Translation from Finnish
Legally binding only in Finnish and Swedish
Ministry of Social Affairs and Health, Finland

Act on Clinical Trials on Medicinal Products

(983/2021)

By decision of Parliament, the following is enacted:

Chapter 1
General provisions

Section 1
Scope of application

This Act applies to the assessment, conduct and supervision of clinical trials on medicinal products for human use as specified in the definition of a clinical trial in Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, hereafter referred to as the *Clinical Trials Regulation*. This Act lays down provisions supplementary to the Clinical Trials Regulation.

Section 2
Relation to other legislation

The Medical Research Act (488/1999), hereafter referred to as the *Research Act*, does not apply to clinical trials that fall within the scope of this Act. However, chapter 3 of the Research Act applies to clinical trials on medicinal products unless otherwise provided in the Clinical Trials Regulation, this Act, provisions issued under them or elsewhere by law.

Provisions supplementing the Clinical Trials Regulation with regard to investigational or auxiliary medicinal products and their supervision are laid down in the Medicines Act (395/1987). Provisions on information to be recorded in patient documents and on the keeping of patient documents are laid down in the Act on the Status and Rights of Patients (785/1992) and the provisions issued under it.

This Act lays down provisions that supplement and specify Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the

processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), hereafter referred to as the *General Data Protection Regulation*, where personal data are processed as part of, or in connection with, clinical trials on medicinal products. Should the provisions of this Act be inconsistent with the provisions of the Data Protection Act (1050/2018), the provisions of this Act apply.

Chapter 2
Certain provisions applied to clinical trials on medicinal products for human use

Section 3
Conditions of qualification

An investigator referred to in point (15) of Article 2(2) of the Clinical Trials Regulation shall be a medical doctor or a dental practitioner with appropriate professional and scientific qualifications.

A member of an investigating team referred to in point (c) of Article 29(2) of the Clinical Trials Regulation who provides information in a prior interview as part of obtaining informed consent shall have adequate knowledge of the clinical trial in question and the regulation on informed consent.

Section 4
Sponsor's legal representative and contact person

If a clinical trial on a medicinal product is intended to be conducted exclusively on the territory of Finland, or exclusively on the territory of Finland and a country that does not belong to the European Union or the European Economic Area, and the sponsor is not established in a Member State of the European Union or a country belonging to the European Economic Area, the sponsor shall appoint a legal representative referred to in Article 74 of the Clinical Trials Regulation. On application by the sponsor, however, the Finnish Medicines Agency may authorise the trial to have a contact person referred to in Article 74(2) of the Regulation, instead of a legal representative.

A sponsor who, pursuant to what is laid down in subsection 1, wishes to appoint a contact person instead of a legal representative may only submit their application concerning a clinical trial on a medicinal product for human use to the EU portal referred to in Article 80 of the Clinical Trials Regulation once the Finnish Medicines Agency's decision to grant an authorisation to appoint a contact person is legally valid.

The Finnish Medicines Agency grants the authorisation referred to in subsection 1 if, according to its assessment, granting this authorisation will not result in significant risks to the protection of subjects or their legal protection, or to the fulfilment of other requirements under the Clinical Trials Regulation.

If the clinical trial is conducted in Finland and at least one other Member State of the European Union or a country belonging to the European Economic Area and the sponsor is not established in a country belonging to the European Union or the European Economic Area, the Finnish Medicines Agency makes a decision referred to in Article 74(3) of the Clinical Trials Regulation. The Finnish Medicines Agency makes its decision on grounds laid down in subsection 3.

Further provisions on the information that should be included in applications referred to in this section and the application procedure may be given by government decree.

Section 5
Insurance or other guarantee

The sponsor shall ensure that insurance or other appropriate guarantee to compensate for damage suffered by subjects is in place that covers the sponsor's and investigator's liability.

Chapter 3
Assessment of an application concerning a clinical trial on a medicinal product

Section 6
Language of application dossier

An application dossier referred to in Annexes I and II to the Clinical Trials Regulation may be submitted in Finnish, Swedish or English. However, the documents referred to in paragraph 60 and Letter L of Annex I shall be submitted in Finnish or Swedish.

