EBMT Annual Meeting – MILAN 2014
13TH Meeting of the Data Management Group

We very much look forward to welcoming all participants to the EBMT Annual Meeting in Milan 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 (see below). And 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 on some of these sessions – to give you a better idea of what will be on offer this year:-

NIH-Defined GvHD
Speaker: Hildegard Greinix

Graft-versus-host disease (GvHD) resulting from an immunological attack by donor lymphocytes transplanted with the stem cell graft on recipient organs and tissues, is a serious and frequent complication of allogeneic hematopoietic cell transplantation (HCT). Clinically, acute GvHD can be distinguished from a chronic form based on differences in organs afflicted and thus, patients' signs and complaints. In acute GvHD skin, liver and the gastrointestinal tract are targets of donor-derived allogeneic T cells - whereas chronic GvHD has more diverse manifestations including lichenoid and sclerodermatous skin lesions, kerato-conjunctivitis sicca, lichenoid mucositis and bronchiolitis obliterans syndrome.
During the last years the incidence of chronic GvHD has been rising due to increasing numbers of older transplant recipients, peripheral blood as stem cell source, use of mismatched and unrelated donors and treatment with donor lymphocyte infusions for recurring malignancy after HCT. Historically, chronic GvHD was classified as "limited" or "extensive" based on the results of a small retrospective study. In the past,

any manifestation of GvHD that was present at day 100 after HCT or thereafter was arbitrarily defined as "chronic GvHD" - even if the clinical manifestation was indistinguishable from that of acute GvHD. Advances in HCT practice in the past two decades have profoundly altered the presentation and natural history of both acute and chronic GvHD and challenged the previous definitions.
In 2005 the National Institutes of Health (NIH) consensus development project developed standardized criteria for diagnosis of acute and chronic GvHD and proposed a new scoring system for describing the extent and severity of chronic GvHD based on expert opinion for use in clinical trials. Meanwhile these NIH-defined criteria for diagnosis and severity scoring of chronic GvHD have been prospectively validated and have demonstrated prognostic significance. In this presentation the new diagnostic criteria will be presented and will be compared to the historic criteria. Furthermore, the clinical implications including their impact on survival and non-relapse mortality will be discussed.

MULTIPLE MYELOMA
Speaker: Curly Morris says –

In my presentation, I will give a definition of myeloma, a brief summary of its history, look at incidence and age distribution and discuss the highly variable features of this disease. We will then look at the numbers of patients being transplanted and the type of transplants which they receive. We will look at the subclassifications of myeloma and the different staging systems which have been used to assist with prognosis and briefly look at the impact of the molecular biology revolution in our understanding of the condition. I will then try to explain why response criteria are so detailed and complex and how patients are assessed in the post-transplant setting. In both autologous and allogenic transplants similar definitions are used in response to standard treatments we will look briefly at the impact of the novel agents place in the management of myeloma.

Viral serology
Speaker: Jan Styczynski

Infections belong to serious complications of hematopoietic stem cell transplantation. Infections can significantly contribute to failure of transplant at each stage of therapy. With respect to etiology, infections are caused by viruses, bacterias, fungi, and parasites. The objective of the lecture is to present basic information on the epidemiology, agents, symptoms, and diagnostics of viral infections. A special attention will be given to viral serology. Viral serology reflects to monitoring the immune system's antibody response to viral antigen exposure, including both infection and immunization. This session will be focused on the following issues: influence of viral status on transplant outcome; methods of detecting viruses (antigens, antibodies and nucleic acids); primary and latent infections; virus reactivation (DNA-emia); role of pre-transplant antibodies and post-transplant viremia; influence of donor and transplant on recipient; and the role of selected viruses (eg. CMV, EBV) in the transplant setting.

Graft manipulation
Speaker: Alvaro Urbano-Ispizua

Hemopoietic progenitor cells (HPCs) for transplantation are obtained from bone marrow, peripheral blood and cord blood. During the process of harvesting HPCs, other cells are also passively collected, among them T lymphocytes, B lymphocytes and Natural Killer cells. These accessory cells are crucial to attain a robust immune reconstitution after the transplant. Thus, immune cells will fight against infections, will facilitate the engraftment of the inoculum, and will eliminate leukemic cells. On the other hand, these cells may attack the recipient's tissues, the so called graft versus host disease (GvHD), which is the main cause of mortality after the transplant. This presentation will explain the different strategies to eliminate partially or totally some of these immune cells, with the aim of decreasing GvHD without affecting their attack against both leukemic cells and microbial pathogens.

Long term follow-up of stem cell transplant recipients
Speaker: Marja Pekkanen

This presentation deals with the experiences of data collection and reporting to EBMT of adult haematological patients transplanted at Helsinki University Central Hospital during the last ten years. Annually 65-75 allogeneic and 40-50 autologous patients are transplanted. The data of allogeneic patients is reported with MED-B and that of autologous patients with MED-A. The methods of data gathering, the difficulties obtaining and evaluating the relevant follow up data are discussed.

Aplastic Anaemia Please come along to find out what **Prof Jakob Passweg** has in store for us in his talk this year!

