

## 新薬申請データパッケージにおける日本人長期投与データの 必要性に関する検討

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### Investigation of the Necessity of Japanese-Specific Long-term Safety Data in New Drug Applications

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#### Summary

Regarding long-term clinical data required for registration of pharmaceuticals for human use, the global consensus on treatment duration and number of patients has been presented in the ICH E-1 guideline. Though there is no ethnic constraint in relation to long-term data in the ICH guideline, the Japanese regulatory authority in 2012 released the Japanese general rules, which require long-term safety data for 100 or more Japanese subjects who have been treated for 1 year. However, the purpose and scientific rationale of this requirement are unclear.

Therefore, we conducted an observational survey using systematic review to explore whether the Japanese-specific long-term data have provided any additional and meaningful information that was not available from the long-term data in non-Japanese.

An exhaustive review of the information on new drugs approved in Japan from 2010 to 2012 with long-term data in Japanese patients showed that no Japanese package inserts had any additional safety information derived from the Japanese long-term data, compared to the descriptions in the corresponding US package inserts. In addition, although some new drugs were approved without Japanese-specific long-term data, we could not identify any consistent or scientific reasons for this difference.

These findings suggest that Japanese-specific long-term safety information should not be requested routinely, but only when there are specific reasons arising from the characteristics of each drug. We hope that these review results will contribute to future discussions on a scientific approach to long-term safety data.

#### Key words

Long-term safety data, New drug application, Japanese regulation, Systematic review