Medical Devices - 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 Medical Devices **Phone** +90 312 218 30 55 **Fax** +90 312 218 32 75 **Address** Söğütözü Mahallesi 2176. Sokak No:5 **ZIP/City** P.K. 06520 Çankaya/ANKARA **Country** Turkey (TR) **Web address** http://www.titck.gov.tr **Additional Information** No local CA.
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Ministry of Health/ Competent Authority Ethics committee(s) **CA - Submission for authorisation mandatory for** Interventional MD investigations Observational MD investigations **CA - Registration/ notification without approval required for** – **CA - Submission required to** National CA **Submission to CA and EC to be performed in the following order** –
Submission of Application	**Responsible for study submission** Sponsor Legal representative domiciled in the respective country

	Entitled to study submission – **Prerequisites for submission** Positive opinion by relevant EC(s) **Guidance on submission of application available** Yes **Guidance on submission of application** A guideline providing detailed guidance on format, content and required appendixes of application is available (Guidance on The Format of Application Form for Medical Device Clinical Trials [to The Ministry]).
Submission Format	**Format option(s)** – **Preferred format** – **Standard application form available** Yes **Standard application form** Standard application forms and cover letter samples for applicaton are posted on the Ministry’s website. **Guidance on submission format available** Yes **Guidance on submission format** A guideline providing detailed guidance on format, content and required appendixes of application is available (Guidance on The Format of Application Form for Medical Device Clinical Trials [to The Ministry]).
Language of Submission	**Language(s) of application** Turkish English **Preferred language of application** – **English accepted** For some documents only, such as investigtors’s brochure and full trial protocol **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** –
Submission Fees	**Fees for trial submission mandatory** Yes

	Fees Application fees are mandatory and shall be paid for the application to the Ministry. Application fees are announced on the Ministry's website annually. Trials for academic purposes or specialty thesis are exempt from fees. **Waiver for academic (non-commercial) studies possible** Yes
Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** Explicit **Timespan counted from** Confirmation of formal completeness **Applicable national legal framework/ Reference** Regulation On Medical Device Clinical Trials 2014 **Additional Information** The sponsor is granted a single opportunity to resubmit amendments upon request of the Ministry.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** All clinical investigations requiring authorisation by CA **Responsible for submission of SA** Sponsor **Standard notification form available** Yes **Standard notification form** A standard notification form and cover letter sample are posted on the Ministry’s website. **Timeline for approval of SA (max nr days)** 60 From submission of the EC decision **National legal framework in place** Yes **Applicable national legal framework/ Reference** Regulation On Medical Device Clinical Trials 2014 **Additional Information** Amendments occurring during conduct of a trial requiring reporting, and those requiring a decision and approval will be determined according to the Guideline for Good Clinical Practice (2014). It is essential for amendments requiring a decision and approval to be reviewed and concluded by the ethics committee within fifteen days, and by the Agency within sixty days after submission of the ethics committee decision

Safety Reporting

Responsible for AE reporting to CA

Sponsor

Sponsor must declare reportable events to

National CA
Relevant EC(s)
All investigators

Reportable AEs

–

SUSAR being life-thereatening or leading to death must be reported

–

All other SUSARs

–

SAE /SADE must be reported

Within a max of 7 d upon first knowledge (+8d for additional information) for events being life-threatening or leading to death
Within a max of 15d upon first knowledge

National standard reporting form available

Yes

Standard Reporting Form

Standard forms are posted on the Ministry’s website.

Reporting format - Options

–

Preferred format

–

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA
Relevant EC(s)

Guidance on AE reporting procedure available

Yes

Guidance on AE reporting procedure

Please refer to the Guideline for Good Clinical Practice 2014 for further details of AE reporting.

National legal framework in place

Yes

Applicable national legal framework/ Reference

Regulation On Medical Device Clinical Trials 2014

Additional Information

The sponsor shall keep detailed records of all adverse events which are reported to him by the principal investigator. These records shall be submitted to the Agency and the ethics committee, if they so request.

Annual safety report: The sponsor shall send a list of all serious adverse device effects observed, containing also information on safety of the subjects, to the ethics committee and the Agency, once every year. When the Agency may so deem necessary or in investigations with short periods, the Agency may also request the report earlier (Regulation On Medical Device Clinical Trials 2014).

