

シンポジウム

第2回早期臨床試験国際会議 — 世界をリードする効率的な開発戦略 —

主催：早期臨床試験国際会議
共催：J-CLIPNET（グローバル早期臨床試験推進のための大学病院ネットワーク）
昭和大病院臨床試験支援センター
後援：日本臨床薬理学会
(2012年2月18日(土) 於：財団法人アクロス福岡 国際会議場)

委員長：内田 英二*
(昭和大研究推進室・昭和大病院臨床試験支援センター)

The 2nd International Symposium of Early Stage Clinical Trial Efficient developmental strategy that leads the world

Organized by : International Symposium of Early Stage Clinical Trial
Co-organized by : J-CLIPNET (Japan Clinical Pharmacology Network for Global Trials)
Clinical Trial Support Center, Showa University Hospital
Under the auspices of The Japanese Society of Clinical Pharmacology and Therapeutics

The Head of the Executive Committee : Eiji Uchida
Office for Promoting Medical Research, Showa University
Clinical Trial Support Center, Showa University Hospital

Abstract

Recently, a large number of clinical trials have been performed in Eastern Europe, South America, and Asian nations. In particular, the progress in Asian countries has been extraordinary. The number of participation in global clinical trials has increased in Japan at a later phase of drug development with the use of EDC. However, it is also true that Japanese people involved in global trials are puzzled by the differences in extrinsic ethnic factors, such as, culture, medical care settings, medical practice, execution procedure, and language, etc. There is room for improvement in these factors by participation in protocol making to recognize and understand these differences. After the entire development is considered, the developmental strategy from the early phase is required to improve such a situation from a long-term viewpoint. Although many people make an effort of a current improvement, the issue is understood by subtracting the current state from the ideal. In this symposium, I invited Professor Kumagai for the plenary session aiming to examine the direction for demonstrating the power of our country. He has conducted many early stage clinical trials and also has performed joint research in Asian countries. In the 1st session, Drs. Hayashi and Miyoshi introduced the development and the usefulness of pharmacometrics as one of the decision making tools during drug development. In the 2nd session, four speakers introduced new approaches and strategies of medical institutions and a pharmaceutical company.

It is my pleasure to share with you the wide spectrum of opinions and ideas presented at this symposium.

Key words

global clinical trials, early phase, extrinsic ethnic factors, pharmacometrics, developmental strategy

Rinsho Hyoka (Clinical Evaluation) 2013 ; 40 : 285-337.

* J-CLIPNET メンバー