



## Minutes of the EBMT General Assembly Meeting

2<sup>nd</sup> April 2008 (08.00-09.00)  
Florence, Italy

A full set of slides presented at the meeting are available for consultation on the EBMT website: <http://www.ebmt.org/3Membership/membership6.htm>

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### 1. President's Report

The EBMT President, Dietger Niederwieser, welcomed members and thanked them for joining the meeting. He then proceeded to present the President's Report:

#### 1.1 Scientific Output

DN highlighted the high volume of scientific output from the EBMT in 2007, testament to the hard work and effective collaborations between EBMT Working Parties, Committees, members and staff.

Publications	46
Prospective Clinical Trials	12
Retrospective Studies	100

#### 1.2 Protocol Tracking

The PCTC protocol tracking table was displayed to show the latest recruitment figures in open Clinical Trials. Two important studies are nearing their recruitment threshold: 1. the Prospective Study of the Incidence and Outcome of Venous-occlusive Disease (VOD) with the Prophylactic Use of Defibrotide (DF, Gentium, Italy) in Pediatric Stem Cell Transplantation (VOD-DF); 2. Allogeneic Stem Cell Transplantation from Unrelated Donors After Dose Reduced Intensity Conditioning Regimen for Patients with Multiple Myeloma and Relapse after Autologous Stem Cell Transplantation (MUDRIC-MM)

#### 1.3 Cell Therapy Registry

The recently established cell therapy registry (CTR) which aims to collect data on patients treated with novel therapies has grown over the past year and on behalf of Katarina Leblanc and Wim Fibbe, DN thanked centres for their efforts in reporting data to this registry and stressed the importance of studies that could potentially stem from the collection of this data.

#### 1.4 Cord blood Committee

An EBMT Cord blood Committee, chaired by Eliane Gluckman, has now been established. The committee's remit is to investigate the potential uses of cord blood in the field of HSCT. The committee's first meeting was held this year in Florence. The committee is working in close collaboration with the CIBMTR in relation to standardisation of data collection and effective data flow.

#### 1.5 Other Co-operations

Discussions are being held with the Inborn Errors Working Party regarding the implementation of the SCECTIDE registry and development of a new Gene Therapy registry within the EBMT Registry.

Meetings have been held with the Anthony Nolan Donor Registry to explore options for data sharing between the EBMT and Anthony Nolan. This project is a pilot for future collaborations with other donor registries in order to share HLA and transplant outcomes data, with a view of reducing the data reporting burden placed on member centres.

## **1.6 CLINT**

The EBMT 2008 meeting in Florence marked the end of the first year of the 2-year CLINT project funded by the EU under the Sixth Framework Programme. DN highlighted the successful progress of the project so far and encouraged members to attend the CLINT sessions (a Statistical Roundtable debate and a Workshop on governance of Clinical Trials in Europe: An EBMT Perspective) organised this year in Florence.

## **1.7 Nuclear Accident Training Course**

DN commented on the success of the 1<sup>st</sup> Nuclear Accident Training course which took place in Munich at the end of November 2007. The course was the first of its kind and constituted a pivotal moment in the activity of the EBMT Nuclear Accident Committee. The invitation of key members of the Nuclear Accident Committee to participate in an RITN meeting in Bethesda in September 2007 was also important to trans-Atlantic cooperation in this area.

## **1.8 EBMT Educational Activities**

The EBMT-ESH Handbook 2008 revised edition was launched during EBMT 2008 and has raised a huge amount of interest from attendees. DN thanked the European School of Haematology (ESH,) for their work in coordinating this new edition, and of course the authors who have created a 'must-have' reference book for all haematologists. A list of educational courses organised by EBMT Working Parties, and other EBMT courses in collaboration with ESH over the course of 2007 was also shown (see slides)

## **1.9 Public Relations (PR) & Public Affairs (PA)**

DN summarised the progress that had been made to date following the decision of the EBMT Board to work with Brussels-based PR/PA Consultants Interel. Throughout EBMT 2008 there were daily press releases which can be viewed by at: [http://www.ebmt.org/1WhatisEBMT/press\\_corner\\_11.html](http://www.ebmt.org/1WhatisEBMT/press_corner_11.html). A press conference was also organised on Monday 31<sup>st</sup> March 2008 which attracted a number of international journalists. Web casts of the event can be viewed at: [http://www.ebmt.org/1WhatisEBMT/press\\_corner\\_11.html](http://www.ebmt.org/1WhatisEBMT/press_corner_11.html).

