

## S42-6 The challenge towards establishment of the safety measures based on a scientific basis

○Kazuhiko MORI<sup>1</sup>

<sup>1</sup>Safety division, Pharmaceutical and Food safety Bureau, Ministry of Health, and Labour and Welfare

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The latest clinical development of the new drug is furthered by planning and conducting appropriate designed clinical trials. Based on the scientific data obtained by these clinical trials, clinical development is furthered logically. However, in the clinical development before new drug application (NDA) approval, sample size of the clinical trial is limited at most thousands patients. Even more usual sample size of the pivotal clinical trials is around hundreds. The evaluation of new drugs is based on these data.