Medical Devices - NORWAY

Competent authority

Contact Details	**Contact Name 1** The Norwegian Medicines Agency - NoMA (Statens legemiddelverk) Area of expertice: Medical Devices **Email General** meddev-no@noma.no **Address** PO Box 240 Skøyen **ZIP/City** 0213 Oslo **Country** Norway (NO) **Web address** https://helsedirektoratet.no/English **Additional Information** No local CA.
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA)/ For certain types of MDs Ethics committee(s) **CA - Submission for authorisation mandatory for** MD CE-marked, use outside label MD CE-marked, use outside label + IMP MD without label MD without label + IMP **CA - Registration/ notification without approval required for** – **CA - Submission required to** National CA **CE-marked MD used within label are exempted from any notification obligation to CA** Yes **Additional Information** A notification must sent to the national competent authority (NCA) in all EEA/EU states where the investigation is going to take place. Clinical investigations of CE marked devices utilised for their intended purpose do only require notification to EC! For national registration, contact the responsible Health Trust. Registration at clinicaltrials.gov may be a requirement for publication in certain journals. **Submission to CA and EC to be performed in the following order** –

Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission** – **Guidance on submission of application** Regulatory guidance is available on the NoMA website in section: legemiddelverket.no > English > Medical devices > Regulatory information regarding medical devices
Submission Format	**Format option(s)** Email Regular mail medisinsk.utstyr@legemiddelverket.no **Preferred format** – **Standard application form available** Yes **Standard application form** Standard Notification form (doc) and guidance document (pdf) inlcuding required documentation is available on the NoMA website in section: legemiddelverket.no > English > Medical devices > Regulatory information regarding medical devices
Language of Submission	**Language(s) of application** Norwegian English **Preferred language of application** – **English accepted** Partly, not for all documents **Documents mandatory to be in official national language** Information material, Documents and Forms intended for study participants and patient information **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of the study participant** –
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)** Tacit (Silent) Explicit approval possible before expiration of time period **Clock-stop possible if complementary information requested** Yes **Timespan counted from** Date of submission of valid application **Additional Information** NB! Application to CA can be submitted before EC's vote has been issued. However, the 60 day time period formally will not formally start until all required documentation has been received. The CA can not take its decision before having received the EC's opinion.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** Significant amendments to the clinical investigation plan **Responsible for submission of SA** – **Timeline for approval of SA (max nr 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 being life-thereatening or leading to death must be reported** Within a max of 2 d upon first knowledge for events being fatal, life-threatening, or deteriorating health No later than 2 calendar days after awareness by sponsor **All other SUSARs** Within a max of 7 d upon first knowledge (+8d for additional information) for events being life-threatening or leading to death No later than 7 calendar days after awareness by sponsor **SAE /SADE must be reported** Immediately (Reportable events must be fully recorded) **National standard reporting form available** European standard SAE reporting form MEDDEV 2.7/3 to be used

Standard Reporting Form

European MEDDEV 2.7/3.

Reporting format - Options

–

Preferred format

–

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

Regulation of 15 December 2005 no 1690 on medical devices, Annexes AIMU VII and ØMU X (no)

Investigator shall report SAE to

–

Reporting timeline

–

End of Trial

End of trial declaration mandatory for

All clinical investigations requiring authorisation by CA

Responsible for End of trial declaration

Not specified

Regular Termination - Declaration timespan (max nr days)

Not specified

Timespan counted from

–

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

Not specified

Reasons for early termination shall be clearly stated

Yes

Ethics committee

Contact Details

Contact Name 1

Regional Committees for Medical and Health Research Ethics REK/ REC

Contact Name 2

4 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** – **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 Central: Møre 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) and ethics committee(s) **Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA)/ For certain types of MDs 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 other Scandinavian language also accepted **Documents mandatory to be in official national language** – **Documents mandatory to be in local language of study site** Basic application form Information material, Documents and Forms intended for study participants and patient information

