解　説

FDAガイダンス「臨床試験のためのアダプティブ・デザイン」概要とアダプティブ・デザイン概論

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Outline of the FDA guidance on adaptive designs for clinical trials: With an overview of adaptive designs

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Abstract

Though adaptive designs have roots in biostatistical researches done in 1960s to 70s, their application to clinical trials were facilitated only after publication of a series of administrative documents by the United States Food and Drug Administration (FDA) in 2000s which pointed out the sharp decrease of the number of launch of new drugs contrary to the steep rise of costs of research and development on them. In November 2019, the FDA finalized a Guidance for Industry, entitled "*Adaptive Designs for Clinical Trials of Drugs and Biologics*" as the required revision stated in the 21st Century Cures Act of 2016. The guidance, consisted of nine chapters, was jointly prepared by the Office of Biostatistics in the Center for Drug Evaluation and Research (CDER) and the Division of Biostatistics in the Center for Biologics Evaluation and Research (CBER) at the FDA to clarify important principles of adaptive designs for clinical trials to provide evidence of the effectiveness and safety of drugs or biologics. Clinical trials with adaptive design should comply with four key principles: 1) the chance of erroneous conclusions should be adequately controlled, 2) estimation of treatment effects should be sufficiently reliable, 3) details of the design should be completely prespecified, and 4) trial integrity should be appropriately maintained. To help readers understanding the guidance, we explained an overview of adaptive designs in this article.

Key words
clinical trial design, governmental guidance, commentary, research integrity

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