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4 November 2008

To: Applicants / Sponsors of Clinical Trials

LAUNCH OF WEB-BASED EXPEDITED SAFETY REPORTING MODULE (ESR)

As part of the Health Sciences Authority ongoing efforts to advance towards electronic regulatory submissions, the Clinical Trials Branch is pleased to inform you that the Online Expedited Safety Reporting (ESR) Module will be implemented with effect from 11 November 2008.

2 This module is an enhancement of the current e-services available in PRISM for clinical trials. The e-services for clinical trials and regulatory submissions can be accessed via E Services & Forms for Clinical Trials.

3 The ESR module was implemented with an initial soft launch phase, from April to November 2008 to a few companies based on the number of expedited safety reports submitted monthly over the past 2 years. The soft launch has been useful, as it had enabled us to assess the system's functionality and refine the system. We would like to acknowledge and thank all these companies for their cooperation and feedback.

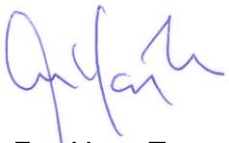
4 We are pleased to proceed with the full launch of the ESR module. In this module, a new mapping function has been introduced to allow *CRIS administrators* to assign drafter roles to local or overseas staff/ partners and map them to selected protocols in order for them to draft the safety reports. Submission of the safety reports could then be completed by staff who are assigned submitter rights within ESR. Local sponsors of clinical trial applications can apply for a *HSA PIN* for overseas staff/ partners to draft the applications on their behalf. This mapping function can be accessed via E Services & Forms for Clinical Trials.

5 A copy of the user manual with detailed instructions on the drafting and submission of the safety reports via the ESR module can be accessed via Guidelines for Clinical Trials. Please note that submissions via the ESR module will only be available for ongoing clinical trials whereby the initial CTC applications were submitted through PRISM. The new ESR module can be accessed via E Services & Forms for Clinical Trials.

6 To factor in the adjustment and familiarity of this new module by the companies, we would like to implement a phased-in approach for this launch. During this transition period, we would encourage incremental submissions through the ESR module although the other means of regulatory submission would still apply. We hope to work together with the companies towards full submission of safety reports through the ESR module to provide a systematic and standardized submission process.

7 We look forward to your company's cooperation and support in this launch of the ESR module. If you require further information or any clarification, please contact Ms Chong Limei (Chong_Limei@hsa.gov.sg) at Tel: 6866-3445 or Ms Valerie Wee (Valerie_Wee@hsa.gov.sg) at Tel: 6866-3422.

Yours sincerely,



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