DATA MANAGEMENT NEWS

EBMT 2011: 10th Meeting of the Data Management Group
Le Palais de Congrès, Paris, France
3 – 6 April 2011

We hope that you can join us in Paris for a varied programme of educational, scientific and training sessions especially tailored to delegates involved in the Data Management field

ProMISe Training
To assist with the process of online data registration, we will again be running training sessions for the ProMISe system at this year's congress. There will be a beginners' Data Entry session on how to enter MED-A registration data and a Data Retrieval session for more experienced users focusing on obtaining data listings, frequencies and running reports. To guarantee your place, please enrol for these sessions in advance by clicking here.

Important notes regarding ProMISe registration:
- You must also be registered for the congress (see congress page for further info)
- We are able to offer Promise registration and training free of charge, but there will be a charge of 150 Euros for non-attendance
- Sessions on Tuesday are a repetition of the Monday sessions to allow more participants to attend and benefit from the courses

Monday 4th April

Data Management Educational Sessions

09:00–12:30	09:00–12:00
09:00 GvHD	ProMISe 2 Data entry (New users only)
09:50 Paediatrics	
10:45 Cord blood	
11:35 Harvest & manipulation	

13:30–16:45	13:30–16:30
13:30 Autoimmune diseases	ProMISe 2 Data retrieval
14:20 Haemoglobin-opathy	
15:15 Nursing management of HSCT	
16:05 Basic transplant registration with Med-A	

Tuesday 5th April

Data Management Educational Session

09:00–12:30	09:00–12:00
09:00 Infectious diseases	ProMISe 2 Data retrieval
09:50 CML	
10:45 Engraftment	
11:35 MPS	

13:30–16:45	13:30–16:30
13:30 Non-Interventional studies	ProMISe 2 Data entry (New users only)
14:20 The role of good data collection	
15:15 Status report on data in the megafile	
16:05 Q&A session	

Educational Sessions

We aim to provide something for data management professionals at all levels of their career. In addition to the educational sessions for people new to the field, such as the introduction to Med-A, we offer sessions with higher scientific context which should be of interest to everybody, regardless of their background. These sessions include GvHD, Harvesting and Engraftment.

We also have sessions on the particularities of Paediatrics and Cord blood, and the role of nurses in transplantation, which are of great interest as they highlight specific issues associated to transplants in particular settings. We recommend participants to attend as many sessions as possible even if they do not seem to relate to their work (you may learn more about adult transplants by finding out what is different in paediatric transplants!).

We also encourage active participation, raising issues and requesting clarifications. The latter is particularly important in those sessions which are more specifically about the data quality of submissions and use of data in studies. To allow more time for this we are pleased to introduce a new Q&A session at the end of our programme on Tuesday

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Basic transplant registration with Med-A (workshop)
V. Chesnel (Paris, FR); C. Ruiz de Elvira (London, UK)
This session will focus on the Med-A form and the pivotal role this plays in recording HSCT data in the EBMT Registry database. We will be looking at a range of frequently asked questions:

- Which form to use?
- Which procedures should not be reported?
- Who should report the data?
- Why are we collecting these data?

We will consider what information is required when reporting an HSCT on a Med-A form and look at areas that frequently present difficulties in recording data notably: Conditioning, Relapse, GvHD and the new HLA requirements. We will also talk about Patient Consent. There will be some hints and tips to ensure your data is being accurately recorded and, of course, how to get help when you need it!
This will be an interactive session and you are welcome to bring along any queries or problems with Med-A forms that you would like any help with for discussion at this session.

Infectious diseases *C. Cordonnier (Creteil, France)*
The goal of this session will be to address the mechanism of the most frequent infections after HCT (primary infection, reactivation), their definitions, and especially the differences between infection and disease, and the differences between superficial and invasive infections. Improving the quality of data collection for infectious complications may provide important information to the transplant community, in order to identify new infections which may be eventually prevented, or to develop screening for early diagnosis.

Autoimmune Diseases
D. Farge-Bancel (Paris, FR); T. Kozak (Prague, CZ); Z. Marjanovic (Paris, FR)
The generalities concerning the major categories of autoimmune diseases for which HSCT are currently recorded in the Registry using specific MED A and MED B forms (namely Multiple Sclerosis, Systemic Sclerosis, Lupus Erythematosus, Crohn Disease, Inflammatory Arthritis) will be presented allowing data managers to better understand the specificities of these pathologies. The difficult items (classification, scoring and follow up) will be analysed in order to overcome the difficulties of completion of the requested data. Part of the session will be dedicated to answer specific questions raised by the audience and to discussion.