Section 7
Finland as the reporting Member State

The tasks of the reporting Member State laid down in the Clinical Trials Regulation are performed by the Finnish Medicines Agency unless otherwise provided in this Act or under it. The Finnish Medicines Agency also performs the tasks related to the selection of the reporting Member State imposed on the Member State concerned under Article 5(1) of the Regulation.

The Finnish Medicines Agency assesses the application concerning a clinical trial on a medicinal product regarding all aspects referred to in Article 6(1) of the Clinical Trials Regulation. The National Committee on Medical Research Ethics referred to in section 16 below (*the Committee*) evaluates aspects referred to in point (b) of Article 6(1) of the Clinical Trials Regulation and issues its opinion. The Finnish Medicines Agency draws up the assessment report (*Part I of the assessment report*) referred to in Article 6(2) of the said Regulation.

In clinical trials involving more than one Member State, the Committee shall, at minimum, express its initial opinion on the application to the Finnish Medicines Agency as part of drawing up the draft of Part I of the assessment report circulated to other Member States. The Committee shall issue its opinion at the latest during the consolidation phase referred to in point (c) of Article 6(5) of the Clinical Trials Regulation.

When making the conclusion referred to in Article 6(3) of the Clinical Trials Regulation, the Finnish Medicines Agency shall take the Committee's opinion into account. A negative opinion issued by the Committee, or an opinion stating that acceptability is subject to compliance with certain detailed specific conditions, is binding on the Finnish Medicines Agency.

The Committee assesses the application with respect to the aspects referred to in Article 7(1) of the Clinical Trials Regulation. Additionally, the Committee draws up the assessment report referred to in Article 7 (1) (*Part II of the assessment report*) and performs the other tasks of the Member State concerned and reporting Member State laid down in Article 7. The Finnish Medicines Agency may express its views to the Committee for the assessment and the drawing up of the assessment report.

Section 8
Finland as a Member State concerned

When Finland is a Member State concerned but not the reporting Member State, the Finnish Medicines Agency performs the tasks related to expressing the considerations of the Member State concerned referred to in Article 5(3) of the Clinical Trials Regulation.

The Finnish Medicines Agency and the Committee assess the application and Part I of the assessment report drawn up by the reporting Member State following the division of tasks laid down in section 7, subsection 2.

The Finnish Medicines Agency is responsible for submitting the considerations referred to in Article 6(5) and (8) of the Clinical Trials Regulation to the reporting Member State. The Finnish Medicines Agency shall express the considerations of the Committee.

The provisions in section 7, subsection 5 apply to the assessment of Part II of the assessment report.

Section 9
Assessment of a substantial modification of a clinical trial on a medicinal product

Where Finland is the reporting Member State and where an assessment concerning a substantial modification referred to in Chapter III of the Clinical Trials Regulation is conducted, the division of tasks and procedures laid down in section 7 apply.

Where Finland is a Member State concerned but not the reporting Member State, the division of tasks and procedure laid down in section 8 apply when assessing the application. The Committee performs the tasks of the Member State concerned laid down in Articles 20 and 22 of the Clinical Trials Regulation unless otherwise provided in this Act or under it.

When applying this section, instead of Articles 5–7 of the Clinical Trials Regulation referred to in sections 7 and 8, the corresponding provisions on validation and assessment in Articles 17, 18 and 20–22 apply.

Section 10
Subsequent addition of a Member State concerned

Where Finland is the reporting Member State and where subsequent addition of a Member State concerned is assessed pursuant to Article 14 of the Clinical Trials Regulation, the division of tasks and procedure laid down in section 7 apply.

Where Finland is added subsequently as a Member State concerned, the Finnish Medicines Agency performs the tasks imposed on an additional Member State concerned under Article 14 of the Clinical Trials Regulation, unless otherwise provided in this Act or under it. The division of tasks and procedure laid down in section 8 apply when assessing the application. The Committee performs the tasks referred to in Article 14(7) and (8) of the Regulation.

When applying this section, instead of Articles 5–7 of the Clinical Trials Regulation referred to in sections 7 and 8, the corresponding provisions on validation and assessment in Article 14 apply.

Section 11

Decision on a clinical trial on a medicinal product

The decisions referred to in Article 8(1), Article 14(3), Article 19(1), Article 20(5) and Article 23(1) of the Clinical Trials Regulation on whether a clinical trial is authorised, authorised subject to conditions or refused are made by the Finnish Medicines Agency, which informs the sponsor of these decisions.

