Medicinal Products for Human Use - FINLAND

Competent authority

Contact Details	**Contact Name 1** Finnish National Agency for Medicines (Fimea) **Contact Name 2** Clinical Drug Trial Unit **Phone** +358 29 522 3341 **Fax** +358 29 522 3001 **Email Department** clinicaltrials@fimea.fi **Address** P.O. Box 55 **ZIP/City** 00034 FIMEA **Country** Finland (FI) **Web address** http://www.fimea.fi **Additional Information** Fimea is the national CA for regulating pharmaceuticals. No local CA.
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s) Other (e.g. in case of radiation) **CA - Submission for authorisation mandatory for** Interventional clinical trials on MP (with or without marketing authorization) **CA - Registration/ notification without approval required for** – **CA - Submission required to** National CA Other (e.g. in case of radiation)

	Additional Information No notification is required for non-interventional trials meeting the criteria as specified in Section 2, Definitions and Glossary Regulation 2/2012. If radiation is used in the clinical investigation, a safety license issued by STUK is required, unless the practice is specifically exempted.
Submission of Application	**Responsible for study submission** Sponsor Legal representative domiciled in the respective country **Entitled to study submission** – **Prerequisites for submission** – **Guidance on submission of application** Information on the application procedure including a list of required documents to be appended to the notification is provided in Section 6 -8 of Regulation 2/2012. Details on notification procedure available on FIMEA website in section: Supervision > Clinical Drug Trials > Notification of a clinical trial - EudraCT **Applicable national legal framework/ Reference** Section 6 -8 of Regulation 2/2012 **Additional Information** If radiation is used in the clinical investigation: A safety license issued by STUK is required, unless the practice is specifically exempted. Instructions for applying safety license are available at STUK website. The license should be valid before trial commencement. Submission of trial notification to Fimea is needed if the clinical trial includes radioactive material, e.g. diagnostic product.
Submission Format	**Format option(s)** Paper + electronic file **Preferred format** – **Standard application form** Notification resp. request for authorization of a clinical trial shall be made using the Clinical Trial Application (CTA) Form available on the EMA- EudraCT database website. **Guidance on submission format** Section 6 -8 of Regulation 2/2012 **Applicable national legal framework/ Reference** Section 6 -8 of Regulation 2/2012
Language of Submission	**Language(s) of application** Finnish Swedish English **Preferred language of application** –

English accepted

By Fimea only!

Documents mandatory to be in official national language

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Submission Fees

Fees for trial submission mandatory

Yes

Fees

An administrative application/ notification fee is charged by Fimea according to the Decree of the Ministry of Social Affairs and Health No 346/2015 (unofficial translation).

• Processing of Clinical trial notification (silent approval): € 2200.-
• Processing of Clinical trial authorization (explicit written approval): € 2500.- (applicable to clinical trials involving medicinal products for gene therapy, somatic or xenogenic cell therapy or medicinal products containing GMOs)

A single fee is payable for multi-centre trials.

Waiver for academic (non-commercial) studies possible

Yes

Official guidance on required fees

Current fees are provided on the FIMEA website in section: Supervision > Clinical Drug Trials.
Further information on payment and applicable regulation (Decree No 346/2015) available in section: About us > Fees

Applicable national legal framework/ Reference

Decree of the Ministry of Social Affairs and Health concerning activities of the Finnish Medicines Agency subject to fees No 346/2015

Additional Information

ad waiver: A waiver of processing fee may be requested in respect of a notification relating to a clinical trial on a medicinal product conducted by an individual investigator, a trial team, a university institute, a university hospital clinic or the National Institute for Health and Welfare without outside financing or with financing by a non-profit corporation. In these cases, the notification concerning a trial must be accompanied by an informal statement to the effect that the investigation will not receive any outside financing.

