



REGISTRIES SUB COMMITTEE (RSC)

Minutes of the meeting held on 26th of October in Basel, Switzerland.

Participants: Carmen Ruiz (Chair); Sandra Allgaier; Helen Baldomero; Katerina Benesova; Ronald Brand; Virginie Chesnel; Sunil de Souza; Nabila Elarouci; Nathalie Fortin-Robertson; Anja Henseler; Shelley Hewerdine; Stephen Marcos Jones; Chantal Kenzey; Beate Lindner; Helga Neidlinger; Rosi Oneto; Hellmut Ottinger; Emmanuelle Polge; Bénédicte Samey; Keiren Towlson; Marie Trnkova; Marie Wilson; .

Members Project: Update on the database, accessible to registries and Study Coordinators for centralized contacts

Sunil de Souza, EBMT Central Registry Office, London UK.

Sunil gave an introduction on how the Members Project works. Although it is also run on ProMISE 2 software, the database structure is different to the MED-AB project that registries are familiar with. The focus of this project is to have a central database of centres. The transfer of all information on the non member centres and Promise users / data managers is almost complete. Nathalie at the London office is dealing with updates or requests for changes to Non Members, whilst the EBMT secretariat in Barcelona is taking care of the Members. In the Membership section of the EBMT website, there is a procedure to follow for member changes to be made and requests must be signed by the Principal Investigator (PI).

The Members project can be a useful tool for National Registries/Study Coordinators and the Sunil De Souza at the London office can give access to the project upon request.

Carmen Ruiz explained that a number of filters and queries had already been created to facilitate reports. In addition, registration summary data will also be available, for example 'Centres performing Acute Leukaemia transplants', however these are manually updated and the procedure is not automatic. Carmen suggested that study coordinators could provide a definition to help with studies, e.g. 'at least 10 Acute Leukaemia transplants in the last year'.

(A copy of the document outlining the pre-designed reports available is attached)

2. EBMT Overview: Presentation on the current EBMT structure

Stephen Marcos Jones, EBMT Secretariat, Barcelona, Spain.

Stephen Marcos Jones, from the EBMT Secretariat in Barcelona presented the history and structure of the EBMT organization.

Stephen has been part of a project (CLINT) working on creating a new Web portal for EBMT which will eventually replace the current website.

Following the presentation, Stephen asked the RSC attendees if they had any questions or requests about the new web portal.

Beate Lindner, from the Austrian Registry, suggested quick links to other registries.

Ronald Brand, who is involved in the web development, explained that the portal can provide a space for specific user groups, i.e. a group of authors working on a paper, or pages dedicated to Working Parties and Committees.

Keiren Towlson, from the British Registry, suggested links to EBMT documentation and links to the user's own National Registry.

Stephen encouraged everyone to send further ideas and suggestions by email.

(A copy of this presentation is attached)

Annual Meeting: Data Management program for EBMT 2008 – Firenze

Shelley Hewerdine, EBMT Central Registry Office, London UK.

Shelley presented the new Data Management programme. Following proposals raised during the previous RSC meeting, some changes to the data management sessions have been introduced.

As for the new Discussion Forum, the Registry must prepare a list of generic topics to start the discussions. Shelley also stressed that it is important to invite physicians and try to gather as many people as possible to share ideas and knowledge. I.e. Physicians/Consultants to receive invitations to the forum a few weeks before the Congress

Here a few suggestions for the Topics:

- Beate Lindner suggests a 'sketch', where a typical Data Managing situation is enacted. i.e. missing data on a patient form
- Carmen Ruiz thought that we may need a controversial topic to get the attendees attention.
- Ronald Brand proposed that inconsistent data should be discussed as well, however it was agreed that the approach should be more positive rather than concentrating on the negative aspects.
- Keiren Towlson suggested presenting an EBMT Overview, similar to Stephen's presentation in point 2 above, Stephen agreed and is willing to present at the Forum in Florence.

Shelley would like to have further opinions and ideas from the National Registries and Data Managers. Other Forum topics mentioned were the new Med-A form and Follow-Ups.

The Registry Office would again like to call on staff to volunteer to help in the group Promise training, the educational sessions and the new Promise Open Learning Centre. Nathalie will set up a volunteer list using the Doodle tool. (A copy of this presentation is attached)

4. Update on new MED-AB forms

Carmen Ruiz, EBMT Central Registry Office, London, UK

A significant number of forms have been modified. The following have been updated and implemented, they are now on the EBMT Website:

- Acute Leukaemia
- Amyloidosis
- Plasma Cell Disorder including Multiple Myeloma
- Chronic Myeloid Leukaemia
- Chronic Lymphocytic Leukaemia
- Allograft & Autograft (**Note: since the meeting Lymphoma and Aplastic Anaemia have also been implemented*)

Because of changes to the Follow-ups, most forms have been, or will be, changed.

The following forms are to be updated shortly:

- MDS & MPS
- Solid Tumours
- *Aplastic Anaemia

Future MED-B changes currently under consideration:

- A funding proposal is underway for the CIBMTR to work on autoimmune forms.
- A page for Cord Blood to be included in the ALLOGRAFT form

- The Inherited Disorders form has been primarily designed for Immune Deficiencies; however the WP would like to implement more, for example Metabolic Diseases.

Shelley Hewerdine will keep Promise users updated on the Forms Modifications and the old codes will be kept as long as necessary. The Med-AB manual will highlight the new changes made on the forms & The Definitions Committee will review the revisions.

Carmen mentioned that a backlog of TBI forms was recently discovered in Seville and a temporary person has been employed to clear this backlog. She will check that this is being done. If there are any problems then the data should be sent to the Paris Office.

Discussions relating to the new MED-A form:

Further changes to the forms are currently being reviewed with the CIBMTR.