The Finnish Medicines Agency is also tasked to form an opinion and inform the European Commission, other Member States and the sponsor if Finland disagrees with the conclusion of the reporting Member State pursuant to Article 8(2), Article 14(4) or Article 19(2) of the Clinical Trials Regulation.

An unfavourable opinion on a clinical trial of a medicinal product issued by the Committee is binding on the Finnish Medicines Agency when it is making a decision and forming its opinion as provided in the Articles referred to in this section and in this Act.

Further provisions on the procedures for assessing an application and making a decision may be given by government decree.

Section 12

Cooperation when assessing an application

The Finnish Medicines Agency and the Committee shall work together to ensure that an application concerning a clinical trial on a medicinal product is assessed to a high standard and that the assessment procedures are streamlined. However, the Finnish Medicines Agency and the Committee each conduct their independent assessment of the application.

In addition to what is provided in and under this Act, the assessment of the application and the cooperation may include at least the following:

1) the Committee may express its considerations to the Finnish Medicines Agency for the validation of the application;
2) the Committee may participate in finalising Part I of the assessment report;
3) the Committee and the Finnish Medicines Agency may provide each other guidance in matters concerning the application or in general scientific, ethical, legal and practical issues.

The Finnish Medicines Agency shall take appropriate notice of the aspects expressed by the Committee.

Chapter 4
Subjects

Section 13
Subject's reduced capacity for self-determination

A subject referred to in point (19) of Article 2(2) and Article 31 of the Clinical Trials Regulation is a person who, because of their illness, disability or similar reason other than merely their age is incapable of understanding information provided pursuant to Article 29 of the Clinical Trials Regulation to the extent that they could, based on this information, give their informed consent to participating in a clinical trial on a medicinal product.

The legally designated representative referred to in point (20) of Article 2(2) of the Clinical Trials Regulation empowered to give informed consent on behalf of a subject referred to in subsection 1 is the person's legal representative or, if there is no legal representative, their close family member or other person close to them.

Section 14
Minor subjects

A person aged under 18 years may only be a subject if the provisions on minors in the Clinical Trials Regulation and the provisions of this Act are applied to them in a clinical trial on a medicinal product.

The legally designated representative of a subject aged under 18 referred to in point (20) of Article 2(2) of the Clinical Trials Regulation who is empowered to give informed consent on behalf of a minor subject is their guardian or other legal representative.

If the subject has reached the age of 15, however, they may independently give informed consent to a clinical trial referred to in point (i) of subparagraph (g) of Article 32(1) of the Clinical Trials Regulation unless, considering their age, level of development and the nature of their illness or the trial, they are incapable of understanding the significance of the trial or procedure. In such a case, their guardian or legal representative shall be informed of their participation.

If a subject aged under 18 who may not be a subject without their guardian's or other legal representative's consent is capable of forming an opinion and evaluating the information provided to them about the trial, their written consent is also required.

Section 15
A subject who is a prisoner or a forensic psychiatry patient

In addition to what is provided in the Clinical Trials Regulation and this Act on informed consent, a prisoner referred to in the Imprisonment Act (767/2005), a remand prisoner referred to in the Remand Imprisonment Act (768/2005), a person who is undergoing an examination or treatment under chapter 3 or 4 of the Mental Health Act (1116/1990) or who has been deprived of their freedom under some other Act may only be a subject if there are scientific grounds for expecting that the trial will produce a direct benefit for their health or a benefit for the health of their relative or the population they represent referred to in this section.

Chapter 5
Ethics committee

Section 16
National Committee on Medical Research Ethics

The National Committee on Medical Research Ethics is an independent and impartial body that operates in conjunction with the National Supervisory Authority for Welfare and Health. The Committee is appointed by the Government on the proposal of the Ministry of Social Affairs and Health for four years at a time.

At minimum, expertise in clinical trials on medicinal products, medical science, statistic, ethics and law, and lay persons who in particular put forward patients' views shall be represented in the Committee.

When appointing the Committee, the Government appoints a chair and a sufficient number of vice chairs for it, who can also serve as other members of the Committee. In addition, the Government appoints at least 30 persons as the other members to the Committee. The Government may complement and otherwise modify the composition of the Committee during its term of office.

