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抗悪性腫瘍薬の臨床データパッケージ分析からみる今後の課題

平川 晃弘[*,#], 木下 文恵[*], 森 由美子[*], 清水 忍[*]

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Underlying Issues in Clinical Data Package of Oncology Drugs

Akihiro HIRAKAWA[*,#], Fumie KINOSHITA[*],
Yumiko MORI[*] and Shinobu SHIMIZU[*]

Summary

Clinical development of oncology drugs in Japan is based on the guideline for clinical evaluation of oncology drugs published by the Ministry of Health, Labour and Welfare in November 2005. Under this guideline, the submission of phase 3 trial results is required to obtain approval of the indication for a specific cancer (e.g., non-small cell lung, gastric, colon, or breast cancer).

In this study, we analyzed the clinical data packages of 106 oncology drugs approved between April 2004 and March 2015 to identify potential issues regarding the clinical data packages submitted for drug approval. We categorized the clinical data packages into 10 types according to the type of clinical trial and evaluated the associations of the package types with fiscal year, drug type (molecularly targeted agent [MTA] or non-MTA), application (new drug application [NDA] or supplementary NDA), cancer type (solid or hematologic), and orphan drug designation (yes or no).

We identified two underlying issues in oncology drug applications, as follows: (1) whether a phase 1 trial in Japanese patients is necessary in the case of a supplementary NDA; (2) whether a phase 2 trial in Japanese patients is necessary when the clinical data package includes a phase 3 trial conducted outside Japan.

Key words

Oncology, Clinical data package, Clinical development, Drug application