Nutrition/Interventional - SERBIA

Competent authority

Contact Details	**Contact Name 1** Medicines and Medical Devices Agency of Serbia **Fax** Faxes: (+381 11) 3951 131, (+381 11) 3951 147 **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/
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Institutional Competent Authority, Institutional Ethics Committeee **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 requirements for clinical trials including patients** Registration in the Principal Investigator (PI) hospital Ethical Committee (EC) register **Registration requirements for clinical trials including healthy participants** Registration in the Principal Investigator (PI) hospital Ethical Committee (EC) register **Registration requirements for clinical trials including vulnerable population** –

	Registration requirements - Additional information In Serbia nutritional clinical trials are registered in the Ethical Committee register, only. Drug Agency (ALIMS) does not register nutritional studies. **CA - Submission required to** National CA Institutional CA International 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
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)** 4 **Time to approval of CA in weeks (minimum) in trials including patients** 9 **Time to approval of CA in weeks (minimum) in trials including healthy participants** 6

Ethics committee

Contact Details	**Contact Name 1** Serbian Medical Society Ethical Commitie + Local Ethical Committee of the Hospital
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** – **Additional Information** only for drug trials
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** International EC National EC Institutional 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** Lead EC + All concerned local ECs for site-specific assessment **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 –
Submission Format	**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 **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)** 1 **Time in weeks from submission to positive approval (maximum)** 9 **Time in weeks from submission to positive approval (average)** 4
Safety Reporting	**Investigator shall report SAE to** Institution, National CA, Sponsor, Trial Coordinator, **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** –

Study specific Requirements

Sponsor	**Sponsorship mandatory** No **Co-sponsorship allowed** Yes **Contracts with external sponsor** Yes **Additional Information** contracts usually set up with external sponsors 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 **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** Inconvenience, Pain, Discomfort Expenses arising from study participation (e.g. Travel) **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	**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 Companies **Funding is an issue during the approval process** No
Study Participants - Recruitment & Trial Outcome	**Mandatory to inform participant of clinical trial outcome** No **Additional Information** In informed consent (IC) the participant can be asked if the/she wants to be informed about the study results. If yes, the PI informs him about the results.
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers **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** – **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) **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** –
Archiving & Data Management	**Study documents must be kept at least (in years)** – **Legal framework for data management exists** Yes **Legal framework for data management** only for pharmaceuticals

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 **Applied regulatory conventions in studies including patients** – **Applied regulatory conventions in studies including healthy participants** – **Applied regulatory conventions in studies including vulnerable population** – **Applicable national laws** The Serbian Law of Food Protection and Quality **Applicable national laws for patients** – **Applicable national laws for healthy participants** – **Applicable national laws for vulnerable population** – **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** ECRIN Serbian Medical Society **Network Email** sld@bvcom.net **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** Further Contacts: Tel:+381113234450 ; +381600326170 ; +38162323411 sld@bvcom.net ; drmaca.kastratovic@gmail.com ; srdjan0302@gmail.com
Nutrition	**Nutrition considered as drug** No

Blood & Tissue Samples	**Tissue samples permitted** Not specified **Tissue samples permitted in trials including patients** Not specified **Tissue samples permitted in trials including healthy participants** Not specified **Tissue samples permitted in trials including vulnerable population** Not specified **Additional Information** Only permitted to take tissue samples 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)** –

Definition

Interventional Study	**Definition in national law** 1) Interventional post-marketing clinical trial is a trial that implies the medicinal product application in respect to the conditions prescribed in the marketing authorisation, and that requires additional diagnostic procedures, as well as the monitoring procedures defined by the clinical trial protocol;
Nutrition Study	**Definition available in national law** No