If a chair, vice chair or other member of the Committee steps down or dies in the middle of the term of office, the Ministry of Social Affairs and Health may appoint another person to replace them for the remainder of the term. This appointment must be made if the composition of the

Committee does not otherwise meet the requirements laid down in subsections 2 and 3. The Ministry of Social Affairs and Health may also modify the composition of the Committee if it finds that one or several of the members can no longer continue as ethical committee members because of their interests or other particular reasons.

When conducting assessments referred to in this Act, the Committee may be divided into divisions. Provisions on the separate Administrative Review Division on ethical assessment of medical research of the Committee are contained in the Research Act.

The Committee may invite experts to participate in its assessment work on a permanent or temporary basis.

The Committee has a permanent secretariat led by a full-time general secretary. The Committee may also have other staff. The permanent secretariat shall have a sufficient number of members and other staff to enable it to perform its tasks in accordance with the obligations laid down in the Clinical Trials Regulation and this Act.

Further provisions on the manner in which the Committee's tasks are carried out and its work is organised as well as on the tasks of the permanent secretariat may be given by government decree.

Section 17
Other tasks of the Committee

In addition to what is provided elsewhere in this Act and in other acts on the Committee's tasks, its duties are to:

1) give a statement on the establishment of a biobank referred to in section 6 of the Biobank Act (688/2012);
2) give a statement referred to in section 27 of the Biobank Act where the study referred to in this section is a clinical trial on a medicinal product;
3) give a statement referred to in sections 11, 19, 20 and 21a of the Act on the Medical Use of Human Organs and Tissues (101/2001) where there is an intention to use organs, tissues or cells in a clinical trial on a medicinal product;
4) give a statement on studies referred to in section 18, subsection 3 of the Medical Devices Act (719/2021);
5) serve as an expert body in issues of research ethics concerning clinical trials on medicinal products;

6) participate in international cooperation between authorities concerning issues of research ethics related to clinical trials on medicinal products;
7) promote discussion about clinical trials on medicinal products among the citizens.

Further provisions on the handling of the tasks laid down in this section by the Committee may be issued by government decree.

Section 18
Composition of the Committee

The Committee has quorum when, in addition to the chair or vice chair, at minimum six members are present. When drawing up an ethical assessment of an application, at minimum one lay member shall participate in the discussion.

When the Committee discusses issues referred to in this Act, members representing the necessary medical expertise as well as legal and ethical expertise shall be present.

An expert in paediatrics shall be represented in or consulted by the Committee when it discusses a clinical trial on a medicinal product involving minors, and an expert in the relevant illness or disability shall be present when the Committee discusses clinical trials on medicinal products involving subjects referred to in section 13. An expert in medical use of radiation shall be represented in or consulted by the Committee if, in a clinical trial on a medicinal product, it is intended that the subject will be subjected to medical exposure referred to in section 4, subsection 10 of the Radiation Act (859/2018). The Committee may also consult experts in other contexts. A public official of the Finnish Medicines Agency may be consulted as an expert.

An expert referred to in subsection 3 above may not participate in the Committee's decision-making. Instead of consulting an expert orally, the Committee may request that they provide a written statement.

Section 19
Discussion on a matter in the Committee

When discussing a matter referred to in this Act, the Committee shall aim for unanimity.

When the Committee discusses its initial opinion referred to in section 7, subsection 3 or issues an opinion on a clinical trial, at minimum two thirds of the members participating in the discussion shall be in favour of it in order for it to be regarded as a favourable opinion of the Committee.

Specific conditions subject to which the trial is acceptable may be included in the opinion. These specific conditions shall be recorded in the opinion in detail.

If the Committee is not unanimous when discussing a matter other than those referred to in subsection 2, the Committee's opinion is decided by a simple majority. A tied vote is resolved by the vote of the chair or, in their absence, of the vice chair.

An authorisation referred to in section 20, subsection 2 below may only be given if the Committee is unanimous.

Section 20
Authorisation to act on behalf of the Committee

Notwithstanding the provisions in sections 18 and 19, a task referred to in section 12, subsection 2 may be performed, and a decision related to it may be made, by the chair, a vice chair, a member, or a member of the permanent secretariat on behalf of the Committee if the matter is not of such significance that it requires discussion in the Committee.

