

A Phase III Control Study of the Safety and Immunogenicity of vYF in Pediatric Population

NCT07103148

Status	RECRUITING
Phase	Phase 3
Sponsor	Sanofi
Enrollment	2,440 participants

Key Eligibility Criteria

Inclusion (9)

- Aged 9 months to 5 years on the day of inclusion*
 - * "9 months to 5 years" means from the day of the 9th month after birth to the day before the 6th year birthday
 - Aged 11 to 15 months* on the day of inclusion for participants enrolled in the MMR co-administration group
 - * "11 to 15 months" means from the day of the 11th month after birth to the day before the 16th month birthday
 - Participants who are healthy as determined by medical evaluation including medical history and physical examination
- ... and 4 more (see full listing online)

Exclusion (20)

- Participants are excluded from the study if any of the following criteria apply:
 - Known or suspected congenital or acquired immunodeficiency; or receipt of immunosuppressive therapy, such as anti-cancer chemotherapy irradiation therapy, within the preceding 6 months; or long-term systemic corticosteroid therapy (prednisone or equivalent for more than 2 consecutive weeks within the past 3 months)
 - Known history of FV infection
 - Known systemic hypersensitivity to any of the study intervention components, eggs or history of a life-threatening reaction to the study interventions used in the study or to a product containing any of the same substances
 - Moderate or severe acute illness/infection (according to Investigator judgment) or febrile illness (temperature $\geq 38.0^{\circ}\text{C}$ [$\geq 100.4^{\circ}\text{F}$]) on the day of study intervention administration. A prospective participant should not be included in the study until the condition has resolved or the febrile event has subsided.
- ... and 15 more (see full listing online)

Locations (9 total)

Investigational Site Number : 3400001, San Pedro Sula, Honduras
Investigational Site Number : 3400002, Tegucigalpa, Honduras
Investigational Site Number : 3400003, Tegucigalpa, Honduras
... and 6 more locations