Medicinal Products for Human Use - ROMANIA

Competent authority

Contact Details	**Contact Name 1** Ministry of Health **Contact Name 2** National Agency for Medicines and Medical Devices (NAMMD)/ Agentia Nationala a Medicamentului si a Dispozitivelor Medicale (ANMDM) **Phone** +40213171100 **Fax** +40213163497 **Email General** informatii@anm.ro **Address** 48 Aviator Sanatescu Street, Sector 1 **ZIP/City** Bucharest, Code 011478 **Country** Romania (RO) **Web address** http://www.anm.ro
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** – **CA - Submission for authorisation mandatory for** – **CA - Registration/ notification without approval required for** – **CA - Submission required to** –
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission** – **Guidance on submission of application available** Yes

	Guidance on submission of application Further information and guidance for application for sponsors is provided on the NAMMD website (in Romanian) **Applicable national legal framework/ Reference** Art 37 Ordin nr. 904/2006
Submission Format	**Format option(s)** – **Preferred format** – **Guidance on submission format** Information and guidance for application for sponsors is provided on the NAMMD/ANMDM website (in Romanian)
Language of Submission	**Language(s) of application** – **Preferred language of application** – **English accepted** – **Documents mandatory to be in official national language** –
Submission Fees	**Fees for trial submission mandatory** Yes **Waiver for academic (non-commercial) studies possible** Not specified **Official guidance on required fees** Payment form available on ANMDM/NAMMD website. http://www.anm.ro/anmdm/en/med_formulare.html
Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** Explicit approval possible before expiration of time period **ATMP/GMO trials (max nr days)** 90 **Mode of approval (ATMP/GMO trials)** Written authorization **External expert advice required (max nr days)** + 90 **Xenogeneic cell therapy (max nr days)** No time limit

	Mode of approval (Xenogeneic cell therapy) Written authorization **Timespan counted from** – **Applicable national legal framework/ Reference** Art 39-42 Ordin nr. 904/2006
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** Any substantial amendments to the study protocol (that are likely to affect the safety of participant or change the interpretation of the scientific documents) **Responsible for submission of SA** Sponsor **Timeline for approval of SA (max nr days)** – **Applicable national legal framework/ Reference** Art 45 a) OMS 904/2006 – Normelor referitoare la implementarea regulilor de bună practică în desfăşurarea studiilor clinice efectuate cu medicamente de uz uman (Order 904/25 Jul 2006 on approval of rules relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use)
Safety Reporting	**Responsible for AE reporting to CA** Sponsor **Sponsor must declare reportable events to** National CA **Reportable AEs** 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 **SAE /SADE must be reported** – **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

National CA

Applicable national legal framework/ Reference

Art 58-63 Ordin nr. 904/2006

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately

Sponsor is obliged to notify all investigators of SAE/ SADE occurrence

Yes

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

–

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

15

Reasons for early termination shall be clearly stated

Yes

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 45 c) OMS 904/2006 – Normelor referitoare la implementarea regulilor de bună practică în desfăşurarea studiilor clinice efectuate cu medicamente de uz uman
(Order 904/25 Jul 2006 on approval of rules relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use)

Ethics committee

Contact Details

Contact Name 1

National Bioethics Committee for Medicine and Medical Devices (CNBMDM)

Phone

021.210.28.80/021.210.28.80

Fax

021.210.28.81

	Address Sos. Stefan cel Mare no. 19-21, Sector 2 / Clinical Hospital COLENTINA – PAVILION K (Secretary) **ZIP/City** BUCHAREST, postal code 020125 **Country** Romania (RO) **E-Mail** comisia.bioetica@adsm.ro **Web address** http://en.bioetica-medicala.ro
Ethical Review – General	**Submission for Ethical review mandatory for** All clinical trials on Medicinal Products (MP) **Submission to CA and EC to be performed in the following order** In parallel Sequentially (in any order) (as selected by sponsor according to Art 35 Ordin nr. 904/2006) **Procedural interaction between CA and EC during approval process** No **Regulatory and ethics bodies involved in approval process** –
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** National EC (National Bioethics Committee for Medicine and Medical Devices CNBMDM)
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Central EC (authorised to issue a single opinion) (National Bioethics Committee for Medicine and Medical Devices CNBMDM) **Submission of application required to** Central EC (authorised to issue a single opinion)
Submission of Application	**Responsible for study submission** Not specified **Entitled to study submission** – **Prerequisites for submission / approval** – **Guidance on study submission available** Yes **Guidance on study submission** Regulamentul de functionare al CNBMDM (Regulations of the Commission)- available in Romanian only.