Authorisation for the chair, a vice chair, a member, or a member of permanent secretariat to take the actions referred to in subsection 1 is given by the Committee. However, no authorisation given by the Committee is needed for performing a task referred to in section 12, subsection 2, paragraph 3 above. The permanent secretariat may also perform the tasks laid down in Article 20(1)–(3) of the Clinical Trials Regulation without separate authorisation.

Section 21
Committee meetings

The Committee may discuss a matter concerning an opinion and other matters and make a decision on the content of an opinion at a meeting where the attenders are present in the same room (*an ordinary meeting*) or at a meeting that takes place partly or fully in an electronic environment (*an electronic meeting*). Matters laid down in section 12, subsection 2 above and an authorisation referred to in section 20, subsection 2 may additionally be discussed using electronic devices (*electronic decision-making procedure*).

Minutes are kept of an ordinary meeting, electronic meeting and electronic decision-making procedure.

Chapter 6
Payments and compensation

Section 22

Investigational medicinal products, other products and procedures provided free of charge for the subject and derogations to their provision free of charge

The costs for investigational medicinal products, auxiliary medicinal products, medical devices used for their administration and procedures specifically required by the protocol are free of charge to the subject unless there is a justified reason for charging for them.

Provisions on the justified reasons referred to in subsection 1 above may be laid down by government decree.

Section 23

Compensation paid to a subject

Point (d) of Article 31(1), point (d) of Article 32(1), and Article 33(d) of the Clinical Trials Regulation lay down a prohibition of offering subjects referred to in sections 13 and 14 and their legally designated representatives as well as subjects who are pregnant or breastfeeding women incentives or financial inducements and provisions on the possibility of paying compensation. In addition to compensation for expenses and loss of earnings directly related to participation in the clinical trial, reasonable compensation for other inconvenience may be paid to other subjects.

Further provisions on the grounds and amounts of compensation may be issued by government decree.

Section 24

Fees and compensation paid to the Committee

Decisions on the grounds of fees and compensation paid to the Committee's chair, vice chair and members and the fees paid to experts are made by the Ministry of Social Affairs and Health.

Compensation for travel costs is paid in compliance with the currently valid collective agreements for public officials and other government employees.

Section 25

Levying of fees

One joint fee may be charged for the ethical and scientific assessment of a clinical trial on a medicinal product as laid down in Articles 86 and 87 of the Clinical Trials Regulation. The collected fee is divided between the Committee and the Finnish Medicines Agency.

Chapter 7
Supervision, request for a review and penalties

Section 26
Governance and supervision

Governance and supervision of clinical trials on medicinal products are carried out by the Finnish Medicines Agency, which operates under the Ministry of Social Affairs and Health.

The Finnish Medicines Agency is the national contact point referred to in Article 83(1) of the Clinical Trials Regulation.

The Finnish Medicines Agency is the competent authority for carrying out the assessment laid down in Article 44 as well as for taking the corrective measures referred to in Article 77 of the Clinical Trials Regulation, and it takes the other measures imposed on the Member State concerned under Article 77. The Finnish Medicines Agency is also the competent authority for performing the other tasks related to the supervision and practical enforcement of the Clinical Trials Regulation, unless otherwise provided in this or another Act.

The competent authority for supervising the processing of personal data is the Data Protection Ombudsman.

Section 27
Inspections

The Finnish Medicines Agency is the competent authority for performing the inspections laid down in Article 78 of the Clinical Trials Regulation and Commission Implementing Regulation (EU) 2017/556 on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council, hereafter referred to as *the Implementing Regulation*.

The documents referred to in Article 10(4) of the Implementing Regulation shall be provided to the Finnish Medicines Agency free of charge. An inspection may also be carried out in facilities used as a permanent residence if there is probable cause to suspect that the conduct of clinical trials on medicinal products puts human health at risk and carrying out the inspection is essential in order

to protect human health, or otherwise to fulfil an obligation laid down in Article 6 or in Article 10(2) or (3) of the Implementing Regulation.

Provisions on the powers of Finnish Medicines Agency inspectors are laid down in Article 10 of the Implementing Regulation. In addition to inspectors who meet the conditions laid down in Article 4 of the said Regulation, the Finnish Medicines Agency may appoint other public officials of the agency to the inspection team as experts. An expert of this type has the same powers as an inspector referred to in the Implementing Regulation.

