CHUGAI

Roche Group

# Annual Report 2020

Fiscal year ended December 31, 2020

# Activity Report

CHUGAI PHARMACEUTICAL CO., LTD.

# Contents


**Chugai in Action**

1 Chugai in Action
2 Outline of Functions
4 Response to the COVID-19 Pandemic
5 Research
7 Development
8 Pharmaceutical Technology and Production
9 Marketing
12 Medical Affairs
13 Drug Safety
15 Quality and Regulatory Compliance
16 Intellectual Property
17 Human Resources
22 Human Rights
23 Environment, Health, and Safety (EHS)
30 Social Contribution
32 Global Health

**Basic Information**

34 Basic Information
35 Basic Information on the Pharmaceutical Industry
38 Oncology
45 Bone and Joint Diseases / Autoimmune Diseases
48 Renal Diseases
49 Neurology
51 Other Diseases

**Financial Information**

55 Financial Information
56 Consolidated Financial Indicators
58 Management's Discussion and Analysis
64 Business Risks
67 Consolidated Financial Statements

# Chugai in Action

# Outline of Functions

| | Roles/Features | Strengths (○)/Weaknesses (△) |
|---|---|---|
| **Research** | ・Focusing on generating a steady stream of innovative new drugs with first-in-class[1] or best-in-class[2] potential to address unmet medical needs[3]<br>・Biopharmaceutical R&D track record of over 30 years. Currently developing antibody engineering technology and drug discovery and technology platform for multiple modalities such as small and mid-size molecules[4]<br>・Building powerful external networks with the Roche Group's world-leading research infrastructure, academia, etc.<br>・Contributing to global healthcare as a whole through presentation of research findings at scientific conferences, etc. | ○ Unique drug discovery technology in biopharmaceuticals and mid-size molecules<br>○ Collaborative system for sharing of the Roche Group's research resources and infrastructure (large-scale, high-quality chemical library, genes and nucleic acids platforms, etc.)<br>△ Infrastructure for recruiting highly specialized researchers is incomplete<br>△ Insufficient drug discovery research resources |
| **Development** | ・Establishment of a lifecycle management (LCM) system for integrated control of functions at the individual project level<br>・Conducting a wide range of clinical studies using scientific methods that combine speed with efficiency in collaboration with numerous medical institutions and clinical research centers<br>・Progressing with wide-ranging global development (global studies) and simultaneous development of drugs and companion diagnostics intended for personalized healthcare (PHC) through alliance with the Roche Group, resulting in advanced development projects and related approval applications<br>・Coordinating with medical professionals and patient groups from the clinical development stage to realize patient-centric healthcare | ○ Extensive development track record across a wide range of diseases<br>○ Track record in development of new molecules using proprietary technology<br>○ High success rate in the in-house development of innovative products<br>○ System for global collaboration with Roche<br>△ Constant and cross-functional operation of the process for proof of value<br>△ Infrastructure development and acquisition of human resources for utilization of real world-data (RWD), data assets, and cutting-edge technologies |
| **Pharmaceutical Technology and Production** | ・Putting in place a worldwide supply chain encompassing production bases and contract manufacturing organizations<br>・Evolving manufacturing functions based on Japan-leading bioproduction technologies, manufacturing facilities and inspection capabilities, and the advantage of Roche Group membership<br>・Building and patenting technology platforms aimed at commercial production of innovative medicines such as next-generation antibodies and mid-size molecules | ○ Advanced therapeutic antibody production technology and state-of-the-art equipment<br>○ Proven track record of global inspections and applications (Hemlibra, Alecensa, and Enspryng)<br>○ Timely identification and response to requests from regulatory authorities that can be shared with the Roche Group<br>△ Creation of an efficient production system utilizing external resources in accordance with rapid changes in demand |
| **Marketing** | ・Contributing to the advancement of healthcare as a leader in the fields of therapeutic antibodies and oncology, including promoting standards of care and proper use of medicines<br>・Working for widespread introduction and advanced development of PHC as a pioneer in the field<br>・Conducting consulting activities including flexible provision of specialist information, liaison services for regional healthcare, and support to healthcare professionals | ○ Leading presence in specialty areas, such as biopharmaceuticals and PHC<br>○ A system for providing advanced solutions based on regional and customer characteristics, multidisciplinary team care and drug safety activities utilizing a database of adverse events, etc.<br>△ Increase in competing products and new market entrants |

## Outline of Functions

| | Roles/Features | Strengths (○)/Weaknesses (△) |
|---|---|---|
| **Medical Affairs** | ・Strengthening systems for healthcare compliance and governance of contract-based post-marketing studies, including by becoming one of the first companies to operate schemes<br>・Initiatives in evidence generation and scientific communication<br>・Expanding and upgrading global medical information functions | ○ Extensive track record in generating evidence<br>○ Global collaboration with Roche and overseas subsidiaries<br>△ Adaptability to conducting increasingly diverse clinical research |
| **Drug Safety** | ・Building pharmacovigilance system to meet the world's strictest standards and most comprehensive global regulations<br>・Providing solutions to patients and healthcare professionals using drug safety information<br>・Formulating drug risk management plans (RMPs) and ensuring their full implementation | ○ Industry-leading achievements (introduction of the database tool and establishment of Safety Experts, etc.)<br>○ Solid partnership with the Drug Safety Division of Roche Group<br>○ A track record of industry activities in areas utilizing epidemiological and medical data<br>△ Response to the constant shortage of high-quality human resources |
| **Quality and Regulatory Compliance** | ・Integrating healthcare compliance, good practice guidelines and regulations (GxP) compliance, and digital compliance in an organizational structure that treats regulatory activities, compliance, and quality as a three-in-one concept<br>・Protecting the rights of patients and clinical trial subjects and ensuring the reliability of data by pursuing product and service quality that resonates with all stakeholders under the slogan "Quality That Inspires" | ○ Active utilization of digital technologies, including the establishment of an electronic signature system, digitalization of the quality assurance system, and introduction of artificial intelligence (AI) in the supervision of activities to provide marketing information<br>○ Quality assurance achieving successful maintenance and strengthening of world-class quality, including in the supply chain<br>○ Digital compliance system to speed up digital transformation (DX)<br>△ Establishment of new Chugai quality adapted to new modalities and new processes |
| **Intellectual Property** | ・Aggressively acquiring intellectual property (IP) rights focused on important R&D projects and actively securing rights outside Japan with a view to global co-development<br>・Strategically seeking to acquire lifecycle patents, as well as patents relating to the substance and use, when filing product patent applications<br>・Building a unique database in antibody engineering technology for use in formulating IP strategy | ○ Expanded and upgraded portfolio of technological patent applications<br>○ Progress in securing rights for products<br>△ Increase in IP disputes related to global development products<br>△ Difficult environment for securing of technological patent rights in Europe and the United States due to more stringent patent registration criteria |

1. An original drug that is highly novel and useful, and will significantly change the therapeutic system
2. A drug that offers clear advantages over other existing drugs in the same category, such as those with the same molecular target
3. Medical need that is not adequately met due to a lack of effective treatments
4. Molecules with a molecular weight between 500 and 2,000. Mid-size molecules are expected to be capable of inhibiting protein–protein interaction (PPI) in intercellular molecules, which is difficult to achieve with antibodies and small molecules.

# Response to the COVID-19 Pandemic

As a business operating in the healthcare industry, our response to the worldwide crisis unleashed by COVID-19 gave priority to ensuring the stable supply of drugs to patients. Accordingly, we introduced measures to prevent the spread of infection among our employees and in our business activities. At the same time, we invested resources in activities to contribute to developing treatments for COVID-19 and preventing its spread.

The swift adoption of a response policy by our Emergency Headquarters and the rollout of the associated measures proved highly effective in combination with the measures taken under the existing corporate business continuity plan (BCP). As a result, there has been no disruption or other impact on the supply of active pharmaceutical ingredients (APIs) or other materials as of March 2021 and we have confirmed sufficient safety stocks of products manufactured at overseas plants.

We are working to contribute to the treatment of COVID-19 and to the prevention of its spread through a range of activities, from research and development and in- and out-licensing of technologies and products to various support initiatives.

In its R&D activities, specifically, as part of its policy to combat the COVID-19 pandemic, Chugai is collaborating with Roche and other pharmaceutical companies and research institutions to initiate development of therapeutic drugs using its proprietary technology and to conduct in-licensing to Japan of promising development items from other companies.

**Main Initiatives to Develop COVID-19 Treatments and Prevent the Spread of Infection**

| Field of Activity | Outline of Initiatives |
|---|---|
| Research and development | ● Domestic phase III clinical study of Actemra in hospitalized patients with severe pneumonia due to COVID-19 (J-COVACTA) (>Activity Report P7)<br>● Joint research between Chugai Pharmabody Research (CPR) and A*STAR (Agency for Science, Technology and Research) into a therapeutic antibody for COVID-19 |
| Technology/product in- and out-licensing | ● Out-licensing of antibody engineering technology to Eli Lilly and Company for research and development of therapeutic drugs for COVID-19<br>● In-licensing from Roche of the development and exclusive marketing rights in Japan for an antibody cocktail therapy against COVID-19 developed by Regeneron Pharmaceuticals, Inc. (>Activity Report P7)<br>● In-licensing from Roche of the development and exclusive marketing rights in Japan for a new oral drug candidate against COVID-19 developed by Atea Pharmaceuticals, Inc. |
| Support activities (donations) | ● Donation of RMB 1 million to the Red Cross Society of China to support COVID-19 response activities in the People's Republic of China<br>● Donation of a total of ¥50 million to The Nippon Foundation and the Tokyo metropolitan government for healthcare professionals in Japan working to provide treatment and prevent infection |
| Other | ● Posting on Chugai's official YouTube channel of a podcast series created to provide "medicine for the mind" during the COVID-19 pandemic in a joint project with a former stage actor |

Note: The page numbers indicated in parentheses above show where in this Activity Report to find more detailed information.

**Main Initiatives Affecting Employees and Business Activities**

| |
|---|
| ● Swift adoption of response policies and rollout of measures by the Emergency Headquarters |
| ● Policies to regulate the work and activities of all employees and rollout of a range of measures to promote hygiene and prevent infection |
| ● Promotion of innovative workstyles for the new normal (>Annual Report P69) |

Note: The page number indicated in parentheses above shows where in the Annual Report to find more detailed information.

# Research

## Strategic Points

- Expansion following success with mid-size molecule drug discovery ahead of global competition
- Progress in the discovery of therapeutic antibodies with a competitive advantage and development of new modalities
- Creation of innovative drug discovery projects aimed at realizing cures through intensified biological research
- Enhancement of the drug discovery process through digital technology
- Pursuit of innovation in drug discovery through external alliances

### Performance in 2020

16
In-house projects in the development pipeline
(As of February 4, 2021)

62
Publications in academic papers and presentations at scientific conferences regarding Chugai's innovative proprietary antibody engineering technologies
(2016–2020)

100
Publications in academic papers regarding Chugai's research findings
(2016–2020)

14.4%
R&D expenditures to revenues (%)
(2020)

## Business Model and Core Themes

To respond to the increasingly diverse range of unmet medical needs, we are committed to developing a succession of innovative new drugs with first-in-class/best-in-class status. To do so, as well as effectively utilizing our external networks, we are working to further strengthen our in-house drug discovery platform consisting of antibodies, small molecules, and mid-size molecules.

To focus resources on the creation of innovative drugs, in addition to building a stable revenue base through efficient development in Japan of products in-licensed from Roche, we have established a system for collaboration with Roche in the late-stage clinical development of in-house projects. Sharing the Roche Group's global research resources, including its large-scale, high-quality chemical library and its state-of-the-art infrastructure, enables us to carry out drug discovery on the scale of the pharmaceutical giants.

## Bioethics and Animal Welfare

Chugai takes seriously the issues of bioethics and animal welfare and has responded with the measures outlined below.

To ensure that research using human-derived samples is carried out appropriately, Chugai has established Ethical Guidelines for Research That Uses Human-Derived Samples and a Research Ethics Committee. More than half of the members of this committee are from outside the Company, enabling fair evaluations from a pluralistic frame of reference.

When handling laboratory animals used in research, Chugai acts in accordance with the Guidelines for the Care and Use of Laboratory Animals it has established to respect their lives from the standpoint of animal welfare, and to minimize pain, keeping in mind the scientific conditions. Chugai's measures, which are based on the principles of the 3Rs (Replacement, Reduction, and Refinement), were positively evaluated by AAALAC International,[1] a global third-party evaluation organization, and the Company has maintained full accreditation since 2007.

1. The Association for Assessment and Accreditation of Laboratory Animal Care International, a private nonprofit organization (NPO) that promotes the humane treatment of animals in scientific research through voluntary inspection and accreditation programs. More than 900 facilities in 39 countries have obtained AAALAC accreditation.

## Strategy and Progress

### Uncompromising commitment to manufacturing as well as enhancement and expansion of the drug discovery platform

Having further enhanced our in-house antibody engineering technology to develop adenosine triphosphate (ATP) Switch-Ig and FAST-Ig/ACT-Ig, we have now begun clinical studies of antibodies to which this technology was applied.

In the field of drug discovery through chemical synthesis, in addition to our existing use of the small molecule modality, we are building a platform in the modality of mid-size molecules, where we have begun screening candidates for use with a number of target molecules. Mid-size molecules represent a particularly useful drug discovery tool for intracellular targets difficult to tackle with antibodies and small molecules, and we believe that this technology will broaden the scope of drug discovery. In 2020, we achieved major progress in the establishment of a technology platform for the creation of hit-to-lead compounds. Having spent more than 10 years in the development of this technology, we plan to commence our first clinical study using mid-size molecules in 2021.

Founded in Singapore in 2012, Chugai Pharmabody Research (CPR) has worked on creating therapeutic antibodies. It has now expanded the scale of its research activities after designing and launching a system able to carry out high-throughput screening of mid-size molecules.

## Application of digital technology to drug discovery

In line with the rapid advances in science and technology centered on the fields of digital and information and communications technology (ICT), we believe that the drug discovery process will also undergo marked changes. In July 2018, Chugai entered into a comprehensive partnership agreement with Preferred Networks, Inc. (PFN), a global leader in artificial intelligence (AI) technology. We are currently conducting multiple cooperative projects with the aim of creating innovative drugs and new value through the application of PFN's cutting-edge deep learning technology and Chugai's expertise, technologies, and data.

