

## EUMDS Registry Newsletter



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**Hello!**

We would like to welcome you to our EUMDS newsletter number 9.

To subscribe/cancel to the EUMDS Registry Newsletter, please send a mail to:

[j.droste@hemat.umcn.nl](mailto: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 emailing Jackie Droste at

[j.droste@hemat.umcn.nl](mailto:j.droste@hemat.umcn.nl) or calling at +31 24 3614794.

**Interim analysis iron parameters**

Feedback from the base line report on first 400 registered patients: where do we stand with the iron parameters?

The registry reported the demographic data of the first 400 registered patients with a median follow up of 177 days during the Investigators meeting in September 2009. Reporting was almost complete for the standard parameters such as morphology, cytogenetics (93%) and the general demographics. Also reporting of important quality items was excellent: Karnofsky (85%), EQ 5D (82%), and Sorrow Score of Co-morbidity was well reported with a mean score varying from 1.5 to 3.0 in various registries.

However, reporting of the iron status at diagnosis was less complete. The serum iron level was reported in 240 patients, the transferrin saturation level in 107 patients only, and the ferritin levels in 289 patients. We need both the serum iron levels and the total iron binding capacity to calculate the percentage of transferrin saturation. The total iron binding capacity (TIBC) can be estimated by adding the serum iron level to the measured unsaturated iron binding capacity. Please, do not

hesitate to contact us if you have any questions concerning this point.

This interim analysis shows that we are able to collect detailed demographic data in the registries eleven different countries: a very gratifying result.

However, we would like to encourage you to monitor the iron status at regular intervals, because the iron status forms an integral part of the monitoring of the sequelae of the transfusions which most of our patients will receive ultimately.

Moreover the iron study has been approved by Novartis and this study will be opened before the end of the year.

Theo de Witte & Jackie Droste

**Organisation of Germany**

In Germany currently five centres are participating in the EU MDS Registry project, namely the University hospitals of Dresden, Düsseldorf, Freiburg and Ulm as well as the St. Johannes Hospital in Duisburg. In Dresden the EU MDS team consists of PD Dr. Uwe Platzbecker, Ines Böde and Annett Haake. Prof. Dr. Michael Lübbert and Dr. Anna Kristina Reuland are working on the project in Freiburg. In Ulm Dr. Richard Schlenk and Carina Morlok and in Duisburg PD Dr. Aristoteles Giagounidis and Vera Lohrbacher are collecting the data. The team in Düsseldorf is composed of Prof. Dr. Ulrich Germing (Principal Investigator and me, Verena Heymann (Country Coordinator and Datamanager). In September Wiebke Martsch joined the team in Düsseldorf and will work as a datamanager. All data are sent to Düsseldorf, where we enter the data of all German sites into the database. Actual 29 patients are included in the EU MDS Registry project in Germany.

In Düsseldorf information about potential new patients are provided to the datamanagers by Prof. Germing. After the inclusion criteria are checked and the patient is eligible we inform the patient about the study and ask for signing the written consent. If the patient agrees in participating, we document his/her data and enter it into the database. We hope to increase the number of

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included patients in the future by closer cooperation with private care haematologists, as these see the vast majority of low and intermediate-1 MDS patients.

Verena Heymann  
 MDS-Studiensekretariat  
 Klinik für Hämatologie, Onkologie und klinische Immunologie  
 Universitätsklinikum Düsseldorf

