

EUMDS Registry Newsletter



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**Hello!**

We would like to welcome you to our EUMDS newsletter number 6.

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.

**Follow-up visit**

Some confusion has risen concerning the follow-up visits and especially the first follow-up visit.

The database follows the protocol:

"Data on patients with low or intermediate-1 risk MDS will be collected prospectively at diagnosis and at 6-months intervals after diagnosis."

This means that the the first follow-up report usually occurs earlier than 6 months after registration.

**Sub-studies**

As you all will probably know several sub-studies will be performed.

We would like to invite each participating site to let us know whether the site is interested in participating in the several sub-studies.

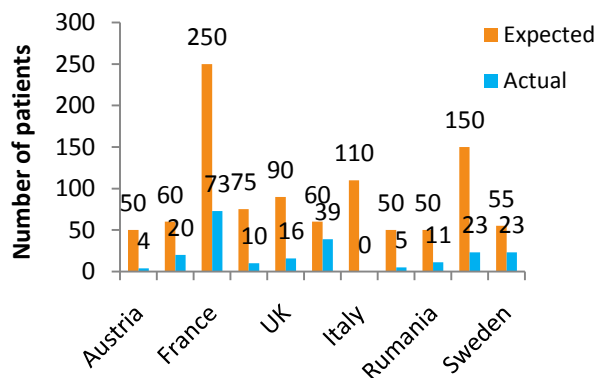
1. Iron pathophysiology sub-study
2. Quality of Life sub-study
3. Central Morphology sub-study
4. Cardiac-evaluation sub-study
5. Protein profile substudy

Please see attached document and please fill in document and return it to the project management of the registry

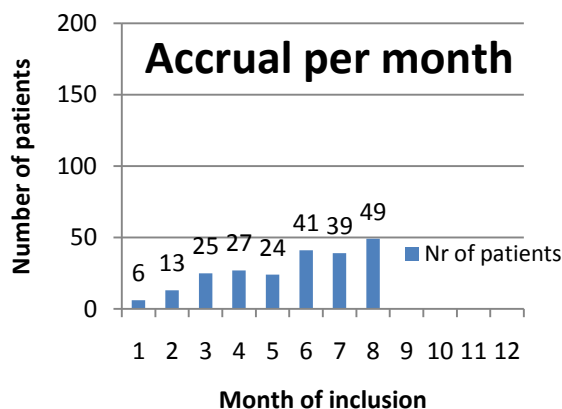
[j.droste@hemat.umcn.nl](mailto:j.droste@hemat.umcn.nl)

**Accrual**

**Accrual per country**



**Accrual per month**



At the end of November 224 patients have been included in the database. Although the accrual shows a slight rise, most registries include fewer patients than expected. We would like to invite all people to reflect on the possible causes and solutions and send their thought to [j.droste@hemat.umcn.nl](mailto:j.droste@hemat.umcn.nl)

Furthermore if you need any help, do not hesitate to contact your referral centre or the project management.

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## Meetings

The next Steering Committee meeting will be the 3<sup>rd</sup> of February 2009 08.00-10.30 CET in Mannheim.

The next Operational Team meeting will also be in Mannheim the 2<sup>nd</sup> of February 2009, 17.00-19.00 CET.

## Organisation of Austria

At the moment there are two centres which include patients into the EUMDS Registry in Austria, namely the Medical University Innsbruck and the Hanusch Hospital in Vienna. Both locations have their own team collecting and entering their data. In addition, both are responsible for their own informed consent procedure. If the team in Hanusch Hospital does have any problems concerning the registry, however, Innsbruck forms the first contact person. The team in Vienna consists of Dr. Pfeilstöcker and Dr. Anabel Makrai. At the moment, they have one patient active, which was included in June 2008. In Innsbruck, Reinhard Stauder and me, Renate Hofer, are working on the project. We have up to now entered three patients into the registry. The procedure of the inclusion of a new patient is as follows: Dr. Stauder and I, we get to know of new MDS patients either from the laboratory of haematology, that informs us, whenever a new case of MDS occurs, or the new patient is hospitalised and treated by Dr. Stauder himself. To decide if the patient meets the inclusion criteria, I investigate the case history. A consultation-hour, specialised in MDS was established to take care of MDS-patients, to plan and apply therapies and to control blood pictures. Patients from this MDS-consultation are checked for inclusion in the MDS-registry. After obtaining the signed informed consent, the patient will be included onto the registry. We hope that in the future, there are more

patients that meet the inclusion criteria in order to achieve our target of 50 patients.

Renate Hofer – ELN Registry Coordinator  
 Division of Haematology and Oncology  
 Department of Internal Medicine  
 Innsbruck Medical University

## First Monitor Visit

In November the first monitor visits were performed in 3 different sites.

In all sites the investigator site file was set-up and maintained correctly (except for laboratory certificates). Of most patients an informed consent was filed.

A striking result was that in all visited centres, data of patients were registered without informed consent.

More detailed information will be sent to the centres monitored.

## 2009

The project team in Nijmegen wishes you a Happy New Year and a fruitful continuation of our ambitious project.

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