Frequently Asked Questions on
Application for the Certificate for Clinical Trial/Medicinal Test

General principles	
Q.1	**What is "clinical trial"?**
A.1	There is no legal definition for clinical trial in the Pharmacy and Poisons Ordinance (Cap. 138). However, the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) has developed the Good Clinical Practice (GCP) guideline, which is adopted by regulatory authorities of the European Union, Japan and the United States as a unified standard to facilitate the mutual acceptance of clinical trial data. In this connection, the Pharmacy and Poisons Board of Hong Kong adopted the definition of "clinical trial" provided by the ICH GCP guideline as follows :-*"Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous."*
Q.2	**Why do I need to apply for the Certificate for Clinical Trial/Medicinal Test (the certificate) before conducting a clinical trial on human? Is it an offence conducting clinical trial of a pharmaceutical product without the certificate?**
A.2	Clinical trials are commonly conducted to test potential medicines in human subjects to see whether they should be approved for wider use in the general population. During the research and development stage, potential medicines are studied in laboratory first to determine their potential toxicity and effects. Subsequently, those with acceptable safety profile and promising effects will then be thoroughly tested on human subjects in clinical trials. As some risks may be inherent in the trial medicine, every endeavour should be made to control the risks to trial subjects. Internationally, most regulatory authorities require companies or investigators conducting clinical trial to either register or obtain a clinical trial certificate before the initiation of the trial. In Hong Kong, Reg.36B of the Pharmacy and Poisons Regulations (Cap. 138A) stipulates that : *A person must not conduct a clinical trial on human beings / medicinal test on animals, or cause or permit such a trial/ test to be conducted except in accordance with a clinical trial certificate/ medicinal test certificate issued to the person.* ***Otherwise, he/she commits an offence and is liable to a fine at level 2*** *(currently is HK$5,000).*

	For the purpose of conducting a clinical trial on human beings or a medicinal test on animals application shall be made in writing to the Committee… *The Committee may, subject to any conditions it thinks fit to impose, issue a clinical trial certificate or medicinal test certificate in the specified form and the certificate is valid for a period not exceeding* 5 *years…* The details of provision can be found at www.elegislation.gov.hk/
Q.3	**What is GCP?**
A.3	Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with GCP assures that the rights, safety and well-being of trial subjects are protected, the trials are conducted in accordance with the principles of the Declaration of Helsinki, and the clinical trial data are credible. The Pharmacy and Poisons Board of HK generally adopt ICH GCP guideline which was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization. Accordingly, these regulatory authorities will require the clinical trials to be in compliance with the ICH GCP guideline in order to accept the study data in supporting the application for registration of the study medicine.
Q.4	**Is off-label use of a registered medicine considered as a clinical trial?**
A.4	When a registered medicine is used in patient treatment not in accordance with the particulars (e.g. indication, dosage, etc) in the label and/or package insert that are approved by the regulatory authority for the medicine, such off-label use of medicine by a physician is generally not regarded as a clinical trial. However, off-label use of a registered medicine for investigational purposes (e.g. exploring a new indication), which may involve trial objective, design, methodology, and statistical consideration, is usually regarded as a clinical trial.
Q.5	**Do I need to apply for a Certificate for Clinical Trial/Medicinal Test before conducting an observational study?**
A.5	Observational studies are those in which the investigator observes rather than influences exposure and disease among participants. They include various study designs such as case series, cross-sectional studies, case control studies, and retrospective cohort studies. Observational studies are not clinical trials and therefore application for the Certificate for Clinical Trial/Medicinal Test is not required.

Q.6	**Should I apply for a Certificate for Clinical Trial/Medicinal Test when conducting an animal study?**
A.6	Application for the Certificate for Clinical Trial/Medicinal Test is required for conducting clinical trial on veterinary medicine. You may refer to reputable international guidelines such as the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products Good Clinical Practice (VICH GCP) for more information regarding clinical trial on veterinary medicine. On the other hand, please note that pre-clinical animal studies fall under the scope of the Animals (Control of Experiments) Ordinance (Cap. 340). The details of provision can be found at www.elegislation.gov.hk/

Application procedures	
Q.7	**How to apply for a Certificate for Clinical Trial/Medicinal Test?**
A.7	To apply for the certificate, applicant can submit the required documents via the Electronic Clinical Trial System (e-CTS) of Drug Office of the Department of Health at https://www.drugoffice.gov.hk/CTCInterWeb/jsp/. Relevant payments can be paid via the e-CTS with credit card/PPS online payment services, or in person by cash or cheque along with the notification of payment at the following address: **Address:** Drug Evaluation and Import/Export Control Division Drug Office, Department of Health Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East, Kwun Tong, Kowloon **Hours of Shroff Office:** **Mondays** **(except public holidays):** 9:00am to 1:00pm; and 2:00pm to 5:45pm **Tuesdays to Fridays** **(except public holidays):** 9:00am to 1:00pm; and 2:00pm to 5:30pm **For Enquiries:** **Telephone No.:** (852) 3974 4180 **Fax No.:** (852) 2803 4962

Q.8	**What is the application fee of a Certificate for Clinical Trial/Medicinal Test?**
A.8	Currently, the application fee of the certificate is HK$1,420. When the application is approved, the applicant is required to pay certificate fee of HK$1,420 to obtain the certificate.
Q.9	**What should I do if I disagree with the decision of the Pharmacy and Poisons (Registration of Pharmaceutical Products & Substances: Certification of Clinical Trial/ Medicinal Test) on the application of the Certificate for Clinical Trial/Medicinal Test?**
A.9	Applicant who aggrieves the Committee's decision in relation to the application for the Certificate for Clinical Trial/Medicinal Test may appeal to the Pharmacy and Poisons Appeal Tribunal.
Q.10	**How can I get more information regarding application for a Certificate for Clinical Trial/Medicinal Test?**
A.10	More information can be found in the following DH Drug Office website: https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_forms.html
Q.11	**What should I submit when applying for a Certificate for Clinical Trial/Medicinal Test?**
A.11	For details regarding the documents to be submitted, please refer to Section 5 of the "Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test": https://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Guidance_Notes_en_Version.pdf?v=xlprj3. Please note that it is NOT required to submit the following documents to Drug Office: (a) Patient materials (e.g. Diary Cards, Patient Alert Cards etc.) (b) Data Collection Forms (c) Case Report Forms (d) Clinical Trial Advertisements

Definition or Glossary	
Q.12	**What is an “investigational product”?**
A.12	An “investigational product” is a medicine or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
Q.13	**What is a “commercially sponsored” clinical trial?**
A.13	In general, a clinical trial initiated, managed, and/or financed by a pharmaceutical company is regarded as commercially sponsored. On the other hand, clinical trials sponsored by public bodies or statutory bodies are generally not considered commercially sponsored.
Q.14	**What is a “protocol”?**
A.14	A protocol is a document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually gives the background and rationale of the trial but these could also be provided in other protocol referenced documents.
Q.15	**What is an “investigator’s brochure”?**
A.15	An “investigator's brochure” is a compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.
Q.16	**What is an “informed consent”?**
A.16	An “informed consent” is a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.
Q.17	**What is an “ethics committee”?**
A.17	An ethics committee is an independent body constituted of medical professionals and non-medical members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.