Present: Pierre Fenaux (PF), Luca Malcovati (LM), Eva Hellström-Lindberg (EH), Jaroslav Cermak (JC), David Bowen (DB), Mario Cazzola MC), Joop Jansen (JJ), Michael Lübbert (ML), Theo de Witte (TdW)

Future meetings:
ELN Breakfast meeting during ASH in New Orleans

TdW will not attend the ASH meeting. LM agreed to represent our WP. TdW, and LM will prepare our presentation during the breakfast meeting

Evidence- and consensus-based practice guidelines for the therapy of primary myelodysplastic syndromes
Mario Cazzola, Luca Malcovati

We all agreed that the guidelines should be published as soon as possible. We discussed the issue of the indication of lenalidomide for 5q- MDS. We reached a consensus that this indication can be recommended with a clear paragraph on the potential risk for progression of low risk MDS to more advanced stages and secondary AML, a clear statement that the EMEA has not approved this indication and a statement that the patient should be informed about this risk.
The aim is to submit the guidelines for publication to Blood or Leukemia before the end of the year. The draft will be circulated as soon as possible and everybody will pay special attention to the lenalidomide paragraph. Mario Cazzola preferred not to publish the guidelines in Haematologica, because he is the editor of this journal.

A prospective, non-interventional multicenter European Registry on IPSS low and intermediate-1 MDS patients Joint-collaboration ELN– Novartis Oncology Region Europe
David Bowen and Theo de Witte

Feedback from the investigators meeting in London, September 25, 2009. Alex Smith presented the planned interim analysis on the first 400 registered patients during this meeting. It is clear that the quality of the data is very high and informative. We are collecting a unique data set which will prove to be very valuable for future questions and studies as well. The abstract of this analysis has been accepted as a poster-presentation for ASH 2009. Theo de Witte will prepare the poster, but he will not attend the ASH meeting personally. The attending steering committee members promised to represent our project during the poster presentation.
The results of the first interim analysis will be used to propagate the enthusiasm of the collaborators and sites by national meetings coordinated and stimulated by Jackie Droste. The effect is already clear because the accrual has risen again to a monthly accrual of almost 50 patients. This means that we have to plan the future of the registry. The first step is to extend the follow-up time from 2 to 5 years; the second step will be to increase the number of patients to 2,000 as originally planned. Negotiations with Novartis will start as soon as we will have reached 700 patients (February/March 2010). We should consider extending the support to a consortium support if Novartis is not prepared to support the extension. We should also seriously consider to merge the low risk MDS- registry with the high risk registry if the support will come from a consortium or other funding (outreach programs, FP-EU programs?)

ELN high-risk MDS registry proposal
David Bowen, Theo de Witte

Despite Celgene's initial enthusiasm it became clear that Celgene is not prepared to provide an educational grant as the sole pharmaceutical company. We agreed that the registry is important, because of its high quality and independent academic nature. The next step is to look for cooperation with a consortium of pharmaceutical companies:

- Celgene (national and international) to be approached by: TdW, PF, DB
- Genzyme to be approached by: DB
- GSK to be approached by: DB
- Amgen
- MSB to be approached by: TdW, EH, DB
- J&J (Orthobiotech) to be approached by: TdW, DB

The interaction with national registries: several countries are collecting data of MDS patients in national registries. It is clear that we should avoid double reporting. We shall ask Alex Smith to

propose a plan for exporting data from the ELN registry to the national registry or the other way around (more likely).
The registry should open a (new?) item on the information of stored material for research: nature of material, quantity, etc).

Novel genetic lesions in myelodysplastic syndromes (MDS) and myeloproliferative syndromes MPS) and MDS/MPS
Joop Jansen

Several novel mutations have been identified in MDS and MPS such as TET-2 mutations in MDS and JAK-2 mutations in MPS. These mutations are not mutually exclusions: TET2 mutations were also reported by Delhommeau & Vainchenker et al in JAK2 positive MPD (reported at ASH dec 2008). Both mutations are early events in the pathogenesis of myeloid malignancies. Mutation acquired during development of disease.
The group was very much in favor to submit a grant application to the 7th Frame Work Proigram of the EU on the role of the new genetic lesions in the prognosis and response of therapy in MDS and MPS (GEMM). We discussed the general outline of the project and the potential collaborators both from the MDS WP and the MPS WP. JJ agreed to prepare the application and to submit it (deadline one week later!) to **HEALTH-2010-2.4.1-8: Predicting individual response and resistance to cancer therapy.** And so he did (Thank you Joop).

Future of ELN and the ELN MDS WP
ELN will continue as a foundation. The EU budget for ELN for the next year is very limited: mainly for meetings/travel costs. We shall carefully watch the development of ELN into a European Foundation. The alternative is to put our WP under the umbrella of EHA/ESH.
We discussed the extension of the steering committee with young investigators. We agreed that TdW will invite Uwe Platzbecker Dresden), Lionel Ades (Avicenne), Arjan van de Loosdrecht (Amsterdam), Luca Malcovati (Pavia) and Martin Jadersten (Huddinge) as steering committee members). We shall identify the topics which they will coordinate.

Reporter: Theo de Witte

Nijmegen, November 5, 2009