DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG EVALUATION AND PHARMACOVIGILANCE DIVISION

Notice of requirement on reporting of local drug related safety report, progress report and final study report in clinical trial

All certificate holders of clinical trial/medicinal test are required to report to this office the following:

1. All local drug-related safety reports i.e. reports on adverse drug reactions (ADRs).

(a) For adverse drug reactions that are both serious[1] and unexpected[2] as soon as possible. (The attached CIOMS form may be used for reporting, except for reporting of adverse events of COVID-19 vaccines under Government COVID-19 vaccination programme with vaccination date on or before 23 December 2023. Please refer to point 5 below.)

(i) Fatal or life-threatening unexpected ADRs should be reported as soon as possible but no later than 7 calendar days after first knowledge by the sponsor that a case qualifies, followed by as complete a report as possible within 8 additional calendar days. This report must include an assessment of the importance and implication of the findings, including relevant previous experience with the same or similar medicinal products.

(ii) Other serious, unexpected ADRs that are not fatal or life-threatening, it should be reported as soon as possible but no later than 15 calendar days after first knowledge by the sponsor that the case meets the minimum criteria for expedited reporting.

(b) For non-serious adverse reactions and serious adverse reactions that are expected, it should be reported in a brief summary at the conclusion of the trial.

2. Progress report on yearly basis and a final study report at the end of the study. Please refer to the table under point 3 regarding how to submit reports. For manual submission, the attached forms on p. 4 and 5 may be used for reporting. For submission via e-CTS, please fill in the forms on webpage directly under Amendment – Category 7.
3. Please refer to the table below regarding how to submit reports.

[1] A serious adverse event (experience) or reaction is any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also usually be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalisation; or development of drug dependency or drug abuse.

[2] An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational medicinal product).

Type of Report (as mentioned on page 1 of this notice)	**The Way that the Certificate of Clinical Trial/Medicinal Test was Issued**	**How to Submit the Report**
Type 1(a)	The Certificate was issued via manual application	Submit via email to: ct@dh.gov.hk
	The Certificate was issued via e-CTS	Submit via email to: ct@dh.gov.hk
Type 1(b) and Type 2	The Certificate was issued via manual application	Submit manually to: Drug Evaluation and Pharmacovigilance Division Drug Office, Department of Health Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street Kwun Tong, Kowloon Hong Kong Or Submit via email to: ct@dh.gov.hk
	The Certificate was issued via e-CTS	Submit via e-CTS at https://www.drugoffice.gov.hk/CTCInterWeb/jsp/

4. For any reportable ADR involved advanced therapy products, in addition to the requirement for reporting ADR of pharmaceutical products, the holders of clinical trial certificate should be referred to Section 6 of "Guidance for Pharmaceutical Industry – Adverse Drug Reaction Reporting Requirements" for consideration.

5. For serious and unexpected adverse event reports of COVID-19 vaccine (i.e. COVID-19 vaccine as a suspect drug or one of the suspect drugs) under Government COVID-19 vaccination programme with vaccination date on or before 23 December 2023 only, please submit online using the COVID-19 Vaccine Adverse Event Online Reporting system via the weblink https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/adr_reporting/index.html only.

   For more details concerning safety reporting related to COVID-19 vaccine, please refer to the "Guidance for Pharmaceutical Industry – Reporting Requirements of Adverse Event Following Immunization of COVID-19 vaccine" available at https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/adr_reporting/index.html.

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

1. PATIENT INITIALS (first. last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab date)										☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING ☐ CONGENITAL ANOMALY

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRO-DUCTION? ☐ YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period. etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		
	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE ☐ INITIAL ☐ FOLLOWUP	

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Clinical Trial Yearly Progress Report

Report period _____ to _____ Date of this report_____

CT cert no.:	
Protocol no.:	
Protocol title:	

Start date: _____ Anticipated end date: _____

Target no. of patient (as stated in protocol) _____

No. of patient intend to recruit (per centre) _____

No. of patient recruited (per centre) _____

No. of patient completed the trial (per centre) _____

No. of patient drop-out from study (per centre) _____

Reasons for drop-out:

Any changes for principal investigator? (If yes please give details)

Summary of amendments during report period (if any)

Summary of Serious Adverse Events (if any)

Does SAE affect the study? How and what action has been taken?

Summary of complaints about the study (if any)

Summary of recent findings (especially information about risks associated with the research)

Progress of study:

☐ According to plan

☐ Extend study period (reason_____)

☐ Premature termination (reason_____)

Name:_____ Signature:_____

Posting:_____ Date:_____

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Clinical Trial Final Report

Report period _____ to _____ Date of this report_____

CT cert no.:	
Protocol no.:	
Protocol title:	

Start date: _____ End date: _____

Target no. of patient (as stated in protocol) _____

No. of patient intend to recruit (per centre) _____

No. of patient recruited (per centre) _____

No. of patient completed the trial (per centre) _____

No. of patient drop-out from study (per centre) _____

Reasons for drop-out:

Summary of Serious Adverse Events (if any)

Does SAE affect the study? How and what action has been taken?

Summary of complaints about the study (if any)

Study duration:

☐ According to plan

☐ Extend study period (reason_____)

☐ Premature termination (reason_____)

Summary of study outcome

Name:_____ Signature:_____

Posting:_____ Date:_____