Medicinal Products for Human Use - NORWAY

Competent authority

Contact Details

Contact Name 1

The Norwegian Medicines Agency – NoMA (Statens legemiddelverk). Area of expertise: clinical trials assessment

Phone

+47 22 89 77 00

Fax

No longer used

Email Department

klut@noma.no

Address

PO Box 240 Skøyen

ZIP/City

0213 Oslo

Country

Norway (NO)

Web address

http://www.legemiddelverket.no/English/

Additional Information

No local CA

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)
Ethics committee(s)

CA - Submission for authorisation mandatory for

Clinical IMP trials
Clinical ATMP trials

CA - Registration/ notification without approval required for

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CA - Submission required to

National CA

National trial registry - Registration mandatory

Yes

Additional Information

For national registration, contact the responsible person at Health Trust. Trials shall be published on the Health Trust's website. Registration at clinicaltrials.gov may be a requirement for publication in certain journals.

Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission** –
Submission Format	**Format option(s)** – **Preferred format** Electronically Electronically, preferably through the Common European Submission Portal (CESP) or by using Eudralink. Submission can also be made by email to post@noma.no. **Standard application form** EuraCT-form (CTA application form) available for download on EudraCT homepage.The CTA application form should be signed by sponsor (scanned pdf file) and in XML. **Guidance on submission format** Further details on the required documentation is available on the website in section Statens Legemiddelverk > English > Clinical trials
Language of Submission	**Language(s) of application** Norwegian English **Preferred language of application** – **English accepted** Yes **Documents mandatory to be in official national language** Labeling proposal should be in Norwegian. If the IMP is only to be handled by Health Personell, exemption can be made.
Submission Fees	**Fees for trial submission mandatory** Yes **Fees** Industry studies: NKR 10.000.- Amendments/Changes: NKR 5.000.- Academic studies: no fees **Waiver for academic (non-commercial) studies possible** Yes
Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** Explicit

	ATMP/GMO trials (max nr days) 90 **Mode of approval (ATMP/GMO trials)** Explicit **External expert advice required (max nr days)** + 90 **Xenogeneic cell therapy (max nr days)** No time limit **Mode of approval (Xenogeneic cell therapy)** – **Timespan counted from** – **Additional Information** NB! The applicant has the right to supplement the application once if additional information or material is requested from applicant. Questions from CA will come after 30-35 days. The applicant has to respond within 45 days if the 60 days response time should apply. If the applicant does not respond within timelines CA will consider to start from scratch again.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** Change of national coordinating investigator; change of sponsor/sponsor's representative; change of sponsor's contact person **Authorisation mandatory for** Any substantial amendments **Responsible for submission of SA** Sponsor **Timeline for approval of SA (max nr days)** 35 From date of receipt of valid application By silent (implicit) approval **Applicable national legal framework/ Reference** Section 5(1) Regulation 2009 for clinical trials **Additional Information** If the Ethics Committee has approved the application, and the Norwegian Medicines Agency does not oppose the amendment within 35 days of receiving a valid application, the sponsor may implement the changes (according to the Norwegian regulation for clinical trials of 30-10-2009, § 5-1). The substantial amendment is considered approved if the NoMA has not responded within 35 days.
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

Reportable AEs

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

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

Within a max of 7d upon first knowledge (+ 8d for additional information)

All other SUSARs

Within a max of 15d upon first knowledge
NoMA only requires that SUSARs originated in patients in Norway are reported.

SAE /SADE must be reported

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National standard reporting form available

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Reporting format - Options

Other
SUSARs should be reported electonically through the EMEA EudraVigilance database. If electronical reporting is not possible, the CIOMS-form should be used.

Preferred format

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Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA
CA(s) of EU&EFTA Member States concerned

Applicable national legal framework/ Reference

Chapter 7 of Regulation 2009

Additional Information

Investigator shall report SEA to sponsor

Investigator shall report SAE to

Sponsor
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

Last patient last visit

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

15

Standard Declaration form

National studies: no specific form
Multinational studies: The European “Declaration of the end of trial form”.

Guidance on End of trial declaration

Related information is provided on the NoMA website in section Statens Legemiddelverk > English > Clinical trials > Regulation.

