REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Unofficial translation of 28.09.2026 Decision RKU4/27

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 Rigshospitalet on 29.06.2026 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (2) and § 99^1 (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 § 99^6 section 1 p and (3) of Medicinal Product Act

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

protocol no:	INCEPT (Version 1.5, dated 01.04.2026)
EU CT number:	2024-516208-41-00
full title of the trial:	The Intensive Care Platform Trial (INCEPT)
sponsor of the trial:	Rigshospitalet
number of subjects in Estonia:	2000
starting date:	September 2026

principal investigators and study locations:
- Dr. Maarja Hallik, East Tallinn Central Hospital, Ravi 18, 10138 Tallinn, Estonia
- Dr. Pille Rennit, Tartu University Hospital, L. Puusepa 8, 50406 Tartu, Estonia
- Dr. Hans-Erik Ehrlich, North Estonia Medical Centre Foundation, J. Sütiste 19, 13419 Tallinn, 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.