

Chugai in Action

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Overview of Activities in 2019

* 1: Value Creation 2: Value Delivery 3: Promote Advances in PHC 4: Strengthen Human Capital and Conduct Fundamental Structural Reform 5: Strengthen Sustainable Platforms

Category	Main initiatives	Connection with IBI 21 strategies*				
		1	2	3	4	5
Research	• Continuously generating first-in-class ¹ and best-in-class ² drugs	●				●
	• Creating molecular targeted drugs that contribute to personalized healthcare (PHC)	●	●	●		●
	• Strengthening innovative proprietary research technologies and creating innovative antibodies	●				●
	• Providing support and education for researchers from Asia				●	
	• Maintaining high animal welfare standards in accordance with international guidelines					●
Development	• Improving clinical development of drugs to address unmet medical need ³	●		●	●	●
	• Identifying latent medical need and achieving early PoC ⁴	●			●	
	• Increasing productivity and speed of global clinical development for early market launches	●		●	●	●
	• Conducting simultaneous development and regulatory filing of drug therapies and diagnostics that contribute to PHC	●		●	●	●
	• Strengthening lifecycle management to maximize product value	●		●	●	●
	• Obtaining early approval for projects in-licensed from Roche	●			●	
Pharmaceutical Technology and Production	• Providing a stable supply of high-quality drugs and investigational drugs	●	●			●
	• Enhancing the system for faster global launches and simultaneous development of multiple products	●	●			
	• Achieving early PoC by raising the level of CMC ⁵ development	●			●	
	• Raising the level of competitive advantages from late-stage development to initial commercial production (including investigation of next-generation industrial technologies)					●
	• Achieving world-class quality control systems and continuously raising their level	●				●
Marketing	• Contributing to advances in medicine as Japan's leading therapeutic antibody company		●			
	• Promoting standards of care and proper use of medicines in oncology		●	●		
	• Promoting PHC for optimal treatment options		●	●		
	• Supporting the resolution of medical issues in mainstay product areas and regions		●			
	• Consideration of patient-centric therapeutic approach		●			
Medical Affairs	• Building a consistent global medical affairs promotion system with proper independence of roles		●			
	• Strengthening systems for healthcare compliance and governance of contract-based post-marketing studies		●			
	• Generating evidence and promoting scientific communication activities		●			
	• Expanding and upgrading global medical information functions		●			

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. PoC is confirmation that the therapeutic effect conceived in the research stage is effective in humans. Early PoC means that in addition to safety, signs of efficacy or pharmacological effect have been confirmed in a limited number of cases.

5. Chemistry, Manufacturing and Controls: Control functions from development of manufacturing processes to drug quality and manufacturing

Main performance indicators in 2019

- Generated multiple drug discovery projects from candidate compounds that originated from the Collaboration Promotion Laboratory at IFReC
 - Created development candidates using proprietary antibody engineering technologies
 - Created development candidates using proprietary middle molecule technologies
 - Started construction of Chugai Life Science Park Yokohama
-
- Conducted development of NXT007 and obtained early approval for Rozlytrek
 - Provided insights for promoting utilization of data, including real-world data (RWD), and maximizing product value
 - Further improved processes by carrying out operational consolidation and analysis of clinical operations, systems and processes, as well as management of contract research organizations and vendors, etc. that are common among projects
-
- Invested in facilities for faster launches and simultaneous development of multiple antibodies and small molecule drugs (started operation of new antibody API manufacturing facility (UK3) at Ukima Plant, began manufacturing Actemra subcutaneous injection using a tray filler at Utsunomiya Plant, and started construction of new manufacturing facility for APIs for small and middle molecule drugs at Fujieda Plant)
 - Received FDA pre-approval inspection for satralizumab
 - Received pre-approval inspection and approval for Hemlibra in countries around the world
 - Strengthened global supply chain management
 - Enhanced next-generation core technologies for API and formulation manufacture
 - Strengthened development ability by reducing costs from the early stage onward and planning and implementing a formulation strategy
 - Conducted structural reform of production functions to enhance competitiveness and improve operational efficiency
-
- Conducted support activities for patient-centric regional healthcare and multidisciplinary team care, including promotion of disease awareness in cooperation with the government
 - Provided an information-sharing support tool to facilitate smooth communication between patients and their healthcare professionals
 - Enhanced communication of safety information through use of post-marketing surveillance and adverse reaction databases and cooperation with Safety Experts
 - Enhanced marketing functions in accordance with regional healthcare conditions
 - Education for MRs with a high level of expertise
-
- Generated clinical evidence by conducting industry-initiated clinical studies and supporting investigator-initiated clinical studies
 - Generated non-clinical evidence by conducting basic research to shed light on modes of action of drugs, etc.
 - Improved business efficiency through introduction of MI chat, a chatbot for product information inquiries
 - Promoted global-level medical activities in cooperation with Roche and overseas subsidiaries
 - Implemented and supported construction of data utilization system for database research, etc.
 - Established appropriate governance and compliance system in response to Guidelines for Prescription Drug Marketing Information Provision and other regulations

* 1: Value Creation 2: Value Delivery 3: Promote Advances in PHC 4: Strengthen Human Capital and Conduct Fundamental Structural Reform 5: Strengthen Sustainable Platforms

Category	Main initiatives	Connection with IBI 21 strategies*				
		1	2	3	4	5
Drug Safety	• Strengthening pharmacovigilance system to meet the world's strictest standards and most comprehensive global regulations					●
	• Providing solutions to patients and healthcare professionals using drug safety information		●			
	• Preparing and implementing risk management plans (RMPs)		●			●
Quality and Regulatory Compliance	• Strengthening global quality governance					●
	• Establishing system to provide product quality solutions from customer's perspective		●			
	• Establishing global quality and regulatory intelligence management system for post-marketing products and late-stage development projects		●			
	• Establishing and conducting new quality and regulatory compliance scheme in response to new business developments (medical devices, regenerative medicine, etc.)		●	●		
	• Establishing quality and regulatory compliance framework and governance for data use		●	●		●
Intellectual Property	• Protecting and effectively using rights for broadly applicable innovative technologies		●	●	●	●
	• Filing high-quality patent applications and effectively allocating resources	●	●	●	●	●
	• Aggressively filing patent applications outside Japan with a view to global co-development	●	●	●	●	●

Highlights of 2019

Products and Development Projects

March	<ul style="list-style-type: none"> • Hemlibra obtained approval for additional indication (severe hemophilia A without inhibitors; Europe) • Rituxan obtained approval for additional indication (CD20-positive chronic lymphocytic leukemia; Japan) (Zenyaku Kogyo Co., Ltd.) • Actemra intravenous infusion obtained approval for additional indication (cytokine release syndrome; Japan) • Risdiplam received orphan drug designation (spinal muscular atrophy; Japan) 	September	<ul style="list-style-type: none"> • Rozlytrek launched (Japan) • Satralizumab received orphan drug designation (neuromyelitis optica and neuromyelitis optica spectrum disorder; Japan) • Tecentriq obtained approval for additional indication (PD-L1-positive triple-negative breast cancer (TNBC)) and additional formulation (840 mg) • FoundationOne CDx Cancer Genomic Profile obtained approval for expanded use as a companion diagnostic for Lynparza
May	<ul style="list-style-type: none"> • Actemra intravenous infusion obtained approval for additional indication (adult Still's disease; Japan) 	October	<ul style="list-style-type: none"> • Telomelysin (OBP-301) receives Sakigake Designation • Hemlibra obtained approval (hemophilia A without inhibitors; Taiwan)
June	<ul style="list-style-type: none"> • FoundationOne CDx Cancer Genomic Profile launched and testing services on consignment started • Rozlytrek obtained approval (<i>NTRK</i> fusion gene positive advanced/recurrent solid tumors; Japan) • FoundationOne CDx Cancer Genomic Profile obtained approval as a companion diagnostic for Rozlytrek 	November	<ul style="list-style-type: none"> • Hemlibra launched (hemophilia A with inhibitors; Taiwan) • Polatuzumab vedotin received orphan drug designation (diffuse large B-cell lymphoma; Japan) • Tecentriq Intravenous Infusion 840 mg (launched in Japan)
August	<ul style="list-style-type: none"> • Tecentriq obtained approval for additional indication (extensive-stage small cell lung cancer; Japan) 	December	<ul style="list-style-type: none"> • Nemolizumab received breakthrough therapy designation (pruritus associated with prurigo nodularis; U.S.) (Galderma S.A.)

Main performance indicators in 2019

- Increased capacity for generating and providing drug safety information using advanced technologies such as epidemiology and information technology, and enhanced the activities of Safety Experts, a specialist position for handling drug safety information
- Established global-level safety functions to prepare for business expansion in Asia
- Led the industry by conducting activities to raise awareness regarding the use of the risk management plan (RMPs) among healthcare providers

- Strengthened quality systems and handled overseas inspections by EMA, FDA, etc. (for all GxP)
- Complied fully with the Guidelines for Prescription Drug Marketing Information Provision
- Established system to provide product quality solutions through coordination among the Marketing & Sales Division, Pharmaceutical Technology Division and Quality & Regulatory Compliance Unit
- Strengthened cooperative schemes including with out-licensees, partners and overseas bases
- Dealt with quality management system and new modalities (regenerative medicine, gene therapy, etc.) for genomic mutation analysis program FoundationOne CDx Cancer Genomic Profile
- Established a digital compliance system for handling human-derived data

- Market defense in lawsuits with manufacturers of similar products with the equivalent effect or developers and manufacturers of biosimilars
- Operated a system for monitoring other companies' patents
- Strengthened cooperation with the Research Division, Pharmaceutical Technology Division and IFRc using IP liaisons as a hub
- Strengthened cooperation with IP functions of Roche and Genentech Inc. and with internal and external stakeholders

Management

January	<ul style="list-style-type: none"> • Transferred rights for Oxarol Ointment 25µg/g, Oxarol Lotion 25µg/g and Marduox Ointment to Maruho Co., Ltd. • Announced new Mission Statement and new mid-term business plan IBI 21, aiming to grow together with society by creating and delivering innovative drugs and services
March	<ul style="list-style-type: none"> • Entered into business partnership agreement with Miraca Holdings Inc. for FoundationOne CDx Cancer Genomic Profile
April	<ul style="list-style-type: none"> • Transferred Ulcerlmin business to Fuji Chemical Industries Co., Ltd. • Entered into exclusive licensing and capital tie-up agreements with Oncolys BioPharma Inc. for Telomelysin (OBP-301) oncolytic viral immunotherapy • Implemented early retirement incentive program • Decided to construct a new manufacturing facility for APIs for small and middle molecule drugs at the Fujieda Plant
May	<ul style="list-style-type: none"> • Decided to establish Chugai Life Science Park Yokohama and to relocate research laboratories
June	<ul style="list-style-type: none"> • Entered into service agreement for logistics operations with Mitsubishi Logistics Corporation
November	<ul style="list-style-type: none"> • Agreed with JW Pharmaceutical Corporation to make their joint venture in Korea, C&C Research Laboratories, a wholly owned subsidiary of JW Pharmaceutical
December	<ul style="list-style-type: none"> • Announced change in representative directors

Stakeholders

January	<ul style="list-style-type: none"> • Started operation of MI chat (Medical Information ChatBot), an automated conversation program that uses AI to respond to product information inquiries from healthcare professionals
February	<ul style="list-style-type: none"> • Chugai was one of four recipients, including Osaka University, of the Minister of Education, Culture, Sports, Science and Technology Award at the 1st Japan Open Innovation Prize for "University-Industry Co-creation from the Basic Research Stage -Collaboration between Organizations-" • Joined the World Federation of Hemophilia Humanitarian Aid Program, together with Roche • Received the President's Award of the Japan Techno-Economics Society for the creation of anti-IL-6 receptor antibody Actemra, at the 7th Technology Management and Innovation Awards
March	<ul style="list-style-type: none"> • Selected as a grant recipient by the Global Health Innovative Technology Fund (GHIT Fund) for a joint research project with the Agency for Science, Technology and Research, Singapore (A*STAR) for an anti-dengue virus antibody
July	<ul style="list-style-type: none"> • Maintained listings on all ESG indices selected by Government Pension Investment Fund
September	<ul style="list-style-type: none"> • Selected as an index component of the Dow Jones Sustainability Asia Pacific Index for the fifth time and the second consecutive year • Donated para-transit vehicles to welfare services • Announced Chugai Group Non-Smoking Declaration • Began providing a treatment support tool using a private medical care SNS for rheumatoid arthritis, lupus nephritis, and chronic kidney disease
December	<ul style="list-style-type: none"> • Rating and Investment Information, Inc. (R&I) raised Chugai's issuer rating from "AA-" to "AA"

Research

Key Points of IBI 21 (2019-2021)

- Development of leading drug discovery technologies and continuous additions to pipeline
- Creation and promotion of innovative projects through the deepening of biological research into human diseases
- Expansion of opportunities to acquire new candidate compounds using external network

- Proprietary drug discovery technology, particularly in biotechnology
- Efficient collaboration with the Roche Group, including infrastructure sharing

S
(Strengths)

W
(Weaknesses)

- Infrastructure for recruiting researchers is incomplete
- Lack of resources for biotechnology research

- Progress in new modalities, including middle molecule drugs
- Mounting social expectations for drug discovery and healthcare as a growth industry

O
(Opportunities)

T
(Threats)

- Increasing difficulty and escalating cost of new drug development worldwide, and intensifying competition
- Potential paradigm shift due to disruptive technologies, etc.

