

## Additional Documents Related to Clinical Evaluation

The European commission issued two new MEDDEV guidance documents in December 2010 related to Clinical Investigations, while a new version of a related ISO standard was released in February 2011:

- **MEDDEV 2.7/4 – Guidelines on Clinical investigations: a guide for manufacturers and notified bodies.** Based on the GHTF guidance document GHTF/SG5/N3:2010 on the same topic, this document addresses when a clinical investigation should be considered and considerations for the design of the clinical investigation.
- **MEDDEV 2.7/3 – Clinical investigations: serious adverse event reporting.** This document clarifies the criteria for the reporting of adverse events experienced during a clinical investigation, and the modalities for this reporting.
- **ISO 14155:2011 - Clinical investigation of medical devices for human subjects – Good Clinical Practices.** The new version supersedes both parts of the previous version of ISO 14155 from 2003. It is expected to become the new harmonized standard under the directives MDD and AIMD.

MEDDEV documents are available for download at <http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/>.  
Additional information on ISO 14155 is available at: [http://www.iso.org/iso/catalogue\\_detail?csnumber=45557](http://www.iso.org/iso/catalogue_detail?csnumber=45557)