Nutrition - 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
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Institutional Ethics Committee National Ethics Committee **CA - Registration requirements for clinical trials** – **CA - Submission required to** National CA Institutional CA
Language of Submission	**Language(s) of application** Official national language Turkish 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)** 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 on ethical requirements
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** National EC Institutional EC
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC (authorised to issue a single opinion) Not validated

Submission of Application	**Entitled to study submission** Principal Investigator Investigator Physician Dietitian **Prerequisites for submission / approval** Proof of GCP Training of applicant
Submission Format	**Standard application form available** Yes **Standard application form** Application forms Clinical Research Ethics Committee
Language of Submission	**Language(s) of application** Official national language English **Preferred language of application** – **English accepted** Yes **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

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Contracts with external sponsor** Yes
Investigator	**Entitled to be principal investigator** Physician Dietitian Nutritionist

	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** Yes **Standard IC form (ICF)** The provided links may be applicable to observational trials or to vulnerable groups. **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** Optional **Compensation is limited to/provided for** Phase I trials A certain amount
Funding	**Trials generally financially supported by industry** No

	Additional Information Observational trials are generally not sponsored by industry. Interventional trials in patients and pharmaceutical trials are more likely to be sponsored by industry.
Study Participants - Recruitment & Trial Outcome	**Mandatory to inform participant of clinical trial outcome** Yes
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Not mandatory **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) **Standards concerning quality assurance and quality control exist** Yes **Regularly performed audits** – **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 **Applicable national laws** Hospital Act Data protection Act Medical device act Drug act **National regulations for volunteers exist for** –
Nutrition	**Nutrition considered as drug** Yes
Blood & Tissue Samples	**Tissue samples permitted** No

Invasive Catheters	**Invasive catheters permitted** No

Definition

Nutrition Study	**Definition available in national law** No