Newsletter European MDS Registry

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Table of contents

From the chairman

This newsletter of the EUMDS registry contains some exciting new developments.

You will read about the newly obtained MDS-RIGHT project, updates of the database, sample collection, new criteria for including MDS-patients, and some future plans.

When you read this newsletter we will have (almost) reached the milestone of the 2.000th patient registered in our data base. We will continue to register newly diagnosed MDS patients and we will extend the Registry to high-risk MDS patients. We are actively seeking new partners to support your contributions to our studies and projects.

Thank you for taking the time to read this information. We appreciate your continuous effort in this project. From principal investigator to monitor, and from research nurse to assistant: all our efforts are crucial to the success of the EUMDS-registry.

THANK you for your involvement!

Prof. Dr. Theo de Witte

Accrual

Currently, 1993 patients from 17 countries and 9277 visits (initial and follow-up) have been registered in the EUMDS registry. We are positive that the target of 2000 patients before the end of 2015 will be reached. The next target is registration of 2500 low-risk MDS patients.

We would like to thank you for your ongoing efforts to make the EUMDS registry a success! Keep up the good work!

Database updates

In 2015, two important changes have been made to the database. As of May 26th, data of ***cytogenetic assessment at diagnosis is required*** to be entered in the database for all new patients registered in the EUMDS Registry. In case cytogenetic assessment at diagnosis fails, a patient will only be eligible if cytogenetic results of a repeated assessment within 6 months of diagnosis are entered. Previously registered patients do not necessarily require a cytogenetic assessment as agreed before.

Secondly, changes have been made in the EUMDS Registry database regarding the ***visits due/overdue flags***. We noticed that the large majority of the visits are reported shortly after the actual 6 months visit, variation in clinical visits and time needed to enter the data in the database taken into account. Therefore, the project team has discussed that change of the warning intervals will give a more realistic overview of the actual visits due or overdue in the 'Visits due/overdue' summaries. In comparison to before, visits will now be flagged ***due*** after 6 months instead of after 5 months, and ***overdue*** after 350 days (11.5 months) instead of 180 days (6 months). This change is solely made for administrative purposes. The follow-up interval of 6 months remains unchanged in the protocol. So, patients should still visit the hospital twice a year. ***Please also continue reporting the visits on a 6-monthly interval and do not wait for the overdue warning***.

Update of the protocol

The combined efforts of all EUMDS participants have made the EUMDS registry a valuable source of data on low-risk MDS across Europe and Israel. To maintain the high standard of the database and to follow developments in MDS, the EUMDS protocol (version 2.2) is currently being amended. The main modifications include:

- ***Increased recruitment target (> 2000)***
- ***Extended follow-up (> 5 years)***
- ***Addition of molecular analyses***
- ***Inclusion of high-risk MDS patients***

The aim is to have the final version of the new protocol, patient information & informed consent, and the CRFs approved by the Steering Committee at their next meeting in Mannheim in February 2016.

After approval by local, regional or national Health authorities or Ethics Committees, the new protocol will be formally effective. More detailed information regarding the implementation will follow.

Samples for molecular research

Increasing knowledge of MDS and rapid progression in science show that genetic research is important for furthering the understanding of MDS and it's treatment options. Until now, participating sites (might) have collected additional serum *(and in the early years also urine)* samples for the EUMDS registry study (protocol version 2.2). Since samples for molecular analysis are not part of the current protocol, this is one of the major amendments in the EUMDS protocol. After approval by the authorities the amended protocol will be implemented for all newly registered *(=prospective)* patients. However, for already included (=retrospective) patients we can only rely on samples taken during regular diagnostic procedures for use in molecular research. Therefore, we aim to retrieve clinical samples taken during regular diagnostic procedures that are stored at sites participating in EUMDS, which might be made available to the registry, after re-consent is given by the patient. We would like to ask you for your help to retrieve these samples. Therefore, you will be contacted by the OT-members of your country soon (some countries have already responded positive and the first batch of retrieved samples will soon be transported to the Netherlands).

MDS-RIGHT

In the previous newsletter several sub studies using the EUMDS registry data were brought to your attention. Here, we would like to highlight the MDS-RIGHT project. This project has been granted 6 million euro's from the Horizon2020 program in a call titled '*Comparing the effectiveness of existing healthcare interventions in the elderly*' and was one of the very few projects that were successfully submitted.

MDS-RIGHT is an acronym for '*Providing the right care to the right patient with Myeolodysplastic Syndrome at the right time*'. The overall goal of MDS-RIGHT is to evaluate and compare the efficacy of existing healthcare interventions in lower-risk MDS patients across 16 European countries and Israel. The EUMDS registry forms the backbone of this project, providing data on existing healthcare interventions.

Several research questions will be addressed, related to comparison of existing health care interventions, introduction of new diagnostic tools, optimization of HRQoL and developing outcome prediction models. The outcome of the different work packages will serve as basis for new evidence-based MDS guidelines. Moreover, an European MDS competence network will be established to share information on MDS. An interactive platform website for researchers, health care providers, institutions and last but not least: patients is under development. We will keep you updated!