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Concerns: „Clinical Trials Directive“ 2001/20/EC Public Consultation

Stakeholder: European LeukemiaNet

The European LeukemiaNet, a Net of Network brings together 104 national leukemia trial groups, 104 interdisciplinary partner groups and about 1000 leukemia specialists from 170 institutions in 33 countries caring for ten thousands of leukemia patients across Europe. Most of the participants perform Investigator initiated trials (IITs) or participate in IITs.

Our comments on the Directive 2001/20/EC (together with the DGHO and competence networks on leukemia and lymphoma) are attached.

We like to point to especially two aspects for consideration:

1) Basically, the principle of proportionality is not considered at all in the Directive.
   - It makes a difference whether you deal with a fatal disease like leukemia or cancer in which you try to prevent imminent death or to prolong survival, or whether you compare prophylactic measures e.g. lipid lowering strategies where a threat to life is not imminent.
   - It makes a considerable difference, too, whether a drug is already approved or not. In oncology there are many trials done with the aim to optimize the use of approved drugs with regard to dosage, duration and sequence of treatment. Such trials typically involve only risks which are close or equal to those of usual medical care (as the drugs used have been approved already and are used in routine health care anyhow).
     The regulations should be adapted to the risk of a trial and the aims e.g. registration of a drug (company sponsored trials) or post-marketing evaluation of optimum-use trials (academic trials).

2) Academic trials (IITs) should be excluded from this Directive and described in separate directives for IITs across Europe. According to the principle of subsidiarity academic trialists could agree to follow GCP/ICH rules but without specific regulations as applicable for commercial trials. ELN could mediate such an agreement.
   Most of the criteria of GCP have been developed and promoted by academic trialists over the past 40 years.

Alternatively, in a revision a special chapter for IITs could be introduced with clear definitions of IITs and regulations for such studies. This should be done in close cooperation with independent academic trialists and networks of excellence.

If academic trials are excluded from the directive the member states should be encouraged to do the same in their national legislations or to go back to the standard before 2004.

On behalf of the Steering Committee of the ELN

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