



## V 5 Seropersistence of tick-borne encephalitis antibodies in adults

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This open-label phase IV clinical study investigated the seropersistence of tick-borne encephalitis (TBE) antibodies 2–5 years after the first booster vaccination with FSME-IMMUN 0.5 ml in healthy adult subjects who had received their primary vaccination series (3 doses) and the first booster vaccination approximately 3 years after the third vaccination in predecessor studies.

TBE antibodies were measured using both ELISA and neutralization test (NT). The second booster vaccination was to be administered depending on the level of serum TBE antibodies observed during the study, i.e., if a subject was considered not to be protected for an entire further tick season (NT titre  $\leq 20$  and/or Immunozyg ELISA  $< 126$  VIEU/ml). Local and systemic reactions were monitored and the immune response was assessed 21–35 days after administration of the booster vaccination.

Subjects were aged 18–65 years at the time of the first vaccination and were eligible for participation in this study if they had not received any other TBE vaccination since the first booster vaccination. Of the 328 eligible subjects, 315 participated in the evaluation of antibody persistence.

The study revealed prolonged antibody persistence up until 5 years after the first booster vaccination, with only 32 subjects presenting with antibody levels that required administration of the second booster.

These data suggest that a 5-year booster interval is appropriate for adults who have completed the 3-dose primary vaccination series and the first booster dose. This study also confirmed that FSME-IMMUN 0.5 ml is very well tolerated as a booster vaccination.