Nutrition/Interventional - 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)

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Country

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Web address

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Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

National Competent Authorities
Institutional Ethics Committee
National Ethics Committee

Regulatory and ethics bodies involved in approval process for trials including patients

–

Regulatory and ethics bodies involved in approval process for trials including including healthy participants

–

Regulatory and ethics bodies involved in approval process for trials including vulnerable population

–

CA - Registration/ notification without approval required for

–

CA - Registration requirements for clinical trials

Registration mandatory

Registration requirements for clinical trials including patients

–

	Registration requirements for clinical trials including healthy participants – **Registration requirements for clinical trials including vulnerable population** – **CA - Submission required to** Institutional CA **Studies including patients - submission required to** National CA **Studies including healthy participants - submission required to** – **Studies including vulnerable population - submission required to** –
Language of Submission	**Language(s) of application** Official national language English **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **Preferred language of application** – **English accepted** Yes **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** –
Timelines Authorisation	**Time to approval of CA in weeks (minimum)** 2 **Time to approval of CA in weeks (maximum)** 32 **Time to approval CA in weeks (average)** 10
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** National Bioethics Committee of Medicines and Medical Research-2Devices **Country** Romania (RO) **Web address** http://www.adsm.ro/en **Additional Information** Local ECs
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory** Yes **Submission to CA and EC to be performed in the following order** –
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** National EC Institutional EC **Ethical approval (favourable opinion) for trials including patients to be obtained from** – **Ethical approval (favourable opinion) for trials including healthy participants to be obtained from** – **Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from** –
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** – **Ethical approval in trials including patients obtained from** – **Ethical approval in trials including healthy participants obtained from** – **Ethical approval in trials including vulnerable population obtained from** –
Submission of Application	**Entitled to study submission** Sponsor Industry **Entitled to submission of trials including patients** –

	Entitled to submission of trials including healthy participants – **Responsible for submission of trials including vulnerable population** – **Prerequisites for submission / approval** –
Language of Submission	**Language(s) of application** Official national language English **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **Preferred language of application** Official national language **English accepted** Yes **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 study participant** –
Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 5 **Time in weeks from submission to positive approval (maximum)** 24 **Time in weeks from submission to positive approval (average)** 14
Safety Reporting	**Investigator shall report SAE to** National CA Sponsor Trial Coordinator **Investigator shall report SAE in trials with patients to** – **Investigator shall report SAE in trials with healthy participants to** – **Investigator shall report SAE in trials with volunteers to** –

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Co-sponsorship allowed** Yes **Contracts with external sponsor** No
Investigator	**Entitled to be principal investigator** Physician Pharmacist **Entitled to be principal investigator for trials with patients** – **Entitled to be principal investigator for trials with healthy participants** – **Entitled to be principal investigator for trials with vulnerable population** –
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** No **Accepted format of Informed Consent (IC) form** Written consent **Accepted format of IC form for studies including patients** – **Accepted format of IC form for studies including healthy participants** – **Accepted format of IC form for studies including vulnerable population** –
Study Participants - Vulnerable Population	**Considered as vulnerable population** Children Unconscious Persons Incapacitated adults People with psychiatric disorder People with dementia **Applicable ethical regulations** –
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Are not reimbursed **Reimbursement for patients** – **Reimbursement for healthy participants** –

	Reimbursement for vulnerable population – **Compensation is limited to/provided for** – **Compensation for patients is limited to/provided for** – **Compensation for healthy participants is limited to/provided for** – **Compensation for vulnerable population is limited to/provided for** –
Funding	**Trials generally financially supported by industry** Not specified **Trials in patients financially supported by industry** Yes **Trials in healthy participants financially supported by industry** Not specified **Trials in vulnerable population financially supported by industry** Not specified **Name of industry company/institution supporting financially** Pfizer **Funding is an issue during the approval process** Not specified **Funding is an issue during the approval process in trials including patients** Not specified **Funding is an issue during the approval process in trials including healthy participants** Not specified **Funding is an issue during the approval process in trials including vulnerable population** Not specified
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** Yes **Mandatory to inform participant of clinical trial outcome** Yes
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** – **Obligation to contract a liability insurance for trials including patients for** –

Obligation to contract a liability insurance for trials including healthy participants for

–

Obligation to contract a liability insurance for trials including vulnerable population for

–

Insurance fee in € value indicated as

–

Insurance fee in € value indicated as

–

Quality Assurance/ Quality Control (QA/QC)

Regularly performed methods

Audits
Monitoring
Audit Trail
Case Report Form (CRF)

Regularly performed methods in trials including patients

–

Regularly performed methods in trials including healthy participants

–

Regularly performed methods in trials including vulnerable population

–

Regularly performed audits

–

Regularly performed audits in trials including patients

–

Regularly performed audits in trials including healthy participants

–

Regularly performed audits in trials including vulnerable population

–

Additional Information

internal and external audits are performed regularly

Archiving & Data Management

Study documents must be kept at least (in years)

–

Legal framework for data management exists

Not specified

National legislation

General Information: Applicable Legislation & Conventions

Applied regulatory conventions

Other ethical principles for medical research (other than Declaration of Helsinki)
ICH-GCP Guidelines
International regulatory requirements
European regulatory requirements - European Directive 2001/20/EC, 2005/28/EC
National regulatory requirements

	Applied regulatory conventions in studies including patients – **Applied regulatory conventions in studies including healthy participants** – **Applied regulatory conventions in studies including vulnerable population** – **Applicable national laws** – **Applicable national laws for patients** – **Applicable national laws for healthy participants** – **Applicable national laws for vulnerable population** – **National regulations for volunteers exist for** –
Nutrition	**Nutrition considered as drug** No **Additional Information** parenteral nutrition
Blood & Tissue Samples	**Tissue samples permitted** Not specified **Tissue samples permitted in trials including patients** Not specified **Tissue samples permitted in trials including healthy participants** Not specified **Tissue samples permitted in trials including vulnerable population** Not specified
Invasive Catheters	**Invasive catheters permitted** Yes **Invasive catheters permitted for trials including patients** Yes **Invasive catheters permitted for trials including healthy participants** No **Invasive catheters permitted for trials including vulnerable population** No

Definition

Nutrition Study	**Definition available in national law** Yes **Definition available for Trials in patients** Yes **Definition available for Trials in healthy participants** No **Definition available for Trials in vulnerable population** No