As part of initiatives to boost the efficiency of drug discovery, we are progressing with laboratory automation and the introduction of robotic technology. The use of robots will enable a dramatic increase in the volume of experimental data obtained and more integrated data analysis, resulting in higher-quality drugs.

Healthcare in the future is expected to center on personalized healthcare (PHC), which provides optimal solutions tailored to individual patient needs, and will need to provide comprehensive value in a sustainable form that encompasses prevention and prognosis in addition to diagnosis and treatment, which are the focus of the current model. Using digital technology will allow us to gauge each patient's degree of satisfaction with their treatment so that we can tailor drug discovery to the individual patient's unmet medical needs.

## Pursuit of innovation in drug discovery through external alliances

In April 2017, the Collaboration Promotion Laboratory began operating under our comprehensive agreement with Osaka University Immunology Frontier Research Center (IFReC) to conduct ongoing assessment and introduction of new candidate compounds from its cutting-edge immunology research. Immunity is involved not only in diseases of the immune system itself, but also in cancer and various other diseases, and immune-mediated therapies are now becoming mainstream cancer treatments. Combining the global top-class research in immunology at IFReC and Chugai's expertise in drug discovery research, accumulated through its proprietary technologies, is expected to result in the creation of innovative new drugs.

We are also looking to innovate the drug discovery process itself, including for next-generation PHC, by applying the highly advanced genomic analysis techniques and other capabilities of Foundation Medicine, Inc. (FMI),[2] which joined the Roche Group in 2015.

Additionally, we are engaged in the out-licensing of antibody engineering technologies developed in-house. In 2020, we concluded licensing agreements relating to Chugai antibody engineering technology with Eli Lilly and Company and three other companies. By making our innovative drug discovery technology available to other operators, we hope to stimulate innovation across the pharmaceutical industry that will result in solutions to unmet medical needs, creation of innovative new drugs, and other benefits.

2. FMI was established in Massachusetts, U.S.A. in 2010. In 2015, Roche took a majority stake, and then acquired the remaining outstanding shares in 2018 to make FMI a wholly owned subsidiary. Chugai carries out commercialization and product value maximization of FMI's Comprehensive Genomic Profiling Service in Japan.

**Comparison of Drug Discovery Modalities**

| | Small Molecules | Mid-Size Molecules | Biologics |
|---|---|---|---|
| Molecular weight | Below 500 | 500–2,000 | 10,000 and above |
| Target specificity | Fair | High | High |
| Intracellular targets | Wide range | Numerous | Limited |
| PPI[3] inhibition | Fair | Good | Good |
| Administration route | Oral/Injection | Oral/Injection | Injection |
| Manufacturing method | Organic synthesis | Organic synthesis | Cell culture |

3. PPI: Protein–protein interaction

# Development

## Strategic Points

- Establishment of development methods for Chugai products with new modalities and mechanisms of action
- Further acceleration of development through use of data assets
- Maximization of product value based on value-based healthcare (VBHC)

### Performance in 2020

54
Pipeline projects
(As of February 4, 2021)

30
New products launched and new indications
(2016–2020)

39
Projects being co-developed with the Roche Group
(As of February 4, 2021)

20
Projects in-licensed from Roche
(2016–2020)

## Business Model and Core Themes

The Translational Research (TR) Division acts as a bridge between preclinical and early clinical development. The division undertakes integrated project implementation from the initial research stage of drug discovery through to the early clinical development stage, in this way ensuring that clinical studies are conducted on a scientifically valid basis and working to establish proof of concept (PoC) at an early stage.

In October 2020, the Clinical Development Division consolidated its own clinical science and operational functions to establish a system that increases operational efficiency from planning through to operation.

By also integrating management functions for strategic planning and execution of clinical studies, including early clinical development, we aim to achieve strategically appropriate and efficient rollout and boost quality improvement. At the same time, sharing clinical development expertise and platforms with the Roche Group will assist us in accelerating global development.

Additionally, we utilize FMI and other partners to generate evidence from the clinical development stage that will contribute to personalized healthcare (PHC) and help to realize patient-centric medicine.

## Strategy and Progress

### A well-stocked pipeline

In 2020, all projects progressed steadily. We filed applications in nine projects and received approval in 11. The pipeline was also further enhanced, with clinical development starting in six projects based on items developed in-house or in-licensed from Roche.

### Speedy global development

Chugai has been working to speed up global development by following a development model with a high probability of success and by making efforts to prove the value of in-house projects from the early stages of research and development. As a result, Alecensa took just seven years from concept to launch, and Hemlibra, for which we filed for approval simultaneously in Japan, the United States, and Europe, in collaboration with Roche, obtained approval in less than five years from initiation of clinical development, far ahead of our initial plan. This has dramatically transformed treatment strategies for hemophilia.

Enspryng (satralizumab) represents the first application of Chugai's proprietary recycling antibody engineering technology. Based on the results of Chugai-led global studies, we received approval for the product in 2020 in more than 10 countries around the world including Japan and the United States following applications filed in collaboration with Roche. In late-stage development projects, nemolizumab (CIM331), crovalimab (SKY59), and other in-house items progressed steadily through global phase III studies.

### Initiatives in pharmaceutical development for COVID-19

As part of our initiatives to develop drugs for the treatment of COVID-19, Actemra entered domestic phase III clinical studies in May 2020. Overseas, Roche is engaged in a number of phase III global studies. We also obtained Japanese development and exclusive marketing rights to an antibody cocktail therapy (casirivimab and imdevimab) developed by Regeneron Pharmaceuticals and in-licensed from Roche in December 2020.

### Evolution of clinical development using digital technology

We are also accelerating digital initiatives through partnerships. In collaboration with NTT DATA Corporation, we carried out a demonstration test of a clinical trial efficiency solution based on AI technology. Meanwhile, we are currently working with Biofourmis on digital solutions aimed at co-developing an objective assessment of pain associated with endometriosis. The utilization of real-world data (RWD) is expected to help realize more efficient and effective clinical studies with shorter development periods by allowing late-stage results to be predicted at the early stage, and to bring higher success rates by enabling more precisely formulated clinical development plans. In order to realize patient-centric healthcare, we will proceed with initiatives to promote the utilization of RWD.

# Pharmaceutical Technology and Production

## Strategic Points

- Acquisition of PoC with world-class speed and establishment of mid-size molecule manufacturing technology
- Strengthening of commercial production through outsourcing of manufacturing and building of an efficient production system through utilization of digital technology and robotics
- Action to mitigate environmental burden toward mid-term environmental goals

### Performance in 2020

Began stable operations of facilities that can handle multiple antibody development projects simultaneously

Upgraded world-class system for pharmaceutical quality management

55
Research papers and other publications from the Pharmaceutical Technology Division
(2016–2020)

## Business Model and Core Themes

Our pharmaceutical technology and production functions play a range of roles, from establishing manufacturing processes for investigational candidates—whether developed in-house, in-licensed from Roche, or originating elsewhere—to ensuring the stable supply of these products. By ensuring continuous evolution of our technologies and working to maintain and strengthen the supply chain, we aim to become a top innovator maintaining the trust of patients and healthcare professionals.

## Strategy and Progress

### Improving flexibility and speed

In its pharmaceutical technology and production operations, Chugai is aiming for simultaneous development of multiple products for the quickest launches possible. Specifically, the Ukima Plant has achieved a significant increase in capacity utilization by employing single-use plastic bioreactors. For development candidates based on next-generation antibody engineering technologies, the plant has also begun full-scale operation of UK3, an antibody API facility capable of high-mix, low-volume production from late-stage development to initial commercial products. At the Utsunomiya Plant, we have increased production flexibility by installing tray fillers that can handle filling of liquid medicines without making line changes or modifications, regardless of the syringe type.

At the Fujieda Plant, we will introduce an API manufacturing facility for investigational drugs for mid-size molecules, which are a next-generation modality, with the aim of starting operations in 2022.

### Evolution of pharmaceutical technology and production functions through DX

In collaboration with IBM Japan, Ltd., we have started work on the digital transformation (DX) of production functions. By realizing “digital plants” through DX focused on human functions, we are driving improved productivity and reliability and innovation in workstyles. Implementation will begin first at the Ukima Plant’s UK3 facility, which will serve as a model, with rollout to other production bases planned for the future.

### Evolving supply chain management

To minimize risks related to the supply and price of raw materials, we promote the globalization of our suppliers of raw materials and intermediate products in tandem with the globalization and establishment of two production bases for each finished product.

### Thorough quality assurance

Quality assurance functions have diversified in recent years in response to the increasing complexity of supplying products and accelerated development with the introduction of the fast-track review system to support the early launch of innovative new drugs. In view of these trends, Chugai is working to further strengthen GMP* management oversight to promote more rigorous and high-level quality assurance. As part of these efforts, Chugai promotes the building and operation of a world-class system for pharmaceutical quality management.

* Good Manufacturing Practice: Standards for pharmaceutical production management and quality control

**Biological API Production: Our Facility Portfolio**

| Plant | Target | Bioreactors | Features | Products |
|---|---|---|---|---|
| Utsunomiya | Commercial production (Large-scale) | 10,000 L x 8 (UT1, UT2: Stainless steel tanks) | • Competitive low-cost production<br>• Dedicated facilities | Actemra |
| Ukima | Commercial production/Production of investigational APIs (Medium-scale) | 6,000 L x 6 (UK3: Stainless steel tanks) | • Emphasis on flexibility<br>• Can handle high-mix, low-volume production | Future development projects |
| Ukima | Commercial production/Production of investigational APIs (Small-scale) | 2,000 L x 4 (UK1, UK2: Single-use plastic bags) | • Improved capacity utilization through the application of single-use bioreactor technology | Hemlibra and future development projects |

# Marketing

## Strategic Points

- Maximization of the value of growth drivers (innovative drugs and services)
- Quick and accurate value delivery to customers through optimized use of digital technology and strengthening of alliances for specialized functions

### Performance in 2020

22.5%[1]
Share of sales in the Japanese therapeutic antibody market

15.2%[1]
Share of sales in the Japanese oncology market

1[2]
Satisfaction ranking based on healthcare professionals' assessments
(Oncology; hospitals with 100 or more beds)

1[3]
Adequacy ranking for provision of safety information based on healthcare professionals' assessments
(Hospitals with 100 or more beds)

1. Copyright © 2021 IQVIA. Source: JPM 2020 (calendar year). Reprinted with permission. The scope of the market is defined by Chugai.
2. Source: INTAGE Healthcare Inc., CS Survey of Oncology, 2020. Based on a survey of overall assessments of companies by physicians, as defined by Chugai.
3. Source: INTAGE Healthcare Inc., 2020 questionnaire about safety information needs.

## Business Model and Core Themes

With growing interest in more sophisticated and individualized medical treatments such as cancer immunotherapy and genomic testing as a way to address unmet medical needs, healthcare professionals will be expected to promptly provide high-quality information. Chugai is responding to this need through three different approaches under the general heading of "consulting."

**For patients**
We conduct patient-centric consulting activities that give the highest priority to patients, including proposing the optimal drug treatment according to each patient's condition, providing relevant information on proper use and safety, and follow-up activities.

**For regional healthcare**
We provide liaison services for regional healthcare with the aim of solving medical issues according to local area characteristics. We conduct consulting activities that improve patients' access to treatment by supporting regional healthcare coordination among healthcare professionals and medical institutions as well as collaboration among local governments, public entities, and other industries.

**For stakeholders**
Multidisciplinary team care has advanced in recent years, with various specialist healthcare professionals working in collaboration to carry out treatment according to each patient's condition. We conduct consulting activities to support our diverse stakeholders, while multidisciplinary teams follow up on treatment through proper management of adverse events.

Because consulting activities necessarily require extensive communication with relevant parties, our medical representatives (MRs) play a key role. In addition to MRs, we also have a system for providing solutions that meet medical need through participation in cross-functional teams by members of the Marketing & Sales, Medical Affairs, and Drug Safety divisions, who have high-level expertise.

We are also innovating business processes using the latest digital technologies such as AI and the Internet of Things (IoT) to build a system that can provide more efficient and effective solutions based on higher-quality consulting activities.

## Strategy and Progress

### Oncology

Sales in the cancer diseases area in Japan in 2020 decreased ¥11.0 billion (4.6 percent), year on year to ¥229.5 billion. Although the restriction of activities accompanying the COVID-19 pandemic had some impact on the market rollout of new products and additional indications, the anti-PD-L1 monoclonal antibody Tecentriq, which has been approved for the additional indication of hepatocellular carcinoma (HCC) in combination with Avastin, enjoyed major sales growth with a year-on-year increase of ¥16.9 billion (82.0 percent) to ¥37.5 billion. There were sales decreases however for some mainstay drugs, including Avastin, impacted by National Health Insurance (NHI) drug price revision, and Herceptin and Rituxan, affected by competition from biosimilars. These impacts were reflected in reduced revenues for the domestic oncology area as a whole. Following a price reduction for exports to Roche, sales of Alecensa outside Japan declined ¥1.0 billion (2.2 percent) year on year to ¥44.3 billion.

In 2021, we expect some products to continue to be impacted by competition from biosimilars. For new products and additional product indications, however, we are aiming for sales growth from increasing market penetration. This applies to Tecentriq, which has been approved for the indications of lung cancer and HCC, and Kadcyla, now approved for the indication of human epidermal growth factor receptor type 2 (HER2)-positive early-stage breast cancer.

### Bone and Joint Diseases

In 2020, sales in the bone and joint diseases area in Japan decreased ¥16.0 billion (14.8 percent), year on year to ¥92.4 billion. Actemra, a first-line biologic for the treatment of rheumatoid arthritis (RA), was impacted by an NHI drug price reduction due to repricing based on market expansion. With the general effect of the reduction in inpatient numbers due to COVID-19, mainstay drugs, including Bonviva for osteoporosis and Edirol, which was additionally impacted by the launch of generics, saw reduced sales revenue overall. Sales of Actemra outside Japan received a major boost from exports to Roche for use against COVID-19 and posted a year-on-year increase of ¥46.1 billion (52.2 percent) to ¥134.4 billion.

In the Japanese market in 2021, Edirol, for which a marketing alliance with Taisho Pharmaceutical Co., Ltd., has ended, is expected to be impacted by the market penetration of generics, resulting in reduced sales revenue. In markets outside Japan, we will work to achieve further market penetration of the subcutaneous formulation of Actemra for RA and to promote its uptake for the additional indication of giant cell arteritis approved in 2017.