If, for an essential reason, the Finnish Medicines Agency finds that it needs the assistance of an external expert to conduct an inspection, it may appoint and engage in the inspection an expert of this type. The precondition for this is that the Finnish Medicines Agency itself carries the main responsibility for conducting the inspection and the conclusions made.

An external expert in an assistant role may participate in measures referred to in Article 6 or Article 10(2) and (3) of the Implementing Regulation and, notwithstanding secrecy provisions, access the information referred to in the said Articles. An external expert may not participate in an inspection conducted in facilities used as a permanent residence. The expert shall have the necessary training and experience needed for their task.

On request made by them or the Finnish Medicines Agency, inspectors and inspection team experts from other European Union Member States and countries belonging to the European Economic Area besides Finland have the right to access a clinical trial site on Finland's territory where clinical trials on medicinal products are conducted, the facilities and operations of other parties related to clinical trials on medicinal products and, notwithstanding secrecy provisions, information related to the trial. Once they have been informed of an inspection of a clinical trial on a medicinal product carried out by a foreign authority in Finland, the sponsor shall inform the Finnish Medicines Agency of it. An inspector and an expert from the Finnish Medicines Agency may participate in inspections carried out outside the Finnish borders.

The Finnish Medicines Agency draws up and approves the quality system for inspection procedures referred to in Article 3(1) and keeps the records referred to in Article 4(8) of the Implementing Regulation. It also draws up procedures for verifying good clinical practice compliance referred to in point (c) of Article 7(1) and makes information on them publicly available.

Section 28
Right to information

On request, the sponsor, investigator, other member of the investigating team, the sponsor's legal representative, the sponsor's contact person and the legal or natural person in whose facilities the clinical trial on a medicinal product is conducted shall submit to the Finnish Medicines Agency the information and accounts associated with clinical trials on medicinal products essential for enabling the Finnish Medicines Agency to perform its tasks laid down in the Clinical Trials Regulation, this Act or a European Union legal act. The Finnish Medicines Agency has the right to obtain from the parties referred to above information essential for carrying out its supervisory task contained in subjects' patient documents and information referred to in Articles 56–58 of the Clinical Trials Regulation essential for carrying out its supervisory tasks. In a situation referred to in section 27, subsection 6 above, an inspector and an expert from another European Union Member State and a country belonging to the European Economic Area besides Finland has the right to obtain the same information as the Finnish Medicines Agency.

On request, the National Supervisory Authority for Welfare and Health, a Regional State Administrative Agency, the Finnish Tax Administration, the Social Insurance Institution of Finland, a regional committee on medical research ethics and the Committee referred to in section 16 are obliged to provide the Finnish Medicines Agency with the information essential for performing the tasks laid down in the Clinical Trials Regulation, the Implementing Regulation and this Act. These authorities may also submit information they regard as essential for the protection of subjects to the Finnish Medicines Agency on their own initiative.

Section 90 of the Medicines Act applies to the Finnish Medicines Agency's right to disclose information obtained under the Clinical Trials Regulation, the Implementing Regulation or this Act unless otherwise provided in or under the Clinical Trials Regulation.

The information referred to in this section may be disclosed and documents may be submitted to the Finnish Medicines Agency notwithstanding secrecy provisions. The information and documents shall be submitted to the Finnish Medicines Agency free of charge.

Section 29
Notice of a conditional fine

To enforce its decision on a corrective measure specified in Article 77(1) of the Clinical Trials Regulation, a request for information and documents specified in section 28, and a decision related to fulfilling some other obligation laid down in the Clinical Trials Regulation, the Implementing Regulation or this Act, the Finnish Medicines Agency may issue a notice of a conditional fine.

Section 30
Request for a review

An administrative review may be requested regarding a decision made by the Finnish Medicines Agency under this Act and Article 77 of the Clinical Trials Regulation. Provisions on requests for an administrative review are contained in the Administrative Procedure Act (434/2003). If the matter that the request for a review concerns is relevant to an aspect discussed in the Committee's opinion, the Finnish Medicines Agency requests a statement from the Committee, unless this is manifestly unnecessary.

Provisions on requesting a review at an administrative court are laid down in the Administrative Judicial Procedure Act (808/2019).

A decision referred to in sections 4 and 11 above and a decision made under Article 77 of the Clinical Trials Regulation shall be complied with regardless of a request for a review unless otherwise ordered by the administrative court.

