Information for Stakeholders

HMA Voluntary Harmonisation Procedure (VHP) for clinical trials – 1000th procedure

The European Voluntary Harmonisation Procedure for clinical trials (VHP) was first established in March 2009. Now, the 1000th application for the evaluation of a clinical trial has been received by several European countries. The VHP procedure fosters simultaneous initiation of the authorisation procedure for clinical trials in more than one European member state by submitting a single application.

Developing new medicinal products is a long and complex process. After a pre-clinical phase of development and manufacture in conformity with GMP (“Good Manufacturing Practice”), new medicines must be evaluated in clinical trials, which assess the efficacy and safety of the product.

Every country within the European Economic Area, in which such a clinical trial is to be conducted, requires a national authorisation. While a separate procedure of validation, assessment, request for information, and approval/rejection was required for each country, the Voluntary Harmonisation Procedure has for several years been a tool for the initiation of an authorisation procedure across several countries selected by the applicant for conducting the clinical trial working together in the assessment.

The procedure was developed by the 'Clinical Trials Facilitation Group' (CTFG), a working group of the HMA ('Heads of Medicines Agencies'). For eight years, the Paul-Ehrlich-Institute (PEI) successfully coordinated this Network effort of national competent authorities.

The VHP reduced the period required for the authorities to authorize a multinational trial to 60 days in all EU countries involved. Meanwhile, around 20 % of all applications for clinical trials to be conducted in more than one European country are submitted using the VHP.

Professor Klaus Cichutek, head of the HMA Management Group and president of the PEI said: “The HMA is proud that the Voluntary Harmonisation procedure has in the meantime been so well accepted by applicants world-wide, simplifying and reducing the period required for the authorisation of such multinational studies. Importantly, the VHP served as a model for the procedure to become applicable with the new regulation on clinical trials in future for the authorisation of multinational European clinical trials in Europe.”