Journal of Pharmaceutical Research and Drug Information
Vol. 7, No. 4+5, 2016, pp. 177-183
Received 16 August 2016, accepted 22 October 2016

# Evaluation of adverse event/serious adverse event reporting management systems in clinical trial sites in Vietnam

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***Summary:*** *The study aimed to evaluate adverse event/serious adverse event reporting management systems in several clinical research sites in Vietnam. The Indicator-based Pharmacovigilance Assessment Tool (IPAT), which was developed by The US Agency for International Development (USAID), was used to evaluate the capacity of current patient safety systems in the country. In general, the capacity of these systems was low (42.1% compared to the standard system), especially in terms of organization (20.5%), standard operation process implementation (24.4%), and policy (30.8%). Besides, the existence of specialized clinical research units inside clinical research sites played an essential role in strengthening their patient safety management capacity. Of note, the capacity of the sites with specific clinical research units was higher than the ones without these units (73.3% vs. 21.8%). Insummary, the sites with clinical research units had higher score compared with those without clinical research units according to IPAT evaluation.*