

第190回国会（常会）に提出された 臨床研究法案第3条に規定する 「臨床研究実施基準」等に関する提言について*

（一財）医薬品医療機器レギュラトリーサイエンス財団

Proposals on “Clinical Research Implementation Standard” stipulated in Article 3 and other issues of the Draft Clinical Research Act submitted to the 190th Diet (Ordinary Session)

Pharmaceutical and Medical Device Regulatory Science Society of Japan

Abstract

The Draft Clinical Research Act was submitted to the Diet and recently, the relevant committee adopted it unanimously. Early enactment is highly anticipated. However, many important points are delegated to the Ministerial Ordinances of MHLW (Ministry of Health, Labour and Welfare). The most important one is stipulated in Article 3 of the Act, which is “Clinical Research Implementation Standard”.

We have articulated 3 points as follows:

1) Required Level for the Standard.

The Standard must comply with ICH-GCP. In US and EU, they require following ICH-GCP in conducting clinical trials involving unapproved medicines. It is quite natural to require the GCP.

2) How to make use of the results of clinical trials conducted according to the Standard.

If the results from clinical trials can only be utilized by submitting academic articles, it means a huge waste of limited resources. Therefore, the Standard must be those according to which results from clinical trials can be used in regulatory submissions under PMDA Act (Pharmaceuticals and Medical Devices Act). The path to use these results for submission must be clearly specified.

3) More involvement of PMDA in the implementation of the Act.

In the draft, PMDA is assigned only the task of sorting and investigating the information on suspected adverse reactions that occurred. However, PMDA’s ample experience and know-how on review, pharmacovigilance, acceptance of clinical study notification, and investigation based on J-GCP, etc. must be utilized more.

The above proposals must be seriously taken into account for the sake of not only efficient use of resources, but many patients eagerly waiting for necessary medicines.

Key words

Clinical Research Act, Clinical Research Implementation Standard, ICH-GCP, Pharmaceuticals and Medical Devices Act (PMD Act), PMDA (Pharmaceuticals and Medical Devices Agency)

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