European Society for Blood and Marrow Transplantation

DATA MANAGEMENT NEWS

Annual Meeting – special edition **March 2015**

EBMT Annual Meeting – ISTANBUL 2015
14th Meeting of the Data Management Group

We very much look forward to welcoming all participants to the EBMT Annual Meeting in ISTANBUL 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:-

Molecular markers and Cytogenetics
Speaker: Johannes Schetelig
In this session information will be provided on techniques applied in the laboratory and their corresponding results. The goal is to improve understanding to help Data Managers with their daily work. With respect to cytogenetics, classical banding analysis in order to determine the karyotype of cell populations and fluorescence in situ hybridisation (FISH) will be described. The nomenclature of karyotype formulas according to ISCN (International System of Cytogenetic Nomenclature) will be briefly outlined. Moreover, the principle of hierarchical classification of cytogenetic abnormalities will be shown for chronic lymphocytic leukemia. Using the example of del(17p) detected with cytogenetic techniques and TP53-mutations detected by PCR, possible constellations of cytogenetic and molecular findings will be shown. Finally, the three most important genetic lesions in normal karyotype AML, FLT3-lesions, NPM1-, and CEBPA-mutations will be discussed. The initiating mutations and the arising advantages for the AML cells will be reviewed. Molecular techniques in order to detect these mutations and their corresponding reports will be presented.

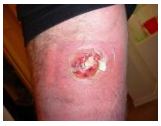
Understanding Genetic and Molecular Markers in Lymphoma
Speaker: Silvia Montoto
Lymphoma cells are characterised by the presence of specific genetic and molecular abnormalities. These abnormalities result in genetic and molecular markers that can be detected using different techniques. Some of them, like FISH (fluorescence in situ hybridisation), detect abnormalities at the chromosomal level, like chromosomal rearrangements, whereas others, such as PCR (polymerase chain reaction) can detect abnormalities at DNA or RNA level. The importance of these abnormalities is that some of them are necessary to make a diagnosis (as *C-MYC* rearrangement in Burkitt lymphoma) and some of them confer a poor prognosis, such as rearrangements of *BCL-2*, *BCL-6* and *C-MYC* when they present in combination in the so-called double-hit or triple-hit lymphomas. This session will show how the understanding and knowledge of these abnormalities allows a better definition and classification of lymphoma sub-types.

Clinical Trials
Speaker: EBMT Clinical Trials Office
It is well known that prospective clinical trials are complex and expensive to run, but simple steps can ensure that a trial produces good clinical data. This talk will give an overview of what needs to be done to run a clinical trial and ensure that

the data is of good quality. The points to be discussed will include Good Clinical Practice (GCP), designing a protocol and choosing the data to be collected, ethical considerations, how to collect good clinical data, data management plans, the data query process, data transfer and storage, and the need for monitoring and auditing of data. There will also be an opportunity to ask questions and to find out more about the EBMT Clinical Trials Office.

Infections in transplants – why is it so difficult to collect reasonable data regarding infections? Speaker: Kate Ward

Infection is a major source of morbidity and mortality in recipients of bone marrow transplants and it is therefore important to collect good data. A general overview will be given of the significant infections that occur after transplant including their frequency. Examples will be given illustrating the current difficulties for data managers of registering data in the database for these different infections. Looking to the future there will be a discussion about possible solutions with audience participation invited.



Data Reporting Problems (Interactive session) Speaker: Shelley Hewerdine

We will be introducing some of the work we have been doing in the Registry Office and how data managers have contributed to the quality of the data. The session will be interactive and we hope you will enjoy testing your knowledge in our quiz. If you ever wondered how to record a rare diagnosis, whether your transplant is a true transplant, how to report multiple DLIs and how to get zero errors in the Data Quality reports, then please come along to find out more. Last year, we concentrated on the MED-A form , and this year we will look at some more complex issues. The info will still be accessible to beginners and we look forward to seeing you there.

Myeloma: How to evaluate response to treatment and relapse?
Speaker: Laurent Garderet

When assessing the status of a myeloma patient, it is important to report correctly the level of response to treatment and the date when the patient is relapsing. This data, to be robust, must be reproducible so that trials can be compared with each other.