### Renal Diseases

Sales in the renal diseases area in Japan in 2020 decreased ¥6.0 billion (17.3 percent), year on year to ¥28.6 billion. Mircera was impacted by the revision of medical fees for hemodialysis in April 2020 and by the switch to biosimilars at dialysis facilities, while Oxarol came under pressure from generics and other factors. As a result, both products again saw year-on-year falls in sales revenue.

In 2021, we aim to maintain the market presence of Mircera and Oxarol in the pre-dialysis and dialysis stages through ongoing provision of information and patient-centric activities rooted in our high level of expertise in the area of renal diseases.

### Other Diseases

Hemlibra is a bispecific antibody created using Chugai's proprietary antibody engineering technologies. It obtained approval and was launched in May 2018 for routine prophylaxis in people with congenital hemophilia A with blood coagulation factor VIII inhibitors. In December 2018, we obtained approval of blood coagulation factor VIII for the additional indication of hemophilia A without inhibitors. Compared to existing therapeutic drugs, it allows longer dosing intervals, which will contribute to improved QoL for hemophilia A patients and their families. Despite a temporary delay in its market rollout due to COVID-19, the strong need among patients and healthcare professionals resulted in sales in Japan of ¥34.1 billion, a year-on-year growth of ¥8.9 billion (35.3 percent). Outside Japan, exports to Roche, which had previously been at the initial shipment price, switched to the regular shipment price in 2020. This and the continuing switch from existing therapeutic drugs, especially in the United States, were the main factors in the year-on-year surge of ¥22.5 billion (625.0 percent) in sales outside Japan to ¥26.1 billion. In 2021, we will devote energies to continuing with the collection of safety information, information provision and activities to promote proper use, working thus to make further contributions to the treatment of congenital hemophilia A.

Enspryng represents the first pharmaceutical product developed using Chugai's proprietary recycling antibody engineering technology. As a fourth growth driver after Actemra, Alecensa, and Hemlibra, it has been approved in 22 countries around the world (as of the end of April 2021), including Japan and the United States, for neuromyelitis optica spectrum disorder (NMOSD). Its Japanese sales launch in August 2020 marked Chugai's entry into the neurology field. Administered at four-week intervals, it is the first subcutaneous formulation for the treatment of NMOSD. We will be promoting its proper use so as to make therapeutic contributions through both reduced recurrence and improved convenience.

As the scale of the influenza epidemic in the 2019–2020 season was extremely limited compared to a regular year, and because the start of the 2020–2021 season was late, sales of Tamiflu were held to ¥4.5 billion.

### Evolution of activities through use of digital technology

Toward delivering patient-centric services, Chugai is pursuing initiatives that make use of digital technology to provide optimal solutions.

**0C (Organic Communication)**

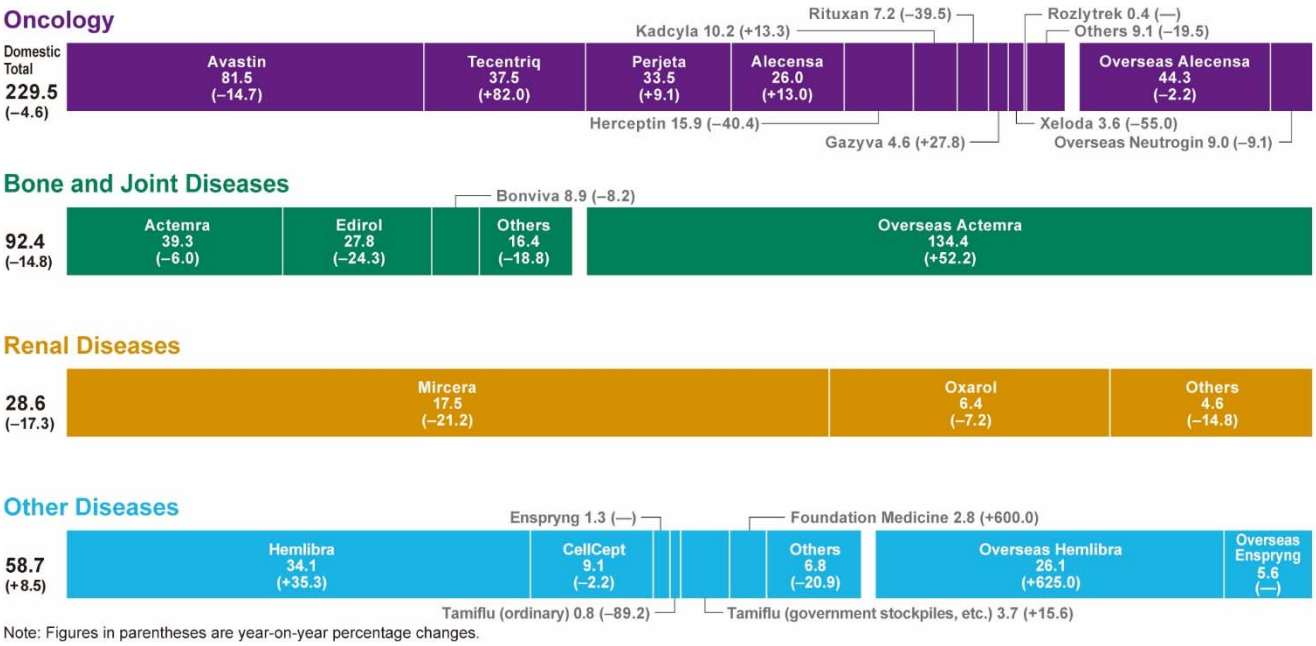
In order to respond flexibly to the needs of healthcare professionals, we have launched a cross-departmental project entitled 0C (Organic Communication), or Zero C, which aims to

build an integrated interface to realize customer-focused marketing. This will allow management via an integrated database of many different categories of data, from records of individual employee activity to market information on Chugai and competitors and customer and area information. In this way, we will create a system to support business activities through access to a range of analyses and an AI-based decision support engine.

**MRs using LINE WORKS for their activities**

In September 2020, we introduced LINE WORKS, which is the business version of the popular Japanese social media app LINE and is provided by WORKS MOBILE Japan Corp. During the COVID-19 epidemic, there has been a major change in how MRs communicate with healthcare professionals due to the limits on face-to-face contact. To continue responding smoothly and swiftly to the needs of healthcare professionals under these conditions, we are using LINE WORKS as a new tool, allowing us to provide optimal solutions without delay while also improving the productivity of MRs.

**2020 Product Sales by Therapeutic Area** (Billions of yen)




Note: Figures in parentheses are year-on-year percentage changes.

# Medical Affairs

## Strategic Points

- Acceleration and advancement of evidence generation to realize patient-centric healthcare
- Delivery of personalized healthcare (PHC) based on the characteristics and values of the individual patient
- Promotion of innovative medical affairs by strengthening collaboration with stakeholders and actively introducing digital and other new technologies

### Performance in 2020

62
Contract-based post-marketing studies
(2020)

7 (as part of the above post-marketing studies)
Database research projects (including real-world data (RWD) research)
(2020)

150
Staff with GCP Passport (Japan Society of Clinical Trials and Research certification)
(As of January 31, 2021)

20
Number of non-clinical joint studies
(2020)

## Business Model and Core Themes

The task of our Medical Affairs Division is to generate scientific evidence, focusing on the mode of action and other properties of the drug in non-clinical studies (basic research), as well as on its efficacy and safety in the clinical setting. Based on the evidence thus generated, we deliver appropriate information to healthcare providers.

Increasingly in recent years, the pharmaceutical industry has been called upon to ensure global-level compliance standards, for instance through appropriate separation of marketing and medical affairs[1] and transparency in funding, and to improve the quality and scientific level of research. It is important to respond to these concerns. With the aim of enhancing the quality and reliability of its research, Chugai has established a research support structure that conforms to the GCP[2] guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Chugai has also acquired third-party accreditation[3] from the Japanese Association of Pharmaceutical Medicine (JAPhMed) for its medical science liaison (MSL) certification program. Additionally, in accordance with the Clinical Trials Act and the Next-Generation Medical Infrastructure Act, which came into force in 2018, we are working to upgrade systems, provide support for the implementation of clinical trials, conduct database research (including RWD[4] research), and meet the other requirements. Furthermore, in response to the Consensus Statement on Medical Affairs Activities and the Consensus Statement on Medical Science Liaison Activities, issued by the Japan Pharmaceutical Manufacturers Association (JPMA) in 2019, and the Guidelines for Prescription Drug Marketing Information Provision, issued by the Ministry of Health, Labour and Welfare in the same year, we have established an appropriate governance and compliance system.

## Strategy and Progress

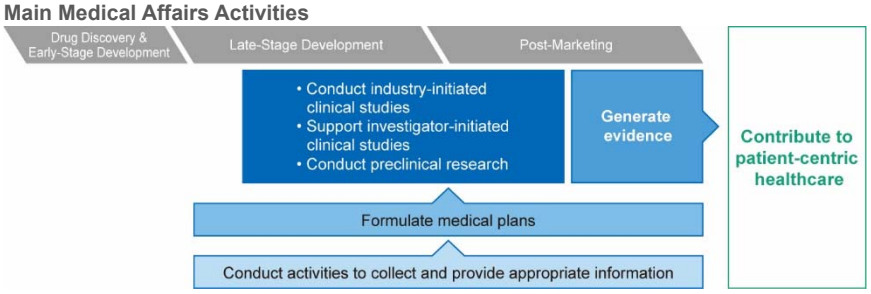
### Enhancing intelligence functions and measures for PHC

In January 2019, we started operation of MI chat, an interactive program that uses AI to respond to inquiries from healthcare professionals. This program improves convenience such as reducing the time spent searching for information. We will continue to work on innovation, including the use of new digital technologies, to provide new solutions.

As a further digital initiative, we are engaged in prospective research into hemophilia through the TSUBASA study. People with hemophilia use the dedicated study app to provide information on their level of physical exercise, which is used to research the correlation with hemorrhagic events. Wearable devices are also used to collect physical data during exercise for analysis. Through this work with digital biomarkers, we aim to contribute to the progress of patient-centric medical research and the development of advanced medical treatments.

1. Activities that contribute to healthcare from a scientific standpoint
2. Good Clinical Practice: Standards for conducting pharmaceutical clinical trials
3. Composed of evaluation criteria (a total of 222 items in 42 categories) from the three perspectives of independence from promotional activities (compliance system), medical and scientific expertise, and the training system. In the accreditation examination, mail-in and on-site surveys of the evaluation criteria are conducted to evaluate whether the MSL certification program at the applicant company is being properly implemented.
4. Real world data

**Main Medical Affairs Activities**



# Drug Safety

## Strategic Points

- Maximization of the value of growth drivers through a commitment to promoting appropriate use
- Generation of unique evidence to contribute to personalized healthcare (PHC) and building of innovative customer engagement models
- Maximization of product value through enhancement of safety measures from the clinical development stage

### Performance in 2020

**201 thousand**
Cases for which safety information was collected in clinical trials and post-marketing studies
(2020)

**20**
Lectures, papers, and conference presentations on drug safety
(2020)

**15 products**
Enforcement of risk management through RMPs
(As of January 20, 2021)

## Business Model and Core Themes

In Japan and overseas, Chugai handles numerous therapeutic antibodies, molecular targeted therapies, and other pharmaceuticals with innovative modes of action. To promote the appropriate use of these pharmaceuticals around the world and gain acceptance from patients and healthcare providers, Chugai establishes pharmacovigilance protocols with Roche and other partners and collects safety information on a global level. We consider expert safety evaluation and speedy decision-making throughout the product lifecycle to be essential for timely provision of safety information and implementation of measures to ensure safety. Accordingly, we have established an independent Drug Safety Division and put in place a safety control system directly linked to management. Chugai sees pharmacovigilance activities as part of its mission as a pharmaceutical company and is committed to continuing with patient-centric activities in this area to build trust, provide truly valuable safety data, and contribute to patients and healthcare worldwide.

## Strategy and Progress

### Collecting and managing safety information

With the principal aim of collecting safety information from real-world clinical settings that is unobtainable from clinical trials, we gather reports from medical institutions and data from the literature and scientific conferences. We also collect safety information proactively from post-marketing surveillance, which includes all-case registration surveillance and database surveys. Data on safety collected from medical institutions is analyzed using diverse methods including epidemiology. Information on the results is provided to medical institutions and announced via scientific conferences, papers, and other means.

Chugai leads the industry in drug safety evaluation and safety measures through its additional wide-ranging and rigorous management methods, such as management of distribution and confirmation of conditions of use, for numerous anticancer agents, innovative new biopharmaceuticals, and other drugs.

### Risk management based on pharmaceutical RMPs

Chugai has been ahead of its competitors in drawing up and applying risk management plans (RMPs), and discloses them on its website. Chugai considers RMPs to be part of its commitment to patients and healthcare professionals. In applying RMPs, we believe we need to strengthen our ability to analyze data from an epidemiological standpoint. This is another area where we have led the industry. To help upgrade Japan's epidemiological database, a group of Chugai experts with responsibility for epidemiological functions has collaborated with specialized enterprises and other bodies in a range of active initiatives, including formulating recommendations and guidance on database research for presentation to the regulatory authorities. We have additionally launched an initiative to apply database research at the practical level to pharmacovigilance for Chugai products in order to ensure swift and effective collection of safety information, which will enhance and strengthen the operation of RMPs.

