

## がんゲノム診療体制構築に向けた取り組みと提言\*

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### An activity and proposal for genome-based cancer treatment

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#### Abstract

With the rapid progress in genome analytic methods, various attempts to construct “precision medicine” have been recently initiated. Genome-based umbrella/basket type IND (Investigational New Drug) registration studies are becoming popular for cancers with actionable gene alterations, which require a huge screening system. For this purpose, we launched a nation-wide genome screening system using a cutting-edge, next generation sequencing (NGS) panel in association with various sponsor/investigator-initiated IND registration trials, as an academia-industry collaborative consortium (SCRUM-Japan), from February 2015. The consortium will contribute to activate the development of new oncology agents possibly followed by new original global evidence from Japan, to make an infrastructure for “precision medicine”, to construct a public genome database with detailed clinical information, and to provide residual sample DNA for new drug discovery. A total of 4,500 patients with mainly lung and gastrointestinal cancers will be accrued from approximately 200 hospitals during the following two years in SCRUM-Japan. For establishing a real “precision medicine”, we are proposing government support, particularly for rare cancers, facilitating discussions with industry and regulatory authorities on how the NGS panel should be approved, and the construction of infrastructure in participating core centers such as a genome counseling system.

The nation-wide organization for genome-based precision medicine has only been established in US, UK, and Japan throughout the world. Future collaborations and data integrations with the US-NCI (National Cancer Institute) group are also under discussion for establishing the real precision medicine in the world.

#### Key words

genome-based treatment, precision medicine, NGS (next generation sequencing) panel, IND (Investigational New Drug) registration trial

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