

臨床試験データ共有の現状と展望

— データを繋ぐ倫理性, 信頼性, 利用可能な技術 —

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Actual status and future perspective of clinical trial data sharing

— Ethics, credibility, and available technology for trial data linkage —

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Abstract

This article is a record of round-table discussion on the actual status and future perspective of clinical trial data sharing (CTDS), focusing technical aspects of data sharing platform, as well as de-identification of trial participants.

Along with the international situation to promote CTDS, e.g., statement of the International Committee of Medical Journal Editors (ICMJE) to require manuscripts submitted to their member journals as of 1 July 2018 to contain data sharing statement; to include data sharing plan in the trial's registration of clinical trials beginning enrollment of participants on or after 1 January 2019, related organizations e.g., international and domestic pharmaceutical company's associations have developed infrastructure for CTDS.

In this article, discussants from companies and academic research institutes introduced how CTDS could be realized and how these data could be utilized, assuring privacy protection and data security of clinical trial participants.

Key words

clinical trial data sharing (CTDS), International Committee of Medical Journal Editors (ICMJE), Pharmaceutical Users Software Exchange (PhUSE), data linkage, individual clinical trial participant-level data (IPD)

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