

感染症予防ワクチンの臨床試験ガイドラインの改訂に伴う課題と対応策の検討

奥本 温子*^{1, *2, #}, 野村 由美子*^{1, *3}, 安藤 剛*², 鹿野 真弓*^{1, *4}, 岡部 信彦*⁵

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Addressing Practical Issues in the Smooth Implementation of Revised Guidelines for Clinical Studies of Vaccines for Infectious Disease Prevention

Atsuko OKUMOTO*^{1, *2, #}, Yumiko NOMURA*^{1, *3}, Tsuyoshi ANDO*²,
Mayumi SHIKANO*^{1, *4} and Nobuhiko OKABE*⁵

Summary

Potential practical issues that could facilitate the smooth implementation of the revised “Japanese Guidelines for Clinical Studies of Vaccines for the Prevention of Infectious Diseases” are discussed, based on public comments on the draft guideline revision and gap analysis with the WHO, FDA, and EMA guidelines. Major issues were identified, including the necessity for Phase I studies on pediatric vaccines in healthy Japanese adults and points to consider in clinical trials of combination vaccines. In the development of pediatric vaccines, studies on healthy Japanese adults can be omitted if the necessary information (tolerability, initial study of dosage, administration, etc.) has been obtained from overseas healthy adult studies or if the vaccine has been used extensively overseas. In the case of combination vaccines, if some of the antigens are less immunogenic than those in the control group, one option would be to consider the threshold required for protection in terms of clinical impact. The results of this study will be presented in Q & As published by the Japanese Ministry of Health, Labour and Welfare. The findings of the present study are expected to facilitate the harmonized development of vaccines globally.

Key words

Vaccines, Infectious disease, Clinical study guidelines, Combined vaccine, Japanese phase I trial