Applicable national legal framework/ Reference

Section 8(5) of Regulation 2009 for clinical trials

Additional Information

Reporting timeline: without delay

Ethics committee

Contact Details

Contact Name 1

Regional Committees for Medical and Health Research Ethics REK/ REC

Contact Name 2

4 Regional REC according to geographical region:

Contact Name 3

(1) REC South East; (2) REC West; (3) REC Central; (4) REC North;

Country

Norway (NO)

E-Mail

post@helseforskning.etikkom.no

Web address

https://helseforskning.etikkom.no/

Additional Information

• REC South East: Vestfold, Buskerud, Telemark, Aust-Agder, Vest-Agder, Akershus, Østfold, Hedmark, Oppland and Oslo
• REC West: Rogaland, Hordaland and Sogn og Fjordane
• REC Central: Møre og Romsdal, Sør-Trøndelag and Nord-Trøndelag
• REC North: Nordland, Troms and Finnmark

ad Email (post@helseforskning.etikkom.no): the name of the respective REC (South East, West, Central, North) should be included in the subject field

The secretariats of the individual RECs can also be contacted directly by telephone, email or via their office addresses, provided on the REK website in section Committees and Meetings.

Ethical Review – General

Submission for Ethical review mandatory for

All research projects involving humans

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

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	Additional Information Research projects involving human beings or any kind of human tissue, cells etc. need approval from a Regional Ethics Committee (REK/REC) There are 4 REK/REC covering the geographical regions as follows: REC South East: Vestfold, Buskerud, Telemark, Aust-Agder, Vest-Agder, Akershus, Østfold, Hedmark, Oppland and Oslo REC West: Rogaland, Hordaland and Sogn og Fjordane REC CentralMøre og Romsdal, Sør-Trøndelag and Nord-Trøndelag REC North: Nordland, Troms and Finnmark **Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s)
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Regional EC competent for the study site resp. health facility **Additional Information** Research projects are assigned to the geographical region in which the investigator has the main place of work.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Regional EC (authorised to issue a single opinion) **Submission of application required to** Regional EC (authorised to issue a single opinion) **Additional Information** Research projects are assigned to the geographical region in which the Principal Investigator has the main place of work. There is a Single opinion procedure: Only one vote (by one EC) shall be issued according to Chapter 3, section 3(4) of Regulation 2009 for clinical trials (en).
Submission of Application	**Responsible for study submission** Principal Investigator Investigator **Entitled to study submission** – **Prerequisites for submission / approval** – **Guidance on study submission** Application Procedure via REK Portal: Submission of application requires a user account for the portal. Further guidance is available on the REK website in section Electronic Application Procedure
Submission Format	**Format option(s)** Online portal **Preferred format** Online portal **Online portal** REK Portal: Submission of application requires a user account for the portal. **Standard application form** The electronic Project Application form (Prosjektsøknad) to be used is available once logged on to the portal on the REK website.

	Guidance on submission format Further guidance is available on the REK website in section Electronic Application Procedure **Additional Information** General Communication: All written communications to and from REC shall be in electronic format. Applications and follow-up enquiries (response, amendments, reports and appeals) to REC should be submitted using electronic forms. Other enquiries should be sent via email to post@helseforskning.etikkom.no with the name of the respective REC in the subject field (REC South East, REC West, REC Central or REC North).
Language of Submission	**Language(s) of application** Norwegian **Preferred language of application** – **English accepted** For Attachments (other than information material for study participants); any Scandinavian language also accepted **Documents mandatory to be in official national language** Basic application form Information material, Documents and Forms intended for study participants and patient information
Submission Fees	**Fees for Ethical review** No fees for academic nor industry
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)** + 30 **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** Chapter 3, Section 3(3) Regulation 2009 for clinical trials **Additional Information** NB! There are application deadlines applicable to all RECs, published for one year at a time! (available on the REK website in section Application Deadlines)

Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Significant changes to the project's purpose, methodology, duration or organization **Responsible for notification of SA** Sponsor **Standard notification form available** Yes **Standard notification form** The electronic Project Amendment form (Prosjektendring) is used when the Chief Investigator is to apply for continued approval for the project under terms. The form is available via the REK Portal (only available in Norwegian). **Timeline Ethical review of SA (max nr days)** 35 **Guidance on submission of SA** Detailed information is available on REK website in section Rules and Procedures >Procedures for Project Amendments **Applicable national legal framework/ Reference** Section 5(1) Regulation 2009
Safety Reporting	**Reportable AEs** Not specified **Investigator shall report SAE to** Sponsor Sponsor **Reporting timeline** Immediately **Responsible for AE reporting to relevant EC(s)** – **SUSAR being life-thereatening or leading to death must be reported** Not specified **All other SUSAR must be reported** Not specified **SAE/SADE must be reported** – **National Standard Reporting form available** – **Reporting format - Options** – **Preferred reporting format** –

