Overseeing clinical trials

Consultez la version française

To ensure the safety of the patients who will have cause to use a new healthcare product or a new treatment strategy, it is necessary to assess its efficacy and its safety on a limited cohort before it is made more widely available. These studies are known as clinical trials. They help determine the best conditions of use of health products. They may also be conducted to assess a new way of using a known treatment.

Clinical trials:

- take place following research phases on experimental models (cells, tissues, animals) known as preclinical studies;
- are generally offered to patients as part of the treatment of an illness, and in some cases to individuals who are not sick, referred to as healthy volunteers;
- are subject to regulations which provide a protective framework. This helps guarantee volunteers' protection and safety;
- are subject to regulations according to the risks to which volunteers are exposed and the category to which they belong.

The different categories of human research

Human research is classified according to the **nature of the intervention** (on volunteers or merely observational) and the **level of risk and constraint** to which the study's volunteers are exposed.

There are 3 research categories:

- **Category 1:** these studies involve non-negligible risks for the healthy volunteers and patients taking part.
- **Category 2:** these studies involve minimal risks and constraints. Their scope is confined to a list of interventions drawn up by the French Ministry of Health (blood tests, sensor data collection, radiological investigations, etc.).
- **Category 3:** these studies include all observational research such as comparisons of practices between two care centres, a quality-of-life questionnaire, use of a small additional volume of blood following sampling, etc.

Clinical trials authorised by ANSM

ANSM is the competent authority for assessing and authorising a clinical trial (category 1 study). For category 2 and 3 studies, ANSM's prior authorisation is not required. However, ANSM must be informed before the trial can commence.

ANSM's evaluation of clinical trial authorisation applications covers the safety and quality of the products used during the clinical trial, as well as the safety of the individuals taking part in these studies.

All trials must also obtain the approval of the approval of an Ethics Committee (the french Committee for the Protection of Persons (CPP)), which assesses the conditions of participant information and consent, the soundness and relevance of the project, as well as its methodological quality. The CPP also checks that patients' rights will be respected, and particularly ensures adherence to confidentiality and personal data management requirements.

Authorisation must be requested from ANSM for clinical trials on medical devices and in vitro diagnostic medical devices, specifically:

- when they involve non-CE-marked medical devices;
- when they involve CE-marked medical devices used in a new indication (different from that covered by CE marking);
- when these medical device clinical trials require investigations with a non-negligible risk for the purposes of the trial.

ANSM also authorises "non-health product" research involving human subjects, conducted in the fields of physiology,

pathophysiology, epidemiology, genetics, nutrition, behavioural sciences, preventive or diagnostic therapeutic strategies, and cosmetics.

Monitoring and inspecting clinical trials

Clinical trials are monitored by ANSM for their entire duration. ANSM is notified in the event of the onset of serious adverse reactions, and of any fact liable to call volunteers' safety into question.

ANSM may be required to take measures: update of information for investigators, amendment of protocol, suspension of enrolment, or even orders disallowing the trial.

ANSM inspects sites where clinical trials are conducted, including healthcare facilities, authorised research sites, and more. It also inspects the facilities of the sponsors of this research and the subcontractors who work for these sponsors. These inspections concern the safety and rights of the individuals participating in the trials and verification of the data obtained.

Medicinal product trials are conducted within the framework of Good Clinical Practice (GCP) guidelines.