

France to tighten up drug trial rules after fatal incident

May 23 2016



This Friday, Jan. 15, 2016 file photo shows a logo of the Biotrial laboratory displayed on its building in Rennes, western France. France's health minister has presented a plan to tighten up the rules regarding human drug trials following an experimental test that killed a volunteer in January. (AP Photo/David Vincent, File)

France's health minister presented a plan on Monday to tighten the rules regarding human drug trials following an experimental test that killed a

volunteer in January.

The minister, Marisol Touraine, also demanded that the Biotrial company which carried out the fatal trial provide an action plan within a month to guarantee that "major breaches" cannot happen again.

"If they don't, we will suspend their activities. If this report is handed in, we will carry out verifications by the end of the year", Touraine said in a news conference.

"This accident should have been reported without delay to the National Agency for Drug safety," she said. "But the laboratory only reported it formally on Thursday, Jan. 14, four days after the first volunteer was taken to a hospital and three days after the decision was made to suspend the test."

Touraine stressed that the investigation by the health administration showed that the conditions under which the trial by the Rennes-based firm were authorized were "compliant with the current legislation," but there were breaches in the way Biotrial handled the problem.

The trial for the Portuguese pharmaceutical company Bial involved 90 [healthy volunteers](#). It was stopped after six people became seriously ill, and one died.

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Citation: France to tighten up drug trial rules after fatal incident (2016, May 23) retrieved 9 April 2024 from <https://medicalxpress.com/news/2016-05-france-tighten-drug-trial-fatal.html>

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