Performance in 2019

14

In-house projects in the development pipeline
(As of January 31, 2020)

55

Publications in academic papers and presentations at scientific conferences regarding Chugai's innovative proprietary antibody engineering technologies
(2015-2019)

88

Publications in academic papers regarding Chugai's research findings
(2015-2019)

14.9%

R&D expenditures to revenues ratio
(2019)

Functions

Chugai began conducting research and development of biopharmaceuticals more than 30 years ago, and the former Nippon Roche had also established world-class technology for the discovery of chemically synthesized agents. Over the years, we have cultivated knowledge and gained experience through our advanced initiatives while also incorporating outside technologies. As a result, we have continuously evolved our capabilities, and have built a technology platform that we can flexibly and appropriately apply to drug discovery.

We are using this platform to generate a steady stream of innovative new drugs with first-in-class or best-in-class potential to address unmet medical need. In addition to developing antibody engineering technologies ahead of other companies, Chugai has industry-leading research and technological capabilities backed by small and middle molecule¹ technologies, the world-class research infrastructure of the Roche Group and a powerful external network with academia and other parties. Through presentations of research findings at scientific conferences and other means, these strengths lead to benefits for the medical community around the world as we leverage them in the creation of in-house projects.

1. Molecules with a molecular weight between 500 and 2,000. Middle 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.

Business Model

One of Chugai's strategic advantages that enables it to continuously create innovative drugs is its ability to concentrate resources on innovative research. Efficient development in Japan of projects in-licensed from Roche provides a stable revenue base while we conduct global development of projects from our own research in collaboration with Roche. This enables us to concentrate personnel and funds on groundbreaking in-house projects, leading to the creation of a steady stream of innovative drugs. Another of our strengths is access to Roche's global research infrastructure. The ability to share Roche's global research resources and infrastructure, including a rich, high-quality compound library for use in high-throughput screening,² is a significant plus for Chugai in terms of cost, efficiency and other factors, and has dramatically increased our research productivity.

In addition, by concentrating on the development of next-generation antibody engineering technologies and the creation of new therapeutic antibodies, Chugai Pharmabody Research (CPR), which we established in Singapore in 2012, is working to continuously create innovative therapeutic antibody drugs and to accelerate the speed of drug discovery.

2. A technology for conducting evaluations at a high speed with robots or other means to select chemical compounds that show activity for drug creation targets from a library consisting of a vast number of compound types with various structures

Allocation of Resources

In allocating research resources, we prioritize each project based on the following criteria:
(1) The project's potential for development as a novel medicine that can be clearly differentiated
(2) Whether it has a scientific basis for addressing unmet medical need
(3) Whether it will enable PHC

At decision points during research, we focus first and foremost on patient need in the belief that creating medicines truly needed by patients and healthcare providers will lead to Chugai's medium-to-long-term growth.

Bioethics and Animal Welfare

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.

Moreover, 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,³ a global third-party

evaluation organization, and the Company has maintained full accreditation since 2007.

3. The Association for Assessment and Accreditation of Laboratory Animal Care International, a private non-profit organization 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.

Main Initiatives and Progress

Promotion of Unique Biological Discoveries

Created based on a novel concept, Hemlibra is the product of innovation achieved by uniquely combining Chugai's extensive understanding of the biology of diseases and its antibody engineering technologies. To continuously generate such innovations and to reinforce and pass down an organizational culture that produces breakthrough medicines with clear value for healthcare, in 2019 we adopted a scheme to allocate 20% or more of approximately half of our researchers' workloads to the creation, testing and verification of new ideas as a cross-departmental activity of the Research Division.

Collaboration with Our External Network

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),⁴ which joined the Roche Group in 2015.

Research at Satellite Labs

Research at satellite labs has also yielded solid results, leading to the successful establishment of stable cell lines of colon cancer stem cells in October 2012 and the identification of new molecular targets at Chugai's wholly-owned subsidiary, Forerunner Pharma Research Co., Ltd. Furthermore, CPR is making steady progress in the discovery of new therapeutic antibodies and the creation of new development candidates to follow GYM329 and SKY59, which have already entered clinical development.

Evolution of Drug Discovery Modalities

In the pharmaceutical industry, modality refers to the material classification of drugs such as therapeutic antibodies or therapeutic nucleic acids. Until around 1990, small molecule drugs were virtually the only modality available, but modality options are

now increasing. Chugai is currently focusing on establishing middle molecules as a third modality in addition to biologics and small molecules, in which it is already strong. Middle molecules are a valuable method for reaching intracellular targets that are difficult to approach using antibodies and small molecules, and we are proactively promoting the establishment of a hit-to-lead compound generation technology platform as we work toward the creation of development projects.

Enhancing Our Intelligence Functions

Rapid scientific and technological advances, especially in life science, digital technology and information and communications technology (ICT), are bringing dramatic changes to society, including the pharmaceutical industry. Chugai's response to emerging issues in the healthcare business is mainly the responsibility of the Science and Technology Intelligence (STI) Department, which was established in April 2017 as an intelligence unit.

Healthcare in the future is expected to center on 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. We aim to contribute to higher-quality healthcare with solutions that lead to new value, and a critical part of that effort is formulating strategies for disruptive innovation,⁵ which will be essential for realizing such solutions.

STI's mission is to find signs of change and to create strategies for bringing it about. In the three areas of life science, digital ICT, and advanced PHC, STI not only collects and analyzes information, but also works to establish conditions for initiating disruptive innovation.

In July 2018, Chugai entered into a comprehensive partnership agreement with Preferred Networks, Inc. (PFN), a global leader in 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.

4. 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 established the FMI business as a specialized unit in October 2018 to carry out commercialization and product value maximization of FMI's Comprehensive Genomic Profiling Service in Japan.

5. Innovation that disrupts the order of existing business and causes drastic changes in the industry structure

Progress of Development Projects in 2019

(February 1, 2019 – January 31, 2020)

	Number of Projects	Breakdown		
		New Molecular Entities	Additional Indications	Additional Dosage and Administration/ Formulations, Expanded Use
Approved	13	1	6	6
Filed	8	3	3	2
Started or moved to phase III	6	2	4	0
Started or moved to phase II	1	1	0	0
Started phase I	5	5	0	0
Development suspended	5	3	2	—

Comparison of Drug Discovery Modalities

	Small Molecules	Middle 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 ⁶ inhibition	Fair	Good	Good
Administration route	Oral/Injection	Oral/Injection	Injection
Manufacturing method	Organic synthesis	Organic synthesis	Cell culture

6. PPI: Protein-Protein Interaction

Development

Key Points of IBI 21 (2019-2021)

- 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 VBHC¹

1. Value-based healthcare

<ul style="list-style-type: none"> ● Comprehensive development track record (total no. of clinical trials: 115²) ● High development success rate of innovative in-house products (FPI³: 1 project; breakthrough therapy designation (BTD)⁴: 1)² ● Global collaboration with Roche (global studies: over 58%; joint development projects: 33)⁵ <p>S (Strengths)</p>	<ul style="list-style-type: none"> ● Evolution of quality and speed at a top global level in early development ● Constant and cross-functional operation of the process for proof of value ● Infrastructure development and acquisition of human resources for utilization of real world-data (RWD), data assets, and cutting-edge technologies <p>W (Weaknesses)</p>
<ul style="list-style-type: none"> ● Increasing expectations for development of innovative drugs using proprietary technology ● Advances in development of PHC using large-scale data such as genetic information ● Greater flexibility and diversification in the application filing process <p>O (Opportunities)</p>	<ul style="list-style-type: none"> ● Intensified global competition in new drug development and escalating development costs ● Potential paradigm shift due to disruptive technologies, etc. ● Decline in competitive advantage of in-house products due to the emergence of new modalities <p>T (Threats)</p>

2. January-December 2019 3. First patient in 4. A system introduced in July 2012 by the U.S. Food and Drug Administration aimed at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms 5. As of December 31, 2019

Performance in 2019

49

Pipeline projects
(As of January 31, 2020)

23

New products launched and
new indications
(2015-2019)

40

Projects being co-developed
with Roche Group
(As of January 31, 2020)

18

Projects in-licensed
from Roche
(2015-2019)

Functions

Chugai has established a lifecycle management⁶ system for project-level integrated management of each of its functions, and cooperates with numerous medical institutions and clinical research centers. In this way, we implement clinical trials distinguished by exceptional speed, efficiency and scientific rigor.

Specifically, in clinical development, we draw up clinical development plans based on the latest scientific findings and invite medical institutions to conduct clinical trials. In pharmaceutical technology and production, we examine commercial production that will turn candidate compounds into pharmaceutical products and manufacture investigational drugs for clinical trials. In drug safety, we ensure a high level of safety in clinical trials by gaining an understanding and beginning assessments of each drug's safety profile from the early stages.

Through our alliance with the Roche Group, we are implementing multiple global development projects (global studies) and strengthening the process that enables simultaneous development of drugs and companion diagnostics intended for PHC. Through these global initiatives, we are creating best practices in development and filing for approval, which we believe contribute to the advancement of the industry.

6. The various measures taken to maximize the potential value of a drug, including shortening development time, expanding sales, extending the product's life, and conducting appropriate cost control. Competitiveness can be strengthened further by using earnings from sales of established drugs to strategically reinvest in new drug development, marketing or other areas.

Enhancement of Functions and Organizational Change

In October 2019, Chugai reorganized the functions of the Translational Research (TR) Division, which acts as a bridge between preclinical and early clinical development. The new Early Clinical Development Department was established to consolidate planning and promotion functions for early clinical development of projects originating at Chugai in order to improve operational efficiency and strengthen early clinical development skills. This is expected to give more impetus to integrated development of in-house products from the research stage to the early clinical development stage. For overseas development of projects from in-house research, overseas subsidiaries Chugai Pharma USA, Chugai Pharma Europe, Chugai Pharma Science (Beijing) and Chugai Pharma Taiwan conduct high-quality clinical trials in close cooperation with medical institutions in each country.

We also accelerate global development by sharing knowledge and platforms for clinical development with the Roche Group. Moreover, we utilize FMI and others to generate evidence from the clinical development stage that will lead to PHC.

Moreover, the Clinical Development Division has assigned a clinical solutions supervisor to carry out integrated management and execution of shared work among projects for all clinical studies, and to take the lead for further process improvement, optimal vendor strategies and other matters.

