Regulation on clinical trials - Comments and points of interest for academic researchers

Last July, the European Commission prepared a proposal for a regulation on clinical trials for the European Parliament, which will ensure that the new rules, once finalized and adopted, will have an immediate and binding impact across the EU avoiding the fragmentation and vagaries of interpretation that have plagued Directive 2001/20/EC. Furthermore, the European Commission has apparently identified many of shortcomings of the current directive and suggested a number of reasonable approaches for international trials. Nevertheless, there are other very alarming suggestions in the rapports from different Committees of the European Parliament which are summarized in the following:

- Suggestion to upload complete clinical trial information including all CRF information into a publicly accessible data base
- Suggestion to store trial master files at sponsor sites and participating sites for an indefinite time period
- Suggestion that only trials registered in a WHO trial registry can even be cited in a trial application
- Deletion of the definition and alleviations for low-intervention trials

Please use your connections to politically support the interests of investigator initiated trials in the new EU legislation!

For further information, please visit ▶ International Trials on the ELN homepage.

9th Information Letter online

Thanks to the contributing authors, we can present the 9th Information Letter of the European LeukemiaNet. For the first time, this issue contains summaries of the most important clinical results from oral presentations of the 54th ASH Annual Meeting which were selected and summarized by ELN experts. ▶ Information Letter online

New participating centers in the ELN

With the enclosure of the five new participating centers - Bornova-Izmir (Turkey), Pilsen (Czech Republic), Beirut (Lebanon), Wroclaw (Poland), and Ankara (Turkey) - the ELN now involves 194 centers in 39 countries. Please have a look at the updated ELN map to see who’s at it. ▶ ELN participating centers

ELN WP10 ‘Diagnostics’ Meeting

From March 15-16, the WP10 ‘Diagnostics’ Meeting takes place in Munich, Germany. The meeting, which is organized and hosted by Marie Christine Béné, Gina Zini, and Torsten Haferlach, respectively, covers aspects of morphology and immunophenotyping. ▶ further information

Publications from the Network (selected)

Acute lymphoblastic leukemia

Chronic myeloid leukemia


Acute myeloid leukemia

- Schnittger S et al. ASXL1 exon 12 mutations are frequent in AML with intermediate risk karyotype and are independently associated with an adverse outcome. Leukemia. 2013 Jan;27(1):82-91.
- Schoofs T et al. DNA methylation changes are a late event in acute promyelocytic leukemia and coincide with loss of transcription factor binding. Blood. 2013 Jan 3;121(1):178-87.
- Sun SM et al. The prognostic relevance of miR-212 expression with survival in cytogenetically and molecularly heterogeneous AML. Leukemia. 2013 Jan;27(1):100-6.

Chronic myeloid leukemia

- Aduwa E et al. Significant weight gain in patients with chronic myeloid leukemia after imatinib therapy.


Chronic lymphoblastic leukemia


Chronic myeloproliferative diseases


Myelodysplastic syndromes


Nolte F et al. Results from a 1-year, open-label, single arm, multi-center trial evaluating the efficacy and safety of oral Deferasirox in patients diagnosed with low and int-1 risk myelodysplastic syndrome (MDS)

Diagnostics

Stem cell transplantation

Supportive Care

Registries

New trials in the ELTR

**ARCADE** A Multicenter, Randomised, Double-blind, Placebo-controlled Study of Darbepoetin Alfa for the Treatment of Anaemic Subjects With Low or Intermediate-1 Risk Myelodysplastic Syndrome (MDS)