

## S42-5 A strategy to activate imagination in safety evaluation of a drug

○Takenobu TASAKI<sup>1</sup>, Chieko MATSUMURA<sup>1</sup>, Norihiro KOBAYASHI<sup>1</sup>, Takahiro HASEGAWA<sup>1</sup>

<sup>1</sup>Biostatistics Department, Pharmaceutical Development Division, Shionogi & Co. Ltd.

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Imagination is indispensable to evaluate safety of a drug using a data base of spontaneously reported adverse events (AEs). However, to exploit imagination efficiently, several templates for use in summarizing or analyzing AE data are necessary. We consider the templates developed with the intent to make efficient use of the AERS (Adverse Event Reporting System), a database administered by FDA. Anyone can down-load the data from the AERS for free, but the data are not suited for direct manipulating. Thus, cleaning (to trim excessive information), organizing (to methodize disordered information) and arranging (to put information in order) are necessary. Though, little reports on the methods to manipulate the AERS data are published. After the data manipulation, it is necessary to detect embedded appeals or whispering as a signal from the database. In order to detect the signal, criteria, such as PRR (Proportional Reporting Ratios) are useful. PRR is a robust and easy to understand index to quantify the departure from proportionality in the reported number of an AE seen for a drug and other drugs. Further, it is useful to comprehend complete profiles of the reported AEs. Clustering method can be applied to grasp the extent with which influences of diseases, drug classes and chemical structures are reflected on the data base. Then, similarities based on the subsets of drugs and AEs will become important keys. The templates to evaluate combined effects of drugs are also necessary. The lift value of the association analysis, a part of data mining is useful to this evaluation. We introduce a system developed in-house, with these templates in mind.