Clinical Evaluation of Effects of Drugs and Foods

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Summary
Regulations of food for specified health uses (FOSHU) are herein explained after introduction of details about the Center for Clinical Evaluation of Drug and Food, Osaka City University Hospital, which has participated in development of FOSHU as part of the Osaka City Regeneration Program. Clarification of the mechanisms of action of specified components of FOSHU is now required by non-clinical studies and evaluation of efficacy and safety by clinical trials. This development is similar to that for drugs, but there are many differences in regulation of clinical trial practice and procedures in the environment at medical facilities. In addition, differences in endpoints of clinical trials are explained using cases of drugs and foods which affect blood sugar as examples.