Investigator shall report SAE to

–

Reporting timeline

–

End of Trial

End of trial declaration mandatory for

All clinical investigations requiring authorisation by CA

Responsible for End of trial declaration

Sponsor
Legal representative domiciled in the respective country

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

–

Early/premature Termination - Declaration timespan (max nr days)

15

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form available

Yes

Standard Declaration form

A standard notification form and cover letter sample are posted on the Ministry’s website.

National legal framework in place

Yes

Applicable national legal framework/ Reference

Regulation On Medical Device Clinical Trials 2014

Additional Information

If the clinical trial was terminated early, its grounds will also be stated and an information letter regarding the measures for maintenance of the treatment of the volunteers enrolled into the study will also be attached. In cases where early termination was due to safety reasons, the Agency shall inform the situation to the European Union Commission through the agency of the Ministry of Economy or electronically.
In cases where early termination was due to safety reasons, the Agency shall inform the situation to the European Union Commission through the agency of the Ministry of Economy or electronically.

Additional Information & Specifics	**Additional Information** Documents provided by the Ministry are in Turkish. No official English translation is available. Unofficial English translations could be provided by Turkish Clinical Research Infrastructure Network (TUCRIN - tucrin.deu.edu.tr) upon request.

Ethics committee

Contact Details	**Contact Name 1** Local Ethics Committees **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. There is no central EC.
Ethical Review – General	**Submission for Ethical review mandatory for** Interventional MD investigations Observational MD investigations **Submission to CA and EC to be performed in the following order** EC first **Additional Information** Simultaneous application to the EC and the CA is not possible; application to the CA must be made with the EC opinion **Regulatory and ethics bodies involved in approval process** –
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Any competent EC **Additional Information** The scientific and ethical approval will be obtained from any EC for Clinical Trials in Turkey. Websites of ECs should be checked for institutional details.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC (authorised to issue a single opinion) **Submission of application required to** Lead EC (authorised to issue a single opinion) **Additional Information** For multicentre clinical trials, it is sufficient to have a single EC decision. Websites of ECs should be checked for instituitional details.
Submission of Application	**Responsible for study submission** Sponsor Legal representative domiciled in the respective country **Entitled to study submission** –

	Prerequisites for submission / approval – **Guidance on study submission available** Yes **Guidance on study submission** A comprehensive guideline providing detailed guidance on format, content and required appendixes of application as well as on the trial conduct (notification on amendments, trial termination etc.) is available (Guidance on The Format of Applications for Clinical Trials and Bioavailability - Bioequivalence Studies to Ethics Committee 2015). **National legal framework in place** Yes **Applicable national legal framework/ Reference** Regulation On Medical Device Clinical Trials 2014
Submission Format	**Format option(s)** – **Preferred format** – **Standard application form available** Yes **Standard application form** Standard application forms and cover letter samples for applicaton are posted on the Ministry’s website. **Guidance on submission format available** Yes **Guidance on submission format** A guideline providing detailed guidance on format, content and required appendixes of application is available (Guidance on The Format of Application Form for Medical Device Clinical Trials [to The Ministry]).
Language of Submission	**Language(s) of application** Turkish English **Preferred language of application** – **English accepted** For some documents only, such as investigtors’s brochure and full trial protocol. **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** –

Submission Fees	**Fees for Ethical review mandatory** Yes **Fees for Ethical review** Application fees are mandatory and shall be paid for the application to the EC. Application fees are similar to the ones announced on the Ministry's website yet must be checked for each EC.
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 15 **General timespan for multi-centre studies (max nr days)** 15 **External expert advice required: Timespan (max nr days)** – **Timespan counted from** Confirmation of formal completeness **Applicable national legal framework/ Reference** Regulation on Clinical Trials of Medicinal and Biological Products 2014 **Additional Information** The sponsor is granted a single opportunity to resubmit amendments upon request of the Ministry
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments **Responsible for notification of SA** Sponsor **Standard notification form available** Yes **Standard notification form** A standard notification form and cover letter sample are posted on the Ministry’s website. **Timeline Ethical review of SA (max nr days)** 15 **Applicable national legal framework/ Reference** Regulation On Medical Device Clinical Trials 2014 **Additional Information** Amendments occurring during conduct of a trial requiring reporting, and those requiring a decision and approval will be determined according to the Guideline for Good Clinical Practice (2014). Amendments requiring a decision and approval to be reviewed and concluded by the ethics committee within fifteen days, and by the Agency within sixty days after submission of the ethics committee decision.
Safety Reporting	**Reportable AEs** SAE (Serious Adverse Event) SADE (Serious Adverse Device Effect)

