S23-4 From the viewpoint of approval examination of drugs etc.

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Any persons who intend to market drugs or medical devices etc. in Japan shall submit approval application of each product attaching data on results of clinical studies etc. and obtain a marketing approval of the Minister of Health, Labour and Welfare based on the Pharmaceutical Affairs Law (PAL). In that case, those data are required to be collected and prepared according to the standard provided by the Minister of Health, Labour and Welfare. This standard, what we call “Reliability Standards”, is provided that application data shall be collected and prepared according as follows: those data shall be adapted to related Ministerial Ordinances including a Ministerial Ordinance on the Standards for Conduct of Clinical Trials on Drugs, what we call “GCP Ministerial Ordinance”; those data shall be prepared correctly from the result of clinical studies etc.; those data shall be described including negative results concerning the quality, efficacy and safety of a product etc.. Moreover, the handling of clinical trials which are conducted in order to collect data on results of clinical studies for approval application of a product is designated by PAL and GCP Ministerial Ordinance based on PAL. Only after sponsors submit approval application attaching data reflected exactly from results of clinical trials which are conducted ethically and scientifically according to such regulations as above, regulatory agency can examine the application scientifically. At present, the Pharmaceuticals and Medical Devices Agency, an incorporated administrative agency conducts approval reviews on the quality, efficacy and safety of drugs etc. as based on PAL reviews approval applications after surveying data attached to approval applications in conformity with Reliability Standards and confirming that clinical trials are conducted ethically and scientifically.