

Nutrition/Interventional - DENMARK

Competent authority

Contact Details

Contact Name 1

Danish Health and Medicines Authority DHMA – Sundhedsstyrelsen

Contact Name 2

Section for Clinical Trials (Medicinal Products)

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Country

Denmark (DK)

Web address

<http://sundhedsstyrelsen.dk/en/>

Additional Information

On 8th of October, Danish Health and Medicines Authority DHMA – Sundhedsstyrelsen was divided in to three institutions (One of them is the Danish Medicines Agency DKMA-Lægemiddelstyrelsen). A new website will be launched in January 2016.

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

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Regulatory and ethics bodies involved in approval process for trials including patients

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Regulatory and ethics bodies involved in approval process for trials including including healthy participants

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Regulatory and ethics bodies involved in approval process for trials including vulnerable population

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CA - Registration/ notification without approval required for

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CA - Registration requirements for clinical trials

Registration mandatory

Registration requirements for clinical trials including patients

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Registration requirements for clinical trials including healthy participants

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Registration requirements for clinical trials including vulnerable population

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CA - Submission required to

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Studies including patients - submission required to

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Studies including healthy participants - submission required to

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Studies including vulnerable population - submission required to

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Ethics committee

Contact Details

Contact Name 1

The National Committee for Health Research Ethics - Den Nationale Videnskabssetiske Komité (DNVK)

Phone

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Holbergsgade 6

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<http://www.dnvk.dk>

Additional Information

The national committee (DNVK) provides information on the system of research ethics committees' electronic application and the regional research Ethics Committees

Ethical Review - General

Submission for Ethical review mandatory for

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Submission to CA and EC to be performed in the following order

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National legislation

Nutrition

Nutrition considered as drug

No

Definition

Clinical Research

Definition in national law

Guideline for applications for authorisation of clinical trials of medicinal products in humans

Nutrition Study

Definition available in national law

No