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## Regulation of pre-clinical & clinical trial approval process in ASEAN countries

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South East Asia region is a developing pharmaceutical market. The regulatory environment has similar characteristics but drug registration requirements and processes differ among the countries. An ASEAN initiative to accord the requirements for drug registration is in progress. Many multi-national research-based pharmaceutical companies have begun to conduct multi-center trials in their global drug development programs involving Asian medical centers for faster patient enlisting to achieve faster drug development. Demonstration of safety and efficacy of the drug product for use in humans is essential before the drug product can be approved for import or manufacturing of new drug by the applicant by regulatory authority in any country. Once the pre-clinical and clinical trial data has been collected, a New Drug Application must be submitted to the regulatory authority for approval. Although in the recent years there is a steady increase in clinical trial activities in South East Asia, filing requirements in developed countries differ from developing countries which makes the approval process tedious and time consuming for the later. ACTD, a common format, has been developed for ASEAN countries for the registration pharmaceuticals for human use for ASEAN Regulatory Authorities.

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