Medical Devices - LUXEMBOURG

Competent authority

Contact Details	**Contact Name 1** Ministry of Health **Contact Name 2** Division of Pharmacy and Drugs - Division de la Pharmacie et des Médicaments DPM **Web address** http://www.ms.etat.lu
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA)/ For certain types of MDs Ethics committee(s) Agency for data protection **CA - Submission for authorisation mandatory for** All clinical investigations of MD **CA - Registration/ notification without approval required for** – **CA - Submission required to** National CA CA(s) of EU&EFTA Member States concerned **Applicable national legal framework/ Reference** Art 13 GDR 2009 (fr) **Submission to CA and EC to be performed in the following order** In parallel
Submission of Application	**Responsible for study submission** Manufacturer Legal representative **Entitled to study submission** – **Prerequisites for submission** – **Guidance on submission of application** The documentation to be submitted to the CA is provided in Annex VIII GDR 2009 (fr)). **Applicable national legal framework/ Reference** Art 13 GDR 2009 (fr) Annex VIII GDR 2009 (fr)
Submission Format	**Format option(s)** No specific requirements **Preferred format** –

	Standard application form available No
Language of Submission	**Language(s) of application** French English **Preferred language of application** – **English accepted** – **Documents mandatory to be in official national language** Information material, Documents and Forms intended for study participants and patient information (in French & German) **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** Since January 2015: Fees for initial submission: 1000€ Substantial amendment: 1000€ **Waiver for academic (non-commercial) studies possible** No
Timelines Authorisation	**General timespan (max nr days)** 60 For Class III and implantable devices and long-term invasive devices in Class IIa or IIb **Mode of approval (General)** Tacit (Silent) Explicit approval possible before expiration of time period, provided that the EC has issued a positive opinion **Timespan counted from** Date of notification **Applicable national legal framework/ Reference** Art 13 GDR 2009 (fr) **Additional Information** Other MDs (Class I, non-invasive, short-term devices in Class II): Notification only – investigations can start provided that favourable opinion from EC in place
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** –

	Authorisation mandatory for Any substantial amendments **Responsible for submission of SA** Sponsor **Standard notification form available** No **Timeline for approval of SA (max nr days)** 35 By explicit (written) notification
Safety Reporting	**Responsible for AE reporting to CA** – **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** – **All other SUSARs** – **SAE /SADE must be reported** Immediately (Reportable events must be fully recorded) **National standard reporting form available** – **Reporting format - Options** – **Preferred format** – **Provision of Annual safety report mandatory** Yes **Annual safety report shall be provided by sponsor to** – **Applicable national legal framework/ Reference** Annex VII, Art 2 GDR 2009 (fr) **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

Manufacturer
Legal representative

Regular Termination - Declaration timespan (max nr days)

–

Timespan counted from

–

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

–

Standard Declaration form available

No

Standard Declaration form

End of trial letter

Applicable national legal framework/ Reference

Art 13(7) GDR 2009 (fr)

Ethics committee

Contact Details

Contact Name 1

Comité National d'Éthique de Recherche (CNER) / National Research Ethics Committee (NREC)

Phone

+352 26 970879

Fax

+352 26 970870

Address

1a-b- rue Thomas Edison

ZIP/City

1445 Strassen

Country

Luxembourg (LU)

E-Mail

contact@cner.lu

Web address

http://www.cner.lu

Additional Information

No local EC.

Ethical Review – General

Submission for Ethical review mandatory for

All research projects involving humans
(Art 25 Hospital Act)

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

In parallel

	Regulatory and ethics bodies involved in approval process Competent Authority/-ies (CA)/ For certain types of MDs Ethics committee(s) Agency for data protection
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** National EC **Additional Information** The national EC (CNER/NREC) provides a single opinion which is valid for all the country's investigational sites
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Central EC (authorised to issue a single opinion) **Submission of application required to** Central EC (authorised to issue a single opinion) **Additional Information** The national EC (CNER/NREC) provides a single opinion which is valid for all the country's investigational sites
Submission of Application	**Responsible for study submission** Not specified **Entitled to study submission** – **Prerequisites for submission / approval** – **Applicable national legal framework/ Reference** 25 Hospital Act of 28th August 1998 (fr) **Additional Information** NB! After submission of the application dossier, the PI shall orally, and shortly, present the study at the next CNER meeting
Submission Format	**Format option(s)** 14 copies (paper) + electronic version of documents on CD-Rom or USB key. **Preferred format** – **Standard application form available** Yes **Standard application form** "Fiche synthétique pour la soumission d'un projet d'étude au CNER" (available on website) **Guidance on submission format** Standard form and accompanying documentation to be submitted to CNER are provided on the CNER website in section Procedures>Submission for a new Study.
Language of Submission	**Language(s) of application** French 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 (in French & German) **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
Submission Fees	**Fees for Ethical review mandatory** Yes **Fees for Ethical review** Trials with commercial sponsor: € 1000.- (+VAT17%) Academic Study: € 500.- (+VAT17%) Substantial Amendment: € 250.- (+VAT17%) Amendments to MNPs (Medical Need Program) and CUPs (Compassionate Use Program): € 250.- (+VAT17%) **Official guidance on required fees** Current fees and related payment information is provided on CNER website in section: Fees
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 60 **General timespan for multi-centre studies (max nr days)** 60 **External expert advice required: Timespan (max nr days)** – **Clock-stop possible if complementary information requested** Yes **Timespan counted from** Date of receipt of valid and complete application **Applicable national legal framework/ Reference** Art 6 RGD 30 May 2005 **Additional Information** Submission deadline for initial applications: at the latest three weeks before the date of the next CNER meeting (every 2nd month). The exact meeting dates and their respective submission deadlines are provided on the CNER website. Copies of the opinion issued by the EC are sent to the CA and the National Data Protection Authority.

Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments affecting the safety of participants, changing the interpretation of the scientific pieces, etc **Responsible for notification of SA** Sponsor **Standard notification form available** No **Timeline Ethical review of SA (max nr days)** 35 **Guidance on submission of SA** Notification Format: in paper + electronically 14 copies of a summary of the amendments made + 14 copies of new full version + electronic version (CD-Rom or USB key) Further guidance and examples of substantial versus non- substantial amendments are provided on the CNER website in section Procedures > Submission of a substantial amendment
Safety Reporting	**Reportable AEs** – **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** – **Reporting format - Options** – **Preferred reporting format** – **Additional Information** No info available- to be completed soon.
End of Trial	**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 info available- to be completed soon.

Study specific Requirements

Sponsor

Sponsor - Definition available in national law

Yes

Sponsor - Definition (pursuant to national law)

The manufacturer or legal representative (Definition according to Art 1(f) GDR 1996)

Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

Yes

Standard IC form (ICF)

Templates for informed consent forms (available in French, German and English) are provided on the CNER/NREC website in section Procedures > Submission of a new study

IC is regulated by law

Yes

Informed Consent - Definition/ Requirements

Written informed consent must be obtained from study participant or legal representative according to Art 78 of the Medical Deontology Code (approved by the Ministerial Decree of 1st March 2013).

Applicable national legal framework/ Reference

Art 78 of the Medical Deontology Code (approved by the Ministerial Decree of 1st March 2013)

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Yes
Special provisions apply

Specific provision

Same provisions as for IMP studies.

Legal framework/Reference (Minors/Children)

Art 4 modified RGD 30 May 2005

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Specific provisions

Same provisions as for IMP studies

Legal framework / Reference (Incapacitated persons)

Art 5 modified RGD 30 May 2005

Emergency situations - Studies allowed

Yes
Special provisions apply

Specific provisions

Only permitted if the legal representative signs the consent form. For studies with no IMP, it depends on the design of the study.

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

–

Legal framework / Reference (Emergency Situation)

Art 5 (a) modified RGD 30 May 2005

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

No specific provisions

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

Yes

Approval/ authorisation required

Not specified

Specific notification timelines before operations start

–

Language of notification

–

Notification format

–

Data Protection Authority/ Agency - Contact Details

Commission nationale pour la protection des données (CNPD) / National Data Protection Commission

Phone

Tel.: (+352) 26 10 60-1

Fax

(+352) 26 10 60-29

Web address

http://www.cnpd.public.lu/fr/index.html

Address

1, avenue du Rock'n'Roll

ZIP/City

4361 Esch-sur-Alzette

	Country Luxembourg (LU) **Additional Information** Generally, research projects involving human subjects also have to be notified to or authorized by the National Data Protection Commission (CNPD). The EC is in contact with the CNPD. Notification form (in french or German) is available on the CNPD website. The national Data Protection Act modified law 02/08/2002 (en)/ Loi modifiée du 2 août 2002 (fr) and the Act of Data Protection and electronic communication 2005 (en) must be considered. **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** National Data Protection Act **National DP act** Data Protection Act 2002 (en)- Modified Law of August 2, 2002 on the Protection of Persons with Regard to the Processing of Personal Data as amended by law of July 27,2007/ Loi du 2 août 2002 (fr) Act of Data Protection and electronic communication 2005 (en)/ Loi modifiée du 30 mai 2005 (protection des données et communications électroniques) (fr)
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Investigator(s) Sponsor Study participants **Responsible for covering insurance** Sponsor Investigator **Applicable national legal framework/ Reference** Art 25 of Hospital Act of 28th August 1998 (fr) **Additional Information** According to Art 25 of Hospital Act of 28th August 1998 (fr) the sponsor / investigator shall subscribe an insurance covering his responsibility as well as the responsibility of all the persons involved. The study insurance covers the risks encountered by the patients during their participation in the trial. In case of malpractice and non-conformity to the protocol, the insurance might of course turn against the physician. It is the responsibility of the physicians in Luxembourg to have a liability insurance and to check whether it covers malpractice or not.
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Not specified **Audit by sponsor** Not specified **Standard Operating Procedures (SOPs)** Not specified
Archiving & Data Management	**Study documents must be kept at least (in years)** Not specified in national law