### Communications on safety

Chugai provides information on noteworthy adverse events to medical institutions and academic societies. We also distribute information leaflets for patients, post information on our website, and present a variety of lectures. In particular, our ability to rapidly provide information according to patient characteristics through the post-marketing surveillance database tool (PMS DB tool) and safety information database tool (SAFETY DB tool) that we began operating in 2016 has won praise from healthcare professionals.* With these tools, which include domestic post-marketing safety data, we can respond in a timely manner to urgent needs for safety information. Starting in 2018, we have additionally rolled out a clinical studies database tool that presents the clinical study safety data submitted for regulatory approval, allowing healthcare professionals to use new products with confidence from immediately after their sales release. In 2020, we continued to enhance the provision of information through database tools, launching an adverse event database tool on our dedicated website for healthcare professionals in May. This has further broadened our

Welby MyKarte ONC

Reference: Welby MyKarte ONC patient introduction webpage
https://oncology.welby.jp/ (in Japanese only)

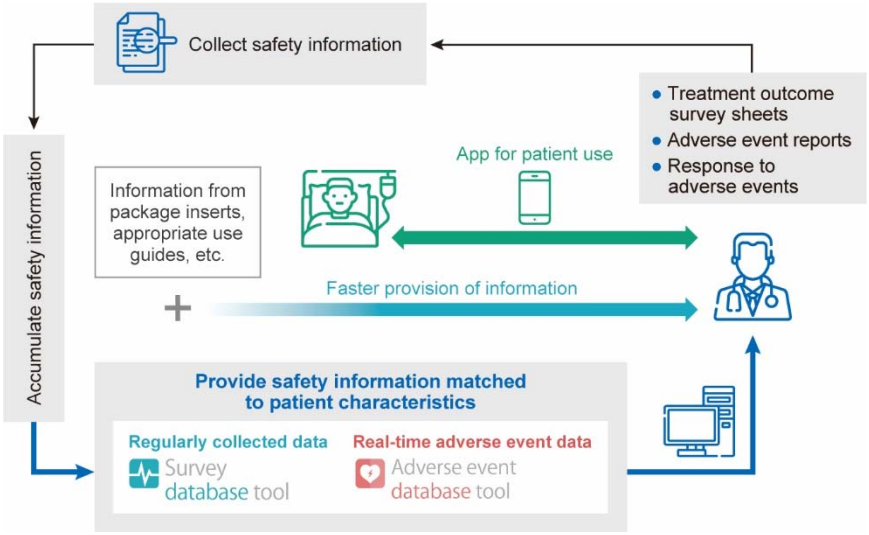
contribution to patient treatment by putting in place a system that enables healthcare professionals to directly access adverse event information on Chugai Pharmaceutical products whenever needed.

At Chugai, we are also concerned with ensuring smooth communication between patients and healthcare professionals so that patients can undergo treatment free of anxiety. In October 2020, in a joint project with Welby Inc., we began operating a patient support program based on Welby MyKarte ONC, a free personal health record (PHR) service provided by our project partner. This program, designed for breast cancer patients being treated with the immune checkpoint inhibitor Tecentriq, performs simple integrated management of information on day-to-day symptoms and treatment status to provide information optimized in line with the type of cancer and the symptoms. These functions support patients to achieve a better understanding of their treatment and are also designed to lead to better outcomes by keeping healthcare professionals constantly informed of the patient's condition, including adverse events and worsening of symptoms.

Meanwhile, to ensure that safety measures are closely attuned to patient needs, we operate a team of some 30 professionals with the job title of Safety Expert—a role unique to Chugai dedicated to handling safety information—who are posted to locations throughout Japan, where they provide safety consultations to meet the needs of healthcare providers and work continuously to build networks with local doctors and pharmacists.

* Source: Online article by Nikkei Medical Publishing, Inc. on AGING Web "Chugai's Ideal Information Prescription: 'PMS and SAFETY Database Tools' Providing Necessary Information to Those Who Need It, When They Need It" (in Japanese only)
Part 1 (November 10, 2017)
https://project.nikkeibp.co.jp/atcl21f/innovator/2017111001/
Part 2 (November 17, 2017)
https://project.nikkeibp.co.jp/atcl21f/innovator/2017111701/

**Cycle of Safety Information Collection, Accumulation, and Provision under PV 2.0**



# Quality and Regulatory Compliance

## Strategic Points

- Upgrading and strengthening of overseas subsidiaries' governance and compliance systems
- Building of Chugai's quality system to provide total assurance for all schemes including new modalities and new businesses in anticipation of joint projects and expansion of contracting
- Strengthening and embedding of digital compliance to accelerate implementation of digital strategy

### Performance in 2020

10
Inspections by GMP regulatory authorities
(2020)

56
GMP/GDP quality audits
(2020)

31
GCP/GVP quality audits
(2020)

7,817
Number of examinations of information and lecture materials
(2020)


* Contract Development and Manufacturing Organizations

## Business Model and Core Themes

The Quality & Regulatory Compliance Unit is responsible for ascertaining trends in pharmaceutical regulations within and outside Japan and ensuring the soundness of the quality management system spanning our business processes. It confirms, improves, and verifies the validity of business processes through audits and other activities throughout the product lifecycle and ensures the quality and regulatory compliance of data by operating a global IT system. By additionally leading activities to foster a self-sustaining quality mindset in organizations across the Chugai Group, it drives product and service quality under the slogan "Quality That Inspires."

## Strategy and Progress

### Initiatives to promote appropriate information Provision activities

To further promote appropriate information provision activities by our medical representatives (MRs) and other staff, we have introduced AI to analyze the content of activity reports. Additionally, following the issue in March 2020 by the Ministry of Health, Labour and Welfare of the notification "Key points to note for pharmaceutical manufacturers and distributors when providing information on ethical pharmaceuticals in response to patient inquiries," we established guidelines for information provision activities in response to inquiries from the public, including patients and their families, based on the Chugai core value of a patient-centric approach.

### Further development of digital compliance system

In 2019, we established a digital compliance system for human-derived data such as genomic data and real-world data (RWD), as part of which we began operating the Digital Compliance Committee. The cases handled in the two years to 2020 showed a great variety and case numbers have continued to increase with the progress of the CHUGAI DIGITAL project. Meanwhile, Chugai is taking the lead in the use of digital technology for compliance, including by establishing guidelines to promote the appropriate use of genomic information and providing appropriate training for employees on an ongoing basis.

### Alliances with external partners and ensuring quality and regulatory compliance

Alliances with contractors and other external partners have become increasingly important in connection with the continuous creation of new drugs and expansion of operations into new modalities and businesses. In 2020, Chugai established the Requirements for GxP Service Provider Management, a set of general quality requirements applicable to all GxP, through which we are working to strengthen alliances with external partners and roll out the Chugai quality brand. To meet requirements in terms of quality assurance and prevention of irregularities, we believe that the quality awareness of individual employees is particularly important. We therefore hold regular Quality Meetings as forums for considering and discussing quality issues with internal departments and selected external partners.

### Development of electronic signature system applicable to GxP documents

To adapt to the teleworking recommended during the COVID-19 crisis, we have developed and begun operating a global electronic signature system that can be used with GxP documents and meets the regulatory requirements of different countries regarding electronic records and electronic signatures. This system, which removes the barrier of physical distance from the signing of contract and GxP documents and greatly reduces compliance-related worries over loss of documents and similar issues, is a practical example of increased efficiency and enhanced compliance from the utilization of digital technology.

# Intellectual Property

## Strategic Points

- Utilization of antibody engineering technology patents through licensing and other means
- Expansion of the patent portfolio in mid-size molecule drug discovery technology and mid-size molecule development projects
- Formulation and execution of a scenario for combating biosimilars and generics

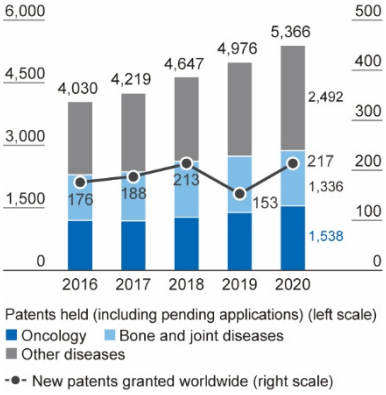
### Performance in 2020

**5,366**
Number of patents held (including pending applications)
(As of December 31, 2020)

**217**
New patents granted worldwide
(2020)

Continued to provide value through resolution of disputes with manufacturers of branded products and manufacturers of biosimilars

**Number of Patents Held (Including Pending Applications) and New Patents Granted**




## Business Model and Core Themes

Chugai views its global intellectual property (IP) strategy as the foundation for creating innovative new drugs. By integrating it with our business and R&D strategies, we protect the competitive advantage of our products and ensure operational flexibility. We focus resources on and secure IP rights for high-priority R&D projects. At the same time, we actively work to secure rights outside Japan with a view to global co-development with the Roche Group. When we apply for patents for products, we include filings for lifecycle patents related to formulation, production method, diagnostic method, and PHC in addition to those for the substance and use. We also work to establish rights globally for significant drug discovery technologies, such as those related to innovative antibody engineering and mid-size molecules. Additionally, we are building a competitor database to identify opportunities for utilization of Chugai's drug discovery technology patents and are formulating and implementing strategies for the utilization of the associated IP. In 2020, initiatives to utilize antibody engineering technology patents through licensing and other means resulted in the conclusion of licensing agreements with four companies.

## Strategy and Progress

### Integration of IP and research strategies (Strategic mix)

At Chugai, we view our antibody engineering technologies as a core drug discovery technology platform, and we are deploying R&D strategies both to cultivate basic technologies and to apply them to product development. We have been dispatching IP liaisons to the Fuji Gotemba Research Laboratories and Kamakura Research Laboratories since 2018, and to the Collaboration Promotion Laboratory at IFReC since 2019, to strengthen collaboration from the initial stage of research. The objective is to promote a stronger strategic mix by building an independent portfolio of technology and development candidates that exploits current gaps in the network of technologies and rights. IP liaisons hold monthly meetings to review IP with the Pharmaceutical Technology Division, which is also promoting the same strategic mix.

### Current patent portfolio

Supported by technological development, we have structured a well-balanced patent portfolio that reflects the diversity of products and development projects generated through Chugai's own research and development. Bone and joint diseases account for approximately 25 percent of patents by therapeutic area, oncology for approximately 29 percent, and other diseases including chronic disorders, hematologic diseases, and drug discovery technology for approximately 46 percent. In 2020, Chugai acquired 217 patents in Japan, the United States, and major European countries, as well as other countries worldwide.

### Maximizing product value in response to changes in the competitive environment

With the globalization of our portfolio of products developed in-house and the expansion of our portfolio of development projects and drug discovery and manufacturing technologies, our competitive environment is becoming increasingly intense. This requires more sophisticated IP activities to maximize the value of Chugai's IP while respecting the effective rights of other parties. This in turn will help to maximize the value of our products, development projects, and technologies.

We carry out IP activities in close cooperation with internal and external stakeholders including Roche, Genentech, and other affiliated companies, outside attorneys, and our business and legal departments. So far, patent disputes relating to Hemlibra, Herceptin, and other major products have been highly effective in maximizing product value. In 2020, we filed patent infringement lawsuits in the United States and Japan relating to generics of Alecensa and Edirol, respectively. By rolling out IP activities of this kind to maximize product value, Chugai will continue to deliver value to society.

# Human Resources

## Strategic Points

- Assignment of the right people to the right positions and provision of growth opportunities through position management and talent management
- Promotion of talent management to quickly identify and develop leaders and highly competent specialists to accelerate strategy execution and innovation
- Maintenance and deepening of employee engagement, fostering of an organizational culture for the pursuit of innovation, and accelerating the success of women

### Performance in 2020

14.6%
Ratio of female managers[1]
(2020)

13.0%
Ratio of female managers[2] (with subordinates)
(2020)

194
Number of employees posted through the Roche Human Resource Exchange Program
(2004–2020)

1. Percentage of all managers on a Chugai Pharmaceutical non-consolidated basis.
2. Percentage based on Chugai Pharmaceutical (non-consolidated) and affiliated companies in Japan.

Chugai was selected as a Nadeshiko Brand for the fifth time in 2021 for its exceptional record in promoting the success of women.

## Basic Approach

Chugai recognizes that its people are its most important asset. That is because human resources are the generators of innovation and the driving force of value creation. We believe that assigning the right people to the right positions and conducting talent management will recognize individuals with independent thinking ability and motivation for self-improvement and support them to take on challenges and demonstrate to the fullest their strengths and expertise. We seek to create workplaces that bring together innovative people regardless of nationality, gender, or other attributes to work enthusiastically together in a diverse environment.

### The All-Employee Survey

Chugai carries out regular employee surveys to identify organizational issues requiring reform and to support the formulation of strategy. The survey consists of two parts: Employee engagement, an indicator of employee commitment to performance and self-motivation; and environment for utilizing employees, an indicator of whether the right people are in the right positions and whether there is a supportive work environment. In the survey results for 2020, our score for “employee engagement” was three points higher than in the previous survey and 10 points above the global average, placing Chugai in the global top ranks. In “environment for utilizing employees,” we advanced by three points to reach the global average. For Chugai to join the global top ranks, some areas require further improvement, notably resource optimization and work process efficiency. Going forward, as we implement our new growth strategy, TOP I 2030, we will shift resources to value-creating operations and ensure the comprehensive rollout of our new personnel system. Alongside these and other strategies to resolve issues across the Company, we will work to identify personnel and structural issues within each department and organization and will seek to resolve them through the plan-do-check-act (PDCA) cycle and other measures.

#### Key Points of 2020 Survey Results

- Chugai scored above the Japanese corporate average in all question categories and achieved overall improvement from the previous survey.
- In “employee engagement,” Chugai was in the global top ranks.
- For further improvement in “environment for utilizing employees,” Chugai will address areas including resource optimization, interdepartmental cooperation, and creating opportunities for highly competent specialists.

#### Outline of Survey

**Number of Eligible Respondents and Response Rate**
Eligible respondents: 7,318 / Respondents: 6,644 / Response rate: 91%

**Question Categories**
Employee engagement: Strategy and direction; leadership; quality and customer orientation; respect for individuals; opportunities for growth; and compensation and benefits
Environment for utilizing employees: Performance indicators; authority and discretion; resources; education and training; framework for collaboration; business processes and organizational structure; and innovation

**Benchmark Data**
Global average for strongly performing companies, global average for all companies, global average for pharmaceutical companies, and average for Japanese companies

## Strategy and Progress

### Position management and talent management based on management strategy

To realize our management strategy and create innovation, we use position management and talent management to assign the right people to the right positions. In position management, we delineate the duties and human resource requirements for realizing corporate strategy and assign staff with the corresponding experience, skills, competencies, or other qualities. In talent management, we work to identify and develop

managerial talent and highly competent specialists at an early stage based on how their competencies, performance, and potential correspond to requirements and expectations. In this way, we are creating a talent pool[3] of future management candidates in each department and visualizing and selecting successor candidates for major positions in Japan and overseas. Medium- to long-term policy for cultivating successors is formulated in discussions between executive management and department managers, and includes off-the-job training programs to drive strategic assignment of human resources and reinforce leadership skills. Executive management takes the lead in implementing this plan-based human resource development and works to accelerate development.

