Independent Clinical Research: It's possible

Investigación clínica independiente: es posible

A few months ago, the Spanish Ophthalmological Society was informed that the Ophthalmology Co-operative Research Thematic Network had been granted a project of the Carlos III Health Institute for analysing the efficacy and safety of the triamcinolone acetonide injection for the treatment of diabetic diff use macular oedema (1).

Subsequently, the second stage of the project was initiated in order to obtain the necessary authorisation of the Medication Agency of Spain.

In recent months, different journals have published reports on the enormous difficulties researchers encounter in Spain to carry out clinical essays after the application of the Royal Decree 223/2004 dated February 6 which regulates clinical trials with drugs (2).

Some reports have stated that only multinational corporations and large pharmaceutical companies are able to go through the complex and laborious administrative process required by the Medication Is Agency (3).

It is true that the difficulties are considerable, but it is also true that in Spain there are groups capable of overcoming them.

On January 23, 2006, said Agency issued a decision authorising the clinical trial EudraCT 2005-001385-14 for testing triamcinolone, which will be carried out in the context of the Thematic Network.

Accordingly, the following stage has been launched for collecting data in the centres which participate in the study: Vall d'Hebron University Hospital, San Carlos Clinical Hospital, Navarra University Hospital, Conxo Hospital Provincial, Murcia General Hospital, Ophthalmological Institute of Alicante and the Applied Ophthalmology University Institute. We trust this stage will also be completed successfully.

In addition, I would like to express in this letter might gratitude to the staff of the IOBA Clinical Essays Unit who are the main heroes of this authorisation for the first clinical essays approved after the standardisation of health legislation in Europe without the support of pharmaceutical company. This proves that high-quality clinical research can be carried out by hospitals, clinics or academic institutes if the right team is in place.

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