Guidance for Industry – Implementing ICH Guideline for Good Clinical Practice E6(R3) in Hong Kong

Version June 2026

Pharmacy and Poisons Board of Hong Kong

Preface

The Pharmacy and Poisons Board of Hong Kong has implemented, with effect from 30 June 2026, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice E6(R3) (ICH Guideline for GCP) — an international standard for the planning, initiating, performing, recording, oversight, evaluation, analysis and reporting of clinical trials involving human participants.

The purpose of this document is to supplement the ICH Guideline for GCP by providing clear local regulatory requirements for clinical trials conducted in the Hong Kong. This supplementary guidance aims to clarify specific requirements not strictly defined in ICH Guideline for GCP, or where the authority to set such requirements is delegated to local regulatory bodies, by consolidating and referencing existing local guidelines and forms. This ensures that all clinical trials in Hong Kong comply with local laws, regulations, and ethical standards, and safeguard the rights, safety, and well-being of trial participants.

This guidance applies to all interventional clinical trials of pharmaceutical products conducted in Hong Kong that require a Certificate for Clinical Trial (CCT) under the Pharmacy and Poisons Regulations (Cap. 138A). This guidance must be read in conjunction with ICH Guideline for GCP. The provisions herein serve to elaborate on or supplement the relevant sections of ICH Guideline for GCP by providing specific local context and requirements. In the event of any inconsistency between this guidance and ICH Guideline for GCP, this guidance shall prevail for trials conducted in Hong Kong.

The Pharmacy and Poisons Board of Hong Kong reserves the right to update this guidance in response to industry feedback and emerging areas requiring further regulatory clarification.

Contents

1. Qualification of Principal Investigator

[Relevant section(s) of ICH E6(R3): Principle 1.5, Annex 1- 2.1 and 2.7]

1.1 The Principal Investigator (PI) must be a registered medical practitioner in Hong Kong and should have the overall responsibility for trial-related medical care and decisions.

1.2 The PI should be qualified by education, training and experience to assume responsibility for the proper conduct of the trial, and should provide a current Curriculum Vitae to demonstrate such qualifications.

1.3 The PI should have completed Good Clinical Practice (GCP) training within the past 3 years and may be requested to provide documentary evidence of such training.

2. Informed consent process

2.1 Requirements in obtaining informed consent

[Relevant section(s) of ICH E6(R3): Annex 1- 2.8.5]

2.1.1 The informed consent process should be conducted by the PI or other site staff delegated by the PI, who should be appropriately qualified, trained, and knowledgeable about the clinical trial. Documentation of delegation and training records should be maintained and available for inspection. Even when delegated, the PI retains ultimate responsibility for ensuring that informed consent is properly conducted and obtained.

2.2 Informed consent by vulnerable subjects

2.2.1 Minors

[Relevant section(s) of ICH E6(R3): Principle 2.1, Annex 1- 2.8.12]

2.2.1.1 A minor is a person under 18 years of age. Enrolment requires consent from the child's parent or legal guardian, supplemented by age-appropriate assent from the minor where feasible. Assent is a process of informing and seeking agreement from children or young people to participate in research. While children and young people typically lack the maturity to provide valid legal consent, they benefit from understanding the research process and having the opportunity to express their interests, questions, and concerns.

2.2.1.2 If, during a clinical trial, the minor reaches the legal age of majority, informed consent should be obtained from the now-adult participant for continued participation.

2.2.2 Mentally incapacitated persons

[Relevant section(s) of ICH E6(R3): Principle 2.1]

2.2.2.1 A mentally incapacitated person is incapable of giving consent if that person is incapable of understanding the general nature and effect of the treatment, for example, individuals with severe mental or neurological disorders. When capacity is lacking, valid consent should be obtained from a guardian appointed under the Mental Health Ordinance (Cap. 136) whose guardianship order confers the power to consent to treatment.

2.2.2.2 Clinical trials involving individuals with impaired decision-making capacity should be ethically justified and scientifically necessary. Key considerations include:

(a) the research is responsive to their health needs and priorities;
(b) the individual or population stands to benefit from resulting knowledge, practices, or interventions;
(c) the research cannot be feasibly or validly conducted in individuals with unimpaired capacity;
(d) the disorder or condition under study directly affects the population enrolled; and
(e) the potential benefits to the participant justify the foreseeable risks or burdens imposed.

2.3 Emergency or intensive care setting

[Relevant section(s) of ICH E6(R3): Principle 2.4, Annex 1- 2.8.8]

2.3.1 For emergency or intensive care research, investigators should obtain ethics approval for the model of consent that they will use or, alternatively, for a waiver of the requirement for informed consent. If it is not possible to obtain consent from the participant, then

investigators should seek consent from the participant's legally acceptable representative, taking into account any relevant jurisdictional restrictions. After the participant regains the capacity to make decisions about participation, the investigators should explain what ongoing participation involves and confirm if the participant is willing to continue the participation and explain the right to withdraw from the research without affecting the quality of care that the participant is receiving.