Submission Format	**Format option(s)** Email Paper hardcopy Electronically on data carrier (CD/USB stick) **Preferred format** – **Standard application form available** Yes **Guidance on submission format available** Yes **Guidance on submission format** Comunicat privind forma in care se vor depune documentele la CNBMDM 17.12.2014; Provided in section "Comunicate CNBMDM" in Romanian only (http://en.bioetica-medicala.ro/category/cnbmdm-comunications/)
Language of Submission	**Language(s) of application** Romanian English **Preferred language of application** – **English accepted** Yes **Documents mandatory to be in official national language** Investigators CV for clinical sites and coordinating investigator' CV in Romania; Consent form/information sheet: Romanian and Minority Language **Applicable national legal framework/ Reference** • HOTĂRÂREA Nr. 50/1512.2006 referitoare la aprobarea Ghidului privind formularul cererii şi documentaţia care trebuie trimise comisiei de etică în vederea obţinerii opiniei acesteia asupra desfăşurării unui studiu clinic cu medicamente de uz uman în România • ANEXA HCS-50 GHID privind formularul cererii şi documentaţia care trebuie trimise comisiei de etică în vederea obţinerii opiniei acesteia asupra desfăşurării unui studiu clinic cu medicamente de uz uman în România (provided in Romanian only on CNBMDM website in section "Legislation of Medical Bioethics In Romania")
Submission Fees	**Fees for Ethical review mandatory** Yes **Waiver for academic (non-commercial) studies possible** No **Fees for Ethical review** Applicable fees (VAT included) from 01.01.2016: Phase I-III: 1690 EURO Phase IV: 768 EURO Bioequivalence studies: 461 EURO Amendments: 308 EURO Non-interventional clinical trials: 310 EURO

	Official guidance on required fees available Yes **Official guidance on required fees** COMUNICAT privind tarifele CNBMDM incepand cu 01.01.2016; (available on CNBMDM website in section "Comunicate" in Romanian only)
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)** 90 **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 + Payment of submission fees **National legal framework in place** Yes **Applicable national legal framework/ Reference** Art 29-31 Ordin nr. 904/2006 Regulament de functionare al CNBMDM (available on CNBMDM website in section "About us" (Useful documents)
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments to the study protocol (that are likely to affect the safety of participant or change the interpretation of the scientific documents) **Responsible for notification of SA** Sponsor **Timeline Ethical review of SA (max nr days)** 35 From date of receipt of valid application **National legal framework in place** Yes

	Applicable national legal framework/ Reference Art 45 a) OMS 904/2006 – Normelor referitoare la implementarea regulilor de bună practică în desfăşurarea studiilor clinice efectuate cu medicamente de uz uman (Order 904/25 Jul 2006 on approval of rules relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use)
Safety Reporting	**Reportable AEs** SAE (Serious Adverse Event) SUSAR (Suspected Unexpected Serious Adverse Reaction) **Investigator shall report SAE to** Sponsor **Reporting timeline** Immediately **Responsible for AE reporting to relevant EC(s)** Sponsor **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 SUSAR must be reported** Within a max of 15d upon first knowledge **SAE/SADE must be reported** – **Sponsor is obliged to notify all investigators of SAE/ SADE occurrence** Yes **National Standard Reporting form available** – **Reporting format - Options** – **Preferred reporting format** – **Provision of Annual safety report mandatory** Yes **Applicable national legal framework/ Reference** Art 58-62 Ordin nr 904/2006
End of Trial	**End of trial Declaration mandatory** Yes **Responsible for End of trial Declaration** Sponsor **Regular Termination - Declaration timespan (max nr days)** 90

Timespan counted from

–

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

15

Reasons for early termination shall be clearly stated

Yes

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 45 c) OMS 904/2006 – Normelor referitoare la implementarea regulilor de bună practică în desfăşurarea studiilor clinice efectuate cu medicamente de uz uman
(Order 904/25 Jul 2006 on approval of rules relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use)

Study specific Requirements

Sponsor

Sponsor - Definition available in national law

Yes

Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

No

IC is regulated by law

Yes

Applicable national legal framework/ Reference

HOTĂRÂREA Nr. 39/27.10.2006 referitoare la aprobarea Ghidului privind buna practică în studiul clinic)

Additional Information

There are specific requirements for vulnerable population.