**SAEs**

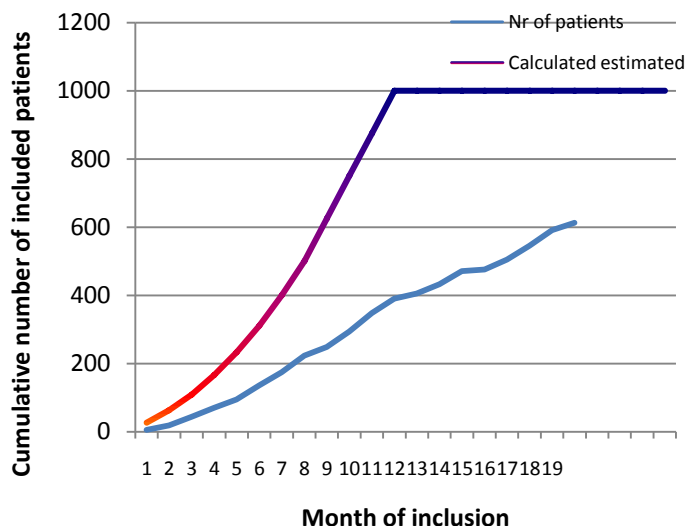
The EUMDS registry of MDS patients of IPSS low and INT-1 does not stipulate treatments for MDS nor for iron overload. Nevertheless data are collected by the registry and the upcoming iron substudy with laboratory evaluations of parameters specific for iron accumulation pathophysiology. Therefore, the registry and the substudy do not collect detailed information about iron chelation medicines' safety nor for the other drugs patients will be taking for treatment of their MDS conditions. However, if during the conduct of the study the investigator becomes aware of the occurrence, in patients receiving the chelation drug, deferasirox (Exjade®), or any other MDS specific drug, of an adverse reaction related/suspected to be related to this drug, the investigator is encouraged and advised to follow the standard reporting procedure for AEs for marketed products as specified in the

Exjade® prescription / patient information sheet or any other specific reporting procedures for AEs.

**Accrual**

At the moment 613 patients are included by 99 sites. Already 575 follow-up visits have been performed and entered in the database.

**Accrual overall**



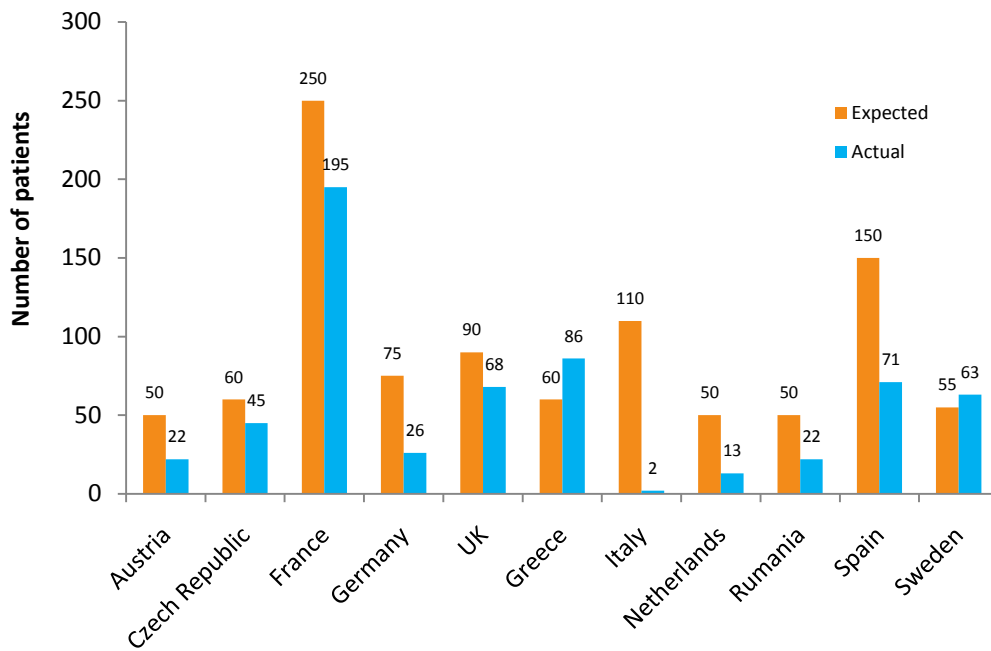
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**Accrual per country**



**Meetings**

The next operational team meeting and the next steering committee meeting will be scheduled during the "7th Annual Symposium of the "European LeukemiaNet" in Mannheim which will be February 1<sup>st</sup> 2010 until the February the 3<sup>rd</sup>

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