



**Minutes of the EBMT General Assembly Meeting**  
**28th March 2007 (08.00-09.00)**  
**Lyon, France**

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 EBMT Strategy Meeting Frankfurt**

Objectives for the continued success of the EBMT, developed by members of the Board, past Presidents and young investigators invited to participate in a Strategy Meeting held in Frankfurt on 24.05.06, were outlined. It was noted that many of the objectives have been, or are well on their way, to being accomplished:

- ❖ Greater focus on Prospective Clinical Trials
- ❖ Establishment of the Developmental Committee, which aims to foster research into Cellular Therapy beyond the haematological field
- ❖ Continued success of JACIE in pushing for harmonisation of standards and implementation of quality systems in BMT centres across Europe
- ❖ Introduction of the 1st EBMT Patient & Family day in Lyon, which was an immense success and is set to become an integral part of future EBMT Annual Congresses
- ❖ Educational training courses organised for Data Managers, Physicians, Nurses and other BMT Professionals
- ❖ The Annual Congress Rules and Regulations have been updated to ensure the quality of the meeting and a Bid Document prepared to create a transparent and accessible process for prospective bidders for future congresses
- ❖ Centralisation of the EBMT Registry in Paris, bringing the coordination of routine registry work and data collection together in one place, in order to make the process more effective and more efficient

Despite these successes there still remains a lengthy 'to-do' list, which will constitute the EBMT's goals for the coming year. For a full list of activities please see accompanying slides.

### **1.2 Worldwide Group for Bone and Marrow Transplantation (WBMT)**

Members were informed of a meeting organised in Lyon on the initiative of the EBMT, CIBMTR, APBMT and WMDA to establish the Worldwide Group for Bone and Marrow Transplantation (WWBMT).

The principle aims of WWBMT are to increase the flow of communication amongst international registries; to collect worldwide data and to harmonise SCT outcome globally. The WBMT will also contribute to facilitating both Retrospective and Prospective Clinical Studies.

A website URL for the group has been created and the webpage is currently under construction. Consult [www.wwbmt.org](http://www.wwbmt.org) for further information on activities and future meetings.

## 2. Secretariat Report

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

### 2.1 New members

The end of year membership figures was announced:

57 countries

519 centres

3086 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 7 centres and 1 individual physician were admitted as new members:

CIC	PI	Institution	City	Country
124	Schmiegel, Wolff	Ruhr- University Bochum, Knappschaftskrankenhaus	Bochum	Germany
398	Blundell, Eve	Gloucestershire Hospitals NHS Foundation Trust	Cheltenham	UK
405	Fernandes, Savio	The Dudley Group of Hospitals NHS Trust	Dudley	UK
406	Baars, J.W	Antoni Van Leeuwenhoek Hospital	Amsterdam	The Netherlands
450	Powles, Ray	Parkside Hospital	London	UK
806	Bertrand, Yves	Hopital Debrousse	Lyon	France
400	Kulkarni, Samar	Individual	Surrey	UK
451	Cuellar-Ambrosi, Francisco	Hospital San Vicente de Paul	Medellin	Colombia

### 2.2 EBMT Accreditation and Audit Processes 2006 – 2007

An overview of the centres awarded EBMT accreditation in 2006/2007 and the centres that had been audited in the previous 12 months were presented:

<b>General overview:</b>	
Total number of units accredited:	302
Total number of units provisionally accredited:	10
<b>Accreditation awarded since April 2006:</b>	
Centres granted allogeneic accreditation:	22
Centres granted autologous accreditation:	29
Centres granted accreditation for harvest:	24

### Centres and inspectors involved in the EBMT audit:

A total of 10 centres in Ireland, Wales, Belgium, Germany, France, Lithuania, Sweden, Spain, The Netherlands and Italy were successfully audited as part of the 2006 internal audit process. The team of auditors was thanked for their time and effort in supporting the audit programme.

