

Minutes ELN-MDS Working package meeting December 11, 2011, San Diego

Minutes by Petra Muus

1. **EU-FP7 Grant application: GO-MDS** (total grant: € 3x10⁶). The application process is supported by professionals from Price Waterhouse Cooper. The first stage has been submitted September 12, 2011 and this has been approved on December 8, 2011. The submission date of the second stage is: February 8, 2012. The green light is expected in April 2012 and the contracts have to be signed in July 2012, if approved.

The call is restricted to non-malignant diseases. Therefore we will stress that the main problem of lower risk MDS is bone marrow failure, rather than its malignant nature.

Aim: This is an observational study on the role of hematopoietic growth factors, transfusions and iron chelation in low risk MDS with the aim to develop evidence-based guidelines

Current registry data (1200 patients with average follow-up of 18 months): almost 50% of the patients have received hematopoietic growth factors; around 35% of the patients have received transfusions and 6% iron chelation. GO-MDS will extend the number of patients to 2,000 with a medium follow-up of 5 years. The percentage of transfused and chelated patients is expected to rise.

The current CRFs need an amendment because we must also collect additional information about doses growth factors and compliance.

DNA sampling: sampling en testing ongoing in Netherlands, Sweden and France. The aim is to integrate these activities in the GO-MDS project and the EU-MDS registry. GO-MDS cannot support the sampling of DNA because of the call guidelines, but the activity will be mentioned. EUBBMRI.EU is another possibility for a grant application. Eva Hellström-Lindberg will find out more about this possibility and share info with MDS working package members.

2. **MDS Trial Platform within ELN MDS WP8**

All participating countries already give info on clinical trials, but no formal cooperation exists at the European level. Uwe Platzberger, Pierre Fenaux and Moshe Mittelman are preparing an European trial platform for MDS (like Eric for CLL). In the near future molecular targeted therapy will be becoming more and more relevant.

One of the objectives of the MDS Trial Platform will be: to develop a common, standard arm in various age and risk groups for national investigator initiated trials. The common dataset will be collected by "EMSCO" = ELN MDS Studies Coordination Office.

The most likely candidate are national trials in high MDS with azacytidine in the standard arm and various combinations in the study arms. The national studies will be supported by different sponsors. EMSCO need to be supported as well.

EU-MDS registry is becoming a recognized trade mark in Europe. EU-MDS Study center (EMSCOR) may achieve the same recognition of a high-quality academic structure if organized properly

Moshe Mittelman, Uwe Platzberger and Pierre Fenaux will write a document on EMSCOR and circulate this prior to the Mannheim meeting.

3. Flowcytometry in MDS: Arjan van de Loosdrecht.

Role of FCM diagnosis and prognosis of MDS. 29 participants from 14 countries form the expert group, including representatives from Australia, USA, Japan and Taiwan.

Standardization of flow cytometry in MDS, will be published in Leukemia in 2012. An ELN consensus guideline for flow cytometry in MDS is now available (ELN, Haematologica, 2009; Leukemia 2012 [in press]; Haematologica 2012 [in press])

Prognostic models beyond FCSS (Flow Cytometry scoring System) will focus on dysplastic erythropoiesis first. A multicenter study will start in 2012 as prelude for WHO 2015 revision.

The 5th international ELN FCM meeting will be organized in Amsterdam q4 2012.

Revised IPSS is not yet ready for publication. FCM and mol biol not yet incorporated in revised IPSS.

4. Therapeutic guidelines. Luca Malcovati and Mario Cazzola

The guidelines have been discussed and formulated in draft form already ready 4 yrs ago. T de Witte will discuss progress with Mario Cazzola /Luca Malcovati at ASH. Therapeutic and diagnostic outlines will be integrated in one document similar to the ELN guidelines for AML. Note added by TdW: Luca and Mario agreed that Luca will circulate a draft before the ELN annual meeting in Mannheim.

5. Ongoing activities within EU-MDS registry:

- Impact of EPO on prognosis by Eva Hellström-Lindberg: study plan approved and analysis plan to be developed in January 2012 by Eva and Alex Smith
- Cytomorphology review: (Marius MacKenzie, Ulrich Germing): review planned in Düsseldorf, January 2012.
- Transfusion and chelation studies by Theo de Witte, and Louise de Swart: study plan approved and analysis planned in January 2012
- QoL sub studies by Reinhardt Stauder: no news
- Diab sub study by Argyris Symeonidis. Theo will ask Argyris to develop a study plan (2 stage plan)
- Guidelines for chelation must be part of the treatment guidelines (Theo de Witte).

Varia: Authorship guidelines are not only valid for the EU-MDS Registry but also for other similar activities within WP8.

9.11 am Meeting adjourned.