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately (followed by a detailed, written report)

Responsible for AE reporting to relevant EC(s)

Sponsor

SUSAR being life-thereatening or leading to death must be reported

–

All other SUSAR must be reported

–

SAE/SADE must be reported

Within a max of 7 d upon first knowledge (+8d for additional information) for events being life-threatening or leading to death
Within a max of 15d upon first knowledge

Sponsor is obliged to notify all investigators of SAE/ SADE occurrence

Yes

National Standard Reporting form available

Yes

Standard Reporting Form

Standard forms are posted on the Ministry’s website.

Reporting format - Options

–

Preferred reporting format

–

Guidance on AE reporting procedure available

Yes

Guidance on AE reporting procedure

Please refer to the Guideline for Good Clinical Practice 2014 for further details of AE reporting.

National legal framework in place

Yes

Applicable national legal framework/ Reference

Regulation On Medical Device Clinical Trials 2014

Additional Information

ad Annual Safety Report: The sponsor shall send a list of all serious adverse device effects observed, containing also information on safety of the subjects, to the ethics committee and the Agency, once every year. When the Agency may so deem necessary or in investigations with short periods, the Agency may also request the report earlier (Regulation On Medical Device Clinical Trials 2014).

End of Trial

End of trial Declaration mandatory

Yes

Responsible for End of trial Declaration

Sponsor
Legal representative domiciled in the respective country

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

–

Early/premature Termination - Declaration timespan (max nr days)

15

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form available

Yes

Standard Declaration form

A standard notification form and cover letter sample are posted on the Ministry’s website.

National legal framework in place

Yes

Applicable national legal framework/ Reference

Regulation On Medical Device Clinical Trials 2014

Additional Information

If the clinical trial was terminated early, its grounds will be stated and an information letter regarding the measures for maintenance of the treatment of the volunteers enrolled into the study will be attached.
In cases where early termination was due to safety reasons, the Agency shall inform the situation to the European Union Commission through the agency of the Ministry of Economy or electronically.

Additional Information & Specifics	**Additional Information** (1) Documents provided by the Ministry are in Turkish. No official English translation is available. Unofficial English translations could be provided by Turkish Clinical Research Infrastructure Network (TUCRIN - tucrin.deu.edu.tr) upon request. (2) An ethics committee is defined as 'a body established with the approval of the Agency to protect the rights, safety and wellbeing of human subjects by, among other things, expressing their scientific and ethical opinion on the methods and documents to be used to inform trial subjects and obtain their informed consent' (Regulation on Clinical Trials of Medicinal and Biological Products 2014). Clinical Trial Ethics Committees whose structure, operating principles and procedures have been set out in the Regulation on Clinical Trials of Medicinal and Biological Products and who have taken approval from the Agency shall evaluate all the medical device clinical investigations that are subject to the provisions of the Regulation On Medical Device Clinical Trials. No separate ethics committee shall be constituted to evaluate the medical device clinical investigations. In addition to the relevant provisions in the Regulation on Clinical Trials of Medicinal and Biological Products, the specialized persons or consultants in the relevant branch or in side branches from whom written opinion is taken by ethics committees may not be elected from amongst the persons who take part in the investigated research. A standard operating procedure for ECs is available (Standard Operating Procedure for Clinical Trials and Bioavailability-Bioequivalence Studies 2014).

