Service
d'immunologie et allergie

What is a clinical study?

A clinical study is one of the final phases of a long and rigorous process. Studies are conducted with volunteers or patients to find out whether promising ideas to the prevention, diagnosis and treatment of a disease are safe and effective.

There are several phases in a clinical study, each with different objectives to help answer one or more specific questions.

PHASE I

The initial phase of a clinical study is the very first testing of the experimental product in humans. The product is first tested on a small group of healthy volunteers (20-80 people).

The aim of this phase is to evaluate the tolerance of the treatment, its potential side effects, to characterize the immune response triggered (immunogenicity) and to find the right dosage of the drug.

PHASE II

The experimental product is then administered to a group of 100-300 patients or people at risk of contracting a disease (e.g. HIV) in order **to determine its efficacy and to further evaluate safety and immunogenicity.**

PHASE III

Once the investigational product has passed the first two phases, it is administered to a large group (1'000-3'000) of patients or people at risk of contracting a disease (e.g. HIV). This large phase **allows for confirmation of efficacy, monitoring of side effects and comparison with a reference or placebo treatment.** Information on the most appropriate use of the product is also collected.

PHASE IV or POST-MARKETING

Once the product has received marketing authorisation and is made available to the general public, it enters phase IV. This is the phase of **long-term monitoring of the product and allows for the identification of possible rare side effects or late complications**