

# 北里大学東病院における市販直後調査への 協力体制の構築とその実施状況に関する評価

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## Evaluation of the Establishment and Enforcement of Early Postmarketing Surveillance Cooperation System in Kitasato University East Hospital

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### Abstract

An in-house system to cooperate in early postmarketing surveillance in line with the procedure for adopting new drugs has been in place independently in Kitasato University East Hospital since October 2001 when the surveillance was introduced. After summarizing how successfully the early postmarketing surveillance proceeded over new drugs under surveillance from the start of the operation of the system to July 2005, we assessed our hospital's system to cooperate in the early postmarketing surveillance and examined the way the system should be in future.

There were 29 pharmaceutical products under surveillance and the frequency of surveillance (how many times lists were prepared for and distributed to doctors and medical representatives [MRs]) per product item was 11.6 on average. The mean surveillance period was 7.7 months and many of the pharmaceuticals were kept under surveillance beyond an early postmarketing surveillance period of 6 months after the start of marketing. This is because our hospital has defined the early postmarketing surveillance period as a period from the start of a prescription for a new drug to the official adoption of the drug after meeting the conditions for application for adoption, or a provisional adoption period. We consider that the circumstances of the development of adverse drug reactions were understood sufficiently during this period and that a contribution was made to an appropriate evaluation of the drug in the deliberation of whether or not to adopt the drug by the Drug Committee. In addition, adequate provision of information to doctors by pharmacists led to the promotion of the proper use of new drugs. However, MRs' activities to provide information to doctors and pharmacists were insufficient in some aspects. We conclude that MRs' more active efforts as well as the active involvement of pharmacists and doctors' understanding and cooperation are important in order to make early postmarketing surveillance meaningful.