

## EUMDS Registry Newsletter

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**Hello!**

We would like to welcome you to our first EUMDS newsletter. We hope to put one together every three months or so to keep you updated on our registry.

To subscribe/unsubscribe 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 "Unsubscribe" in the subject line.

**Send Your Suggestions**

Is there anything you'd like to see in the next newsletter? We'd like to hear from you! Please contact us if you have any suggestions, questions, or comments on any of the topics described in this Newsletter and on 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.

**Feasibility Report**

The feasibility report was finished at the beginning of July 2007. At the moment the feasibility report is at Novartis for approval.

The most important conclusions of the feasibility study were:

- All 11 visited centres are definitely interested in joining the EUMDS registry.
- A total number of patients that can be included during 18 months is 2247 in 147 different centres, but only if the circumstances are optimal.
- The factors that were established to influence the recruitment were:
  - Lack of financial support for coordinator/researchnurse/datamanager
  - Assessments of cytogenetics not always performed in all centres in The Netherlands and not yet performed in Rumania
- Although currently there is a different level of organization in the different countries, the present networks can be used as a basis for the EUMDS registry.

**Contracts**

At the moment the contracts between the sponsor and Novartis have high priority. To guarantee the

most optimal situation the legal department of University of Nijmegen is busy to develop an independent legal entity in which the MDS consortium can be embedded. This (probably) foundation will be the vehicle in which the ownership of the database and the intellectual property, and organisational and financial responsibility can be arranged. The referral centres will also have contracts with this legal entity. Details will be discussed at the next steering committee meeting.

**Budget**

Novartis has changed their policy. Contracts will be made with a maximum duration of 3.5 years. This means that for the EUMDS registry, the inclusion period will be 12 months and the follow-up will be 2 years for now. During the first year, Novartis will evaluate the registry and decide whether to increase the number of patients and to extend the inclusion period and follow-up period.

The referral centres will be given budget to employ a coordinator. The budget will depend on the number of centres that will participate in the particular country according to the table below:

| Categories            | <40 sites | <20 | <10 | <5  |
|-----------------------|-----------|-----|-----|-----|
| Fte required per year | 0,8       | 0,5 | 0,3 | 0,2 |

Fte=fulltime equivalent

Furthermore the patient dependent costs are calculated at 16 hours per patient during inclusion and 2 years of follow-up.

**Database**

At the moment the Central Data Management and Statistical Unit (CDMSU) in York is building the database. Hopefully this will be finished in November 2007.