The EBMT has also initiated a number of contacts with relevant directorate of the European Commission with a view of communicating the EBMT's activities and evaluating the most relevant funding opportunities at the EU level. This is intended to be the ground work for future applications under the Framework 7 and Public Health programmes, and it is anticipated that this will bear fruits in the near future.

## **1. 10 2<sup>nd</sup> EBMT Patient and Family day**

The 2<sup>nd</sup> EBMT Patient and Family Day was a major achievement. Feedback was highly positive from both the event organisers and attendees. Simultaneous translation crossed language barriers and 501 patients and their families enjoyed the informative and stimulating programme of Workshops and Sessions. It is expected that the 3<sup>rd</sup> EBMT Patient and Family Day in Göteborg will build on the success of the last two years.

## **1.11 Worldwide Network for Blood and Marrow Transplantation (WBMT)**

DN reported on the progress of the WBMT following the launch meeting held at the EBMT 2007 meeting in Lyon. A follow-up meeting was organised by WMDA in Minneapolis in November 2007 and a meeting would take place on 2<sup>nd</sup> November in Florence. The key activities currently being addressed by the WBMT are:

- Management of a global activity survey
- Development of unique patient, donor and centre codes
- Development of regional registries

## **1.12 Additional projects**

DN announced a number of projects which are to be launched in 2008, subject to budgetary availability:

- Clinical trials software
- Programmer for Registry
- Inborn Errors database integration
- Data manager for 3 smaller WPs (ADWP, LEWP, STWP)
- Data manager for the CLWP
- EBMT Statistician
- Support for cord blood data collection
- LWP (statistical support)
- Increased support for the Developmental Committee

## 2. Secretariat Report

The EBMT Secretary, Per Ljungman, presented the Secretariat Report.

### 2.1 New members

The end of year membership figures were announced:

59 countries

549 centres

3417 individuals

The list of new membership applications that had been received over the past 12 month were presented for approval. No objections were raised by the Assembly and the following 16 centres and 3 individual physicians were admitted as new members:

CIC	Membership Type	PI	Institution	City	Country
128	Prov Full	Nicholas Dodd	The Ipswich Hospital NHS Trust	Ipswich	United Kingdom
147	Prov Full	Dürk Heinz	St. Marien-Hospital	Hamm	Germany
210	Prov Full	Marco Montanaro	ASL Viterbo Polo Ospedaliero Centrale	Viterbo	Italy
927	Prov Full	Luigi Montalbetti	Ospedale di Circolo de Busto Arsizio	Busto Arizio	Italy
368	Prov Full	Filiz Buyukkeçeci	Tulay Aktas Oncology Hospital	Izmir	Turkey
400	Prov Full	S. Sema Anak	Istanbul University	Istanbul	Turkey
401	Prov Full	Ismail Sari	Pamukkale University - Faculty of Medicine	Denizli	Turkey
402	Prov Full	Mustafa Pehlivan	Gaziantep University Medical School	Gaziantep	Turkey
406	Prov Full	Tahir Shamsi	Bismillah Taquee Institute	Karachi	Pakistan
407	Prov Full	Vlatko Pejsa	University Hospital Dubrava	Zagreb	Croatia
554	Prov Full	Saad Al Ismail	Swansea NHS Trust	Swansea	United Kingdom
631	Prov Full	Jean-Huges Dalle	Hôpital Robert Debre	Paris	France
661	Prov Full	Thierry Lamy	Centre Hospitalier Universitaire de Rennes	Rennes	France
757	Prov Full	Jonathan Cullis	Salisbury NHS Foundation Trust	Salisbury	United Kingdom
832	Prov Full	M. P. Macheta	Blackpool Victoria Hospital	Blackpool	United Kingdom
998	Prov Full	Rob Pieters	Sophia Children's Hospital	Rotterdam	The Netherlands

