of the national groups and the EBMT website.

On the 5th of November 2011, the first Study Day for Nurses and other allied health care professionals took place at the University Hospital Zürich, Switzerland. This event was organised by the EBMT Swiss Nurses Group & the EBMT Nurses Group. The study day attracted 180 participants, the majority of which were from Switzerland, but there were also attendees from 16 other European countries. This event will be repeated in collaboration with the other National Groups.

Educational Initiatives

An important goal identified by the EBMT-NG Board is to expand and optimise existing educational projects making them accessible to all SCT and haematology nurses across Europe. With this in mind the EBMT NG has worked on and implemented several educational projects including translation regarding ITP, CML, Adherence and Compliance in CLL and Bone Health in MM. Furthermore the Board took the initiative to get more involved in the Educational Committee to work on combined education and contributed as authors in the chapter Supportive Care to the EBMT Handbook in 2011.

There will be a general reorganisation of the EBMT including the Nurses Group and these changes will be implemented in the coming year. The EBMT Nurses Group will keep on investing in research and education. Improving the care for the patients is our primary objectives for 2012. Moreover, we want to develop

contacts with other Working Parties and Committees but also with individual nurse members.

Arno Mank

EBMT Nurses Group President

About the EBMT Nurses Group

The EBMT Nurses Group (NG) is one of the leading groups in the field of Haematology and Haematological Stem Cell Transplantation (HSCT) nursing. It represents nurses and allied health professionals from over 500 transplant centres from over 50 countries worldwide.

The group is dedicated to improving the care of patients receiving HSCT and works towards promoting excellence in the provision of blood and marrow transplant and haematological care by supporting nurses and health care professionals in the provision of evidence based practice. By recognising and building upon good practice, the group provides information and forums to support and share knowledge in research, education and training and clinical practice.



Information and communication

One of the main developments in 2011 was the launch, in October, of the new EBMT website which aims to offer a more attractive and dynamic platform to keep up to date with EBMT and its activities. We are continually interested in feedback on the site and ideas for content improvements.

In March 2011, the Nurses Group and the main EBMT Newsletters were merged. This way we have a single tri-annual EBMT e-newsletter, available electronically, containing news and information for physicians, nurses, data managers, quality managers and corporate sponsors. A special congress edition was also produced highlighting the success of the EBMT 2011 congress in Paris.

Moreover, a new EBMT-JACIE 100m2 stand was designed and unveiled during the EBMT Annual Meeting in Paris. Visitors could easily walk around the floor space, where they could consult presentations on education, activity survey, JACIE accreditation, clinical trials and the registry through plasma screens and additional computers. People could also hold meetings and of course exchange with the EBMT and JACIE staff. All personal investigators were welcomed to renew the Chairs of the Inborn Errors, Immunobiology, and Paediatric Diseases Working Parties and to elect the new treasurer.

A press conference entitled "fostering advances in haematology and bone marrow transplantation" was held during the congress. French and international journalists had the opportunity to hear KOLs presentations and to listen to the moving testimonial of a patient who suffered from acute B lymphoblastic leukaemia, and his sister who testified as a donor.

The Industry Meeting, a one-hour meeting between the Board and the Pharmaceutical Industry was organised during the Annual Meeting in Paris, with a specific



The new EBMT Website: www.ebmt.org

focus on the presentation of the 3-year Strategic Plan; the state of the art in stem cell therapy and EBMT in that field; and the trends in HSCT, a report from the Activity Survey.

Finally, a Communication Working Group has been created with the broad objective to develop the Society's communication policy and initiatives in the coming year. The Group gathered in Basel at the beginning of January 2012 for their first workshop.

Mélanie Chaboissier
EBMT Communication
Coordinator

Sandrine Ehrmann
EBMT Marketing and
Fundraising Coordinator



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20 Corporate Sponsors supported the day-to-day work of the society in 2011.

With their generous support, EBMT Corporate Sponsors join the mutual efforts of EBMT Members to promote all aspects of blood and marrow transplantation. The EBMT aims for long-term relations with its Corporate Sponsors in order to ensure a safe development

of its activities, thanks to their first three-year commitment of three years.

In 2011, 4 new Corporate Sponsors joined the EBMT: Macopharma, Astellas, Millenium Pharmaceuticals and Exem Consulting, and we are extremely grateful for their support.

Platinum - 100.000 €



Gold - 50.000 €



Silver - 20.000 €



Bronze - 10.000 €





The membership statistics

	FY2009		FY2010		FY2011	
	Number	Real income	Number	Real income	Number	Real income
Membership	536	443.890,00 €	537	478.152,00 €	545	492.205,00 €
Corporate sponsors	19	489.448,00 €	19	626.779,00 €	20	470.000,00 €
Annual congress	1	859.252,00 €	1	743.581,00 €	1	1.053.505,00 €
Clinical trials	8	554.920,00 €	9	352.729,00 €	9	284.888,00 €
Other	-	31.322,00 €	-	145.000,00 €	-	288.800,00 €
Total income		2.378.832,00 €		2.346.241,00 €		2.589.398,00 €

EBMT financial highlights

The increase of activities of EBMT is shown in the consolidated financial figures. The total cost incurred are almost 2,7 million euro. The income has shown the same effects and will be 8% higher than last year and reach 2,6 million euro. A change in the accounting policy have led to improvements in the balance sheet presentation. The Board would like to thank and express it's appreciation to all who have contributed to the financial success of EBMT. Especially the corporate partners who's generous support is essential for the society.

