【GDA Forum Report】

International Committee members: Michie Mochizuki from EIDIA
Tamotsu Tadokoro from Sysmex
Kimiyo Shono from SHIONOGI
Hitoshi Nishiumi from Sysmex

GDA Forum 2015 was held in Goethe Institute Tokyo on Thursday, May 28, 2015 from 1:30 p.m. Main theme of the forum was "Development of regulatory systems and Prospect of Genetic test progress".

Firstly, Mr. Tetsuya Teramoto, the chairperson of JACRI（Japan Association of Clinical Reagents Industries）, addressed on the opening speech. GDA works for enhancing the value of IVD and gaining recognition of IVD from the public and medical workers. To achieve the aim of GDA's activities, the forum had been planned under the theme of genetic test progress as part of activities. After that representatives of academia, the government, and GDA associates from overseas gave their presentations.

【Dr.Tsutomu Nobori: Emeritus professor of Medical Faculty in Mie University】

Dr. Nobori talked about four issues which Japanese society and medical field are facing under the theme of "What are required to advance Precision Medicine in Japan?" Aging society is progressing in Japan at faster speed than any other countries in the world, so advancement of medical technology is remarkable. Our aging society has brought us tax increase, self-pay ratio, and medical fees to secure social security expenses.

Our society needs the specific ideas of legal restraints and establishment of a third-party institution to solve following four issues.

1. The reimbursement of medical fees is unclear and is not decided by Health Technology Assessment.

2. Human genetic test is applied to the reimbursement system. However, medical service fees vary from IVD to Home Brew Assay.

3. The link of companion diagnostics and molecularly-targeted therapy is unclear i.e., an applicable diagnostics procedure of ALK inhibitor which is used depending on original brand name or generics.

4. Current registration standard of clinical laboratories is not enough to conduct advanced genetic examinations. Therefore, the effectiveness of advance medical services is inadequate.

【Dr.Sumimasa Nagai: The Institute of Medical Science in The University of Tokyo】
Dr. Nagai reported on the activities of working group for companion diagnostics established in April, 2012 in PMDA under the theme of "The Prospect and the Challenge for Personalized Medicine and Diagnostics in Japan." As the activities, following issues were addressed that were the definition of companion diagnostics, the improvement of biomarker in clinical studies, and the information of companion diagnostics in drug classification. The guidance for the definition and the progress of companion diagnostics was released to regulate these issues. Moreover, results of their activities showed Japanese regulations for companion diagnostics and patient selection based on biomarker have consisted with those in EU. On the other hand, Japanese regulations for NGS clinical evaluation must be established.

【Ms. Tharini Sathimorthy: Vice-chairperson of AdvaMedDx】
Ms. Tharini mainly talked about the trend of LDT restriction under the theme of "Regulation of Molecular Diagnostics in the United States." When LDT was started in laboratories, FDA did not control it because LDT was considered a low risk test.

However, recently LDT has included complex and high risk test items more than genetic tests, so FDA has been improving the regulatory systems with risk-based thinking. FDA issued the guideline draft of LDT in 2014, and they have been discussing with related groups about the LDT regulations.

【Mr. Jesus Rueda Rodrigeuz: Director International Affairs, EDMA, Europe】

Mr. Jesus explained how the regulatory amendments of IVD being promoted in EU would effect on genetic testing under the theme of "IVD Regulatory Amendments in EU and Influence to Molecular Test Market." Companion diagnostics has classified C and regulated severely by regulatory amendments. As a result, submission of clinical evidence and the involvement of certification bodies must be required. However, the certification process has a lot of controversial issues such as consistency with approval of related pharmaceutical products. Moreover, the development of Health Technology Assessment guideline for IVD is under consideration, and In house assay corresponding to LDT will be under control.

【Mr. Fabio Arcuri de Carvalho: President of CBDL, Brazil】

The theme of Mr. Fabio was "Molecular Biology and Other Innovative Products: How to pave the Way to assure Access in Developing Countries?" He said from the perspective of developing countries that Brazil needs global consistency with their regulations and product quality to introduce the latest products into their market. Regulatory authorities of Brazil and other Latin American nations make various efforts to ensure consistency with global rules.