Typical investigational medicinal products follow relatively uniform regulations in 10 European Clinical Research Infrastructures Network (ECRIN) countries

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Abstract:
BACKGROUND:
In order to facilitate multinational clinical research, regulatory requirements need to become international and harmonised. The EU introduced the Directive 2001/20/EC in 2004, regulating investigational medicinal products in Europe.
METHODS:
We conducted a survey in order to identify the national regulatory requirements for major categories of clinical research in ten European Clinical Research Infrastructures Network (ECRIN) countries-Austria, Denmark, France, Germany, Hungary, Ireland, Italy, Spain, Sweden, and United Kingdom-covering approximately 70% of the EU population. Here we describe the results for regulatory requirements for typical investigational medicinal products, in the ten countries.
RESULTS:
Our results show that the ten countries have fairly harmonised definitions of typical investigational medicinal products. Clinical trials assessing typical investigational medicinal products require authorisation from a national competent authority in each of the countries surveyed. The opinion of the competent authorities is communicated to the trial sponsor within the same timelines, i.e., no more than 60 days, in all ten countries. The authority to which the application has to be sent to in the different countries is not fully harmonised.
CONCLUSION:
The Directive 2001/20/EC defined the term 'investigational medicinal product' and all regulatory requirements described therein are applicable to investigational medicinal products. Our survey showed, however, that those requirements had been adopted in ten European countries, not for investigational medicinal products overall, but rather a narrower category which we term 'typical' investigational medicinal products. The result is partial EU harmonisation of requirements and a relatively navigable landscape for the sponsor regarding typical investigational medicinal products.

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