

Clinical trials and pharmaceutical industry: An insight into their regulation in France and Europe as of early 2014

Prescrire Editorial Staff ^{*1}

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Abstract

France's medicines policy was widely called into question in the wake of the scandal caused by the medicine benfluorex (Mediator[®]). It led to several changes, including: the implementation of a "French Sunshine Act", a little bit stricter regulation of off-label use of medicines in France, and minor improvements to the European legislation on pharmacovigilance adopted at the end of 2010.

In early 2014, the proposal for a new European Regulation on clinical trials is an historic opportunity to obtain greater transparency on the results of clinical trials.

Key words

"French Sunshine Act", European regulations, clinical trials, pharmacovigilance

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