An opinion regarding a clinical trial on a medicinal product issued by the Committee may not be appealed against separately.

Section 31
Infringement in a clinical trial on a medicinal product

A person who intentionally or by gross negligence

1) in a document submitted for the purposes of an assessment of an application concerning a clinical trial on a medicinal product provides false or misleading information that is likely to have an essential impact on the acceptability of the clinical trial on a medicinal product,
2) conducts a clinical trial on a medicinal product without authorisation granted under Article 8(1), Article 14(3), Article 19(1), Article 20(5) or Article 23(1) of the Clinical Trials Regulation or essentially infringes the conditions of the authorisation,
3) conducts a clinical trial on a medicinal product despite the fact that the Finnish Medicines Agency, pursuant to point (b) of Article 77(1) of the Clinical Trials Regulation, has suspended the trial,
4) conducts a clinical trial on a medicinal product that essentially infringes the regulation on informed consent laid down in Articles 29, 31 or 32 of the Clinical Trials Regulation or section 13 or 14 of this Act,

5) essentially neglects the recording, documenting, submission, updating or notifying obligations laid down in Article 38(1), Articles 41–43 or 46, Article 53(1) or Article 54(2) of the Clinical Trials Regulation,
6) records, processes or stores information essentially in violation of Article 56(1) of the Clinical Trials Regulation or essentially neglects the obligation of maintaining a master file laid down in Article 57 or the obligation related to archiving laid down in Article 58 of the Clinical Trials Regulation, or
7) exerts financial or other undue influence on a subject or other person referred to in section 23, subsection 1 in violation of what is provided in point (h) of Article 28(1), point (d) of Article 31(1), point (d) of Article 32(1) or Article 33(d) of the Clinical Trials Regulation or section 23 that would be likely to essentially influence the decision of the subject or other person,

shall be sentenced to a fine for *an infringement in a clinical trial on a medicinal product*, unless a more severe punishment for the act is provided elsewhere by law.

For an act that is punishable under subsection 1 above, the punishment is imposed on the person whose obligations the act or negligence infringes. When assessing this, due consideration shall be given to the position of the relevant person, the nature and extent of their duties and powers, and also otherwise their involvement in the emergence and continuation of the unlawful situation.

Section 32
Reference to the Criminal Code

Provisions on the punishment for an infringement in a clinical trial on a medicinal product are laid down in chapter 44, section 9a of the Criminal Code of Finland (39/1889). Provisions on the punishment for violating the secrecy obligation laid down in section 38 are laid down in chapter 38, section 1 or 2 of the Criminal Code unless the act is punishable under chapter 40, section 5 of the Criminal Code or a more severe punishment is provided elsewhere by law.

Chapter 8
Miscellaneous provisions

Section 33
Processing of personal data in a clinical trial on a medicinal product

Personal data may be processed in a clinical trial on a medicinal product pursuant to point (e) of Article 6(1) and point (i) of Article 9(2) of the General Data Protection Regulation if such processing is necessary:

1) to comply with an obligation related to the reliability and certainty of data associated with conducting a trial or otherwise to study a medicinal product or to ascertain its quality, efficacy or safety; or
2) to ensure the safety of subjects or other persons or to protect their health, and the processing is proportionate considering this objective.

Personal data may be processed in a clinical trial on a medicinal product pursuant to point (c) of Article 6(1) and point (i) of Article 9(2) of the General Data Protection Regulation if such processing is necessary:

1) to comply with an obligation laid down in Chapter VI or VII or Articles 52–54 of the Clinical Trials Regulation or other similar obligation laid down in this Regulation;
2) to comply with an obligation related to disclosure of information pursuant to Articles 77–79 of the Clinical Trials Regulation, the Implementing Regulation or section 28, subsection 1 of this Act; or
3) to comply with the archiving obligation referred to in Article 58 of the Clinical Trials Regulation.

The processing provided for in this section may be carried out by a public and private sector actor.

Section 34
Using information contained in patient documents in a clinical trial

Notwithstanding secrecy provisions and regardless of the provisions in the Act on Secondary Use of Health and Social Data (552/2019), the sponsor, their representative, an investigator and a member of an investigating team have the right to obtain and process information recorded in patient documents in order to conduct the trial and to comply with an obligation associated with the trial laid down in the law if obtaining and processing the information are necessary in order to perform a task or fulfil an obligation of the sponsor, their representative, an investigator or a member of an investigating team.

