New European Clinical Trials Regulation: perception and expectations in Italy

R30

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Background

In July 2012 the European Commission formalized the proposal for a European Clinical Trials Regulation (ECTR), which would repeal the EU Clinical Trials Directive 2001/20/EC. The new regulation, which entered into force in June 2014, is expected to be applied in the European Union (EU) no earlier than May 2016.
The ECTR aims at creating a productive environment that should favour the management of clinical trials (CT), highlighting on the highest standards of patient safety, increased transparency and swift application procedures.

Methods

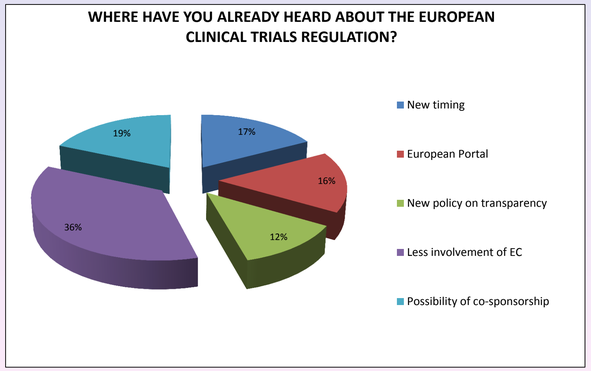
An anonymous online survey was distributed among italian Clinical Research Coordinators (CRC) and professionals in the field of clinical research.
The survey, composed by 19 questions, was levelled at obtaining a picture of the insiders' knowledge of regulations and an understanding of which aspects will have a major impact on their work.

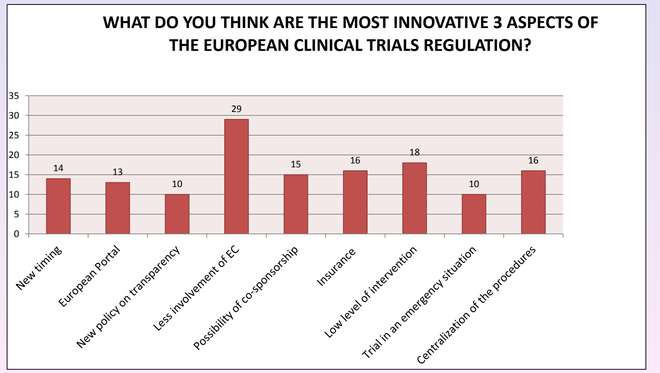
What topics, including the following, do you think that has not been dealt with sufficiently clearly?	N
New timing	14
European Portal	13
New policy on transparency	10
Less involvement of EC	29
Possibility of co-sponsorship	15
Insurance	16
Low level of intervention	18
Trial in an emergency situation	10
Centralization of the procedures	16

Do you think that the staff currently in the service of ethics committees and / or scientific secretaries have enough preparation to face the new challenges imposed by Regulation ?	%
Yes	6,30
No	16,10
For the most part	31,30
A fraction	46,40

Results

112 professionals, mostly CRC (87.5%), answered the questionnaire. Of these, 80.4% were aware of the new ECTR through courses/congress (48.2%), internet research (33%), personal reading (33%), network (15.2%) and other sources (15.2%).
All respondents feel the need to transmit ECTR information to their Principal Investigators and 65.2% believes site staff is not yet fully aware of the novelty. Indeed, 92% deems that, so far, the Institutional conduits have not provided adequate training and 88.4% believes that Hospital Managements have failed to engage in or plan out for the changes needed to adapt to ECTR.
According to the respondents the most innovative aspects of ECTR are the centralization of procedures (74.2%), the European Portal (71%) and new timing (44.1%).
ECTR will have important consequences both on Investigator Initiated CT and Commercial ones and will facilitate their conduct for 51.6% of respondents.
The responses show that some topics have not been adequately addressed, as the minor involvement of Ethics Committees in the procedures (41.4%).
Most respondents (71.4%) admit lacking in a clear stance about ECTR despite almost all (85.7%) are sure that it will have direct and immediate impact on their work.





Conclusions

The ECTR will definitely be a great challenge therefore adjustment and adaptation to new procedures are urgently solicited to reinforce competitiveness and attraction of italian investigational sites