シンポジウム

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第3回早期臨床試験国際会議
― 患者を対象とした早期臨床試験 ―

主催：大分大学医学部附属病院臨床薬理センター
聖マリアンナ医科大学薬理学・聖マリアンナ医科大学病院治験管理室
共催：一般社団法人臨床薬理試験推進ネットワーク
後援：一般社団法人日本臨床薬理学会
公益社団法人日本医師会治験促進センター
日本製薬工業協会

（2013年2月2日（土） 於：県民共済みらいホール）

幹事：松本　直樹
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The 3rd International Symposium of Early Stage Clinical Trial
Early stage clinical trials on patients

Organized by：Clinical Pharmacology Center, Oita University Hospital
Department of Pharmacology, St. Marianna University School of Medicine
Clinical Trial Support Unit, St. Marianna University Hospital
Co-organized by：Japanese Network of Clinical Pharmacology
Under the auspices of the Japanese Society of Clinical Pharmacology and Therapeutics,
Center for Clinical Trials, Japan Medical Association and Japan Pharmaceutical Manufacturers Association
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The Organizer of the Executive Committee：Naoki Matsumoto
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Abstract

Outcome report of core clinical research center at Oita University has been addressed in the opening of the session. This institute is the leader of the clinical pharmacology institutes network, which will handle difficult clinical research on rare diseases. The first part of the session has been held for knowledge sharing and discussion for the surrogate endpoint setting. Multiple Sclerosis (MS) is one of the most difficult diseases to be evaluated for possible treatment, because of its complexity in the clinical symptoms and their course with its long and slow progression. HAM (HTLV-1 Associated Myelopathy) and other neurological disorders are also very difficult to be evaluated, thus the presentations from the expert physicians/investigators on these diseases were valuable. Utilization of biomarkers and setting the surrogate endpoint were discussed among the investigators including an expert from a pharmaceutical company. The second part of the session handled the novel field of regenerative medicine. It has grown very rapidly, almost reaching the clinical trial stage. This means that the experts on clinical trials will have to conduct many trials on the regenerative medicine quite soon. Thus basic knowledge sharing and further discussions were held. Adipose-derived regenerative cell was the center of the discussion, because this material has already reached the bed side stage as a trial. Session presentation included the basics and clinical presentation on Critical Limb Ischemia (CLI), and also the discussion extended to the regulatory issues, together with investigators and a regulatory authority member, because this field still involves on-going regulatory problems and also promotion initiatives.

Key words
clinical research, biomarker, evaluation, endpoint, regenerative medicine

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