Medicinal Products for Human Use - DENMARK

Competent authority

Contact Details

Contact Name 1

Danish Health and Medicines Authority DHMA – Sundhedsstyrelsen

Contact Name 2

Section for Clinical Trials (Medicinal Products)

Email General

sst@sst.dk

Email Department

kf@dkma.dk

Address

Axel Heides Gade 1

ZIP/City

2300 Copenhagen S

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 Ageny DKMA-Lægemiddelsstyrelsen). A new website will be launched in January 2016.

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)
Ethics committee(s)
Agency for data protection
Other (e.g. in case of radiation)

CA - Submission for authorisation mandatory for

All prospective trials
Radiopharmaceuticals
Phases I-IV clinical trials (including pilot studies)

CA - Registration/ notification without approval required for

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CA - Submission required to

National CA

Applicable national legal framework/ Reference

Section 88 of Danish Medicines Act

	Additional Information Notification obligation to CA also applies to herbal medicinal products and strong vitamin and mineral preparations. Non-interventional trials are not to be notified to the CA unless it concerns certain types of non-interventional PASS (post-authorisation safety study) studies. NB! The use of the „Guide to assessing if a trial falls under the definition of a clinical trial“ is recommended to assess whether notification is required or not (available on the DKMA website in section: Medicines & medical devices / Medicines regulation / Clinical trials / Trials in humans).
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission** – **Guidance on submission of application available** Yes **Guidance on submission of application** A detailed guidance for trial submission is provided on the CA website in "Guideline for applications for authorisation of clinical trials of medicinal products in humans". **Additional Information** The sponsor must also notify the manufacturer of the IMP of the application at the same time of the application to the CA (pursuant to Section 88(5) Danish Medicines Act (en).)
Submission Format	**Format option(s)** Via DKMAnet, on CD-ROM (accompanied by a duly signed cover letter on paper, sent by regular mail) or via Eudralink **Preferred format** – **Online portal** (1) DKMAnet: DKMAnet is a shared portal for applications for clinical trials on medicinal products to both authorities, the Danish Health and Medicines Authority and the Scientific Ethical Committee System. Companies, including CROs can apply for authorisation of clinical trials and submit notifications about ongoing trials to DKMAnet. Further info are provided on website in Section: Medicines & medical devices / Medicines regulation / Clinical trials / Trials in humans / Applying via DKMAnet. (2) Eudralink: the documentation shall be sent to kf@dkma.dk. Application for Eudralink account: Email to eudralink@ema.europa.eu.

Additional Information

ad DKMAnet:
It provides 4 services:
(1) Application for new clinical trial authorisation (CTA)
(2) Application to amend an authorised clinical trial
(3) Safety surveillance of authorised clinical trial, such as:
Annual safety reports (ASR/DSUR), change of trial status (end, temporarily halted, or premature closure), other safety-related information.
(4) Notification about authorised clinical trial, such as: Final report, trial extension, new trial sites, change of PI or coordinating investigator, other notifications.

NB! In future, use of DKMAnet will be mandatory. Exact date not yet decided.

Language of Submission

Language(s) of application

Danish
English

Preferred language of application

–

English accepted

For the protocol (NB! Only one protocol to be submitted, it is up to the sponsor to decide on the language used; same language must be used for EC submission)

Documents mandatory to be in official national language

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Submission Fees

Fees for trial submission mandatory

Yes

Fees

Authorisation of a clinical trial: DKK 7628 (≈ € 1020)
Amendments to an authorised trial protocol: DKK 1730 (≈ € 230)

Waiver for academic (non-commercial) studies possible

No

Official guidance on required fees

All fees must be paid to the DHMA no later than one month after receipt of the invoice. When submitting the application (unless applied via DKMAnet), the e-form for invoice details must be completed.
Further details available on DHMA website in section: Medicines & medical devices / Medicines regulation / Clinical trials / Fees

Additional Information

The submission fee applies to all trials comprised by section 88 of the Danish Medicines Act, and the Danish Medicines Agency does not hold the statutory authority to grant any exemptions.

