The Fallout from the Fatal Drug Study in France

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The aftermath of a catastrophic clinical trial in France has raised concerns regarding the lack of data shared about the incident.

Last week, the French Health Ministry reported that six patients taking part in a Phase 1 clinical trial administered by Portuguese drug manufacturer Bial for an alleged painkiller containing cannabinoids were rushed to a local hospital after experiencing adverse events. The situation deteriorated over the weekend when one of the patients who was in a coma passed away while the others remained hospitalized, but stable.

More information arrived later, shedding insight into what happened.

First, investigators determined that the drug in question didn’t contain cannabis or any substance linked to it. A report in *Nature* [1] indicated the treatment was a fatty acid amide hydrolase (FAAH) inhibitor, which is an “enzyme produced in the brain and elsewhere in the body that breaks down neurotransmitters known as endocannabinoids.”

*Nature* adds that other companies have developed FAAH inhibitors to test their painkilling capabilities. However, clinical research has shown these compounds to
be ineffective for this purpose, although they proved to be safe.

Bial wasn’t immediately forthcoming about which molecule was used in these trials.

STAT [2] writes two scientists identified the compound as BIA 10-2474, despite it not being available in the databases where clinical trials are usually registered. A Bial spokeswoman confirmed to STAT this was indeed the drug, although she declined to elaborate on whether more information would be released.

All of this emphasizes why scientists are calling for greater transparency when it comes to clinical trials.

Another STAT report [3] explains Phase 1 trial results “are not required to be publicly released to data repositories in Europe or the United States” because this specific set of trials are exempt from a disclosure law that requires the public reporting of late-stage clinical tests.

Phase 1 tests tend to be small-scale in order to determine the safety of a certain drug. Early-stage results can be voluntarily submitted, but the law necessitates submitting information from later-stage trials since this part of the process involves closely analyzing a drug’s safety and efficacy profile.


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