	Provision of Annual safety report mandatory No **Applicable national legal framework/ Reference** Chapter 7 of Regulation 2009 for clinical trials **Additional Information** No reports on side effects and SUSARs (as a matter of routine) shall be sent to REC (furhter details provided on REK website in section Rules and Procedures > Procedures for Project Reports)
End of Trial	**End of trial Declaration mandatory** No **Responsible for End of trial Declaration** – **Regular Termination - Declaration timespan (max nr days)** – **Timespan counted from** – **Early/premature Termination - Declaration timespan (max nr days)** – **Additional Information** No 90 day end of trial report following the conclusion of a clinical trial to be sent to REC (only to CA!).

Study specific Requirements

Sponsor	**Sponsor - Definition available in national law** Yes **Sponsor - Definition (pursuant to national law)** Sponsor is an individual, company, institution or organisation that takes responsibility for the initiation, management and/or financing of a clinical trial, and that signs the request for authorisation. - Chapter 1, Section 1(5-8) Regulation 2009 (en) **Sponsorship mandatory** Yes **Sponsorship mandatory - Additional information** Investigator and sponsor may be one and the same person. **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
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Yes

Standard IC form (ICF)

Templates for Participation Information and Consent is available in Norwegian and English on the REK website in section Deadlines and Forms > Templates for Participation Information and Consent

IC is regulated by law

Yes

Informed Consent - Definition/ Requirements

'A written, dated and signed statement about participation in a clinical trial which is given by a person who is capable of giving consent. The statement must be made voluntarily after the trial subject has received full information about the nature, significance, scope and risk associated with the trial. If the person is not capable of giving consent, consent is given by the person who can give consent on behalf of the person concerned'

Specific requirements regarding to informed consent (including vulnerable populations) are stipulated by Chapter 2 of Regulation 2009 for clinical trials (en) and Chapter 4 of The Health Research Act.

Applicable national legal framework/ Reference

Chapter 1, Section 1(5) Regulation 2009 for clinical trials (Definition)
Chapter 2 of Regulation 2009 for clinical trials
Chapter 4 of The Health Research Act

Additional Information

The EC will approve the Informed Consent Form.

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Yes
Special provisions apply

Legal framework/Reference (Minors/Children)

Section 2(8) Regulation 2009 for clinical trials
Art 17&18 The Health Research Act

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Incapacitated persons)

Section 2(8) Regulation 2009 for clinical trials
Art 17&18 The Health Research Act

Emergency situations - Studies allowed

Yes
Special provisions apply

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

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Conditions allowing trial participation in emergency setting without prior consent

Conditions for the conduct of trials if the patient is unable to give consent, and where it is impossible to obtain prior consent of that person's next of kin:
a) any risk or inconvenience to the person is insignificant
b) the person does not oppose it, and there is no reason for scientists or other personnel to believe that she/he would have opposed the plan if he had had to consent ,
c) it is only possible to carry out research in clinical emergencies
d) research is undoubtedly justified by the prospect of results with great preventive, diagnostic or therapeutic value.

The person or his next of kin shall as soon as possible given information about the research and consent should be obtained as soon as possible .

Legal framework / Reference (Emergency Situation)

Art 19 The Health Research Act

Pregnant or breastfeeding women - Studies allowed

No

Specific provisions

Pregnant or breastfeeding women should not be included in studies involving IMP.

National legal framework for protection of vulnerable populations in place

Yes

Applicable legal framework / Reference (Vulnerable Population)

Chapter 2 of Regulation 2009 for clinical trials
Chapter 4 of The Health Research Act

Additional Information

ADDITIONAL PAEDIATRIC INFORMATION

LEGAL AGE OF CONSENT:
18 years

MANDATORY / SUGGESTED AGE RANGES DEFINED FOR ASSENT:
Competence to give consent: The following people are entitled to consent to take part in medical and health research:
a) legally competent persons
b) minors aged 16 and over, unless otherwise follows from statutory provisions or the nature of the activity.
Specifications regarding assent: Adolescents over the age of 16 must of their own accord, consent to taking part in a research project. However, if the research entails surgical intervention or participating in a Clinical Trial, their parents/guardians must also give their consent. If the adolescent is under the age of 16, only their parents/guardians can consent to their child's participation.