## New individual members:

CIC	Membership Type	Name	Institution	City	Country
10123	Prov Individual	Jeffrey H Lipton	Princess Margaret Hospital	Toronto	Canada
10164	Prov Individual	Dariusz Boruczkowski	Polish Stem Cell Bank	Warsaw	Poland
10775	Prov Individual	Cesare Perotti	IRCCS Policlinico S. Matteo	Pavia	Italy

## 2.2 EBMT Accreditation and Audit Processes 2007 – 2008

An overview of the centres awarded EBMT accreditation in 2007/2008 and the centres that had been audited in the previous 12 months were presented:

<b>General overview:</b>	
Total number of units accredited:	265
Total number of units provisionally accredited:	22
<b>Accreditation awarded since March 2007:</b>	
Centres granted allogeneic accreditation:	98
Centres granted autologous accreditation:	104
Centres granted accreditation for harvest:	97

## Centres and inspectors involved in the EBMT audit:

A total of 10 centres in Italy, Scotland, Austria, Sweden, Germany, Greece, Czech Republic, Spain, Poland and Portugal were successfully audited as part of the 2007 internal audit process. The EBMT Board thanked the team of auditors for their time and effort.

## Audit 2007

CIC	PI	City	Country	Auditors	Auditor CIC	Audit Date
226	Dr. Sergio Morandi	Cremona	Italy	Dr. Marco Bregni	813	07/02/2008
228	Dr. Peter Johnson	Edinburgh	UK	Dr. Ian Franklin	244	15/11/2007
271	Dr. Günther Gastl	Innsbruck	Austria	Dr. W Linkesch	308	29/10/2007
283	Dr. Stig Lenhoff	Lund	Sweden	Dr. Anders Wahlin	731	13/11/2007
348	Dr. Rainhardt Osieka	Aachen	Germany	Dr. Jurgen Finke	810	03/12/2007
561	Dr. Athanasios Fassas	Thessaloniki	Greece	Dr. Anna Efremedis	751	04/12/2007
718	Dr. Vladimir Koza	Pilsen	Czech Republic	Dr. Jiri Mayer	597	26/11/2007
728	Dr. M. N. Fernández	Madrid	Spain	Dr. Alvaro Urbano	769	28/11/2007
800	Dr. Jan Walewski	Warsaw	Poland	Dr. W Wiktor-Jedrzejczak	954	22/01/2008
826	Dr. Aida Botelho Sousa	Lisboa	Portugal	Dr. Manuel Abecasis	300	26/10/2007

## 2.3 Update on Membership Status

Following the implementation last year of the membership motion linking Full EBMT Membership to data reporting, the following EBMT Associate member centres shown a commitment to begin data reporting and have accordingly had their Associate membership changed to Full EBMT Membership:

CIC	Institution	Country
300	Inst. Portugues Oncologia	Portugal
375	Thomayer Memorial Teaching Hospital	Czech Republic
393	Hospital de Cruces	Spain

450	Parkside Hospital	United Kingdom
520	Clinic of Haematology and Cellular Therapy	Russia
621	Ege University	Turkey
688	Dokuz Eylül Üniversitesi	Turkey
690	Oulu University Central Hospital	Finland
759	L'Hospital Universitari de Bellvitge	Spain
760	Istanbul Tıp Fakültesi	Turkey
761	Cerrahpasa Medical School	Turkey
781	Birmingham Children's Hospital	United Kingdom
799	Medical University of Gdansk	Poland

## 2.4 Future Annual Congresses

The next annual meeting will be held in Göteborg, Sweden from 29<sup>th</sup> March – 1<sup>st</sup> April 2009.

