

The Administrative Management Division of Clinical Drug  
Trials (ACDT) at Fukuoka University Hospital  
—Recent Laboratory Examinations for Clinical Drug Trials

Etsuko SAKIYAMA, Hisamitsu TAKASE, Keita NODA,  
and Keijiro SAKU\*

*The Administrative Management Division of Clinical Drug Trials,  
Fukuoka University Hospital, Fukuoka 814-0180, Japan*

**Abstract :** Laboratory examinations are an essential part of clinical drug trials to obtain scientific data. This study was designed to evaluate the performance of laboratory examinations in all clinical drug trials from April 2001 to March 2003 at Fukuoka University Hospital. The laboratory examinations were classified into three types: in-hospital type, where all laboratory examinations were performed by the Department of Laboratory Medicine of Fukuoka University Hospital, out-of-hospital, where all laboratory examinations were performed by an outside laboratory, and mixed, where laboratory examinations were performed both in-house and by outside laboratories. From 2001 to 2003, the percentage of in-hospital examinations decreased from 27.3% to 14.8%, and 14.3%, respectively. On the other hand, the number of out-of-hospital examinations in 2003 was three times greater than that in 2002. When the pharmaceutical company that provided the clinical drug trial was classified as either domestic or foreign, the number of out-of-hospital and mixed examinations involving a foreign company significantly changed over the three year period. With regard to the nature of laboratory examinations, out-of-hospital biochemistry examinations increased significantly year by year. Both out-of-hospital and in-hospital examinations of white blood cell morphology decreased, and there was also a significant increase in the complete omission of such examinations. Out-of-hospital laboratory examinations related to the main evaluation or a sub-evaluation of a clinical drug trial increased, and the number of in-hospital or mixed examinations for this purpose decreased, but these changes were not significant. As a result, the administrative management division of clinical drug trials in Fukuoka University Hospital has summarized the recent trends and problems associated with laboratory examinations for clinical drug trials performed from 2001 to 2003.

**Key words :** Laboratory examination, Laboratory company, Clinical drug trial,  
Administrative management division of clinical drug trials