Regulations on Good Clinical Practice for Medical Devices

FAQs

1. **Can a medical device clinical trial be conducted after obtaining central competent authority approval only?**
   a. According to Article 4 of "The Regulations[1]", the sponsor shall draft a clinical investigation plan and submit it to the IRB[2] and the central competent authority for approval before conducting the clinical trial.
   b. According to Paragraph 1, Article 37 of "The Act[3]", clinical trial institutions or trial sponsors shall file an application with the central competent authority and obtain its approval before initiating any clinical trial. However, this shall not apply to those that do not involve significant risks as announced by the central competent authority.
   c. In summary, clinical trials that do not involve significant risks can be conducted after obtaining IRB approval only. While trials that do not fall under this category shall be conducted after obtaining both IRB and TFDA[4] approvals.

2. **Is a medical device firm permitted to submit a medical device clinical trial plan to the TFDA and the IRB simultaneously?**
   Parallel submissions are allowed in medical device clinical trial plan submissions (submitting the same plan to the TFDA and the IRB simultaneously), as one should be noticed that the final conducted version of the clinical investigation plan and the informed consent form shall be approved by the IRB and TFDA; moreover, the contents, versions and serial numbers of the approved documents shall be consistent.

3. **What supporting documents shall be submitted along with amendments or new applications of medical device clinical trials?**
   a. In the case of a new application, please refer to Article 58 of "The Regulations".
   b. In the case of an amendment, please refer to Article 61 of "The Regulations".
   c. Applicants may download the application form and other related forms from the TFDA website.

4. **What contents shall be featured in the informed consent form and the clinical investigation plan?**
   a. For the informed consent form, please refer to Article 54 of "The Regulations".
   b. For the clinical investigation plan, please refer to Article 59 of "The Regulations".

5. What shall investigational medical devices be labeled?

All investigational medical devices shall be labeled as "for clinical trial use only".

6. Please specify "cases of emergencies" stated in Paragraph 2, Article 37 of "The Act".

According to Article 51 of "The Regulations", emergencies are situations where all of the following situations are fulfilled, and where the clinical investigation plan has specified that the clinical trial may be conducted prior to obtaining informed consent form from the subject, or the subject's legal representative, assistant, or guardian.

a. The subject in a life-threatening emergency situation.
b. No sufficient clinical benefits are anticipated from the currently available treatment.
c. There is a fair possibility that the life-threatening risk to subject can be avoided if the investigational medical device is used.
d. Anticipated risks are outweighed by the potential benefits of applying the investigational medical device.
e. The subject is inability to communicate with, and their legal representative, assistant, or guardian cannot immediately be contacted for consent.

7. Are retrospective studies conducted by reviewing CT[5] images classified as cases of clinical trials that do not involve significant risks?

a. Considering the variety of these studies, virtual scenarios are made in advance for comprehensive evaluation.
   i. Scenario 1 (clinical trials that do not involve significant risks):
   Studies involving investigational medical devices (domestic listed CT), which perform researches within the listed approved scope of work on subjects.
   ii. Scenario 2 (clinical trials that do not involve significant risks):
   Studies utilizing domestic listed CT to (legally) acquire images of subjects, then analyze the information by investigational medical devices. While the diagnosis or treatment of subjects shall not base on the result of said investigation.
   iii. Scenario 3 (clinical trials that do not fall under this category):
   Studies claim to utilize self-developed CT imaging system (investigational medical device) to collect subjects' information. Considering the operating principle of these medical devices involves ionizing radiation, these trials shall be conducted after obtaining both IRB and TFDA approvals.

iv. Scenario 4 (clinical trials that do not fall under this category):
Studies (legally) obtaining their CT information through hospitals, National Health Insurance Administration or open data platforms, then proceed to analyze the information by investigational medical devices. Due to the absence of subjects (clinical data used only), these studies belong to researches in clinical assessment rather than medical device clinical trials.

b. If an applicant is uncertain about whether a case belongs to the announced "cases that do not involve significant risks" or not, they may refer to "Information on Applying for Medical Device Clinical Trials", then proceed to apply for an inquiry about the classification of the risk of said medical device clinical trial, along with the application form, related documents and application fee (NT$[6] 20,000).

***Abbreviations:**

1. **The Regulations**: Regulations on Good Clinical Practice for Medical Devices.
2. **The Act**: Medical Devices Act.
3. **IRB**: Institutional Review Board.
4. **TFDA**: Taiwan Food and Drug Administration.
5. **CT**: Computed Tomography.
6. **NT$**: New Taiwan Dollar.