European Society for Blood and Marrow Transplantation

DATA MANAGEMENT NEWS

Annual Meeting – special edition **March 2016**

EBMT Annual Meeting – VALENCIA
15th Meeting of the Data Management Group

We very much look forward to welcoming all participants to the EBMT Annual Meeting in VALENCIA this year, where a varied programme of DATA MANAGEMENT EDUCATION SESSIONS and DATABASE TRAINING SESSIONS will be on offer.

EDUCATION SESSIONS are open to everyone interested in the field of Data Management. These are **open sessions –** no need to book, just turn up at the session. Some are aimed to assist people who are new to the field to enhance their knowledge while others have a higher scientific content of interest to everybody, regardless of background. We do encourage active participation in sessions, raising issues and requesting clarifications so that we can all learn from each other. Below you will find further information regarding some of these sessions – to give you a better idea and a flavour of what will be on offer this year:-

Conditioning for allos
Speaker: Herman Einsele
This session will look at the wide variety of different conditioning regimens currently administered prior to autologous and/or allogeneic stem cell transplantation. A full conditioning induces a complete eradication of the hematopoietic system of the recipient purely by the conditioning regimen. In addition, for allografts, there is a reduced intensity conditioning which induces transient aplasia. In the absence of an allograft, autologous reconstitution of the hematopoietic system is highly likely. In this case the complete eradication of the hematopoiesis of the recipient and the induction of full chimerism is obtained through the graft versus hematopoiesis effect of the transplanted allogeneic immune system. Furthermore, there is also the mini or micro transplantation procedure, mainly performed with 2 Gy TBI plus additional immunosuppressive drugs, which induces only mild myelosuppression. In this case, the effect of the new immune system, the allo versus hematopoiesis reaction, is even more important to induce complete chimerism and thus cure the underlying hematologic malignancy.

Performing a study: from study proposal to publication
Speakers: Cora Knol; Anja van Biezen
In this presentation we will go through all phases of an EBMT study. What is needed to start a study? How do we collect patient data and improve the quality of these data? What should we do when a study is coming to its end? Within the EBMT we perform different types of studies. How do these studies differ from each other? What are the different phases and requirements involved in these studies? These and other topics will be discussed and will show how essential your data management is in performing studies within the EBMT.

Inherited disorders – management and follow up (Focusing on Primary Immunodeficiency)
Speaker: Andrew Gennery
Whilst specific primary immunodeficiencies are rare, collectively they are relatively common, and for many, haematopoetic stem cell transplant is the treatment of choice. Diagnosis and subsequent management can be challenging, and approaches to transplantation differ to those for malignancy. Furthermore, long-term follow up requiring careful documentation of relevant immune reconstitution is necessary. This session will discuss presentation, management and follow up of these patients.

JACIE – the process explained
Speaker: Eoin McGrath
Data management is a key area addressed in the FACT-JACIE International Standards. The intent of the requirements is to ensure accurate data keeping and reporting. This talk will explain the accreditation process in general and the aspects affecting data managers in particular.

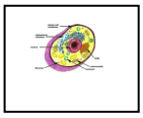
Donor outcome follow up – why we need a donor outcome registry
Speaker: Jörg Halter
This presentation will explain the rationale of why there is a need for outcome research for all donors. Currently, most data on donor outcome comes from unrelated donor registry studies. However, in the past decade, the importance of outcome research of related donors has become increasingly recognized by the transplant community and authorities. Characteristics of different donor populations and scientific progress explain the need for outcome follow up of both unrelated and related donors in order to ensure donor safety and high donor motivation in the future. Current results, practise and tools, - including the donor outcome follow up tool in ProMISe - will be discussed and opportunities for development of synergism between unrelated donor registries and data collection teams will be addressed.

Optimising data collection at a BMT unit
(Centre presentation)
Speaker: Camilla Roepstorff; Heidi Petersen
Our centre performs approximately 120 allogeneic transplants each year and we are required to provide data for different registries. This presentation will be about creating tools for essential data collection according to the requirements of different registries in order to provide accurate and useful data. We will also share our experience on providing data on day 0 for the registries.

Burning issues regarding de novo and secondary AML classification
Speaker: Jordi Esteve
During the session, with a clear vocation for practical education, the essential basis of the diagnosis of myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) will be reviewed, as well as the concept of transformation of AML from MDS. In addition, the basic principles of WHO classification for both diseases, emphasizing the relevance of some genetic markers for identification of specific entities, will be addressed. Some of the grey zones or concepts that usually generate confusion, such as AML with myelodysplasia-related changes, or therapy-related myeloid neoplasms will also be briefly discussed. Moreover, related topics previously raised by data-managers or during the session by attendees will be considered.

The Co-morbidity index
Speaker: Roberto Raimondi
In this presentation the “Comorbidity Index ” (CI), I will discuss mainly the following topics: what is the CI, how and why it was developed, why it is needed and what is its clinical utility, where it is in ProMISe and how to calculate it - with particular attention to the definitions of the comorbidities.

