Medical Devices - ROMANIA

Competent authority

Contact Details	**Contact Name 1** National Agency for Medicines and Medical Devices NAMMD **Phone** +40 (0)21-222 86 52; +40 (0)21-260 01 58; +40 (0)21-260 01 59 **Fax** Fax: +40 (0) 21-222 86 83 **Email General** informatii@anm.ro **Address** 48 Aviator Sanatescu Street, Sector 1 **ZIP/City** 011478 Bucharest **Country** Romania (RO) **Web address** http://www.anm.ro/anmdm/en/
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Ministry of Health/ Competent Authority National Ethics Committee **CA - Submission for authorisation mandatory for** All clinical trials on Medicinal Products (MP) **CA - Registration/ notification without approval required for** – **CA - Submission required to** – **Submission to CA and EC to be performed in the following order** In parallel
Submission of Application	**Responsible for study submission** Manufacturer Legal representative domiciled in the EU/EEA **Entitled to study submission** – **Prerequisites for submission** Positive opinion by relevant EC(s) **Guidance on submission of application available** Yes

	Guidance on submission of application Ordinul ministrului sanatatii nr. 792/2006 privind desfăşurarea procedurii de investigaţie clinică şi a procedurii de evaluare a performanţei pentru dispozitivele medicale **National legal framework in place** Yes **Applicable national legal framework/ Reference** Ordinul ministrului sanatatii nr. 792/2006 privind desfăşurarea procedurii de investigaţie clinică şi a procedurii de evaluare a performanţei pentru dispozitivele medicale Standardul SR EN ISO 14155/2012 Investigaţia clinică a dispozitivelor medicale pentru subiecţi umani. Bună practică clinică – se procura contracost de la ASRO (www.asro.ro), numar de catalog 1412
Submission Format	**Format option(s)** Paper hardcopy **Preferred format** – **Standard application form available** Yes **Use of standard application form binding** Yes
Language of Submission	**Language(s) of application** Romanian **Preferred language of application** – **English accepted** – **Documents mandatory to be in official national language** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of the study participant** – **National legal framework in place** Yes **Applicable national legal framework/ Reference** Ordinul ministrului sanatatii nr. 792 din 29 iunie 2006 privind desfasurarea procedurii de investigatie clinica si a procedurii de evaluare a performantei pentru dispozitivele medicale, cu modificarile si completarile ulterioare
Submission Fees	**Fees for trial submission mandatory** Yes **Fees** 200 lei (RON)

Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** Tacit (Silent) Explicit approval possible before expiration of time period **Timespan counted from** –
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** – **Responsible for submission of SA** – **Timeline for approval of SA (max nr days)** –
Safety Reporting	**Responsible for AE reporting to CA** Manufacturer Legal representative **Sponsor must declare reportable events to** – **Reportable AEs** – **SUSAR being life-thereatening or leading to death must be reported** – **All other SUSARs** – **SAE /SADE must be reported** – **National standard reporting form available** – **Reporting format - Options** – **Preferred format** – **Annual safety report shall be provided by sponsor to** – **Investigator shall report SAE to** – **Reporting timeline** –

End of Trial	**End of trial declaration mandatory for** – **Responsible for End of trial declaration** – **Regular Termination - Declaration timespan (max nr days)** – **Timespan counted from** – **Early/premature Termination - Declaration timespan (max nr days)** –

Ethics committee

Ethical Review – General	**Submission for Ethical review mandatory for** All clinical trials on Medicinal Products (MP) All clinical investigations of MD **Submission to CA and EC to be performed in the following order** In parallel **Regulatory and ethics bodies involved in approval process** Ministry of Health/ Competent Authority National Ethics Committee
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Central EC
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Central EC (authorised to issue a single opinion) **Submission of application required to** –
Submission of Application	**Responsible for study submission** Sponsor Investigator Manufacturer Legal representative **Entitled to study submission** – **Prerequisites for submission / approval** Proof of payment of fees **Guidance on study submission available** Yes **Guidance on study submission** - on the CNBMDM website : http://www.bioetica-medicala.ro/category/comunicate Cf. Comunicate CNBMDM - only in Romanian

Submission Format	**Format option(s)** Paper hardcopy Electronically on data carrier (CD/USB stick) **Preferred format** – **Standard application form available** Yes **Standard application form** - on the CNBMDM website : http://www.bioetica-medicala.ro/category/comunicate (see Comunicate 24.02.2016, 17.12.2014) **Use of standard application form binding** Yes **Guidance on submission format** - on the CNBMDM website : http://www.bioetica-medicala.ro/category/comunicate (see Comunicate 24.02.2016, 17.12.2014)
Language of Submission	**Language(s) of application** Romanian English **Preferred language of application** – **English accepted** Yes 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 study participant** Information material, Documents and Forms intended for study participants and patient information
Submission Fees	**Fees for Ethical review mandatory** Yes **Waiver for academic (non-commercial) studies possible** Not specified **Fees for Ethical review** CNBMDM fees fall into several different categories depending on the type of study and the type of review **Official guidance on required fees available** Yes **Official guidance on required fees** Guidance povided on CNBMDM website (see COMUNICAT privind tarifele CNBMDM incepand cu 01.01.2016)

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** –
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments **Responsible for notification of SA** Not specified **Timeline Ethical review of SA (max nr days)** 35
Safety Reporting	**Reportable AEs** SAE (Serious Adverse Event) **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** –
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)** –

Study specific Requirements

Sponsor	**Sponsor - Definition available in national law** No **Sponsor - Definition (pursuant to national law)** No definition provided for clinical investigations of medical devices
Investigator	**Entitled to be principal investigator** Physician
Study Participants - Vulnerable Population	**Minors / Children - Studies allowed** With limitations **Incapacitated persons - Studies allowed** With limitations **Emergency situations - Studies allowed** With limitations **Emergency situation without prior consent of patient or proxy - Studies allowed** Yes **Pregnant or breastfeeding women - Studies allowed** –
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** – **Compensation is limited to/provided for** Not specified
Data Protection	**Approval/ authorisation required** Not specified **Specific notification timelines before operations start** – **Language of notification** – **Notification format** – **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** –
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** –

	Responsible for covering insurance –
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Not specified **Audit by sponsor** Not specified **Standard Operating Procedures (SOPs)** Compulsory