The information contained in patient documents may be accessed and otherwise processed, provided that the subject has given their informed consent to participating in the trial as laid down in the Clinical Trials Regulation. If, pursuant to section 13 or 14 of this Act, the subject is incapable

of giving their informed consent to participating in the trial themselves, the information contained in patient documents may be accessed and otherwise processed, provided that the subject's legally designated representatives referred to in the cited sections has given their informed consent to participation in the trial and, in situations referred to in section 14, subsection 4, the subject themselves has also given their consent to participation.

If the trial is a clinical trial on a medicinal product conducted in an emergency situation referred to in Article 35 of the Clinical Trials Regulation, information contained in patient documents may be accessed and processed as laid down in subsection 1, provided that the preconditions for conducting the trial laid down in Article 35 are met. A provision on the right to object to the use of data obtained from the clinical trial is contained in Article 35(3) of the Clinical Trials Regulation.

Section 35
Application of administrative procedure legislation

The Administrative Procedure Act does not apply to the processing of an application concerning a clinical trial on a medicinal product referred to in the Clinical Trials Regulation and this Act unless otherwise provided in this Act.

By derogation from subsection 1 above:

1) chapter 2, section 21 and chapter 8a of the Administrative Procedure Act apply to the Committee;
2) chapter 2, section 21 and chapters 7a and 8a of the Administrative Procedure Act apply to the Finnish Medicines Agency; in addition, the provisions in sections 46–49 of the Administrative Procedure Act apply, without the requirement of the documents referred to in these sections being attached to a decision referred to in section 11 or section 26, subsection 3 of this Act, as they can be submitted as separate documents.

When the Finnish Medicines Agency is processing a matter related to an application referred to in section 4 or some other matter referred to in the Clinical Trials Regulation or this Act, other than those referred to in subsections 1 and 2, the Administrative Procedure Act applies, unless otherwise provided in the Clinical Trials Regulation or this Act.

The Act on Electronic Services and Communication in the Public Sector (13/2003) does not apply to a matter processed pursuant to the Clinical Trials Regulation and this Act. However, the said Act applies to processing a matter related to an application referred to in section 4 of this Act and a request for a review.

In addition to what is laid down in section 6, by derogation from what is provided in the Language Act (423/2003), the Finnish Medicines Agency and the Committee may, when discussing a matter referred to in the Clinical Trials Regulation or this Act, use not only Finnish and Swedish but also English as a working and discussion language.

Section 36
Declarations of interests

Before the Committee is appointed, persons proposed as Committee members shall give the Ministry of Social Affairs and Health a written declaration of their financial and other interests that may be significant for performing the task.

Committee members and experts who participate in assessing applications shall give an annual declaration of their interests referred to in Article 9(1) of the Clinical Trials Regulation to the Ministry of Social Affairs and Health.

Those participating in assessing an application in the Finnish Medicines Agency submit the declaration referred to in subsection 2, and inspectors submit the declaration of their financial interests referred to in Article 5(3) of the Implementing Regulation to the competent party pursuant to section 3 of the Act on the Finnish Medicines Agency (593/2009).

Section 37
Disqualification and liability for acts in office

The provisions of the Administrative Procedure Act on a public official's disqualification apply to the disqualification of a public official of the Finnish Medicines Agency and a member and an expert of the Committee when they participate in the proceedings laid down in this Act. In addition, Article 5(1) and (2) of the Implementing Regulation apply to an expert referred to in section 27, subsection 4 above.

The provisions on criminal liability for acts in office apply to a Committee member and an expert referred to in section 27, subsection 4 when they perform the tasks referred to in this Act. Provisions on liability for damages are laid down in the Tort Liability Act (412/1974).

Section 38
Secrecy

A person who, when handling matters referred to in the Clinical Trials Regulation, provisions issued under it or in this Act, has obtained knowledge of confidential information concerning a study

protocol, information on another person's characteristics, health, personal circumstances or financial position, or a matter referred to in Article 9(1) of the General Data Protection Regulation or an entrepreneur's business secrets, shall not disclose the information obtained in this way to outsiders, unless otherwise provided in the Clinical Trials Regulation, provisions issued under it, this Act or another Act.

Section 39
Entry into force

This Act enters into force on 31 January 2022.