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実施済み海外第 III 相試験の申請時利用のための条件**

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How to Apply Data from Phase III Studies in Non-Japanese Patients in the Japan NDA Package?

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Summary

With the new guidelines on clinical development of anti-cancer agents issued in Japan last year, it is expected that number of Japan new drug applications (NDAs) with multinational phase III data that include non-Japanese and/or Japanese patients will increase.

However, the questions of how to use non-Japanese data in the Japan NDA package and how to clarify the minimal requirements have not been resolved. EFPIA-Japan discussed issues experienced in planning, study conduct or CTD writing for NDA packages that include non-Japanese data. EFPIA-Japan proposes that industry, government and academia should collaborate to develop supplemental guidance on how to apply data of phase III studies in non-Japanese patients in Japan NDA packages, i.e., these three groups should work together to identify the minimal requirements for supplemental studies in Japanese patients or essential elements to be addressed in the Japanese NDA package.

Key words

NDA (New Drug Application), CTD (Common Technical Document), EFPIA-J, TFT, The new guideline, Global phase III, Japan NDA package, Guidance