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COMMENTARY

Ethics and practical mitigations for ongoing clinical trials during the COVID-19 pandemic

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Abbreviations

AE	Adverse event
CGM	Continuous glucose monitoring
COVID-19	Coronavirus disease 2019
SAE	Severe adverse effect

The recent pandemic of Coronavirus disease 2019 (COVID-19) has markedly affected the health care system and society worldwide. Now, we have to carefully consider the balance between ethics and regulations to continue ongoing clinical trials and practical mitigations to rescue study participants.

Indeed, securing the safety of the study participants should come first, as stated in the Pharmaceuticals and Medical Devices Agency (PMDA), Japan Pharmaceutical Manufacturers Association (JPMA) and U.S. Food and Drug Administration (FDA) guidelines [1–3]. Securing the safety of health care providers and study-related personnel is also important. What are the ethical considerations regarding continuing ongoing clinical trials in such an emergency? One of the requirements to justify the continuation of ongoing clinical trials is that the study participants are not exposed to the additional risk of being infected by COVID-19. To enable this, satisfactory actions are required to minimize the frequency of actual study site visits as much as possible in order for subjects to stay home, and be safe and well. Examples of practical mitigations in clinical trials collecting electronic data, such as continuous glucose monitoring (CGM), and the pros and cons are listed in Table 1.

It is possible that some of the study participants will decide to withdraw consent to be involved in the clinical trials because of the COVID-19 pandemic. Such decisions must be respected; however, it is important to keep the records due to the COVID-19 pandemic for later purposes. The same applies to all deviations such as the delay of study visits or missing data due to the COVID-19 pandemic.

Clinical trials require a great amount of time and resources to prepare, execute, and analyze, but the safety of study participants, health care providers, and study-related personnel must be secured. Moreover, if continuation of the ongoing clinical trial can be ethically justified after sufficient mitigations, endeavors to complete the clinical trial should be encouraged.

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Table 1 Examples of practical mitigations for ongoing clinical trials during the COVID-19 pandemic

	Pro	Con
Change study visit from physical visit to over the phone or internet	• Reduction of the infection risk • Electronic data, such as those of CGM, can be retrieved by alternative methods	• Difficulty in blood sampling • I ncreased chance of missing risks
Extend the interval between visits	• Reduction of the infection risk • Give a sense of security	• Prolongation of the total study period • Possibility for increased incidence of AE and SAE • Increased study cost
Give up secondary outcomes	• Primary outcome may be rescued	• Damage to the study quality

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Compliance with ethical standards

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Ethics policy This article does not contain any studies with human or animal subjects performed by any of the authors.

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