Nutrition - SERBIA

Competent authority

Contact Details	**Contact Name 1** Medicines and Medical Devices Agency of Serbia ALIMS (Agencija za lekove i medicinska sredstva Srbije) **Phone** +381 11 3951-169; +381 11 3951-163 **Fax** +381 11 3951-131 **Email General** hygia@alims.gov.rs **Address** 458, Vojvode Stepe Street **ZIP/City** 11221 Belgrade **Country** Serbia (RS) **Web address** http://www.alims.gov.rs/ **Additional Information** No local CA.
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Institutional CA, Institutional EC, **CA - Registration requirements for clinical trials** Registration mandatory **Registration requirements - Additional information** Observational studies are registered in the Principal Investigator (PI) hospital Ethical Committee (EC) register. In Serbia we register nutritional clinical trials in Ethical Committee register, only. Drug Agency (ALIMS) doesn't register nutritional studies. **CA - Submission required to** National CA Institutional CA International CA
Submission Format	**Standard application form available** Yes
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)** 9 **Time to approval CA in weeks (average)** 6

Ethics committee

Contact Details	**Contact Name 1** Serbian Medical Society Ethical Commitie + Local Ethical Committee of the Hospital **ZIP/City** Belgrade **Country** Serbia (RS)
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** exists only for drug trials
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** International EC National EC Institutional EC
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC + All concerned local ECs for site-specific assessment

Submission of Application	**Entitled to study submission** Sponsor Principal Investigator Investigator **Prerequisites for submission / approval** –
Submission Format	**Standard application form available** Yes **Standard application form** There is no standard application form for all institutions / investigation sites. Every institutional Ethical Committee (EC) has its own list of documents needed for EC submission, but all of them are similar: investigators CVs, summary, study protocol, IC, contract.
Language of Submission	**Language(s) of application** Official national language English **Preferred language of application** – **English accepted** – **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)** 1 **Time in weeks from submission to positive approval (maximum)** 8 **Time in weeks from submission to positive approval (average)** 4
Safety Reporting	**Investigator shall report SAE to** Institution, National Agency, Sponsor, Trial Coordinator

Study specific Requirements

Sponsor	**Sponsorship mandatory** No **Co-sponsorship allowed** Yes **Contracts with external sponsor** Yes **Additional Information** Contracts with external sponsors are usually set up in commercial studies

Investigator	**Entitled to be principal investigator** Physician **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 **Applicable ethical regulations** Institutional National International EU directive (2001/20/EC)
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Compensation is limited to/provided for** Inconvenience, Pain, Discomfort Expenses arising from study participation (e.g. Travel)
Funding	**Trials generally financially supported by industry** Not specified

	Name of public company/institution supporting financially Ministry, hospital **Name of private company/institution supporting financially** Investigators **Name of industry company/institution supporting financially** Pharmaceutical Company **Funding is an issue during the approval process** Not specified
Study Participants - Recruitment & Trial Outcome	**Mandatory to inform participant of clinical trial outcome** On patients request **Additional Information** This question may be included in the Informed Consent Form.
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** not mandatory **Name and contact insurance companies insuring clinical research** Grawe, Dunav, Wiener Städtische, Ddor, Uniqa **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 audits, external audits
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 International regulatory requirements European regulatory requirements - European Directive 2001/20/EC, 2005/28/EC National regulatory requirements Institutional regulatory requirements **Applicable national laws** The Serbian Law of Food protection and quality **National regulations for volunteers exist for** Nutrition intervention in healthy people Pharmaceuticals/drug trials Invasive procedures Catheters Isotopes Tissue samples **Network providing information on regulations and ethical requirements in studies** for ECRIN: Serbian Medical Society **Network Email** sld@bvcom.ne **Network contact person** Dragana Maca A. Kastratovic, Srdjan Djani Z. Markovic, Suzana Bjelogrlic **Personal Email** drmaca.kastratovic@gmail.com **Official website providing relevant national legislation** Website of Serbian Medical Society: www.sld.org.rs **Additional Information** Telephone number: +381113234450 ; +381600326170 ; +38162323411 srdjan0302@gmail.com; drmaca.kastratovic@gmail.com
Nutrition	**Nutrition considered as drug** No
Blood & Tissue Samples	**Tissue samples permitted** Yes **Tissue samples permitted - Additional information** only in pharmaceutical trials
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)** –

Invasive Catheters	**Invasive catheters permitted** Yes **Additional Information** only in pharmaceutical trials

Definition

Observational Study	**Definition in national law** 1) Non-interventional post-marketing clinical trial (pharmacoepidemiological testing) is a trial that implies the medicinal product application in respect to the conditions prescribed in the marketing authorisation and where the election of the patient is not predetermined by the clinical trial protocol but is a part of a ongoing practice of the usual type of treatment; in addition, the medicinal product prescription is clearly separated from the decision to involve the patient into the trial. Additional diagnostic procedures or the monitoring procedures are not applied, and the epidemiological methods are used to analyze the derived data;