

## EUMDS Registry Newsletter



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**Hello!**

We would like to welcome you to our EUMDS newsletter number 8.

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**

The interim analysis for the first 400 patients is performed.

The results of the interim analysis will be presented during a meeting the 25<sup>th</sup> of September in London. One representative per active site is invited to attend this meeting.

**Database:  
Missing information**

Thank you all for your co-operation and fast replies in response to the data checks we may have recently made for the interim analysis. It is very important for the success of the project that the data is as complete as possible - this includes information such as height and weight.

Information that has been entered as missing can be changed at any time should the data become available at a later date. To reset a missing value, double click the box. The missing value code (-9) will be removed and you will be able to enter the value. If the visit is locked, Country Coordinators and the Data Management Centre are able to unlock visits. To unlock a visit, click the visit date, click the edit button (it looks like a pencil), tick the

'ignore timeout' box and click 'save'. Locked visits that have no height or weight data entered can only be unlocked by the Data Management Centre. Finally, if you are unable to enter data due to it being outside of expected ranges (shown by the red exclamation mark); send an email with details of the problem and the ranges can be amended.

If you have any problems, please check the data manuals and FAQ section of the website, where more information can be found. We are happy to assist with any queries or problems; please email us at [eumds@egu.york.ac.uk](mailto:eumds@egu.york.ac.uk).

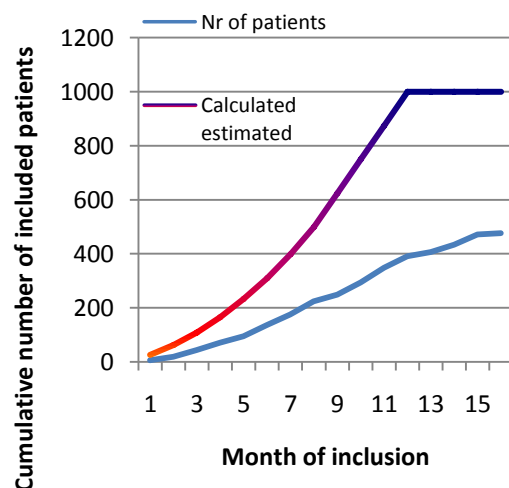
Best wishes

Alex & John.

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

**Accrual**

At the moment 476 patients are included by 87 sites.

**Accrual overall**

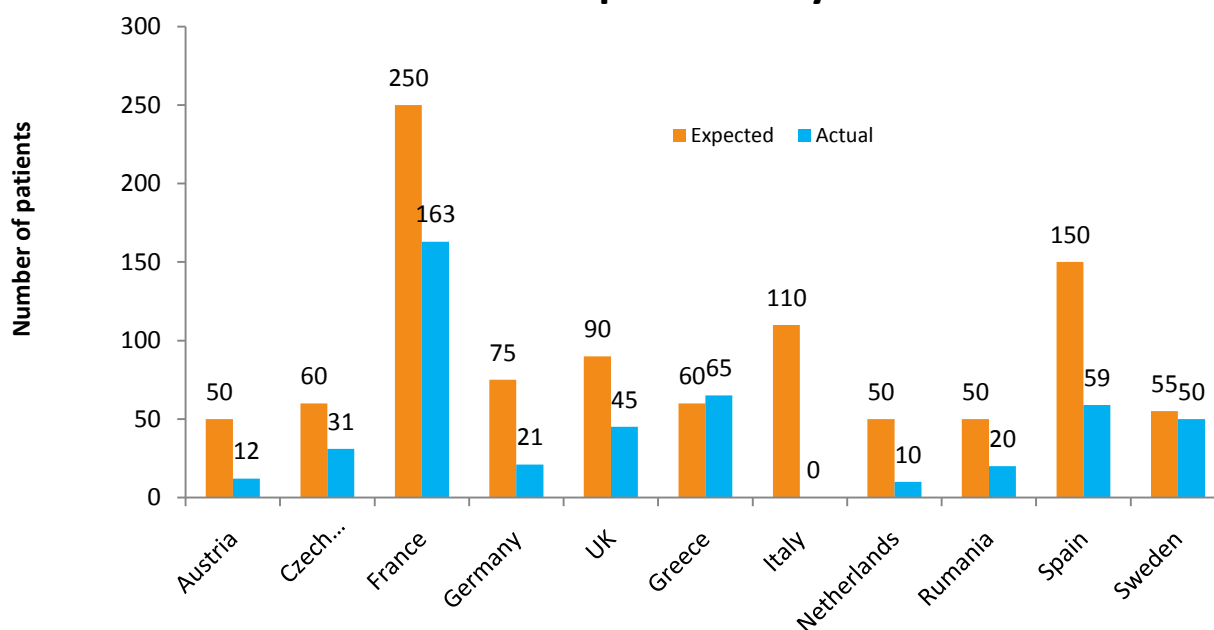
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### Accrual per country



