Case study
Vaccines Elderly

A Phase II study to evaluate the safety, reactogenicity and immunogenicity of a vaccine in elderly patients. 4 visits foreseen with CMI samples and 6 months of safety follow up.
Enrolment period duration : 8 weeks.

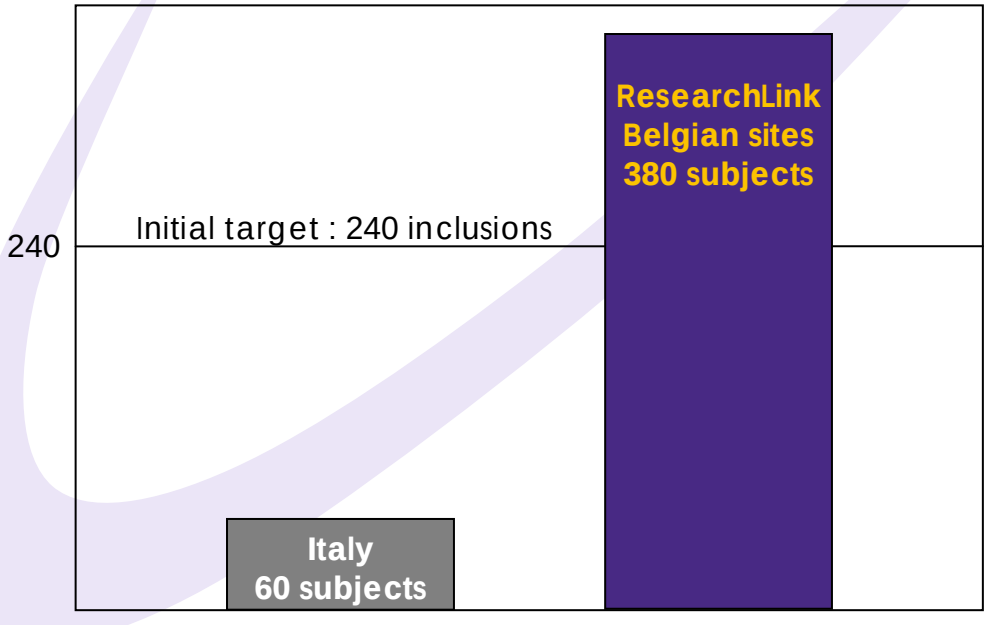
The commitment of the Clinical Trial Network was to include 240 elderly subjects into a vaccine study. Age stratification : 3 age groups (61-65y, 66-70y, >70y with allocation ratio 1:1:1).
The same amount of subjects was to be included by several sites located in another European country.

In the mean time, the protocol changed and the study finally sheduled 7 visits and 3 phone calls over 8 months followed by a second study in order to evaluate the immunogenicity after 12 and 24 months.

Our CTN set up 4 GP sites recruiting each 60 subjects. This target was met ahead of the deadlines.

Unfortunately several sites of the other country did'nt start any inclusion and the sponsor asked to the GP network to recruit more subjects.

The existing sites started to recruit more subjects and three more sites were quickly initiated.



Recruitment per country in an elderly patient vaccination trial