

EUMDS Registry Newsletter



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**Hello!**

We would like to welcome you to our EUMDS newsletter number 7.

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**

In the database 375 patients have been registered at the moment. We are approaching the first 400 patients, which means that the first interim analysis can be performed.

To be able to do this analysis, the patient data need to be as complete as possible.

**Please check your data! Also check your warnings and solve or answer these questions!**

**Database**

We would like to remind you to the frequently asked questions (FAQ) page at the EUMDS.org website. Here you can find questions and answers that have been asked by several people.

**Sub-studies**

The contract proposal for the substudies is on the desk of Novartis. We expect to have received the final reaction before the next newsletter.

**Inclusion period**

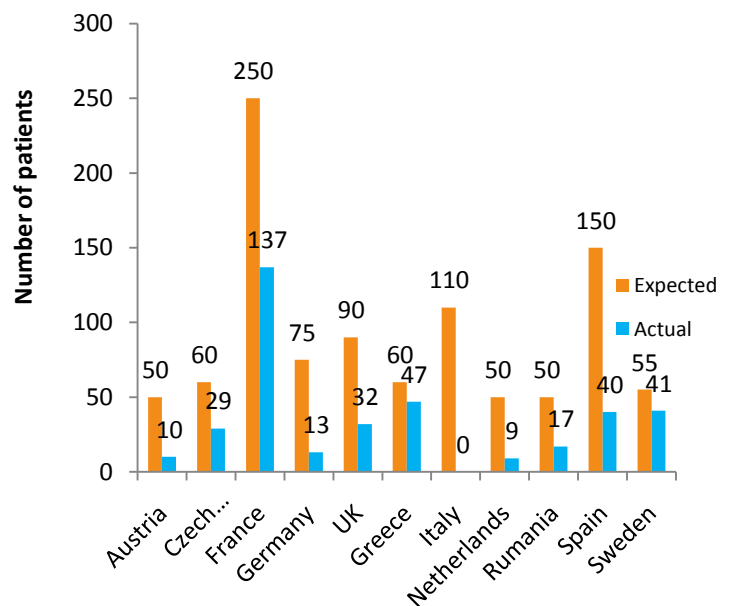
Although the inclusion is going well, we did not succeed in an accrual of 1000 patients in one year. Novartis will probably support us to extend the

inclusion period with 1 year to be able to include 1000 patients.

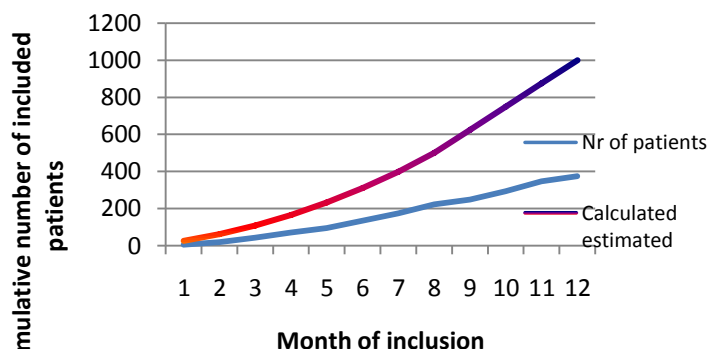
**Accrual**

At the moment 375 patients are included by 73 sites.

**Accrual per country**



**Accrual overall**



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We made an inventory at the referral sites. We asked them to think about possible reasons for the lower than expected accrual and also to mail us suggestions to increase the accrual. The main findings are:

- Not all sites are open yet
- In some countries not all patients are referred to participating sites
- Regular contact between the referral site (coordinator) and other sites is essential. To keep the sites informed and to offer assistance.
- The frequency of the contact between the referral site and other sites varies between weekly to once every 2 months.

The main suggestions are:

- Organise meeting/teleconference with participating sites in your country
- Regularly contact between referral site and other sites at least once a month
- Circulate a monthly newsletter within own country by referral site to try to motivate and encourage the people involved in the registry

### Follow up visits

As the inclusion of the registry started almost a year ago, the first follow up visits have been performed already. Please be aware that a follow up visit may be scheduled 6 months after diagnosis.

At the moment 173 follow up visits have been performed.

### Meetings

The next Steering Committee meeting will be the 6<sup>th</sup> of May 2009 16.00-18.00 CET in Patras, Greece.

The next Operational Team meeting will be scheduled in June.

### Organisation of Greece

The concept of generation of a National Bone Marrow Failure Syndromes' Registry was first proposed in Greece in 1997. In that period the

**Hellenic MDS and Bone Marrow Failure Study Group**, which is a Scientific Group functioning under the authority of **Hellenic Hematology Association**, adopted the idea of such a registry.

This concept was initially introduced by Dr. A. Symeonidis, and consisted of Word-type forms, which were completed, collected and entered into in a database. The Registry was named: **Hellenic National Registry of Myelodysplastic and Hypoplastic Syndromes** (acronym in Greek: EAKMYS). The first patient was registered early 1998 on paper CRFs. The result of this first attempt was presented at Hellenic congress of hematology in 2000; at that moment only 210 patients were registered. Because of the difficulties of completing paper CRFs, in the year 2002, a Web-based electronic database was constructed, which was uploaded in a server working at the Department of Computer Engineering of the University of Patras, aiming to facilitate faster (electronic) patient registration.

Because of bureaucratic reasons and of course a lot of discussions between members of Hellenic Society of Hematology to set up correctly the site, the start of working with the eCRFs was delayed. When these problems were solved, finally the EAKMYS started and the first patient with MDS was registered electronically in Greece on April 2007.

Today **EAKMYS** is under the supervision of Professor Argiris Symeonidis and is a Web-based network of CRFs, addressed to Greek specialist haematologists, who are able to online register and record complete data of patients with an MDS, as well as hypoplastic syndrome, treated in 34 hospitals and Haematological Departments of the country. The collected data include epidemiology, classification, clinically and laboratory data, prognosis, treatment approaches and the course and evolution of the disease.

After one year intensive work, by the end of 2008 almost 1300 patients from 34 different hospitals diagnosed since 1995 had been recorded in **EAKMYS**.

Concerning EUMDS Registry, in Greece at the moment 47 patients are included from 10 different sites, while 14 sites are ready. The initial target for

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Greece was 60 patients, which means that 78 % are included.

## Collection of data:

The Principal Investigator of every site is responsible for collecting data and all procedures such as informed consent. We developed a paper form, where all the data can be noted according to the protocol. Subsequently the completed form is faxed or emailed to the University Hospital of Patras to Dr. Tavernarakis, Dr Tavernarakis is responsible for entering data in EUMDS-Registry network. The good Greek results in the EUMDS registry are a responsibility of all the PIs of the sites and with this article I would like to thank them for their help and participation and for success of the study.

Finally I would take the opportunity with this newsletter to thank Professor Nickolaos Zoumbos (Director of Hematology Division, University hospital of Patras) and Professor Argiris Symeonidis for giving me the confidence to perform many big projects and clinical trials such as the EUMDS-Registry.

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**Monitor Visit**

Monitor visits have been performed In November and January. 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 and will be presented at the different meetings.

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