Virginie Chesnel, from the EBMT Data Office in Paris, asked if the Reduced Intensity Section on the Med-A form could be improved, as it is not being completed properly by the centres. Keiren Towlson added that there could also be problems with the Donor section, when there is a patient with multiple donors. Carmen agreed to change these sections of the form and to reorganize it according to the number of donors.

It was agreed that the HLA Antigen (Haploidentical) section needs to be clarified in the Manual. (We can also suggest that centres attach their lab results if they are not sure how to interpret the data). Marie Wilson (UK registry) agreed to help with definitions regarding antigens and allelic after checking with the Anthony Nolan Trust. Some text from the current manual on HLA (Emmanuelle Polge) could also be incorporated. A new MED-A draft form is attached showing all the proposed changes in a quick visual format. Carmen will review these changes with the CIBMTR as necessary.

There was a query on the unit dose for Carboplatin. Carmen explained that for the drugs there is a wider choice of unit measures in Promise, but paper form users will need to specify the unit in the margin if it is not given on the form, due to lack of space.

Donor Cell Infusion

Carmen Ruiz explained that she wants to remove 'donor' from the Cell Infusion Section because Cell Infusion can also be autologous. She proposed to change that section to insert a question: Donor or Autologous. Emmanuelle Polge, from the EBMT Data Office, noticed that it can be hard to identify Cell Infusion in the case of a Relapse. Carmen Ruiz explained that the only way to know is to look at the date of Cell Infusion and the date of relapse. It was agreed that there is a need for a disease dependent definition of treatment and that this section needs improvement and will be revised.

5. Follow-Up Procedures

Carmen Ruiz, EBMT Central Registry Office, London, UK

Carmen Ruiz presented some data on the current number of Follow-Ups being reported to the Registry by the centres. The EBMT Board has requested new measures to ensure an increase in the numbers of Follow-Ups on patients as the EBMT does not receive enough Follow-Up data.

There is a need for guidelines on how to collect Follow-Ups for all EBMT centres to ensure a more consistent gathering of data.

A number of National Registries already have their own guidelines and timelines to collect Follow-Up data. Carmen would like to introduce a Follow-Up Procedure to the Board that would be introduced to all centres as a minimum requirement.

We provisionally agreed on the following Guideline to be implemented:

- Annually for 10 years from the date of first Treatment
- Every 2 years for the next 10 years
- Then every 5 years

The Paris Office sends automated annual follow up requests to the centres. National Registries were asked if they would like the Paris Office to send requests on their behalf, or if they preferred to use their own system. It was agreed that the Paris office would send all follow up requests to centres without a national registry, plus France, Spain, Turkey & Italy.

There is still a query over the follow ups and study requests for The Netherlands, as a new registry manager not yet in post. (See point 6).

The Germany registry is using a data quality checking program (presented by Anja Siebinger to the RSC last year) which incorporates annual follow up requests. It has not yet been evaluated whether this has led to an improvement in the level of follow up reporting.

6. Any Other Business and News

VACANCY FOR A DATA MANAGER

Ronald Brand announced that there is a vacancy for a Data Manager for Ongoing Studies in the HOVON registry (Dutch national registry based in Leiden).

Anja Van Biezen is currently acting as an Interim and can be contacted if anyone would like to get more information about the post and pass on the information.

PROMISE

Keiren asked if the design of the Record Locator in Promise data entry could be altered slightly in order to distinguish exact or approximate dates. For example, the text for approximate dates could be in italics. Ronald agreed to work on this request.

DATA QUALITY COMMITTEE

We have discussed and agreed the need for the creation of a Data Quality Committee in the past RSC meetings. This would help automatize the data quality checks and ensure a uniform procedure is in place to check data quality. Once the group is created, its responsibility would be to create Standard Operating Procedures for Data Quality Checks.

Carmen Ruiz has made a request to the Board to create a new post for a Data Quality officer and is still waiting for some news. We will hopefully have more information on that issue at the next RSC Meeting, taking place at the 2008 Annual Meeting in Florence.

RSC Meeting in EBMT 2008 in Florence.

Our next meeting should take place on Sunday March 30th 2008, after 10am. The EBMT Central Registry will keep you informed on the exact time and content prior to the meeting.

NEXT AUTUMNAL RSC MEETING

Sandra Allgaier, from the German Registry, first proposed Ulm as a potential venue
Rosi Oneto, of the Italian Registry, also offered to host a future RSC Meeting in Genoa.

Actions arising from the EBMT

Registries Sub Committee Meeting

*26th October 2007
Basel, Switzerland*

Action	Person Involved	Due Date if applicable
<i>Draw up a Doodle poll for help in the Open Learning Centre</i>	<i>Nathalie Fortin-Robertson</i>	<i>January 2008</i>
<i>Change in Record Locator</i>	<i>Ronald Brand</i>	<i>TBC</i>
<i>Tissue Typing: How to record Antigen and Allelic mismatches</i>	<i>Marie Wilson to check with the Anthony Nolan Trust</i>	<i>January 2008</i>
<i>Creation of an Evaluation Questionnaire about the improved Data Management Programme to be handed at the End of the Annual Meeting in Florence</i>	<i>Shelley Hewardine</i>	<i>January 2008</i>
<i>Send Info to the Data Managers to Promote the Data Management Program and Forums</i>	<i>Shelley Hewardine</i>	<i>January 2008</i>
<i>Suggestions about the new EBMT Web Portal are welcome. Please send your ideas to Stephen Marcos Jones at the EBMT Secretariat Office.</i>	<i>Stephen Marcos Jones</i>	
<i>Submit the MED-A Forms changes to CIBMTR</i>	<i>Carmen Ruiz</i>	