#### Audit 2006

CIC	PI	City	Country	Auditor
257	Dr. McCann	Dublin	Ireland	Dr. Morris
303	Dr. Wilson	Cardiff	Wales, UK	Dr. Robinson
339	Dr. Zachée	Antwerp	Belgium	Dr. van Riet
519	Dr. Aul	Duisberg	Germany	Dr. Hallek
523	Dr. Gratecos	Nice	France	Dr. Faucher
644	Dr. Slobinas	Vilnius	Lithuania	Dr. Everaus
731	Dr. Wahlin	Umea	Sweden	Dr. Brune
242	Dr. Iriondo- Atienza	Santander	Spain	Dr. Carrera-Fernández
237	Dr. Schattenberg	Nijmegen	The Netherlands	Dr. Schouten
796	Dr. Donfrancesco	Rome	Italy	Dr. Arcese

### 2.3 Update on Membership Status

In May 2006, 202 European Centres were not reporting data to the EBMT. In March 2007 only 92 centres are not reporting data to the EBMT and 29 of these Centres have confirmed a desire to start reporting.

In accordance with the membership motion passed at the General Assembly in Prague 2005, the 63 Centres who have not chosen to report data will become Associate Members of the EBMT following this meeting.

A list of the 63 Centres who will become Associate Members of the EBMT was shown. Please see supporting slides for full list.

### 2.4 Future Annual Congresses

The next meeting will be held in Florence, Italy from 30<sup>th</sup> March – 2<sup>nd</sup> April 2008.

It was announced that the Board had selected Goeteborg, Sweden as the venue for EBMT 2009. The congress will be held from 29<sup>th</sup> March – 1<sup>st</sup> April 2009 and the Congress President will be Mats Brune.

Manuel Fernández, Tapani Ruutu, and Taner Demirer were thanked for the time and effort that they and the local teams put into preparing their respective bids.

A Call for Bids to host the 2010 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:

- [EBMT Venue Bid Manual](#)
- [EBMT Annual Meeting Rules and Regulations](#)

The deadline for submitting an Expression of Interest to host the EBMT 2010 meeting is set at 1st May 2007.



## 2.5 JACIE Accreditation update

### **JACIE Board and Staff:**

Alvaro Urbano stepped down as President in October 2006 after many years of dedication to JACIE. The post of President is now held by Ineke Slaper-Cortenbach from the Netherlands, in representation of ISCT. Jane Apperley has been appointed as Vice President in representation of EBMT. In May 2006 Eoin James Mac Hale replaced Sarah Craig as the JACIE Assistant, based at the JACIE Office in Barcelona.

### **Inspections:**

As of March 2007, 61 centres had been JACIE inspected and of those inspected 36 have now been accredited. The remaining 25 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 2007. 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 are forecast at 135,406.33€. The EBMT Board has committed to paying 40,000 € to help fund the accreditation programme in 2007. 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 2006

The Balance Sheets as of 31 December 2006, for both EBMT Society and EBMT Foundation, were presented along with the profit and loss accounts for 2006. Full details of the finances are given in the accompanying slides and the Annual Reports for 2006 have been included in the Operations Manual on the EBMT website.

### 3.2 Membership Fees

Members were informed of a change to the fee applied when an additional nurse is added to a CIC. The fee for additional nursing members was reduced from 75€ to 40€ to bring it inline with the fee for Individual Membership of the Nurses Group. For sake of clarity it is noted that the Centre Membership fee remains at 750€ for a team comprising 3 physicians, 1 nurse and 1 data manager. The fee for any additional nurse thereafter is 40€ and the fee for any additional physicians or data managers remains at 75€.

### 3.3 Cancellation of membership of non-payers 2004 - 2006

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 12 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.

### 3.4 Corporate Patrons in 2006

The list of Corporate Patrons was presented. For 2007 the EBMT has the generous support of:

<b>Senior Patron</b> AMGEN Europe	<b>LEVEL III</b> F. Hoffmann - La Roche Ltd Gilead Sciences UK Miltenyi Biotec GmbH Schering Plough Celgene Internationa SARL
<b>LEVEL II</b> Chugai-Aventis Fresenius Biotech GmbH Gambro BCT Pfizer Genzyme Schering AG Therakos Bristol Myers Squibb Novartis	<b>LEVEL I</b> GE Healthcare Pierre Fabre Cephalon

## 4. Registry Report

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

### 4.1 Registry Centralisation

The Centralisation of the EBMT Registry to the EBMT Data Office in Paris is well on its way to completion. This centralisation process was justified on the following basis:

- ❖ To improve the overall efficiency of the registry personnel;
- ❖ To eliminate the movement of paper forms between sites (reduction in mailing costs, time and actual loss of data) ;
- ❖ To improve the quality of the data by having one central office coordinating all aspects relating to quality control;
- ❖ To equalize the access to research orientated data management across WPs;
- ❖ To release those same WPs from budgetary responsibilities as to the daily registry work;
- ❖ To increase and improve the communication between the Registry and the centres by providing one single source of information relating to their data.

