September 2013
Issue No 11

EUMDS Registry Newsletter

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Hello!

We would like to welcome you to our EUMDS newsletter number 11.
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**.

Participating countries

Much has changed since our previous newsletter.
Already 17 countries are participating in the EUMDS registry:
Austria, Czech Republic, Denmark, France, Germany, Greece, Israel, Italy, the Netherlands, Poland, Portugal, Republic of Serbia, Romania, Spain, Sweden, United Kingdom and Croatia has started as a new country recently.
In total 128 sites included at least one patient.

Accrual

We have reached the target of 1500 included patients. We would like to thank everybody for their ongoing contribution. Now we are heading for the next target, which is set at 2000 patients.

Furthermore at the moment 4440 visits (initial and follow-up) have been registered in the database.

Stockholm meeting

During the EHA congress in Stockholm a steering committee meeting took place the 13th of June.
The main topics which were discussed:

- A new website has been developed with a public part which is accessible for everybody and which will contain abstracts, publications, newsletters etc. As soon as this website will go live you will receive a message
- Monitor findings have been presented and discussed, see next topic in this newsletter
- Progress and planning of publications/projects
- Sample collection

Substudies

The following substudies are at different stages of analysis. The abstracts, posters, publications will be published at the EUMDS website:

- **ESA analysis**: European distribution of usage and impact on outcome for treatment with erythropoietic stimulating agents within the EUMDS lower-risk registry programme.
- **QoL**: A longitudinal observational study on the health-related quality of life in IPSS low-risk MDS - impact of time course and transfusion need
- **Cytomorphologic substudy**
  Cytomorphologic substudy within the ELN low/int1 risk MDS Registry project
- **Iron Substudy:** Pathophysiology of Iron accumulation in Patients with Low and Int-1 Risk MDS - A substudy of the ELN MDS low and INT-1 registry
- **Cytopenia:** Prognostic relevance of the kinetics of worsening of cytopenias in lower-risk MDS: a substudy from the European Leukemia Net low risk MDS (EUMDS) registry
- **Iron Chelation substudy:** Matched set cohort study of 300 patients within the EUMDS registry
- **Diabetes substudy**: The impact of Diabetes Mellitus as a comorbid condition in the diagnosis and the course of the disease of patients with Low/Intermediate-1 risk MDS

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- **Fibrosis substudy:** Analogous to the cytomorphologic substuty central review of of the biopsies.

Sample collection

Agreed upon by the steering committee starting immediately:
NO MORE COLLECTION OF URINE SAMPLES

Proposed to the steering committee and waiting for approval:

For all new included patients:

- Extra serum sampling only at screening for future research
- 2 EDTA-blood tubes (each 7 ml) for molecular analyses at screening (protocol and patient information will be adapted), whole blood can be frozen immediately without any handling

For already included patients:

- Only if it is feasible for all included patients from a specific site: 2 EDTA-blood tubes (each 7 ml) at next visit or blank BM smears of screening visit.

New Monitor

As some of you already know, since the beginning of this year a new monitor joined the EUMDS team, Carla Janssen.
She will visit countries/sites to check the quality of the Investigator site file, data entered in database.
Main issues she found so far:

- One of the visited sites stopped collecting data after 2 years of follow-up. Further research revealed that this was happening in several sites. Follow-up period at the moment is 5 years for the first cohort of 1000 patients. Each country has a contract for this follow-up period.
- In some countries/sites, data entry is only performed 2 or 3 times annually. This means that in some countries only twice a year a data manager enters data for all patients. Therefore there is a backlog in data entry. Proposal: to increase the interval between data entry to 4/5 times a year to reduce the number of overdue visits.
- Sometimes warnings are not cleared. Reminder will be sent out once every 2 months.
- Data entry errors from source on datasheets and from datasheets into database
- Lab data have not been collected and/or reported
- QoL Questionnaires have not collected/ entered in the database
- Database is very slow It will be checked whether is possible to speed up the database

We would like you to read carefully the main issues and pay attention to these items in your country or at your site.

Abstract ASH

For the next ASH in December the following abstract has been submitted:

Validation of the Revised International Prognostic Scoring System (R-IPSS) in 1000 newly diagnosed MDS patients with low- and intermediate-1 risk MDS in the European LeukemiaNet MDS (EUMDS) registry

Publications

The first full paper on the EUMDS Registry will be submitted for publication before the end of 2013. The main topics are: demographics of the first 1,000 patients, the contribution of the revised IPSS and the new cytogenetic classification on prognosis, and the impact of transfusion dependency at diagnosis (first 6 months) on outcome. This analysis formed the basis of the abstract which is, submitted to ASH (see previous item). For full abstract , see website of EUMDS.
The final analysis of transfusion study, including time dependant analysis, will be completed in the next few months leading to submission of the second full publication of the EUMDS Registry. At the same time the ESA (erythropoietin stimulating agents) analysis will be completed and finalized into the third full publication.

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New countries

We gladly welcome Croatia as new country in our EUMDS Registry.

Meetings

The operational team meeting is scheduled the 1st of October in Paris. The next steering committee meeting will be during the LeukemiaNet Meeting in Mannheim February 2014.

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