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Hello!

We would like to welcome you to our EUMDS newsletter number 10.
To subscribe/cancel to the EUMDS Registry Newsletter, please send a mail to: j.droste@hemat.umcn.nl with the word "Subscribe" or "Cancel" in the subject line.

Send Your Suggestions

Is there anything you would like to see in the next newsletter? We would like to hear from you! Please contact us if you have any suggestions, questions, or comments concerning any of the topics described in this Newsletter and the Registry in general either by contacting the project management by emailing Jackie Droste at **j.droste@hemat.umcn.nl** or calling at **+31 24 3614794**.

Barcelona meeting

In Barcelona the yearly meeting of the operational team took place. During the presentations of Alex Smith (datamanagement and statistics York) and Mike van der Kolk (monitor of the EUMDS registry) everybody was reminded of accuracy in the database, like:

Investigator site file (ISF):

Keep up-to-date: screening and signature log, patient identification list, CV's and training log. And keep dates in ISF accordant with EUMDS database, as well as correspondence with ethical committee, if applicable.

Data collection:

1.Please use all relevant available data to complete the database. Results can be informative even if obtained prior to regular visits. Add medication that has been given to treat MDS (symptoms) to the **History of MDS** pages, with start and stop dates, with option of ongoing medication.

2. All blood transfusions prior to inclusion must be entered at the first visit. Not before diagnosis, because otherwise transfusions may be missed.

Please add concomitant medication to the General Medical History or Concomitant Treatment pages, with start and stop dates, with option of ongoing medication.

If clinically relevant medical treatment does not apply for any of the treatment categories, please add this to "Other" in the General Medical History or Concomitant Treatment pages.

3. If clinically relevant concomitant disease does not apply for any of the disease categories, please add this to "Other" in the Concomitant Disease page. Example: **hypertension.** Please enter blood parameters only taken at time of (or at the latest date before) diagnosis or follow up visits. If collection date is different from visit date, please add parameter and collection date in comment field below.

4. Please collect **iron parameters**, especially for patients who need transfusions and patients with RARS. Parameters erythropoetin, serum iron, iron binding capacity, ferritin (also before transfusions and iron chelation therapy). Please collect EQ-5D and health status (follow instructions: draw a line from black box through health scale), Karnofsky at any visit.

5. When patient is withdrawn, please collect relevant data, at least reason, but also number of transfusions and laboratory data before withdrawal.

Tricks and Tips Datacenter, York

We have nearly completed the second interim analysis on the first 800 included patients. Thanks to everyone for ensuring the data is of high quality. The analysis has highlighted some issues that we would like to share with you below:

1. Please make sure you complete each section of the database for each patient. For example if a patient has not received any blood transfusion it is important to record this in the red cell transfusion section. If you are unsure of what sections are incomplete for your patients please visit the report at www.eumds.org/EUMDS-Secure/reports/incompleteVisitSummary.aspx

2. If a test has not been done please record **-9** as a missing value code and **not** 0 or 1.

3. If a patient is receiving iron chelation therapy, please do not forget to recode the serum Ferritin

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value if available and, likewise, for blood transfusions the number of units received.
4. At follow-up visits for ongoing concomitant diseases and treatments, you need to enter 'YES', the date of the previous visit as the start date, and then 'ongoing' if the patient is still experiencing the disorder.
5. If you are entering a laboratory value and the database will not let you save the value, please contact us – do not enter the data into the comments field.
6. Be careful to ensure that laboratory data is entered with the correct units – you may need to convert the values yourself.
7. Any problems or queries please email us at eumds@york.ac.uk. Thank you, John & Alex (Data Management Team).

Organisation of Sweden

by Lotta Hartler Ahlin, national study coordinator Sweden.
The Swedish EU MDS Registry is progressing very well. Sweden has 17 sites involved in the study – 11 are active so far. It differs a lot between the sites what staff is involved. All centres have their own PI and some of them have a research nurse. In the Stockholm Karolinska site Eva Hellström-Lindberg is the PI (as well as the National PI for the whole registry) and Lotta Hartler Ahlin is the National study coordinator. Datamanagement,blood and bone marrow sampling are performed locally. All sites involved are university hospitals or central hospitals.

