Abstract of Master's Dissertation

No.1

Course	Master of Public Health	Name	Chie Narita
Thesis Title	What policy/regulation impacts the number of Multi Regional Clinical Trials in ASEAN (Association of Southeast Asian Nations) countries?		

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Background:

Clinical trials are essential to confirm the safety and efficacy of a new drug. Since 1998 when International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) initiated by EU, US, and Japan, the number of clinical trials globally has been accelerated to increase, according to the ClinicalTrials.gov provided by the U.S. National Library of Medicine.

ASEAN (Association of Southeast Asian Nations) countries, especially several leading ones in this area were stimulated by ICH movement and their governments have been trying to set the national system to fit to the international harmonization. Since 2000, they have produced several important regulations and laws which might influence the number of international clinical trials performed in those countries.

Objectives:

To identify possible or probable candidate regulations and laws which could influence the number of Multi Regional clinical trials (MRCTs) by retrospective observation, concordance of regulations and laws with any changes of annual number of MRCTs were investigated.

To confirm those regulations and laws' practical impact in each country, qualitative investigation by individual interview with clinical trial professionals from regulatory authority, industry, and institution, as three major roles involved in MRCT, were performed.

Materials and methods:

Annual number of MRCTs during a period between 2000 and 2020 were obtained through the website, ClinicalTrials.gov. Related regulations and laws in each country were selected by Analysis Report Identification and Clarification of the Differences in Regulatory Requirements between Asian Economies (APAC report) which have been published every year. The interviews to the clinical trial professionals from regulatory, industry, and institution in ASEAN countries were conducted to ask if my hypothesis about the causes (regulations and laws) and those results (increase or decrease of the number of MRCTs) is reasonable or not.

＊ The abstract, containing the objective, method, result and conclusion should not exceed 300-500words and printed double sided on A4 paper)

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Results:

Two regulations were independently identified as influencing factors in Thailand and in the Philippines, namely "Parallel clinical trial application" and "per invoice/shipment import license". In Thailand, the "parallel clinical trial application" was adopted in 2016 and increase of MRCT number was seen in 2018 (+64.1% comparing to 2017). In the "Parallel clinical trial application", ethical committee (EC) review and regulatory review (for import license) can be done simultaneously. The similar regulation change was seen in the Philippines (2019) but the increase of MRCT number has not yet been observed. All nine interviewees from both Thailand and the Philippines answered that "parallel clinical trial application" had positive impact. And seven interviewees agreed with my idea that the "parallel clinical trial application" contributed the reduction of timeline. From the interviewees, other factors which impact the timeline of clinical trial start-up were pointed out.

Conclusion:

In this research, it was found that the "parallel clinical trial" application positively impacted the MRCT number since it reduces the timeline to start the clinical trials. However, I did not find any regulations and laws that reduced the number of MRCTs. Further investigation is desired to expand wider range of factors. (483 words)

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