Timelines Authorisation

General timespan (max nr days)

60

Mode of approval (General)

Tacit (Silent)

ATMP/GMO trials (max nr days)

90

Mode of approval (ATMP/GMO trials)

Explicit (written)

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 **Applicable national legal framework/ Reference** Section 11 of Regulation 2/2012 **Additional Information** In case of further clarification asked by the CA: Any requests for clarification must be made in writing within the respective time span.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** Any substantial amendments (e.g . to trial protocol or its appendices) **Responsible for submission of SA** Sponsor **Standard notification form** “Substantial Amendment Notification Form” available on the European Commission website EudraLex - Volume 10 Clinical trials guidelines – Chapter I: Application and Application Form. The forms may be filled in electronically on the EMA website, but Fimea requires submission of signed paper printouts. **Timeline for approval of SA (max nr days)** 35 By silent (implicit) approval **Applicable national legal framework/ Reference** Section 9 of Regulation 2/2012 **Additional Information** Silent approval procedure if no further information are requested, but a positive EC vote must be obtained before implementation.
Safety Reporting	**Responsible for AE reporting to CA** Sponsor **Sponsor must declare reportable events to** National CA CA(s) of EU&EFTA Member States concerned Investigators shall also be notified **Reportable AEs** SUSAR (Suspected Unexpected Serious Adverse Reaction) **SUSAR being life-thereatening or leading to death must be reported** As soon as possible Within a max of 7d upon first knowledge (+ 8d for additional information)

All other SUSARs

As soon as possible
Within a max of 15d upon first knowledge

SAE /SADE must be reported

–

National standard reporting form available

No, European standard SUSAR reporting form CIOMS-I recommended
Other (see info in 'Standard Reporting Form')

Standard Reporting Form

(Non-commercial) sponsors, not being registered with the EudraVigilance network, must submit the report to Fimea in writing (fax or email is not accepted), in form of a free form letter or by using the CIOMS-I form or equivalent.
The minimum content of the report is itemised in Section 10 of Regulation 2/2012

Reporting format - Options

Online portal
Via Eudralink (EMA)
Depends on trial sponsor (commerical vs. non-commercial)
Other

Preferred format

–

Online Safety Reporting Portal

EMA- EudraVigilance: Registration with EMA’s EudraVigilance network is mandatory for commercial sponsors and recommended for non-commercial sponsors (Guidance on registration).
Registered sponsors must submit electronic notifications to EudraVigilance. SUSARs occurring in Finland must be reported both to the Fimea database (receiver identifier FINAM) and EMA, SUSARs occurring abroad only to the EMA.

Commercial sponsors registered with the EudraVigilance network who are not yet submitting their reports electronically to the Fimea should contact the Clinical Trial Unit (Kliinisten lääketutkimusten yksikkö) to commence testing and usage.

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA

Guidance on AE reporting procedure

(1) Fimea Website in section: Supervison > Clinical Drug Trials > Electronic Reporting of Adverse Reactions.
(2) Further guidance has been issued by the European Commission: 'Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use'

Applicable national legal framework/ Reference

Section 10 of Regulation 2/2012
Section 10 f of Act No. 488/1999

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately

Sponsor is obliged to notify all investigators of SAE/ SADE occurrence

Yes

End of Trial

End of trial declaration mandatory for

All clinical trials requiring notification to resp. authorisation by CA

Responsible for End of trial declaration

Sponsor
Investigator

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

Last patient - last visit at involved trial sites

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

15

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form

Notification of early and regular trial termination must be made by using the EudraCT form “Declaration of the End of Trial” available on the European Commission website EudraLex - Volume 10 Clinical trials guidelines – Chapter I: Application and Application Form.

The forms may be filled in electronically on the EMA website, but Fimea requires submission of signed paper printouts.

Guidance on End of trial declaration

Section 11 of Regulation 2/2012

Applicable national legal framework/ Reference

Section 11 of Regulation 2/2012

Additional Information

In the event that a multinational trial ends in Finland earlier than at the other trial sites, a separate notification is required.

For trial interruptions and re-commencement of the trial, the EudraCT form “Substantial Amendment Notification Form” must be used.