Timelines Authorisation

General timespan (max nr days)

60 calendar days; however, the CA aims to give grounds for non-acceptance or grant authorisation within 30 working days counted from receipt of a valid application.

Mode of approval (General)

–

ATMP/GMO trials (max nr days)

90

	Mode of approval (ATMP/GMO trials) – **External expert advice required (max nr days)** + 90 **Xenogeneic cell therapy (max nr days)** No time limit **Mode of approval (Xenogeneic cell therapy)** – **Clock-stop possible if complementary information requested** No **Timespan counted from** Date of submission of valid application
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** Any amendments **Authorisation mandatory for** Substantial amendments (as determined by CA) **Responsible for submission of SA** – **Timeline for approval of SA (max nr days)** – **Guidance on submission of SA available** Yes **Guidance on submission of SA** A detailed list of amendments requiring authorisation, notification or none of the two is provided on the website in section: Medicines & medical devices / Medicines regulation / Clinical trials / Trials in humans (5. Amendments to clinical trials) Further details on submission of amendments are provided on the CA website in Section 11.2 of the 'Guideline for applications for authorisation of clinical trials of medicinal products in humans'.
Safety Reporting	**Responsible for AE reporting to CA** Sponsor **Sponsor must declare reportable events to** National CA **Reportable AEs** SAE (Serious Adverse Event) SUSAR (Suspected Unexpected Serious Adverse Reaction) **SUSAR being life-thereatening or leading to death must be reported** Immediately Within a max of 7d upon first knowledge (+ 8d for additional information) **All other SUSARs** Immediately Within a max of 15d upon first knowledge

SAE /SADE must be reported

–

National standard reporting form available

Yes
Other

Standard Reporting Form

• Non-commercial sponsors:
(1) Standard e-form to be used: Reporting of suspected unexpected serious adverse reactions (SUSARs) seen in clinical trials. OR
(2) CIOMS Form (provided in Annex 9 of "Guideline for applications for authorisation of clinical trials of medicinal products in humans" available on the DKMA website)

• Commercial Sponsors:
(1) Standard e-form to be used: Reporting of suspected unexpected serious adverse reactions (SUSARs) seen in clinical trials OR
(2) Via EudraVigilance (if registered)

Reporting format - Options

Electronically

Preferred format

–

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

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Guidance on AE reporting procedure available

Yes

Guidance on AE reporting procedure

Further details are available on the DHMA website in section: 'Reporting of adverse reactions in clinical trials' and in the 'Guideline for applications for authorisation of clinical trials of medicinal products in humans'-

Applicable national legal framework/ Reference

89(2i)+(2iii) of Danish Medicines Act

Additional Information

SUSARs arising from clinical trials with the same protocol (same EudraCT number) in other EU countries must also be reported to the CA. The DHMA forwards all reported SUSARs to EudraVigilance, so that they are included in the complete European adverse reaction data for the product concerned.

Annual safety report: list of all serious suspected adverse reactions and a report on trial subject safety .

Investigator shall report SAE to

Relevant EC(s)
Sponsor

Reporting timeline

Immediately

End of Trial

End of trial declaration mandatory for

All clinical trials requiring authorisation by CA

Responsible for End of trial declaration

Sponsor

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

Trial completion in the respective country (multinational trials)

Early/premature Termination - Declaration timespan (max nr days)

15

Standard Declaration form

1) Standard form to be used: European Declaration of the End of Trial Form (2) Via DKMAnet

Guidance on End of trial declaration

Further details on end of trial declaration obligations are provided on the CA website in section 13 of the 'Guideline for applications for authorisation of clinical trials of medicinal products in humans'

Applicable national legal framework/ Reference

Art 89 of Danish Medicines Act

Ethics committee

Contact Details

Contact Name 1

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

Phone

+45 72 26 93 70

Address

Holbergsgade 6

ZIP/City

1057 København K

Country

Denmark (DK)

