



Agencia Española de Medicamentos y Productos Sanitarios AEMPS

THE SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES (AEMPS) RECOMMENDS USING VOLUNTARY HARMONISATION PROCEDURE BEFORE THE OFFICIAL SUBMISSION OF A MULTI-STATE CT APPLICATION

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The Voluntary Harmonisation Procedure is an efficient tool to achieve harmonised and quick approvals of clinical trials in 2 or more Member States of the EU in one procedure.

It has been more than two years since the launch of the Voluntary Harmonisation Procedure (VHP) in the European Union for the evaluation of multistate clinical trials. The process is coordinated by the *Clinical Trials Facilitation Group (CTFG)*, a working group established in 2004 by the Heads of Medicines Agencies of the EU (HMA) to coordinate the implementation of Directive 2001/20/CE on clinical trials in all Member States and comprising representatives of national agencies.

The VHP consists in a coordinated and simultaneous evaluation of the documentation of a clinical trial by the competent authorities of Member States involved in the clinical trial. This procedure is described in the guide "*Guidance document for a Voluntary Harmonisation Procedure (VHP) for the assessment of multinational Clinical Trial Applications*".

Key Facts of the VHP

- It is for clinical trials taking place in two or more Member States in the European Union.
- Only electronic documents sent to one address (one stop shop).
- Only general documents required, which are part of any clinical trial application (Protocol, Investigators brochure, Investigational Med. Product Dossier).
- Reliable timelines for Sponsor and Member States (average <60 days).



- Substantial Amendments can be filled after a VHP.
- Harmonised scientific discussion resulting in harmonised applications in the Member States. For every document, the same version is accepted by all Member States. Consolidated lists of grounds for non-acceptance, if needed.

Experience and Achievements of VHP

- The Voluntary Harmonisation Procedure is quick. Clinical Trial Applications in several Member States (e.g. 14) of the EU in parallel, without VHP, can take 120 days to more than 1 year from application to approval by the national Competent Authorities. A comparable VHP took 90 days*.
- The average assessment during a VHP takes around 52 days.
- Different sponsors from different places can apply for a VHP. The distribution of sponsors is: 50% from the European Union; 13% from Switzerland, 36% from the USA, and 1% from other regions.
- Spain has been concerned in 114 out of 184 VHP applications received since March 2009 until 1st June 2012. AEMPS has participated in all of them.

* The VHP decision is binding for the subsequent official application to the AEMPS. In order to get an authorisation letter within 10 days of receiving a valid application, the opinion by the Ethics Committee and the agreement of the management board ("Conformidad de la dirección del centro") of at least one of the participating sites should be provided in the CT dossier. If this is not the case, the deadline for the authorisation would be prolonged until such documents are submitted.