It was announced that the Board had selected Vienna, Austria as the venue for EBMT 2010. The congress will be held from 20<sup>th</sup> March – 24<sup>th</sup> March 2010 and the Congress President will be Werner Linkesch.

Jakob Passweg, was thanked for the time and effort that he and the local team had put into preparing their bid to host the meeting in Geneva, Switzerland.

In view of the increasing competition for venues of the size required by EBMT, the Board has decided to select the 2011 and 2012 venues together in 2008. A Call for Bids to host the 2011 and 2012 meeting was announced. Members interested in presenting a bid were asked to inform the EBMT Secretariat Office and consult the following documents in the Operational Manual on the EBMT website at <http://www.ebmt.org/1WhatisEBMT/whatisebmt2.html>:

- EBMT Venue Bid Manual ([http://www.ebmt.org/1WhatisEBMT/Op\\_Manual/EBMT\\_Venue%20Bid%20Manual\\_1st\\_Edition\\_Jan2007.pdf](http://www.ebmt.org/1WhatisEBMT/Op_Manual/EBMT_Venue%20Bid%20Manual_1st_Edition_Jan2007.pdf))
- EBMT Annual Meeting Rules and Regulations ([http://www.ebmt.org/1WhatisEBMT/Op\\_Manual/EBMTAnnualmeetings\\_Rules\\_Regulations\\_Board%20approved\\_2006.pdf](http://www.ebmt.org/1WhatisEBMT/Op_Manual/EBMTAnnualmeetings_Rules_Regulations_Board%20approved_2006.pdf))

The deadline for submitting an Expression of Interest to host the EBMT 2011 and 2012 meetings was set at 1<sup>st</sup> May 2008.

## 2.5 JACIE Accreditation update

### JACIE Board and Staff:

Diana Samson stepped down as JACIE Medical Director. PL thanked Diana for her enormous support and efforts for JACIE. Derwood Pamphilon will be taking over as JACIE Medical Director as of 1<sup>st</sup> April 2008.

### Inspections:

As of March 2008, 91 centres had been JACIE inspected and of those inspected 53 have now been accredited. The remaining 38 are awaiting the inspection report or are in the process of implementing changes required to rectify identified deficiencies. A further 7 centres have formally applied for accreditation and are making preparations for inspection in 2008. For the full details of centres inspected and level of compliance please see the accompanying slides.

**Finances:**

The costs for the JACIE programme in 2007 were presented. Core costs for the year were 124,616.06€. The EBMT Board has committed to paying 40,000 € to help fund the accreditation programme in 2008. The remainder of the costs should be covered by the Inspection fees.

**Overall Applications per Country:**

A slide was shown to illustrate the countries where applications to JACIE were most numerous. At present, Germany, UK, France and the Netherlands have made the highest volume of JACIE applications.

**3. Treasurer's Report**

The EBMT Treasurer, Harry Schouten, presented the Treasurer's Report:

**3.1 Annual Reports 2007**

The Balance Sheets as of 31<sup>st</sup> December 2007, for both EBMT Society and EBMT Foundation, were presented along with the profit and loss accounts for 2007. Full details of the finances are given in the accompanying slides and the Annual Reports for 2007 have been included in the Operations Manual on the EBMT website: <http://www.ebmt.org/1WhatisEBMT/whatisebmt2.html#rep>

**3.2 Motion to amend articles of Association**

A Board motion was presented to pass a resolution to amend the articles of Association as follows:

'Article 9 (3): The members of the Board of Directors will receive no remuneration for their work. Any legitimate expenses incurred will be reimbursed in consultation with the Board of Directors.'

No objections were raised by those present and the amendment will be duly made. This amendment will guarantee the not for profit status of the EBMT Association.

**3.3 Cancellation of membership of non-payers 2005 - 2007**

In advance of the General Assembly meeting member centres that had omitted to pay their membership fees for the past three years were sent a letter advising them that the membership rights for the centre and members listed will be cancelled at the end of April 2007, should the account not be settled by that time. Centres were given the opportunity to make a representation either in writing or in person at the General Assembly meeting in order to explain any reasons for non-payment.