Main Initiatives and Progress

A Well-Stocked Pipeline

In 2019, all projects made steady progress. Chugai filed for regulatory approval for eight projects, and obtained approval for one project. Chugai's pipeline grew even richer, with eight new projects (in-house or in-licensed from Roche) advancing to the clinical phase.

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 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, obtained approval in less than five years from initiation of clinical development, far ahead of our initial plan. Hemlibra is dramatically transforming treatment strategies for hemophilia and achieving unprecedented results.

Moreover, after nemolizumab (CIM331) received BTD and satralizumab (SA237) obtained positive results in global studies under Chugai's management, in 2019 we completed filings in Japan, the United States and Europe in collaboration with Roche.

Pharmaceutical Technology and Production

Key Points of IBI 21 (2019-2021)

- Acquisition of PoC with world-class speed
- Realization of a production system with a strong competitive advantage from the pre-launch stage
- Structural reform of the commercial production system

- Advanced therapeutic antibody production technology and state-of-the-art equipment
- Proven track record of global inspections and applications (Hemlibra, Alecensa, and satralizumab)
- Timely identification and response to requests from regulatory authorities that can be shared with the Roche Group

S
(Strengths)

W
(Weaknesses)

- Creation of an efficient production system utilizing external resources in accordance with rapid changes in demand

- Fast-track review system to support early approval of innovative new drugs
- Initiation of a system for pharmaceutical quality management
- Increase in product supply volumes as a result of expansion of the Asian (Chinese) market

O
(Opportunities)

T
(Threats)

- Progress in global control over drug costs, loss of premium pricing status for new drug creation on mainstay products amid drastic reform of NHI drug prices, and cost reductions in response to the emergence of generic drugs and the increased need for greater productivity

Performance in 2019

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

Upgraded world-class system for pharmaceutical quality management

62
Research papers and other publications from the Pharmaceutical Technology Division (2015-2019)

Functions

Our pharmaceutical technology and production functions play a wide range of roles in the pharmaceutical value chain – from turning drug candidates into products to stably supplying them. These candidates may be compounds created in our laboratories or products in-licensed from Roche or elsewhere.

Product creation includes research on production methods for active pharmaceutical ingredients (APIs), formulation and packaging design, production of investigational APIs, and collection and analysis of production data. Among these activities, we have most recently been taking positive steps to build and patent a new technology platform that will give us a distinct advantage in commercial production of innovative medicines such as next-generation antibodies and middle molecules.

Through stable supply of our products, we maintain the trust of patients and healthcare professionals – a responsibility central to Chugai's existence as a pharmaceutical manufacturer. That is why we need to build and maintain a robust supply chain with production bases (including contract manufacturing organizations) around the world.

Chugai has competencies at Japan's top level, including bioproduction technology and the ability to accommodate inspections. We will leverage our strengths as a member of the Roche Group to become a top innovator in our pharmaceutical technology and production operations.

Main Initiatives 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, at the Ukima Plant, we have achieved a significant increase in capacity utilization by employing plastic single-use bioreactors. For development candidates that apply next-generation antibody engineering technologies, we have started operation of UK3, a new 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 middle molecules, which are a next-generation modality, with the aim of starting operations in 2022.

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.

Our subsidiary Chugai Distribution Co., Ltd. handles distribution of pharmaceuticals in Japan. The company's computerized inventory management and inspection ensure stable and safe distribution, and the staff conducts ongoing process innovation in packaging.

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)	<ul style="list-style-type: none"> • Competitive low-cost production • Dedicated facilities 	Actemra
Ukima	Commercial production/ Production of investigational APIs (Medium-scale)	6,000 L x 6 (UK3: Stainless steel tanks)	<ul style="list-style-type: none"> • Emphasis on flexibility • 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)	<ul style="list-style-type: none"> • Improved capacity utilization through the application of single-use bioreactor technology 	Hemlibra and future development projects

Close-Up 1 Standout Initiatives under IBI 21

Advancing Middle Molecule Drugs to the Clinical Phase

In relation to our goal of starting clinical development of middle molecule drugs during the term of IBI 21, particular challenges lie ahead in production of investigational APIs and clinical trial design as well as drug discovery. Given our aim of achieving a high level of convenience as well as efficacy and safety, our middle molecule drugs have highly specific structures and physicochemical properties. The manufacturing process is more complicated than for the small molecule drugs we have produced in the past, and we must overcome the hurdle of mass production. Moreover, demonstrating

new concepts in molecular therapeutic effect also entails the establishment of a clinical prediction system for human subjects, which is extremely difficult, as well as appropriate methods for setting and evaluating biomarkers. Despite facing difficulties that we have not encountered before, various departments are cooperating from the earliest stages as we work to establish this next-generation modality of middle molecule drugs, so that we can deliver innovative medicines to patients as quickly as possible.

Satoshi Tanida

Discovery Technology
Dept.,
Research Div.



Mikiko Nakamura

Clinical Pharmacology Dept.,
Translational Research Div.



Akie Honma

API Process
Development Dept.,
Pharmaceutical
Technology Div.



Stepping Up Initiatives and Future Outlook at Chugai Pharmabody Research

When Chugai Pharmabody Research (CPR) was first established in Singapore in 2012, its role was to concentrate on creating new antibodies. Having produced results in line with this objective, its functions have expanded since 2017. A compact organization with diverse human resources, CPR possesses all drug discovery research functions from antibody production to drug metabolism and pharmacokinetics, pharmacological evaluation, and development of new technologies. CPR and the Research Division are now leveraging

their individual strengths and expertise to collaborate on joint projects, technology development and discussions of new ideas.

Stepping up initiatives at CPR will expedite Chugai's drug discovery and help to demonstrate that diversity is the wellspring of innovation. We will generate further synergies to create innovative drugs with value for patients.

Priyanka Chichili

Protein Production Unit,
Chugai Pharmabody
Research Pte. Ltd.



Hitoshi Katada

Discovery
Biologics Dept.,
Research Div.



Takaaki Noguchi

Discovery
Pharmacology Dept.,
Research Div.



Realizing Sustainable Supply Chain Management

Establishing robust supply chain management that enables us to work together with suppliers to address sustainability issues is essential for stably delivering high-quality drugs to patients and helping to resolve global social issues.

In 2019, in addition to creating a comprehensive system for evaluating suppliers and starting supplier due diligence based on this policy, we established a model for cooperation between the Pharmaceutical

Technology Division and the Sustainability Department. However, despite a high level of awareness of sustainability, only a limited number of suppliers have codified and established sustainability in their policies and systems, and we have the sense that the differing languages, cultures, and customs in the global supply chain make it difficult to ascertain actual labor conditions. This initiative will take time, but we will carry it out steadily and emphatically while defining our priorities.

Shinobu Aizawa

Supply Chain Management Dept.,
Pharmaceutical Technology Div.



Koichi Kawahara

Business Ethics Group,
Sustainability Dept.



Marketing

Key Points of IBI 21 (2019-2021)

- Maximization of the value of growth drivers (innovative drugs and services)
- Enhancement of consulting activities to select the best treatment using innovative products according to each patient's condition
- Provision of solutions through cooperation with diverse specialized human resources and incorporation of digital technology

<ul style="list-style-type: none"> • Leading presence in specialty areas, such as biopharmaceuticals and PHC • 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. 	S (Strengths)	W (Weaknesses)	<ul style="list-style-type: none"> • Response to an increase in competing products and new entrants • Response to the emergence of biosimilars¹ and generic drugs²
<ul style="list-style-type: none"> • Further increase in unmet medical need³ as a result of the aging population as well as rare and refractory diseases • Increase in therapeutic opportunities due to early detection and promotion of testing • Progress in personalized and advanced healthcare, including genetic diagnosis 	O (Opportunities)	T (Threats)	<ul style="list-style-type: none"> • Progress in global control over drug costs, and the shrinking domestic market amid drastic reform of NHI drug prices • Loss of premium pricing status for new drug creation on mainstay products and the emergence of generic drugs • Tighter regulations on promotional activities due to higher ethical and transparency standards

1. Follow-on products to biopharmaceuticals whose patent term has expired, made by manufacturers other than the manufacturer that developed the antecedent biopharmaceutical
2. Drugs approved after the expiry of the patents for original drugs with the same active ingredients and efficacy
3. Medical need that is not adequately met due to a lack of effective treatments

Performance in 2019

23.9%⁴

Share of sales in the Japanese therapeutic antibody market

16.4%⁴

Share of sales in the Japanese oncology market

1⁵

Satisfaction ranking based on healthcare professionals' assessments

(Oncology; hospitals with 100 or more beds)

1⁶

Adequacy ranking for provision of safety information based on healthcare professionals' assessments

(Hospitals with 100 or more beds)

4. Copyright © 2020 IQVIA. Source: JPM 2019. Reprinted with permission. The scope of the market is defined by Chugai.

5. Source: INTAGE Healthcare Inc., CS Survey of Oncology, 2019. Based on a survey of overall assessments of companies by physicians, as defined by Chugai.

6. Source: INTAGE Healthcare Inc., 2019 questionnaire about safety information needs.

Functions

The need for new therapeutic agents to deal with cancers or rare or refractory diseases that lack effective treatments (unmet medical need) is high, and more sophisticated and individualized medical procedures such as cancer immunotherapy and genomic testing are attracting attention. Chugai is pursuing initiatives to meet unmet medical need based on its extensive lineup of first-in-class and best-in-class drugs and new diagnostic technologies.

As medicine becomes more sophisticated and individualized, healthcare professionals will be expected to promptly provide high-quality information. Chugai takes three approaches to this process, which it refers to as "consulting."

For patients

We conduct patient-centric consulting that gives 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 that improves 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 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 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 artificial intelligence and the Internet of Things to build a system that can provide more efficient and effective solutions based on higher-quality consulting.

Main Initiatives and Progress

Oncology

In 2019, sales in the oncology area in Japan increased 6.6 percent year on year to ¥240.5 billion. The contribution from new products included ¥20.6 billion from rapid market penetration of Tecentriq, an anti-PD-L1 monoclonal antibody launched in 2018 and used primarily for lung cancer, and ¥3.6 billion from Gazyva, a treatment for CD20-positive follicular lymphoma launched in 2018 to which we actively promoted a switch from Rituxan. In addition, market uptake substantially exceeded expectations for Perjeta, which obtained approval for the additional indication of HER2-positive early breast cancer in 2018, and sales increased ¥14.6 billion (90.7 percent) to ¥30.7 billion, contributing significantly to results.

In addition, amid the emergence of various new drugs in each area and their changing position in treatment, we were able to minimize the impact of the launches of biosimilars for Herceptin and Rituxan by maintaining sales volume for mainstay drug Avastin and growing sales of new and existing products. Meanwhile, overseas sales of Alecensa, including exports to Roche, continued to be firm due to its widespread use in first-line treatment, increasing ¥15.8 billion (53.6 percent) to ¥45.3 billion.

In 2020, despite the expected impact on Avastin from the loss of premium pricing status and from biosimilars, we aim for further growth in the oncology area led by Tecentriq, which obtained approval in 2019 as a first-line treatment for small cell lung cancer and triple-negative breast cancer, as well as from market uptake of Gazyva, Kadcyla, Alecensa and other products.

Bone and Joint Diseases

In 2019, sales in the bone and joint diseases area in Japan increased ¥7.9 billion (7.9 percent), year on year to ¥108.4 billion. Growth was driven by Actemra, a first-line biologic for the treatment of rheumatoid arthritis (RA) that is growing based on an additional indication for a rare disease, Ediol, which has been recognized as a base treatment for osteoporosis, and Bonviva, which is available in an oral formulation in addition to the intravenous formulation. Sales of Actemra outside Japan including exports to Roche increased ¥7.7 billion (9.6 percent), to ¥88.3 billion due to firm global sales by Roche.

In 2020, although there will be negative factors in Japan including the expected launch of a generic of Ediol, we foresee growth in sales of Actemra outside Japan, mainly due to further uptake of the subcutaneous formulation for RA and sales for giant cell arteritis, which became an additional indication in 2017.

