Object: procedures to set up observational studies on medicines.

In order to guarantee homogeneity in the assessment activity of the Ethics Committees, according to the deliberation AIFA 20 March 2008 “Linee guida per la classificazione e conduzione degli studi osservazionali sui farmaci” (Guidelines for classification and conduction of observational studies on medicines), this letter intends to draw your attention to the general procedures for setting up observational studies:

- prospective cohort studies;
- other types of studies (different from prospective cohort study).

In particular, the AIFA Guideline, in section 10 “General procedures for the start up of observational studies” defines the instructions to be followed by sponsors and Ethics Committees pertaining the start up of other types of observational studies. In fact, it specifies the types of studies (retrospective cohort, case-control, case series, transversal, appropriateness studies) for which a simple notification to the Ethics Committees of the participating clinical sites is required.

To set up this type of studies, contrary to what has been decided for prospective cohort studies, the AIFA Guideline does not require the Ethics Committee’s formal approval; therefore the sponsor may set up the study after 60 days from the date of its notification, applying the silence/consent rule.

Therefore, it seems appropriate to remind you as follows:

- the Ethics Committees have the right of assessing the notified studies in all their aspects according to their own internal procedures reporting, if noticed, any inconsistencies with sponsor’s declaration;
- in accordance with the AIFA Guideline, the Ethics Committee has the right of going into assessment of the notified studies; this does not involve any obligation of payment of a fee by the sponsor, unless specific regulations or guidelines of the regions or autonomous provinces establish a payment;
- where fees payment is provided for the above mentioned activities as well, it is advisable that this would be published in website of the Osservatorio (OsSC) in the electronic showcase (bacheca in Italian) of the Register of the Ethics Committees;
- in any case, after 60 days from the notification of an application in the format established by the AIFA Guideline, the study ma be commenced by the sponsor according to the silence-consent rule.

Thank you for precious collaboration.
Kind regards,

Head of Research and Clinical Trials Office
Dr. Carlo Tomino

Roma, 31st May 2010