3. A group from which next-generation leaders are drawn

### Strategic focus on core businesses and securing and strengthening of highly competent specialists

Leveraging its unique strength in science and technology, and its strategic alliance with the Roche Group, Chugai delivers innovative drugs and works to develop sophisticated solutions by driving advances in personalized healthcare (PHC). Chugai strives to realize growth by linking its core businesses with human resources. Specifically, we are focused on the recruitment and development of human resources who have strong expertise in medical science, DX, and other fields and who are motivated by a frontier spirit to take on challenges. Chugai in return supports the growth of these human resources by offering them opportunities to demonstrate their individual expertise and a wide range of career possibilities.

### Establishing a personnel system that encourages a spirit of challenge regardless of age or other attributes

Following its revision in April 2020, our new personnel system puts in place a competitive remuneration system based not on individual abilities and past contribution but on the value of duties performed in each position. In this way, it shifts the deciding factor from the individual to the role and the relevant duties and realizes a pay-for-position approach.

The job profile of all positions is now made available company-wide and all personnel are eligible for appointment regardless of age, thus abolishing age limits for managerial posts and supporting self-directed career development toward a future vision under the concept of “Career for Future.” Setting and strictly implementing rules for assignment and dismissal will further promote the rejuvenation of the organization.

The accompanying evaluation system sets indicators both for the performance required for a job (commitments) and for taking on challenges beyond that (targets). By doing so, we will improve satisfaction with evaluations and promote a spirit of challenge among employees. By setting indicators at the level of both commitments and targets and specifying their relative weight, the system allows a balanced evaluation in line with performance. It also provides appropriate and timely feedback from superiors, which encourages employees to challenge themselves.

To ensure fully effective operation of the new personnel system, managers receive regular training to enhance their skills for feedback and dialogue with team members. We also carry out continuous employee surveys and implement the PDCA cycle to improve not only the system content but also the operational rules.

### Supporting self-directed learning and growth

Chugai implements a range of human resource development measures and provides a variety of training programs to deepen and widen employee expertise, reinforce skills, and support career planning. Level-specific training consists of programs to impart the mindset, knowledge, and skills required for the particular position or role. Our leadership competency program strengthens the seven competencies required of all Chugai human resources through a training package to build conceptual, human, and technical skills and improve English-language ability. To promote self-directed career development, we offer a career design program as a regular opportunity for employees in all age groups to take stock of their career. Additionally, we support self-improvement by enabling employees to set their own goals and pursue them through continuous self-directed learning.

In 2021, we introduced a new learning management system based around on-demand programs. The resulting learning environment enables employees to work on their own development by pursuing continuous self-motivated study and growth toward their individual career aims. In this way, we are fostering a learning culture that encourages self-directed activity in the area of learning, re-skilling, and career development.

## Establishing new workstyles for improved productivity and work-life synergy

The COVID-19 pandemic is driving a shift to new workstyles, among them the rise of remote working. Against this background, Chugai has addressed the issue of new workstyles by gathering opinions in employee surveys, holding discussions within each organization and between labor and management, and examining the issue at the management level. Workstyle reform based on cooperation between labor and management has already produced a range of initiatives, but we see the changes accompanying the pandemic as a major opportunity to further accelerate existing workstyle reforms to realize new ways of working.

As workstyles vary depending on factors such as the character of the organization, job type, and specific work duties, our declared vision is to realize through digitalization a range of workstyles that are highly flexible in response to these factors. This “smart working” will meet the demands of both productivity improvement and work-life synergy, and result in continuous innovation. The implementation of new workstyles will be guided by four themes: (1) Introduction of the Telework System based on work-from-home (WFH) and satellite offices, (2) Creation of workplace environments that operate highly flexible workstyles yet still maintain and improve productivity, (3) Review of office-related systems coordinated with the introduction of the Telework System, and (4) Realization of personnel evaluation and management methods adapted to the Telework System.

By reconciling productivity improvement with work-life synergy, the introduction of new patterns of work offers a way forward to generating continuous innovation. In this way, continued initiatives for workstyle reform will enable us to go on contributing to patient wellbeing worldwide as a top innovator in the healthcare industry.

## Creating a culture of innovation through D&I and health and productivity management

Chugai has identified diversity and inclusion (D&I) as a key management issue. We believe that D&I is essential in order for employees to generate new value—in other words, diversity is necessary for generating innovation. As such, in 2010 we launched a working team led by the president, and in 2012 we established a dedicated organization that has since been conducting initiatives to promote diversity.

Amid demands for more active participation by diverse human resources, we provide e-learning on the topic of unconscious bias for managers, who play a key part in promoting D&I, as a way of enhancing their practical workplace skills. We also conduct annual training for managers and leader candidates to help women plan and develop their careers. In 2020, as part of an ongoing program of initiatives, we held task management training to equip managers to facilitate career planning and growth for team members navigating major life events. We will continue our focus on promoting the success of women, with a target for the end of 2023 of achieving 17 percent for both female management position ratio and female manager ratio.

Meanwhile, we are seeking to provide a variety of work arrangements and support systems so that all employees can benefit from work-life synergy. A healthy and vital organizational culture that supports both the mental and physical wellbeing of diverse human resources is essential to innovation. By rolling out health and productivity management based on workstyle reform and employee health management, we will work to further enhance the workplace environment.

Moreover, in 2020 we held Chugai Diversity DAYS with the aim of firmly establishing the practice of D&I to build an inclusive organizational culture that fosters innovation. As part of this initiative, the president delivered to employees a message emphasizing that the active participation of human resources who are diverse in terms of gender, age, cultural background, and other attributes is essential to implementing corporate strategy. In his message, the president named three activities key to inclusion: Spreading the message, talking to one another, and acceptance. By firmly establishing these practices, we will work to actively create a culture of innovation.

**Examples of initiatives by executives and department managers to promote the success of women**

- Messages from senior management on the importance and significance of D&I and female success delivered in the annual New Year’s address and at diversity-related events
- Commitment to activities for female success, with key performance indicators (KPIs) established to drive the appointment of women to managerial positions and a committee

consisting of senior management, executives with relevant responsibility, and all departmental managers that meets every year to check progress toward female advancement, discuss issues toward achieving the KPIs, and investigate career development plans and other relevant measures

- Nomination of women as successor candidates for all key positions in talent management (division head or equivalent)

**Creation of network for former employees through alumni system**

With the aim of building a two-way network between Chugai and its former employees and also of securing human resources for immediate effective deployment, Chugai introduced an alumni system in May 2020. The system makes it possible to respond to arising corporate recruitment needs by re-deploying alumni, in principle with regular employee status. Currently, around 100 former staff members are registered as alumni, and three have been redeployed. The network is a forum for lively interaction, with regular news bulletins from Chugai, sponsored events, and email contact between alumni.

**Establishing Systems and Environments to Promote the Success of Diverse Employees**

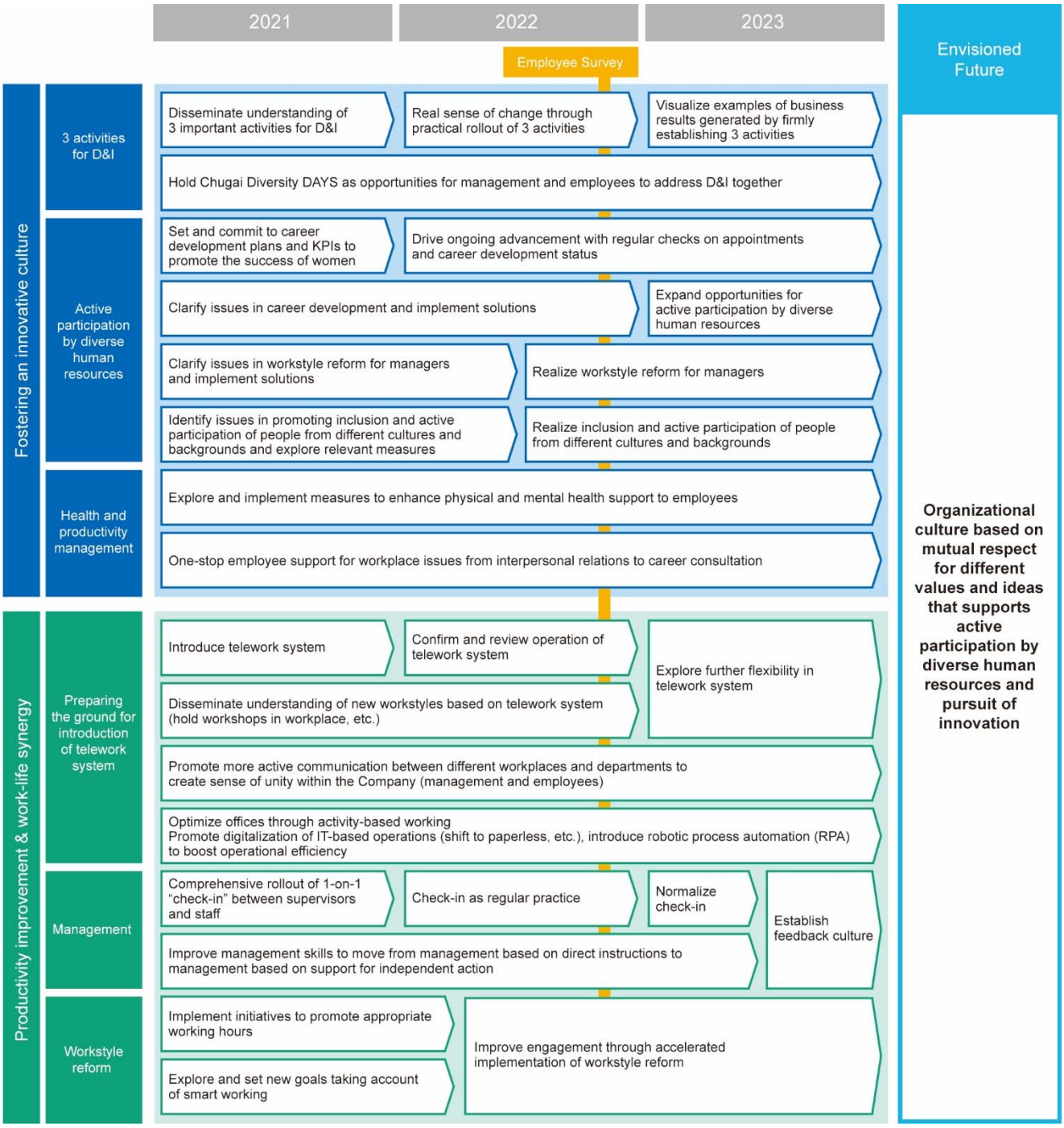
| | |
|---|---|
| More flexible workplaces | • Introduction of the Telework System<br>• Introduction of satellite offices<br>• Introduction of free address workspace (Head Office) |
| More flexible work schedules | • Super-flextime system (no core time) (including for MRs and other remote workers)<br>• Discretionary work system (for researchers)<br>• Paid leave system in units of half-days or hours |
| Support for work-life balance | • Support plan for living with spouse who is transferred (MRs)<br>• Use of Company vehicles to take children to/from childcare<br>• Consortium-managed childcare center (Head Office)<br>• Leave system for employees whose partner gives birth<br>• Leave system to nurse sick children (preschool age)<br>• Introduction of concierge for finding nursery care |
| Support for career planning | • Career consulting service<br>• Career reporting<br>• In-house job posting system<br>• Out-of-house job posting system<br>• Alumni system<br>• Re-employment system (transfer from contract to regular employment)<br>• Joint or secondary employment (where certain criteria are met)<br>• Leave for education and acquisition of qualifications<br>• Volunteer leave system<br>• Interviews and e-learning offered before childbirth leave and after childcare leave |

**Results of Workstyle Initiatives (Non-consolidated)**

| | Performance |
|---|---|
| Percentage of annual paid leave taken (Average days taken) (April 2019–March 2020 results) | 65.6% (14.7 days) |
| Average overtime hours/month[4] (April 2019–March 2020 results) | 2.6 hours/month |
| Percentage of male employees taking childcare leave (Average days taken) (2020 results) | 77.0% (15.3 days) |
| Percentage of employees using the WFH system | WFH as norm due to the COVID-19 pandemic |

4. Excluding employees on a de facto or discretionary working hours system

### Roadmap for Implementing D&I



# Human Rights

## Strategic Points

- Continue to conduct human rights awareness training
- Conduct human rights due diligence, including for suppliers
- Identification of human rights issues and implementation of solutions in cooperation with third-party organizations

### Performance in 2020

Continued to conduct human rights awareness training

8
Supplier evaluations conducted based on the PSCI Principles*

Continued to exchange opinions with third-party organizations

* The Pharmaceutical Industry Principles for Responsible Supply Chain Management established by the Pharmaceutical Supply Chain Initiative (PSCI), a non-profit group of global pharmaceutical companies

Employee training (2019)

Note: The 2020 training was conducted via e-learning.

Roundtable dialogue (Online meeting)

## Basic Approach

At Chugai, we declare our respect for human rights in the Chugai Group Code of Conduct, which is based on our shared Core Values. In respecting human rights, we aim to realize workplaces that prize diversity, where each person values their own feelings and accepts the values of others—allowing everyone to fully demonstrate their abilities, based on an organizational climate of appreciation for oneself and others. In such a workplace, people are empowered to work creatively with enthusiasm and engagement, which leads in turn to improved levels of achievement and increased productivity for the organization as a whole. We also believe that a workplace culture of this kind that encourages all employees to become more sensitive to human rights and to act with greater respect for the individual can help to eliminate social discrimination and infringements of human rights in society in general through corporate activities and their private lives.

In the increasingly important social issue of business and human rights, we believe that companies need to ensure respect for human rights not only in their own activities but throughout the supply chain. As an operator in the healthcare industry, we are committed to acting with a greater awareness of respect for human rights.