National legislation

Investigations on Medical Devices	**Applicable national regulations** National Act on Medical Devices Transposition of EU Directives on MD Other **Act on Medical Devices (or comparable national legal framework)** (1) Loi du 16 janvier 1990 (fr), relative aux dispositifs médicaux (2) Loi du 20 juin 2001 (fr), relative aux dispositifs médicaux (modifying Loi du 16 janvier 1990)- hereinafter referred to as 'Medical Device Act 2001' **Transposition of Directive 90/385/EEC** Regulation on Active implantable MD (Transposition of EU Directive 90/385/CEE & 2007/47/CE) • Grand Ducal Regulation of 5 February 1993 (fr) • Grand Ducal Regulation of 17 February 2009 (hereinafter referred to as GDR 2009 (fr)), modifying RGD Feb 1993/ RGD du 17 février 2009, modifiant le RGD modifié du 5 février 1993 relatif aux dispositifs médicaux implantables actifs, et le RGD modifié du 11 août 1996 relatif aux dispositifs médicaux **Transposition of Directive 93/42/EEC** Regulation on Medical Devices (Transposition of EU Directive 93/42/EEC & 2007/47/CE) • Grand Ducal Regulation of 11th August 1996 (fr) / GDR 1996 (fr) on Medical Devices/ RGD du 11 août 1996 relatif aux dispositifs médicaux • Grand Ducal Regulation of 27th August 2001 (fr) on modifications of RGD 26 Aug 2001/ RGD du 27 août 2001 modifiant le RG du 11 août 1996 • Grand Ducal Regulation of 17 February 2009 (hereinafter referred to as GDR 2009 (fr), modifying RGD Feb 1993/ RGD du 17 février 2009, modifiant le RGD modifié du 5 février 1993 relatif aux dispositifs médicaux implantables actifs, et le RGD modifié du 11 août 1996 relatif aux dispositifs médicaux **Transposition of Directive 98/79/EC** Regulation on In-vitro diagnostic MD (Transposition of EU Directive 98/79/EC) • Grand Ducal Regulation of 24 July 2001 (fr)/ RGD du 24 juillet 2001, relatif aux dispositifs médicaux de diagnostic in vitro **Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)** (1) Hospital Act of 28th August 1998 (fr)/ Code de la Santé - 11 Hôpitaux - A - Dispositions Générales Article 25 states that no trial, study or experimentation can be done on a human being with the aim of furthering knowledge in the fields of biological and medical sciences if the project has not firstly been submitted to the approval of a research ethics committee (2) Medical Deontology Code (fr), approved by the Ministerial Decree of 1st March 2013/ Arrêté ministériel du 1er mars 2013 approuvant le Code de déontologie médicale (2005); Chapter 5 (Art 76-79) on human experimentation, in particular, states that any study protocol, whether it is done in a hospital context or not must have been authorized. The trial can only start after the delivery of a positive opinion from the research ethics committee and after the implicit or explicit approval of the health Minister, in agreement with the legal and regulatory requirements that are to be applied in the matter.
Radiation & Radiotherapy	**Use of radiation or radioactive compounds - Specific requirements** Yes **Additional Information** Radiation: Specific regulations must be considered if ionising radiation is involved (MoH Website in section Accueil > Législation > Protection radiologique dans les applications médicales) The Division of Radioprotection of the MoH deals with all questions regarding protection from radiation.

Data Protection	**Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** National Data Protection Act **National DP act** Data Protection Act 2002 (en)- Modified Law of August 2, 2002 on the Protection of Persons with Regard to the Processing of Personal Data as amended by law of July 27,2007/ Loi du 2 août 2002 (fr) Act of Data Protection and electronic communication 2005 (en)/ Loi modifiée du 30 mai 2005 (protection des données et communications électroniques) (fr) **Additional Information** Related acts and regulations are provided on the CNPD website in section Home > Legislation > National legislation

Definition

MD/MD Investigation	**MD - Definition available in national law** Yes **MD - Definition** Medical Device (according to Art 1 GDR 2009 (fr)): 'Dispositif médical: tout instrument, appareil, équipement, matière ou autre article, utilisé seul ou en association, y compris le logiciel nécessaire pour le bon fonctionnement de celui-ci, destiné par le fabricant à ê tre utilisé chez l'homme ou l'animal à des fins: - de diagnostic, prévention, contrô le, traitement ou atténuation d'une maladie, - de diagnostic, contrô le, traitement, atténuation ou compensation d'une blessure ou d'un handicap, - d'étude ou de remplacement ou modification de l'anatomie ou d'un processus physiologique, - de maî trise de la conception, et dont l'action principale voulue dans ou sur le corps humain ou animal n'est pas obtenue par des moyens pharmacologiques ou immunologiques, mais dont la fonction peut ê tre assistée par de tels moyens;' A MD for clinical investigation (according to Art 1 GDR 2009 (fr)) means any device intended to be made available to a duly qualified medical practitioner for a clinical investigation **Investigation of MD - Definition available in national law** Yes