Renal Diseases

Sales in the renal diseases area in Japan in 2019 decreased ¥1.7 billion (4.7 percent), year on year to ¥34.6 billion. Mircera, which only needs to be administered once every four weeks, has established a reputation in the pre-dialysis segment for convenience and long duration of action, and prescriptions are increasing. However, sales decreased slightly due to competition from biosimilars and other therapeutic agents in the dialysis field and as a result of the NHI drug price revision. Sales of Oxarol decreased partly due to the impact of generics.

In 2020, we aim to maintain and improve 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, Hemlibra also obtained approval for an additional indication for people with hemophilia A without factor VIII inhibitors, enabling administration regardless of the presence of such inhibitors. The approval also allowed dosing intervals of two weeks or four weeks in addition to once-weekly administration, enabling treatment options according to the

needs of people with hemophilia A and their healthcare professionals. Because Hemlibra's product characteristics are different from those of conventional coagulation factor agents, we focused on providing information on clinical results demonstrating its high level of efficacy in reducing the frequency of bleeding episodes, and sales in Japan totaled ¥25.2 billion in 2019. In 2020, by focusing on collecting and providing safety information on people who are already using Hemlibra as well as continuing our activities to promote its proper use among people with and without factor VIII inhibitors, we anticipate further uptake of Hemlibra as a treatment for congenital hemophilia A.

In the influenza segment, where Chugai plays an important role as a provider of Tamiflu, we focus on providing information on the product's safety and effectiveness, including prevention of the disease, based on extensive clinical data accumulated over a long period. Sales of Tamiflu, including sales for government stockpiles, were ¥10.6 billion.

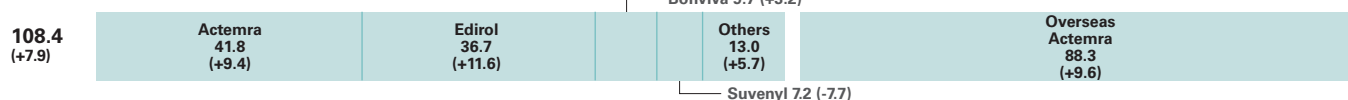
Sales of CellCept, an immunosuppressant, increased ¥0.3 billion (3.3 percent), to ¥9.3 billion in 2019 due to the effect of an increase in kidney transplants and an increase in use in treating lupus nephritis, a refractory disease. Despite expectations of a decrease in sales, we will continue to maintain a presence in the transplant segment in 2020 and expect further uptake for lupus nephritis.

2019 Product Sales by Therapeutic Area (Billions of yen)

Oncology



Bone and Joint Diseases



Renal Diseases



Other Diseases



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

Medical Affairs

Key Points of IBI 21 (2019-2021)

- Acceleration and advancement of evidence generation to realize patient-centric healthcare
- Promotion of innovative medical affairs by strengthening collaboration with stakeholders and actively introducing new technologies

<ul style="list-style-type: none"> • Extensive track record in generating evidence • Global collaboration with Roche and overseas subsidiaries 	S (Strengths)	<ul style="list-style-type: none"> • Systematic development of clinical research infrastructure 	W (Weaknesses)
<ul style="list-style-type: none"> • Improved quality of clinical research in association with the promulgation of the Clinical Trials Act • Increase in opportunities to use internal and external databases following the promulgation of the Next-Generation Medical Infrastructure Act • Unmet medical need appearing with the advancement of medical care • Greater awareness due to the announcement of the JPMA's Consensus Statement on Medical Affairs Activities and Consensus Statement on Medical Science Liaison Activities 	O (Opportunities)	<ul style="list-style-type: none"> • Increase in clinical research costs in association with the promulgation of the Clinical Trials Act • Potential paradigm shift due to disruptive technologies or other factors • Greater complexity of medical systems in association with the development of many new drugs, the implementation of genetic testing, etc. 	T (Threats)

Performance in 2019

37

Contract-based post-marketing studies (2019)

155

Staff with GCP Passport (Japan Society of Clinical Trials and Research certification) (As of January 31, 2020)

29

Number of joint preclinical studies (2019)

Functions

In addition to creating a steady flow of innovative drugs, Chugai recognizes the importance of ensuring that the value of its products is delivered accurately to patients, which will lead to better treatment. In support of this objective, we have been focusing on generating evidence on efficacy and safety in the clinical setting and on the modes of action of drugs through non-clinical studies (basic research), as well as on supplying appropriate information on the evidence generated from clinical and non-clinical studies to healthcare providers. We have also been working to establish a global support system for post-marketing studies. We are one of the first companies to operate a scheme for contract-based post-marketing studies to guarantee the independence and transparency of research, and have established a research support structure that conforms to the GCP¹ guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to raise the quality and reliability of research. We also established an implementation and support system for post-marketing studies under the Clinical Trials Act that was

promulgated in Japan in April 2018, and we are supporting the implementation of multiple clinical trials under this act. In addition, we conducted database research based on the Next-Generation Medical Infrastructure Act, which was promulgated in May 2018. In 2017, Chugai acquired third-party accreditation² for its medical science liaison (MSL) certification program from the Japanese Association of Pharmaceutical Medicine, and we maintain global-level compliance standards, including transparency in funding and appropriate separation of marketing and medical affairs.³ At the same time, we are working to further enhance our internal systems to help raise the quality and scientific level of clinical and preclinical (basic) research and to deal with changes in our operating environment. Furthermore, in response to the Consensus Statement on Medical Affairs Activities and the Consensus Statement on Medical Science Liaison Activities (announced by the Japan Pharmaceutical Manufacturers Association (JPMA) in April 2019), and the Guidelines for Prescription Drug Marketing Information Provision (promulgated by the Ministry of Health, Labour and Welfare in April 2019), we have established an appropriate governance and compliance system for conducting high-quality medical activities.

Main Initiatives and Progress

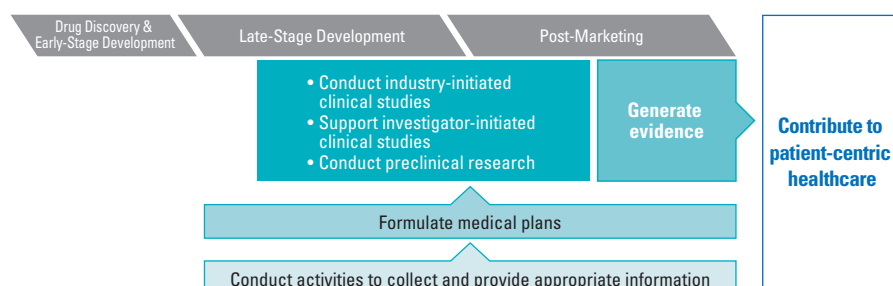
Enhancing Intelligence Functions and Measures for PHC

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.

Future changes in the healthcare environment are expected to include progress in establishing preventive and treatment methods based on the elucidation of pathological conditions caused by diseases, genetics and other factors as well as the establishment of healthcare that takes environmental and lifestyle differences into consideration. We will respond promptly to this changing environment by enhancing our intelligence functions, such as using ICT and other means to obtain medical information and gain insights from its analysis. We also intend to provide more suitable healthcare through the generation of new evidence with higher scientific value and other activities that provide solutions. Through these measures, we will contribute to the development of patient-centric medical research and advanced healthcare.

1. Good Clinical Practice: Standards for conducting pharmaceutical clinical trials
2. 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.
3. Activities that contribute to healthcare from a scientific standpoint

Main Medical Affairs Activities



Drug Safety

Key Points of IBI 21 (2019-2021)

- Maximization of the value of growth drivers through a commitment to promoting appropriate use
- Provision of new value based on insights garnered from customer needs
- Strengthening of systems for evaluating drug safety from the early stage of clinical trials

- Industry-leading achievements (introduction of the database tool and establishment of Safety Experts, etc.)
- Solid partnership with the Drug Safety Division of Roche Group
- A track record of industry activities in areas utilizing epidemiological and medical data

S
(Strengths)

W
(Weaknesses)

- Response to the constant shortage of high-quality human resources

- Rising need for safety information to effectively launch innovative new drugs
- Possible automation of some business operations and solutions due to disruptive technologies
- Deepening PHC and growing demand for provision of safety information

O
(Opportunities)

T
(Threats)

- Strengthening of global pharmacovigilance (PV) regulations in Europe, Asia and other regions
- Dramatic increase in the volume of safety information
- Fewer opportunities to convey drug safety information due to tighter regulations on visits to medical institutions

Performance in 2019

185 thousand

Cases for which safety information was collected in clinical trials and post-marketing studies
(2019)

29

Lectures, papers and conference presentations on drug safety
(2019)

12 products

Enforcement of risk management through RMPs
(As of January 31, 2020)

Functions

In Japan and overseas, Chugai handles numerous biopharmaceuticals, 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 to be essential for timely provision of safety information and implementation of measures to ensure safety. Consequently, Chugai has established an independent Drug Safety Division and a system directly linked to management. Through measures such as these, Chugai is building greater credibility, with the aim of providing truly valuable safety data and contributing to patients and healthcare worldwide.

Main Initiatives and Progress

Collecting and Managing Safety Information

Post-marketing surveillance, which includes all-case registration surveillance and database surveys, is conducted in (real world) clinical settings to collect safety information unobtainable in clinical trials. Data on safety collected from medical institutions through post-marketing surveillance are analyzed using diverse methods including epidemiology. Information on the results is provided to medical institutions and announced via scientific conferences, papers and other means.

Moreover, Chugai leads the industry in drug safety evaluation and safety measures through its 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.

Leading the Industry in Risk Management Plans

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. To achieve this, a specialized internal group in charge of epidemiology functions is cooperating with specialized companies and others to help upgrade Japan's epidemiological database. We are also driving the industry in ways such as proactively working to formulate industry-wide recommendations and guidance for database research for proposal to regulatory authorities.

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.¹ With these tools, which include domestic post-marketing safety data, we can respond in a timely manner to urgent needs for safety information. In 2018, we broadened our contribution through the rollout of a clinical trial database tool that presents safety information from clinical trials submitted for regulatory approval so that healthcare professionals can use new products with confidence immediately after their launch. In 2019, we added product information about new approvals and additional indications. We also use an app² that supports adherence to medication and helps to alleviate the anxiety of patients undergoing treatment by facilitating smooth communication between patients and healthcare professionals. In addition, our Safety Experts, who are professional safety staff, are at the core of ongoing efforts to provide safety consultations that meet the needs of healthcare providers and to build networks with local doctors and pharmacists. Through these initiatives we aim to offer safety measures that are closely attuned to patient needs.

1. 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" (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/>

2. A service developed by Chugai to support multidisciplinary team care in cancer treatment. The app is linked with MedicalCareSTATION, a completely private SNS developed exclusively for healthcare providers and operated by Embrace Co., Ltd., and promotes drug adherence and adverse event management.

Quality and Regulatory Compliance

Key Points of IBI 21 (2019-2021)

- Development of quality and regulatory compliance system for medical device program, regenerative medicine and other fields
- Establishment of quality and regulatory compliance and governance for use of digital technology in PHC strategy
- Enhancement of global quality assurance standards and quality and regulatory compliance framework

<ul style="list-style-type: none"> • Excellence in global inspections and quality assurance • Corporate culture and organizational climate in pursuit of compliance and quality 	S (Strengths)	<ul style="list-style-type: none"> • Response to expected cost performance demands and need for high-speed development • Global countermeasures against counterfeit pharmaceuticals 	W (Weaknesses)
<ul style="list-style-type: none"> • Rising expectations on quality management through technology revolution • Advancement of pharmaceutical regulations and compliance for global standardization • Advancement in the use of digital technology 	O (Opportunities)	<ul style="list-style-type: none"> • Need for enhanced quality compliance in complex business partnerships • Strict demands for ensuring data integrity and the quality of digital healthcare 	T (Threats)

Performance in 2019

8
Inspections by GMP regulatory authorities
(2019)

78
GMP/GDP quality audits
(2019)

37
GCP/GVP internal audits
(2019)

5,274
Number of examinations of information and lecture materials
(2019)

Functions

Protecting the rights of patients and clinical trial subjects and ensuring the reliability of data are serious responsibilities for the pharmaceutical industry. Chugai aims for product and service quality that resonates with all stakeholders under the slogan “Quality That Inspires.” The Quality & Regulatory Compliance Unit is responsible for ascertaining trends in pharmaceutical regulations and ensuring the soundness of the quality management system spanning our business processes. It also ensures the reliability of data by confirming, improving and verifying the validity of these business processes through audits that cover the entire product lifecycle, as well as by introducing and operating a global IT system. Moreover, in leading cross-divisional activities for maintaining and improving quality, the unit aims to foster a self-sustaining quality mindset Company-wide and build a sturdier quality management system.