### Meetings

The 1<sup>st</sup> of July the operational team meeting was scheduled in Amsterdam. Main points from the minutes:

- Denmark will participate in the registry under the flag of Sweden (Nordic countries) with 5 sites and will soon start inclusion.
- In several countries national or regional MDS meetings are organised
- Most country coordinators try to contact the participating sites in their country regularly.
- Furthermore when somebody involved in the registry leaves the department, please inform York, so login code can be deleted.
- PI approval is often missing. PIs will be informed once more by an email from York.

- An abstract will be submitted for the ASH, using the interim analysis data
- Monitor visits have been performed to 4 countries, 11 sites with the main finding that **attention for the informed consent procedure is needed** because for example:
  - Missing informed consents.
  - Date signed consent before day of diagnosis.
  - Patient included without informed consent.

So everybody is asked to be extra careful with the informed consent procedure. If there are any doubt, please contact your coordinator or PI.

In some sites differences between source data and electronic-CRF were observed. All participating sites should be careful with data entry

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The next Steering Committee meeting will be together with the interim analysis meeting the 25<sup>th</sup> of September in London.

### Organisation of Czech Republic

The Czech Society of Hematology has been founded in 1951 as Czechoslovak Society for Hematology and Transfusion. After the split of Czechoslovakia into Czech and Slovak Republic the Czech Society of Hematology has been established in 1993. The Czech Cooperative Group for MDS has been working since 1994. The group has been consisted from about 30 hematologists who were interested in MDS and took care of the MDS patients. Since 1998 the group became an official committee of the Czech Society of Hematology. The group participated in several EORTC MDS trials and also in companies conducted trials and organized the 5th International Symposium on Myelodysplastic Syndromes in Prague in the year 1999. A national Czech registry of patients with MDS has been built since 1994 and within previous 15 years we collected data from more than 2000 MDS patients. The data has been used for several retrospective analyses. The largest registry from a single centre is MDS registry in Institute of Hematology and Blood Transfusion with data obtained from more than 500 patients and also these data served for publications in international journals.

The basic care of the MDS patients is taken in regional hospitals. For second opinion and for special care in indicated cases the patients are sent from more than 30 regional departments of hematology to 7 university centers for intensive and special care including stem cell transplantation. These centers are performing intensive combination chemotherapy, allogeneic stem cell transplantation and are participating in clinical trials with new drugs. In the current project of European LeukemiaNet MDS registry these 7 university centers serve as reference centers for all patients diagnosed in local hospitals. After confirmation of the diagnosis, patient's data are sent by the data manager in center into the

registry. Patients with low and intermediate-1 risk who are not indicated for stem cell transplantation or for participation in clinical trials are generally followed in regional departments of hematology. Patients with intermediate-2 and high risk as well as patients who are candidates for stem cell transplantation or clinical studies are treated in centers for intensive care and transplantation. Approximately 60 patients with MDS are transplanted per year and Czech MDS study is currently participating in several international clinical studies with new drugs (e.g. decitabine or romiplostin). The group is actively participating in national and international meetings including International MDS Symposia, EHA or ASH meetings. The members of the group are also involved in the work for the organization of MDS patients including educational meetings and care of the web pages for MDS patients.

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