Patient Centricity Initiatives

In our Group, "Patient Centricity" means that our corporate slogan, "Passion for Innovation. Compassion for Patients.®," which embodies our shared commitment of all employees to being a source of hope for patients in their treatment journey, is at the core of our corporate activities. We continually focus on patients and strengthen various initiatives across the entire value chain to further contribute to their well-being.

Initiatives in the Value Chain

Passion for Innovation. Compassion for Patients.®

Drug discovery and research	Clinical development	Supply chain	Sales/ Information provision

Patient-oriented value chain activities and creating shared value with patients. Listening to patient's voices, promoting PPI[*1] in everything from R&D to post-marketing activities, and providing information to patients, and support their activities.

Drug discovery and research	Clinical development	Supply chain	Sales/ Information provision
Understand unmet medical needs (COMPASS[*2] activities) Promote utilization of PRO[*3] in clinical trials Example ❷ Promote patient-focused drug development (PFDD[*4]) Example ❸ ・Prepare straightforward and easy-to-understand clinical trial-related explanatory documents ・Send Thank You Letters to participants ・Prepare and publish Lay Summary[*5]	Develop new patient-oriented dosage forms, combination drugs, and LCM formulations, and improve packaging Direct to patient activities: Supply investigational drugs to the homes or nearby facilities of patients who are unable to go to hospitals due to infectious disease outbreaks or other circumstances	Provide evidence for efficacy, safety, etc. according to the needs of healthcare professionals and patients and implement a drug risk management plan Example ❶ Provide medication assistance and respond to inquiries from healthcare professionals and patients Implement an EAP[*6] and patient support program

Collaboration with patient groups and patient advocacy activities (Solutions to problems related to policies and programs from the patient's perspective, support for the educational activities of patient groups, etc.)

*1 Patient and Public Involvement
*2 Compassion for Patients Strategy. Initiatives to understand the realities of diseases and treatments, as well as patient needs through communication with patients.
*3 Patient Reported Outcome: Patient-centered endpoints focusing on QoL and patient experience
*4 Patient-Focused Drug Development
*5 A summary of clinical trial results written in plain, easy-to-understand language
*6 Expanded Access Program: A system for providing unapproved drugs in clinical trials conducted from a humanitarian perspective

❶ CSPV Initiatives to Ensure Patient Safety

The CSPV (Clinical Safety & Pharmacovigilance) Unit has set a 2030 Vision to become a "Global Unit which contributes to ensuring patient safety by providing high quality safety information in a timely manner for all products while expanding oncology products and new modality from development to post-marketing." We lead proactive safety monitoring and risk management throughout the entire product lifecycle from development to post-marketing and ensure Patient Safety.

We implement various initiatives to ensure the safety of our medicines and enable patients in need to use them as quickly as possible, while complying with regulations in each country. The concept of Patient Centricity is the fundamental principle of our safety management..

For example, we have programs that allow patients to access our products imported from overseas prior to new drug approval and market launch. Even in such exceptional cases, to ensure patient safety, we implement various measures such as conducting training for healthcare professionals, distributing materials explaining proper usage, and continuously monitoring usage conditions. These efforts ensure that treatments are administered appropriately.

Additionally, under the leadership of the CSPV Unit, we implement safety management through close collaboration with the development department, medical affairs department, and partner companies.

We tailor our activities to the regulations and conditions of different countries around the world, by collecting safety-related needs from healthcare professionals and patients in various countries, sharing those safety issues and developing safety management strategies.

In Japan, we have established an information provision system using a real-time side effects search system. This system enables us to quickly provide healthcare professionals with the latest side effects information, including detailed clinical courses for individual patients. This helps reduce the risks of side effects and improves treatment continuity for patients.

Activities of CSPV: Proactive Safety Monitoring and Risk Management

Message from the Head of CSPV Division

Medicines become truly effective only when "top-quality pharmaceutical products" are combined with the "provision of appropriate information." Additionally, no matter how excellent a drug's efficacy may be, there is no medication without the risk of side effects. It is important to analyze the safety and efficacy information of pharmaceuticals, evaluate them based on the benefit-risk balance, and provide the necessary information to ensure that our products with excellent efficacy are used appropriately. The CSPV Unit upholds the "Patient First" mindset and implements safety monitoring and risk management globally throughout the product lifecycle, from development to post-marketing. We strive to provide timely and appropriate usage information so that healthcare professionals, particularly physicians, can offer optimal treatments to patients, ensuring that patients can use our products with confidence.

Head of CSPV Division
Wada Kento

❷ Promoting the Use of Patient-Reported Outcomes (PRO)

Our Group actively utilizes Patient-Reported Outcomes (PRO), which incorporate patients' subjective assessments of symptoms, Quality of Life (QOL), and other factors into clinical trials. For Enhertu®, the PRO-DUCE study conducted in Japan demonstrated that breast cancer patients who used electronic Patient-Reported Outcomes (ePRO) monitoring via devices such as smartphones, in addition to usual care, showed a significant improvement in QOL scores compared to the usual care group. Additionally, the DESTINY-Breast02, 03, and 04 trials have also demonstrated significant control and improvement of health conditions, such as fatigue and pain, during the treatment period. Moving forward, we will continue to utilize PRO to accurately capture the patient's perspective and pursue further contributions.

❸ Patient-Focused Drug Development (PFDD) Reflecting Patients' Voices in Drug Development

Reflecting "patients' voices" in clinical trials leads to reduced burden on patients, improved understanding, enhanced quality of clinical trials, and accelerated progress, ultimately allowing new drugs to reach patients more quickly. Since 2022, we have established a specialized team within our development function dedicated to executing Patient-Focused Drug Development (PFDD) initiatives that reflect "patients' voices" in drug development. This team has built a framework for timely communication with patients and clinical trial coordinators, focusing on the review of clinical trial-related materials and actively engaging in Patient and Public Involvement (PPI). As specific examples of our activities, we not only review clinical trial protocols and informed consent forms (ICF) but also provide lay summaries and Thank You Letters[*7]. Based on the feedback from patients, we have made changes to clinical trial plans, including adjustments to in-hospital waiting times for patients, the testing schedule related to the initiation of investigational drug administration, and the relaxation of exclusion criteria. For the ICF, we addressed issues such as literal translations from English that resulted in awkward Japanese expressions, insufficient explanations of medical terminology, and sentence structures that could easily lead to misunderstandings. These improvements have been incorporated into the templates for clinical trial-related documents. Currently, PFDD initiatives are being implemented in Japan. However, we plan to expand these efforts globally by taking into consideration ICH and FDA guidelines and collaborating with our overseas Group companies. Moving forward, we will strive to contribute to better healthcare by promoting and strengthening industry-wide efforts to reflect "patients' voices" into clinical trials.

*7 A card that includes a thank you message to clinical trial participants and information about the disclosure of clinical trial results.

PFDD Framework