

# 日本における治験補償ガイドラインの改定

## — 改定の経緯と最近の質問に対する見解 —

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## Revision of Clinical Trial Compensation Guideline in Japan

### — History of revisions and our thoughts on recent questions —

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### Abstract

In Japan where detailed governmental regulations on compensation for clinical trial-related injury did not exist, an industry's voluntary Compensation Guideline was established by the Japan Pharmaceutical Industry Legal Affairs Association (JPILA) to address the trial sponsors' new responsibilities under Good Clinical Practice Ordinance to pay compensation to trial subjects in 1999 and has been used to handle compensation claims by subject patients since then.

In August 2015, JPILA made a 2nd revision to respond to inquiries and requests from various stakeholders, which includes updating compensation standards, simplification of payment procedures, and clarification of ambiguous statements.

In this paper, we will provide (i) the history of the Guideline, as well as the background for the revisions thereof; (ii) answer to inquiries we received after we published the latest Guideline in last August; and (iii) information on JPILA's establishment of a special committee to provide its member companies with good and clear explanations of the Guideline.

### Key words

compensation, clinical trial, trial-related injuries, compensation guideline, GCP ordinance

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