Chugai Group Human Rights Statement
https://www.chugai-pharm.co.jp/english/sustainability/humanrights/policy.html

## Issues and Initiatives

Chugai conducts ongoing human rights initiatives for its employees in areas such as prohibition of workplace discrimination and harassment, respect for diversity, and safety and health. In 2020, we provided training to impart an understanding of the main points of the revision to the law on prevention of harassment as well as training to help eliminate discrimination from a variety of perspectives, including those forms that have become more conspicuous during the COVID-19 pandemic. Meanwhile, based on the United Nations' Guiding Principles on Business and Human Rights, we formulated the Chugai Group Human Rights Statement, which commits us, in the framework of supplier management, to conducting human rights and environmental risk assessments in addition to the existing assessments of stable supply and quality management. To do this, we have formulated guidelines based on the PSCI Principles, in which we call on our business partners to comply with laws and social norms. The guidelines also specify other requirements including eliminating child labor and forced labor; prohibiting all forms of discrimination by race, gender, or other attribute; respecting the dignity of individual employees; and maintaining safety and health. The guidelines thus establish due diligence on human rights including attention to working conditions. In October 2020, Chugai participated for the third consecutive year in the international Business and Human Rights Conference in Tokyo, an event in its ninth year which is sponsored by the Caux Round Table Japan, where we engaged in individual dialogue with overseas experts. These experts stated that it was important for companies, when conducting human rights due diligence for suppliers, to add to the existing assessment items an analysis of the impact of COVID-19 on business and human rights issues. We also exchanged opinions on the creation of a trusted and user-friendly mechanism for handling complaints.

Due to the impact of COVID-19, the number of supplier assessments so far has been limited to eight, with no significant human rights-related risk identified. We were able to secure the understanding of suppliers regarding the need for human rights due diligence and their agreement to cooperate in addressing human rights issues. In 2021, we will continue with human rights due diligence focused on the contract manufacturing operators who are among our major suppliers.

In addition, Chugai has established an Anti-Bribery Policy as part of the proper management of its corporate activities. As well as setting our own code of conduct, it prohibits our business partners from engaging in bribery of government officials, civil servants, corporate staff, and other parties, whether corporations or individuals. We will continue our comprehensive efforts to prevent bribery.

# Environment, Health, and Safety (EHS)

## Strategic Points

- Implementation of plan toward achieving new mid-term environmental goals
- Strengthening of global EHS promotion system with emphasis on cross-departmental functions
- Execution of priority items for health and productivity management and reassessment of evaluation indicators

### Performance in 2020

**–17%**[1]
Energy consumption per employee compared with 2010
(2020)

**–20%**[1]
$CO_2$ emissions per employee compared with 2010
(2020)

**97%**[1]
Waste recycling ratio
(2020)

1. Chugai Group in Japan

### Certification as a "White 500" Health and Productivity Management Organization 2021 (Large Enterprise Category)

2021 健康経営優良法人 Health and productivity ホワイト500
(Large Enterprise Category)

## Basic Approach

As an R&D-driven pharmaceutical company, Chugai is engaged in many specialized scientific activities. One aspect of these activities involves handling numerous antibodies and highly active pharmaceutical substances, which means that ensuring environmental protection and maintaining health and safety are extremely important for us.

At the same time, the demands of society have grown more diverse and sophisticated. Integrated management of EHS is required worldwide because of the close connection between environmental protection and health and safety. Accordingly, in 2016, Chugai developed an integrated management system for EHS and has been implementing the plan-do-check-act (PDCA) cycle for ongoing improvement of its EHS promotion activities based on a consistent policy company-wide, from top management to each facility. Having established an EHS risk assessment system in 2017, we are now working to eliminate EHS risk in the workplace. Since 2008, we have implemented a Group-wide assessment system to reduce the risk of occupational injuries from exposure to all substances handled, not only restricted substances.

EHS management extends throughout the value chain, from the procurement of raw materials and manufacture of products through to their supply to patients and healthcare professionals. We are therefore working in cooperation with customers and suppliers, partners, and industry organizations to broaden our activities to cover the whole of the value chain.

## Strategy and Progress

### Outline of previous mid-term environmental goals

Chugai's aims encompass not only its own sustainable development but also environmental protection in local communities and globally. We have set priority items to be addressed as well as medium- to long-term targets.

The priority items of the previous mid-term environmental goals, which were set in 2014 to cover the period up to 2020, were climate change countermeasures, energy conservation, resource conservation, waste management, biodiversity protection, prevention of environmental pollution, and improvement of environmental literacy. Placing particular focus on the management of energy consumption and waste, we set the four mid-term environmental goals indicated in the table below, with corresponding goals for each individual year, and worked toward meeting each of these targets.

We have been progressing steadily with initiatives toward meeting the mid-term environmental goals by their final year of 2020. The reduction in energy consumption per employee compared with 2010 was held to 17 percent, but in $CO_2$ emissions per employee, we achieved a 20 percent reduction. In energy consumption per employee, we aim to use renewable energy certificates to reach a 20 percent reduction in non-renewable energy consumption.

**Mid-Term Environmental Goals (Target Year: 2020)**

| Item | Target | Performance in 2020 |
|---|---|---|
| Energy consumption per employee | 20% reduction from 2010 | 17% reduction from 2010[3] (20% reduction in $CO_2$ emissions per employee from 2010) |
| Average fuel efficiency of MR fleet | 16 km/L or higher | 27 km/L |
| Specified fluorocarbons (CFCs, HCFCs) | Eliminate use | Achieved |
| Zero emissions of waste[2] | 3 facilities | 2 facilities |

2. A waste recycling ratio of 99 percent or higher
3. We aim to reach a 20 percent reduction in non-renewable energy consumption by using renewable energy certificates to cover the equivalent of 3 percent.

**Performance in Environmental Goals for 2020**

| Item | Target | Achieved |
|---|---|---|
| Energy consumption | Year-on-year reduction of 2% or more | 6% reduction |
| $CO_2$ emissions | Year-on-year reduction of 2% or more | 6% reduction |
| Ratio of eco-friendly cars[4] | 80% or higher | 85% |
| Average fuel efficiency of MR fleet | 16 km/L or higher | 27 km/L |
| Industrial waste recycling ratio | 99% or higher | 97% |
| Final disposal ratio | Lower than previous year (2019: 1.1%) | 0.5% |
| On-site verification of waste disposal contractor facilities | 100% over a three-year period | 71% |
| Plain paper copier (PPC) paper purchased | Lower than previous year (2019: 126 tons) | 71 tons |
| Recycling ratio for PPC paper | 80% or higher | 78% |
| Whole effluent toxicity (WET) tests: Conduct at each plant and research laboratory | Once every year | Conducted once every year |

4. Includes hybrids and fuel-efficient vehicles

## Formulation of mid-term environmental goals 2030

In 2020, to reflect analysis results from the previous mid-term environmental goals and changes in the expectations and aspirations of society, Chugai formulated a more comprehensive set of mid-term environmental goals for 2030 from a longer-term perspective. In the items selected for inclusion in the new targets, the four items of the previous mid-term environmental goals are increased to 10, including items such as water risk and chemical substance management, to enable us to address material issues from a medium- to long-term perspective. For many of these items, we have designated 2025 as a milestone on the way to 2030. In the area of climate change, to respond to the need for long-term and large-scale countermeasures, we have selected zero $CO_2$ emissions as a long-term goal with a target year of 2050.

**New Mid-Term Environmental Goals (Target Year: 2030)**

| Area | Item | KPI (Base year 2019) |
|---|---|---|
| Climate change countermeasures (prevention of global warming) | Scope 1+2[5] $CO_2$ emissions | 40% reduction by 2025<br>60–75% reduction by 2030<br>Zero emissions by 2050 |
| | Scope 1+2[5] Energy consumption | 5% reduction by 2025[6]<br>15% reduction by 2030[6] |
| | Sustainable electricity ratio | 100% by 2025 |
| | Fuel consumption by MR vehicles | 35% reduction by 2025<br>75% reduction by 2030 |
| | Halogenated hydrocarbons | 25% reduction by 2025<br>100% reduction by 2030<br>(Base year 2020) |
| Use of renewable/ recycled resources (resource conservation, waste management) | Industrial waste reduction | 5% reduction by 2025[6]<br>10% reduction by 2030[6] |
| | Plastic waste reduction | 5% reduction by 2025[6]<br>10% reduction by 2030[6] |
| | Water resource conservation (water withdrawal) | 15% reduction by 2030[6] |
| Biodiversity protection (environmental burden mitigation) | Chemical substance management (SVHC)[7] | After 2021, manufacturing processes without using SVHC-listed chemicals are established for all Chugai original candidate molecules by commercial productions. |
| | Hazardous waste reduction | 5% reduction by 2025[6]<br>10% reduction by 2030[6] |

5. Scope 1: Direct emissions, Scope 2: Indirect emissions from the generation of purchased energy
6. Per total floor area (Excluding leased properties)
7. Substances of very high concern

### Climate change countermeasures

Viewed with increasing seriousness worldwide, climate change is an important issue for which reinforced regulation of fluorocarbons is envisaged. Given this situation, it is essential that we step up to initiatives at a higher level, as simply continuing with the current course of action will have limited effect. By 2025, we aim to realize a sustainable electricity ratio of 100 percent by opening a new research facility at Chugai Life Science Park Yokohama and relocating research laboratories, reducing and making more efficient

use of energy, and switching to sustainable electric power sources. As direct $CO_2$ emissions from fuel consumption (Scope 1) also need to be reduced, we are studying options in this area as well, including conversion, rationalization, and redesign of our existing facilities.

**Use of renewable/recycled resources**
With the current emphasis on the circular economy, businesses need to take a proactive approach to efficient resource utilization rather than simply meeting their fixed obligations. As well as making essential progress toward zero waste emissions, Chugai has designed its own unique business activities to promote the circular economy. In the area of water risk, although we have relatively low exposure due to our business activities being located mainly within Japan, we will respond to increasing expectations from society by ensuring comprehensive risk assessment and management.

**Biodiversity protection**
Stronger initiatives are required to manage not only substances covered by Pollutant Release and Transfer Register (PRTR) Law and specially controlled industrial waste, but also substances of very high concern (SVHC) under the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations. In addition to reinforcing measures to reduce harmful chemical substances, including wastewater management and verification of the product manufacturing plan, we will also enhance partnership with local communities.

## Scenario analysis to assess climate change risk

As the effects of climate change become more severe year after year, stakeholders, including investors, have been calling for adequate disclosure of its impact on corporate business activities. To respond to these stakeholder expectations and aspirations, Chugai conducted a scenario analysis applying the steps outlined below based on the framework in the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD).[8]

STEP 1 Qualitative assessment of risks and opportunities
- Survey of a range of published information and interviews with experts
- Identification of physical risks, transition risks, and opportunities
- Assessment and classification of each risk

STEP 2 Risk scenario analysis
- Setting of scope of risk scenario analysis
- Analysis of storm and flood risk now and after climate change
- Estimate of financial impact

The analysis results and qualitative assessment did not identify any major climate-related risk requiring large-scale business conversion and investment over the long term, which is the TCFD characterization of a high-risk sector. However, the results did indicate climate-related risks common to the manufacturing industry in general which make ongoing analysis essential, such as risks to manufacturing bases and product procurement from climate-related disasters, water shortages, and carbon taxes in the value chain. Moreover, some research indicates that the pharmaceutical manufacturing sector may have a relatively high level of greenhouse gas (GHG) emissions (Scope 1 and 2), and we therefore think that the possibility of regulatory strengthening across the industry needs to be considered. (See table on next page for an outline of the qualitative assessment of climate change-related risks and opportunities.)

The qualitative assessment consisted of climate change scenario analyses of our main product manufacturing and distribution bases in Japan assuming a 2°C and a 4°C temperature rise scenario. The estimated results indicated that, compared to the current estimate of ¥3.96 billion/year, the fall in sales revenue from storm and flood risk would be approximately 37 percent greater under the 2°C scenario (¥5.41 billion/year) and approximately 60 percent greater under the 4°C scenario (¥6.33 billion/year).

The analysis was carried out using the procedure indicated below.
- The probability distribution of floodwater depth for each building was calculated using the global coordinates of each business site to access data on plan scale and floodwater depth.
- Current storm and flood risk was calculated in terms of the expected reduction in sales revenue based on the number of days of business suspension at each floodwater depth and the frequency of such events.
- Distribution data was adjusted to account for climate change-related change in the frequency of high-intensity rainfall events.
- Storm and flood risk after climate change was estimated in terms of the expected reduction in sales revenue for each scenario.

The risk items included in the TCFD scenario analysis correspond to the items covered by the business continuity plan and other existing provisions, and the countermeasures associated with the latter resulted in a reduction in the financial impact estimated in the analysis of climate change-related risk. Specifically, the construction of the third facility (UK3) at the Ukima Plant included the provision of a five-meter-high defense against earthquake and flood damage, while the new distribution center to which operations relocated in January 2021 included flood defense measures based on a disaster map.

Going forward, we will continue applying the results of the scenario analysis to manage climate change-related risks and opportunities and working to further enhance information disclosure.

8. Disclosure of climate-related information that has a financial impact on a company
TCFD https://www.fsb-tcfd.org/

**Outline of the Qualitative Assessment of Climate Change-Related Risks and Opportunities**

| | | |
|---|---|---|
| Physical Risks | | |
| Acute risk | ✓ Increased risk of interruption of the supply chain, including raw material procurement and product shipment and distribution, due to increased frequency of localized torrential rain and major typhoons<br>✓ Increased frequency of damage to facilities and increased repair costs from abnormal weather and meteorological disasters, suspension of business activities due to damage to manufacturing facilities | General |
| Chronic risk | ✓ Risk of relocation of plants and other bases becoming necessary due to rising sea levels | General |
| | ✓ Risk of lower staff productivity and increased rates of absence due to heat and cold waves causing deterioration of the workplace environment and diseases with increased incidence due to climate change | General |
| | ✓ Risk of increased temperature control expenses in drug manufacturing, storage, and distribution, and risk of deterioration in product quality, due to rising outdoor temperature | Pharmaceutical |
| | ✓ Risk of water shortage and deterioration of water quality due to drought, etc. | Pharmaceutical |
| Transition Risks | | |
| Official policy and laws | ✓ Risk of increase in manufacturing-related energy costs and price of procured products due to rising carbon taxes<br>✓ Risk of capital investment costs arising from facility replacement to meet GHG emissions reduction targets set by national governments, industry organizations, etc. | General |
| Technology | ✓ Risk of growing capital investment costs arising from the introduction of new technologies (in-house power generation, storage batteries, etc.) accompanying the spread of clean energy technology | General |
| Markets | ✓ Risk of reduced demand due to rise in product prices following rise in market price of procured products<br>✓ Risk of change in consumer behavior | General |
| Reputation | ✓ Risk of impact on share price due to delay in implementing climate change countermeasures | General |
| Opportunities | | |
| Resource efficiency | ✓ Manufacturing cost reduction driven by improved resource efficiency in areas including energy use, water consumption, and waste management | General |
| Energy | ✓ More stable energy costs and energy supply due to improvement in distributed clean energy technology | General |
| Products and services | ✓ Opportunity for expansion of demand for pharmaceuticals due to diseases arising from climate change (existing drugs) | Pharmaceutical |
| Markets | ✓ Opportunity for expansion of demand for pharmaceuticals to treat infectious diseases caused by rising temperatures and abnormal weather (new market) | Pharmaceutical |
| Resilience | ✓ Minimization of physical risk-related damage due to plan-based implementation of countermeasures<br>✓ Greater operational stability due to climate-related risk assessment and risk diversification measures | General |

Pharmaceutical: Risk with high specificity to the pharmaceutical manufacturing sector
General: Risk for enterprises in general, particularly in manufacturing industry

## 2020: Initiatives and progress in environmental protection activities

As measures to conserve energy, we are reducing energy consumption by introducing highly energy-efficient facilities, switching fuels, introducing eco-friendly cars, and conducting an energy conservation program in daily business activities while curbing GHG emissions,[9] which is the key to combating climate change. Before proceeding toward our

mid-term environmental goals for 2030, we have entered into an agreement with an electric power company to begin installing sustainable power sources at the Utsunomiya Plant, Ukima Representative Office, Kamakura Research Laboratories, and Fuji Gotemba Research Laboratories from 2021. To prevent environmental pollution, we are also working to reduce the use of chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs) to halt the destruction of the ozone layer, and to prevent the leakage of environmental pollutants. Meanwhile, the Ukima Plant, which is covered by the Tokyo Cap-and-Trade Program, received a certificate of appreciation from the Tokyo governor dated January 4, 2021, in recognition of the plant's cooperation in 2020 with the metropolitan government's efforts toward a Zero Emissions Tokyo.