Main Initiatives and Progress

Compliance with Guidelines for Prescription Drug Marketing Information Provision

Chugai responds promptly to new regulatory requirements and has established a system to conduct appropriate activities in accordance with the Guidelines for Prescription Drug Marketing Information Provision (announced by the Ministry of Health, Labor and Welfare in September 2018, and came into partial effect in April 2019).

Establishing a Digital Compliance System for Human-Derived Data

In anticipation of trends in the regulatory environment, Chugai is taking the lead in the use of digital technology for compliance with the establishment of a digital compliance system data that handles genomic and other human-derived data.

Enhancing Measures for Data Integrity

In 2019, Chugai demonstrated a flexible response to recent changes in the regulatory environment by updating its Guidelines for Ensuring Regulatory Compliance and Quality Assurance in the Product Lifecycle (revised in

November 2019, applicable from April 2020). The update, which is part of our efforts to strengthen global quality governance based on our Policy for Regulatory Compliance and Quality Assurance, codifies new quality requirements for data integrity, which is a topic of growing attention in regulatory inspections in Japan and overseas, establishing it as a quality requirement applicable to all GxP.

Fostering a Culture of Quality

Chugai has many procedures and rules to enhance quality and regulatory compliance, including the above, and continuously updates its quality and regulatory compliance systems and processes amid the ongoing issuance of new pharmaceutical regulations. Furthermore, we consider each employee’s awareness of quality to be particularly important, and we hold Quality Meetings at each workplace (i.e. each division, overseas subsidiary, etc.) in Japan and overseas as forums to think about and discuss quality at our front lines.

In addition to complying with laws and regulations, we will endeavor to anticipate stakeholder expectations and demands to continue making improvements and reforms that deliver quality that inspires.

Digital Compliance System



Intellectual Property

Key Points of IBI 21 (2019-2021)

- Creation and use of a database of Chugai's competitors to search out opportunities for utilizing the Company's rights
- Utilization of antibody engineering technology patents through licensing and other means
- Formulation and execution of a scenario for combating biosimilars and generics

- Expanded and upgraded portfolio of technological patent applications
- Progress in securing rights for products

S
(Strengths)

W
(Weaknesses)

- Negative impact on the development of technological patent rights due to early applications for "Freedom to Operate" (FTO)*
- Limited to capturing one-time opportunities for utilizing technological patents

- Increasing importance of protecting intellectual property based on the establishment of drug discovery technology infrastructure
- Increase in opportunities to generate intellectual property due to progress in digital technology

O
(Opportunities)

T
(Threats)

- Ensuring FTO in the intense, competitive R&D environment
- Attacks by competitors on the Company's patent portfolio, including for biosimilar products

* The ability to conduct business without the possibility of infringing the rights of others

Performance in 2019

4,976

Number of patents held
(including pending applications)
(As of December 31, 2019)

153

New patents granted worldwide
(2019)

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

Functions

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 innovative antibody engineering technologies, and use those rights in planning and executing our IP strategy. Moreover, we are building our

own database for patents related to antibody engineering technologies, which are becoming increasingly complex and sophisticated, and are using this database to plan IP strategies, including monitoring trends at other companies.

approximately 28 percent, and other areas including chronic disorders, hematologic diseases, and drug discovery technology for approximately 45 percent. In 2019, Chugai acquired 153 patents in Japan, the United States, and major European countries, as well as other countries worldwide.

Main Initiatives and Progress

Integration of IP and Research Strategies (Strategic Mix)

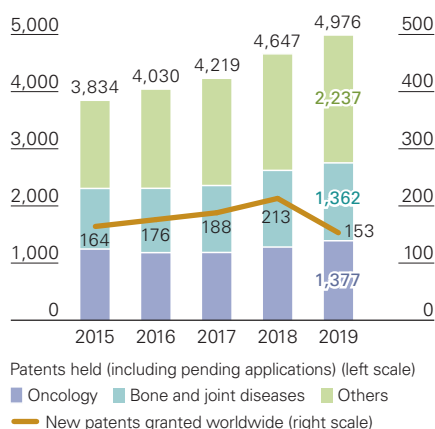
At Chugai, we view our antibody engineering technologies as a core drug discovery technology platform, and we are deploying research and development strategies both to cultivate basic technologies and to apply them to product development. Since 2018, we have been dispatching IP liaisons to the Fuji Gotemba Research Laboratories and Kamakura Research Laboratories to strengthen cooperation at the initial stage of research, and they are enhancing and promoting a strategic mix that builds a portfolio of our own technologies and development compounds in the white spaces (gaps) of technologies and rights. IP liaisons hold monthly meetings to review intellectual property with the Pharmaceutical Technology Division, which is also promoting the same strategic mix in manufacturing. In 2019, we dispatched an IP liaison to the Collaboration Promotion Laboratory at IFR&C and began similar initiatives there.

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 intellectual property 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 Inc. and other affiliated companies, outside attorneys, and our business and legal departments. In 2019, we had numerous successes in maximizing product value, including a ruling in favor of Chugai relating to Hemlibra at the Intellectual Property High Court and the implementation of a strategy for Herceptin to respond to other companies' biosimilars. Chugai will deepen cooperation in its intellectual property activities so that it can continue to provide value to society.

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



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 R&D. Bone and joint diseases account for approximately 27 percent of patents by therapeutic area, oncology for

Close-Up 2 Standout Initiatives under IBI 21

Introducing a New Personnel System in Japan

With a view to achieving the five strategies of mid-term business plan IBI 21, we are introducing a new personnel system in April 2020. It is important that all employees understand and follow the new system, and the reasoning and purpose behind it. To that end, the Human Resources Management Department has been cooperating with HR Business Partner introduced in October 2019 to consider and implement measures for promoting the system's use. Following

explanatory meetings for employees, we will hold discussions to identify issues and necessary measures at each division. To ensure the greater satisfaction of employees, we will also make enhancements to the personnel system intranet site, and consider and implement methods for operating and promoting the use of the system based on conditions at each division.

Yusuke Tokita

Human Resources Management Group, Human Resources Management Dept.



Masahito Kawasaki

Head of Marketing & Sales Human Resource Management Dept., Marketing & Sales Div.



Chizuko Tagawa

Human Resource Business Partner, Project & Lifecycle Management Unit



Contributing to Next-Generation PHC through Advances in Cancer Genomic Medicine

Although Japan is promoting cancer genomic medicine nationwide, many issues remain – few patients are able to undergo gene panel profiling, and the rate at which it leads to effective drug administration is currently low, at about 10 percent to 20 percent – and understanding and awareness of the significance of this domain have yet to become sufficiently widespread. Consequently, Chugai has been intensively disseminating information and holding study sessions for healthcare

professionals to introduce two key products as an integral set: the cancer genomic profiling program FoundationOne CDx Cancer Genomic Profile and Rozlytrek, a tumor-agnostic therapy. We feel that these initiatives have begun to achieve a certain level of understanding. Through ongoing collaboration with various parties, we hope to help change cancer genomic medicine from “next-generation” to “standard” medicine.

Yusuke Yamashita

Precision Medicine Group, Foundation Medicine Business Dept., Foundation Medicine Unit



Yoshinari Kunihiro

FMI Planning Group, Foundation Medicine Business Dept., Foundation Medicine Unit



Ryouta Ishibe

Oncology Marketing & Sales Promotion Dept., Marketing & Sales Div.



Maximizing the Value of Hemlibra

Hemlibra is a drug with the potential to significantly change the lives of people with hemophilia A. To succeed, we must not only provide a product but also conduct activities to increase its value for patients. This entails consulting activities for healthcare professionals in close communication with patients and their families, safety measures and provision of information to minimize the risk of adverse effects such as thromboembolism and thrombotic microangiopathy, and collection of evidence regarding unresolved issues such as effectiveness for

treating complications of hemophilia A and the activity level of patients. As we collect feedback throughout Japan from people who have taken Hemlibra and share that information internally, we are getting a stronger sense of the importance of this drug. The three divisions responsible for providing solutions – Marketing & Sales, Drug Safety and Medical Affairs – will continue working together to develop better drugs for people with hemophilia A.

Satoru Ito

Primary Lifecycle Management Dept., Project & Lifecycle Management Unit



Haruko Yamaguchi

Medical Science Dept., Medical Affairs Div.



Naoto Oiri

PV & Safety Science Dept., Drug Safety Div.



Human Resources

Key Points of IBI 21 (2019-2021)

- 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 2019

13.7%

Ratio of female managers^{1,2}
(2019)

12.3%

Ratio of female managers²
(With subordinates)
(2019)

188

Number of employees posted through the Roche Human Resource Exchange Program
(2004-2019)

1. Number of female managers as a percentage of the total number of managers 2. Non-consolidated employee basis: Calculated based on Chugai Pharmaceutical (non-consolidated) employees, including employees assigned to affiliated companies and external companies.

Talent That Spearheads Innovation

Our people are our greatest asset in generating innovation to realize our Mission, and we therefore position human resource management as a key management theme.

Our Envisioned Future is to become a top innovator in the healthcare industry. Chugai will pursue this objective by building understanding and connection with the Mission Statement (corporate philosophy) among all employees. Furthermore, we will encourage employees to embody the Mission Statement while fulfilling their potential in accordance with their role.

Establishing an Organizational Culture That Generates Innovation

Chugai provides career development support over many years so that employees can excel in roles that reflect their expertise and ability, as well as their aptitude.

Since 2012, we have instituted various measures and systems, including introducing a talent management system, promoting diversity and revising our personnel systems. As a result of these initiatives, we have secured leaders capable of driving sustainable growth, assigned roles and growth

opportunities according to each individual's ability and aptitude, and created an environment that supports the success of women.

At the same time, the pace of change in the business environment is escalating. Clarifying each employee's approach and responsibilities to improve quality and speed in strategy execution will be essential to realizing our management strategies and establishing a competitive advantage. In addition to these issues, an important theme is to support our employees in proactively taking on challenges to generate innovation and new added value.

We have determined the following human resource management priorities as measures for these objectives and themes. With these measures, we aim to establish an organizational culture in which employees support each other to continuously generate innovation.

1. Assignment of the right people to the right positions and provision of growth opportunities through position management and talent management.
2. Promotion of talent management to quickly identify and develop leaders and highly competent specialists to accelerate strategy execution and innovation.
3. Promotion of diversity and inclusion (D&I) to accelerate the success of women.

In addition, to promote organizational reforms linked to IBI 21, we switched to a new employee survey in 2018 to set more ambitious targets and identify issues more accurately. From 2020 onward, we will revise our personnel and remuneration systems to promote changes in attitude conducive to a corporate culture that embraces challenge.

Main Initiatives and Progress

Introducing a Balanced Personnel System That Assigns the Right People to the Right Positions to Reflect Roles and Results

The personnel system we are introducing in April 2020 will determine grades and wages based on the value of duties performed in each position, and assign the right people to the right positions. We have also designed it so that personnel can be assigned to management positions regardless of age, which will enable us to fast-track young employees. Moreover, setting and strictly implementing rules for assignment and dismissal will promote the rejuvenation of the organization.