E-Mail

DKetik@DKetik.dk

Web address

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

All research projects involving humans (or any kind of human tissue, cells etc)

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

In parallel
Sequentially (in any order)

	Additional Information Non-interventional trials involving medicinal products shall not be notified to the committee system! There are 11 Regional Research Ethics Committees (authorized to performed the Ethical review of the project). The National Committee for Health Research Ethics provides information on the system of research ethics committees' electronic application and the regional research Ethics Committees. **Regulatory and ethics bodies involved in approval process** –
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Regional EC (competent for the area where investigator is located) **Additional Information** Notification to be sent to the regional EC in the region, where the investigator is located. The regional research ethics committee performs an overall assessment of the trial's ethical aspects.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Regional EC (competent for the area where coordinating investigator is located) authorized to issue a single opinion **Submission of application required to** Regional EC (competent for the area where coordinating investigator is located) authorized to issue a single opinion **Additional Information** The co-ordinating investigator submits the application for a multi-site study to the regional scientific ethical committee of the area in which he/she is operating. This regional committee must make its decision, which forms the basis for an opinion, and then informs the other regional committees and the Danish National Committee for Biomedical Research Ethics.
Submission of Application	**Responsible for study submission** Sponsor Principal Investigator **Entitled to study submission** – **Prerequisites for submission / approval** – **Guidance on study submission available** Yes **Guidance on study submission** Further details are provided on the website in section: Notification of clinical trial of medicinal products. The notification to the research ethics committee shall meet the requirements stated in „Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics., No 9154, 5 May 2011" **Applicable national legal framework/ Reference** Section 14 & 15 of the Committee Act

Submission Format	**Format option(s)** Online portal **Preferred format** – **Online portal** DKMAnet: Only one application to the common submission portal. (Currently the use of the DKMAnet is not mandatory, but in future it will be. Exact date is not yet decided) **Guidance on submission format** Further details are provided on the website in section: Notification of clinical trial of medicinal products The notification to the research ethics committee shall meet the requirements stated in „Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics., No 9154, 5 May 2011“
Language of Submission	**Language(s) of application** Danish English **Preferred language of application** – **English accepted** – **Documents mandatory to be in official national language** –
Submission Fees	**Fees for Ethical review** Notification fee for projects: General: DKK 4000 (≈ € 540) For a supplementary protocol: DKK 1500 (≈ € 200)
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 60 **General timespan for multi-centre studies (max nr days)** 60 **ATMP/GMO trials (max nr days)** 90 **External expert advice required: Timespan (max nr days)** + 90 **Xenogeneic cell therapy: Timespan (max nr days)** No time limit **Clock-stop possible if complementary information requested** Yes **Timespan counted from** Date of submission of valid application

	Applicable national legal framework/ Reference Section 23 of Committee Act **Additional Information** In case of non-acceptance, the applicant may appeal against the decision within 30 days at the Danish National Committee on Biomedical Research Ethics (pursuant to Section 26 of the Committee Act).
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments to the study protocol **Responsible for notification of SA** Principal Investigator Investigator **Standard notification form available** Yes **Standard notification form** Standard amendment notification form to be used. Submission Format: electronically (using digital signature) **Timeline Ethical review of SA (max nr days)** 35 From date of receipt of valid application **Guidance on submission of SA available** Yes **Guidance on submission of SA** Detailed guidance on the notification of amendments, the required format and the characterisation of substantial amendments are provided in Section 6.0 of the Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics. **Applicable national legal framework/ Reference** Part 6, Section 27 of the Committee Act
Safety Reporting	**Reportable AEs** SUSAR (Suspected Unexpected Serious Adverse Reaction) occurring in the respective country **Investigator shall report SAE to** Relevant EC(s) Sponsor **Reporting timeline** Immediately **Responsible for AE reporting to relevant EC(s)** Sponsor Investigator **SUSAR being life-thereatening or leading to death must be reported** – **All other SUSAR must be reported** –

SAE/SADE must be reported

–

National Standard Reporting form available

Yes

Standard Reporting Form

Reporting options:
(1) via the Eudravigilance Database (e.g. CIOMS report)
(2) it is possible to use the Danish Health and Medicines Authority’s e-form, available from the authority’s website: Reporting of suspected unexpected serious adverse reactions (SUSARs) seen in clinical trials (e-form.)
(3) Standard form available and downloadable on the website of the National Research EC in Section: Reporting of adverse reactions, completion of trials, etc.