3. Conduct of clinical trials

3.1 Delegation of sponsor's responsibilities

[Relevant section(s) of ICH E6(R3): Annex 1- 3.6.6]

3.1.1 According to the ICH Guideline for GCP, the sponsor is responsible for the overall management and quality assurance of the clinical trial, including ensuring compliance with GCP. The sponsor may delegate or transfer trial-related tasks, duties, or functions to a qualified delegate, contract research organisation (CRO), or other third party through a signed sponsor delegation letter, clearly defining the scope of responsibilities. Provision of delegation letters may be requested to demonstrate accountability and facilitate inspection of compliance with GCP and applicable regulations.

3.1.2 If the sponsor is not the CCT holder, the CCT holder bears the ultimate responsibility for ensuring that all trial-related activities conducted locally are in compliance with GCP and applicable regulations. The sponsor should coordinate with the delegate(s) and maintain adequate oversight to ensure that delegated activities are performed appropriately in accordance with their obligations.

4. Regulatory reporting timeframes

[Relevant section(s) of ICH E6(R3): Annex 1 - 2.5-2.7, 2.13, 3.12, 3.13, 3.17]

4.1 The CCT holder is responsible for ensuring compliance with regulatory timelines for subsequent trial notifications. As evidence of timely notification to the local institutional review board/independent ethics committee (IRB/IEC), the PI must provide the IRB/IEC's reply letter to ensure continuous oversight of the trial. The notification requirements and reporting timelines for regulatory submission include:

Event	Notification timeline
Substantial amendments[1]	As soon as IRB/IEC approval/acknowledgement is available
Updates to the Investigator's Brochure or new safety information	As soon as possible (Submit IRB/IEC approval/acknowledgement in due course)
Serious breaches[2]	As soon as possible, but no later than 7 days
Urgent safety measures[3]	As soon as possible, but no later than 7 days
Progress reports [Refer to the "Notice" by Drug Office[4]]	Yearly
Serious unexpected adverse drug reactions – Fatal or life threatening[4]	As soon as possible, but no later than 7 calendar days after first knowledge by the sponsor, followed by a follow-up report as complete as possible within 8 additional calendar days
Serious unexpected adverse drug reactions – Non-fatal or non-life threatening[4]	As soon as possible, but no later than 15 calendar days after first knowledge by the sponsor
Suspension of trial	Within 15 calendar days (include reason and specify follow-up measures)
Resumption of suspended trial	
Premature termination of trial	
Final report [Refer to the "Notice" by Drug Office[4]]	Within 30 calendar days of the trial completion
Final clinical study report / summary results	Within 1 year from date of trial completion, unless otherwise agreed by Drug Office

[1] Substantial amendments to the trial refer to amendments which are likely to have a significant impact on:

- the safety, or physical or mental integrity of the trial participants, or
- the scientific value of the trial, or
- the conduct or management of the trial, or
- the quality and safety of any investigational product used in the trial.

[2] Serious breach is a breach of the protocol, the principles of GCP, or the regulations, during the clinical trial which is likely to affect to a significant degree the safety and rights of a trial participant or the reliability and robustness of the data generated in the clinical trial.

[3] Urgent safety measures refer to measures taken to protect the health and safety of the trial participants when an unexpected event occurred.

[4] "Notice" refers to Notice of requirement on reporting of local drug related safety report, progress report and final study report in clinical trial available at:
http://www.ppbhk.org.hk/eng/doc/guidelines_forms/Reporting_Requirement_en_Version.pdf

4.2 If the CCT holder is unable to comply with the above regulatory timelines, the CCT holder should notify the Drug Office in writing of the reason(s) for the delay and corrective and preventive actions implemented to prevent a recurrence.

5. Management of investigational product(s) (IP(s))

5.1 Import/export of IP(s)

[Relevant section(s) of ICH E6(R3): Annex 1- 3.15.3]

5.1.1 Under the Import and Export Ordinance (Cap.60), all imports and exports of pharmaceutical products and medicines must be covered by import and export licences issued by the Trade and Industry Department. For import/export licence applications involving clinical trials on human beings or medicinal tests on animals, the application must be supported by a valid certificate for clinical trial/medicinal test. If the applicant is not the holder of the certificate, the application must also be supported by authorisation from the relevant holder of certificate for clinical trial/medicinal test. For more information on the applications for import/export licences, please refer to "Guidance for Application for Import and Export Licences for Pharmaceutical Products and Medicines":
https://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Guidance_for_Application_for_IE_Licences_for_PP_and_medicines.pdf

5.2 Labelling requirements for IP(s)

[Relevant section(s) of ICH E6(R3): Principle 11.5, Annex 1 - 3.15.2]

5.2.1 IPs should be appropriately labelled in order to ensure subject safety and the reliability and robustness of data generated in clinical trials, and in order to allow for the distribution of those products to clinical trial sites.