Position profiles delineate the duties, performance responsibilities and human resource prerequisites required, as well as the criteria and processes for assignment

The All-Employee Survey

In 2018, Chugai conducted an all-employee survey to identify the organizational issues requiring reform in order to achieve its Envisioned Future and promote the strategies of IBI 21. The results showed that employee engagement was at a very high level, on par with strongly performing global companies, and suggested that establishing an environment where employees reach their potential would spur further innovation. Based on this, we are conducting initiatives on both tangible and intangible levels to resolve issues including implementing a framework to optimize Company-wide resources, introducing a personnel system that rewards employees who take on challenges and produce good results, establishing a system that allows

employees to take the initiative in making their proposals a reality, and fostering personal commitment in the "patient-centric" approach that is part of Chugai's Envisioned Future and Core Values.

Question Categories

Employee engagement; environment for utilizing employees; strategy and direction; leadership; quality and customer orientation; respect for individuals; opportunities for growth; compensation and benefits; performance indicators; authority and discretion; resources; education and training; framework for collaboration; business processes and organizational structure; and innovation

and dismissal, and are made available to employees. Identifying all positions in the Company and the requirements for assuming those positions will facilitate self-directed career development and the ability to assume higher-level roles. We will also introduce a “challenge assignment” system that allows early selection for promotion, and expand our in-house job posting system to cover management positions.

Remuneration will be set at a level that is competitive according to the value of relevant duties, but we will also set 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 and support a spirit of challenge among employees.

Talent Management

Structuring Human Resource Development Plans with the Strong Commitment of Management

Chugai conducts talent management to identify and develop leaders and highly skilled specialists at an early stage in order to realize its corporate strategy and accelerate the creation of innovation.

Since 2012, Chugai has been promoting a talent management system for developing individuals based on visualization of human resources and their capabilities.

We are creating a talent pool of future management candidates in each department, discussing the selection of successor candidates for major positions in Japan and overseas as well as medium-to-long-term policies for cultivating successors, and formulating individual human resource development plans. To expedite the development of successor candidates, executive management and department managers discuss the plans, hold training and strategically allocate human resources to strengthen leadership.

In addition, we identify leadership and highly skilled specialist positions that are important for realizing our corporate strategy, and work to acquire and develop suitable candidates. To this end, we hold discussions among executive

management and department managers, select human resources from inside and outside the Company, formulate and implement plans for their assignment, and monitor the status of their development.

Under IBI 21, we will review our training system to improve our ability to acquire, develop and deploy world-class human resources with the aim of identifying and training them more quickly. In addition to talent management, we will also use position management to assign the right people to the right positions throughout the Chugai Group.

Establishment and Enhancement of the Foundations of Human Resource Management Promoting D&I and Work-Life Synergy to Improve Productivity

Chugai has positioned D&I as a material issue for the establishment and enhancement of the foundations of human resource management. We believe that D&I, which leads to the creation of a diverse workforce that works together with enthusiasm, 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.

To promote gender diversity, we conduct annual training for prospective managers and leader candidates to help women plan and develop their careers. In 2019, we continued to conduct various measures to promote the success of women, including task management training for managers of employees using the short-time work system for childcare, in order to facilitate team members’ career planning and growth while navigating life events. To promote the success of older employees and foreign employees in Japan, we are building awareness of their potential through training and other programs and creating environments including workplace systems to help them play active roles. Meanwhile, amid demands for more active participation by diverse human resources, we conducted e-learning on the topic of unconscious bias for managers, who play a key part in promoting D&I. We aim to enhance managers’ practical workplace skills through this three-month program to help them recognize and control their own bias.

We also provide work arrangements and support systems so that all employees can benefit from work-life synergy that accommodates a variety of life events including childbirth, child care and nursing care. With respect to “work-style reform,” which is currently a focal issue in Japan, studies and initiatives between labor and

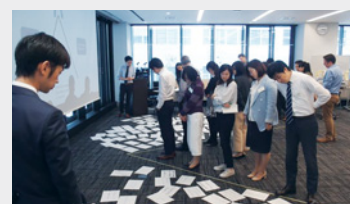
Establishing Systems and Environments to Promote the Success of Diverse Employees

More flexible workplaces	<ul style="list-style-type: none"> • Telecommuting system (maximum 10 days per month; no maximum for “spot” telecommuting³) • Satellite office (pilot introduction) • Introduction of free address workspace (Head Office)
More flexible work schedules	<ul style="list-style-type: none"> • Flextime system (core time reduced to 11:30–13:30) • Discretionary work system (for researchers) • Paid leave system in units of half-days or hours
Support for work-life balance	<ul style="list-style-type: none"> • Support plan for living with spouse who is transferred (MRs) • Use of Company vehicles to take children to/from childcare • Consortium-managed childcare center (Head Office)
Support for career planning	<ul style="list-style-type: none"> • In-house job posting system • Leave for education and acquisition of qualifications • Volunteer leave system • Registration program for rehiring employees who left the Company due to marriage, spouse transfer, childcare or nursing care • Introduction of concierge for finding nursery care

3. Telecommuting for short periods before leaving home or after returning home (usable in units of 15 minutes)

Cooperation to Promote and Spread Group-Wide Personnel Strategies

To resolve medium-term management issues and achieve its business targets, the worldwide Chugai Group is fostering a culture of innovation and conducting talent management. In May 2019, personnel managers from overseas affiliates gathered in Japan to deepen their understanding of the Group-wide personnel strategies of IBI 21. Participants shared issues and success stories from each company on the theme of raising employee engagement as they formulated specific action plans for each company.



Workshop at the Global HR Forum

management are under way with the goals of improving the work environment to enable employees to fully demonstrate their capabilities and promoting innovation by organically combining diverse knowledge.

Promoting D&I and work-life synergy is all about supporting the autonomy and growth of individuals to help realize an organization that generates innovation, which in turn contributes significantly to improving organizational productivity and increasing corporate value over the medium to long term.

IBI 21 sets forth a target outcome of innovation stories generated by leveraging the strengths of D&I, and we have created a roadmap for expedited realization of our



Non-Japanese employees engaged in follow-up training

strategies. Based on respect for different values and ideas, we are working to address the following three issues to foster an inclusive organizational culture in which diverse human resources can succeed and pursue innovation.

1. Fostering an organizational culture that generates innovation and is accepting of failure
2. Improving engagement of diverse talent
3. Proactively appointing and deploying women and people from different cultures and backgrounds to take on business challenges



For four years in a row since fiscal 2014, Chugai was selected as a Nadeshiko Brand for its exceptional record in promoting the success of women.



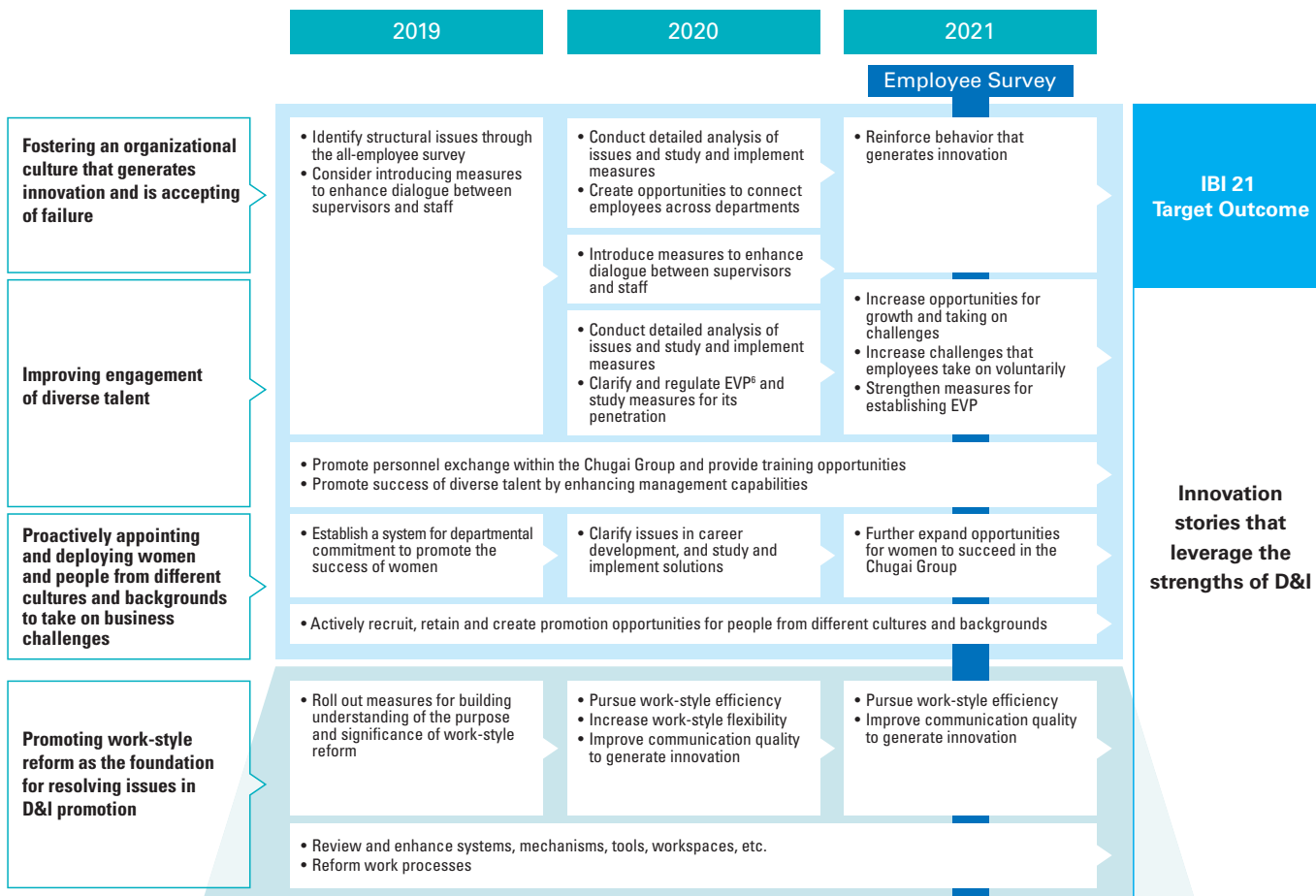
We are targeting a 16 percent or higher female manager ratio (non-consolidated employee basis) by the end of 2021, and will continue to focus on career planning and development measures for women.

Results of Work-Style Initiatives (Non-consolidated)

Rate of annual paid leave taken (average days taken) (April 2018 – March 2019 results)	61.2% (13.6 days)
Average overtime hours per month ⁴ (April 2018 – March 2019 results)	5.6 hours/month
Percentage of male employees taking childcare leave (average days taken) (2019 results)	83.9% (14.7 days)
Percentage of employees using the telecommuting system ⁵ (2019 results)	50.1%

4. Excluding employees on a defacto or discretionary working hours system
5. Excluding MRs

D&I Roadmap for Promotion IBI 21



6. Employee Value Proposition: The value a company can provide to its employees

Human Rights

Key Points of IBI 21 (2019-2021)

- Continue to conduct human rights awareness training
- Conduct human rights due diligence, including for suppliers
- Cooperation with third-party organizations to execute measures for resolving social issues

Performance in 2019

Continued to conduct human rights awareness training

8

Supplier evaluations conducted based on the PSCI Principles¹


Continued to exchange opinions with third-party organizations

1. 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

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. This is because we believe that a culture of respect for human rights is indispensable for a highly productive company where employees can work comfortably. It is also a cornerstone for a company to be recognized as a member of society and to earn trust. In respecting human rights, we aim to realize workplaces that prize diversity, where each person values his or her own feelings and accepts the values of others – allowing everyone to fully demonstrate his or her abilities, based on an organizational climate of appreciation for oneself and others. People in such a workplace can work creatively with enthusiasm and engagement, thus increasing their achievements. Moreover, helping build each employee's achievements will lead to improved productivity as an organization. We believe that the actions of individuals who raise their sensitivity to human rights and show respect for others in a workplace where human rights are respected in this way can also help to eliminate social discrimination and infringements of human rights in society in general through corporate activities and their private lives.

