Clinical Drug Evaluation: The Regulatory Perspectives

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Abstract

***Introduction**: This paper presents the regulatory perspectives of the clinical drug evaluation process and the role of the newly established Centre for Drug Evaluation in Singapore in this process. It describes the major drug evaluation systems in the developed countries and their similarities and differences. **Methods**: The issues related to the benefits and risks assessments of new drugs are discussed, with examples, against the backdrop of the various drug evaluation systems and medical practices. **Results**: The implications of Singapore's Medicines (Clinical Trial) (Amendment) Regulations 1998 and the Singapore Good Clinical Practice Guidelines published by the Ministry of Health in 1998 were discussed. The future development of international harmonisation in the context of the International Conference on Harmonisation was explored. **Conclusions**: Building the capability for the evaluation of new drugs is essential as part of the regulatory infrastructure for a knowledge-based economy in Singapore. To conduct better clinical trials, investigators should develop a good understanding of the clinical drug evaluation process and an appreciation of the regulatory angle.*

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