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IMPACT OF THE NEW EUROPEAN REGULATION ON CLINICAL TRIALS IN THE ACTIVITY AND DYNAMICS OF RESEARCH ETHICSCOMMITTEES FROM CATALONIA

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BACKGROUND

Clinical research proposals on human subjects as clinical trials (CT), post-authorization studies or any project must be submitted to an independent research ethics committee (REC). Different legislations have regulated CT in Spain, being the last two European transpositions that significantly modified the dynamics of REC, especially the most recent one, currently in force. Spain was the first European country to apply Regulation (EU) No 536/2014 with the publication in December 2015 of Royal Decree 1090/2015.

PURPOSE

The objective was to analyze and quantify the impact of Regulation (EU) on the dynamics and activity of RECs from Catalonian regarding CT evaluation.

MATERIALS AND METHODS

Through an official request to the Catalonian Health Service, annual activity reports that RECs from Catalonian have to present to the competent government agency were analyzed.

Two periods were established:
Period 1: period 2007-2015 (under Directive 2001/20/CE)
Period 2: Period 2016 (under Regulation (EU) nº536/2014).

Descriptive statistical analysis was performed using SPSS.v.19. No normal distribution was resulted (Kolmogorov-Smirnov test), so U de Mann-Whitney test was used, statistical significance p <0.05.

Number of meetings and evaluation activity were recorded:

RECs were classified into three groups:
GROUP 1: High evaluation activity (>100 CT per year)
GROUP 2: Medium evaluation activity (30-100 CT per year)
GROUP 3: Low evaluation activity (< 30 CT per year)

RESULTS

374 reports from 47 RECs were reviewed. Median number of meetings per period, analyzing by type of REC were:

	PERIOD 1	PERIOD 2	p
GROUP 1:	22 (IQR=11)	47 (IQR=25)	0.117
GROUP 2:	22 (IQR=10)	16.5 (IQR=14.7)	0.469
GROUP 3:	10 (IQR=12)	8.5 (IQR=11.2)	0.232

P= 0,227 (Period 1 against Period 2, globally)

Median REC evaluation activity:

	PERIOD 1	PERIOD 2	p
GROUP 1:	184 (IQR=97)	51 (IQR=4)	0.50
GROUP 2:	73 (IQR=66.2)	20 (IQR=42)	0.02
GROUP 3:	1 (IQR=11)	0 (IQR=3)	0.15

P= 0,011(Period 1 against Period 2, globally).

CONCLUSIONS

Regulation (EU) No. 536/2014 has not modified dynamics in REC, nevertheless activity has been significantly altered, but in a different way depending on its activity.
The most affected REC are low and medium activity because of the drastic decrease in the number of CT evaluated per year due to only one REC currently evaluates for all centers involved.
Current legislation has caused CT evaluation have focused on REC of large hospitals.

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