	Documents mandatory to be in language of study participant –
Submission Fees	**Fees for Ethical review mandatory** No **Fees for Ethical review** No fees for academic nor industry
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 10 A reasonable opinion can be expected within three weeks following the date of the first upcoming meeting of the Committee which will review the application. **General timespan for multi-centre studies (max nr days)** Same as for single-centre trials **External expert advice required: Timespan (max nr days)** 90 **Timespan counted from** Date of receipt of valid application **Additional Information** Processing times are described on REK website in section: Rules and Procedures > Administrative Procedures for REC > Application Requirements and Processing Times. 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** Any substantial amendments Significant changes to the project's purpose, methodology, duration or organization **Responsible for notification of SA** Sponsor **Timeline Ethical review of SA (max nr days)** 35
Safety Reporting	**Reportable AEs** Not specified **Investigator shall report SAE to** – **Reporting timeline** – **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

–

National Standard Reporting form available

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Reporting format - Options

–

Preferred reporting format

–

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

Not specified

Responsible for End of trial Declaration

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Regular Termination - Declaration timespan (max nr days)

–

Timespan counted from

–

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

–

Study specific Requirements

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

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 **Incapacitated persons - Studies allowed** Yes Special provisions apply **Emergency situations - Studies allowed** Yes Special provisions apply **Emergency situation without prior consent of patient or proxy - Studies allowed** Special provisions apply **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/her next of kin shall as soon as possible be given information about the research and consent should be obtained as soon as possible . **Pregnant or breastfeeding women - Studies allowed** Not specified
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** Not specified **Specific notification timelines before operations start** – **Language of notification** – **Notification format** – **Data Protection Authority/ Agency - Contact Details** The Norwegian Data Protection Authority

E-Mail

postkasse@datatilsynet.no

Web address

https://www.datatilsynet.no/English/

Address

P.O.Box 8177 Dep.

ZIP/City

0034 Oslo

Country

Norway (NO)

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
Other legislation covering DP related issues

National DP act

Lov om behandling av personopplysninger (personopplysningsloven) - Law on processing of personal data, 15 June 2018 No 38 („Personal Data Act (en)“)

Insurance

Liability insurance or alternative arrangements for damages mandatory for

Study participants

Responsible for covering insurance

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Additional Information

Insurance may be provided by:
(1) Private Insurance company OR
(2) Norwegian System of Patient Injury Compensation (Norsk Pasientskadeerstatning; NPE)
A confirmation or certificate of insurance must be submitted accompanying the application dossier.

Quality Assurance/ Quality Control (QA/QC)

Monitoring

Not specified

Audit by sponsor

Not specified

Standard Operating Procedures (SOPs)

Not specified

National legislation

General Information: Applicable Legislation & Conventions

Official website providing relevant national legislation available

Yes

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.

Investigations on Medical Devices

Applicable national regulations

National Act on Medical Devices

Act on Medical Devices (or comparable national legal framework)

Regulation of 15 December 2005 no 1690 on medical devices § 4-5, § 5-6, Annex/vedlegg AIMU I, AIMU VI, AIMU VII, ØMU I, ØMU VIII, ØMU X) (In Norwegian)

Additional Information

International regulatory framework and guidance documents

• Directive 93/42/EEC (Article 15, Annexes I, VIII, X), directive 90/385/EEC (Article 10, Annexes 1, 6, 7)
• MEDDEV 2.7/1 Clinical evaluation: Guide for manufacturers and notified bodies (incl. Appendix 1 Clinical Evaluation of Coronary Stents)
• MEDDEV 2.7/2 Guide for Competent Authorities in making an assessment of clinical investigation notification
• ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice

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
Other legislation covering DP related issues

National DP act

Lov om behandling av personopplysninger (personopplysningsloven) - Law on processing of personal data, 15 June 2018 No 38 („Personal Data Act (en)“)

Definition

MD/MD Investigation

MD - Definition available in national law

Yes

MD - Definition

Medical Devices (MDs):
'any device intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, compensation for an injury or handicap.
In addition some devices for control of conception, and devices for disabled fall under the definition.'
Medical devices are further defined in Regulation of 15 December 2005 no 1690 on medical devices § 1-5a.

Active implantable medical device (AIMD): 'any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure' (ref Regulation of 15 December 2005 no 1690 medical devices §1-5 d).

Investigation of MD - Definition

Clinical Evaluation: «The assessment and analysis of clinical data pertaining to a medical device in order to verify the clinical safety and performance of the device when used as intended by the manufacturer» (MEDDEV 2.7.1 Rev.3 Clinical Evaluation: A guide for manufacturers and notified bodies.)