NUMBER OF REQUIRED SIGNATORIES:
Main rule: both parents sign the consent form if they have parental responsibility for the child.

OFFICIAL LANGUAGE OF INFORMED CONSENT:
Norwegian

INFORMATION ON MATERIAL USED TO DESCRIBE THE CLINICAL TRIAL TO THE MINOR:
The children's information sheet will need to be adapted to their age and their level of understanding, and at the same time provide information about the type of research that they are being invited to participate in.
The Children's Act 1981 states that when a child reaches the age of seven, they must be given an opportunity to express their opinion before a decision is made concerning personal matters affecting them. They will therefore have a greater and increasing right to be heard in terms of their health, in accordance to their age and maturity.

ADDITIONAL INFORMATION (INCLUDING REFERENCE FOR TEMPLATE):
• New regulation from 2017: Minors aged 12-16 may consent to projects that cannot be completed with the parents' consents because the project may reveal information that the parents do not want to be revealed, e.g. violence or lack of parental care.

• Reference legislation:
o Lov om medisinsk og helsefaglig forskning (helseforskningsloven) (in Norwegian)
o Forskrift om barn mellom 12 og 16 år sin rett til selv å samtykke til deltakelse i medisinsk og helsefaglig forskning (in Norwegian)
o Lov om barn og foreldre (barnelova) (in Norwegian only)

• IC template(s) / guidelines / information sources
o The Norwegian Medicines Agency -> Clinical Trials -> Regulations
o National database for Laws and Acts -> Lov om medisinsk og helsefaglig forskning (helseforskningsloven) – information available only in Norwegian.
o Guidance to Helseforsknings-loven (in Norwegian only) Additional info.
o Regional Committees for Medical and Health Research Ethic-> Templates for Participation Information and Consent

SOURCE(S):
https://legemiddelverket.no/english/clinical-trials/regulation-relating-to-clinical-trials-on-medicinal-products-for-human-use-
https://lovdata.no/dokument/NL/lov/2008-06-20-44?q=helseforskning
http://www.legemiddelverket.no/English/Sider/default.aspx
https://lovdata.no/dokument/LTI/forskrift/2017-06-28-1000
https://lovdata.no/dokument/NL/lov/1981-04-08-7
https://helseforskning.etikkom.no/frister/malforinformasjonsskriv?p_dim=34672&_ikbLanguageCode=us
https://www.regjeringen.no/globalassets/upload/hod/hra/veileder-til-helseforskningsloven.pdf

Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** No specific provisions **Compensation is limited to/provided for** –
Data Protection	**Notification to DP Authority/ Ombudsmann is mandatory** No **Approval/ authorisation required** No **Specific notification timelines before operations start** – **Language of notification** – **Notification format** – **Additional Information** The permission to process personal data is regulated in Chapter 1, Section 1(10) Regulation 2009 for clinical trials (en). Accordingly, the Sponsor is responsible for ensuring that the prior approval to process health data is obtained from the regional EC pursuant to Chapter 3 and Section 33 The Health Research Act. Identifiable personal data may only be transmitted between Norway and a country outside the EEA area if the conditions in Article 45 of the Personal Data Act are fulfilled. Section 2-5 of the Regulation 2009 for clinical trials (en) covers the protection of physical and mental integrity and personal data as follows: Pursuant to the regulation, a clinical trial can only be initiated if the trial subject's right to physical and mental integrity and to a private life are respected and information concerning the trial subject is protected in accordance with the provisions of Personal Data Act (en) and Section 2 (3) of The Health Research Act. Trial participants' data are protected by the Norwegian Social Science Data Services **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** General Data Protection Regulation (GDPR) **National DP act** Lov om behandling av personopplysninger (personopplysningsloven) / Law on processing of personal data, 15 June 2018 No. 38 („Personal Data Act")
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Study participants **Responsible for covering insurance** Sponsor