Harvest & manipulation of harvesting
F. Lanza (Cremona, IT); J. Petriz (Barcelona, ES)
The presentation will focus on the gold standard for priming and collecting hematopoietic stem cells (HSC), including assessment of type of regimens, mobilisation, harvest and transplantation of autologous HSC. Strategies for handling of "poor mobilisation" will also be discussed. Special emphasis will be given to the different protocol used for enumeration of CD34+ cells, together with complimentary data on culture assays of colony-forming cells that were originally proposed for the assessment of the stem cell graft.

Engraftment
T. Ruutu (Helsinki, FI)
The session will cover the definition of engraftment, problems in the interpretation and registration of engraftment, methods to study chimaerism and treatments for graft failure

Status report on data in the megafile
B. Lindner (Innsbruck, AT); E. Polge (Paris, FR)
We will show some insight on megafile data from a data quality perspective. We decided to look at the time span 1990 – 2009 and see how complete data is on disease classification, disease status, best response and follow-up. What do we know about donors? How do we check if data is correct and complete in our own data segment? Finally we would like to discuss with data managers how to improve data entry and data checks. What is your everyday experience? What are your requests and suggestions?

Non interventional studies: Your data is the key to research *A. van Biezen (Leiden, NL)*
A step-by-step presentation of study procedures from proposal through to analysis and publication

Quality management – role of good data collection
J.Williams, S. Barrott (Sheffield, UK)
This presentation will focus on how a small paediatric centre tackled quality management issues and how data management fits into the quality management system. It aims to prove that data management provides a crucial role in maintaining and improving quality systems by sharing our experiences.

The pivotal role of nurses *E. Aerts (Zürich, CH)*
The presentation will cover the latest developments, current best practice of the special nursing care of patients with a haematological disease and haematopoietic stem cell transplantation. The multidisciplinary cooperation is characteristic for work in a haematological setting. Because of the coordinating role they have, nurses often function as key figures.

Issues you have raised – question & answer session
Members of the Registry Sub-Committee
The final Data Management Education session of the Annual Meeting : a chance for you to bring to the table any problems, issues, queries, or comments which you have encountered during your regular work reporting transplant data. In addition, we will also look in more detail at specific Data Management issues which may have arisen during earlier presentations. Various members of the EBMT Registry and Working parties will be present – and so this is a really good chance to pick their brains! During this session we hope we can work together to brain storm and solve problems and issues.

Quality Managers' & Data Managers' reception

On Monday evening from 17:00 – 18:30 there will be an opportunity to socialise with your colleagues and put names to those faces behind the computer screens at the National Registries, Help Desk, Working Parties, Study co-ordinators etc

This year we are looking forward to a joint drinks reception with Quality Managers and if you have a role in both, you don't have to be in two places at once!

There will be something for everyone at the Annual Meeting and we would like to encourage as many Data Managers as possible to attend. There is still a chance for you to book: visit the congress page and follow the Registration links.

EBMT

37ᵗʰ Annual Meeting of the European Group for Blood and Marrow Transplantation
27ᵗʰ Meeting of the EBMT Nurses Group
10ᵗʰ Meeting of the EBMT Data Management Group
3ʳᵈ EBMT Quality Management Meeting
5ᵗʰ EBMT Patient & Family Day • Saturday, 2 April 2011

Paris, France, 3 – 6 April 2011

Modification to the MED-AB data collection forms

There have been some additions to the Med-B forms, as explained below. Re-ordering of the Complications section has been necessary in order to implement the changes in ProMISe.

Allograft
A set of cGvHD items has been added to allow reporting of cGvHD status using this form. This may be useful if only one form is submitted due to early death of the patient.

All Med-B Disease specific forms
A set of aGvHD items has been added to the follow up section of these forms to allow reporting of aGvHD status with no time limit. This is consistent with the NIH consensus which recognises that the separation of cGvHD from aGvHD on the basis of time elapsed from HSCT is no longer valid. The following categories can be reported:
(1) Only acute GvHD (absence of features consistent with chronic GvHD), comprising:
      (a) classic acute GvHD (before day 100)
      (b) persistent, recurrent, or late acute GvHD (after day 100, often upon withdrawal of immunosuppression)
(2) Only chronic GvHD (no signs of acute GvHD)
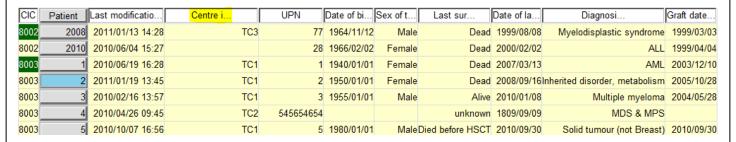(3) Features of aGvHD and cGvHD present simultaneously (also known as overlap syndrome)