In waste management, we aim to increase the waste recycling ratio and further reduce landfill waste to achieve zero emissions of waste, and our initiatives are yielding results.

We are conducting risk management for water, given its importance as a raw material in pharmaceutical manufacturing and as a crucial global resource. As water-related risks, Chugai considers raw material procurement risks and water damage risks in distribution. Although Chugai believes its procurement-related risks to be low at present, it monitors the volume of water it uses and the wastewater it discharges each year, and is building awareness of the effective use of water resources. Chugai's countermeasures for the risks to stable supply posed by water damage include diversification of risk such as by storage and management at multiple storage facilities. Moreover, from the standpoint of protecting biodiversity, we began conducting WET tests[10] in 2013 to ascertain the ecological impact of wastewater discharged from our facilities. The purpose of this additional test is not only meeting the effluent standards of laws and regulations, but also making a general judgment of the ecological impact of chemicals involved in wastewater. In 2020, we again conducted a WET test once at each plant and research laboratory, and confirmed that there were no problems.

Meanwhile, our production bases continued with the water resource conservation activities begun in 2019. In 2020, we collaborated in forest maintenance activities with a local NPO in the wooded highlands of Kawanehoncho in Shizuoka Prefecture, which is the Fujieda Plant's water source. As well as minimizing the environmental impact of production activities, we want to help conserve the water resources Chugai shares with local residents. In our business activities, we use water with care and release it in a clean state, and we will continue with activities to maintain forests that sustain clean water.

9. In Sustainability Policy and Data 2020, which will be released separately, we intend to receive independent verification for 2020 energy consumption, GHG emissions (Scope 1, Scope 2, Scope 3, Categories 1, 4, 5, and 6), and industrial waste generated.
10. A method for comprehensive evaluation of the safety of wastewater and the aquatic environment by determining the impact on crustaceans (*Daphnia*), algae, and fish (*Oryzias latipes* and others) immersed in diluted wastewater

## Promotion and progress of health and safety activities

Chugai engages in health and safety activities as one aspect of its health and productivity management, in the belief that sound employee physical and mental health and a satisfying and rewarding work environment where all employees can do their jobs with enthusiasm are the foundation for growth.

To create such an environment, we established a company-wide health and safety promotion framework in 2017 based on a policy of cooperating with the health insurance society and the labor union in simultaneous pursuit of both individual and organizational health. We also established six priority items: support for employees with cancer, measures to prevent and treat lifestyle diseases among employees, measures for employee mental health, measures to address employee presenteeism (working while sick), improvement of health literacy, and workplace safety measures. In September 2019, as part of activities to promote health and productivity management, we decided to further strengthen measures against smoking, which is strongly linked to cancer and lifestyle-related diseases. With the aim of reducing the employee smoking rate to zero by the end of 2030, we issued the Chugai Group Non-Smoking Declaration and were able to declare all Company premises smoke-free in September 2020 after a concerted company-wide effort. We are also working with corporate departments to offer support to employees identified as having high stress levels in a stress check questionnaire. At the same time, we are seeking to improve organizational health based on the results of organizational analysis. Of course, in addition to these preventive measures, we continue to conduct our existing programs to support employees during cancer treatment and after they return to work, as well as mental health awareness activities.

In 2021, we plan to formulate new mid-term health and safety goals.

### Mid-Term Health and Safety Goals

| Item | Target | Performance in 2020 |
|---|---|---|
| Cancer screening participation rate[11, 12] | 90% or higher | Gastric cancer 83%, colorectal cancer 85%, lung cancer 95%, breast cancer 86%, cervical cancer 64% |
| Percentage of employees at high risk for lifestyle-related diseases | 2% or lower by 2020 | 4.7%[12, 13] |
| Awareness of Company programs | 90% or higher | 63% |
| EHS risk assessment | Conduct at each site at least once every three years | Conducted at 8 out of 16 sites |

11. Screening rate for lung cancer, gastric cancer, colorectal cancer, breast cancer, and cervical cancer in the eligible age group
12. Based on medical checkup data from April 2019 to March 2020
13. High-risk criteria are under review for a more proactive approach

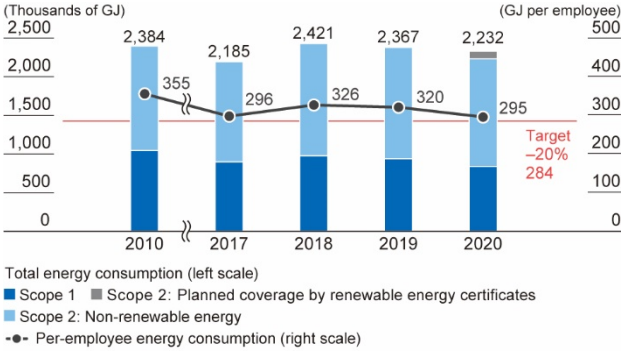
### Initiatives by Theme

| Theme | Details of Initiatives |
|---|---|
| Employee health management<br>Improvement of health literacy | Maintain a support system based on cooperation with the health management organization and related departments.<br>Improve health literacy as the basis for all health and safety activities, and conduct training for all employees. |
| Countermeasures against cancer | Step up recommendations for screening for early detection of cancer and provide enhanced support for continuing to work while undergoing cancer treatment. |
| Measures to prevent and treat lifestyle-related diseases among employees | Encourage high-risk individuals to take appropriate treatment and strengthen health guidance for them to reduce leaves of absence, job departures, and accidents caused by lifestyle-related diseases. |
| Measures for employee mental health | Conduct return-to-work programs and countermeasures to improve working environments based on the results of stress checks in cooperation with relevant departments. |
| Measures to address employee presenteeism (working while sick) | Plan, implement, and determine the effectiveness of measures based on health survey results. |

## Performance by EHS indicators

### Total and per-employee energy consumption

Total and per-employee energy consumption in 2020 decreased by 6 percent and 17 percent, respectively, compared with the base year of 2010. The goal of a 20 percent reduction in per-employee energy consumption was not met, but we plan to use renewable energy certificates to reach a 20 percent reduction in non-renewable energy consumption.



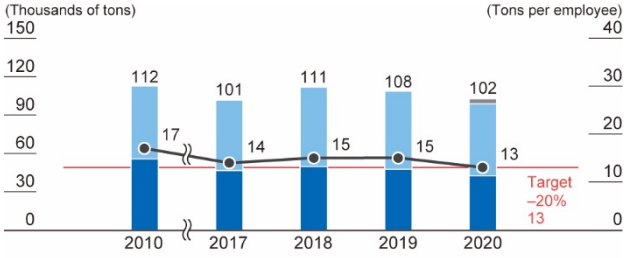

Total energy consumption (left scale)
Scope 1 Scope 2: Planned coverage by renewable energy certificates
Scope 2: Non-renewable energy
Per-employee energy consumption (right scale)

Per-employee energy consumption after utilization of renewable energy certificates in 2020: 284 GJ

Note: The year 2010 is the base year for mid-term environmental goals.
Overseas energy consumption (electricity and heat) is included from 2018.

### $CO_2$ emissions and $CO_2$ emissions per employee

Total $CO_2$ emissions decreased 6 percent from 2019 to 101,663 tons. $CO_2$ emissions per employee decreased 20 percent compared with 2010. The main factor was a reduction in direct $CO_2$ emissions from fuel consumption (Scope 1), achieved through measures such as introducing highly energy-efficient facilities, fuel switching, and promoting energy-saving measures.



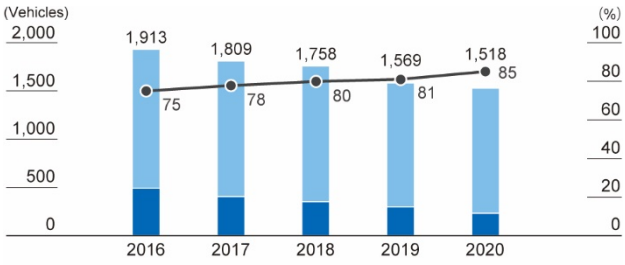

$CO_2$ emissions (left scale)
Scope 1 Scope 2: Planned coverage by renewable energy certificates
Scope 2: Non-renewable energy $CO_2$ emissions per employee (right scale)

$CO_2$ emissions per employee in 2020 after utilization of renewable energy certificates: 13,000 tons

Note: The year 2010 is the base year for mid-term environmental goals.
Figures from 2018 include overseas emissions (electricity and heat).

### Ratio of eco-friendly cars

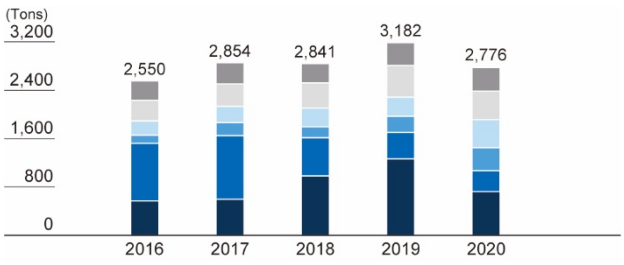
As of December 31, 2020, Chugai had introduced a cumulative total of 1,294 hybrid and fuel-efficient vehicles in its MR fleet. The ratio of eco-friendly cars was 85 percent, meeting the year's target of 80 percent or higher.




Number of gasoline and diesel vehicles (left scale)
Number of eco-friendly vehicles (left scale)
Ratio of eco-friendly cars (right scale)

### Industrial waste

Industrial waste generated decreased by 406 tons from 2019 to 2,776 tons. The main factor was the decrease in sludge generation due to the decline in production accompanying the decrease in production lines at the Utsunomiya Plant. The Fujieda Plant, which had the highest waste oil emissions, is progressing with measures to reduce waste, including introduction of an oil-water separation process in its waste treatment facilities to reduce the volume of waste oil.

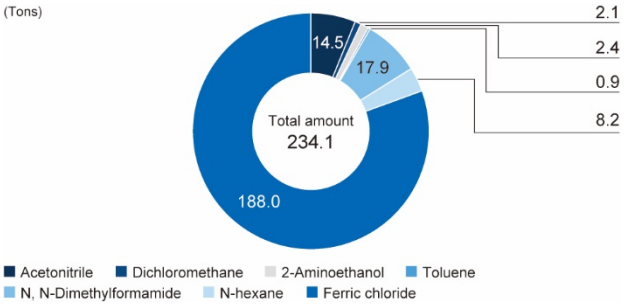



Sludge Waste oils Waste acids Waste alkalis
Waste plastics Others

Note: The amount of waste generated overseas is included from 2018.

### Volume of substances covered by PRTR Law[14] (Statistical period: April 2019–March 2020)

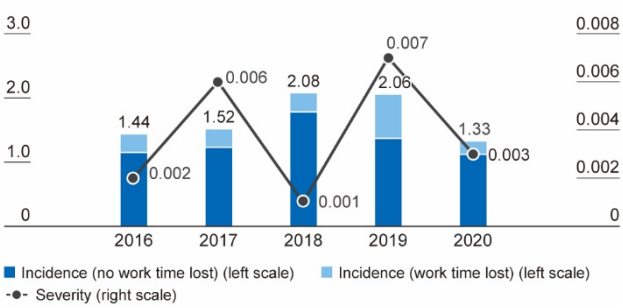
The volume of substances was 234 tons. Of this figure, 188 tons consisted of ferric chloride, which is used to treat the wastewater generated in the biopharmaceutical manufacturing process. The volume therefore increases with production amount.




14. Handled amounts of chemical substances covered by PRTR Law

### Incidence and severity[15] of occupational injuries

Based on the principle that employee safety comes before business, we work actively to ensure safety, prevent occupational injuries, maintain and enhance employee health, and create a comfortable workplace environment.




15. Incidence: Indicator of frequency showing the number of occupational deaths and injuries per million hours worked (Incidence = Number of occupational deaths and injuries / Total number of hours worked × 1,000,000)
Severity: Indicator of severity of occupational injuries showing number of working days lost per thousand hours worked (Severity = Number of working days lost / Total number of hours worked × 1,000)

Note: Figures from 2020 include employees of contractors engaged in joint operations with Chugai employees at the same plant or research facility.

