Regione Lombardia

ASL Milano

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For the attention **Sanco**

Brussels

Subject: Comments on the "Concept Paper"

The document seems not to take into account the debates and elaborations (cultural, methodological, organizational) that have characterized the world of clinical research (experimental or not) during the last 10 years, not to mention the difficult evolution of the areas linked with the development of new drugs. The themes proposed by the Concept Paper for review, in fact, concern only some aspects of the management of a trial, with the main target of reducing the delays in the procedures such as the trials registry, and their related costs, implicitly because of a lack of coordination between Member States and, within-states, because of the activities of the Ethical Committees (IRBs). In fact, the data collected in the preliminary phase of this consultation were about the numerical trends of trials not allowing an analysis of causes, aimed at involving positively or negatively the different policies of Member States.
In conclusion, these remarks are nothing more than few technical-operational comments, whose usefulness will depend on the logic that will guide the revision of the Concept Paper within EU.

1 - The proposal of a Coordination (CAP) seems reasonable when limited to regulatory trials involving a large number of Member States. The data collection suggest that this kind of trials is not frequent, so if this CAP is a standing and mandatory structure, then it will require a robust support infrastructure and consequently fees.

2 - The terminology used to define the different categories of trials (non-commercial, non-interventional, etc ...) is less than satisfactory and therefore does not afford to resolve this state of uncertainty and confusion, which is the real cause of the delay in protocol preparation and submission and in their evaluation by Ethical Committees (IRBs)and national / regional authorities, particularly in relation to insurance, legal, and ethical issues.
It would be useful, and urgent, to create a reference dictionary with definitions

AZIENDA SANITARIA LOCALE DI MILANO
Segreteria Tecnico-Scientifica Comitato Etico
Via Statuto n. 5 – Milano – 20121 - Tel. 02/85789749 fax. 02/85782550
e-mail: comitatoetico@asl.milano.it
Codice fiscale e P.IVA 12319130154 - sito: http://www.asl.milano.it

that consider the multiplicity of the clinical trials (experimental or not), the methods that must be adopted, the people involved. In fact, it is very restrictive to focus only on regulatory trials, when 36% of trials to be evaluated is neither drug-centered, nor registered.

3 - A reasonable decision would be to limit the regulations to trials for registration of new drugs or indications, even if it is time to expand the rules to the devices. All the principles stated in the CAP should apply to the other trials, but not all the procedures. The relevance of the protocols should be assessed by competent Authorities, in particular in relation to patients' rights according to SOPs prepared by the Investigator and/or the Sponsor.
For this reason, the variability of protocols and of criteria of evaluation should not be considered as negative, since a certain degree of variability is usually present in the scientific literature and is the object of the peer reviewing process.

4 - Proposals to revise the procedures for obtaining informed consent should be carefully considered, with the aim of providing information for citizen's participation and not just legal protection of the Investigator." For this reason, it may be important to distinguish the drug trials for registration, with very strict patient's inclusion/exclusion criteria , from those with different targets, for which the preservation as much as possible of the routine clinical standards should be pursued.

5 - Finally, it will be very important to review the criteria for insurance (amount, duration of coverage, conditions of coverage, extent of coverage), keeping into special consideration the relation with different types of research and patient populations involved.

Kind regards.

ETHICS COMMITTEE ASL MILAN
(Head: dr. Gianni Tognoni)

AZIENDA SANITARIA LOCALE DI MILANO
Segreteria Tecnico-Scientifica Comitato Etico
Via Statuto n. 5 – Milano – 20121 - Tel. 02/85789749 fax. 02/85782550
e-mail: comitatoetico@asl.milano.it
Codice fiscale e P.IVA 12319130154 - sito: http://www.asl.milano.it