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CLINICAL INVESTIGATIONS:
European Commission Publishes two New MEDDEV Guidelines

Changes introduced by Directive 2007/47/EC amending Council Directive 90/385/EEC and Council Directive 93/42/EEC conducted the European Commission to publish revised or new MEDDEV Guidelines. The last ones dated December 2010 but available in January 2011 concern Clinical investigations.
Let's have a look at these new documents.

MEDDEV 2.7/4 Guidelines on Clinical investigations: a guide for manufacturers and notified bodies

In fact this document is a summary on the use of Clinical Investigations to support clinical evaluation and a conformity assessment procedure. It refers to articles of directives 90/385/EEC and 93/42/EEC, to MEDDEV 2.7.1 Rev.3: "Clinical Evaluation A Guide for Manufacturers and Notified Bodies") and of course to the EN ISO 14155 which outlines good clinical practice for clinical investigations of medical devices.
Although this is a good synthesis of the regulatory environment, there is nothing new in this guidance.

MEDDEV 2.7/3 Clinical investigations: serious adverse event reporting
On the contrary of the MEDDEV 2.7/4 , this document is very useful for the application of the Directive 2007/47/EC amendment telling that *"All serious adverse events must be immediately notified to all competent authorities of the Member States in which the clinical investigation is being performed* (instead of the competent authority of the country where the serious adverse event occurred before the amendment).

A summary tabulation reporting format (Excel) is included and new Serious Adverse Event (SAE) is added to the list of previous reports. For having personally utilized once this form, I can say that it saves time and is very informative for National Competent authorities (NCA). The only negative comments to make are the small bold type (Arial 6) and the lack of horizontal space in the section "Description of the event".
With such a tabular format which harmonize individual SAE forms requested until now by the NCAs for SAEs occurring within their jurisdictions, it does not add administrative burden when reporting to all NCAs rather than to only one such as before. It shall be noted that the sponsor must report only to the NCAs where the clinical investigation has commenced.

This form shall be used also for SAEs which occurred with CE marked devices which are used within the comparator arm of a pre-market clinical investigation or when the right to bear the CE marking has been obtained before the end of the clinical investigation.

The SAE occurring outside EEA, Switzerland and Turkey in which a clinical investigation is performed under the same clinical investigation plan have to be reported as well on this form.

Regarding the reporting timelines, a SAE which indicates an imminent risk of death, serious injury, or serious illness and that requires prompt remedial action for other patients/subjects immediately, shall be reported not later than 2 calendar days after awareness by sponsor and not later than 7 calendar days for the other SAEs.

The definition of reportable SAE is given in this guidance MEDDEV 2.7/3 that you can download with its SAE reporting form at:

http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm

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