Expenses

Changes in the organisation and increase of scientific research activities have led to consequently raise of costs. The scientific and educational mission of the EBMT results in approximately 80% of the total costs and is used for Clinical Trials, Registry, Working Parties and educational activities.

Income

The income from membership fee has increased with 2% to almost 0,5 million euro this year. Although the contribution of corporate sponsors has decreased EBMT is able to stabilise this income at a level of 0,5 million euro per year. EBMT maintained the income of clinical trials and studies on the same level as previous years. The EMBT annual meeting 2011 in Paris was very successful for all participants and profitable. These incomes allow EBMT to perform the planned activities.

Fred Falkenburg
EBMT Treasurer

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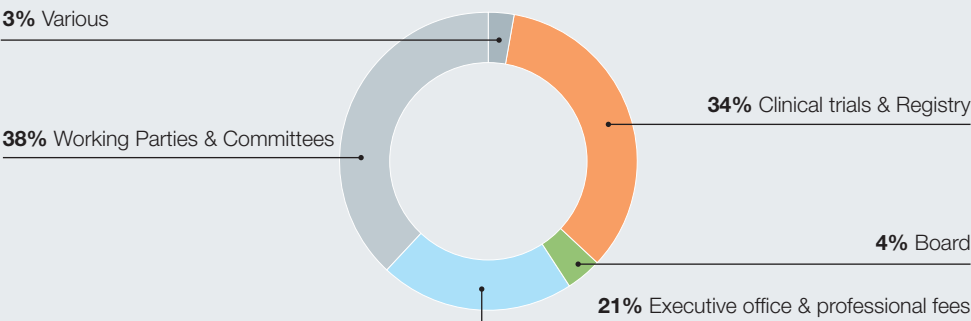
The EBMT Corporate Sponsors

The Membership statistics

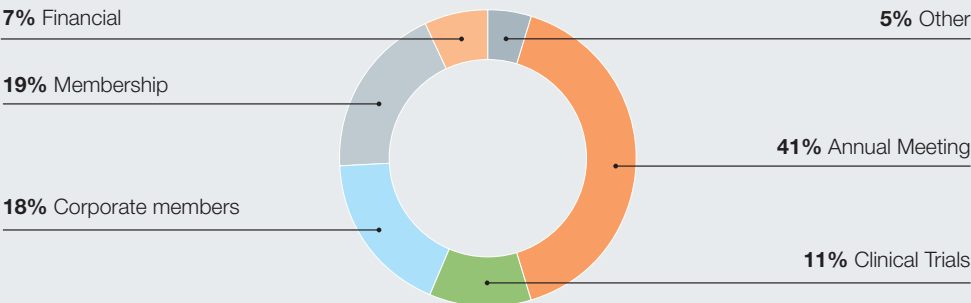
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Operating expenses EBMT 2011



Income EBMT 2011



The EBMT Board, Committee Chairs and Board of Counsellors in 2011

Executive Committee

President

Alejandro Madrigal
London, UK

Secretary

Anna Sureda
Cambridge, UK

Treasurer

J.H. Frederik Falkenburg
Leiden, The Netherlands

EBMT Working Parties Chairs, Nurses' Group President and Congress President

Aplastic Anaemia

Judith Marsh
London, UK

Autoimmune Diseases

Dominique Farge Bancel
Paris, France

Immunobiology

Andrea Velardi
Perugia, Italy

Infectious Diseases

Simone Cesaro
Verona, Italy

Lymphoma

Peter Dreger
Heidelberg, Germany

Solid Tumours

Marco Bregni
Milan, Italy

Acute Leukaemia

Mohamad Mohty
Nantes, France

Chronic Leukaemias

Theo De Witte
Nijmegen, The Netherlands

Inborn Errors

Bobby Gaspar
London, UK

Late Effects

André Tichelli
Basel, Switzerland

Paediatric Diseases

Christina Peters
Vienna, Austria

Nurses Group President

Arno Mank
Amsterdam, The Netherlands

Congress President 2011

Norbert Claude Gorin
Paris, France

EBMT Committee Chairs

Education Committee

Tamás Masszi - Budapest, Hungary

Nuclear Accident Committee

Ray Powles - London, UK

CT2-EBMT Committee

Hermann Einsele - Würzburg, Germany

Statistical Committee

Myriam Labopin - Paris, France

Quality Management Committee

Pierre Donot - Lyon, France

Nominations Committee

Anna Sureda - Cambridge, UK

Outreach Committee

Donor Registry

Cell Processing

Board of Counsellors

John Goldman - London, UK
Andrea Bacigalupo - Genova, Italy
Gösta Gahrton - Stockholm, Sweden

Bob Löwenberg - Rotterdam, The Netherlands
Mary Horowitz - Wisconsin, USA

Thanks to Jakob Passweg and his team from the Haematology Department of the Basel University Hospital, Switzerland.

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