Virginie Chesnel will now be supervising the EBMT Registry in Paris and the tasks of the team will be:

- ❖ Routine data entry of all paper forms submitted to the EBMT
- ❖ Regular submission to the centres of queries relating to missing or inconsistent data
- ❖ Regular requests for follow-up throughout the year

The centralisation of the EBMT Registry is expected to be completed by the end of the third quarter of 2007.



## 4.2 Feedback to Centres

In autumn 2006 the Registry contacted centres with the first summary of EBMT registrations, providing centres with an overview of their transplant numbers by year, disease and paediatric/adult. The registration summaries will be produced and sent to centres on a bi-annual basis. All feedback from the centres will be used to improve the Summary Document.

## 4.3 Data Quality

### **ProMISe Training Sessions:**

Nine group training sessions for Data Managers have been organised by the EBMT since March 2006. 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.

The success of these sessions has encouraged the London Office to schedule more sessions in 2007. Please see accompanying slides for exact locations.

### **Documentation on Data Management:**

A number of documents have been compiled on the use of ProMISe to access the EBMT database, in an attempt to make it easier for centres to use ProMISe as a daily working tool.

- **On the use of ProMISe to access the EBMT database:**
  - User Guide to ProMISe 2.2 (Revised) – Shelley Hewerdine
  - Guide to Retrieving Data from the MED-AB Database – Shelley Hewerdine
  - Guide to Obtaining Statistical Summaries from the Complete MED-AB Database – Shelley Hewerdine
  - Catalogue of pre-programmed Data Retrieval queries available in the MED-AB database (50% complete)
- **User Guide Translations:**
  - Dutch: Promise Handleiding EBMT / Handleiding Promise general – Marjon Smeets, Thekla Jansen, Esther Beekhuizen
  - Spanish: Guía de Usuario de Promise 2.2 - Pascual Balsalobre
  - French: Guide de l'utilisateur de Promise 2.2 - Nathalie Fortin- Robertson, Virginie Chesnel
  - Italian: Guida a ProMISe 2.2 - Barbara Bruno
- **Med-A paper form merging, instructions**
- **Med-AB Complete Manual (minor updates)**

The Registry would also like to thank the following people for translating the ProMISe 2.2 User Guide into their native tongues:

Marjon Smeets, Thekla Jansen, Esther Beekhuizen, Pascual Balsalobre, Nathalie Fortin-Robertson, Virginie Chesnel, Barbara Bruno.

### **Definitions Committee:**

The Definitions Committee has been working on the revision of all existing Med-B forms to cater for procedural changes and different fields of interest. The Med-B Manual will be updated accordingly.

### **In development:**

One of the major goals of the Registry this year is to improve communication with centres by expanding the 'members' database to extend its use to EBMT Research Co-ordinators. The Registry would also like to further automate/standardise requests for missing data and follow-up.

There is currently a project running to expand the Med-A paper form merge module to selected Med-B's.

In an attempt to improve data quality pre-programmed reports that are to able to capture inconsistencies will be created for Data Managers to use themselves in their own centres. Automated procedures will also be developed to capture, list and mail inconsistent data (old database/uploads).

## **5. Report of the Prospective Clinical Trials Committee (PCTC)**

Gerard Socié, as Chair of the PCTC presented a report outlining achievements in 2006 and goals for 2007.

### **5.1 Infrastructural Development**

Following the decision of the Board to support the development of the infrastructure for managing prospective clinical trials important progress has been made on a number of fronts:

- ❖ Development of core SOPs – to standardise practice in Leiden and London Clinical Trials Offices.
- ❖ Establishment of Pharmacovigilance procedures in compliance with EMEA reporting requirements.
- ❖ Centralisation of Competent Authority applications
- ❖ Recruitment of a Senior Coordinator/Training Supervisor role to support CTO activities in all offices. This post will be based in London and will supervise prospective trial management staff as well as formalise training for all staff.

