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Decision
Ref. no. FIMEA/2026/001628

EU CT 2024-516208-41-00

Rigshospitalet

Blegdamsvej 9

2100 Copenhagen Oe

Denmark

AUTHORISATION FOR THE CONDUCT OF A CLINICAL TRIAL

Application

Rigshospitalet has applied for authorisation for the conduct of the following clinical trial:

The Intensive Care Platform Trial (INCEPT).

AM-2

Decision

Finnish Medicines Agency (Fimea) has decided to authorise the above-mentioned clinical trial in Finland.

The decision was given on the date of the electronic signature of the document.

Reasoning

Under Article 14(1) of EU Regulation 536/2014 (hereinafter “Regulation”), where the sponsor wishes to extend an authorised clinical trial to another Member State, the sponsor shall submit an application dossier to that Member State

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through the EU portal. According to Article 14(2) of the said Regulation, the initial reporting Member State shall be the reporting Member State also for the authorisation procedure of the application dossier referred to in the Article 14(1).

Fimea and the National Committee on Medical Research Ethics (Tukija) have participated in the assessment of the application in accordance with the procedure laid down in Section 10 of the Act on Clinical Trials on Medicinal Products (983/2021).

Aspects covered by Part I of the assessment report

Denmark has acted as the reporting Member State in the assessment of the initial application. The conclusion of the reporting Member State regarding Part I of the assessment report is that the clinical trial is acceptable. Under Article 14(4) of the Regulation, where the conclusion of the reporting Member State as regards Part I of the assessment report is that the clinical trial is acceptable.

For more detailed reasoning regarding the acceptability of Part I of the application, a reference is made to Part I of the assessment report.

Aspects covered by Part II of the assessment report

Under Article 14(7) of the Regulation the additional Member State concerned shall assess, for its territory, the aspects addressed in Part II of the assessment report and submit, through the EU portal, Part II of the assessment report, including its conclusion, to the sponsor.

Tukija has assessed the application with respect to the aspects covered in Part II of the assessment report. Tukija concluded that the application fulfils the

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requirements of the Regulation and of the Act on Clinical Trials on Medicinal Products 983/2021 and issued a favorable opinion.

For more detailed reasoning regarding the acceptability of Part II of the application, a reference is made to Part II of the assessment report.

Conclusion

Since the assessment with the respect to the aspects covered in Part I and Part II of the application has shown that the clinical trial is acceptable, the trial may be authorised in Finland.

Applicable legal provisions

Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, Articles 4 and 14

Act on Clinical Trials on Medicinal Products (983/2021), Sections 10, 11 and 12

Signatures

This document has been signed electronically.

Merja Viikki, Senior Medical Officer

Under Article 8(9) of the Regulation if no subject has been included in the clinical trial in Finland within two years from the granting of this authorisation, the authorisation shall expire in Finland unless an extension, on request of the

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sponsor, has been approved following the procedure laid down in Chapter III of the EU Regulation on clinical trials.

Appeal

Under Article 8 of the EU Regulation 536/2014, this decision may not be appealed.

Processing fee

The application has been processed free of charge on the grounds of the Decree of the Ministry of Social Affairs and Health on Chargeable fees for Clinical Trials (194/2024) Section 3.

Further information

For further information in the matter, please contact:

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Asiakirjan sähköinen allekirjoitus
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EU CT 2024-516208-41-00, 108-2025

Asiakirja / Dokument / Document:
FIMEA/2026/001628-1
EU CT 2024-516208-41-00 AM-2 decision Finland.docx

Allekirjoitukset / Underskrifter / Signatures:

Signed By:Merja Viikki
Signed at:2026-03-18 18:10:07 +02:00
Reason:Witnessing Merja Viikki