# Information for Medical Device Clinical Trials

# -Frequently Asked Questions

❑ Clinical Trial Questions and Answers

Q: What is the procedure for applying for a medical device clinical trial with the TFDA?

A: The TFDA has established the Information on Applying for Medical Device Clinical Trials. For the relevant application procedures and forms, you may refer to that document (web link attached).

❑ Priority Review Program for Medical Device Registration

Q: I have heard that the TFDA has formulated a priority review channel available for medical devices to be registered. How do I know if my case meets the criteria for priority review?

A: You may make an inquiry by sending a letter to the TFDA and applying for determination regarding qualification for priority review. For the application procedure and documents to be enclosed, you may refer to the Priority Review Program for Medical Device Registration (web link attached) and complete the Self-Assessment Form for Priority Review for Medical Device Registration (web link attached).

❑ In-vitro Diagnostic Medical Devices

Q: What are the differences between the TFDA's requirements for registration of IVD products and for general medical devices?

A: In accordance with the properties of IVD products, the TFDA

has additionally formulated the Information on Registration of In-vitro Diagnostic Medical Devices as the supplementary requirements for registration review. You may refer to the information (web link attached).