Today, companies are expected not only to conduct in-house initiatives regarding business and human rights, which have been increasing in importance as a social issue, but also to conduct business activities that respect human rights throughout the entire supply chain. With our deep involvement in people's lives and health as a member of the healthcare industry, we are promoting measures 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 has been conducting human rights initiatives for its employees in areas such as prohibition of workplace discrimination and harassment, respect for employee diversity, and safety and health. Furthermore, to conduct business activities in various regions of the world as a global company, we recognize the need to address human rights issues in our entire supply chain, including labor-related rights at stakeholders involved in our business activities. Based on the United Nations' Guiding Principles on Business and Human Rights (UNGPs), we formulated the Chugai Group Human Rights Statement and conducted employee training on corporate responsibility to respect human rights as set forth in the UNGPs. For supplier management, in addition to our conventional measures for stable supply and quality control, we have formulated guidelines based on the PSCI Principles for conducting human rights and environmental risk assessments and have started human rights due diligence.



Employee training

In October 2019, Chugai participated for the second year in the Business and Human Rights Conference in Tokyo sponsored by Caux Round Table Japan (the eighth yearly conference), and engaged in dialogue with individual experts from overseas. We received opinions and advice regarding procedures for and implementation of human rights due diligence for suppliers and methods of supplier management. We provided an explanation of the supplier management initiatives that Chugai has been conducting, and the experts evaluated those initiatives

and expressed their expectations that we should incorporate and implement due diligence in our business activities based on the nature of approaches to human rights issues when conducting audits.

Based on the opinions received through this dialogue, we will also call on our business partners to comply with laws and social norms and respect human rights, as we conduct our human rights due diligence. Specifically, we will work with those partners in considering working conditions in ways including eliminating child labor and forced labor, prohibiting all forms of discrimination by race, gender or other attributes, respecting the dignity of individual employees and maintaining safety and health.



Roundtable dialogue

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.

We recognize Chugai's responsibility for respecting the human rights of all people involved in its business activities, and will work to fulfill that responsibility by ensuring that we do not infringe on the human rights of these people, and by responding appropriately with corrective action in the event of an infringement.

Environment, Health and Safety

Key Points of IBI 21 (2019-2021)

- Establishment of a global EHS promotion system
- Achievement of mid-term environmental goals and formulation of new mid- and long-term environmental goals
- Execution of priority items for health and productivity management and reassessment of evaluation indicators

Performance in 2019

-9.9%¹

Energy consumption per employee compared with 2010
(2019)

91.6%¹

Waste recycling ratio
(2019)

1.1%¹

Final disposal ratio
(2019)



(Large Enterprise Category)

1. Chugai Group in Japan

Functions

As an R&D-driven pharmaceutical company, Chugai is engaged in many specialized scientific activities. One aspect of those activities involves handling numerous antibodies and highly active pharmaceutical substances. We consider environmental protection and health and safety to be fundamental to the success of our business activities.

At the same time, the demands of society have grown more diverse and sophisticated. Integrated management of environment, health and safety 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 PDCA cycle for ongoing improvement of its EHS promotion activities based on a consistent policy Company-wide, from top management to each facility.

To utilize the PDCA cycle effectively, we began safety risk assessments in 2014, and then following the integration of EHS management, we introduced EHS risk assessment in 2017 to eliminate EHS risks 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 to the manufacture of products and their supply to patients and healthcare professionals. Going forward, we intend to broaden our activities to cover the overall value chain in closer cooperation with customers and suppliers, partners and industry organizations.

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 meet these stakeholder demands, Chugai is conducting a scenario analysis based on the framework

outlined in the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD)² and will use it to address climate change risks and opportunities and further enhance disclosure of information.

2. Disclosure of climate-related information that has a financial impact on a company

 TCFD
<https://www.fsb-tcdf.org/>

resource conservation and waste management, biodiversity protection, prevention of environmental pollution and improvement of environmental literacy as priority items. In 2010, we set four mid-term environmental goals focusing on management of energy consumption and waste from a medium-term perspective, with 2020 as the final year. We are implementing the PDCA cycle and conducting initiatives to meet these goals.

Main Initiatives and Progress

Promotion and Progress of Environmental Protection Activities

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.

Chugai has designated climate change countermeasures, energy conservation,

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 greenhouse gas emissions,³ which is the key to combating climate change. To prevent environmental pollution, we are also working to reduce the use of CFCs and HCFCs to halt the destruction of the ozone layer, and to prevent the leakage of environmental pollutants. In waste management, we aim

Mid-Term Environmental Goals (Target year: 2020)	<ul style="list-style-type: none"> • Energy consumption per employee: 20% reduction compared with 2010 • Average fuel efficiency of MR fleet: 16 km/L or higher • Discontinue use of chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs) • Zero emissions of waste:⁵ Three facilities
Environmental Goals for 2019	<ul style="list-style-type: none"> • Energy consumption: Reduction of 2% or more compared with the previous year 2% reduction • CO₂ emissions: Reduction of 2% or more compared with the previous year 3% reduction • Ratio of eco-friendly cars:⁶ 80% or higher 81% • Average fuel efficiency of MR fleet: 16 km/L or higher 19.6 km/L • Recycling ratio: 95% or higher 91.6% • Final disposal ratio: Lower than the previous year (2018: 1.2%) 1.1% • On-site verification of waste disposal contractor facilities: 100% over a three-year period 49% over a two-year period • Plain paper copier (PPC) paper purchased: Less than the previous year (2018: 147 tons) 126 tons • Recycling ratio for PPC paper: 80% or higher 76% • WET tests: Conduct at each plant and research laboratory once every year Conducted once during the year
Mid-Term Health and Safety Goals	<ul style="list-style-type: none"> • Cancer screening participation rate:⁷ 90% or higher • Percentage of employees at high risk for lifestyle diseases: 2% or lower by 2020 • Awareness of Company programs: 90% or higher • EHS risk assessment: Conduct at each site at least once every three years

5. A waste recycling ratio of 99% or higher

6. Includes hybrids and fuel-efficient vehicles

7. Screening rate for lung, breast, gastric, colon and cervical cancer

Initiatives by Theme

Theme	Details of Initiatives
Implementation of EHS risk assessment Workplace safety measures	Create work environments that are free from unacceptable EHS risks.
Climate change countermeasures Energy conservation	Reduce greenhouse gas emissions by reducing energy consumption. Focus not only on reducing energy consumption at plants and laboratories but also promoting eco-friendly cars in the MR fleet and other Company-wide initiatives.
Resource conservation Waste management	Achieve zero emissions of waste by improving recycling ratio and further reducing landfill waste. Promote awareness of effective use of water resources by monitoring water consumption and wastewater discharge.
Biodiversity protection Prevention of environmental pollution	Curb destruction of the ozone layer by eliminating usage of specific CFCs. Prevent emissions of pollutants into the environment by observing laws, regulations, agreements and other rules for air, water quality and soil. To protect the water environment, conduct whole effluent toxicity (WET) tests and participate in river water and environmental conservation activities for rivers used by plants and laboratories.
Improvement of environmental literacy	Circulate information on laws and regulations among related staff and raise awareness through ISO 14001 internal auditor training.
Chemical substance management	Advance the establishment of a system for proper management of chemical substances, and promote safety and the prevention of environmental pollution. Continue risk assessments to prevent exposure to substances handled.
Reduction of environmental risk	Ensure thorough compliance with environmental laws and regulations by conducting extensive environmental law checks through external consultants.
Employee health management Improvement of health literacy	Maintain a support system based on cooperation with the health management organization and related departments. Improve health literacy as the basis for all health and safety activities, and conduct training for all employees.
Support for employees with 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 diseases among employees	Recommend check-ups for high-risk individuals and provide health guidance to those diagnosed to reduce leaves of absence, job departures and accidents caused by lifestyle diseases.
Measures for employee mental health	Conduct a return-to-work program for employees on leave due to mental health issues and implement working environment improvement measures based on the results of stress checks in cooperation with related departments.
Measures to address employee presenteeism (working while sick)	Plan, implement and determine the effectiveness of measures based on health survey results.

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

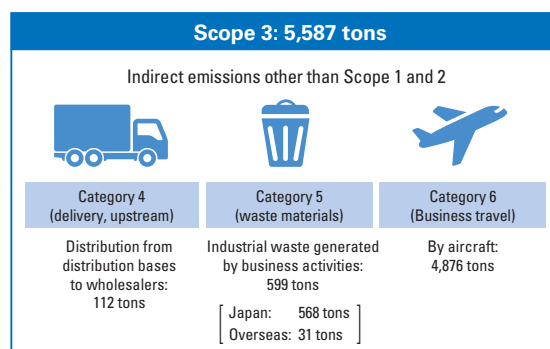
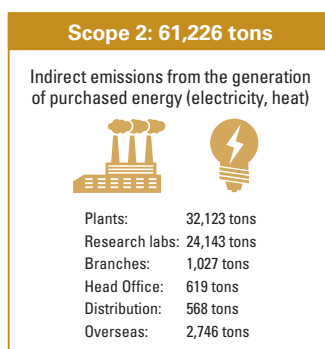
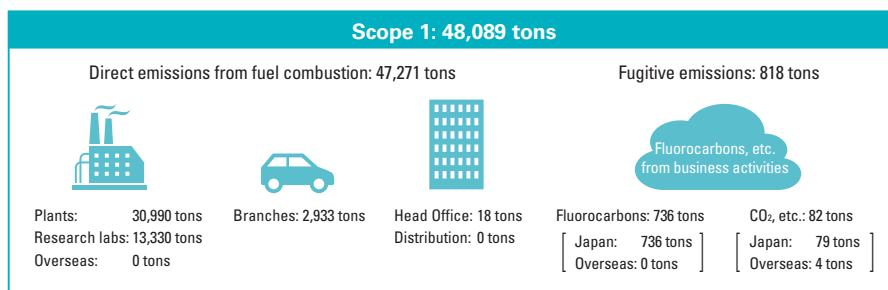
We are conducting risk management for water, given its importance as a raw material in pharmaceutical manufacturing and as a crucial global resource. As water-related risks, Chugai considers raw material procurement risks and water damage risks in distribution. Although Chugai believes its procurement-related 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 tests⁴ 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 2019, we again conducted a WET test once at each plant and research laboratory, and confirmed that there were no problems. We also took our initiatives one step further as employees assisted with tree thinning in the wooded highlands of Kawanehoncho in Shizuoka

Prefecture, the source of water for the Fujieda Plant, as part of efforts to conserve water at production facilities. 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.

3. We received independent verification of our 2019 greenhouse gas emissions associated with energy consumption, leakage of CFCs and HCFCs, use of aircraft for business travel, transport and delivery from logistics centers to wholesalers, and industrial waste generated.
4. Whole effluent toxicity test: 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

GHG Emissions



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,

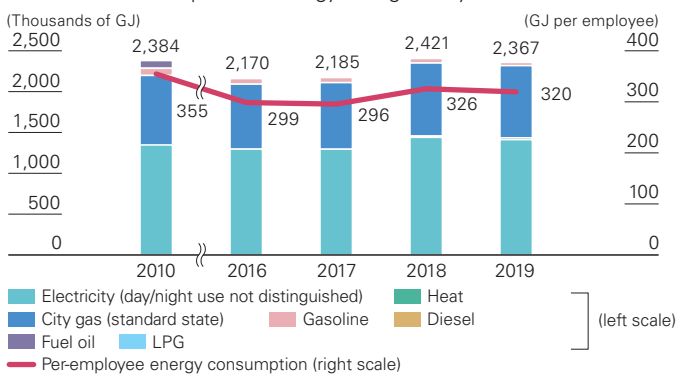
measures to address employee presenteeism (working while sick), improvement of health literacy and workplace safety measures. In September 2019, the Chugai Group announced the "Chugai Group Non-Smoking Declaration" to promote health management and further strengthen measures against smoking, which is strongly linked to cancer and lifestyle-related diseases. With the aim of reducing the smoking rate among employees to zero percent by December 31, 2030, we have decided to prohibit smoking altogether throughout the Company. To improve health literacy, we provided education on lifestyle-related diseases as part of the Chugai Group Code of Conduct (CCC) and human rights training. We are working with related departments to improve organizational health using the results of stress check 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.

