

## 全例調査をどう考えるか\*\*

—学より—

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**Reconsidering Drug Use Investigation in Japan**

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**Summary**

To ensure the safety and efficacy of drugs (chemical entities, biotechnology-derived products, and vaccines), drug use investigations after approval must be conducted for specific purposes with appropriate design. Comparison groups should be set up if necessary. In addition to conducting clinical/observational studies, we must consider the use of other data sources such as medical databases. A large national claims database is to be developed by 2011 in Japan. It is expected to be important data source to address safety problems and to aid pharmacoepidemiology studies.

**Key words**

Drug use investigation, Pharmacoepidemiology, ICH E2E, National claims database