Nutrition - 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** National Competent Authorities National Ethics Committee **CA - Registration requirements for clinical trials** Registration mandatory **CA - Submission required to** Institutional CA
Language of Submission	**Language(s) of application** Official national language English **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)** 4 **Time to approval of CA in weeks (maximum)** 24 **Time to approval CA in weeks (average)** 12
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
Submission of Application	**Entitled to study submission** Sponsor Industry **Prerequisites for submission / approval** Application is limited to the institution
Language of Submission	**Language(s) of application** Official national language English **Preferred language of application** – **English accepted** Yes

	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)** 8 **Time in weeks from submission to positive approval (maximum)** 24 **Time in weeks from submission to positive approval (average)** 12
Safety Reporting	**Investigator shall report SAE to** National CA Sponsor Trial Coordinator

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 **Regulations concerning the inclusion or exclusion available** Not specified **Applicable ethical regulations** –
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Not permitted **Compensation is limited to/provided for** –
Study Participants - Recruitment & Trial Outcome	**Mandatory to inform participant of clinical trial outcome** Yes
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Audits Monitoring Audit Trail Case Report Form (CRF) **Regularly performed audits** – **Additional Information** internal and external audits are performed regularly

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 **Applicable national laws** – **National regulations for volunteers exist for** –
Nutrition	**Nutrition considered as drug** No

Data Protection	**Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** –