

Medical Devices - ROMANIA

Competent authority

Contact Details

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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

	<p>Guidance on submission of application</p> <p>Ordinul ministrului sanatatii nr. 792/2006 privind desfășurarea procedurii de investigație clinică și a procedurii de evaluare a performanței pentru dispozitivele medicale</p> <p>National legal framework in place</p> <p>Yes</p> <p>Applicable national legal framework/ Reference</p> <p>Ordinul ministrului sanatatii nr. 792/2006 privind desfășurarea procedurii de investigație clinică și a procedurii de evaluare a performanței pentru dispozitivele medicale</p> <p>Standardul SR EN ISO 14155/2012 Investigația clinică a dispozitivelor medicale pentru subiecți umani. Bună practică clinică – se procura contracost de la ASRO (www.asro.ro), numar de catalog 1412</p>
Submission Format	<p>Format option(s)</p> <p>Paper hardcopy</p> <p>Preferred format</p> <p>—</p> <p>Standard application form available</p> <p>Yes</p> <p>Use of standard application form binding</p> <p>Yes</p>
Language of Submission	<p>Language(s) of application</p> <p>Romanian</p> <p>Preferred language of application</p> <p>—</p> <p>English accepted</p> <p>—</p> <p>Documents mandatory to be in official national language</p> <p>—</p> <p>Documents mandatory to be in local language of study site</p> <p>—</p> <p>Documents mandatory to be in language of the study participant</p> <p>—</p> <p>National legal framework in place</p> <p>Yes</p> <p>Applicable national legal framework/ Reference</p> <p>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</p>
Submission Fees	<p>Fees for trial submission mandatory</p> <p>Yes</p> <p>Fees</p> <p>200 lei (RON)</p>

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

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

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

Timelines Ethical Review	<p>General timespan for single-centre studies (max nr days)</p> <p>60</p> <p>General timespan for multi-centre studies (max nr days)</p> <p>60</p> <p>External expert advice required: Timespan (max nr days)</p> <p>—</p> <p>Clock-stop possible if complementary information requested</p> <p>Yes</p> <p>Timespan counted from</p> <p>—</p>
Amendments/ Substantial Amendments (SA)	<p>Ethical review mandatory for</p> <p>Any substantial amendments</p> <p>Responsible for notification of SA</p> <p>Not specified</p> <p>Timeline Ethical review of SA (max nr days)</p> <p>35</p>
Safety Reporting	<p>Reportable AEs</p> <p>SAE (Serious Adverse Event)</p> <p>Investigator shall report SAE to</p> <p>—</p> <p>Reporting timeline</p> <p>—</p> <p>Responsible for AE reporting to relevant EC(s)</p> <p>—</p> <p>SUSAR being life-threatening or leading to death must be reported</p> <p>—</p> <p>All other SUSAR must be reported</p> <p>—</p> <p>SAE/SADE must be reported</p> <p>—</p> <p>National Standard Reporting form available</p> <p>—</p> <p>Reporting format - Options</p> <p>—</p> <p>Preferred reporting format</p> <p>—</p>
End of Trial	<p>Responsible for End of trial Declaration</p> <p>—</p> <p>Regular Termination - Declaration timespan (max nr days)</p> <p>—</p>

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