

Drugs trial tragedies: a rarity

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Drugs trial tragedies like [that reported in France on Friday](#) which left one person brain dead and three others facing irreversible brain damage are a rarity, experts say.

"This type of incident is tragic, but very rare in the world of [clinical trials](#)," said Professor Jayne Lawrence, chief scientist of the Royal Pharmaceutical Society.

"There are very strict regulatory standards across the EU for performing clinical trials and phase 1 trials, where a drug molecule is tested for the first time in humans, (and) are subject to particular scrutiny to minimise any risk to human health," she added.

Six volunteers were hospitalised last week in France's western city of Rennes after taking part in the Phase I trial of a new medication meant to treat mood disorders such as anxiety, developed by Portuguese pharmaceutical company Bial.

France's public body Oniam, which is responsible for compensating the victims of medical accidents, said this kind of accident is "exceptionally rare."

It said it had in its files only around 10 cases of accidents during drugs trials over the past 15 years, and "with consequences infinitely less serious" than the case in Rennes.

The French medicines agency ANSM said the new accident was the

worst of its kind ever in France.

Although a rarity, there have been precedents in other countries.

A comparable accident took place in 2006 in London when six people taking German drug manufacturer TeGenero's TGN1412, which it was developing to treat certain types of cancer and other immunological diseases, fell seriously ill, with one suffering from multiple organ failure.

Two of the volunteers were in a critical condition and one lost all his fingers and toes. The victims said they had the impression that their brains were on fire and that their eyes were coming out of their sockets.

Although they all survived, experts said at the time that their immune systems would be damaged for life.

In the United States in June 2001 a healthy young volunteer who had taken part in a study into the causes of asthma died.

The death of 24-year-old Ellen Roche came about a month after inhaling the chemical hexamethonium in an experiment to study the mechanism by which airways constrict when exposed to allergens.

It was the first death of a human volunteer since 1986 in the prestigious Johns Hopkins University and prompted US authorities to halt all its federally-funded medical research involving human guinea pigs.

The authorities said the university had violated, on 24 points, regulations governing the use of human volunteers.

"Hundreds of clinical trials involving thousands of people are under way at any time. It is very common for there to be side effects since all medicines (approved or in testing) exert both the desired effect and

unwanted effects," said Dr Ben Whalley, a professor at Britain's Reading University.

"For the most part side effects are limited and tolerable, although, for some medicines, they determine the upper limit for a dose that can be used," he explained.

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