Reporting format - Options

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Preferred reporting format

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Provision of Annual safety report mandatory

Yes

Guidance on AE reporting procedure available

Yes

Guidance on AE reporting procedure

SUSAR reports to the committee system must comply with the Danish Health and Medicines Authority's clinical trial guidance 'Guideline for applications for authorisation of clinical trials of medicinal products in humans' (sections 12.1 and 12.3 on reporting of adverse reactions).

Applicable national legal framework/ Reference

Section 30(1)&(2) of the Committee Act

Additional Information

Reporting Format: as Pdf, electronically (encrypted) or on CD-ROM.
The reported material can be in either Danish or English

Once every year during the entire trial period, an Annual Safety Report (providing a list of all SUSARs encountered during the period + information about the safety of the trial subjects) or a Development Safety Update Report (DSUR, ICH E2F) shall be submitted by the sponsor or the investigator to the regional EC in all kinds of clinical trials
(pursuant to Section 30(2) of the Committee Act)

End of Trial

End of trial Declaration mandatory

Yes

Responsible for End of trial Declaration

Sponsor
Investigator

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

Last patient - last visit in the respective country

Early/premature Termination - Declaration timespan (max nr days)

15

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form available

Yes

Standard Declaration form

Standard notification form (in Danish) available and downloadable on the website of the National Research EC in Section Reporting of adverse reactions, completion of trials, etc.

Submission format: electronically using digital signature

Applicable national legal framework/ Reference

Section 31(1&2) of the Committee Act

Additional Information

The investigator and the sponsor must jointly notify the regional EC.

Study specific Requirements

Sponsor

Sponsor - Definition available in national law

Yes

Sponsor - Definition (pursuant to national law)

'the person, institution or company being responsible for the initiation, management and possibly financing of a clinical trial' (pursuant to Art 88 (2) Danish Medicines Act)

Sponsorship mandatory

Yes

Co-Sponsor - Definition available in national law

No

Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:

Yes

Additional Information

The sponsor or its legal representative must have a permanent address in an EU/EEA country (pursuant to section 88(7) Danish Medicines Act.

Study Participants - Informed Consent (IC)

IC is regulated by law

Yes

Informed Consent - Definition/ Requirements

Definition is provided in section 2(10) of the Committee Act.
It is a decision to participate in a research project which has been made upon due information on the nature, significance, implications and risks of the project and receipt of suitable documentation. The decision is made voluntarily by a person who is capable of giving his or her consent. The consent shall be in writing, dated and signed or provided using an electronic signature.
Specific requirements apply to vulnerable populations.

The requirements on written information, application, notification and reporting is described in detail in the 'Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics'.

Applicable national legal framework/ Reference

The procedures of how to inform and obtain consent from subjects participating in clinical trials are regulated by:
(1) Executive Ministerial Order No 806 of 12 July 2004 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects
(2) Committee Act

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Yes
Special provisions apply

Legal framework/Reference (Minors/Children)

• Art 20 & 21 of Ministerial Order No 806
• Part 3, section 9 and Part 5, section 17&19 of the Committee Act
• Further details on „Trials with children and young people under the age of 18“ are provided in in section 4.4 of the 'Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics'.

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Incapacitated persons)

• Art 22 of Ministerial Order No 806
• Part 3, section 3-5 of the Committee Act
• Further details are provided in in section 4.4 of the 'Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics'.

