

Biomarker-driven Drug Development

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Biomarkers play important roles in drug development to confirm target engagement of drug candidates, to determine right dose, to select right patients and to supply right medication. Pharmacodynamics (PD) is the study of the biochemical and physiological effects of drugs on the body by interacting drugs with the target molecules. PD is deeply related with mode-of-action of drug candidates, therefore PD biomarkers can achieve proof-of-mechanism (POM). Recent progress of disease etiology has provided sub-category of the disease. It is now highly important to identify right patient population among several disease sub-categories to increase response rate of the drug candidates and reduce number of subjects in phase II and /or phase III studies. Patient stratification is expected to increase the success rate and accelerate product creation, and leads patients toward personalized medicine era. To determine “right patients”, we need to enhance the technology platform and covert biomarkers to diagnostics. Response/efficacy markers, which can be detected in early clinical study to increase confidence of projects, and exclude poor-response patients from clinical trials at earlier time points, which is useful to avoid unnecessary adverse effects on poor-responders. Efficacy biomarkers can also encourage patients to continue taking right medicine. Therefore, using the response markers brings a benefit to patients as “right medication”. Biomarkers are also keys to diagnose disease and monitor disease situation. Several biomarker examples will be discussed.

Biography

Yoshiya Oda received his B.S. degree in Pharmaceutical Science from Kyoto University, and he earned his Ph.D. from Kyoto University. He is working in Eisai for 24 years. He has published 72 original papers. Among them, he has made several major contributions to the field of proteomics including metabolic stable isotope labeling method for quantitative proteomics. He has received several awards: Research Award from the Society of Chromatographic Sciences, Japan (1999), Division Award from Pharmaceutical Research Vision in the Pharmaceutical Society of Japan (2005), Research Award from the Mass Spectrometry Society of Japan (2005), and Nature-Invitrogen Award (2006).

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