

製造販売後臨床試験の実際と問題点 (ACTS-GC)\*\*

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**Actual Problems in Post-marketing Clinical Studies of Anticancer Drugs**

—ACTS-GC as an Example—\*\*

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**Summary**

We conducted a large post-marketing clinical study for curatively resected gastric cancer patients. More than 100 hospitals in Japan participated in this study, and data have been collected from more than 1000 patients. To reduce the burden on investigators participating in this study, clinical research coordinators (CRCs) have been introduced and now collaborate with physicians at about half of the hospitals. Support provided by CRCs increased the enrollment rate of the contracted number of patients and shortened the time required to prepare case reports. However, several problems remain, such as higher costs for the work required, as compared with clinical trials of new drug development.

Clinical studies of postoperative adjuvant chemotherapy characteristically require long-term follow-up. However, about half of the initially participating investigators move to other positions or hospitals during the study. Clinical research associates (CRAs) employed by pharmaceutical companies also frequently change. There are many administrative problems, such as the awareness and positioning of the study.

Post-marketing clinical studies must be performed in accordance with the guidelines for Good Clinical Practice, similar to clinical trials. Therefore, many CRAs are required and costs are high. It is therefore difficult to perform several large clinical studies at the same time. To efficiently conduct large clinical studies for the establishment of evidence-based medicine in Japan, better clinical study monitoring and improved support systems for investigators are necessary.

**Key words**

Post-marketing clinical study, Large scale study, Anticancer drug development, Clinical research coordinator