Ethics committee

Contact Details

Contact Name 1

National Committee on Medical Research Ethics (TUKIJA)

Address

Postal Adress: TUKIJA, Valvira; P.O. Box 210

ZIP/City

00531 Helsinki

	Country Finland (FI) **E-Mail** tukija@valvira.fi **Web address** http://tukija.fi/en **Additional Information** TUKIJA operates under the auspices of Valvira. It previously operated as sub-committee on Medical Research Ethics of the National Advisory Board on Health Care Ethics (ETENE)/ Ministry of Social Affairs and Health.]
Ethical Review – General	**Submission for Ethical review mandatory for** All scientific health research projects All clinical trials on Medicinal Products (MP) **Submission to CA and EC to be performed in the following order** – **Additional Information** (1) National Committee on Medical Research Ethics (TUKIJA): is responsible for issuing opinions on the ethics of clinical drug trials that are to be run in Finland unless this task is delegated to a regional ethics committee. Upon request, TUKIJA also issues opinions on proposals that have been previously rejected by regional ethics committees. (2) Regional Ethics Committees: Each of the 21 hospital districts operating a university hospital must have at least one (regional) ethics committee. The Hospital District of Helsinki and Uusimaa, the largest of the Finnish hospital districts, have currently four ethics committees. **Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s) Other (e.g. in case of radiation)
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** National EC or Regional EC (competent for the area where investigator is located) **Additional Information** In Finland, statutory ethics committees include the National Committee on Medical Research Ethics (TUKIJA) and regional ethics committees. Ethical evaluation of research projects and issuing an opinion on them is the responsibility of the EC of the region where the person responsible for the research is based or where the major part of the research is to be conducted. TUKIJA shall deliver the opinion if the task has not been delegated to a regional EC.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Central EC (authorised to issue a single opinion)- can be delegated to a Regional EC **Submission of application required to** –

	Additional Information TUKIJA gives national ethical opinions on international multi-centre clinical trials on medicinal products. This can also be delegated to regional ECs of hospital districts, where the person responsible for the research (National Coordinator) is based, which will then issue any necessary national opinion.
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission / approval** Pre-Notification/ Application for a ruling (more info in 'Additional Information') **Guidance on study submission** TUKIJA has published a detailed guidance on the application procedure and related duties of the sponsor and investigator: “Operating procedures of the National Committee on Medical Research Ethics (TUKIJA) (Update May 2015)” **Additional Information** Pre-Notification: The first step in all clinical trials is for the sponsor to apply for a ruling from TUKIJA or by one of the regional EC. Sponsor can apply for a ruling on jurisdiction as soon as it becomes likely that the trial will be run in Finland, even if the actual application is not yet complete. The application for rulings on jurisdiction shall be made to TUKIJA using the form “Prior notification of a clinical drug trial”, provided in Appendix 1 to Decree No. 841/2010 of the Finnish Ministry of Social Affairs and Health (NB: Appendices are not available in the English version!). Applicants are requested to submit the application in electronic format by email to TUKIJA’s secretary, considering the submission deadlines posted on TUKIJA’s website. Depending on the ruling, which is communicated via email to the applicant, the sponsor then applies for an ethical review to be carried out either by TUKIJA or by the relevant regional EC.
Submission Format	**Format option(s)** – **Preferred format** – **Standard application form** The standard application form to be used is contained in Appendix 2 to Decree No. 841/2010: “Request for opinion on a clinical drug trial” NB: Appendices are not available in English! The documents listed on the form must be included in all applications. **Applicable national legal framework/ Reference** Decree No. 841/2010
Language of Submission	**Language(s) of application** Finnish Swedish **Preferred language of application** – **English accepted** Partly, not for all documents e.g. Investigator’s brochure + trial protocol

