Nutrition/Interventional - TURKEY

Competent authority

Contact Details	**Contact Name 1** Ministry of Health - Turkish Medicines and Medical Devices Agency (TMMDA)/ Türkiye İlaç ve Tıbbi cihaz Kurumu (TITCK) **Contact Name 2** (Shortly referred to as Ministry or Agency) **Contact Name 3** Department of Clinical Drug Studies **Phone** +90 (312) 218 30 00 **Fax** 90 (312) 218 34 60 **Address** Söğütözü Mahallesi 2176. Sokak No:5 P.K. **ZIP/City** 06520 Çankaya/ANKARA **Country** Turkey (TR) **Web address** http://iegm.gov.tr **Additional Information** No local CA.
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Ministry of Health Institutional Ethics Committee National Ethics Committee **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 requirements for clinical trials including healthy participants** – **Registration requirements for clinical trials including vulnerable population** – **CA - Submission required to** National CA Institutional CA **Studies including patients - submission required to** – **Studies including healthy participants - submission required to** – **Studies including vulnerable population - submission required to** –
Language of Submission	**Language(s) of application** Official national language Turkish 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** 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)** 20 **Time to approval of CA in weeks (maximum)** 32

	Time to approval CA in weeks (average) 24
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Local ECs **Country** Turkey (TR) **Web address** https://www.titck.gov.tr/UnitsPageDescription.aspx?BirimId=CVgRV0Ms3dY=&KonuId=YvRiEmNsOw4= **Additional Information** A list of the ECs in Turkey is provided on the website of the Ministry of Health.
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** National declaration
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** 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 (authorised to issue a single 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** Principal Investigator Investigator Physician **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** Proof of GCP Training of applicant
Submission Format	**Standard application form available** Yes **Standard application form** Standard application form to EC
Language of Submission	**Language(s) of application** Official national language Turkish 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** 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 study participant** –

Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 12 **Time in weeks from submission to positive approval (maximum)** 24 **Time in weeks from submission to positive approval (average)** 16
Safety Reporting	**Investigator shall report SAE to** National CA Institution 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** Yes **Contracts with external sponsor** Yes
Investigator	**Entitled to be principal investigator** Depends on study population **Entitled to be principal investigator for trials with patients** Physician Dietitian Nutritionist Not validated **Entitled to be principal investigator for trials with healthy participants** Physician Not validated **Entitled to be principal investigator for trials with vulnerable population** Physician Not validated
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Yes **Standard IC form (ICF)** Standard informed consent forms: (Standard, Observational trials, vulnerable population)

	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** Not specified **Applicable ethical regulations** Institutional National International EU directive (2001/20/EC)
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Depends on study population (healthy subjects or patients) **Reimbursement for patients** – **Reimbursement for healthy participants** Optional **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** Phase I trials A certain amount **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 in patients financially supported by industry** Yes

	Trials in healthy participants financially supported by industry No **Trials in vulnerable population financially supported by industry** No **Name of industry company/institution supporting financially** e.g. Baxter **Funding is an issue during the approval process** Yes
Study Participants - Recruitment & Trial Outcome	**Mandatory to inform participant of clinical trial outcome** Yes
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** – **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) 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

–

Regularly performed audits - Additional information

internal and external audits are performed regularly

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)
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
Medical device act
Drug act

Applicable national laws for patients

–

Applicable national laws for healthy participants

–

Applicable national laws for vulnerable population

–

National regulations for volunteers exist for

Pharmaceuticals/drug trials

Nutrition

Nutrition considered as drug

Yes

Blood & Tissue Samples

Tissue samples permitted in trials including patients

Yes

Tissue samples permitted in trials including healthy participants

No

	Tissue samples permitted in trials including vulnerable population No
Invasive Catheters	**Invasive catheters permitted for trials including patients** Yes **Invasive catheters permitted for trials including healthy participants** No **Invasive catheters permitted for trials including vulnerable population** Yes