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Science and Art in Drug Development and Fostering in Japan

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“Souyaku” in Japanese means “Drug discovery and development” which is used for investigational drugs from more or less 1980 in this Japan. “Ikuyaku” means “Drug fostering and evolution” which is used especially for post-marketing drugs. For the rational drug therapy next two are essentially important; (1) Drugs which have been confirmed the efficacy and the safety scientifically by clinical trials, and (2) Evidence for rational usage of drugs. Ikuyaku is important for evaluating the real usefulness of post-marketing drugs in the world, and especially for achieving the rational drug therapy to patients.

Some examples of ikuyaku activities mainly by our research group will be presented at the lecture. These results show the significance of ikuyaku to achieve the rational drug therapy and drug effects are generally produced through an interaction between a drug and a human body. Therefore, the effects and side effects of drugs depend on a condition of each patient, and a careful attention should be paid for the patient’s present condition and life style.

To promote drug development and fostering the most important abilities to be needed at the present and in the future are creative power and communication skills. Therefore, communication skills are important issues to be trained to collaborate all individuals involved in the clinical study as part of the research team including patients as well as investigators, clinical staff, clinical research organizations (CRO’s), site management organizations (SMO’s), sponsors and regulatory staff. Building effective teams takes time. It is essential to think of each other as “Partners” to work toward the common goal of conducting reliable clinical trials for patients. Training is an ongoing, multi-step process.

Japanese Society of Clinical Pharmacology and Therapeutics (JSCPT) established the certification system for the “Board certified clinical research coordinator (CRC) , JSCPT” in 2002. In the examination for board certification, knowledge, skills and attitude in the field of clinical trials are evaluated independently. In the lecture, I would like to talk about “Science” and “Art” in drug development and fostering in Japan.