

## S42-2 **Analysis of Drug Safety Information using AERS (Large-scale Database of Adverse Drug Reactions)**

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The value of pharmaceutical products is determined by the balance between efficacy and safety. In particular, regarding safety, scientific evaluation becomes possible using huge post-marketing safety data. Recently the worldwide situations of drug safety have changed greatly. Drugs are used based on the evaluation of safety data collected in clinical practice worldwide. For example, US FDA requires manufacturers to report adverse reactions related to US marketed drugs occurring worldwide. These worldwide data are available through the Adverse Event Reporting System (AERS) (about 2.6 million reports, for 11 years; 1997.4<sup>th</sup> qr ~ 2008.1<sup>st</sup> qr ). The current issues are how to analyze and utilize such large-scale safety data. Although the database are based on spontaneous reports, its huge volumes and exhaustiveness (390,000 reports per year) allow for sufficient scientific evaluation with the aid of current IT technology, despite the lower precision than interventional studies. Therefore, analysis of large-scale adverse event reporting database becomes a new research area not only from the medical but also from the statistical viewpoint. In this symposium, we introduce some case studies in which we analyzed the AERS data: psychotropics, antiarrhythmic drugs, anti-HIV drugs, etc. The analysis and evaluation of large-scale spontaneous adverse reaction reports are the most important issues in ensuring the postmarketing safety of pharmaceutical products..