Emergency situations - Studies allowed

Yes
Special provisions apply

Specific provisions

Proxy consent from the „trial guardian“ must be obtained prior to the trial commencement if the trial subject is unable to give his/her informed consent and it is impossible to obtain an „ ordinary“ surrogate consent from the guardian, the custodial parent, the next of kin and the general practitioner alternativly the medical officer of health.

Emergency situation without prior consent of patient or proxy - Studies allowed

With limitations

Conditions allowing trial participation in emergency setting without prior consent

According to section 2(12) of the Committee Act, the „trial guardian“ is a unit consisting of two doctors who may give proxy consent on behalf of the trial subject in acute situations; they are appointed for all the trial subjects in a clinical trial or ad hoc for individual trial subject

This is normally applicable to trials involving individuals in acute settings who are temporarily incapacitated, e.g. unconscious.

Legal framework / Reference (Emergency Situation)

• Section 2(12) & 12 of the Committee Act
• Further details are provided in Section 4.6.2 of the Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics.

Pregnant or breastfeeding women - Studies allowed

No national legal framework available

Legal framework / Reference (Pregnant or breastfeeding women)

There are no common provisions mentioned in Danish law regarding the inclusion of pregnant or lactating women.

National legal framework for protection of vulnerable populations in place

Yes

Applicable legal framework / Reference (Vulnerable Population)

(1) Ministerial Order No 806
(2) Committee Act
(3) Further details on the inclusion of vulnerable population in a clinical trials are provided in Section 4.6.2 of the Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics.

Study Participants - Compensation & Reimbursement

Reimbursement for study participants

Depends on study population (healthy subjects or patients)

Compensation is limited to/provided for

Inconvenience, Pain, Discomfort
Expenses (e.g. transportation, meals, and others such as salary lost)

Additional Information

In general a distinction is made between compensation for documented loss of earnings or for documented transportation costs and inconvenience compensation, which relates to the invasiveness, duration, pain and discomfort of the trial. Healthy trial subjects may receive all this types of remuneration.

Trial patients, who participate in a trial because they have a disorder or condition which is required for participation in the trial, cannot be offered inconvenience compensation.
However model trial patients may receive the same types of remuneration as healthy trial subjects. These trial subjects are patients but there must be no possible treatment benefit of trial participation.

Further details are provided in the 'Guidelines for remuneration or other payment for voluntary trial subjects, Appendix 6 in the Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics'

Study Participants - Recruitment & Trial Outcome	**Additional Information** Publication obligation: publication of negative, inconclusive and positve results is mandatory according to section 20(8) Committee Act.
Data Protection	**Notification to DP Authority/ Ombudsmann is mandatory** Yes **Specific notification timelines before operations start** – **Language of notification** – **Notification format** – **Data Protection Authority/ Agency - Contact Details** Danish Data Protection Agency **Phone** +45 3319 3200 **Web address** http://www.datatilsynet.dk/english/ **Country** Denmark (DK) **Additional Information** Clinical trial on IMP shall also be notified to the Danish Data Protection Agency (according to the Act on Processing of Personal Data). This may take place at the same time as the application to the CA. More information on notification requirements can be obtained by the Agency. If information from patients' records is to be used – in register research projects without the use of biological material – an application for such approval shall be submitted to the DKMA. **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** –
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Investigator(s) Sponsor Study participants **Responsible for covering insurance** – **Applicable national legal framework/ Reference** (1) Section 20(7) of the Committee Act (2) Danish Act on the Right to Complain and Receive Compensation (2009) and Danish Liability for Damages Act (2005): regulate the conditions for paying compensation

	Additional Information Insurance or other compensation arrangemens must be in place to cover any harm or injury of the study participant/ patient as well as the liability of the investigator and the sponsor. Persons taking part in biomedical trials that do not form part of the diagnosis or treatment of their illness shall also be regarded as patients. The same shall apply to donors from whom tissue and other biological material are taken. The website of the Patient Compensation Association deals with compensation claims for patients injured in connection to treatment by the Danish Health Service. It als covers drug injury cases, i.e. cases where patients are injured because of adverse reactions to the medicines they take The system is supplemented by private compensation and reimbursement schemes.
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Compulsory **Audit by sponsor** Compulsory **Standard Operating Procedures (SOPs)** Compulsory

