——抗悪性腫瘍薬開発フォーラム——

バイオマーカーに期待するもの**
—規制側から—

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What is a biomarker ?
—Regulator's perspective—

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Summary

Biomarkers are useful for screening, monitoring, differential diagnosis, and play important roles as prognostic factors, effect predictors, risk factors, etc. In anticancer chemotherapy, biomarkers can assume a key role in individualizing/personalizing treatment; indeed, there is a trend toward individualized therapy using biomarker-based therapeutic decisions. For instance, biomarkers are used for identifying a therapeutic target population clearly and effectively. Biomarkers can also be a powerful tool for guiding risk reduction strategies. However we must consider the balance of advantages and disadvantages carefully when using biomarkers.

The Pharmaceutical and Medical Devices Agency is introducing various approaches to reduce the delay in introducing new drugs (the so-called drug lag). A part of our strategy involves face-to-face consultation meetings concerning pharmacogenomic biomarkers, as from April 2009. Although we at the PMDA so far have little experience of such consultation meetings and new drug approval reviews for biomarkers, this topic is of great interest, and here, I would like to describe our experience to date with the review of biomarkers in Japan.

Key words

Biomarker-based therapeutic decisions, Individualized therapy, Pharmaceutical and Medical Devices Agency