

Dear members of the ELN,

since the Clinical Trials Directive (2001/20/EC) has been implemented into the national law of all European countries, the Directive has been criticized by researchers, industry, and patients. Now the European Commission responds to the constant criticism. For more details on their new proposal, the ELN presence at this year's EHA meeting and other current topics from the network please have a look below.

We hope you will enjoy reading.

Kind regards,

European Leukemia Information Center - ELIC

■ **Revamp of Directive (2001/20/EC)**

The Clinical Trials Directive (2001/20/EC) has long since been criticized by researchers of the ELN for its disproportionate regulatory requirements, especially in terms of IITs. Now as it has become evident that the Directive also had a significant negative impact on the number of clinical trials conducted in Europe the Commission proposes a new legislation. The new proposal will be discussed in the European Parliament and Council as well as at a stakeholder workshop which takes place September 5 in Brussels. ▶ more information on the legislative proposal

■ **Successful presentation of the ELN at the EHA 2012**

This year's 17th Congress of EHA took place from June 14-17 in Amsterdam, The Netherlands. On June 14, the official EHA scientific working groups (SWG) as well as the ELN working groups met to discuss new clinical trials and other current issues. Among the SWG were ERIC, EWALL and the European Group for MDS all of which arose at least in part from the European LeukemiaNet. The ELN working groups were represented by WP4 (CML), WP5 (AML), WP9 (MPD), WP10 (Diagnostics), WP12 (MRD), and WP14 (SCT). ▶ ELN working group meetings at EHA 2012

■ **Advance notice: Rating of congress contributions**

Many but not all physicians and scientist of the ELN are visiting the main annual congresses on oncology and leukemia. At these meetings, the most important findings of the past year are presented and the hottest topics are discussed, often times before they are published. For those who could not join the congresses many institutes organize post-congress meetings to recapitulate the current-interest issues. In order to provide all network members with information on "advances in the field" WP lead participants will hereafter be asked to rate selected congress contributions of the ASH, EHA, and ASCO meeting, respectively. The rating will be published in this newsletter giving all ELN members an overview of the progress in leukemia research.

■ **Publications from the Network**

- ▶ U. Germing et al., *Leuk Res.* 2012 Jun;36(6):727-34.
- ▶ FJ. Giles et al., *Leukemia.* 2012 Jul 9. [Epub ahead of print]
- ▶ G. Helbig et al., *Am J Hematol.* 2012 Jun;87(6):643-5.
- ▶ M. Hengeveld et al., *Ann Hematol.* 2012 Jun;91(6):825-35.
- ▶ S. Luatti, F. Castagnetti et al., *Blood.* 2012 Jul 26;120(4):4761-767.
- ▶ T. Prébet et. al., *Br J Haematol.* 2012 Jun;157(6):764-6.
- ▶ D. Rea et al., *Curr Hematol Malig Rep.* 2012 Jun;7(2):103-8.
- ▶ JM. Ribera et al., *Br J Haematol.* 2012 Jul 24. [Epub ahead of print]
- ▶ S. Saussele, M. Pfirrmann, *Curr Hematol Malig Rep.* 2012 Jun;7(2):109-15.

■ **New trials in the ELTR**

EuroSKI Multicenter prospective trial estimating the persistence of molecular remission in chronic myeloid leukemia after stopping TKI

HOMB An open-label, multi-center study investigating the safety and efficacy of Ofatumumab therapy versus physicians' choice in patients with bulky Fludarabine refractory chronic lymphocytic leukaemia (CLL)

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