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To: Applicants / Sponsors of Clinical Trials

IMPLEMENTATION OF GCP COMPLIANCE INSPECTION FRAMEWORK

Clinical trials on medicinal products currently must comply with the Medicines Act (Chapter 176, Sections 18 and 74), the Medicines (Clinical Trials) Regulations and the Singapore Guideline for Good Clinical Practice (SGGCP).

2 The Clinical Trials Branch, Health Sciences Authority (HSA) is pleased to inform all applicants / sponsors of clinical trials about the implementation of the GCP Compliance Inspection Framework.

3 The objectives of the GCP Compliance Inspection Framework include the following:

- (i) To safeguard the rights, safety and well-being of trial subjects.
- (ii) To verify the quality and integrity of the clinical trial data submitted to the Regulatory Authority
- (iii) To assess compliance to protocol and applicable regulations, guidelines and standard operating procedures for clinical trials.

4 The GCP Compliance Inspection Framework applies to clinical trials on medicinal products, where a Clinical Trial Certificate (CTC) has been issued by the Health Sciences Authority. The scope of GCP Inspection will initially focus on the site where the clinical trial is being conducted, and subsequently Phase I Units, Sponsor and / or Contract Research Organizations (CROs). The inspection of Phase I Units may also include the assessment of the adequacy of the site facility.

5 The GCP Inspections may either be routine, triggered or conducted in response to a pre-marketing approval application.

6 The first GCP Site Inspection is expected to commence in Nov 2009. The Clinical Trials Branch will be taking an educational approach in conducting GCP Inspections. Guidances to help sites to prepare for a GCP Site Inspection will be available on our HSA website in Oct 2009.

7 The GCP Inspection Framework summarizing the GCP Inspection Process is enclosed for your information.

8 If you require further information or clarification, please contact Mr Foo Yang Tong (Deputy Director, Clinical Trials Branch) via email at foo_yang_tong@hsa.gov.sg or telephone at 6866 3442.

Thank You.

Yours sincerely,



Dr Christina Lim
Deputy Group Director
Health Products Regulation Group
Health Sciences Authority

Encl. GCP Inspection Framework

GCP SITE INSPECTION PROCESS

