



Unofficial translation of 21.09.2026 Decision RKU4/26

to grant authorisation for clinical trial on the basis of Regulation (EU) No 536/2014 of the European Parliament and of the council

State Agency of Medicines has received the application from sponsor Sanofi Vaccines US Inc., represented in these proceedings by Sanofi R&D Vaccins, on 01.06.2026 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99¹ (1) of Estonian Medicinal Products Act (MPA).

Based on art 8 of Regulation (EU) No 536/2014, considering the aspects covered by Part I and Part II of the assessment report, on the basis of § 99⁶ section 1 p 1 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no VCA25397 under the following conditions:

protocol no: VCA25397 (Version 4.0, dated 19.08.2026)

EU CT number: 2026-526177-42-00

full title of the trial: A Phase 2b, randomized, placebo-controlled, observer-blind study in adults 60 years and older to evaluate the efficacy, safety, and immunogenicity of a bivalent protein vaccine candidate against Respiratory Syncytial Virus (RSV) and Human Metapneumovirus (HMPV)

sponsor of the trial: Sanofi Vaccines US Inc.

number of subjects in Estonia: 500

starting date: October 2026

principal investigators and study locations:

- Dr. Airi Põder, Kliiniliste Uuringute Keskus OÜ, Sõbra 54/1, 50106 Tartu, Estonia
- Dr. Marie Ott, Innomedica OÜ, Narva mnt 7, 10117 Tallinn, Estonia
- Dr. Riin Lanno, Merelahe Haldus ja Eriarstiabi OÜ, Paldiski mnt 68a, 10617 Tallinn, Estonia
- Dr. Rain Jõgi, Tartu Ülikooli Kliinikum SA (Tartu University Hospital), L. Puusepa 1a, 50406 Tartu, Estonia

According to § 71(1) and § 75 of the Administrative Procedure Act a challenge to this decision may be filed within 30 days as from notification of the decision. Where the recipient wishes to contest the decision in administrative court, he or she may in accordance with the Code of Administrative Court Procedure § 7 subsection 1 and 46 subsection 1 file complaint against the decision to Tartu Administrative Court within 30 days as from notification of the decision.