	Applicable national legal framework/ Reference (1) - Chapter 2, Section 2(4) Regulation 2009 for clinical trials (Insurance for trial subjects agaist any harm that may arise during the trial) - Chapter 3, Section 3(2) Regulation 2009 for clinical trials (Insurance or compensation to cover the liablility of investigator and sponsor) (2) These provisions are based on the regulations set out in The Product Liability Act (en) of 23 December 1988, Chapter 3, concerning liability in the case of injuries caused by drugs. **Additional Information** Pursuant to the national legislation, the manufacturers and importers of drugs and persons conducting clinical trials on drugs are obliged to join the Drug Liability Association/ Legemiddelansvarsforeningen (LAF) and take out a special insurance, the Drug Insurance, which will indemnify any injured persons on a no-fault basis, that is, regardless of culpability. Detailed information is provided on the LAF website in section Liability Insurance in connection with Clinical Trials of Drugs. Insurance may be provided by: (1) Private Insurance company OR (2) Norwegian System of Patient Injury Compensation (Norsk Pasientskadeerstatning; NPE)
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Compulsory **Standard Operating Procedures (SOPs)** Compulsory
Archiving & Data Management	**Study documents must be kept at least (in years)** 15 **Applicable national legal framework/ Reference** 8(2) Regulation 2009 for clinical trials **Additional Information** Sponsor and investigator shall store documents of major significance to the clinical trial for the given time period.

National legislation

General Information: Applicable Legislation & Conventions	**Official website providing relevant national legislation** REK website in section Acts of Legislation **Official governmental legal database available** Yes **Official governmental legal database** The Lovdata Foundation: Norwegian regulations are publicly available in the legal information system run by the Ministry of Justice and the Faculty of Law in Oslo . **Additional Information** English translation of the Norwegian legislation can be found in the Law Library of the University of Oslo.
Clinical Trials on IMPs in Humans	**Applicable national regulations** General Act(s) on Medical/Clinical Research in Humans Transposition of (CT) Directive 2001/20/EC Other

	Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework) Lov om legemidler m.v. (legemiddelloven) / Norwegian Regulation relating to clinical trials on medicinal products for human use, of 30 Oct 2009 („Regulation 2009 for clinical trials (en)“- unofficial english translation): National implementation of the European requirements of Directive 2001/20/EC; Non-interventional trials are not covered! **Transposition of (GCP) Directive 2005/28/EC** – **General legislation on Medical/ Clinical Research in Humans** Lov om medisinsk og helsefaglig forskning (helseforskningsloven - hfl) / Act relating to medical and health research, no.44 June 2008 („The Health Research Act“- unofficial english translation) It applies to medical and health research on Norwegian territory or when the research takes place under the auspices of a Research Manager (Institution Responsible for Research) who is established in Norway. **Other applicable regulations/ implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)** Lov om behandling av etikk og rederlighet i forskning (Forskningsetikkloven-fel) / Act on ethics and integrity in research (en) **Additional Information** Guideline on transitory period for the application of Regulation (EU) No 536/2014
Radiation & Radiotherapy	**Use of radiation or radioactive compounds - Specific requirements** No **Additional Information** No specific requirements requirements if any kind of radiation is used in the clinical trial
Biobanking	**Specific requirements** Yes **Applicable legal framework** Lov om endringar i pasientrettslova og biobanklova (helsehjelp og forsking - personar utan samtykkekompetanse) / Act amending the Patients' Rights Act and the Biobank Act (health care and research - persons without competence to give consent) (en)
Data Protection	**Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** General Data Protection Regulation (GDPR) **National DP act** Lov om behandling av personopplysninger (personopplysningsloven) / Law on processing of personal data, 15 June 2018 No. 38 („Personal Data Act“)

Definition

IMP/IMP Study	**IMP - Definition available in national law** Yes

IMP - Definition

Investigational Medicinal Products (IMP) pursuant to Chapter 1, Section 1(5) Regulation 2009:
„A pharmaceutical form of an active substance or placebo which is being tested or used as a reference in a clinical trial. Medicinal products with marketing authorisation are also regarded as investigational medicinal products if they are used, formulated or packaged in a manner other than the approved form, or used for a non-approved indication, or to procure further information about the authoirised form“

IMP Study - Definition available in national law

Yes

IMP Study - Definition

Clinical trial of Medicines pursuant to Chapter 1, Section 1(5) Regulation 2009:
“Any systematic study of medicinal products for human use for the purpose of acquiring or verifying knowledge of the effects or influence of the products on physiological function, interactions, adverse reactions, absorption, distribution, metabolism and secretion, or to study their therapeutic value”

Additional Information

Definition: Non-interventional trial (pursuant to Chapter 1, Section 1(5) Regulation 2009):
“A study where one or more medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. A therapeutic strategy for each individual patient is not decided in advance by a trial protocol, but falls within current practice, and the prescription of the medicinal products is clearly separated from the decision to include the patient in the study. Additional diagnostic or monitoring procedures for patients shall not be necessary and epidemiological methods shall be used to analyse the collected data