Newsletter **European MDS Registry**
April 2014, Issue No 12

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Hello!

It has been some time since the last newsletter, so we are happy to present you our EUMDS newsletter number 12.

As some of you already know, since the beginning of this year Jackie Droste has passed her tasks as Project Manager for the EUMDS on to her successor, Corine van Marrewijk. We would like to say special thanks to Jackie for all her contributions to the EUMDS Registry and wish her good luck in her work as General Head of the Trial coordination and Data office at the department of Haematology of the Radboudumc.

We would like to welcome Corine van Marrewijk to the EUMDS team. She is a Biomedical Health Scientist (major in epidemiology) with a PhD in Medical Science. She will perform her work under the supervision of Jackie.

We would also like to welcome all other new members who joined the EUMDS team as well and thank all members who have left for their contributions and hard work.

Accrual

Currently, over 1620 patient and 6800 visits (initial and follow-up) have been registered in the EUMDS registry. With an inclusion rate of 100 patients in the half year since the last newsletter, we are nicely heading to the next target of 2000 patients. We would like to thank everybody for their ongoing contribution. Keep up the good work!

Mannheim meeting

During the 11th Annual symposium of the European LeukemiaNet in Mannheim, a steering committee meeting took place on February 4th.

The main topics which were discussed:

- The molecular sub study (TRIAGE-MDS) was presented, and feasibility of sample collection was discussed.
- Progress of New contract
- Amendments of the study protocol to include molecular analyses and agreements of the new contract. We will elaborate on this in the next newsletter.
- Progress of Demographics paper (see publications)
- Horizon2020 application (see below)
- Progress and planning of publications/projects

Sub studies

The following new sub studies have been proposed and added since the last newsletter:

- **Molecular (TRIAGE-MDS):** Identification and biological classification of genetic mutations in MDS using next generation sequencing in 1000 patients and correlation of genetic mutations to clinical parameters
- **MDS and solid tumors:** Association between MDS and solid tumours within the EUMDS Registry
- **del5q lenalidomide:** Clinical effectiveness and utility data for lenalidomide therapy in IPSS Low/INT-1 patients with del(5q) within the EUMDS Registry
- **QoI and geriatrics:** QoI sub study has been extended to include geriatric assessments

Horizon2020 application

In March, a first stage research proposal entitled: *'Providing the right care to the right patient with **M**yelo**D**ysplastic **S**yndrome at the right time (MDS-RIGHT)'* has been submitted for a Horizon2020 grant on behalf of the EUMDS Registry. The specific challenge and scope of the call topic: *'Comparing the effectiveness of existing healthcare interventions in the elderly'* closely fit the possibilities of our well established registry. The decision whether we may continue the application for the second stage is expected mid-May.

Database: points of attention

The quality of the entered data is generally high, however, we would like to bring to your attention a few data entry aspects to improve the quality of the database even further.

- If cytogenetics have been performed, it is important that this is recorded according to the revised IPSS in the section: Bone Marrow Assessment. An example is given at the end of this newsletter.
- If a laboratory test has not been performed or the results are not known, please use the missing value code (-9) instead of entering zero. This can be done easily by either double clicking the box or typing in -9.
- Medical history as well as all relevant concomitant diseases and treatments should be entered in the sections: '*General Medical History and Concomitant Diseases*' and '*Concomitant Treatment for Concomitant Diseases*' respectively for a screening visit and in: '*New Concomitant Disease*' and '*Concomitant Treatment for Concomitant Diseases*' for each follow-up visit. We have noticed that ***New*** in '*New Concomitant Disease*' is somewhat confusing, as ***all*** concomitant disease and treatment present at the time of the visit should be entered here, including those that are indicated as ongoing at the previous visit. In general, the date of the last visit is automatically set as start date for such an ongoing disease or treatment. In some cases, e.g. when the disease or treatment started before 1970, the date is not entered automatically. Please check ongoing disease or treatments carefully and if necessary entre the date of the previous visit manually.
- Last year the focus of the monitor was set on reducing the number of database warnings. Whenever data entered into the database is outside the limits of the expected range of values a 'database warning' is created. For example, this is often the case with lab data. If lab data create a warning, please also check the unit entered. At most sites the database warnings are not an issue anymore. However, please continue to clear warnings on a regular basis, take the time to walk through these warnings to clear/approve them. This will help to improve the data quality.
- This year the focus of the monitor will be on visits (over)due. Regular evaluation and entry of visits, at least every 3 months, is advised.

Please pay attention to these issues in your country or at your site. Once every 3 months, warnings and visits (over)due are monitored and reminders will be sent.

Whom to contact when

Due to the start of the new project manager, there are some changes in contact information. Therefore, you find a summary of whom to contact when below.

Whenever you have a question or experience a problem with the Database, please check the data manuals and frequently asked questions (FAQ) section on the www.eumds.org website first, as information on many issues can be found here. You can also contact the Data Management in York (CDMSU) by sending an e-mail with your question, remark or suggestions to: eumds@ecsg.york.ac.uk. They are happy to assist you.

For local site coordinators or members of the local teams: you can direct you questions, e.g. on eligibility, financial or practical issues, to your Country Coordinator or Principal Investigator of your country. They are aware of all agreements within your country and in general will be able to assist you. If not, they will contact the Project Management to discuss the issue.

Whenever there is a change in personnel responsible for the EUMDS registry within your team, you should inform your Country Coordinator. The Country Coordinator will inform Project Management, who will arrange the creation and authorisation as well as shut down of EUMDS accounts with the CDMSU. You will need to register for this account yourself at the EUMDS-website after a message from the Project Management.

If there is anything you would like to see in the next newsletter or when you have questions or remarks regarding the protocol or the Registry in general you can address these to the Project Management You can send your suggestion, contribution, comment concerning the newsletter, or general questions and remarks to: Corine.vanMarrewijk@radboudumc.nl or call at +31 24 3614794.

New ideas or proposals, or protocol amendments should be addressed to the sponsor via the project management (see details above).

Patients should address their questions to their treating physician.

Abstracts and Posters

- An abstract entitled: *Assessment of quality of life – a comparison of a German reference population, a cohort from an Innsbruck senior fair and MDS-patients* has been submitted to the Spring meeting of the Austrian Society of Hematology, April 2014 in Innsbruck by prof. Stauder.
- At the ASH in December 2013 Louise de Swart presented a poster entitled: *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 has been submitted to Journal of Clinical Oncology. It describes the 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.

The ESA (erythropoietin stimulating agents) analyses have been updated recently and the manuscript is being finalized for review by the co-authors.

The analyses of the transfusion and cytomorphology sub studies are in the final stage and submission is planned during the summer 2014

Meetings

The next steering committee meeting will take place on June 12th 2014 during the EHA Meeting in Milan.

The operational team meeting is scheduled in conjunction with the ELN Frontiers meeting in Berlin half October 2014.

Participating countries

The 17 countries participating in the EUMDS registry are:

Austria, Croatia, Czech Republic, Denmark, France, Germany, Greece, Israel, Italy, the Netherlands, Poland, Portugal, Republic of Serbia, Romania, Spain, Sweden, United Kingdom.

In total 134 sites included at least one patient.