Nutrition - HUNGARY

Competent authority

Contact Details	**Contact Name 1** National Institute of Pharmacy and Nutrition NIPN/ OGYÉI **Contact Name 2** Clinical Trials Unit **Phone** +36 1 8869-300 **Fax** +36 1 8869-460 **Email General** ogyei@ogyei.hu **Email Department** clinadr@ogyei.gov.hu **Address** Zrinyi u. 3/ Mail: 1372 P.O. Box: 450 **ZIP/City** 1051 Budapest **Country** Hungary (HU) **Web address** http://www.ogyei.gov.hu/main_page/ **Additional Information** Co-authority: ETT KFEB (Hungarian Medical Research Council Ethics Committee for Clinical Pharmacology) Co-authority for non-interventional trials: ETT TUKEB Co-authority for trials conntected with reproduction: ETT HRB (Committee of Human Reproduction)
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Institutional Competent Authority National Competent Authorities Regional Ethics Committee **CA - Registration requirements for clinical trials** Registration mandatory **CA - Submission required to** Institutional CA
Submission Format	**Standard application form available** Yes

Language of Submission	**Language(s) of application** Official national language Hungarian **Preferred language of application** – **English accepted** No **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)** 20 **Time to approval CA in weeks (average)** 12
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Central Ethics Committee (CEC)/ Public co-authority for IMP studies: **Contact Name 2** Committee for Clinical Pharmacology and Ethics of the Medical Research Council – KFEB **Phone** (+36 1) 795-1195 or (+36 1) 795-4873 **Fax** (+36 1) 795-0168 **Country** Hungary (HU) **E-Mail** kfebtitkarsag@emmi.gov.hu **Web address** http://www.ett.hu/kfeb.htm **Additional Information** For Safety Reporting/ SUSARs: safetyreport@emmi.gov.hu

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** Institutional EC
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC (authorised to issue a single opinion)
Submission of Application	**Entitled to study submission** Principal Investigator Investigator Physician **Prerequisites for submission / approval** Proof of GCP Training of applicant Application is limited to the institution
Language of Submission	**Language(s) of application** Official national language Hungarian **Preferred language of application** – **English accepted** No **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)** 4 **Time in weeks from submission to positive approval (maximum)** 10 **Time in weeks from submission to positive approval (average)** 5
Safety Reporting	**Investigator shall report SAE to** Institution Sponsor Trial Coordinator

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes

	Set up contracts with external sponsor for trials including patients Yes **Set up contracts with external sponsor for trials including healthy participants** No **Set up contracts with external sponsor for trials including vulnerable population** No
Investigator	**Entitled to be principal investigator** Physician Dietitian PhD **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 Elderly Unconscious Persons Incapacitated adults **Regulations concerning the inclusion or exclusion available** No **Regulations concerning the inclusion or exclusion** available only in interventional trials **Applicable ethical regulations** Institutional
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional

	Compensation is limited to/provided for Adults only Inconvenience, Pain, Discomfort
Funding	**Trials generally financially supported by industry** No **Funding is an issue during the approval process** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Researchers Sponsor **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Audits Inspections Monitoring Standard Operating Procedures (SOP) Audit Trail Case Report Form (CRF) **Standards concerning quality assurance and quality control exist** Yes **Regularly performed audits** – **Regularly performed audits - 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** Yes

National legislation

General Information: Applicable Legislation & Conventions	**Applied regulatory conventions** Declaration of Helsinki ICH-GCP Guidelines National regulatory requirements Institutional regulatory requirements **Applicable national laws** Hospital Act Data protection Act Drug act **National regulations for volunteers exist for** Isotopes Tissue samples

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

Definition

Nutrition Study	**Definition available in national law** Yes