

**DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG EVALUATION AND IMPORT/EXPORT CONTROL 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* and unexpected** as soon as possible. (The attached CIOMS form may be used for reporting, except for reporting of adverse events of COVID-19 vaccines. Please refer to point 4 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 a complete 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.

* Serious Adverse Drug Reaction or Adverse Event :

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.

** Unexpected Adverse Drug Reaction:

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).

2. Progress report on yearly basis and a final study report at the end of the study. The attached forms may be used for reporting.
3. Please send the reports to the following address:

Drug Evaluation and Import/Export Control 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

Fax no.: 2803 4962

Email: ct@dh.gov.hk

4. 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), 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.

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)										

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
16. ROUTE(S) OF ADMINISTRATION	
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, allergies, 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 <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> 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: _____
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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)
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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)
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Summary of recent findings (especially information about risks associated with the research)
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Progress of study:
<input type="checkbox"/> According to plan
<input type="checkbox"/> Extend study period (reason _____)
<input type="checkbox"/> Premature termination (reason _____)

Name: _____
Posting: _____

Signature: _____
Date: _____

