In-vitro Diagnostics (IVD)

IVD were first defined in 1985 under the Pharmaceutical Affairs Law. Since then, laws and regulations for IVD and insurance coverage rules for medical fees have been developed. Along with progress in testing technology and shifts in social and medical environments, the value and positioning of clinical testing have significantly changed. IVD are not only used for disease prevention, diagnosis, decision on treatment policy and clinical monitoring of prognosis, but also for various clinical settings for purposes other than diagnosis, such as companion diagnostics (CoDx) to stratify patients for drug administration.

Looking back over the past decade, as innovations in the IVD field that have made significant contributions to improving patient outcomes, we introduce CoDx and tests before medical examination.

The advent of CoDx

CoDx is a biomarker testing IVD used mainly for predicting the efficacy and safety of a drug and optimizing the dose of a drug in pharmacotherapy including anticancer drugs. It is expected to be widely used in future medical care, and to be indispensable for personalized medicine, enabling selection of treatments and medications suited to individual patients.

Pharmaceutical companies and diagnostics manufacturers develop a drug and CoDx concurrently, and market them almost simultaneously after PMDA review. This requires unprecedented innovative development process, review process, and insurance coverage based on a new idea. Thus, diagnostic manufacturers created a new process in collaboration with pharmaceutical companies, and the PMDA / MHLW. Since 2012 when the first CoDx was approved as an IVD, several CoDxs have been approved and covered by insurance.

The introduction of testing before medical examinations

Testing before medical examination is clinical testing performed prior to medical examination by doctors for outpatients. The patient sees the doctor after the test results are obtained. With the introduction of this testing, test results are available in a timely manner, and patients can receive appropriate treatment without revisiting the hospital to verify the test results or take additional tests. This resulted in changes in patient behavior and daily living since social activities are not restricted due to hospital visits.

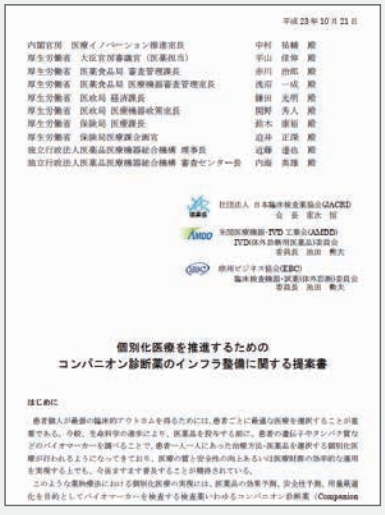
Testing before medical examinations was introduced in the clinical setting more than 10 years ago. Diagnostics manufacturers not only pursued the automation and shortening of testing time, but also requested Chuikyo to add points of outpatient rapid clinical testing within medical fees, in cooperation with academic societies related to clinical testing. In 2006, a new calculation was implemented. Initially, one point was added for each item, up to 5 items. However, test-related academic societies, manufacturers, and industry groups pressured the government, and the calculation was changed to the addition of 5 points for each item in 2008, and the addition of 10 points for each item in 2010. We were also successful in our policy guidance to implement tests before medical examinations for medical institutions.

The two examples above were achieved through a combination of innovation in the regulatory system related to clinical testing and innovation in testing technology. Above all, innovation of the regulatory system could not have been achieved without collaboration between industry groups such as the AMDD and stakeholders.

To contribute to a prolonged healthy life span, we continue with our activities to improve testing technology and design and optimization of the regulatory system including the introduction of a specimen measurement room (2014), and addition of an item for OTC IVD for the first time in 25 years (2016).

The role played by clinical testing will be more diversified and its continued contribution to the healthy lives of the public is expected as shown in: the Global Action Plan on Antimicrobial Resistance (AMR), which was adopted at the 2015 World Health Assembly and further mentioned at the 2018 G20 held in Argentina; the contribution from Japan's action plan; early detection of cancer with microRNA testing; and the promotion of testing information management using ICT. In December 2018, cancer-related multigene panel testing obtained the first regulatory approval in Japan as a combination medical device, and its insurance coverage began in June, 2019. Multigene panel testing has the potential to significantly change the future of medical care and people's lives. Thus, while hoping and anticipating its future development and prevalence, we will watch closely the insurance coverage of panel testing and the possibility of recalculation upon its market expansion.

A page, set up on the PMDA website for the companion diagnostics WG



Paper on a Joint Position of three IVD organizations: Proposal on Infrastructure Development for Companion Diagnostics to Promote Personalized Medical Care