

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

—

	<p>Documents mandatory to be in local language of study site</p> <p>–</p> <p>Documents mandatory to be in language of the study participant</p> <p>–</p>
Timelines Authorisation	<p>Time to approval of CA in weeks (minimum)</p> <p>20</p> <p>Time to approval of CA in weeks (maximum)</p> <p>32</p> <p>Time to approval CA in weeks (average)</p> <p>24</p>
Safety Reporting	<p>Sponsor must declare reportable events to</p> <p>–</p>

Ethics committee

Contact Details	<p>Contact Name 1</p> <p>Local ECs</p> <p>Country</p> <p>Turkey (TR)</p> <p>Web address</p> <p>https://www.titck.gov.tr/UnitsPageDescription.aspx?BirimId=CVgRV0Ms3dY=&Konuld=YvRiEmNsOw4=</p> <p>Additional Information</p> <p>A list of the ECs in Turkey is provided on the website of the Ministry of Health.</p>
Ethical Review - General	<p>Submission for Ethical review mandatory for</p> <p>–</p> <p>Submission of study mandatory</p> <p>Yes</p> <p>Submission to CA and EC to be performed in the following order</p> <p>–</p> <p>National declaration on Ethical requirements exists</p> <p>Yes</p> <p>National declaration</p> <p>National declaration on ethical requirements</p>
Single-Centre Studies - Ethical Review	<p>Ethical approval (favourable opinion) to be obtained from</p> <p>National EC Institutional EC</p>
Multi-Centre Studies - Ethical Review	<p>Ethical approval (favourable opinion) required from</p> <p>Lead EC (authorised to issue a single opinion) Not validated</p>

Submission of Application	<p>Entitled to study submission</p> <p>Principal Investigator Investigator Physician Dietitian</p> <p>Prerequisites for submission / approval</p> <p>Proof of GCP Training of applicant</p>
Submission Format	<p>Standard application form available</p> <p>Yes</p> <p>Standard application form</p> <p>Application forms Clinical Research Ethics Committee</p>
Language of Submission	<p>Language(s) of application</p> <p>Official national language English</p> <p>Preferred language of application</p> <p>—</p> <p>English accepted</p> <p>Yes</p> <p>Documents mandatory to be in local language of study site</p> <p>—</p> <p>Documents mandatory to be in language of study participant</p> <p>—</p>
Timelines Ethical Review	<p>Time in weeks from submission to positive approval (minimum)</p> <p>12</p> <p>Time in weeks from submission to positive approval (maximum)</p> <p>24</p> <p>Time in weeks from submission to positive approval (average)</p> <p>16</p>
Safety Reporting	<p>Investigator shall report SAE to</p> <p>National CA Institution Sponsor Trial Coordinator</p>

Study specific Requirements

Sponsor	<p>Sponsorship mandatory</p> <p>Yes</p> <p>Contracts with external sponsor</p> <p>Yes</p>
Investigator	<p>Entitled to be principal investigator</p> <p>Physician Dietitian Nutritionist</p>

	<p>Entitled to be principal investigator for trials with patients</p> <p>–</p> <p>Entitled to be principal investigator for trials with healthy participants</p> <p>–</p> <p>Entitled to be principal investigator for trials with vulnerable population</p> <p>–</p>
Study Participants - Informed Consent (IC)	<p>Standard IC form (ICF) available</p> <p>Yes</p> <p>Standard IC form (ICF)</p> <p>The provided links may be applicable to observational trials or to vulnerable groups.</p> <p>Accepted format of Informed Consent (IC) form</p> <p>Written consent</p> <p>Accepted format of IC form for studies including patients</p> <p>–</p> <p>Accepted format of IC form for studies including healthy participants</p> <p>–</p> <p>Accepted format of IC form for studies including vulnerable population</p> <p>–</p>
Study Participants - Vulnerable Population	<p>Considered as vulnerable population</p> <p>Children Elderly Pregnant women (Pregnancy) Lactating women Unconscious Persons Incapacitated adults People with psychiatric disorder People with dementia Prisoners</p> <p>Regulations concerning the inclusion or exclusion available</p> <p>Not specified</p> <p>Applicable ethical regulations</p> <p>Institutional National International EU directive (2001/20/EC)</p>
Study Participants - Compensation & Reimbursement	<p>Reimbursement for study participants</p> <p>Optional</p> <p>Compensation is limited to/provided for</p> <p>Phase I trials A certain amount</p>
Funding	<p>Trials generally financially supported by industry</p> <p>No</p>

	<p>Additional Information</p> <p>Observational trials are generally not sponsored by industry. Interventional trials in patients and pharmaceutical trials are more likely to be sponsored by industry.</p>
Study Participants - Recruitment & Trial Outcome	<p>Mandatory to inform participant of clinical trial outcome</p> <p>Yes</p>
Insurance	<p>Liability insurance or alternative arrangements for damages mandatory for</p> <p>Not mandatory</p> <p>Insurance fee in € value indicated as</p> <p>—</p> <p>Insurance fee in € value indicated as</p> <p>—</p>
Quality Assurance/ Quality Control (QA/QC)	<p>Regularly performed methods</p> <p>Audits Inspections Monitoring Standard Operating Procedures (SOP) Case Report Form (CRF)</p> <p>Standards concerning quality assurance and quality control exist</p> <p>Yes</p> <p>Regularly performed audits</p> <p>—</p> <p>Regularly performed audits - Additional information</p> <p>internal and external audits are performed regularly</p>

National legislation

General Information: Applicable Legislation & Conventions	<p>Applied regulatory conventions</p> <p>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</p> <p>Applicable national laws</p> <p>Hospital Act Data protection Act Medical device act Drug act</p> <p>National regulations for volunteers exist for</p> <p>—</p>
Nutrition	<p>Nutrition considered as drug</p> <p>Yes</p>
Blood & Tissue Samples	<p>Tissue samples permitted</p> <p>No</p>

Invasive Catheters

Invasive catheters permitted

No

Definition

Nutrition Study

Definition available in national law

No