Global Clinical Trials (GCTs) based NDA in Japan Increased Year-On-Year

February, 2014
Issue 1

Japan is the second largest individual market in the world after U.S characterized with sustainable growth and optimistic future outlook. However, foreign sponsors hesitated for Japanese market because the exclusion of foreigner' data, different interpretation of GCP and language barriers.

In 1998, Japan's regulatory authority, Pharmaceutical and Medical Devices Agency (PMDA) adopted the International Conference on Harmonisation(ICH) "Guideline on Ethnic Factors in the Acceptability of Foreign Clinical Data" and established operation procedures of multinational data in Japan. Furthermore, in 2007, PMDA approved a new guideline "Basic Concepts for International Joint Clinical Trials". The guideline expands application criteria for accepting non-Japanese clinical data and encourages international joint clinical trials.

With the improving regulatory environment, since 2007 foreign data has reached more than 50% of data-packaging for regulatory application in Japan. In addition to the increment of bridging-based New Drug Application (NDA), GCTs based NDA also increased year-on-year and reached 15% of total NDA in 2012 as shown in Fig.1

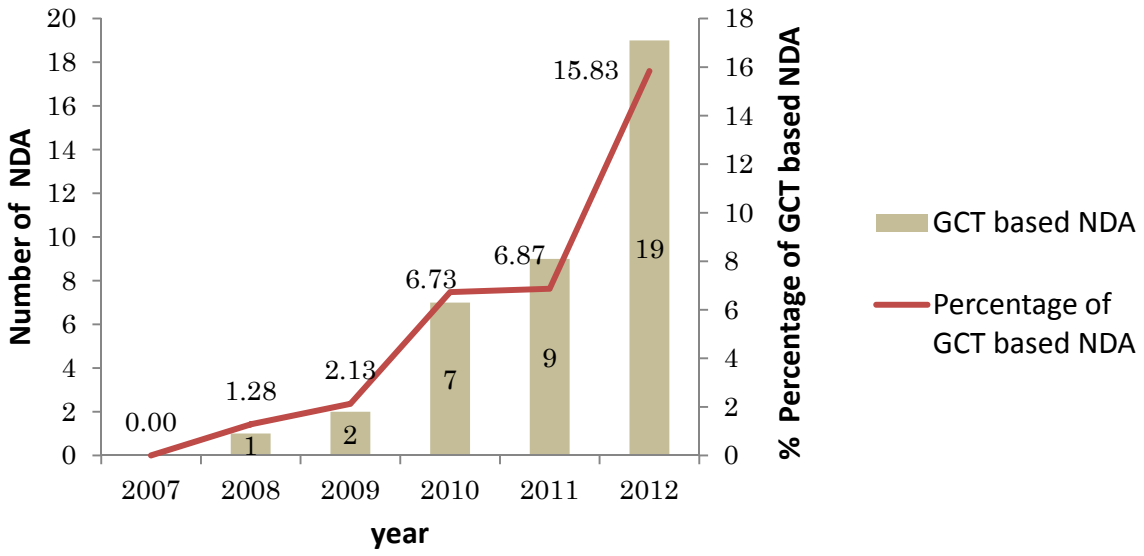

Fig1. Increment of GCT-based NDA

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To take advantage of these opportunities, DOT International provides one-stop services for foreign sponsors. We tailor the optimal Japanese clinical development plans, and lead successful regulatory negotiation which firmly speeds up the regulatory approval and draw down your development cost.

Reference

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http://www.jpma.or.jp/information/evaluation/allotment/pdf/shouninhinmoku_1_20130724.pdf

About DOT INTERNATIONAL

DOT International is a Japanese full-service CRO providing best gateway to Japanese pharmaceutical market. We are experienced with PMDA negotiation which speeds up your clinical development in Japan.

Our mission is to shorten the time–line for the clinical development of medicines and medical devices for their manufacturers as well as patients in need.
We contribute to the early launch of new medicines, new devices and EBM through the execution of clinical trials. We are eager to serve an important role in successive developmental processes.
For more information, please visit http://www.crodot.jp/english/index.html

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