



Novel, Challenge and Change

革新への挑戦と変革

国立研究開発法人 **国立がん研究センター**

**National
Cancer
Center**

**TOP-GEAR Project Aiming to Realize Genome Treatment
Genetic Testing Lab Established within National Cancer Center Hospital
Introduction of Comprehensive Genetic Testing to Select Patient
Treatments**

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National Cancer Center

The National Cancer Center (President: Tomomitsu Hotta; Location: Chuo-ku, Tokyo, Japan) has established a laboratory meeting international standards within the National Cancer Center Hospital (Director: Yasuaki Arai) to introduce comprehensive genetic testing using next-generation sequencing (NGS) for routine treatment. To date, NGS has been used only at the research and pharmaceutical development stages. Scheduled to begin operations in January 2016, the lab will conduct clinical research, through the second phase (TOPICS-2 testing) of the TOP-GEAR Project, aimed at using genetic information of cancer patients directly for selection of treating method and intends to establish cancer treatments based on genetic information.

Background

Currently, genetic testing conducted for routine treatment involves testing the effectiveness and side effects for specific drugs by studying specific genes (a process known as “companion diagnosis”). This process typically requires around two weeks to study a single gene. By comparison, comprehensive genetic testing enables multiple genes to be studied simultaneously. To date, this approach has been used in basic research and clinical research. There are numerous problems in introducing this testing for routine treatment, however, such as ensuring the reliability of testing, as well as ethical issues of handling gene information. These issues have resulted in delays in introducing this testing for routine treatment, even internationally.

Overview of the Comprehensive Genetic Testing Lab

The new comprehensive genetic testing lab, located within the National Cancer Center Hospital's Clinical Laboratories Division (which has obtained certification under the ISO^{*1} 15189 international quality standards) has been established jointly with Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu), which possesses genetic analysis and other leading-edge measurement technologies and instruments. The lab will also be operated in collaboration with

RIKEN GENESIS Co., Ltd. (HQ: Tokyo, Japan; President & CEO: Yusuke Tsukahara), which is Japan's first registered CLIA² lab, ensuring the quality of genetic analysis satisfies international standards. In conducting actual comprehensive genetic testing, for analysis we expect to use the NCC Oncopanel, a testing kit developed by the National Cancer Center Research Institute (Director: Hitoshi Nakagama), which allows around 100 genetic mutations to be studied simultaneously over a period of approximately two weeks.

Through quality certification according to international standards, we anticipate the realization of appropriate cancer treatments based on a greater amount of genetic information.

Overview of the TOP-GEAR Project

The TOP-GEAR (**T**rial of **O**nco-**P**anel for **G**ene-profiling to **E**stimate both **A**dverse events and **R**esponse by cancer treatment) Project involves studying gene abnormalities related to individual patients' clinical results and side effects. The National Cancer Center Hospital launched this comprehensive genetic testing project in 2013 in the aim of reflecting these results in treatment.

In the first phase of the project (TOPICS-1 testing), a comprehensive genetic testing system targeting 131 patients was configured and verified to confirm its utility in selecting treatments for individual patients.

The center then organized a specialized team (expert panel) of medical oncologists, clinical genetics specialists, molecular biologists, bioinformatics specialists, pathologists and bioethics specialists, which met to determine the clinical significance of the abnormalities by looking at genetic analysis and treatment information, and created a system to reflect gene abnormalities in treatment.

While this phase confirmed the usefulness of introducing comprehensive genetic testing into actual clinical practice, it also led to the realization that quality assurance of testing was essential in order to reflect diagnostic results into patient treatment selection.

In the current second phase of the project (TOPICS-2 testing), we will guarantee the quality of clinical testing of genetic analysis results by establishing a genetic testing laboratory within the hospital according to international standards. Using the expert panel and other systems created for the first phase, TOPICS-1, we will consider the use of comprehensive genetic testing in routine treatment.

For the foreseeable future, subject patients will include patients being treated at the National Cancer Center Hospital and Hospital East, with their attending physicians determining the utility of comprehensive genetic testing in treatment selection and asking the patients to participate in clinical research. Subject patients will include those who have already completed standard anti-cancer treatment, patients expected to complete treatment, orphan cancer patients and young patients in the AYA generation (15–39 years).

We aim to test around 200 cases per year, providing personalized medicine based on individual

patients' genetic information, with the objective of creating a diagnostic system to realize genome treatment.

Terminology

***1 ISO**

The International Organization for Standardization (ISO) is a body providing certification according to international standards in industrial fields outside the fields of electronics.

***2 U.S. Clinical Laboratory Improvement Amendment (CLIA)**

A CLIA lab is certified as conducting testing with quality assurance in accordance with the U.S. Clinical Laboratory Improvement Act standards. CLIA labs are required to undergo periodic inspections to ensure quality maintenance. Being registered as a CLIA lab certifies quality control for genetic testing.

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