原　著

治験関連文書における電磁的記録の活用について

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The application of electromagnetic record to the Clinical Trial-related Documents for the conduct of a clinical trial

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Abstract
Objective：This study aims to propose the application of electromagnetic means to deliver and retain the Clinical Trial-related documents for the conduct of clinical trials (“the CT-related Documents”) in accordance with the current regulations.
Methods：This was performed through the interpretation of the related ordinances and the discussion about them. The study was supported by the Health and Labour Sciences Research Grants 2012 (Research on Regulatory Science of Pharmaceuticals and Medical Devices).
Results：It was clarified that some of the CT-related Documents could be delivered and retained by electromagnetic means under the current regulations. It is due to the special characteristics of the documents; sponsor and investigator shall appropriately retain the same documents, providing the authenticity of the documents. The check points to cover their readability and their preservability are also provided. As one example, the application of the electromagnetic means to the procedure and the records of an Institutional Review Board (IRB) is presented.
Discussion：Even though the use of electromagnetic handling of the CT-related Documents is limited under the current situation, it is expected that this will improve the efficiency of the clinical trial in the future.
Conclusion：Under the current regulations, a portion of the CT-related Documents which satisfy some special conditions can be handled by electromagnetic means.

Key words
electromagnetic record, Clinical Trial-related Documents, clinical trial, institutional review board (IRB)

Rinsho Hyoka（*Clinical Evaluation*）2013；41：209-40.