

# The Administrative Management Division for Clinical Drug Trials (ACDT) at Fukuoka University Hospital

—A New Contentment Index as a Potent Predictor of  
the Drug Trial Working Ratio

Hisamitsu TAKASE, Etsuko SAKIYAMA, Tomoko INOUE,  
Keita NODA, Nobufumi ONO and Keiji SAKU

*The Administrative Management Division for Clinical Drug Trial, Fukuoka University Hospital*

**Abstract:** The Administrative Management Division for Clinical Drug Trials (ACDT) at Fukuoka University Hospital reports the actual working ratios of drug trials to the Institutional Review Board (IRB). However, it is not reasonable to compare these ratios among drug trials, since they depend on the stage; i.e., the trials can be performed at either an early or late stage of the enrollment period. Therefore, a Contentment Index (CI) was calculated as the working ratio of each trial divided by the percentage of the entire trial period completed. The CI during the enrollment period could be classified into 4 types: (1) a rapid-saturation type, (2) a rapid-steady-state type, (3) a delay-steady-state type, and (4) an early-dormant type. Of the 42 drug trials in our hospital from 1998 to 2002 that included more than 6 trial cases, 11 were early-dormant type, 11 were delay-steady-state type, 6 were rapid steady-state type, and 9 were rapid-saturation type. The rapid-saturation, rapid-steady-state, and delay-steady-state types showed significantly higher working ratios than the early-dormant type. No relationships were found between the number of assigned cases, the physicians in charge, the age of the patients, the number of exclusion criteria, the clinical trial period or the final working ratio among the 4 patterns. The enrollment period for the early-dormant type was significantly ( $p < 0.05$ ) longer than those for the rapid-and delay-steady-state types. We found that when 50% of the enrollment period had passed, the CI was a good predictor of the final enforcement rate. In conclusion, the CI patterns and the CI at 50% of the enrollment period are thus considered to be useful predictors for the working ratio of drug trials, and the ACDT should report the present status to drug trial teams at the middle of the enrollment period based on the CI.

**Key words:** Administrative Management Division for Clinical Drug Trials (ACDT), Institutional Review Board (IRB), Working ratio, Contentment Index (CI), Enrollment period