Nutrition/Interventional - LITHUANIA

Competent authority

Contact Details	**Contact Name 1** State Medicines Control Agency **Phone** +370 5 263 9264 **Fax** +370 5 263 9265 **Email General** vvkt@vvkt.lt **Address** Žirmūnų g. 139A **ZIP/City** 09120 Vilnius **Country** Lithuania (LT) **Web address** http://www.vvkt.lt/
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** National Competent Authorities Regional Ethics Committee National Ethics Committee Agency for data protection **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** National CA **Studies including patients - submission required to** – **Studies including healthy participants - submission required to** – **Studies including vulnerable population - submission required to** –
Submission Format	**Standard application form available** Yes **Standard application form** http://bioetika.sam.lt/
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** – **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)** 8 **Time to approval of CA in weeks (maximum)** 12 **Time to approval CA in weeks (average)** 8

Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Lithuanian Bioethics Committee **Contact Name 2** Lietuvos bioetikos komitetas **Phone** (+370 5) 212 45 65 **Fax** (+370 5) 260 86 40 **Address** Vilniaus str. 16 **ZIP/City** LT-01402,Vilnius **Country** Lithuania (LT) **E-Mail** lbek@sam.lt **Web address** http://bioetika.sam.lt/index.php?3221858831 **Additional Information** Kaunas Regional Biomedical Research Ethics Committee: LUHS Kaunas Region Biomedical Research Ethics Committee
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** – **National declaration on Ethical requirements exists** Yes **National declaration** http://bioetika.sam.lt/
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** National 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** Single Opinion Multiple Opinion **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 Investigator **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** – **English accepted** – **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)** 8 **Time in weeks from submission to positive approval (maximum)** 12 **Time in weeks from submission to positive approval (average)** 8
Safety Reporting	**Investigator shall report SAE to** National CA Sponsor **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** –
Additional Information & Specifics	**Additional Information** The Lithuanian Bioethics Committee (LBEC) is the main institution responsible for bioethics policy in Lithuania and it is also responsible (among other functions) for the ethical review of multi-site biomedical research projects (including clinical trials on IMP), issuing the single opinion for the country. The LBEC is established by and is accountable to the Ministry of Health.

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes
Investigator	**Entitled to be principal investigator** Physician 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 Pregnant women (Pregnancy) Lactating women Unconscious Persons Incapacitated adults People with psychiatric disorder People with dementia Prisoners **Regulations concerning the inclusion or exclusion available** Yes **Regulations concerning the inclusion or exclusion** Law on Biomedical research **Applicable ethical regulations** Institutional National International EU directive (2001/20/EC)
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Not specified **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** Expenses arising from study participation (e.g. Travel) Phase I trials **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** No

	Name of public company/institution supporting financially Medical university or university hospital **Name of industry company/institution supporting financially** Pharma and biotech companies **Funding is an issue during the approval process** No
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Researchers Sponsor **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 Inspections Monitoring Standard Operating Procedures (SOP) 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** – **Standards concerning quality assurance and quality control exist** Yes **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

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Regularly performed audits - Additional information

Uncertain

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

Applied regulatory conventions in studies including patients

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Applied regulatory conventions in studies including healthy participants

–

Applied regulatory conventions in studies including vulnerable population

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Applicable national laws

Data protection Act
Drug act

Applicable national laws for patients

–

Applicable national laws for healthy participants

–

Applicable national laws for vulnerable population

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National regulations for volunteers exist for

Not specified

	Network providing information on regulations and ethical requirements in studies Medicines Control Agency of Lithuania **Network Email** vvkt@vvkt.lt **Official website providing relevant national legislation available** Yes **Official website providing relevant national legislation** http://www.vvkt.lt/lit/English **Additional Information** http://bioetika.sam.lt/
Nutrition	**Nutrition considered as drug** No
Blood & Tissue Samples	**Tissue samples permitted** Yes
Invasive Catheters	**Invasive catheters permitted** Yes