5.2.2 A mock-up of the label is not mandatory for submission. The language of the information on the label should be in English. Multiple languages are allowed. A list of information which is to appear on the outer packaging and immediate packaging is set out below:

(a) name, address and telephone number of the main contact; this may be the sponsor, CRO or investigator;

(b) the name of the substance and its strength or potency, and in the case of blind clinical trials the name of the comparator or placebo;

(c) pharmaceutical form, route of administration, quantity of dosage units;

(d) the batch number;

(e) a clinical trial reference code;

(f) directions for use (reference may be made to a leaflet or other explanatory document intended for the subject or person administering the product);

(g) 'For clinical trial use only' or similar wording;

(h) the storage conditions;

(i) period of use (expiry date or re-test date as applicable); and

(j) "Keep out of reach of children", except when the product is for use in trials where the product is not taken home by subjects.

5.2.3 The address and telephone number of the main contact shall not be required to appear on the label if subjects have been given a leaflet or card which provides these details and have been instructed to keep this in their possession at all times.

5.2.4 For additional labelling requirements of advanced therapy product, please refer to "Guidance on Labelling Requirements of Product Code, Unique Donation Identifier and Unique Recipient Identifier for Advanced Therapy Products":
https://www.ppbhk.org.hk/eng/files/PPB_Guidance_Code_ATP_en.pdf

5.3 Proper procedure for disposal of IP(s)

[Relevant section(s) of ICH E6(R3): Annex 1- 3.15.3]

5.3.1 Waste containing expired or unserviceable medicine (including dangerous drugs) are classified as chemical waste under the Waste Disposal Ordinance (Cap. 354). The disposal of chemical waste is regulated under the Waste Disposal (Chemical Waste) (General) Regulation (Cap. 354C) which is enforced by the Environmental Protection Department (EPD). More information can be found at the EPD and Drug Office websites:

(a) Guide books on Chemical Waste Control by the EPD: https://www.epd.gov.hk/epd/english/environmentinhk/waste/guide_ref/guide_cwc.html

(b) For licensed pharmaceutical traders, please refer to "Guidance on Disposal of Unserviceable / Expired Medicines for Licensed Pharmaceutical Traders" by Drug Office: https://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/drugdisposalguidance_eng.pdf

6. Data management

6.1 Requirements on retention of records related to clinical trial

[Relevant section(s) of ICH E6(R3): Principle 9.5]

6.1.1 The investigator/institution and sponsor of the trial should retain the essential records (See ICH Guideline for GCP Appendix C) for a period of 5 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 5 years after the investigation is discontinued and Drug Office is notified. These minimum periods are subject to any longer requirements stipulated by local law or contractual agreement.

6.1.2 For clinical trials involving advanced therapy product (ATP), please refer to the following Guidance.

(a) "Guidance on Record Keeping for Medical Practitioners, Dentists and Institutions Providing Advanced Therapy Product Treatment": https://www.drugoffice.gov.hk/eps/do/en/doc/atp_guidance/DO_Guidance_Record_HCP_ATP-EN.pdf;

(b) "Guidance on Application of Certificate for Clinical Trial - Advanced Therapy Products": https://www.ppbhk.org.hk/eng/files/PPB_Guidance_CT_ATP_en.pdf; and

(c) "Guidance on Record Keeping for Licensed Manufacturers and Licensed Wholesale Dealers–Advanced Therapy Products":

https://www.ppbhk.org.hk/eng/files/PPB_Guidance_Record_Keeping_LM_WDL_ATP_en.pdf

6.2 Protection of personal data

[Relevant section(s) of ICH E6(R3): Principle 1.6]

6.2.1 In Hong Kong, personal data is governed by the Personal Data (Privacy) Ordinance (Cap. 486). Sponsor, investigators, IRBs/IECs, relevant government agencies and/or regulatory authorities and their respective designees (if applicable) must always ensure protection of personal data and confidentiality when handling trial data, safeguarding against unauthorised access or disclosure. The details of provision can be found at https://www.elegislation.gov.hk/hk/cap486!en?INDEX_CS=N.

7. Insurance/ Indemnification/ Compensation

[Relevant section(s) of ICH E6(R3): Annex 1- 3.14]

7.1 The sponsor or sponsor-investigator should assume responsibility for the medical treatment or the costs of treatment of trial participants in the event of trial-related injuries; and establish insurance, indemnity, or equivalent arrangements to compensate participants for trial-related injuries, with coverage adequate and proportionate to the nature and degree of the associated risks. Sponsors should additionally comply with any institutional policies or requirements established by participating institutions and their respective IRBs/IECs.

8. GCP Inspection

8.1 Type of trials subject to GCP inspection

[Relevant section(s) of ICH E6(R3): Annex 1 - 2.3.5]

8.1.1 For interventional clinical trials of IPs that are intended to be submitted to regulatory authorities to support marketing authorisation, the clinical trial is required to be conducted in full compliance with ICH Guideline for GCP. CCT holders should allow and facilitate GCP inspection to be conducted by inspectors of the Drug Office at all relevant premises related to the trial. Respective IRB/IEC of such trials may also be inspected to ensure compliance with ICH Guideline for GCP.

8.1.2 For interventional clinical trials of IPs that are declared not intended to be submitted to regulatory authorities, the conduct of the clinical trial should adhere to the principles as stipulated in ICH Guideline for GCP.