MEDICAL DEVICE CLINICAL INVESTIGATIONS AND PERFORMANCE EVALUATION STUDIES IN TURKEY
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INTRODUCTION

Medical device investigations can be defined as systematical research or studies carried out on the volunteers to evaluate the safety and/or performance of the medical device in one or more than one center. Whereas the performance evaluation studies realized with in-vitro medical diagnostic devices that are described in the Medical Diagnostic Devices Regulations express the inspections related to the device designed for validating the performance statements of these devices under the expected usage conditions. The rules that the investigations are required to obey in the process of finding an answer to resolution of a certain problem by using scientific methods, as in the other researching types are defined for the medical devices investigations and performance evaluation made with in-vitro medical diagnostic devices, many national and international regulations have been changed or established making the research and have the research studies that are carried out with the similar study discipline. When reviewed from the point of view of legislation compliance, it shall be easily seen that the valid legal legislation in our country for the medical device clinic research studies and performance evaluation studies is in parallel with the legislation in the European Union countries, application and approval processes and documents demanded in this process show similarity with the processes in these countries.

MEDICAL DEVICE CLINIC INVESTIGATIONS IN TURKEY

Even though regulative matters are included in the Turkish Criminal Law, Health Services Fundamental Law and Medical Deontology Guideline related to the clinic investigations in our Country, these arrangements are the general content arrangements and matters related to the clinical investigations to be made with medical devices are defined in detail in the Medical Device Regulations prepared and issued in line with the council directive 93/42/EEC on Medical Devices. As is known, in the Medical Device Regulations minimum basic requirements that the medical devices and their accessories have to bear are described and the medical devices and accessories related to these devices that shall be offered to the market according to the related regulations must reach to the performance foreseen by the manufacturer and produced in accordance with the health and safety of the patients, implementers and third persons. However this situation can only be shown by a clinical evaluation to be made with the clinical data to be obtained from medical device. According to the medical device regulations, the clinical data used in clinic evaluation can only obtained from the clinic investigations related to the subject matter device or from clinic investigations included in scientific literature related to a similar device equality of which can be shown to this device or from other studies, or from the safety and/or performance information obtained from the reports issued and/or unissued reports related to other clinic experiences concerning with the subject matter device or with a device equality of which can be shown to this device (1).

Because clinical data are possible to be clinic originated investigations, for the purpose of protecting the rights and safety of the people participating in the study, ensuring the security of the data obtained from clinic investigations and defining the responsibilities of the parties take place in the study, as national arrangement in our country; Medical Device Regulations, Implantable Active Medical Devices Regulations, as in the international area, Convention about Convention for the Protection of Human Rights and Dignity of the Human Being with Respect to the Application of Biology and Medicine except article 20 to which our country is a party and attached annotation, Convention about Human Rights and Biomedicine, Helsinki Declaration and Clinic Research Guide Documents prepared by the European Union Commission have been issued.

For the medical device clinical investigations related to the good clinic practices the standard named “ISO 14155:2011 Medical Device Clinic Investigations Made on Human Being – Good Clinic Practice” issued by the International Standards Organization has also gained acceptance by our country and meticulously put into practice. In this standard, in brief, the cases related to duties and responsibilities of the researcher and supporter, ethical behavior principles, applying ethical rules and study presentation methods, those required to be informed, required approvals, criteria about including locals in studies, obtaining informed volunteer form, features of research protocol and research device, safety of the data obtained, audit of the research, starting and terminating criteria of the research, reporting of the research, observer and his/her responsibilities, cases that are required to be informed to the competent authority, protecting the rights of volunteers and ensuring their safety are included.

PERFORMANCE EVALUATION STUDIES PERFORMED IN TURKEY WITH IN-VITRO MEDICAL DIAGNOSTIC DEVICES

As it is known, according to the In-Vitro Medical Diagnostic Devices Regulation, to show that the in vitro diagnostic medical devices work in a way as declared, the manufacturer is required to provide evidence in his/her technical documents. (2) However, such evidences can be shown by data currently held by the manufacturer, scientific literature and data obtained from the performance evaluation studies performed in accordance with the designed use in clinic or another proper environment.

These studies are carried out under the responsibility of a coordinator, many requirements similar to the rules to be obeyed when the clinic research is done are also valid for these studies and there are similar ethical committee and ministry study notice processes.

As it is known, the performance evaluation studies performed by using in-vitro medical diagnostic devices are the studies made by the manufacturers of the device and these studies include the studies in the process before affixing “CE” mark on the product. Within this scope, these performance studies realized by the manufacturer are carried out according to the TS EN 13612 In Vitro Medical Diagnostic Devices – Performance Evaluation studies standard and this standard scientifically explains to the manufacturer how to undertake a reasonable responsibility of performance evaluation study (3). Again, availability of making the performance evaluation studies; first of all it depends on the positive decision of medical ethical committee on line and developments insured both methods against the diseases in the human beings. However, the important thing here is to ensure the welfare and health of those participating in the research within the advantage/risk frame (4). In this line, although the related law and regulations lay variously arranged on the part that matters to medical device and the research have been made, also they impose observation and auditing obligations to the competent authorities from the point of view of the volunteer safety of these studies. Within this scope, beginning from 2007, our Institution started to record the medical device investigations, study applications made to our institution related to years 2012-2013 are given in Table: 1.

The health sector in Turkey grows in line with the factors such as increase of accessibility and increased purchasing power as a result of the positive economic developments and in the current years the supportive developments realized related to the sector. (5) Our country that aims to be one of the biggest 10 economies of the world, to increase the level of its export to dollars 500 billion, per capita income level to Dollar 25 thousand in 2023, within the scope of Vision 2023, aims in the health area, to provide everybody living in the borders of the country, with high-quality, economic health services having adaptability talent to the innovations in the biology areas, equipped with contemporary technology, to develop and produce high technology treatment systems and the materials and devices used for this purpose; by having a medicine industry that also have research capacity along with the production of the manufactured medicine, to be an expert in the medicine and medical area in global conception. (6,7) Within this scope, medical device production in our country is included through various funds ensured by the Organizations such as Scientific and Technological Research Council of Turkey. According to the 2012 data, when 75 million of country population(8) and increased level of welfare are taken into consideration, it is considered that the health sector that reached to a magnitude of Dollar 76 billion shall continue its growth(9). In accordance with the growth of the health sector and the created 2023 Vision, with the increase of the incites towards the production of the new devices in the health sector, it is foreseen that the number of clinic investigations, which are currently in limited number, shall increase. Within this context, many trainings have been planned by our Organization towards either to the sector or to the researchers, and by means of these trainings it is aimed ensuring performing the clinic investigations in accordance with the ethical considerations and the legal legislation.

Table 1: 2012-2013, Medical Clinic Investigation applications made to our Organization in Turkey and their results.

References:
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