

**Present**

90 participants present, 76 registered.

**Chairs:** T. de Witte, P. Fenaux

**Future meetings in 2012**

- EHA Congress, Amsterdam, 14-17 June
- EHA MDS Working group, Amsterdam June 14
- EU-MDS steering committee meeting at EHA, June 14
- ASH Congress, Atlanta, 8-11 December
- Meeting in Frankfurt, 20-22 September (more info: dr. R.Padua)
- Please, inform us about any ELN-related meetings.

**Latest minutes**

- ELN WP8 meeting Mannheim, February 1, 2011
  - ELN WP8 meeting San Diego, ASH meeting, December 11, 2011 (attached)
- See the ELN website for presentation and minutes.

**GENERAL ISSUES****1 Future of ELN MDS WP8 / integration EHA MDS Working group and ELN WP8**

*P.Fenaux / U. Platzbecker*

The working group meets once a year. The two groups have merged (chairs: P. Fenaux, U. Platzbecker). The joint group will organize a combined meeting during the annual meeting of EHA. The remaining activities will be integrated in the activities already running within the MDS WP8 of ELN. Importance to create a platform for the younger investigators has been recognized.

**2 Report activities WP8 for ELN Newsletter**

*T. de Witte*

The last ELN Newsletter (nr 8) contains a summary of various activities within the MDS WP8. See the report on the website: [www.leukemia-net.org/content/home/information\\_letter/info\\_letter](http://www.leukemia-net.org/content/home/information_letter/info_letter).

**3 Cooperation with Pharma**

*T. de Witte*

Pharma are inclined to include less European patient in clinical trials. It is more difficult to get (educational) grants for meetings, workshops, and studies. Input and fresh ideas to obtain new funding are most welcome. This personal relationship of the clinical PIs (advisory boards) and the study activities with Pharma are the most appropriate ways to establish cooperation.

**4 Iron substudy**

*M. MacKenzie*

From 300 patients throughout Europe serum- and urine samples have been collected. The first analysis of 23 patients with at least 5 visits has been performed and the preliminary data show correlation between ferritin and transferrin saturation. The centrally determined ferritin levels and the reported ferritin levels show a very high correlation despite the interval between the hospital analysis and the central analysis. NTBI and GDF15 will be analyzed within a few months. Results of a round robin to know the best method to measure NTBI is expected within a couple of months. The relation between transfusion dependency and CRP is part of the study as well.

**5 EPO studies**

*T. de Witte* (in absence of E. Hellström)

The first statistical plan has been completed by E. Hellström and A. Smith (statistician). From 1000 patients 50% is treated with HGF and erythropoietin stimulating agents. ESA is a time dependant variable. The plan is to develop patient treatment pathways based on the analysed data. The outcome is expected in April-May 2012.

*Comment:*

In the US financial incentives stimulate treatment with EPO. In Europe this is not the case, EPO is not a registered drug in most European countries. The financial reimbursement system varies from country to country.

## **6 Diabetes Mellitus (DM) and MDS**

*A. Symeonidis*

The impact of DM on MDS is approached in two ways:

- 1) Biased diagnosis: to what extent does the presence of DM, interfere with the diagnosis of MDS?
- 2) Does MDS cause DM or does MDS and/or transfusions for MDS induce complications or other co-morbidities associated with MDS?

*Comments:*

- Interesting to investigate the impact of DM or insulin dependency on cytogenetic aberrations? Are these lower in patients with DM?
- Relation with the EPO studies: DM might have lower EPO levels (with or without renal impairment?)
- What's first: DM or MDS? The analysis of the EUMDS Registry will show.
- Is the NTBI also taken into account? > This might be related, will be part of future study.

## **7. Dynamics of cytopenias on low-risk MDS**

*P. Fenaux*

A new study is proposed with the use of two models to determine progression, based on cytopenias and bone marrow aspirates and blood counts:

- 1) Mutations in the future related to AML and high risk MDS.
- 2) Immune disorders and the influence of treatment.

The goal is to follow patients with more than 3 blood counts and 3 bone marrow aspirates. Using the mathematical approach the type of progression can be seen lineal and step-by-step. A formal proposal has been presented to the steering committee of the EU-MDS Registry.

## **8. Quality of Life substudy**

*R. Stauder*

See also the Mannheim minutes of February 1, 2011. The HR-QoL is evaluated by EQ5d. The conclusion is to continue with EQ5d and determine whether it is relevant to use extra tools to evaluate the QoL. The goal is to find the impact of MDS on the QoL and to investigate whether the QoL is an independent prognostic factor or not.

## **9. Cytomorphologic review**

*M. MacKenzie*

See also the minutes of February 1, 2011. The review is expected in April-May 2012. Hundred slides have been selected at random in York and will be reviewed by a panel of experts and non-experts. Results will not be reported by to the doctors individually, because the slides are anonymized. It is meant as a quality control of the morphology in general and interobserver variability.

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## **Translational research / biobanking: relationship with EUMDS-Registry activities**

*T. de Witte* (in absence of J. Jansen and E. Hellström)

Extra funding is needed to collect RNA/DNA samples.

**Action point:** a survey will be distributed to know if RNA/DNA is being collected.

## **GO MDS-application 7<sup>th</sup> Framework program, second stage**

*T. de Witte*

The application is submitted within the theme of "Management of rare diseases". The amount of the grant is 3 million. The application has successfully passed the first stage (December 7, 2011), deadline of the second stage is February 8, 2012 and the result is expected in April 2012.

GO MDS stands for "Evidence based Guidelines for Optimal treatment of patients with lower risk MDS". The aim is to extend and expand the EUMDS-R for the amount of patients, the FU period (from 18 > 30 months) and to 2000 subjects. The databases will be integrated.

The three main objectives are:

1. To develop optimized, evidence-based guidelines for MDS by conducting a prospective, longitudinal, observational European-wide study
2. To estimate the clinical impact of these optimized guidelines by comparing the effect of optimized treatment versus non-optimized (business as usual) treatment on survival, disease progression, quality of life, and cost-effectiveness.
3. To interact with all stakeholders in a participation-oriented way to develop, to promote and to disseminate well-accepted evidence based guidelines for MDS treatment of each individual patient with MDS.

#### **Platform for international studies, progress**

*U. Platzbecker*

See also the minutes of February 1, 2011. The focus is on European clinical trials in MDS. Small subgroups will collaborate with the ELN as ideal platform (comparable effort: [www.ericll.org](http://www.ericll.org)). Agreement for two phases:

- 1 a) Discuss the basis of an MDS studies coordination office  
b) Set up a common trial (GFM / GMDS-SG)
- 2 a) Agreement on name and location of the coordination office  
b) Decide which studies are applicable  
c) Decide on participation of committee and countries  
d) Find funding and create a robust infrastructure\

*Comments:*

FU of patients behind the clinical trials (even after phase II).

Involve pharmaceutical companies.

Develop a database.

Add studies other than MDS in the future.

Coordinate also translational research at the same time.

#### **Flow cytometry on MDS, report Pavia meeting**

*A. van de Loosdrecht*

Currently 30 participants within 14 countries globally. See also the presentations on the ELN website. 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]).

#### **Therapeutic guidelines**

*T. de Witte* (in absence of L. Malcovati and M. Cazzola)

Therapeutic guidelines have been created.

Note request for all: follow the web-based training program on: <http://mds.haematologica.org/>

**Action point:** the guidelines will be circulated to the some key persons in February and after review distributed to all co-authors for review. Submission to Blood is planned in May 2012.

T de Witte has reported a selection of the activities during the general ELN meeting on Wednesday February 1, 2012, see power point presentation attached.