The activities of the Ethics Committee of Lecce following the reorganization of the Committees Ethics: Law Balduzzi (189/12) and D.M. 02/08/2013

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The Ethics Committee (EC) Area 3 ASL Lecce was established with DGR n. 1227 of 04.07.2013 in accordance with Law 189/2012, this gave to AIFA responsibility of clinical trials phase I; the Competent Authority for the experimentation goes by the Director General of each ASL to AIFA; the number of the EC has been significantly reduced, in Puglia the EC went from 13 to 6. The DM 08.02.2013 has changed the composition of the EC by adding new professionals to the previous one: a geneticist, a clinical engineer, an expert in medical devices, an expert in nutrition, a clinical and a more expert in diagnostic procedures. The EC ASL of Lecce decided to draw up a report on its activities in about 2 years of his mandate.
Materials and Methods:
The analysis of the EC in the period September 2013 - May 2015 was carried out by examining a database excel studies, prepared by the Technical and Scientific Secretariat for the management of the archive of the EC. Through this consultation.
It was possible to analyze the following parameters: number of clinical studies evaluated, type(Interventional / observational, profit / non-profit), therapeutic area / Hospital and outcome evaluation.
Results:
252 studies were analyzed and evaluated of which 32% and 68% respectively, observational and clinical, of this profit 54.5% and 45.5% nonprofit. An interesting fact is represented by the percentage of UO involved: anesthesia and intensive care (1%), Cardiology (5%), hematology (44%), Internal Medicine (1%), Nephrology (1%), Neurology (7%), oncology (40%), Pneumology(1%), etc. The EC gave a negative opinion on 22 studies, of which 65% is non-profit; 82% of the experimental studies are carried out at Ospedale V. Fazzi of Lecce. 5 were expressed a single opinion, with an average time of evaluation of 18 days.
Conclusions:
Emerging data show that research in the ASL of Lecce takes place mainly in Oncology and Hematology. Both the Balduzzi law and D.M. 08.02.2013 have introduced numerous innovations to the EC, it was desirable its reorganization to facilitate the increase in the number of clinical trials in Italy, approached, especially, the simplification of theburocrazy associated with the presence of new professionals will surely allow our country to reach European gold standard in the shortest time possible.