Case study
Vaccine Adolescents

A Phase II, partially double-blind, randomised, controlled, primary vaccination single center study to assess the immunogenicity, safety and reactogenicity of one intramuscular dose of four different formulations of a **meningococcal vaccine** versus one subcutaneous dose of a marketed meningococcal vaccine **in healthy adolescents / young adults aged 15-19 years**. Subjects were stratified for enrolment according to age : one half of the subjects was aged 15-17 years, the other half of the subjects was aged 18-19 years.

Previous vaccination against meningococcal disease and previous vaccination against tetanus within the last 6 months were exclusion criteria's.

After selection of seven schools and meetings with their managements, it was decided to work with 3 of them for the recruitment of subjects. All information regarding the disease, the vaccine, the benefits, the risks, advantages and disadvantages related to the study have been given to the volunteers and their parents by ResearchLink's investigators.

In accordance with the ICH GCP guidelines subjects can only be enrolled in a trial with the consent of his/her legal representative (e.g. minors). The Informed Consent Form was signed for approval by the subject him/herself and his/her legal representative.

Schedule : Two visits with an interval of 30 to 42 days.

The first visit was the vaccination visit during which the vaccinated subjects were carefully observed for at least 30 minutes. The observation was realised with the availability of the appropriate medical treatment and staff in case an unexpected anaphylactic reaction following the vaccine administration happened.
The second visit was the safety and immunogenicity visit, with blood sampling for antibody determination.

Unfortunately, the recruitment in the schools was below our expectations. We decided, in agreement with the sponsor, to complete the recruitment in 4 of our investigative sites.

The target of 125 eligible subjects was reached within 6 weeks, which was in the foreseen timelines.