

Case study

Vaccine Young Adults

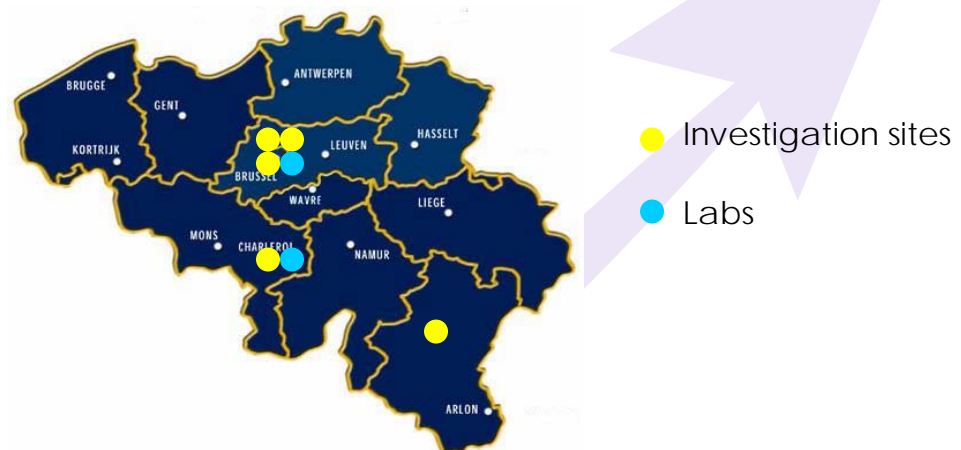
A phase II, multicentre, randomised, partially-blinded dose-ranging study to assess in healthy volunteers (18-57 years at enrolment), the immunogenicity and safety of an intradermal, trivalent, inactivated, split-virion influenza vaccine using a microinjection system in comparison with a licensed intramuscular control vaccine during 3 successive years, 9 visits per patient.

This was the first vaccine study asked to ResearchLink. Our target was 500 subjects.

ResearchLink set up 5 investigation sites. Each site was managed by an Investigator Coordinator, supported by a Study Nurse and by 4 co-investigators. The transfer of all the biological samples to the central lab were coordinated by ResearchLink.

All 500 subjects were included in less than 6 weeks.

The second year of the study, the sponsor asked us to follow the Cell Mediated Immunity of 80 subjects in one site. ResearchLink identified a second lab responsible for the CMI dosages.



Sic Stéphanie Pépin-Covatta, Clinical Coordinator :

"The Clinical team members and I wish to express sincere gratitude to you and yours co-investigators for the excellent collaboration in this big challenge which is this clinical study"