MED-A
Very minor re-ordering of the Complications items in the Follow Up

Please download the new form versions from our website
http://www.ebmt.org/4Registry/registry3.html
and start using them now

Changes to ProMISe navigation
These changes have now been implemented in ProMISe. If you experience any navigation problems please email the Registry Helpdesk as soon as possible and attach a screen shot

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ProMISe: Minor change to the Data Entry Index

CIC	Patient	Last modificatio...	Centre i...	UPN	Date of bi...	Sex of t...	Last sur...	Date of la...	Diagnosi...	Graft date...
8002	2008	2011/01/13 14:28	TC3	77	1964/11/12	Male	Dead	1999/08/08	Myelodisplastic syndrome	1999/03/03
8002	2010	2010/06/04 15:27		28	1966/02/02	Female	Dead	2000/02/02	ALL	1999/04/04
8003	1	2010/06/19 16:28	TC1	1	1940/01/01	Female	Dead	2007/03/13	AML	2003/12/10
8003	2	2011/01/19 13:45	TC1	2	1950/01/01	Female	Dead	2008/09/16	Inherited disorder, metabolism	2005/10/28
8003	3	2010/02/16 13:57	TC1	3	1955/01/01	Male	Alive	2010/01/08	Multiple myeloma	2004/05/28
8003	4	2010/04/26 09:45	TC2	545654654			unknown	1809/09/09	MDS & MPS	
8003	5	2010/10/07 16:56	TC1	5	1980/01/01	Male	Died before HSCT	2010/09/30	Solid tumour (not Breast)	2010/09/30

You may have noticed a slight change to the Index in Data Entry. This had to be made so that we can continue our check for duplicate UPNs in a centre index, while excluding patients from other centres that appear in that centre index because one of their transplants was performed at a different hospital. The column Centre in which this transplant was performed (highlighted above) had to be added and the width of the survival status column has been reduced in order to retain all default index items as before.

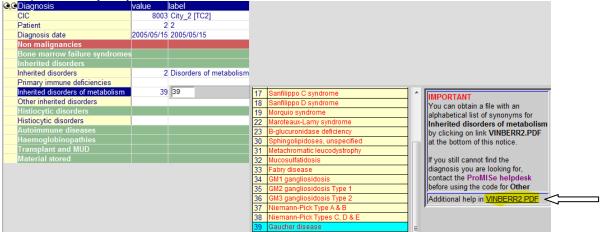# New documentation available

Click on the links to view

Clinical Manuals & Reference Documents:
[Summary of Disease status and Response by disease](#)
A tabular description of the relevant disease status or response for each disease

In ProMISe:
A help file with synonyms for Inherited disorders of metabolism has been added to this field in ProMISe:

Sharing MED-AB data with other organisations: Eurocord
We would like to remind you that a [Permission Request Form](#) is available to allow consent to data sharing between the EBMT and Eurocord. If we receive the signed consent form from your Principal Investigator (as shown in the membership list), Eurocord will have access to your cord blood data submitted to EBMT and your centre will not have to fill two different sets of forms

Updates

ProMISe User Guides:
The [User Guide to ProMISe 2.2](#) (Data Entry) has recently been updated. Printed copies will be available at the congress.

Multiple Donors: we have made minor changes to the data collection forms and manual to clarify that "Multiple donors" refers to donors <u>and</u> different sources of stem cells for the same donor

Interested in working with us?

We have 3 new vacancies for a **Data Manager** at the **EBMT Registry Office**, **London**

The position
The data manager will be expected to accurately enter data submitted by centres into the EBMT Registry database using the ProMISe system, engage in procedures to maintain and improve data quality and enhance the data submission rate of centres.

The ideal candidate must be very well organised, with high attention to detail, self motivated and capable of working independently to high standards. They must have experience in data entry, preferably in a medical, clinical or academic environment, be competent users of Microsoft Office, must be fluent in another European language aside from English, and must have excellent communication skills both verbally and in writing in both languages. Familiarity with the ProMISe system and the EBMT Registry database is an advantage. Willingness to travel to international venues is desirable.

To apply: Please visit the [Jobs Board](#) on the EBMT web site for further info.
Closing date for applications: 20 March 2011