特別インタビュー

Dr. Robert Templeインタビュー：米国FDA医薬品評価の方針について

― プラセボ対照試験，効果比較研究の倫理と科学 ―[*1]

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Interview with Dr. Robert Temple on drug evaluation policy of FDA

― Ethics, science of placebo-control and comparative effectiveness studies ―

Interview and translation: Chieko Kurihara
Molecular Imaging Center, National Institute of Radiological Sciences (NIRS)
(June 13, 2014, Washington D.C., United States)

Abstract

This is the record of an interview with Dr. Robert Temple, Deputy Director for Clinical Science of the Center for Drug Evaluation and Research (CDER) and also Acting Deputy Director of the Office of Drug Evaluation I (ODE-I), Food and Drug Administration, U.S. Department of Health and Human Services.

Dr. Temple is one of the key-persons in the international debate on the ethics and science of placebo-controlled clinical trials, who greatly contributed to the ICH-E10 guidelines on the choice of control group, as well as 2008 revision of the Declaration of Helsinki, for its paragraph of the use of placebo control. In addition to this subject Dr. Temple has for a long time played a very important role in the establishment of FDA's philosophy and policies on clinical science, and has had an important role in many CDER and ICH guidances (ICH E-3, E-4, E-5, E-7, E-10, and E-14).

The wealth of ideas about clinical trial design discussed here could contribute to future perspectives that might contribute to more attention to individualized medicine, shifting the mega-pharma-approach of "one-size fit all."

Key words

U.S. Food and Drug Administration, placebo controlled clinical trial, comparative-effectiveness study, enrichment study, clinical science

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[*1] 本インタビュー記事は，本誌ホームページで英語版を掲載する（http://homepage3.nifty.com/cont/42_2/p539-51.pdf）.

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