HSA
Health Sciences Authority

CDA (PER) Ref: 025:38

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6 January 2006

To: Applicants / Sponsors of Clinical Trials

RE: CHANGES TO THE CLINICAL TRIAL APPLICATION PROCESS

The Clinical Trials Branch (CTB), HSA would like to inform applicants / sponsors of clinical trials on the administrative changes to the application process for regulatory approvals of clinical trials. These changes would take effect from January 2006.

Electronic Clinical Trial Certificates (e-CTC)

2. The online PRISM* application system for the various clinical trial modules has been in use since July 2003. The following clinical trial modules for the various submission types are available at http://www.hsa.gov.sg/html/business/ct.html:

** Pharmaceutical Regulatory and Information System*

- Application for CTC and CTM import permit
- Addition of Clinical Trial Site
- Amendment of Protocol and/or Patient Informed Consent Form
- Change of Principal Investigator
- Extension of Clinical Trial
- Notification of Updated Investigator Brochure
- Submission of Clinical Trial Status Report
- Submission of Clinical Trial Final Report - only for completed trial

3. In order for applicant to transact electronically with HSA, the applicant's company has to be registered with the HSA Client Registration & Identification Service (CRIS). The application form for CRIS registration can be downloaded at http://www.hsa.gov.sg/html/business/cris.html. The following support services are available to assist applicants with the CRIS registration and online submissions.

- cybertutor@hsa (http://www.hsa.gov.sg/html/business/cybertutor.html)
- helpdesk@hsa (http://www.hsa.gov.sg/html/business/prism_helpdesk.html)

4. Applicants will be able to access the PRISM system securely with their SingPass to find out the status of their applications under *track@prism*, or to print a copy of the electronic Clinical Trial Certificate (CTC) or the Clinical Trial Material Import Permit (CTM) under *enquire@prism*. The applicant can also amend the company information such as company name, address and contact numbers under *amend@prism*.

5 The system has been utilised to a large extent, and the majority of applicants are also familiar with the various submissions. In particular, this is seen for the main module of CTC application whereby the principal investigator (PI) of each site has to endorse online using SingPass. All applications received in 2005 are already entered into the system. Although a few of the applications were submitted in hardcopies, CTB had 'counter-submitted' or guided the applicants in making the online submissions. In view of the usage rate and the functionalities that the system provides to the users, such as retrieving the CTC records, it would now not be necessary to continue issuing hard copy CTCs.

6. With effect from January 2006, HSA will cease to issue the hard copy CTC for all newly approved applications received from 2006 onwards. As hard copy CTCs will not be issued, CTB would also cease sending the hard copy approval letter. The applicant as well as the PI(s) and IRB(s) would be notified by e-mail upon study approval. The applicant can then access the online module *enquire@prism* to retrieve the eCTC for study documentation purposes. Similarly, the applicant could also print the CTM for importation of the study drug(s).

7. Applicants are strongly encouraged to utilise the online system fully. In the event that applicants are unable to make online applications, hardcopy submissions for new trials would be accepted.

8. For ongoing trials that were not submitted online i.e. the initial application was not submitted via PRISM, HSA would continue to issue the hard copy CTC if the trial requires an extension after the 2-year validity period of the CTC, or when new site(s) are added. For amendments to such trials, please continue to make hard copy submissions. CTB would issue the hard copy approval letters as per current practice.

Parallel Submissions

9. We are also pleased to inform the applicants that with effect from January 2006, parallel submissions can be made to both the HSA and to the respective Institutional Review Board / Domain Specific Review Board (IRB/DSRB).

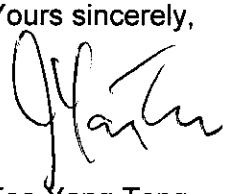
10. The regulatory approval would be issued independent to the ethics approval. The applicants should initiate the study only when both regulatory and ethics approvals have been obtained. A copy of the ethics approval letter should be forwarded via e-mail to CTB. It is the applicant's responsibility to ensure that any changes requested by either HSA or IRB/DSRB be communicated to the other party and any such amendments are approved by both parties before they are implemented.

Submission Documents

11 CTB has also reviewed the supporting documents needed for new clinical trial certificate applications. It has been assessed that advertisements, translated informed consent forms and diary cards need not be submitted with effect from January 2006. These documents should continue to be submitted to the IRB/DSRB.

12. If you need further information or any clarification, please contact Ms Dorothy Toh at Tel: 6866-3443 or Dr Lisa Tan at Tel: 6866-3444, or e-mail your queries to hsa_ct@hsa.gov.sg. Thank you

Yours sincerely,



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