

# 治験関連文書の電磁的記録の活用における 統一書式のファイル名称について

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## The consideration about the file name of the unified form in the application of electromagnetic records of Clinical Trial-related Documents

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### Abstract

The standards to deliver or retain some of the Clinical Trial-related Documents by electromagnetic means under the current regulations is illustrated by the Memorandum from the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare. The nomenclature of the file created by the unified form is also shown in the Memorandum. However, the current nomenclature is not sufficient to identify the contents of the filename easily. This study shows that the addition of the version number of the form, the identifier of the subject, and the report number to the filename based on the Memorandum makes it easier to identify its contents.

### Key words

unified form, electromagnetic record, version number, identifier of the subject, report number

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