Nutrition/Interventional - AUSTRIA

Competent authority

Contact Details

Contact Name 1

Bundesamt für Sicherheit im Gesundheitswesen BASG/ Federal Office for Safety in Health Care

Contact Name 2

Agentur für Gesundheit und Ernährungssicherheit AGES/ Austrian Medicines and Medical Devices Agency

Phone

0043 50 555-36111, -36820

Email Department

clinicaltrials@ages.at

Address

Traisengasse 5

ZIP/City

1200 Vienna

Country

Austria (AT)

Web address

http://www.ages.at/ages/geschaeftsfelder/medizinmarktaufsicht/

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Medicines Agency
Institutional Competent Authority
Institutional Ethics Committee
Not validated

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

–

Regulatory and ethics bodies involved - Additional information

Institutional competent authority is not financially involved in the approval process

CA - Registration/ notification without approval required for

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CA - Registration requirements for clinical trials

Registration recommended

	Registration requirements for clinical trials including patients – **Registration requirements for clinical trials including healthy participants** – **Registration requirements for clinical trials including vulnerable population** – **Registration requirements - Additional information** Registration in EudraCT is not required by law (only generally referred to soft law) Employees can be required to register clinical trials (eg Medical University of Vienna - Good Scientific Practice) **CA - Submission required to** Institutional 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** No **Standard application form** only for medicinal products Website refers to Medicinal Products only. (website in German an English available)
Language of Submission	**Language(s) of application** Official national language German **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** Yes Case by case May vary by region **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 CA in weeks (average)** 5 **Additional Information** 35 days by law
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Institutional Ethics Committee **Contact Name 2** Ethics Committee Mecical University of Vienna **Phone** +43 1 40400 21470 **Fax** +43 1 40400 16900 **Address** Borschkegasse 8b/E06 **ZIP/City** 1090 Wien **Country** Austria (AT) **E-Mail** ethik-kom@meduniwien.ac.at **Web address** http://ethikkommission.meduniwien.ac.at/
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory - Additional information** Submission of a study to the Ethics committee is regulated on institutional level. **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

	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** All local ECs of participating sites EC review not required Not validated **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 Principal Investigator Investigator Physician Dietitian Nutritionist PhD Industry National citizen **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** – **Additional Information** Regional differences may exist for: Sponsor, Dietitian, Nutritionist, PhD, Industry and national citizen
Submission Format	**Standard application form available** Yes **Standard application form** "Forum Österreich" provides an agreement but not a law (only in German)

Language of Submission	**Language(s) of application** Official national language German **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** Yes May vary by region **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)** 4 **Time in weeks from submission to positive approval (maximum)** 12 **Time in weeks from submission to positive approval (average)** 7
Safety Reporting	**Investigator shall report SAE to** Sponsor Other **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	**Contracts with external sponsor** Yes
Investigator	**Entitled to be principal investigator** –

Entitled to be principal investigator for trials with patients

Physician

Entitled to be principal investigator for trials with healthy participants

Each investigator
May vary by region

Entitled to be principal investigator for trials with vulnerable population

Physician

Additional Information

It is only regulated for medicinal products and medical devices who may act as principal investigator.

Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

Yes

Accepted format of Informed Consent (IC) form

Written consent

Accepted format of IC form for studies including patients

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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)
Unconscious Persons
Incapacitated adults
People with psychiatric disorder
People with dementia
Prisoners

Vulnerable population - Additional information

It depends on the mental status if or if not elderly are considered as vulnerable population.
it is not validated if of if not lactating women are considered as vulnerable population

Regulations concerning the inclusion or exclusion available

Yes

Regulations concerning the inclusion or exclusion

federal states monitor inclusion or exclusion of vulnerable groups.

Applicable ethical regulations

Institutional
National
International
EU directive (2001/20/EC)
Not validated

	Additional Information AMG – Arzneimittelgesetz apply for pharmaceuticals/drug trials
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** Time effort Inconvenience Expenses arising from study participation (e.g. Travel) Depends on study population May vary by region **Compensation for patients is limited to/provided for** Time effort Inconvenience Expenses arising from study participation (e.g. Travel) May vary by region **Compensation for healthy participants is limited to/provided for** – **Compensation for vulnerable population is limited to/provided for** Time effort Inconvenience Expenses arising from study participation (e.g. Travel) May vary by region
Funding	**Trials in patients financially supported by industry** Yes **Trials in healthy participants financially supported by industry** No **Trials in vulnerable population financially supported by industry** Yes **Funding is an issue during the approval process** Yes
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Recruitment process** specific for each region **Mandatory to inform participant of clinical trial outcome** No

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** e.g. Zürich Versicherungen **Insurance fee in € value indicated as** – **Insurance fee for lowest risk research - Additional Information** € 17,00-€ 22,00 / study Participant, depending on contract negotiations **Insurance fee in € value indicated as** – **Insurance fee for highest risk research - Additional Information** € 17,00-€ 22,00 / study Participant, depending on contract negotiations
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Monitoring Standard Operating Procedures (SOP) Case Report Form (CRF) Depends on study population Regional differences may exist **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)** –

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 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** Hospital Act Data protection Act Genetical engineering act Medical device act Drug act hospital act applies only if study is performed in the hospital setting, Genetical engineering act, Medical device act and drug act only in relevant context **Applicable national laws for patients** – **Applicable national laws for healthy participants** – **Applicable national laws for vulnerable population** – **National regulations for volunteers exist for** –
Nutrition	**Nutrition considered as drug** No
Blood & Tissue Samples	**Tissue samples permitted** Yes **Tissue samples permitted - Additional information** differerences in blood and tissue samples exist

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)** – **Additional Information** standard requirements regarding data protection exists
Invasive Catheters	**Invasive catheters permitted** Yes **Additional Information** trial automatically becomes MPG §40 – Medizinproduktegesetz (medical device directive)

Definition

Interventional Study	**Definition in national law** regulated only for drug trial in AMG (Arzneimittelgesetz (drug act) §2a, paragraph 1: "systematic investigation to: 1. demonstrate or investigate effects or side effects of drugs, 2. side effects 3. determine resorption, distribution, metabolism or excretion of drugs ethical committees extend this definition to all other investigations of this type by analogy
Nutrition Study	**Definition available in national law** No