What is the examination necessary for pharmaceutical drug development?

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The non-clinical animal toxicity studies are conducted to define the properties of the drugs, and it is important to extrapolate the animal findings to human as much as possible. The purpose of the examinations and information obtained from the toxicity studies differ according to the drug-development process. Several guidelines have been issued by various regulatory agencies regarding toxicity studies for new drug application based on the discussions at ICH in order to speed up development time, obviate duplicated tests, utilize data, homogenize the quality of the studies, and reduce unnecessary use of animals. It is important to clarify the objectives of the studies and conduct the required studies within the appropriate timeframe. These guidelines for toxicity studies were established at the time when drugs were mainly low molecular compounds. They have been revised over time and the most recent guidelines for immunotoxicity studies were issued in April 2006. Recently, by using new biotechnology such as genome decoding and in Silico, it is possible to design a pharmacological function and structure for the target drug. Regarding a molecular targeted drug and antibody drugs, it has become difficult to obtain useful information from toxicity studies according to conventional guidelines. We would like to consider what non-clinical information is truly necessary for pharmaceutical drug development.