Case study
Influenza Vaccine

For this open-label multicenter uncontrolled trial, total of 210 adult and elderly subjects had to be included.

Subjects had to be vaccinated as soon as the first commercial lots the vaccine were available, pending regulatory approval to conduct clinical trial. They had to be followed for a clinical safety assessment (i.e., solicited injection site reactions, solicited systemic reactions, unsolicited adverse events and serious adverse events) from D0 through D7 after vaccination.

The sponsor opted for a multi-center trial conducted in 6 centers in Belgium.

The planned trial period was from mid-September 2014 (First Visit First Subject) to mid-October 2014 (Last Visit Last Subject). Due to a delay to the delivery of the study vaccines, the inclusions could only start on October 2nd. The last subject was included on October 10th. **All 210 subjects were vaccinated in 9 days.**

Clinical study report was signed one month after the last visit of the last subject.