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Regulatory issues on the companion diagnostics in Japan

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Companion diagnostics (CDx) play an important role in the personalized medicine. Current development of new medicinal drugs often requires co-development of CDx from early stage. The US FDA released the final guidance document on the *in vitro* companion diagnostic devices in which requires the CDx to be approved simultaneously with the corresponding new therapeutic product. The new paradigm of CDx developments and approvals are challenging task for both manufacturers and regulators. The Ministry of Health Labor and Welfare (MHLW) in Japan released similar guidances on the CDx as FDA. Basic concepts on the regulation of CDx and technical guidance for the co-development of CDx with a new drug were indicated. There are, however, still complicated issues on the regulation of new CDx such as a bridging of clinical performance data produced by a developmental test and a final diagnostic product or different type of CDx diagnosing the same molecular target. A detailed strategy and guidance should be shown for the evaluation of clinical performance data produced by different CDx. The feasibility of an integration of different sets of clinical data should be determined depending on the type of CDx in regard of their target molecules, methodology and purpose. A bridging is easier for the genotypic diagnosis such as mutations or SNPs in DNA but is difficult for the pathological examinations by immune histochemistry. Other regulatory issues on CDx such as the laboratory developed tests and the next generation sequencers are also discussed.

Biography

Takayoshi Suzuki has completed his PhD from Nagoya City University and started working at NIHS in 1990. He stayed at the Divisions of Genetics and Mutagenesis and Cellular & Gene therapy products. Now he is a Chief of Molecular Diagnosis section of Div. Molecular Target and Gene Therapy Products. He works on the regulatory science on the molecular diagnostics and responsible for a regulation of companion diagnostics. He also works on the proteomics using the LC-MS and genomics using the next generation sequencer.

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