Cell Therapy
Speaker: Willem Fibbe

In addition to hematopoietic stem cells, the bone marrow contains another class of stem cells termed mesenchymal stromal cells (MSC). These cells are able to differentiate into various mesenchymal lineages, including bone, cartilage and adipose tissue. Recent evidence indicates that MSCs also exhibit potent immune modulatory activity and are able to suppress auto- and allo-immune in-vitro and in-vivo. MSC treatment is currently evaluated in clinical trials for treatment of graft-versus-host disease after allogeneic stem cell transplantation. During the session, the characterization, biology and clinical applications of MSCs will be further discussed.

Common Data Reporting Problems
This will be a general and interactive session run by the **Data Management team at the EBMT Registry in London**. We will be looking at common problems that affect the quality of data. Issues to be covered include crucial missing items; optimal coding; reporting drugs correctly; inconsistencies in disease status and relapse. The session is targeted to all those reporting HSCT data to the EBMT whether online or on paper. There will be an opportunity for questions and discussion. The aim of the session is to improve the quality of data for everyone – data managers in centres or those analysing the data - by reducing the number of queries concerning the data.

Haploidentical transplants - almost everyone has a donor
Speaker: Daphna Hutt The field of haploidentical transplants is evolving in the last few decades. In this lecture we will go over the main concepts of these transplants. How did it all start? How can we overcome the HLA barrier of an HLA mismatched donor? What are the different ways for T-cell depletion? We will gain understanding on the complexity and implications of these kinds of transplants.

There will also be sessions on: **Graft loss and reconsitution; Cytogenetics and markers**

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The following sessions are intended for new or nearly new Data Managers (but of course, everyone is welcome to attend them!)

Introduction to HSCT and the Med-A form: Bridging the clinical and data management Speaker: Tuula Rintala
The aim of this session is to give a brief overview of the HSCT process for both autologous and allogeneic HSC transplant and some of the common complications following HSCT. This will be very practical review of the patient journey and some of the clinical decisions the Transplant team will take. The second part of the session will aim to give some insight on how the data for Med-A forms is collated as well as discuss some of the common problems and issues in ensuring the quality of data on Med-A form.

The role of Data Management in the EBMT Speaker: Carmen Ruiz de Elvira
Carmen's presentation will explain the essential elements and the importance of the Data Manager's role within EBMT.

Data Confidentiality
Speaker: Henk Jan van der Wijk
A person's medical information is highly privacy sensitive and disclosure can have severe effects on a person's life. Anyone working with medical data, including for medical research, is therefore obliged to protect the data by complying with several laws and guidelines. There is new European law in the making where anyone processing personal information will be responsible for the security and will be liable for any breech of that security. Informing patients about the use of their data, restricting access to the information required for each purpose and protecting the information from misuse are the key components to a responsible way of working with sensitive medical information. This session will explain: details and implementation of the laws relating to patients and to health professionals; how to protect digital medical information; systems to ensure proper authorization and management; audit system to detect and prevent misuse; why is it necessary to restrict access?; protecting extracted data; data encryption.

This year we will be offering the following **EBMT REGISTRY DATABASE TRAINING SESSIONS**. **Please register in advance for the sessions on Monday using the registration link included below:-**

MONDAY 31ST MARCH 2014 9.00- 12.00 TIDY UP YOUR DATA
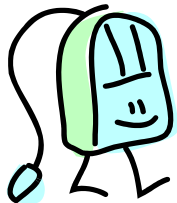
This will be a practical session to help you to prepare your data for the migration to the new database. We will use the existing EBMT Registry Database software (ProMISe) for this session. The session will show you how to run pre-prepared reports to check the accuracy of your data and to identify: Invalid data; missing data; duplicate information; incorrect diagnosis or diagnosis dates; error messages; conflicting information & etc. We will show you how to correct the errors in the database and how to print out the reports if required. The "tidier" your data – the easier the data transfer to the new database will be! You will need to have some experience of Data Entry using ProMISe for this session

MONDAY 31ST MARCH 2014 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 will help you to check your data and to prepare for data migration. 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.

Please click here for a link to the booking form to register for the above training courses

In addition to the above sessions, on **TUESDAY 1ST APRIL 2014** there will be **preview sessions** of the new EBMT Registry system. The sessions on Tuesday will be **open sessions** (i.e. no need to book) and details will be available nearer the time.

And don't forget, on Monday evening 31st March (17.00-18.15) there will be an opportunity to relax and socialise with colleagues at the Data Manager's reception – look out for further details at the conference!

FINALLY, 2014 is an important year in the history of EBMT as we will be celebrating our **40th anniversary** at the Annual Meeting in Milan in 2014. EBMT has been a driving force of the biomedical and clinical history of hematopoietic stem cell transplantation during this period, and we are proud to be part of this history. Data Managers have made a significant contribution to EBMT over this period in ensuring that data is consistently and accurately recorded into the EBMT Registry Database. We very much look forward to welcoming you to the **13TH Meeting of the Data Management Group in MILAN** and look forward to celebrating our **40th Anniversary** with you!

For further information contact: registryhelpdesk@ebmt.org
Registration link:
 http://www.ebmt2014.org/