Fees applicable to clinical trials with medicinal products from 1 January 2026

Trials submitted and processed in CTIS under the Clinical Trials Regulation pursuant to Executive Order (BEK) no. 11 of 8 January 2024
Total fee payable to the Danish Medicines Agency and the Medical Research Ethics Committees

	Fees for mono-national clinical trials	**Amount**
A.	Application for authorisation of a clinical trial involving a medicinal product for which a marketing authorisation has been issued in an EU or ICH country (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)	DKK 71,707
	For non-commercial trials *The Danish Medicines Agency fee is waived; the fee therefore covers the Medical Research Ethics Committees' processing of the application.*	DKK 42,799
B.	Application for authorisation of a clinical trial where documentation of the investigational medicinal product's manufacture and quality is submitted in the form of an Investigational Medicinal Product Dossier (IMPD) If the following conditions are met, however, the fee is the same as for marketed medicinal products (A): – The submitted IMPD is substantially simplified. – The investigational medicinal product is a modification of a medicinal product for which a marketing authorisation has been issued, and the modification concerns only the medicinal product's packaging, labelling, form or appearance.	DKK 108,976
	For non-commercial trials *The Danish Medicines Agency fee is waived; the fee therefore covers the Medical Research Ethics Committees' processing of the application.*	DKK 42,799
C.	Substantial modification (SM) – Modification of Part I or Part I and II	DKK 22,489

	For non-commercial trials *The Danish Medicines Agency fee is waived; the fee therefore covers the Medical Research Ethics Committees' processing of the application.*	DKK 10,802
	– Modification of Part II	DKK 10,802
D.	Annual fee payable to the Danish Medicines Agency for commercial trials	DKK 14,530
	Annual fee payable to the Danish Medicines Agency for non-commercial trials	DKK 7,264
Fees for clinical trials where Denmark is a Member State Concerned, including applications to add Denmark as an additional Member State Concerned		
A.	Application for authorisation of a clinical trial involving a medicinal product for which a marketing authorisation has been issued in an EU or ICH country (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)	DKK 65,867
	For non-commercial trials *The Danish Medicines Agency fee is waived; the fee therefore covers the Medical Research Ethics Committees' processing of the application.*	DKK 42,799
B.	Application for authorisation of a clinical trial where documentation of the investigational medicinal product's manufacture and quality is submitted in the form of an Investigational Medicinal Product Dossier (IMPD) If the following conditions are met, however, the fee is the same as for marketed medicinal products (A): – The submitted IMPD is substantially simplified. – The investigational medicinal product is a modification of a medicinal product for which a marketing authorisation has been issued, and the modification concerns only the medicinal product's packaging, labelling, form or appearance.	DKK 75,715
	For non-commercial trials	DKK 42,799

	The Danish Medicines Agency fee is waived; the fee therefore covers the Medical Research Ethics Committees' processing of the application.	
C.	Substantial modification (SM) – Modification of Part I or Parts I and II	DKK 22,489
	For non-commercial trials *The Danish Medicines Agency fee is waived; the fee therefore covers the Medical Research Ethics Committees' processing of the application.*	DKK 10,802
	– Modification of part II	DKK 10,802
D.	Annual fee payable to the Danish Medicines Agency for commercial trials	DKK 14,530
	Annual fee payable to the Danish Medicines Agency for non-commercial trials	DKK 7,264
Fees for clinical trials where Denmark is the Reporting Member State (RMS)		
A.	Application for authorisation of a clinical trial involving a medicinal product for which a marketing authorisation has been issued in an EU or ICH country (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)	DKK 84,847
	For non-commercial trials *The Danish Medicines Agency fee is waived; the fee therefore covers the Medical Research Ethics Committees' processing of the application.*	DKK 42,799
B.	Application for authorisation of a clinical trial where documentation of the investigational medicinal product's manufacture and quality is submitted in the form of an Investigational Medicinal Product Dossier (IMPD) If the following conditions are met, however, the fee is the same as for marketed medicinal products (A): – The submitted IMPD is substantially simplified. – The investigational medicinal product is a modification of a medicinal product for which a marketing authorisation has been issued, and the modification concerns only the medicinal product's packaging, labelling, form or appearance.	DKK 137,869

	For non-commercial trials *The Danish Medicines Agency fee is waived; the fee therefore covers the Medical Research Ethics Committees' processing of the application.*	DKK 42,799
C.	Substantial modification (SM) – Modification of part I eller part I and II	DKK 22,489
	For non-commercial trials *The Danish Medicines Agency fee is waived; the fee therefore covers the Medical Research Ethics Committees' processing of the application.*	DKK 10,802
	– Modifcation of part II	DKK 10,802
D.	Annual fee payable to the Danish Medicines Agency for commercial trials	DKK 14,530
	Annual fee payable to the Danish Medicines Agency for non-commercial trials	DKK 7,264

Veterinary clinical trials pursuant to Danish Executive Order (BEK) No. 10 of 8 January 2024		**Amount**
A.	Application for authorisation of a clinical trial involving a medicinal product for which a marketing authorisation has been issued in an EU or ICH country (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)	DKK 27,922
	For non-commercial trials	DKK 0

B.	Application for authorisation of a clinical trial where documentation of the investigational medicinal product's manufacture and quality is submitted in the form of an Investigational Medicinal Product Dossier (IMPD) If the following conditions are met, however, the fee is the same as for marketed medicinal products (A): – The submitted IMPD is substantially simplified. – The investigational medicinal product is a modification of a medicinal product for which a marketing authorisation has been issued, and the modification concerns only the medicinal product's packaging, labelling, form or appearance.	DKK 55,434
	For non-commercial trials	DKK 0
C.	Substantial amendments	DKK 5,782
	For non-commercial trials	DKK 0
D.	Annual fee payable to the Danish Medicines Agency for commercial trials	DKK 15,583
	Annual fee payable to the Danish Medicines Agency for non-commercial trials ¨ *The annual fees apply only to trials for which an application was received after June 2017.*	DKK 7.791

Clinical trial fees are adjusted each year by the price and wage index and are laid down in the following executive orders:

Executive Order on fees for clinical trials with medicinal products under the Clinical Trials Regulation, BEK no. 11 of 8 January 2024

Executive Order on fees for clinical trials with medicinal products under the Danish Medicines Act, BEK no. 10 of 8 January 2024