

Rennes clinical trial: the ANSM is pursuing its investigations

Within the framework of its surveillance of clinical trials, the ANSM is pursuing its investigations in an aim to identify the factors which led to the dramatic accident which occurred 3 weeks ago.

These investigations address all the elements for assessing the involvement of the medicine tested in the serious accident which occurred during the clinical trial.

These analyses supplement those led with the judiciary authorities, the French General Inspectorate of Social Affairs (Inspection Générale des Affaires Sociales - IGAS) and the Ministry for Health.

The different investigations currently led by the agency are as follows:

- continuation of the inspection work that the agency has performed on the site of the research centre in Rennes,
- search for the medical causes which led to the death of one of the volunteers and serious consequences for 4 others. For this, the agency has appointed clinical experts in charge of analysing the available medical data gathered to date,
- creation of a temporary specialist scientific committee (Comité Scientifique Spécialisé Temporaire - CSST), which gathers French and European toxicology and pharmacology experts and clinicians. Its task is to explore all the pharmacological and toxicological hypothesis which could have led to this accident. All the pre-clinical and clinical data will be examined. The committee was created on 21 January. It will meet for the first time on 15 February. The list of experts and the agenda will be published at the latest two days before the session. This committee's report will be made public.

Further reading

IGAS progress report on the accident which occurred within the framework of a clinical trial (05/02/2016) - Ministry website

DG decision no. 2016-17 of 21/01/2016 - Creation of the CSST Inhibitors of the FAAH (Fatty Acid Amide Hydrolase) (21/01/2016)  (420 KB)