# Comparison between Observational, Interventional, and medical devices clinical trials: how a Technical and Scientific Secretariat of an Ethics Committee works on their evaluation

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The main scope of a clinical trial is to detect the clinical, pharmacological and/or other pharmacodynamic effects of one or more experimental medicinal products, as stated in Legislative Decree No. 211/2003 'Transposition of Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for clinical use'. Articles 2 and 6 of the above mentioned Decree highlight the role of Ethics Committees (ECs), whose main task is the preventive approval of clinical research projects submitted by the sponsor to a medical structure where the trial is supposed to be conducted. The competences of an EC with regard to clinical trials evaluation, as well as its territorial distribution and all the relevant documentation to be managed are regulated by the Law n.189/2012 'Urgent dispositions to promote the Country development through an higher protection of health'. The strength of an EC is mostly based on the presence of a qualified Technical and Scientific Secretariat, whose primary commitment is to submit the trial data through the National Clinical Trials Register (OsSC) of the Italian Medicine Agency (AIFA), the national authority responsible for drug regulation in Italy, operating autonomously, transparently and according to cost-effectiveness criteria, under both the direction of the Ministry of Health and the vigilance of the Ministry of Health and the Ministry of Economy. In Italy, different regulations aim to protect the patients enrolled in clinical trials: Interventional studies (Legislative Decree 211/2003; Ministerial Decree 21st December 2007), Observational studies (determination of the Italian Medicine Agency, 8 march 2008 'Guidelines for the classification and conduction of observational studies'), and Medical devices trials (D. Lgs. 507/92, all. 7 p.2.1; D. Lgs. 46/97 all. 10 p. 2.1.; D.M. 2 august 2005). Clinical trials are further divided in profit and non profit (the latter regulated by the Ministerial Decree 17th December 2004), which are funded by academic institutions or pharmaceutical companies, respectively. The present work was supported by the 'Preclinical and Clinical Drug Development: technical-scientific, regulatory and ethical aspects' Master Degree Program, Catholic University Medical School, Rome, in order to address the following issues: 1) to analyze the Technical and Scientific Secretariat activity of 'A. Gemelli' academic hospital; 2) to give a general overview of the above cited trials, with regard to their evaluation from January to December 2011 as well as to their classification (typology, developmental phase, organizational); 3) to analyze studies having the 'A. Gemelli' hospital as coordinator center. Among the evaluated trials, profit studies represented the majority (209) when compared to no-profit ones (126). The percentage of observational trials was the highest for both typologies, reaching 40.66% and 61.1% for profit and non-profit studies, respectively. The 22.48% of profit trials was approved as phase 2 studies, unlike the no-profit ones in which phase 1 trials represented the highest percentage (11.9%). 'A. Gemelli' hospital had a role of coordinator center in 12.91% of profit trials and in 86.5% of non profit ones. An increase in the number of evaluations released by the EC of Policlinic Gemelli as coordinator center from 2009 to 2011 was noticed (74 vs 33), ranking the Gemelli EC in the sixth position among the Italian ECs. The present results show the pivotal role played by the Technical and Scientific Secretariat in the evaluation of all the relevant documentation submitted to start a trial conduction. It acts, indeed, as a filter for the EC members in order to ease their assessment work, hence avoiding the likely delays which would occur without such preliminary evaluation.