Study specific Requirements

Sponsor	**Sponsor - Definition available in national law** Yes **Sponsor - Definition (pursuant to national law)** Sponsor is defined as 'an individual, institution or organization who takes responsibility for the initiation, conduct and/or funding of a clinical trial' (Regulation On Medical Device Clinical Trials 2014). **Sponsorship mandatory** Yes **Sponsorship mandatory - Additional information** Legal representative based in Turkey is mandatory where Sponsor is located outside the country. **Co-Sponsor - Definition available in national law** No
Study Participants - Informed Consent (IC)	**IC is regulated by law** Yes

Informed Consent - Definition/ Requirements

Informed consent form is defined as 'a documented proof of consent, given based on detailed and comprehensible information about the study'.

The person who volunteers to participate into the research or his legal representative shall, before commencement of the investigation, be given information on the purpose, methodology of the investigation, the expected benefits, foreseeable risks, difficulties, aspects that are not appropriate in light of the health and personal characteristics of the person, the conditions at which the investigation will be conducted, continued, and the fact that the person has the right to withdraw from the investigation at any stage he may so desire, sufficiently, and comprehensibly, by a principal investigator from the investigation team or an investigator who is a medical doctor or dentist, who is well-informed on the subject of the investigation.
The consent of the volunteer, which the volunteer has given at his own free will in order to be included into the research, which is not dependent on provision of a benefit, will be taken and this fact shall be documented with the informed consent form.

The volunteer can leave the research at any time he way wish at his own consent with or without showing grounds, and he will not lose his rights at the time of subsequent medical follow up and treatment.

Additional Information

Specific requirements for obtaining informed consent apply to vulnerable population (minors, incapacitated persons, unconscious persons, etc).

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Yes
Special provisions apply

Specific provision

If a child is capable of expressing assent, written consent of the child's parents, or custodian, where applicable, must be also obtained, in addition to the child's assent.
In cases where the research directly interests children or it is a clinical situation that can be investigated only on children or in cases where it is compulsory to prove the applicability of data that have been obtained as a result of researches conducted on adult persons also in respect of children, if the research does not pose a foreseeable risk for the health of the volunteer and if there is a general medical opinion to the effect that the research will produce a direct benefit on volunteers, permission may be granted for a research to be conducted on children within the framework of the principles specified below:
a) There must be a general medical opinion to the effect that the clinical research does not involve a known risk on children.
b) If the child has the power to disclose his own consent, in addition to his own consent, also the written consent of his guardians or parents shall be taken.
c) If the child refuses to participate in the research or if the child wishes to withdraw from the research at any stage of the research, the child will be taken out of the research.
d) If the child has the capacity to make an evaluation regarding the information provided to him and form an opinion on this subject, all the information related to the research shall be explained to the child in an appropriate manner.
e) The ethics committee shall be given information regarding clinical, psychological and social problems in connection with the investigation by a pediatrician and the protocol shall be evaluated from that stance.
f) In all kinds of clinical trials that will be conducted on children, ethics committee shall not grant approval for such trial unless there is place an affirmative opinion of a pediatrician for such research to be conducted on children. In case it is deemed necessary for these studies, opinion shall be taken from a physician or dentist who has completed his doctorate or specialization degree in the branch related to the subject of the research and the decision as to whether permission will be granted or not for such research shall be made according to such opinion.
f) For clinical trials that will be conducted on children, no persuasive incentives or financial offers may be made, except reimbursement of compulsory expenses that will arise as a result of children's participation into the research.

Legal framework/Reference (Minors/Children)

Regulation On Medical Device Clinical Trials 2014
A detailed guideline is available (Guidance on Ethical Approaches for Clinical Trials Conducted with A Pediatric Population 2013).

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Specific provisions

If the subject of the trial directly concerns incapacitated persons or if it is clinical case that can be investigated only on incapacitated persons or in cases where the existing treatment options related to the disease of the incapacitated person have been entirely consumed, if it does not involve a foreseeable risk for the health of the incapacitated person, and if there is a general medical opinion to the effect that the research shall bring a direct benefit for the incapacitated persons, permission maybe granted for a research to be conducted on incapacitated persons within the principles specified below:
a) There must be a general medical opinion to the effect that the clinical trial does not involve any known risk on incapacitated persons.
b) If such incapacitated person has the capacity to give his own consent, the written consent of the his own and the consent of his guardian shall be taken.
c) If the incapacitated person has the capacity to evaluate the information given to him and form an opinion in this respect, and if refuses to participate in the research or if they wish to withdraw from the research at any stage of the research they will be promptly taken out of the research.
d) The ethics committee shall be given information regarding clinical, ethical, psychological and social problems in connection with the investigation by a physician specialised in the relevant branch and a psychiatrist, and the protocol shall be evaluated from that stance.
d) For the clinical trials that will be conducted on incapacitated persons, no persuasive incentives or financial offers may be made, except reimbursement of compulsory expenses that will arise as a result of their participation into the research.