National legislation

General Information: Applicable Legislation & Conventions	**Official website providing relevant national legislation available** Yes **Official website providing relevant national legislation** The website of the CA provides legal information in section: About us / Targets and tasks / Legislation. **Official governmental legal database available** Yes **Official governmental legal database** Retsinformation.dk: Danish national system for legal texts (in Danish only).
Clinical Trials on IMPs in Humans	**Applicable national regulations** National Act on Medicinal Products Transposition of (CT) Directive 2001/20/EC Transposition of (GCP) Directive 2005/28/EC Other **Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)** (1) Lov om lægemidler (Lægemiddelloven) / Danish Medicines Act (en): unofficial translation including all amendments up until 1 February 2013 This act is the transposition of the Directive 2001/20/EC. (2) Lov om et videnskabsetisk komitésystem og behandling af biomedicinske forskningsprojekter / Act on Research Ethics Review of Health Research Projects: unofficial translation, hereinafter referred to as the Committee Act (en)This act contains provisions that implement parts of Directive 2001/20/EC as well as parts of directive 2005/28/EC.

	Applicable to ATMP/ GMO trials Yes **Transposition of (GCP) Directive 2005/28/EC** – **Other applicable regulations/ implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)** Informed Consent & Trial Subjects: Ministerial Order No 806 of 12 July 2004 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects
Radiation & Radiotherapy	**Use of radiation or radioactive compounds - Specific requirements** Yes **Applicable legal framework** Danish Act on the Use of X-rays Danish Act on Use of Radioactive Substances Danish Act on Nuclear Installations **Additional Information** Radiation: Approval is required in case that radiation is used in the clinical trials More information on notification and approval may be obtained by contacting the institute: The National Institute of Radiation Protection Knapholm 7 2730 Herlev Denmark Tel. +45 4454 3454 24-hour hotline: +45 4494 3773 Fax +45 7222 7417 Email sis@sis.dk (Head of Division: Mette Karin Øhlenschlæger Email: moe@sis.dk, Phone +45 4454 3481) Contact is provided on the CA website in section: About us / Contact / Contact the Danish Health Authority
Gene Therapy	**Specific requirements** Yes **Applicable legal framework** Gene therapy follows the same regulations as clinical trials on medicinal products. Additional requirements are covered in the Executive Order on Genetic Engineering and the Working Environment of the Danish Working Environment Authority.
Data Protection	**Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** – **National DP act** Lov om behandling af personoplysninger/ Act on Processing of Personal Data -Act No. 429 of 31 May 2000 (unofficial english version; updated with amendments until Dec 2012)

Definition

IMP/IMP Study	**IMP - Definition** Medicinal Product (Definition provided in part 1, section 2 of the Danish Medicines Act). **IMP Study - Definition** Health Research Project/ Clinical trial of Medicines (Definition according to part 2, section 2(1) of the Committee Act): „Any trial on humans with the aim of uncovering or verifying the clinical, pharmacological or other pharmacodynamic effect of one or several trial medicines or to identify adverse reactions to one or several trial medicines or to investigate absorption, distribution, metabolism or excretion of one or several trial medicines with a view to assessing their effect or safety.“ **Additional Information** Non-interventional trial: • The MP(s) in the trial are prescribed in the usual manner in accordance with the terms of the marketing authorization • The decision to prescribe the medicine concerned is clearly separated from the decision to include a specific patient in the trial • The actual treatment follows normal practice and is not decided by a trial protocol • No additional diagnostic or control procedures are carried out (in Denmark, questionnaires are not considered to be additional procedures) • Epidemiological methods are used for the analysis of the gathered data.