

**DEPARTMENT OF HEALTH  
PHARMACEUTICAL SERVICE  
PHARMACEUTICALS REGISTRATION  
SECTION**

**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 [Appendix 2] may be used for reporting.)
    - (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.

\* 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 [Appendix 3 & 4 respectively] may be used for reporting.
  3. Please forward all reports to the following address :

Pharmaceuticals Registration Section  
Department of Health  
3/F Public Health Laboratory Centre,  
382 Nam Cheong Street,  
Shek Kip Mei, Kowloon,  
Hong Kong

(Fax: 2803-4962)

<b>SUSPECT ADVERSE REACTION REPORT</b>												

**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)										<input type="checkbox"/> PATIENT DIED  <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  <input type="checkbox"/> INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING  <input type="checkbox"/> CONGENITAL ANOMALY

**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)	16. ROUTE(S) OF ADMINISTRATION	
17. INDICATION(S) FOR USE		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
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 <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 site)	_____
No of patient recruited (per site)	_____
No. of patient completed the trial (per site)	_____
No. of patient drop-out from study (per site)	_____
Reasons for drop-out:	

Any changes for principle investigator? (If yes please give details)
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Summary of amendments during report period (if any)
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Summary of serious Adverse Events (if any)
Does SAE affect the study? How and what action has been taken

Summary of complains 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: \_\_\_\_\_

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:	_____
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Target no. of patient (as stated in protocol)	_____
No of patient intend to recruit (per site)	_____
No of patient recruited (per site)	_____
No. of patient completed the trial (per site)	_____
No. of patient drop-out from study (per site)	_____
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:	
<input type="checkbox"/> According to Plan	
<input type="checkbox"/> extended study period (reason _____)	
<input type="checkbox"/> Premature termination (reason _____)	

Summary of study outcome	

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Posting: \_\_\_\_\_

Date: \_\_\_\_\_