
Impression of the Conference for Promotion of International Collaborative Clinical Research, Beppu, January 13, 2007

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To the editor: On January 13, 2007, the Conference for Promotion of International Collaborative Clinical Research (theme: “What must be done in clinical research settings”) was held in Beppu City, Oita Prefecture, Japan. In recent years, clinical research has changed significantly worldwide, including the active development of clinical research in Eastern European, South American, and Asian countries due to the evolution of social infrastructures there. Despite the advances in global approaches to drug development, Japan has primarily imported drugs that have been developed in Europe and the United States (the so-called “drug lag”). Since the need for the rapid development of a system for implementing international collaborative clinical research in Japan has been realized [1], the present conference discussed the factors necessary for the establishment of clinical research in Japan [2].

Through discussions on the necessary conditions for Japan to participate in international collaborative clinical research, the following needs were identified: (1) language ability (English), (2) mutual understanding, (3) presence of experts, (4) improvement of infrastructure, and (5) motivation.

- (1) Language ability: it is regrettable that Japan is unable to participate in international collaborative clinical research due to language problems. Although an increasing number of case report forms (CRFs) require comments in English, language should not be a serious problem once English is mastered by non-native speakers.
- (2) Mutual understanding: mutual understanding begins with mutual respect of cultures and requires various discussions before the start of clinical research, regarding issues such as standardization of criteria for adverse events and test values.
- (3) Presence of experts: the presence of experts in applicable fields in clinical research facilities has become an essential requirement. Requests for collaborative research are no longer based on facility names. While Japan may face difficulty receiving global recognition despite conducting

quality research, involvement in international research must be actively maintained.

- (4) Improvement of infrastructure: at present, lack of infrastructure such as computers connected via LAN is not an impediment to clinical research at most facilities. In today’s sophisticated clinical research, which demands accuracy, the participation of active and capable clinical research coordinators (CRCs) is of greater importance. The education of CRCs is thought to be a common issue for all facilities.
- (5) Motivation: finally, while this need may not be as academic as other needs, motivation among principal investigators and subinvestigators of clinical research is vital. In Japan, doctors receive no monetary compensation for direct involvement in clinical research, and they must conduct clinical research while being occupied with clinical practice, other research, and education. While doctors may be expected to strive toward providing better medical care and drugs for patients as quickly as possible, conscience has its limits. It is necessary for not only the institutions in charge of clinical research but also for the Japanese Society of Anesthesiologists (JSA) to implement measures that provide incentives to medical personnel involved in actual clinical research [3].

Due to various impediments, global studies and even bridging studies are currently being shifted from Japan to Korea and China, on the basis of their common Asian pharmacokinetic/pharmacodynamic characteristics. For the clinical use of world-class anesthetic agents at the same time as they are used in developed Western countries, anesthesiologists and facilities conducting clinical research must take pride in their work. In addition, articles that present the results of clinical research should be globally reported by at least publishing them in English-language journals listed in the Index Medicus.

The most representative example of clinically used drugs in Japan that have been developed in the field of anesthesiology from the start of clinical research is remifentanyl, an ultra-short-acting opioid analgesic [4]. A drug that is currently being evaluated in a bridging study is rocuronium, a non-depolarizing neuromuscular blocking agent [5]. Both drugs required over 10 years of development and testing to be put into clinical use after their approval in Europe and the United States. Meanwhile, a drug that is being developed in a bridging study almost simultaneously with global clinical research is sugammadex, a selective reversal agent for rocuronium/vecuronium [6]. This drug is expected to become available for clinical use in Japan no later than in the rest of the world. In conclusion, clinical research must be advanced with speed and accuracy. These efforts will lead to opportunities to participate in international collaborative clinical research.

References

1. Takaku F (ed) (2007) ABC for clinical practice in Japanese. J Jpn Med Assoc 135(Suppl):1–350
2. Ohashi K (ed) (2007) Abstract of the Conference for Promotion of International Collaborative Clinical Research in Beppu in Japanese. pp, 1–17. Oita University Hospital Clinical Pharmaceutical Center, Oita, Japan
3. Homepage of Japan Pharmaceutical Manufacturers Association (<http://www.jpma.or.jp>)
4. Yamakage M, Namiki A (2005) A long-awaited ultra-short acting opioid—remifentanyl (in Japanese with English abstract). Jpn J Clin Anesth 29:1739–1753
5. Iwasaki H (2006) An overview of the pharmacokinetics and pharmacodynamics of rocuronium bromide (in Japanese with English abstract). Masui (Jpn J Anesthesiol) 55:826–833
6. Suzuki T (2006) Sugammadex (Org 25969, modified gamma-cyclodextrin) (in Japanese with English abstract). Masui (Jpn J Anesthesiol) 55:834–840

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