DATA MANAGEMENT NEWS

March 2017

New MED-A for Cell Therapy

We are pleased to announce that the new Cell Therapy form and manual are now available:


CIC: ..... Hospital UPN: ..... Date of the first cell therapy infusion ..... - ..... - .....
(Do not write here the date of any HSCT) yyyy mm dd

Cell Therapy - MED - A

Registration to month 6

CENTRE IDENTIFICATION

The New Cell Therapy data can be registered in **ProMISe data entry** from now on using codes **21** and **22** in "*form about to be entered*". (The former codes have been deactivated). **We recommend that you start using the Cell Therapy Med-A for all types of non HSCT cell therapy including DLI.** Although DLI can still currently be collected through the standard HSCT MED-A, this will most probably change in the future, once we finalise some restructuring of both the HSCT and Cell Therapy MED-As in agreement with various working groups with whom we are discussing the issue.

The new expanded **Cell Therapy Med-A form** has been developed by the **Cellular Therapy Registry Committee** led by **Chiara Bonini** and implemented by Carmen, Tunde & Lucas in the **EBMT Registry team**. It was also harmonised with the **CIBMTR** and **Japanese Stem Cell Societies** to make sure the same or comparable data is captured.

The **Cell Therapy Registry** (CTR) aims to collect data on stem cells, or progenitors or mature cells, such as T-lymphocytes, unmanipulated, such as DLI, or sorted and/or cultured and/or genetically manipulated, such as CAR-T cells, used for treatment in combination with hematopoietic stem cell transplantation or alone, and including advanced therapeutic medicinal products (ATMP), as well as data on the clinical characteristics and outcome of the patients.

The new form also collects details of **laboratory manipulation** for all types of cells before they are infused into the patient. They include: selection, modification, genetic engineering and others.

Clinical Trials and commercially sensitive information

Any trial data can be stored in the EBMT database can be **hidden** from the working parties so it cannot be used for studies, but can still be accessed by the centre itself.

The EBMT would use this data exclusively for reporting total numbers, which are never broken down neither by centre nor by country. To hide the registration you need to answer the relevant question and enter the date when the data can be made available for research.

☐ Tick here if you want this registration hidden until ..... - ..... - .....
(indicate by which date the registration can be made available for research) yyyy mm dd

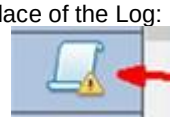
MACRO New Registry System

We are delighted to inform you that the EBMT has just appointed Elsevier to work on our new registry system. The development will be based on MACRO, a powerful, flexible and user friendly Electronic Data Capture system that can be customised further to meet EBMT Registry requirements. We'll keep you updated as the project progresses.

Scheduled reports in ProMISe

Data Retrieval: If you run scheduled report jobs in ProMISe, we would like to remind you to refresh your repeating jobs once in a while, especially following any Promise updates. (The job should be deleted and then re-scheduled again, using the same filters). Usually if a report runs without any problem it will show a Log symbol in the [Export] tab – Secure download facility:

If there is an error in a repeating job, this yellow warning triangle will display in place of the Log:



EBMT 2017: Data Management Sessions

We look forward to welcoming data managers very soon in Marseille!

We have a full educational programme taking place on Monday 27th and Tuesday 28th March:
http://www.ebmt2017.org/data-management

ProMISe training

We will cover data entry of the **new Cell Therapy form** that has just been released. Plus, data entry of MED-A, HLA, Donor Outcome, Advanced Data Entry & Data Retrieval. As courses take place in the computer room (Room Riou) we ask that you **book a place for ProMISe training** (in addition to your congress registration). Please go to the online booking form **(by Thursday 23rd March**)

Education Sessions

Please see the following page for a taster of some of the education sessions that will be on offer:

Education Sessions for Data Managers at EBMT 2017:

Below is an illustration of some of the Education Sessions on offer at EBMT 2017. There is no need to book in advance for these talks. We hope to see you there. **Room Samena** on Monday & Tuesday starting at 09:00.
http://www.ebmt2017.org/data-management