Legal framework / Reference (Incapacitated persons)

Regulation On Medical Device Clinical Trials 2014

Emergency situations - Studies allowed

Yes
Special provisions apply

Specific provisions

If the subject of the trial directly concerns unconscious persons or if it is clinical case that can be investigated only on unconscious persons or in cases where the existing treatment options related to the disease of the unconscious person have been entirely consumed, if it does not involve a foreseeable risk for the health of the unconscious person, and if there is a general medical opinion to the effect that the research shall bring a direct benefit for the unconscious persons, permission maybe granted for a research to be conducted on unconscious persons within the principles specified below:
a) There must be a general medical opinion to the effect that the clinical trial does not involve any known risk on unconscious persons.
b) Written consent shall be taken from the legal representatives of such unconscious persons, if any, and if there is no legal representative, his relatives,
c) If the unconscious persons regain the capacity to evaluate the information given to them and form an opinion in this respect, and if they refuse to participate in the research or if they wish to withdraw from the research at any stage of the research they will be promptly taken out of the research.
d) The ethics committee shall be given information regarding clinical, ethical, psychological and social problems in connection with the investigation by a physician specialised in the branch related to the subject of the research, and the protocol shall be evaluated from that stance,
e) For the clinical trials that will be conducted on unconscious persons, no persuasive incentives or financial offers may be made, except reimbursement of compulsory expenses that will arise as a result of their participation into the research.

Emergency situation without prior consent of patient or proxy - Studies allowed

Yes
Special provisions apply

Conditions allowing trial participation in emergency setting without prior consent

In case the written consents cannot be taken since the legal representatives or relatives of the unconscious persons being inaccessible, the unconscious persons may be included into the research under the responsibility of the principal investigator or an investigator who is a physician, in case of presence of the conditions listed below along with the provisions of the first paragraph:
a) The ethics committee must have evaluated in prior whether or not the proposed research protocol or other documents cover the ethical matters under such research sufficiently.
b) If there is a general medical opinion to the effect that the research will bring direct benefit for the unconscious persons
in cases, such as cardiac arrest, head trauma, central nervous system infections, bleeding in the brain, where the physician must promptly intervene and where the existing treatment alternatives have been entirely consumed.

Legal framework / Reference (Emergency Situation)

Regulation On Medical Device Clinical Trials 2014

Pregnant or breastfeeding women - Studies allowed

Yes
Special provisions apply

Specific provisions

If the subject of the trial directly concerns pregnant postpartum or breastfeeding women or if it is clinical case that can be investigated only on pregnant, postpartum or breastfeeding women, if it does not involve a foreseeable risk for the health of the volunteer or the fetus or the baby, and if there is a general medical opinion to the effect that the research shall bring a direct benefit for the volunteers, permission maybe granted for a research to be conducted on pregnant, postpartum and breastfeeding women within the principles specified below:
a) There must be a general medical opinion to the effect that the clinical trial does not involve any known risk on the pregnant, postpartum and breastfeeding women and the fetus or the baby.
b) The written consent of the pregnant, postpartum and breastfeeding women shall be taken.
c) If the pregnant, postpartum and breastfeeding women refuse to participate in the research or if they wish to withdraw from the research at any stage of the research, they will be taken out of the research.
d) The ethics committee shall be given information regarding clinical, ethical, psychological and social problems in connection with the investigation by a physician specialised in the relevant branch particularly in respect of the fetus or baby health, and the protocol shall be evaluated from that stance.
e) For the clinical trials that will be conducted on pregnant, postpartum and breastfeeding women, no persuasive incentives or financial offers may be made, except reimbursement of compulsory expenses that will arise as a result of their participation into the research.