The Swedish sites are:
Eskilstuna, Göteborg, Halmstad, Karlstad, Linköping, Luleå, Lund, Malmö, Norrköping, Skövde, Stockholm Karolinska Huddinge and Solna, Stockholm St Görans hospital, Stockholm Södersjukhuset, Sundsvall, Umeå, Uppsala and Örebro.
We have included 79 patients so far, which is far above our target of 55. Denmark is now participating under the "flag" of Sweden and Denmark has included 2 patients so far.

I am planning a site visit to Umeå in the near future, as soon as there is an eligible patient to include. In addition I will make an appointment with the site of Karlstad. Then I have contacted all the sites who are able to participate. Some of the sites will not be participating for various reasons (previous PI has left).
The Nordic countries (Denmark, Finland, Iceland, Norway and Sweden) have an association called *"the Nordic MDS Group"*, of which Eva Hellström-Lindberg is the president and I am the secretary. The association has two annual conference meetings where participants from the Nordic countries meet and discuss MDS related matters such as studies, guidelines for classification and treatment e.g. During one of these meetings the European MDS-study was first brought up and interested sites were invited to participate.

In spite of ash clouds we had - the annual Nordic MDS spring meeting, the 16th of April at Arlanda. We spread the flyers on the EU MDS Registry and Eva showed some Swedish data from the registry that Alex had provided. The European MDS study is always a topic on the agenda at these meetings. The next Nordic MDS Group conference is scheduled in Stockholm, the 18-19th of November 2010.

Iron parameters

by Marius MacKenzie (Principal investigator Iron substudy) and Louise de Swart (Junior investigator Iron substudy).

In the EUMDS iron overload and iron toxicity is one of the main problems in patients with MDS, particularly when they are transfusion-dependent. Therefore, the issue of iron overload is subject of the EUMDS Iron substudy to focus on the pathophysiology and long-term consequences of iron overload. To establish the iron overload the serum iron parameters have to be recorded at baseline and at regular intervals during follow-up.

At the second interim analysis it was obvious that in many patients the iron parameters were missing in the EUMDS database. This applied not only for

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the serum ferritin level an serum iron level, but particularly for the iron binding capacity and the erythropoietin level. It is important to measure the serum ferritin levels at regular intervals, especially in patients with frequent blood transfusions. At baseline, the other iron parameters have to be recorded as well, including the serum iron, total iron binding capacity and the erythropoietin level. In several participating centers the transferrin levels are determined instead of the total iron binding capacity and different units are used for the iron binding capacity and transferrin level. In that case the units have to be converted to the units required in the EUMDS database.

In the Radboud University Medical Center, we determine the total iron binding capacity (TIBC) in µmol/L with a normal range of 45-80 µmol/L. When you want to enter the TIBC in mg/dL you have to convert to transferrin.
The formula is: TIBC (µmol/L) = 25 * transferrin (g/L), e.g. 50 µmol/L TIBC = 2 g/L transferrin = 200 mg/dL transferrin. This makes the normal range for transferrin in our laboratory 180-320 mg/dL. Due to a problem with the permitted range (0 – 0.056 mg/dL) in the EUMDS database, iron binding capacity cannot be entered in mg/dL. At the moment the problem is being looked at, but it is not possible to resolve it on short term. If your center determines the iron binding capacity/transferrin level in mg/dL, please convert it to TIBC in µmol/L. E.g. 200 mg/dL transferrin = 2 g/L transferrin = 2 g/L transferrin * 25 = 50 µmol/L TIBC.

We kindly ask all centers to assess the required iron parameters at baseline and record them in the database. For all patients good follow-up with serum ferritin levels at regular intervals is mandatory to determine the occurrence of iron overload. If there are any remaining questions, please do not hesitate to contact project management.

Abstracts ASH

For the ASH Congress in December abstracts are submitted with results of the second interim analysis.
The next abtracts are submitted:
"The Population-Based 'real world' of Low Risk Myelodysplastic Syndromes; Second Interim Analysis of the European LeukemiaNet MDS Registry at 800 Registered New Patients", by David Bowen.
"Disease-Management of Low- and Intermediate-1 Risk Myelodysplastic Syndromes: Report on 800 Newly Diagnosed MDS Patients From the European LeukemiaNet MDS Registry" by Louise de Swart.
"*Health-Related Quality of Life In Newly Diagnosed Low Risk and Intermediate-1 Risk MDS: Report on the First 683 Patients From the European LeukemiaNet Registry"* by Reinhard Stauder.

New countries

We gladly welcome Denmark (under the flag of Sweden), Portugal (under the flag of Spain) and Poland as new countries in our EU MDS Registry.

