

ICMJE 臨床試験データ共有の声明の 背景と今後の課題

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On the ICMJE clinical trial data sharing statement: Its background and summary of its issue

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Abstract

Background : In January 2016, the International Committee of Medical Journal Editors (ICMJE) proposed a draft report (Proposal) on clinical trial data sharing (CTDS) for public consultation. After that, in June 2017, the ICMJE issued a statement (Statement) on CTDS; however, the reason why it was issued needs further explanation.

Methods : Non-systematic, narrative review of literature concerning the ICMJE statements and CTDS.

Results : In comparison of the Proposal and Statement, both of them lack a description on the disadvantages of CTDS. The Statement clearly specified 7 items on data sharing to be disclosed in any manuscripts reporting the results of clinical trials submitted to the ICMJE journals. Advantages of CTDS explained in the Proposal are mainly endorsing research integrity which are in line with past activities of the ICMJE. Many academic -pharmaceutical organizations, as well as a regulatory authority and prestigious medical journals, already have fostered a CTDS policy. Recent progress of individual participant data meta-analysis (IPD-MA) demands CTDS.

Conclusions : CTDS might improve both the transparency and integrity of clinical trials and quality of meta-analysis.

Key words

clinical trial data sharing (CTDS), individual participant data (IPD), research integrity, editorial policy

Rinsho Hyoka (Clinical Evaluation). 2017 ; 45 : 481-92.