	Documents mandatory to be in official national language Summary of the trial protocol must be in Finnish or Swedish
Submission Fees	**Fees for Ethical review mandatory** Yes **Waiver for academic (non-commercial) studies possible** Yes **Fees for Ethical review** Provision on fees charged for the regional or national EC's opinions are laid down by Decree No. 1168/2014 and are reviewed on a yearly basis: Clinical drug trial: EUR 2700.- Amendments to the research plan: EUR 900.- Waiver is possible for researcher-driven research without outside funding or by funding from a non-profit corporation. **Applicable national legal framework/ Reference** Decree No 1168/2014 of the Ministry of Social Affairs and Health on Fees Charged by the National Advisory Board on Health Care Ethics and Regional Ethics Committees (only in Finnish)
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 10 d of Act No. 488/1999 **Additional Information** The EC shall communicate its vote to Fimae for information.
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments to research plan

Responsible for notification of SA

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Standard notification form

Standard form to be used is provided in Appendix 3 to Decree No. 841/2010: “Request for opinion on a significant change ot the clinical drug trial”.
NB: Appendices are not available in English!

Timeline Ethical review of SA (max nr days)

35
From date of receipt of valid application

Guidance on submission of SA

Further information is provided in the guidance 'Operating Procedures of the National Committee on Medical Research Ethics (TUKIJA)' in section: 3.5 Amendments to trial protocols.

Applicable national legal framework/ Reference

Section 10d of Act No. 488/1999

Safety Reporting

Reportable AEs

SAE (Serious Adverse Event)
SUSAR (Suspected Unexpected Serious Adverse Reaction)

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately

Responsible for AE reporting to relevant EC(s)

–

SUSAR being life-thereatening or leading to death must be reported

–

All other SUSAR must be reported

–

SAE/SADE must be reported

–

Sponsor is obliged to notify all investigators of SAE/ SADE occurrence

Yes

National Standard Reporting form available

–

Reporting format - Options

–

Preferred reporting format

–

Provision of Annual safety report mandatory

Yes

Applicable national legal framework/ Reference

Section 10e&f of Act No. 488/1999

Additional Information

The investigator must communicate to the sponsor and the relevant EC any information requested by them about deaths of research subjects (pursuant to Section 10e of Act No. 488/1999).

Ad Annual Safety Report: The sponsor must compile and submit a list of SUSARS identified in connection with the trial must be submitted to the relevant EC according to Section 10g of Act No. 488/1999. The lists must be accompanied by reports on the safety of subjects and the investigator's opinion on the impacts of the reported cases.

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

–

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

End of trial notification to the relevant EC shall be made by use of the form provided in Appendix 4 to Decree No. 841/2010: "Notification of termination of a clinical drug trial".
NB: Appendices are not available in English!

Applicable national legal framework/ Reference

Section 10h of Act No. 488/1999

Additional Information & Specifics

Additional Information

The structure, responsibility, duties and composition of Finnish ECs are described in Chapter 4, Section 16-20 of Act No. 488/1999). Decree No. 820/2010 specifies the role and activities of TUKIJA.

Study specific Requirements

Sponsor

Sponsor - Definition available in national law

Yes

Sponsor - Definition (pursuant to national law)

An individual, company, institution or organisation that takes responsibility for the initiation, management or financing of a clinical trial. If an outside party participates in the trial only by financing it, the investigator and the sponsor can agree between themselves that the investigator is also the sponsor. The investigator himself is regarded as the sponsor in the case of trials where there is no outside sponsor. (pursuant to Section 2 of Regulation 2/2012)

