Pharmaceuticals and Medical Devices Agency (PMDA)
独立行政法人　医薬品医療機器総合機構

PMDA Takes Further Steps to Speed up Clinical Development of COVID-19 Products

10 April, 2020

The PMDA plays a key role in facilitating the development of medical products, and this becomes more important if the products are in urgent need, such as those for COVID-19. As announced last month, The PMDA has already taken several actions for acceleration on clinical development of COVID-19 candidate products. We also recognize that it needs our continuous commitment to combat this devastating pandemic. Today, I would like to provide update with latest information on how the PMDA has been taking additional steps in response to the novel coronavirus outbreak since our last announcement.

1. Q&A on how to manage clinical trials during the COVID-19 pandemic

On 27th March, a Q&A document on how to manage the conduct of clinical trials in the context of COVID-19 pandemic was published on PMDA's website. It provides information on alternative measures that can be taken by the sponsor and/or clinical trial site when the process predetermined in the study protocol is not deemed feasible due to the COVID-19 situation, e.g. in cases where trial participants cannot visit the clinical trial site to receive study drugs, devices or other medical products used in clinical trials. In any situation, protection for the safety of trial participants should be given first priority, and any changes/deviations from the study protocol should be well documented.

This Q&A document is periodically updated and available here in Japanese.

2. IRB meetings may be held in an exceptional way

As of 1st April, the Administrative Notice was issued by the Research and Development Division of the Health Policy Bureau and the Pharmaceutical Evaluation Division and the Medical Device Evaluation Division of the Pharmaceutical Safety and Environmental Health Bureau, MHLW, to allow flexibility in the methods to hold Institutional Review Board (IRB) meetings. IRB is a group to review study protocols and related materials to safeguard ethical conduct and participants' rights in clinical trials. An IRB meeting has to be held before the start of a clinical trial, and it is usually held in person at the clinical study site or other relevant institution. The Administrative Notice allows IRB meetings to be held in a way other than usual manner, i.e. via email or virtually. This is only applicable when the IRB meeting needs to be held immediately to enable a quick start of clinical trials for COVID-19 candidate products. When an IRB meeting was held this way, its actual process and conduct should be well noted.

These are just a part of our efforts to tackle this global threat. Recently, the PMDA participated a virtual meeting held under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA) to discuss regulatory considerations related to the development of SARS-CoV-2 vaccine candidates and treatments. Through these ongoing commitment at national and global level, the PMDA continues to take every necessary step in order to assist faster access to products for COVID-19.

FUJIWARA Yasuhiro, MD, PhD

Chief Executive

Pharmaceuticals and Medical Devices Agency