A list of 10 centres that had still not initiated payment or provided a reasonable explanation was presented and is included in the slides presented at the meeting. Any of these centres which have not made full payment by the end of April are to be automatically deleted from the membership list.

A list of 25 centres that have not paid their membership fees for the past two years was also displayed. HS asked centres to make sure that their CIC (Centre Identification Code) is always included on the bank transfer so Secretariat is able to recognise the origin of the payment.

### 3.4 Corporate Patrons in 2007

The list of Corporate Patrons was presented. In 2007 the EBMT enjoyed the generous support of:



## 4. Registry Report

The Head of the Registry, Carmen Ruiz de Elvira, presented the Registry Report:

### 4.1 Registry Centralisation

The Registry centralisation process is complete. There are now 3.5 full time dedicated Registry staff located in the Data Office in Paris under the supervision of Virginie Chesnel.

Data Quality has always been an important topic for the Registry and the Registry has now felt it appropriate to apply to the EBMT Board for funding for a Data Quality Officer. The result of this will be known before the end of this year.

### 4.2 Feedback to centres/ Follow-up

At the Registry Subcommittee meeting held in Basel in October 2007 it was agreed that in order to prevent centres becoming overburdened with requests for follow-up on post transplant patients there needed to be a general rule for follow-up frequency. The following was agreed:

‘All patients to be followed up annually for the first 10 years and every 5 years thereafter’

A summary of follow-up data will be produced and sent to centres of patients that meet the above follow-up criteria.

### 4.3 ProMISe Training Courses

Five ProMISe Training Courses were organised throughout the course of 2007 (see slides). The objective of these sessions is to introduce Data Managers to ProMISe, enabling them to learn how to report their centre’s data electronically through the ProMISe interface.

More ProMISe Training Courses will be scheduled in 2008 and exact locations and dates will be communicated to centres by the EBMT Central Registry.

#### **4.4 MED-B forms and Manuals**

A large number of MED-B forms have been reviewed, re-written and implemented in the EBMT database to make data collection as relevant as possible. A list of forms along with their status was shown (see slides).

#### **4.5 Standardisation and Collaborations**

As previously commented by DN a number of important collaborations in relation to registry data are currently being discussed with CIBMTR, Eurocord and the donor registries.

#### **4.6 Future of the EBMT Registry**

CR ended by commenting that the registry is being used in more diverse ways than previously and there are projects being aired that will increase its complexity. This in turn requires a reconsideration of the funding, system and structure of the registry, with a view to securing the necessary ongoing funding and support for the registry.

As the database develops it is hoped that an increasing number of diagnoses, including those more related to non-HSCT cell therapy.

### **5. Clinical Trials Report**

Zoë Doran, Director of Clinical Trials Operations and Gérard Socié, Chair of the PCTC, presented a report outlining achievements in 2007 and goals for 2008.

A number of IT and Database issues were resolved in 2007. A dedicated ProMISe database for Prospective Clinical Trials (PCT) has been created and implemented for the Myfortic and MMVAR studies. At the same time alternative software solutions have been evaluated, leading to a Board decision to implement commercial software for clinical trials management. The new software will be implemented in 2008/9 enabling the EBMT to run registration levels in the future.

The following achievements were also mentioned:

- Strengthened Pharmacovigilance Support
- Pharmacovigilance reporting centralised in London
- Improved documentation

#### **5.2 Operational Structure**

The Operational Structure of the PCT has now been consolidated to make it pan-EBMT as opposed to Working Party specific. All operations have been re-focussed to London and Leiden into one virtual reality Clinical Trials Office, with the support of a monitor based in Leipzig. Communications between the offices has been strengthened through weekly inter office conferences, bi-annual team meetings and 6 weekly visits of senior staff to Leiden Office.

