

Provide the world's leading drugs/medical devices to the people Making drugs/medical devices the driving force of growth in Japan

Group of measures aimed at up-front development in Japan or simultaneous worldwide development with participation from Japan

- ① Intensive investment of research funds
- Focused allocation/expansion of drugs/medical devices related budget
 - Establishment of an organization to make adjustment on intensive development areas by industry, academia, and public sector.
 - Discussion on improvement/enhancement of research and development taxation system
 - Discussion on comprehensive/efficient management of research funds in special zone for advanced medical care development
 - Focused/centralized distribution of research funds related to special zone for advanced medical care development
- ② Development of venture business
- Expanding research funds
 - Joint use of facilities and devices
 - Development of industrialization support system, utilization of experienced human resources, improvement of consultation
 - Improvement of support measures for utilization of the "angel taxation" system
 - Implementation of support internationalization of Bio-Venture
 - Promotion of industrialization of new technologies that are important for national economy
 - Discussion on support for examination expenses
 - Discussion on measures to facilitate offering of medical devices

- ③ Development of environment for clinical research/trials
- Promotion of joint international clinical trials
 - Establishment of "medical cluster", a system in which National Center for Advanced and Specialized Medical Care conduct clinical research in close cooperation with industry, academia, and public sector
 - Establishment of bridging research support facilities, regenerative medicine facilities, and clinical research system
 - Utilization of facilities, networks, and IT in clinical trials led by medical clusters
 - Training/securing human resources to support doctors and clinical trials
 - Measures to improve clinical performance evaluation of doctors
 - Promotion of appropriate regulations of clinical research
 - Establishment of global clinical research facilities with central IRB functions for enabling advanced joint international research
 - Establishment of conference for dual track talk from development stage between parties on research/development side and regulation side in special zone for advanced medical care development

- ④ Cooperation with Asian countries
- Promotion of joint research on diseases of importance
 - Joint research on utilization of data collected in east Asia

- ⑤ Speeding up and quality improvement of examination
- Reducing the period before marketing for drugs by 2.5 years (elimination of drug lags)
 - Doubling the number of drug examination staff and quality improvement (increase of 236 staff members over 3 years)
 - Clarification of the examination approval processes and standards and improved execution of GCP (Good Clinical Practice)
 - Establishment of a consultation system for clinical trials for handling every consultation in timely manner
 - Discussion on the introduction of a consultation system for joint clinical trials among executives of Japan, the United States, and Europe
 - Reducing the period before gaining approval of new medical devices by 19 months (elimination of device lags)
 - Increasing the number of medical device examination staffs and quality improvement (increase of 69 members in 5 years)
 - Introduce 3-track examination system for new medical devices/innovated medical services/generic medical devices, and promote rationalization of approval examination.
 - Improving quality and quantity of consulting operation.
 - Improved execution of GCP for medical devices

- ⑥ Proper evaluation of innovations
- More proper evaluation of innovative products in drug pricing system

⑦ Government and private sector discussion

Enhanced cooperation among related ministries, research institutions, and industries

Implementation of regular government and private sector discussion