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Yes
Special provisions apply

Legal framework/Reference (Minors/Children)

• LEGE nr. 17 din 22 februarie 2001 privind ratificarea Convenţiei europene pentru protecţia drepturilor omului şi a demnităţii fiinţei umane fata de aplicaţiile biologiei şi medicinei, Convenţia privind drepturile omului şi biomedicina, semnată la Oviedo la 4 aprilie 1997, şi a Protocolului adiţional la Convenţia europeană pentru protecţia drepturilor omului şi a demnităţii fiinţei umane fata de aplicaţiile biologiei şi medicinei, referitor la interzicerea clonării fiinţelor umane, semnat la Paris la 12 ianuarie 1998 (MONITORUL OFICIAL nr. 103 din 28 februarie 2001)

• ORDIN nr. 904 din 25 iulie 2006 pentru aprobarea Normelor referitoare la implementarea regulilor de buna practica în desfăşurarea studiilor clinice efectuate cu medicamente de uz uman

• HOTĂRÂREA Nr. 39/27.10.2006 referitoare la aprobarea Ghidului privind buna practică în studiul clinic

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Incapacitated persons)

• LEGE nr. 17 din 22 februarie 2001 privind ratificarea Convenţiei europene pentru protecţia drepturilor omului şi a demnităţii fiinţei umane fata de aplicaţiile biologiei şi medicinei, Convenţia privind drepturile omului şi biomedicina, semnată la Oviedo la 4 aprilie 1997, şi a Protocolului adiţional la Convenţia europeană pentru protecţia drepturilor omului şi a demnităţii fiinţei umane fata de aplicaţiile biologiei şi medicinei, referitor la interzicerea clonării fiinţelor umane, semnat la Paris la 12 ianuarie 1998 (MONITORUL OFICIAL nr. 103 din 28 februarie 2001)

• ORDIN nr. 904 din 25 iulie 2006 pentru aprobarea Normelor referitoare la implementarea regulilor de buna practica în desfăşurarea studiilor clinice efectuate cu medicamente de uz uman

• HOTĂRÂREA Nr. 39/27.10.2006 referitoare la aprobarea Ghidului privind buna practică în studiul clinic

Emergency situations - Studies allowed

Yes
Special provisions apply

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

Yes
Special provisions apply

Legal framework / Reference (Emergency Situation)

• HOTĂRÂREA Nr. 39/27.10.2006 referitoare la aprobarea Ghidului privind buna practică în studiul clinic
• HOTĂRÂREA Nr. 1 din data 18.03.2015 (Academia de stiinte medicale, CNBMDM)

Pregnant or breastfeeding women - Studies allowed

Not specified

Legal framework / Reference (Pregnant or breastfeeding women)

• HOTĂRÂREA Nr. 39/27.10.2006 referitoare la aprobarea Ghidului privind buna practică în studiul clinic

National legal framework for protection of vulnerable populations in place

Yes

Applicable legal framework / Reference (Vulnerable Population)

• Law of patient's rights : Legea nr. 46/2003, legea drepturilor pacientului (Monitorul Oficial, Partea I nr. 70 din 03/02/2003)
• Ratification of the Oviedo Convention (Law no 17/2001) LEGE nr. 17 din 22 februarie 2001privind ratificarea Convenţiei europene pentru protecţia drepturilor omului şi a demnităţii fiinţei umane fata de aplicaţiile biologiei şi medicinei, Convenţia privind drepturile omului şi biomedicina, semnată la Oviedo la 4 aprilie 1997, şi a Protocolului adiţional la Convenţia europeană pentru protecţia drepturilor omului şi a demnităţii fiinţei umane fata de aplicaţiile biologiei şi medicinei, referitor la interzicerea clonării fiinţelor umane, semnat la Paris la 12 ianuarie 1998 (MONITORUL OFICIAL nr. 103 din 28 februarie 2001)
• ORDIN Nr. 904 din 25 iulie 2006pentru aprobarea Normelor referitoare la implementarea regulilor de buna practica in desfasurarea studiilor clinice efectuate cu medicamente de uz uman (MONITORUL OFICIAL NR. 671 din 4 august 2006) (http://legislatie.just.ro/Public/DetaliiDocument/74051)
• HOTĂRÂREA Nr. 39/27.10.2006 referitoare la aprobarea Ghidului privind buna practică în studiul clinic

National legislation

General Information: Applicable Legislation & Conventions

Official website providing relevant national legislation available

Yes

Official website providing relevant national legislation

The websites of the National Agency for Medicines and Medical Devices (NAMMD) and the Bioethics Committee of Medicines and Medical Devices (CNBMDM) provide applicable national legislation (in Romanian).

Official governmental legal database available

Yes

Official governmental legal database

http://legislatie.just.ro

Clinical Trials on IMPs in Humans

Applicable national regulations

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Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)

ORDIN Nr. 904 din 25 iulie 2006 pentru aprobarea Normelor referitoare la implementarea regulilor de buna practica in desfasurarea studiilor clinice efectuate cu medicamente de uz uman (MONITORUL OFICIAL NR. 671 din 4 august 2006)/
Order 904/25 Jul 2006 on approval of rules relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

- Transpositon of EU Directive 2001/20/EC

Transposition of (GCP) Directive 2005/28/EC

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