### GHG Emissions (Tons)[16]

| Scope 1: Total 42,771 | | | | Scope 2: Total 59,935 | |
|---|---|---|---|---|---|
| Energy-related: 41,728 (Direct emissions) | | Non-energy-related: 1,043 (Fluorocarbons, etc., from business activities) | | Indirect emissions from the generation of purchased energy (Electricity, heat) | |
| Plants | 29,070 | Fluorocarbons | 959 | Plants | 31,178 |
| Research laboratories | 11,192 | • Japan | 959 | Research laboratories | 23,984 |
| Branches | 1,446 | • Overseas | 0 | Branches | 913 |
| Head Office | 21 | $CO_2$, etc. | 84 | Head Office | 528 |
| Distribution | 0 | • Japan | 72 | Distribution | 561 |
| Overseas | 0 | • Overseas | 12 | Overseas | 2,770 |

| Scope 3: Total 1,052,337 (excl. calculations in progress) (Other indirect emissions) | | | | |
|---|---|---|---|---|
| Classification | | Category | Scope of Calculation | Emissions Volume |
| Upstream | 1 | Purchased goods and services | Raw materials, procurement from Roche/CMOs | 811,546 |
| | 2 | Capital goods | Capital investment | 212,816 |
| | 3 | Fuel- and energy-related activities not included in Scope 1 or Scope 2 | Scope 1 and 2 energy purchase | 19,883 |
| | 4 | Upstream transportation and distribution | Transport from logistics centers to wholesalers and airports, and from airports in Japan to overseas airports | 4,594 |
| | 5 | Waste generated in operations | Industrial waste | 237 |
| | 6 | Business travel | Business travel by aircraft in Japan and overseas | 774 |
| | 7 | Employee commuting | All employees | 2,352 |
| | 8 | Upstream leased assets | Not covered | — |
| Downstream | 9 | Downstream transportation and distribution | Transport from wholesalers to hospitals | Calculation in progress |
| | 10 | Processing of sold products | Not covered | — |
| | 11 | Use of sold products | Not covered | — |
| | 12 | End-of-life treatment of sold products | Packaging materials sold | 84 |
| | 13 | Downstream leased assets | Not covered | — |
| | 14 | Franchises | Not covered | — |
| | 15 | Investments | Joint research activities with academia | 51 |

16. In Sustainability Policy and Data 2020, which will be released separately, we intend to receive independent verification for 2020 energy consumption, GHG emissions (Scope 1, Scope 2, Scope 3, Categories 1, 4, 5, and 6), and industrial waste generated.

# Social Contribution

## Strategic Points

- Contribution to health in local communities
- Promotion of understanding of diversity to realize an inclusive society

### Performance in 2020

Promoted awareness of and supported para-sports

3
Number of SPOTLIGHT events
(2020)

## Basic Concept of Social Contribution Activities

As a member of society, Chugai engages in social contribution activities to help solve social issues, contributing our resources and professional capabilities without seeking direct compensation. We actively promote activities that contribute to society while maintaining partnerships with society. We also encourage and support the engagement of individual employees in social contribution activities. Chugai keeps its stakeholders informed properly about its efforts in social contribution activities. Based on this approach, we have identified five priority areas: healthcare, social welfare, creating an inclusive society, next-generation development, and local community.

Basic Concept of Social Contribution Activities
https://www.chugai-pharm.co.jp/english/sustainability/community/concept.html

## Main Initiatives for Social Contribution

### Disease Awareness

**SPOTLIGHT**

We have been engaged since November 2019 in SPOTLIGHT, a project for patient-centric activities to help resolve social issues in the field of rare diseases. Many of these diseases are difficult to treat and patients may struggle to receive adequate understanding and support from society for their condition and the associated challenges. Our aim in launching SPOTLIGHT was to share information on its activities with stakeholders in and outside the Company to highlight the situation of patients whose voices would otherwise go unheard and thereby help resolve the social issues related to rare diseases.

One of the regular activities is a seminar for the media designed to promote improved understanding of social issues in the area of neuromuscular diseases through lectures and discussions with patients, healthcare professionals, and experts. The theme in 2019 was “Neuromuscular Diseases and Employment: Towards Improvement” and in 2020 “Definite Diagnosis and Emotional Support.” These events spread the message that, when people with disabilities receive the appropriate support to enable them to participate in society, it not only enhances their QoL but also improves sustainability for the whole of society.

In 2020, to coincide with World Hemophilia Day, we launched a dance video for children with hemophilia, who often experience deterioration of muscular strength through lack of physical activity. The video introduces a range of enjoyable dance exercises accessible to everyone. We also held an in-house workshop with the participation of a certified genetic counselor. Through sharing of information on the current state and issues of genetic disease counseling and the experiences of patients and their families, the session provided an opportunity for renewed reflection on the meaning of the “patient-centric” approach that we advocate.

Patient-Centric Activities to Help Resolve Social Issues in the Field of Rare Disease
https://www.chugai-pharm.co.jp/english/sustainability/patient/spotlight.html

### Initiatives for generation AYA

In March 2017, Chugai launched AYA Life, a website for young cancer patients offering regularly updated content. Recognition of generation AYA* has been growing gradually, but there are still many patients facing a wide range of issues in areas from higher education and employment to marriage. To help even in a small way to relieve these anxieties and issues, in 2020 we held the online AYA Roundtable, a series of open discussions among people affected, whose content has been published on the website six times. As a leader in the area of oncology, Chugai will continue improving the website to provide a space that supports generation AYA cancer patients to face their treatment with peace of mind.

*AYA stands for Adolescent and Young Adult and is aimed at the 15 to 39 age group.

AYA Life
https://aya-life.jp/ (in Japanese only)

ART FUNK BREAKIN

**Supporting children's activities**
We provide support as a top program partner to the CP Adaptive Sports Class, a regular exercise class designed mainly for children who are wheelchair users. To give children with disabilities and their families the opportunity to participate in outdoor activities, we also sponsor kayak and handcycling classes for parents and children to enjoy together, thus encouraging the children to challenge themselves with activities that are sometimes considered difficult for them.

A new addition to our wide range of support activities is our sponsorship of ART FUNK BREAKIN, Japan's first breakdance competition exclusively for people with disabilities, organized by the Japan Adapted Breakin Association and the Agency for Cultural Affairs.

**Raising awareness of para-sports**
With the aim of promoting understanding of diversity, we provided support for the making of a booklet to raise awareness of hearing disabilities and a handbook for wheelchair softball.
- *What Does Being Deaf Mean?*, published by the Japan Deaf Football Association
- *Wheelchair Softball Handbook*, published by the Japan Wheelchair Softball Association

Action to assist an evacuation center operated by a support group
(Kuma district, Kumamoto Prefecture)

## Disaster relief

**Support to areas hit by torrential rains in July 2020**
To provide emergency relief following the torrential rains that hit especially the Kyushu and Chubu regions in July and to support regional recovery, Chugai made financial donations to the Association for Aid and Relief, Japan, and the AMDA Group. Both groups provided daily living assistance and support for recovery to local people through evacuation centers, where appropriate measures were taken to prevent COVID-19 infection.

**Support to areas of western Japan hit by torrential rains**
Chugai is a regular participant in the Roche Group charity event Roche Children's Walk. Chugai matches the funds raised by employees with an equal sum and the total amount is donated to associations in Malawi and other countries and disaster-hit areas of Japan. In 2020, we supported Nozomi, an NPO based at Kurashiki in Okayama Prefecture that provides assistance in areas including employment, child development, and after-school day service facilities. Following the destruction of the organization's facilities in the torrential rains of July 2020, it relocated its activities to the neighboring city of Soja. The donation will be used to cover the cost of moving its office back to Kurashiki.

## Para-transit vehicle donations

Chugai's program to donate specially equipped para-transit vehicles began in 1985 as part of activities to commemorate the Company's 60th anniversary. The program marked its 36th year in 2020. A total of 263 vehicles have been donated since the start of the program. Securing the means for senior citizens and disabled people living at home to go to places such as hospitals, day service centers, and day care centers and for staff from these facilities to visit homes to perform in-house care is significant from the viewpoint of enhancing welfare services. The para-transit vehicle donation program is conducted in cooperation with the Japan National Council of Social Welfare and Central Community Chest of Japan, and through it vehicles have been donated to recipients in all of Japan's 47 prefectures.

# Global Health

## Strategic Points

- Rolling out global health activities that contribute to both the creation of corporate value and the resolution of social issues
- Contributing to the sustainable improvement of healthcare, mainly in low- and middle-income countries
- Prioritizing local needs and promoting activities that utilize Chugai's capabilities

### Performance in 2020

Held workshop on multidisciplinary team care in Cambodia in February as part of activities to support childhood cancer treatment

Entered into partnership with City Cancer Challenge Foundation (C/Can) in July

## Chugai's Basic Approach to Global Health

Chugai has adopted creating shared value with stakeholders as its basic management policy and is rolling out global health activities that contribute to both the creation of corporate value and the resolution of social issues, with the aim of "the realization of advanced and sustainable patient-centric healthcare". These activities will be continued in our new growth strategy "TOP I 2030".

Basic Policy for Creating Shared Value
https://www.chugai-pharm.co.jp/english/sustainability/sharedvalue/policy.html

There are still many people around the world who suffer from diseases without a cure, or who, despite the availability of treatment, are denied access due to poverty or institutional reasons, etc. Chugai has adopted creating shared value with stakeholders as its basic policy. We identified 25 material issues that should be given priority, one of which is improving access to healthcare. In this area, we aim to generate corporate value and at the same time contribute to resolving social issues through a range of activities including partnerships with public bodies, NGOs, industry organizations, and other entities. Our Basic Approach to Global Health, issued in 2019 to outline this strategy, sets the following priority initiatives: developing and improving access to new products for diseases with no treatments, and improving access to sustainable healthcare. Before launching specific activities, we undertake detailed research into local needs with the emphasis on activities that make the best use of Chugai's capabilities in terms of strengths, technologies, and expertise, and activities that can contribute to sustainable improvement of healthcare mainly in low- and middle-income countries.

Chugai's Basic Approach to Global Health
https://www.chugai-pharm.co.jp/english/sustainability/globalhealth/concept.html
Activity Reports: Global Health
https://www.chugai-pharm.co.jp/english/sustainability/activity/index.html?year=&category=2

## Main Initiatives for Global Health

### Main Projects We Participate In

**GHIT Fund**

Jointly established with funding from Japanese pharmaceutical companies, the Japanese government, the Bill & Melinda Gates Foundation, and the United Nations Development Programme, the Global Health Innovative Technology Fund (GHIT Fund) is Japan's first public-private partnership to support and promote research and development of drugs, vaccines, and diagnostics for infectious diseases in developing countries. Chugai joined the GHIT Fund in December 2014. In addition to making donations, Chugai is active on the fund's council and contributes to its administration.

GHIT Fund
https://www.ghitfund.org/

**Access Accelerated (AA)**

AA was established in January 2017 by 22 global pharmaceutical companies including Chugai and follows a strategy decided jointly by members. In partnership with the World Bank Group, the City Cancer Challenge Foundation, and other organizations, AA is working for the prevention, diagnosis, and treatment of noncommunicable diseases (NCDs) in low- and middle-income countries. Its aim is to contribute to the target set in the United Nations Sustainable Development Goals (SDGs) of achieving a one-third reduction in premature deaths from NCDs by 2030.

Access Accelerated
http://www.accessaccelerated.org/

Khmer staff attending the workshop

## Chugai Independent Initiatives

### Target disease areas: cancer, hemophilia, and other non-communicable diseases

**Activities to support childhood cancer treatment (Cambodia)**

The Cambodian economy has been growing in recent years, particularly in urban areas. In the field of healthcare and hygiene, however, equal access to quality medical care remains a challenge for reasons including the shortage of healthcare professionals, insufficient medical knowledge, and the lack of a well-developed health insurance system. One of the issues that needs to be addressed is how to enhance coordination between doctors, nurses, and the numerous other healthcare professionals to deliver high-quality medical care within the constraints of the limited human resources and facilities available to frontline services. To help resolve this issue, Chugai, bringing together the expertise in supporting team care it has accumulated over many years as a leader in the area of oncology, held a workshop on multidisciplinary team care in Cambodia for local healthcare professionals in February 2020. The workshop, which took place at the Children's Medical Center operated by the NPO Japan Heart, welcomed twenty-one participants. We aim to host a total of 50 healthcare professionals at the workshop over the next three years.

**Enhancing the Quality of Patient-Centric Cancer Care (Yangon, Myanmar)**

In Myanmar, the therapeutic approach adopted for cancer patients is not based on multidisciplinary coordination, and no standard therapy has been established. To contribute to enhancing the quality of patient-centric cancer care in Yangon, we entered into a partnership in July 2020 with the NGO City Cancer Challenge Foundation (C/Can), which supports cancer treatment in units of cities in the developing world. Specifically, we provided support for the formulation of cancer treatment guidelines tailored to local conditions, and education and training to support implementation of the guidelines by multidisciplinary teams of healthcare professionals including doctors, nurses, and caregivers, with training for approximately 400 staff planned over a period of three years. The aim is to promote team care based on multidisciplinary coordination for types of cancer with strong treatment needs locally, and to encourage the consolidation and further dissemination of this practice. So far, guidelines for breast cancer and cervical cancer have been formulated and received approval from the Myanmar Ministry of Health and Sports.

Treatment in a developing country
(provided by WFH)

## World Federation of Hemophilia (WFH) Humanitarian Aid Program

The WFH Humanitarian Aid Program, comprising a network of patient organizations in 140 countries, aims to improve access to care and treatment for people with inherited bleeding disorders in developing countries, where there is a severe lack of access to healthcare. Chugai, the originator of the hemophilia A agent Hemlibra, is participating together with Roche as a member of the Roche Group. The Roche Group will provide prophylactic treatment to approximately 1,000 people with hemophilia A in developing countries by donating supplies of Hemlibra over a course of five years. Additionally, the Group is providing support to put in place the infrastructure and conditions required for healthcare professionals to make proper use of treatments.

Mobile medical clinic in Myanmar

**Support for Safer Childbirth and Health Camps Against NCDs (Rural areas of Myanmar)**

In partnership with the NPO AMDA Multisectoral and Integrated Development Services (AMDA-MINDS), Chugai is engaged in rural areas of Myanmar in projects to promote safer hospital-based childbirth and maternity healthcare and to combat NCDs. In the latter project, healthcare professionals traveled to villages and set up mobile clinics, with a target of examining more than 4,000 people at 48 locations throughout Meiktila Township. People in rural areas face hurdles to outpatient consultation and treatment due to the distances and cost burden, resulting in the issue of delayed initial treatment and progression to serious illness. In 2020, of some 2,500 villagers examined, 30 percent were diagnosed as having an NCD, for which treatment and follow-up care were arranged. We also provided education and training to prevent the spread of COVID-19 infection as well as protective masks and gowns. To gain an accurate understanding of local needs for each project, we listen carefully to the opinions and requests of patients, healthcare professionals, and local health departments in such a way that we can continue helping to improve access to healthcare even after the project is completed.