	Sponsorship mandatory Yes **Sponsorship mandatory - Additional information** Each clinical trial on a medicinal product must have a sponsor (or a legal representative in the EU). **Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:** Yes
Investigator	**Entitled to be principal investigator** – **Additional Information** Definition 'Investigator' (pursuant to Section 2 of Regulation 2/2012): 'An authorised physician or dentist with the appropriate professional and scientific qualification who is responsible for performance of the clinical trial at the trial site. If a trial group is conducting a trial at some trial site, the term 'investigator' refers to the physician or dentist acting as the leader of the group.'
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Yes **Standard IC form (ICF)** Templates for Informed Consent and Clinical trial information leaflet are provided on the TUKIJA website in section: Publications. **IC is regulated by law** Yes **Informed Consent - Definition/ Requirements** Definition according to Regulation 2/2012: 'A document given to the trial subject which contains an explanation of the trial subject's rights, the purpose and nature of the trial and procedures to be used therein and any associated risks and disadvantages, and which is signed by the giver and recipient of the consent (further information in the Medical Research Decree 986/1999, 313/2004). The document may be independent or comprise the trial subject information leaflet (or patient information leaflet) and consent form.' Informed consent of the subjects is an elemental condition for carrying out medical research. Volunteer research subjects must also be allowed to withdraw their consent at any time without justifying their decision to anyone. Participation in medical research can only be genuinely voluntary if the subjects understand the information that they have been given. In order to obtain informed consent, the researcher or the sponsor must produce written information for prospective subjects, describing the trial in sufficient detail and in plain language. The information must cover all of the issues that the subjects need to be aware of in order to give their informed consent to participating in the trial in question. Ideally, each of the procedures associated with the trial in question should also be explained both to the subject and to a representative of the same (where applicable). **Applicable national legal framework/ Reference** Section 2 of Regulation 2/2012 (Definition) Section 6 of Act No. 488/1999 Section 3 of Decree No. 986/1999
Study Participants - Vulnerable Population	**Minors / Children - Studies allowed** Yes Special provisions apply

Legal framework/Reference (Minors/Children)

Section 8 of Act No. 488/1999

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Incapacitated persons)

Section 7 of Act No. 488/1999

Emergency situations - Studies allowed

Yes
With limitations

Specific provisions

In Finland is allowed to include patients to clinical trial without his/her prior consent.
However, proxy consent is required (close relativ, other person closely connected, or legal representative) according to ClinicalTrialsFinland:
'Also patient in intensive care may not able to give their consent themselves due to their condition.
In case the person does not have the capacity to give consent, as mentioned above, he/she may be entered into the trial as a research subject only when written consent for this has been given by his/her close relative or some other person closely connected with the subject or by his / her legal representative after having been provided essential study information.'

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

No

Legal framework / Reference (Emergency Situation)

Information available on the ClinicalTrialsFinland website in section: Persons not Able to Consent
Section 7 of Act No. 488/1999

Pregnant or breastfeeding women - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Pregnant or breastfeeding women)

Section 9 of Act No. 488/1999

Study Participants - Compensation & Reimbursement

Reimbursement for study participants

–

Compensation is limited to/provided for

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

Additional Information

No payment is allowed for research subjects (patients or healthy volunteers). Only an appropriate remuneration for any expenses (e.g. travel, daily allowance), loss of earnings or other inconvenience resulting from the participation in the trial may be paid (according to Section 21 of Act No. 488/1999 and Decree No. 82/2011).

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

Yes

Specific notification timelines before operations start

Latest 30 days before collecting and saving the data at issue

Language of notification

–

Notification format

–

Notification fee required

No

Guidance on notification requirements

The ‘Notification to the Data Protection Ombudsman (letter)’ and the ‘Notification of Transfer of Personnel Data outside the EU or EEA form’ must be completed and submitted to the Data Protection Ombudsman ahead of time.

Further information and notification forms and letters are provided on the Data Protection Ombudsman website > Publications.

Data Protection Authority/ Agency - Contact Details

Office of the Data Protection Ombudsman

Phone

+358 29 56 66700 (exchange)

E-Mail

tietosuoja@om.fi

Web address

http://www.tietosuoja.fi/en/

Address

P.O. Box 800 (Visiting adress: Ratapihantie 9, 6rd floor- 00520 HELSINKI)

ZIP/City

00521 HELSINKI

Country

Finland (FI)

Additional Information

The collection and keeping of patient files in clinical trials are governed by the Personal Data Act No. 523/1999 (unofficial English translation).

Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)

National Data Protection Act

National DP act

The collection and keeping of patient files in clinical trials are governed by the Personal Data Act No. 523/1999 (unofficial English translation).

Insurance

Liability insurance or alternative arrangements for damages mandatory for

Investigator(s)
Sponsor
Study participants

Responsible for covering insurance

Sponsor

	Applicable national legal framework/ Reference Section 10 b of Act No. 488/1999 **Additional Information** 1) Pharmaceutical Injuries Insurance: For clinical trials with medicinal products in Finland, the study sponsor's responsibility is to confirm the validity of the study subjects' insurance to cover all pharmaceutical injuries related to the investigational medicinal product. This may be either the Pharmaceutical Injuries Insurance, or other equivalent Insurance. Pharmaceutical injuries insurance or other equivalent insurance must cover any bodily injury (pharmaceutical injury) of study subjects during the clinical trial resulting from the investigational drug or pharmaceuticals used as comparators in the trial if the specified criteria are met. (2) Patient Injuries Insurance: In Finland, all health and medical care providers must be covered by Patient Injuries Insurance against liability arising as provided under the Patient Injury Act No. 585/1986. All legally operating health care units in Finland (i.e. hospitals, public health centers and private health care clinics) are obliged to have the insurance for all employees working with patients, and for a valid insurance cover all employees must have valid and signed employment contracts with the unit or hospital where they (i.e. study personnel) are working. For more information please see Finnish Patient Insurance Centre.
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Not specified **Audit by sponsor** Not specified **Standard Operating Procedures (SOPs)** Not specified
Archiving & Data Management	**Study documents must be kept at least (in years)** 15 **National legal framework in place** Yes **Applicable national legal framework/ Reference** Section 14 of Regulation 2/2012

National legislation

General Information: Applicable Legislation & Conventions	**Official website providing relevant national legislation available** Yes **Official website providing relevant national legislation** CA (FIMEA) and National EC (TUKIJA) websites provides applicable national legislation in Finnish and English (non-official translations). **Official governmental legal database available** Yes **Official governmental legal database** FINLEX: a free legal database maintained by the Finnish government. It is updated frequently and contains many translations of Finnish acts and decrees.

	Additional Information Note: all English translations are unofficial since Finnish legislation is legally binding only in Finnish and Swedish.
Clinical Trials on IMPs in Humans	**Applicable national regulations** General Act(s) on Medical/Clinical Research in Humans National Act on Medicinal Products Transposition of (CT) Directive 2001/20/EC Other **Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)** Administrative Regulation 2/2012 – Clinical trials on medicinal products (en/ unofficial translation)/ Kliiniset lääketutkimukset (fi): the Finnish Medicines Agency issued this regulation pursuant to section 15 a and 87 of the Medicines Act and section 10i of the Medical Research Act. Regulation 2/2012 nationally implements Directive 2001/20/EC and 2005/28/EC and replaces earlier Regulation 1/2007 **Transposition of (GCP) Directive 2005/28/EC** Incorporated in transposition act(s) of Directive 2001/20/EC **General legislation on Medical/ Clinical Research in Humans** Finnish Medical Research Act No. 488/1999, as amended by No 295/2004, 794/2010 (unofficial English translation) The Act covers all medical research intervening with the inviolability of a human being, human embryo or foetus, including clinical trials on medicinal products in human subjects. **Other applicable regulations/ implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)** Medicines Act No. 395/1987 (amendments up to 1340/2010 included, unofficial translation)
Radiation & Radiotherapy	**Use of radiation or radioactive compounds - Specific requirements** Yes **Applicable legal framework** Provisions concerning clinical trials involving ionising radiation or radioactive material are given in: • Radiation Act No 592/1991 • Radiation Decree No 1512/1991 • Decree on the medical use of Radiation No. 423/2000 and • Regulations and instructions based on these. Radiation practices and its safety are also bound by International agreements relating to radiation safety and the EC legislation. **Additional Information** Further Finnish and EU- legislation can be found on Stuklex (a legal database on statutes, regulations and instructions in Radiation and Nuclear Safety Authority's field of operation.
Gene Therapy	**Specific requirements** Yes

