26G-ISMS44 **Regulatory Science for R&D Promotion of Innovative Pharmaceuticals***

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At present the nation's policy for research and development (R&D) promotion of innovative pharmaceuticals and improvement of environments for the R&D is formulated by Japanese government. In the policy the enhancement and promotion of Regulatory Science (RS) touching the appropriate and rapid predict, evaluate, and judgment of quality, efficacy and safety of pharmaceuticals is especially stressed. Following the nation's policy, the MHLW is promoting the strategy package (Strategy of SAKIGAKE) facilitating all the process from R&D, clinical research/trials, pre- and post- marketing safety, insurance coverage, through globalization of innovative products which are to be put into practical use, targeting innovative pharmaceuticals which can cure serious illnesses. In concert with the MHLW, the PMDA is building up the systems, such as priority consultations, prior assessment, and priority reviews. The PMDA is taking various approaches such as the introduction of data mining methods and safety evaluation of drugs based on pharmaco-epidemiological methods utilizing electronic medical records, or construction of medical information database (MID-NET), to enhance and advance safety measures. The PMDA has also established the Science Board consisting of external experts to discuss the evaluation methods of innovative drugs. The pharmaceuticals-related divisions in the NIHS have carried out RS research to develop the point-to-consider documents or standardized methods for evaluating mainly quality and non-clinical safety of innovative products such as nanomedicines, fully engineered protein drugs, oligonucleotide drugs, and so on. The AMED is supporting about 80 research projects by the Grant Program naming "Research on Regulatory Science of Pharmaceuticals and Medical Devices".

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