Accrual

We have reached the target of 800 patients for the second interim analysis! We would like to thank everybody for their contribution sofar. Now we are heading for the next target, which is set on 1000 patients by the end of 2010. At the moment 879 patients are included by 110 different sites.

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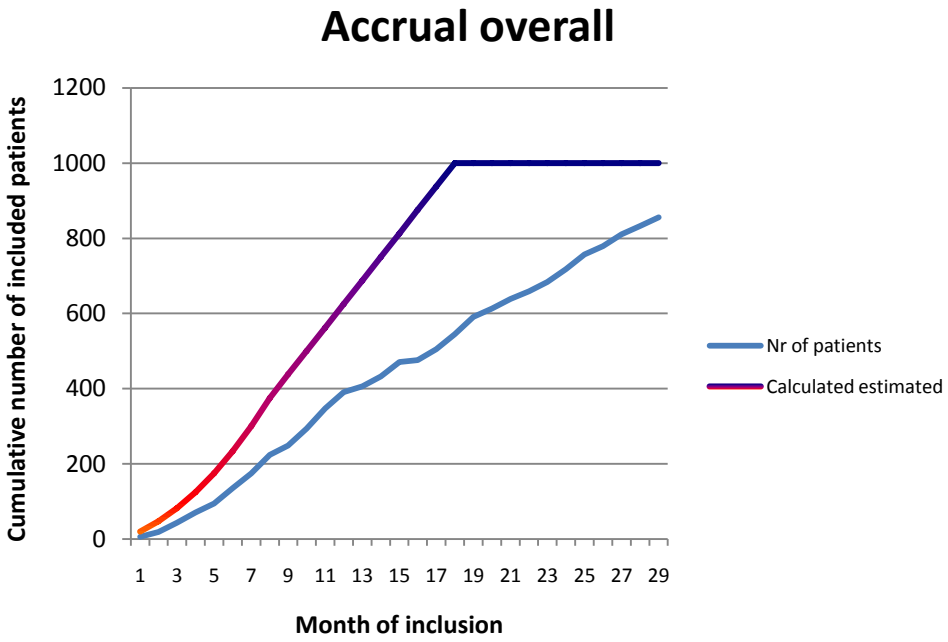

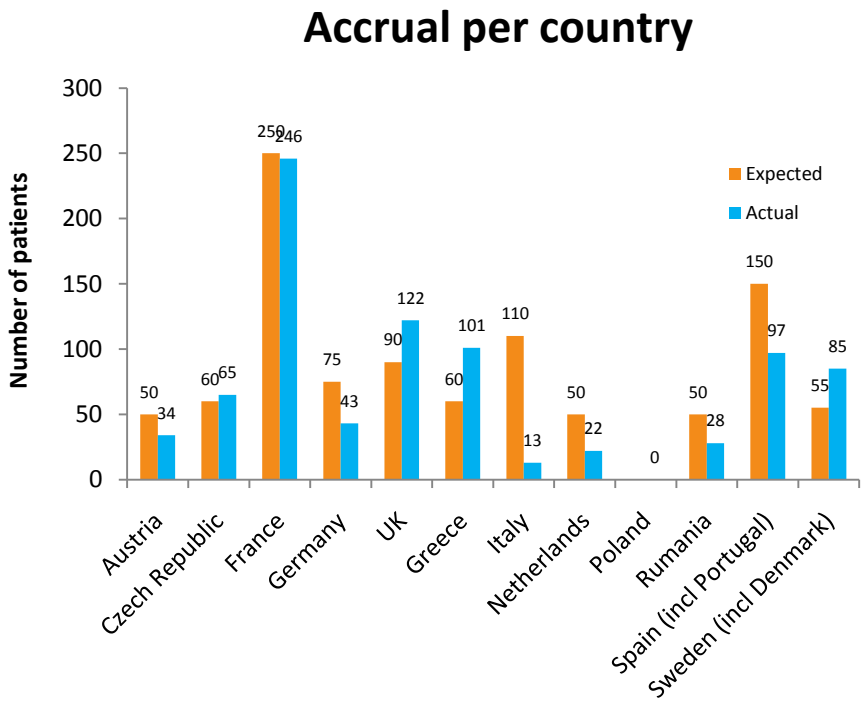

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The next steering committee meeting is scheduled in December at ASH. The next operational team meeting is scheduled in Mannheim in the beginning of February 2011.