	Applicable legal framework For clinical gene therapy: - Medical Research Act 488/1999 (including amendment 295/2004) (see also the unofficial translation published by the Ministry of Social Affairs and Health: Finnish Medical Research Act 488/1999, English version) - Medicines Act and Medicines Decree (see the unofficial translation of Medicines Act and Decree (Finland), English version) Due to the fact that gene therapy medicinal products are covered by the Medical Research Act 488/1999 the legal procedure is generally the same as for medicinal products for human use. Exceptions and peculiarities regarding EC and CA application procedures are covered in Section 87 (2-4) Medicines Act 395/1987 and Section 10d (10) of the Medical Research Act. - Gene Technology Act No. 377/1995 (unofficial English translation): regulates genetic research and the use of GMOs (in preclinical research, in particular) - As a matter of principle Good Manufacturing Practice (GMP) is required for the manufacture of medicinal products for human use. The EC-GMP-Guideline covers this issue.
Blood & Tissue Samples	**Specific requirements** Yes **Applicable legal framework** The Act on the Medical Use of Human Organs and Tissues No. 101/2001 (unofficial English translation) deals with the removal, storage and use of human organs and tissues.
Data Protection	**Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** National Data Protection Act **National DP act** The collection and keeping of patient files in clinical trials are governed by the Personal Data Act No. 523/1999 (unofficial English translation).
EC operations/ Fees	**Separate legal framework available** Yes **Applicable legal framework** TUKIJA's (National EC on Medical Research) operations are primarily based on the • Finnish Medical Research Act No. 488/1999 (unofficial English translation) and the associated amendments and decrees: • Medical Research Decree No. 986/1999, as amended No. 313/2004 (unofficial English translation) • Government Decree on the National Committee on Medical Research Ethics No. 820/2010 (unofficial English translation) • Decree of the Ministry of Social Affairs and Health on the Fees Charged for Opinions of the Regional Ethics Committees and the National Committee on Medical Research Ethics No. 1168/2014 (only in Finnish) • Decree of the Ministry of Social Affairs and Health of Clinical Drug Trials No. 841/2010 (unofficial English translation) • Decree of the Ministry of Social Affairs and Health on Remuneration Payable to Research Subjects No. 82/2011 (unofficial English translation)
CA operations/ Fees	**Separate legal framework available** Yes

Applicable legal framework

Fimea's (CA's) operations are regulated by the following act and decrees:

• Act on the Finnish Medicines Agency 24 July 2009/593 (in Finnish)
• Government decree on the Finnish Medicines Agency (in Finnish)
• Decree of the Ministry of Social Affairs and Health No 346/2015: On fees chargeable by the Finnish Medicines Agency (unofficial English translation)

Definition

IMP/IMP Study

IMP - Definition available in national law

Yes

IMP - Definition

"A pharmaceutical form or an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different form the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form" (pursuant to Section 2 of Regulation 2/2012)

IMP Study - Definition available in national law

Yes

IMP Study - Definition

Definitions pursuant to Section 2 of Regulation 2/2012:

• Clinical trial:
'An interventional clinical trial conducted with human subjects in order to discover the effects of medicinal products in human subjects (effectiveness or safety, i.e. pharmacodynamics) or their pharmacokinetics in the human organism (absorption, distribution, metabolism or excretion), or both.

• Interventional clinical trial:
'A trial which intervenes with the inviolability of the trial subject for the purpose of the investigation. For example, the administration of an investigational medical product to the trial subject or use of some extra means of intervention (i.e. samples, tests or questionnaires) that would not otherwise be used.'

• Non-interventional clinical trial:
'A study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is wholly independent of the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of the data.'