Hospital Pharmacists from 31 countries have voted unanimously to approve a statement that calls for urgent changes to the framework for clinical trial regulation across the European Economic Area.
The statement, issued by the European Association of Hospital Pharmacists (EAHP), highlights the declining number of trials taking place since the introduction of a Commission Directive on the subject in 2001, and adds the Association's support to the number of organisations calling for streamlined assessment and approval mechanisms.

More specifically, the statement supports:
• the suggestion of a single electronic portal for submitting trials for assessment;
• the maintenance of ethical assessment of trials at a national level;
• greater distinction being made in the assessment process between high risk and low risk trials; and,
• a process being created to enable multi-sponsor trials.

The statement goes on to explore the identified problem of underrepresented participation in trials by key patient groups such as the elderly, children and females. The EAHP calls on the Commission to acknowledge and examine this issue within the scope of forthcoming changes to the regulation. EAHP suggest that the EU Paediatric Regulation of 2007 has helped to improve the consideration of children within the trial process and that other regulatory solutions of a similar nature could be available.

Finally the statement calls for an opening up of access to clinical trial data for the purposes of independent analysis and the development of predictive models. The EAHP recommend that it should be a condition of licence applicants to publish all available trial data provided to the European Medicines Agency in peer-reviewed Journals.
Commenting on the statement, Dr. Roberto Frontini, President of the EAHP, said:
"The 21,000 Hospital Pharmacists across Europe are the secondary and tertiary care experts in medicines, pharmacotherapy and pharmacokinetics. On a daily basis, they play a central role in the implementation and conduct of clinical trials in every European country. This statement is a product of that experience, and our profession's desire to achieve better regulation that enables improvements to new medicine development.
We look forward to meeting the Commission later in the summer to discuss our proposals. The proposed reform of the regulation presents a unique opportunity to streamline assessment, give more attention to particular patient groups, and improve access to essential trial data. We want to ensure the opportunity is not missed."

Statement **here** [1].

29 June 2012

Links
[1] http://www.eahp.eu/Advocacy/Statements/EAHP-statement-on-clinical-trial-regulation