Centre Presentation on how the new Med-A has affected working practices in centres
Massimo Berger, Italy (Monday 13:45 – 14:25).
The Italian registry (GITMO) was one of the first to indicate how timely the Day 0 registration was. By recording on day 0, scientific and regulatory interests converge.
New items include: a) more info on cytogenetic and molecular data at diagnosis and at HSCT (including which type of molecular markers have been tested), b) more data on pre-transplant therapy for some diseases (eg lymphoproliferative diseases), c) co-morbidity index, d) site specific GvHD.
These changes, together with the new paper-free Registry. have both greatly improved the quality of the registry and the collaboration between clinicians and data managers (DMs), but also an increased workload for DMs.we estimate a minimum of 30 mins for each new transplant for Day 0 registration is needed.

Chronic GvHD
Fiona Dignan, UK (Monday 14:30 – 15:10).
My talk will include an overview of chronic graft versus host disease. I will discuss why GVHD occurs and the problems that it causes for patients. I will then move on to the National Institute for Health criteria and how these are captured on Med A forms. I will then use a real life case study to illustrate the complexity of the condition and the importance of accurate data collection.

Data Protection
Jeroen Knijpenga, The Netherlands (Tuesday 11:00 – 11:40).
The new General Data Protection Regulation will apply directly in all EU countries from 2018 onwards. How does this affect collecting and using personal data? The new research exemption does allow for certain usage without consent. What type of usages and sharing will be allowed, and what are the limitations for health data? What will change on other privacy issues, a practical update.

Long-term survivors
Monika Sztankay, Austria (Tuesday 11:45 – 12:25)
Cancer and its treatment often result in long-term physical and psychological sequelae, impairing patients' quality of life. For informing comprehensive oncological practice and research, routinely assessed patient-reported outcomes, such as quality of life, are important to supplement clinical data. The presentation will give a short introduction to patient-reported outcomes in oncological patients, its benefits and areas of use (e.g. in clinical trials and practice) as well as different modes of assessment. Aforementioned theoretical background will be illustrated by quality of life data of long-term survivors of haematopoietic stem cell transplantation treated at the University Clinic of Innsbruck, Austria.

HLA: Lost in trans(p)l(ant)ation?
Johannes Schetelig, Germany (Tuesday 13:45 – 14:25).
This presentation will provide information on the role of HLA molecules in transplantation. HLA-information allows for assessing immunologic tolerance between host and recipient. HLA-compatibility therefore is an important risk factor for many clinically relevant outcomes after transplantation such as graft failure, GVHD, relapse and non-relapse mortality. Different nomenclatures used in HLA-reports will be mentioned and useful links for translation will be provided. The impact of HLA-data on clinical and immunogenetic decision-making will be discussed and selected publications which highlight this role will be shown.

Myelodysplastic syndrome (MDS)
Marie Robin, France (Tuesday 14:30 – 15:10).
Myelodysplastic syndrome is a bone marrow disease characterized by dysmyelopoiesis and a risk to transform into acute myeloblastic leukemia (AML). The incidence rate in 4.15 cases/100 000/year. Severity of the disease can be estimated according to prognostic scores giving expected median survival and rate to transformation into AML. The MDS prognosis is related to cytopenia, marrow blast count, and genetic alterations including cytogenetics abnormalities and somatic mutations. Some treatments like 5-azacytidine have been reported to induce remission and prolong survival in higher risk MDS patients but the only curative treatment is allogeneic hematopoietic stem cell (HSCT) for these patients. Low risk patients or patients with comorbidities impacting life expectancy don't benefit from transplantation. Regarding higher risk patients who received HSCT, outcome after transplant will be related to comorbidities, type of donor and the disease status at time of transplant: remission after treatment, blast count, cytogenetic and somatic mutations. According to these risk factors 30-50% of MDS patients can be cured after HSCT.