

EUMDS Registry Newsletter



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Hello!

We would like to welcome you to our second EUMDS newsletter.

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

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 concerning 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 or calling at +31 (24)3614794.

Ethical Committee

Until now, four countries have submitted the protocol to their ethical committee(s) and two countries have already approval. When you have approval please inform the project management!

Contracts

The overall contract (12 months of inclusion of 1000 patients and 2 years of follow-up) between University of Nijmegen and Novartis has been signed. The contracts between Nijmegen and the 11 participating countries has been sent to the principal investigators. Until this moment already 5 countries have approved the contract and we have started collecting the signatures.

Binder

Each coordinator of a referral centre will receive or has received binders as Investigator Site File and is kindly asked to distribute these binders over the participating hospitals in their country, so all the participating centres will have uniform Investigator

Site Files. This might be easier for the monitor when visiting the participating centres.

Database

The completion of the Database and input program has been delayed in order to incorporate the changes to the CRF as suggested by Dr Bowen. We are hoping that it will be completed in the next couple of weeks and are still aiming to have the web-based training programme and manual finished before the end of 2007. The website will go live shortly (www.eumds.org).

Protocol

Because of the changes to the database, there will be an amendment to the protocol which will be finished within a week. This amendment will be sent to all members of the SC.

Meetings

The next Steering Committee meeting will be in Heidelberg at the 28th of January 2008. Next to the Steering Committee meeting, the first operational team meeting will take place. Between these two meetings, a database training will be planned. Further details will follow.

2008

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