### **5.2 Strategic Development/ Streamlining**

The Clinical Trials team has adapted its strategy and has focussed on improving the following points:

- ❖ Communication between the two Clinical Trials teams (Leiden & London) through bi-annual team meetings and holding two weekly teleconferences.
- ❖ Increased support for protocol development by creating templates for non-scientific sections
- ❖ CTA applications/submission packages
- ❖ Translations
- ❖ Implementation of a protocol review process with Working Party, administrative and internal/external reviews
- ❖ Fostering of a closer partnership with Pharmaceutical companies thereby increasing the number of collaborative projects.
- ❖ Review of resources by industry by identifying progress and remaining deficits.

### **5.3 Goals for 2007**

The Clinical Trials Committee has outlined the following goals for 2007:

- ❖ To address IT/Database Issues – this involves the creation of a dedicated Prospective Clinical Trials database in ProMISe. A survey will also be done on software options to facilitate data management to registration study standards
- ❖ Strengthen Pharmacovigilance Support by training all Co-ordinators and increasing resource.
- ❖ Improve documentation
- ❖ Consolidate Operational Structure



## 6. Election Results 2007

The results of the elections held in 2007 were announced by Dietger Niederwieser:

Position	Candidate	Votes
STWP Chairperson	Lisbeth Barkholt	35
	Marco Bregni	72
	No Vote	29

Marco Bregni was congratulated on his election to the chair of the STWP. Commiserations were given to Lisbeth Barkholt, who was thanked for standing for election and for her willingness to serve the EBMT.

### 6.1 Re-Election Results 2007

Position	Candidate	Votes
EBMT Secretary	Per Ljungman	102
	No Vote	34
AAWP Chairperson	Jakob Passweg	112
	No Vote	24
ADWP Chairperson	Riccardo Saccardi	96
	No Vote	40
ALWP Chairperson	Vanderson Rocha	105
	No Vote	29
IDWP Chairperson	Hermann Einsele	113
	No Vote	23
LWP Chairperson	Anna Sureda	105
	No Vote	29

All existing post holders were re-elected for a second three-year term in office and were congratulated on their progress to date.

### 6.2 EBMT 2008 Elections

The elections to be held in 2008 at the annual meeting in Florence from 30<sup>th</sup> March-2<sup>nd</sup> April 2008 were announced. The following positions will be due for re-election:

Position	Post holder
EBMT Treasurer	Harry Schouten
Immunobiology WP Chairperson	Alejandro Madrigal
Inborn Errors WP Chairperson	Marina Cavazzana-Calvo
Paediatric Diseases WP Chairperson	Georgio Dini

### 6.3 Outgoing Board members and handover of office

Appreciation was expressed to Taner Demirer who is the outgoing Chairperson of the Solid Tumours Working Party and was awarded a plaque to acknowledge his invaluable contribution to the Solid Tumours Working Party from 2001 - 2006.



## 7. Nature Publishing Awards

John Goldman 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: P626**

**'Estimation of duration and success of unrelated stem cell donor searches, based on HLA-DRB1 allele and DRB1-DQB1 haplotype frequencies'**

**Authors:** K. Hirv, K.Bloch, M.Fischer, H.Schrezenmeier, J.Mytilineos (Ulm, DE)

### **Best Clinical: P460**

**'Allogeneic stem cell transplantation in children and adolescents with high-risk alveolar rhabdomyosarcoma'**

**Authors:** P.Badel, J.Soerensen, A.Jarisch, G.Weber, H.Kreyenberg, R.Esser, A.Willasch, E.Rettinger, U.Koehl, S.Kuci, T.Klingebliel (Frankfurt, DE)

## 8. EBMT Annual Meeting 2008

Alberto Bosi, Congress President of the forthcoming meeting in Florence (30<sup>th</sup> March – 2<sup>nd</sup> April 2008) 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 is available for consultation on the Related Meetings section of the Website: Annual Meetings: Future and Past: <http://www.ebmt.org/2RelatedMeetings/abosi2008present.pdf>

The meeting was brought to a close with a promotional video on city of Florence.