Three international guidelines have been published so far (Blade J,et al BJH 1998, Durie BGM, et al, Leukemia 2006, Rajkumar SV,et al, Blood 2011). The difficulties arise because:

- Treatment has improved with the necessity of new response definitions such as Very Good Partial Remission (VGPR) and a new category of complete response (CR) called stringent CR
- New technologies have emerged. It is now possible to measure the serum free light chain. This measurement has been incorporated to evaluate response, especially useful for light chain myeloma.

The depth of response has also improved with the necessity to use improved flow cytometry and molecular biology to define even more stringent response (Phenotypic and molecular CR). Therefore, over time, response categories have been modified and when added to dealing with missing raw data, it is not an easy task to evaluate myeloma nowadays! Within a clinical trial, team work now involves working with the data manager for the first assessment followed by a first check by the local medical principal investigator followed by a second check by the medical monitor of the trial and finally by a group of 3 International Myeloma experts! The session will give a practical (and hopefully more simple) approach to assess myeloma.

Introduction to HSCT and the Med-A form
Speaker: Deborah Anderson

This presentation aims to link the clinical practice of HSCT with data management requirements. There will be an overview of the HSCT process followed by an introduction to the MED-A form; translating clinical issues into the data form set.
This session is highly recommended for new or nearly-new Data Managers

***What is it that makes nursing in Paediatrics so special?*Speaker: Eugenia Trigoso**

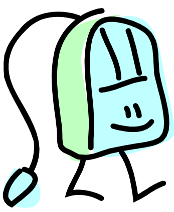
It is the children who make *nursing in Paediatrics so special!.* As WHO says, "*children are not little adults"*. Each age group is different and their treatment differs significantly from that of adults. Although cancer is a rare disease in children and adolescents, there are 15,000 new cases every year in Europe. More than 60 different types of cancer affect these young patients. In this session we will look at HSCT as a commonly used treatment for patients with certain types of cancers, and consider the drawbacks of this treatment and the risk of severe

complications, including infection, organ dysfunction and late complications such as growth retardation, infertility and development of another type of cancer. There will also be an explanation of the mandatory training and education requirements for all health professionals caring for children and adolescents. The importance of a multidisciplinary team approach involving the children and their family, caregivers, physicians, psychologists and social workers will also be considered.

Data Managers and Literature: Getting the broader picture and helpful reference works
Speaker: Beate Lindner
This session will focus on reference works and websites that help us in our daily work of documenting transplant related data. For example: *Where can I quickly look up disease definitions or find out more about cancer drugs and therapies?* In the second part of the session some works of literature by patients, doctors, relatives and writers will be introduced. There should also be room for discussion and input from the audience.

In addition there will be sessions on the following topics:
DLIs – when & why used; Autoimmune – Overview of cell therapy; Changes in the Med-A; Transplant complications – including VOD; Update regarding the Registry System; Handling complex problems in ProMISe (training session- details to be advised) . *We hope you agree that this looks like a very informative educational programme.*

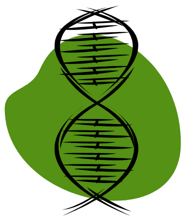
This year we will be offering the following EBMT REGISTRY DATABASE (ProMISe) TRAINING SESSIONS. If you would like to attend any of these sessions please register in advance using the link to the registration form included below:-



MONDAY 23rd MARCH 2015 from 9.00- 12.00 DATA ENTRY
This is an introductory session for **new users** to ProMISe illustrating how to enter a MED-A registration and including subsequent transplant details and patient follow-ups.

For further information contact: registryhelpdesk@ebmt.org
Registration link: http://www.ebmt2015.org/

MONDAY 23rd MARCH 2015 14:00 – 17.00
DATA RETRIEVAL
This is a practical session which will focus on obtaining data listings, frequencies, report running. You will learn about the different classes of reports; filtering; converting reports to Excel; checking reports; adding filters; saving and exporting reports. The session is open to all users but experience of using ProMISe is required and it is **not** recommended for people who are absolute beginners.



TUESDAY 24TH MARCH 2015 10 - 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** ProMISe users.

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 conference if you would like to attend any of these training courses.

And don't forget, on **Monday evening 23rd March (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!

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 **14th Meeting of the Data Management Group in ISTANBUL** and to meeting you there.