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Primo autore

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Area tematica

Miscellanea

Titolo

Descriptive analysis for characteristic and distribution of phase I clinical research structures in Italy

Testo

Background

On 05 April 2016 the new law that establishes the minimum requirements for Italian clinical units and laboratories to perform phase I clinical trials (Determina AIFA n. 809/2015), became finally effective. This Determination was issued after an increase (80%) of approved phase I trials in Italy from during the last 4 years and it was intended identifying selected centers that were really able to carry out this type of studies.

In order to verify the trend of self-certification procedures we decided to investigate, 2, 12 and 24 months after the entry into force of this Determination, the characteristics and distribution of the self-certified research structures.

Methods

Our analysis was conducted based on 3 of the periodic lists of self-certified clinical units and laboratories, published by Italian competent Authority (AIFA) on 16 Jun 16, 06 Jul 17 and 1 Mar 18.

Results

The first self-certification was sent on 08 Apr 16, only 3 days after the first applicable date and the concerned center was able to start all activities on 7 Jul 16.

On 1 Mar 18 a total of 71 clinical units (+500% compared to Jun 16 and +14,5% to Jul 17 respectively) were self certified , for a total of 50 research structures qualify to phase I study conduction. 30 of these structure (60%) were located in the north of Italy, 12 (24%) in the centre while only 8 (16%) in the south.

Interesting, Lombardy and Emilia-Romagna regions host the 46,5% (n=20) of overall self-certified research structure. 36 of self-certified clinical units (50,7%) concern oncology/onco-hematology unit and only 9 (12,7%) are certified for studies on healthy volunteers.

A similar geographical distribution was observed for self-certified laboratories, that were 48 at the last analyzed timepoint (+343% compared to Jun 16 and +9% to Jul 17 respectively).

Conclusions

Despite the Determination has been issued with the intent to select sites of excellence able to deal with phase I studies, we have observed a real "race for self-certification" nevertheless we need the official results of AIFA inspections to really understand how many of these sites really meet all the required criteria and will be able to carry out phase I trials.

Our data, admittedly, show the intent of Italian clinical research structures to invest in phase I clinical trial for the future (especially regarding oncology and onco-hematology), but with a typically Italian geographical heterogeneity between north and south.

Parole Chiave

1. phase I studies
2. clinical research
3. self certification

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