#### **5.3 PCTC Approval Process**

The PCTC approval has undergone a number of modifications due to the increased workload of the committee and the essential need for pan EBMT prioritisation and Board oversight of the scientific strategy. A new trials approval process has been signed-off by the Board and will be implanted in forthcoming months. See slides for new approval process.

## 5.4 Goals for 2008

The following goals for 2008 were expressed:

- Implement new Software
- Meet the Industry Standard
- Increase grant support
- Increase proportion of Clinical Trials Office driven approval submissions
- Formalise Quality Assurance programme
- First major audit planned May 2008

## 6. Election Results 2008

The results of the elections held in 2008 were announced by Dietger Niederwieser:

Position	Candidate	Votes
EBMT Treasurer	Jan Cornelissen	177
	No Vote	28
IWP Chairperson	Andrea Velardi	99
	Fred Falkenberg	88
	No Vote	18
IEWP Chairperson	Bobby Gaspar	107
	Mario Abinun	45
	No Vote	53
PDWP Chairperson	Christina Peters	106
	Franco Locatelli	91
	No Vote	8

Jan Cornelissen, Andrea Velardi, Bobby Gaspar and Christina Peters were congratulated on the election to their respective posts Thanks were given to Fred Falkenberg, Mario Abinun and Franco Locatelli for standing for election and for their willingness to serve the EBMT.

### 6.1 Re-Election Results 2007

Position	Candidate	Votes
EBMT President	Dietger Niederwieser	158
	No Vote	47

Dietger Niederwieser was elected for a second term of two years as EBMT President.

### 6.2 EBMT 2009 Elections

The elections to be held in 2009 at the annual meeting in Göteborg from 29<sup>th</sup> March-1<sup>st</sup> April 2008 were announced. The following positions will be due for re-election:

Position	Post holder
Late Effects Working Party Chair	André Tichelli
Chronic Leukaemia Working Party Chair	Theo de Witte

### 6.3 Outgoing Board members and handover of office

Having completed their second terms in office the following incumbents stepped down from the EBMT Board: Harry Schouten, EBMT Treasurer; Alejandro Madrigal, Chair of the Immunobiology Working Party; Marina Cavazzana, Chair of the Inborn Errors Working Party; and Giorgio Dini, Chair of the Paediatric Diseases Working Party. Monica Flidner's office as President of the EBMT Nurses Group also came to an end and Erik Aerts will take over the post of NG President.

As a token of appreciation Dietger Niederwieser invited each of the outgoing board members on stage to receive a plaque for their service to the EBMT.

## **7. Nature Publishing Awards**

DN presented the Nature Publishing Prizes, awarded for the best Clinical Poster and the best Science Poster. The awards were made to the following groups:

### **Best Science: P563**

Aplastic anaemia and other autoimmune diseases. A link or just coincidence?

P. Stalder, A. Rovó, J. Halter, D. Heim, C. Arber, A. Buser, S. Meyer-Monard, J.R. Rischewski, M. Stern, A. Tichelli, A. Gratwohl (Basel, CH)“

### **Best Clinical: P513**

Evaluation of engraftment and graft-versus-host reactivity of ex vivo modified human donor T-cell grafts in a chimeric NOD/SCID/IL2Rgcnnull transplantation model

M. Nonn, M. Hörz, S.A. Khan, L. Shultz, R. Handgretinger, C. Huber, W. Herr, U.F. Hartwig (Mainz, DE; Bar Harbor, US; Tübingen, DE)

## **8. EBMT Annual Meeting 2009**

Mats Brune, Congress President of the forthcoming meeting in Göteborg (30<sup>th</sup> March – 2<sup>nd</sup> April 2009) presented an overview of the local organising and national scientific committees, congress venue and initial ideas for the scientific and social programmes. A copy of the slide presentation can be viewed at: [http://www.ebmt.org/2RelatedMeetings/Goteborg\\_presentation.pdf](http://www.ebmt.org/2RelatedMeetings/Goteborg_presentation.pdf)