Clinical Trials

Voluntary Harmonisation Procedure for multinational clinical trials in Europe (VHP)

The Clinical Trials Facilitation Group (CTFG) is an operational working group which has been established by the EU Heads of Medicines Agencies (HMA) ; it is composed by heads of clinical trials units of the 27 national competent authorities. It is chaired by Afssaps (France) and cochaired by PEI (Germany).
The new CTFG mandate and its action plan clearly highlight the objective to coordinate and harmonise the implementation of the EU clinical trials directive 2001/20/EC accross the member states.

The CTFG offers to clinical trials sponsors a pilot phase of a coordinated and simultaneous assessment of multinational clinical trials applications by the national competent authorities concerned, on a voluntary basis : the Voluntary Harmonisation Procedure (VHP).
A modified version of the VHP (version 2) is proposed with immediate effect.
The main changes in version 2 with respect to version 1 refer to :

- The enlargement of the scope of the VHP and acceptability of all multinational clinical trials on medicinal products 'with and without marketing authorisation)
- the inclusion of substantial amendments in coordinated assessment process
- the improrement of time lines of the procedure with the detection of the pre-procedural step.

The VHP can be found on the HMAs CTFG web site :
http://www.hma.eu/uploads/media/VHP_version_2_March_2010.pdf