Ex-vivo manipulation
Speaker: Andrea Velardi
A Scientific session designed to give Data Managers a clearer understanding of what is involved with ex-vivo manipulation and the importance of it. The session will highlight issues which are relevant to data managers to clarify the fact that there are variety of protocols and also a variety of ex vivo manipulations. Data Managers are often asked by PIs to put together data from different protocols, each with different results. Using examples where applicable to illustrate that people use at least five or six dramatically different protocols and graft processing procedures (each with different pros and cons…).



The new Med-A
Speaker: Jane Apperley
This session will offer the opportunity to discuss and review the new Med-A form which was implemented in December 2015 – focussing on the changes which have been introduced into the form. (Further timelines included overleaf). The session will include information about the changes to key fields for example: cytogenetics, donors & donor products, cell therapy, relapse, Day 0 data entry, GvHD & the NIH criteria, molecular markers and lymphoma prognostics. It will be an interactive session and we are keen to hear feedback regarding how you are finding the new form – the positive and the negative - and any problems you have encountered in completing it. Please come along and let us know what you think.

Myeloma: How to evaluate response to treatment and relapse – case studies
Myeloma is a highly heterogeneous disease with various manifestations. In order to assess tumor load decline after treatment and increase during relapse/ progression, multiple parameters need to be taken into account. The definitions of response have changed over time and the tools to measure the disease have also improved. The goal of this presentation is to define, describe and clarify the methodological aspects of disease evaluation in response to therapy and ensuing progression or relapse. Definitions will be briefly reminded and each scenario will be addressed with “real life” examples. It is planned to be very practical and interactive. We therefore expect the session to help data managers and other research personnel in data collection for registries, databases and clinical trial reporting.

In addition to the above, there will also be sessions on the following topics:
CELL THERAPY ***CORD BLOOD.***

We hope you agree that this looks like a very informative educational programme

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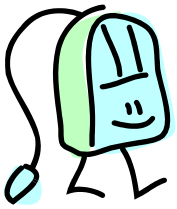
This year we will be offering the following EBMT REGISTRY DATABASE (ProMISe) TRAINING SESSIONS. Please click here for the link to the *registration form* for the database training sessions. Please note that you will need to be registered for the congress if you would like to attend any of these training courses.

MONDAY 4th April 2016 from 9.00 - 12.30
DATA ENTRY

This is an introductory session for **new users** to ProMISe, illustrating how to enter a MED-A registration, including subsequent transplant data and patient follow-ups. The session will start with an introduction to HSCT given by a Speaker who has worked in the clinical setting, followed by a Demo of how to enter a Med-A form, given by EBMT Registry staff. There will be time at the end for some hands-on practice using example data



MONDAY 4th APRIL 2016 14:00 – 17.00 DATA RETRIEVAL

This session will focus on obtaining data listings, frequency tables and cross-tabulations using pre-programmed queries in ProMISe. The session is recommended for those who are already entering data, but need further guidance on running pre-designed queries to help with reporting and management of their centre data.

TUESDAY 5th APRIL 10.00 - 12.00
HLA DATA ENTRY

This session will explain how to enter HLA typing reports for those users who want to enter the HLA reports themselves. This session is aimed primarily at **experienced** data entry users.

TUESDAY 5th APRIL 14.30 – 16.30
EXPORTS AND SHARING REPORTS

During this session you will learn how to use the following features:

- Retrieving data for various purposes
- Downloads to Excel and running the macros
- Example SPSS report and typical use
- Running the MED-A Merge
- Using the Secure Download Facility (SDF)

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And **don't forget**, on **Monday evening 4th April (17.00-18.15)** there will be an opportunity to relax and socialise with colleagues at the Data Managers' reception –
look out for further details at the conference!

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FINALLY, EBMT has been a driving force of the biomedical and clinical history of hematopoietic stem cell transplantation for over 40 years.We appreciate the fact that Data Managers have made a significant contribution to this work & in ensuring that data is consistently and accurately recorded into the EBMT Registry Database. We very much look forward to welcoming you to the **15th Meeting of the Data Management Group in VALENCIA** and to meeting you there.

Further info: registryhelpdesk@ebmt.org
Registration linkhttp://www.ebmt2016.org/

THE NEW MED A	
Timeframe for release	**New Timepoints for reporting data**
New MED-A paper form went online – November 2015	In December 2015, EBMT Registry started collecting data on day 0 from all centres: • Day 0 for baseline data • Day 100 on early outcome • Day 365 and yearly for follow-up. (Or follow ups at least every 5 years for transplants more than 20 years ago)
New MED-A implemented in Registry database December 2015	
MED-AB manual will be updated – work in progress. Target online date: May 2016	
New MED-A items will be incorporated into MED-B work in progress. Target online date: May 2016 MED-B users should continue as usual until further notice.	