Nutrition - POLAND

Competent authority

Contact Details	**Contact Name 1** The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products – URPL („The Office“) **Phone** + 48 22 492 11 00 **Fax** + 48 22 492 11 09 **Email Department** pl@urpl.gov.pl **Address** Al. Jerozolimskie 181C **ZIP/City** 02-222 Warszawa **Country** Poland (PL) **Web address** http://www.urpl.gov.pl **Additional Information**
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Not involved **CA - Registration requirements for clinical trials** Not mandatory **CA - Submission required to** Not required
Submission Format	**Standard application form available** No
Language of Submission	**Language(s) of application** Official national language Polish **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)** 6 **Time to approval CA in weeks (average)** 4
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Local Research Ethics Committees (REC), in Polish „Komisje Bioetyczne“ -„Bioethics Committees“) **Contact Name 2** 50 local independent RECs **Web address** http://www.oil.org.pl/xml/oil/oil68/tematy/komisje/stale/bioetyki/komisje **Additional Information** The local ECs are established at academic institutions (e.g. medical universities), non-university medical research centres and health institutes or at the Regional Chambers of Physicians and Dentists. List of ECs is provided on the website of the Regional Chamber of Physicians and Dentists in Warsaw (Okręgowa Izba Lekarska). There is no central EC.
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory** No **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** EC not required
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 **Prerequisites for submission / approval** –

Submission Format	**Standard application form available** Yes **Standard application form** Standard Application form
Language of Submission	**Language(s) of application** Official national language **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)** 6
Safety Reporting	**Investigator shall report SAE to** Institution

Study specific Requirements

Sponsor	**Sponsorship mandatory** No **Co-Sponsor - Definition available in national law** Yes **Contracts with external sponsor** No **Additional Information** contracts are usually set up in interventional trials
Investigator	**Entitled to be principal investigator** Physician Dietitian Nurse Pharmacist PhD Each investigator **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 Pregnant women (Pregnancy) Lactating women Unconscious Persons Incapacitated adults People with psychiatric disorder People with dementia Prisoners **Regulations concerning the inclusion or exclusion available** No **Regulations concerning the inclusion or exclusion** not for observational trials **Applicable ethical regulations** Do not exist
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Compensation is limited to/provided for** Adults only Time effort Expenses arising from study participation (e.g. Travel) Phase I trials
Funding	**Trials generally financially supported by industry** No **Funding is an issue during the approval process** Not specified

	Additional Information trials including medicinal products or vulnerable population are generally sponsored by industry.
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Mandatory to inform participant of clinical trial outcome** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Not mandatory **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Not specified **Standards concerning quality assurance and quality control exist** Yes **Regularly performed audits** – **Regularly performed audits - Additional information** internal and external audits are not regulary performed in Poland
Archiving & Data Management	**Study documents must be kept at least (in years)** – **Legal framework for data management exists** No

National legislation

General Information: Applicable Legislation & Conventions	**Applied regulatory conventions** Declaration of Helsinki Regional regulatory requirements Institutional regulatory requirements **Applicable national laws** Hospital Act Data protection Act Genetical engineering act Medical device act Drug act **National regulations for volunteers exist for** Do not exist
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** No