Legal framework / Reference (Pregnant or breastfeeding women)

Regulation On Medical Device Clinical Trials 2014

Study Participants - Compensation & Reimbursement

Reimbursement for study participants

–

Compensation is limited to/provided for

Expenses arising from study participation (e.g. Travel)

Additional Information

For clinical trials that will be conducted on children, no persuasive incentives or financial offers may be made, except reimbursement of compulsory expenses that will arise as a result of children’s participation into the research.

Data Protection	**Notification to DP Authority/ Ombudsmann is mandatory** No **Approval/ authorisation required** No **Specific notification timelines before operations start** – **Language of notification** – **Notification format** – **Additional Information** Confidentiality: Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a volunteer's identity. The confidentiality of records that could identify volunteers should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements. The monitors, auditors, the Ethics committee, Turkey Pharmaceuticals and Medical Device Agency and the other relevant health authorities will have direct access to the original medical records of the volunteer, but such information will be kept confidential. Pursuant to the applicable regulation requirements, the records directly identifying the volunteer will be kept confidential, they will not publicly disclosed and the identity of the volunteer will be still kept confidential even if results of the trial are published (Guideline for Good Clinical Practice 2014). Medical device clinical trials including observational medical device studies shall be registered into a public database with due regard for the rules of privacy of personal data (Regulation On Medical Device Clinical Trials 2014). **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** –
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** – **Responsible for covering insurance** Sponsor **Additional Information** For clinical investigations that are conducted with medical devices bearing the CE mark, in line with the purpose of use indicated by its manufacturer, the condition for insurance, aimed at securing the volunteers against losses or damages that may arise in connection with the clinical investigation, shall not be sought, with the condition that the ethics committee finds it appropriate based on benefit-risk ratio, however, it is obligatory to arrange insurance for the volunteers in all other medical device clinical investigations (Regulation On Medical Device Clinical Trials 2014). A comprehensive guideline is available (Guidance on Insurance Coverage for Clinical Trials 2013).
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Optional

Audit by sponsor

Optional

Standard Operating Procedures (SOPs)

Optional

National legislation

Investigations on Medical Devices

Applicable national regulations

National Act on Medical Devices
Other

Act on Medical Devices (or comparable national legal framework)

Regulation On Medical Device Clinical Trials, No. 29111 of the Official Gazette, September 6, 2014 (available in Turkish only).
This Regulation is issued based on Supplemental Article 10 of Fundamental Law #3359 dated 07.05.1987 on Health Services and Articles 27 and 40 of Decree Law #663 on the Organization and Mandate of the Ministry of Health and Its Subordinate Agencies. Retrospective studies and performance assessment studies involving use of in vitro medical diagnosis devices are outside the scope of this Regulation.

Additional Information

Please refer to the Guideline for Good Clinical Practice (2014) for general principles regarding clinical trials. Guidelines on other relevant topics are also provided by the Ministry.

An overview on the current legislation related to the conduct of clinical trials in Turkey has been recently published and is publicly available:
Ilbars H. Clinical Trials in Turkey. Turk J Haematol 2013;30:111–114

Definition

MD/MD Investigation

MD - Definition

IMD is defined as 'any device that has been manufactured for use by a qualified medical practitioner or a person authorized to conduct clinical investigations in an adequate human clinical environment, in order to evaluate the performance of the device under normal conditions of use or any undesired side effect under normal conditions of use and to evaluate whether such effect constitutes acceptable risk when weighed against the intended performance of the medical device' (Regulation On Medical Device Clinical Trials 2014).

Investigation of MD - Definition

• Clinical trial is defined as 'the systematic researches or studies conducted on volunteers in order to evaluate the safety, efficacy or performance of the medical device, at one or more than one centre'

• Observational medical device study is defined as 'a study in which device or devices bearing “CE” marking in compliance with the Medical Device Regulations are used spontaneously in line with the purpose of use specified by the manufacturer, and the clinical safety or performance data in relation with the medical device are gathered' (Regulation On Medical Device Clinical Trials 2014).