Climate Change Countermeasures

Total and Per-Employee Energy Consumption

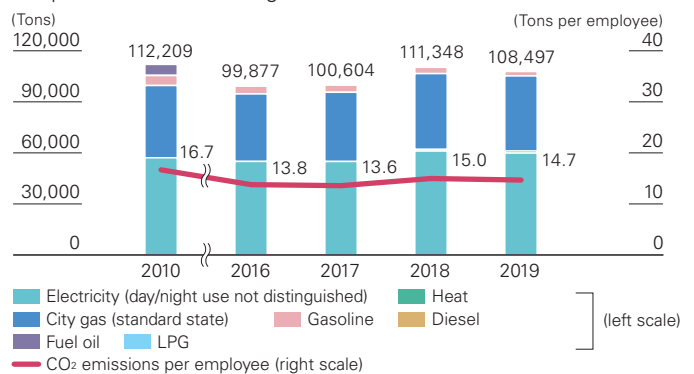
The Chugai Group's energy consumption and energy consumption per employee in 2019 decreased 2 percent respectively compared with the previous year. In addition to introducing highly energy-efficient equipment and switching fuels, the Group introduced a system for visualizing energy use as measures to promote energy saving in daily business activities.



Note: 2010 is the base year for mid-term environmental goals. Overseas energy consumption (electricity and heat) is included from 2018. Overseas energy consumption was 57,000 GJ in 2019.

CO₂ Emissions and CO₂ Emissions per Employee

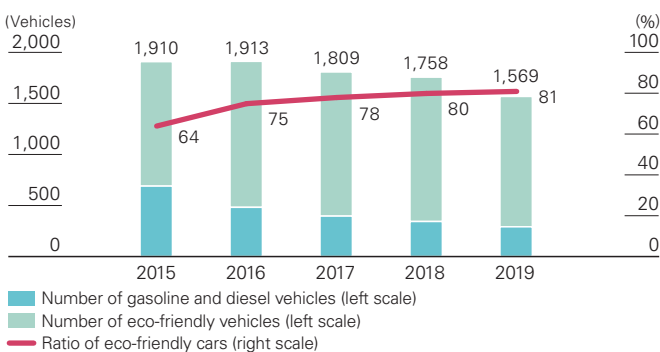
Total CO₂ emissions decreased 3 percent from 2018 to 108,497 tons. CO₂ emissions per employee decreased 0.3 tons. Factors included significant progress on measures to reduce gasoline and diesel oil consumption in the MR fleet, such as introduction of eco-friendly cars and promotion of eco-driving.



Note: 2010 is the base year for mid-term environmental goals. Overseas emissions (electricity and heat) are included from 2018. Overseas emissions were 2,745 tons in 2019.

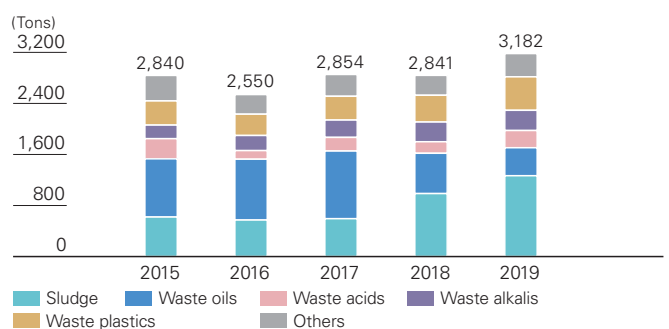
Ratio of Eco-Friendly Cars

As of December 31, 2019, Chugai had introduced a cumulative total of 1,278 hybrid and fuel-efficient vehicles in its MR fleet. The ratio of eco-friendly cars was 81 percent, remaining above the target of 60 percent. Since the MR fleet is being continuously reduced, the number of gasoline and diesel vehicles is also decreasing.



Industrial Waste

The amount of industrial waste generated increased 12 percent compared with 2018 to 3,182 tons, although progress was made on several measures to reduce that amount, such as at Fujieda Plant, the largest generator of waste oil, which enhanced its wastewater treatment facilities to separate water from aqueous waste oil.



Note: The amount of waste generated overseas is included from 2018. The amount of waste generated overseas was 11 tons in 2019.

Social Contribution and Global Health

Key Points of IBI 21 (2019-2021)

- International contribution in the field of global health
- Contribution to health in local communities
- Promotion of understanding of diversity to achieve a society of co-existence

Performance in 2019

Promoted awareness of and supported para-sports

592

Participants in 24-hour charity event Relay for Life Japan (Chugai employees and their family members)
(2019)

Conducted projects to promote safer childbirth and maternity healthcare in Myanmar, and measures for people living with noncommunicable diseases

Participated with Roche in the World Federation of Hemophilia Humanitarian Aid Program¹


1.  Together with Roche, Chugai Joins the World Federation of Hemophilia Humanitarian Aid Program
https://www.chugai-pharm.co.jp/english/news/detail/20190206150000_594.html

Chugai's Social Contribution Activities

As a responsible pharmaceutical company in healthcare, we work to raise awareness of diseases.

In the area of social welfare, in conjunction with our business activities in the renal and bone and joint areas, we conduct ongoing donations of specially equipped para-transit vehicles as we understand the importance of transportation assistance services for people who require in-home nursing care. Regarding support for the next generation, as a company that deals with leading-edge science we conduct activities to raise awareness of science and medicine among students, from elementary school children to university students, as well as among adults.

Moreover, we cooperate with local communities and engage in disaster preparedness education, mainly in areas where our research laboratories and plants are located. We also support para-sports to help create a society where everyone can participate in sports.

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

Main Initiatives for Social Contribution

Disease Awareness

Chugai participates in a variety of activities to support cancer patients and their families. One such activity is Relay For Life Japan, an awareness support campaign that forges ties in the fight against cancer. This event, a 24-hour walk-a-thon in which cancer patients, their families and supporters participate as relay teams, was held in 48 locations throughout Japan in 2019. Chugai employees have participated as volunteers in Relay For Life Japan since 2007. A total of 600 employees took part as "Team Chugai" at 31 locations in 2019.

This year, we also conducted the awareness raising activity of screenings with the "Try! Scope," which uses a fiberscope, and participants in various locations enjoyed the experience. As Team Chugai members provided explanations, participants experienced a simulated endoscopy, gaining an understanding of the importance of screening and early detection and treatment. We also promoted understanding of the importance of screening by using "Try! Scope" in health events hosted by local governments.



Initiatives for Generation AYA

Chugai launched the website AYA Life for young cancer patients in March 2017 and has been continuously updating its content. Recognition of generation AYA has been gradually growing, but there are still many patients facing a wide range of issues alone, including higher education, employment and marriage. In 2018, Chugai added new content in the form of roundtable discussions. As a leader in the area of oncology, Chugai will continue improving the website to help provide an environment where generation AYA cancer patients can receive treatment with peace of mind.

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

Promotion of Measures against Locomotive Syndrome

Locomotive syndrome is a condition in which muscles, bones, joints, cartilage, intervertebral discs and other parts of the musculoskeletal system become impaired and motor function declines. The progression of the syndrome is highly likely to impede daily life. The Japanese Orthopaedic

Association proposed it as a concept in 2007 and has been working to prevent the syndrome, establish measures for coping with it, and improve awareness. In cooperation with the prefectural chapters of the Japanese Clinical Orthopaedic Association, Chugai holds the Musculoskeletal Disorder/Bone and Joint Forum 10 or more times a year to deliver the latest information to healthcare professionals. We will continue helping to promote healthy life expectancy through this activity.

Support for Para-Sports

Chugai co-sponsors the Japanese Para-Sports Association (JPSA) as an official partner, and cooperates in activities to help realize the JPSA's philosophy of "creating a vital and inclusive society." The main activities Chugai conducted in 2019 are as follows.

Dispatch of Volunteers to Competitive Sports Events

Chugai held the Chugai Pharmaceutical 2019 Wheelchair Softball Tournament in Tokyo as the title sponsor, and provided support by sending 24 employee volunteers to assist with set-up, event management, English interpreting and other matters.

Raising Awareness of Para-Sports

- Co-sponsorship of a chair ski school for parents and children held by the Japan Chair Ski Association
- Operated a booth for experiencing wheelchair softball and handcycling at local community events and other venues
- Presentation of the para-sports related webpages "Another Sport" and "ATHLETE MOTHERS" on the Chugai website (Japanese only)



Parent and child enjoying chair skiing class

Initiatives for Employees and Their Families

To deepen understanding of para-sports and people with disabilities, Chugai held a hands-on event for experiencing blind sports in cooperation with the Yokohama City Special Support School for the Visually Impaired. There were 23 participants from Chugai, including employees and their family members.

Disaster Relief

Support for Children in Stricken Areas

Chugai once again participated in the global charity event Roche Children's Walk conducted by Roche to support children in need. In this annual initiative, Chugai matches the total amount of funds raised by its employees, with half of the total amount donated to Malawi and other countries, and the remainder donated to an organization in a stricken area in Japan. In 2019, the recipient organization was the non-profit organization Ayumu, which offers day service for disabled children in Ozu City, Ehime Prefecture.

Charity Sale

As part of its support for recovery from the 2011 Great East Japan Earthquake, Chugai held a charity sale at its Head Office and Kamakura Research Laboratories. As employees at each location looked over the goods and conversed with sales staff and local producers, they renewed their hopes and prayers for the restoration and recovery of the affected areas.



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 35th year in 2019. A total of 258 vehicles have been donated since the start of the program, including five vehicles in 2019.

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 Activities

There are still many people around the world suffering from diseases that currently have no effective treatments, and even when treatments do exist, people lack access due to poverty or for reasons pertaining to healthcare systems. To fulfill its Mission of benefiting the medical community and human health around the world, Chugai considers it essential to contribute to global health by improving access to healthcare. Accordingly, in addition to discovering and providing new drugs on our own, we proactively cooperate with a variety of organizations. Our priority initiatives as set in Chugai's Basic Approach to Global Health are (1) developing new products for diseases with no treatments by utilizing our pharmaceutical technologies and expertise, and (2) improving quality of healthcare and access to pharmaceuticals by improving the capabilities of healthcare professionals, promoting disease awareness in local communities, and establishing social infrastructure, particularly in low- and middle-income countries.

Chugai's Basic Approach to Global Health
<https://www.chugai-pharm.co.jp/english/sustainability/globalhealth/concept.html>

Reports: Global Health
<https://www.chugai-pharm.co.jp/english/sustainability/activity/index.html?year=&category=2>

Main Initiatives for Global Health

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.

In addition to joining the GHIT Fund and contributing capital in December 2014, Chugai has also been using its innovative discovery technologies and research resources to conduct a program to develop drugs to prevent and treat dengue fever and joint research to develop a treatment for tuberculosis.

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

Access Accelerated

Access Accelerated was established in January 2017 by 22 global pharmaceutical companies including Chugai at the annual meeting of the World Economic Forum. In partnership with the World Bank Group and the City Cancer Challenge foundation, Access Accelerated is working to achieve the SDG target of reducing premature mortality from non-communicable diseases by one-third by 2030.

Through Access Accelerated, Chugai is conducting its own projects in Myanmar with AMDA-MINDS (AMDA Multisectoral & Integrated Development Services) to promote safer hospital childbirth and maternity healthcare and measures for people living with non-communicable diseases. We visit local communities to listen directly to the opinions and requests of patients, healthcare professionals and local health departments in order to gain an accurate understanding of their needs. We aim to use this information to continue helping to improve access to healthcare even after these projects are completed.



Update and feedback session on funding for emergency transportation of pregnant women

Access Accelerated website
<http://www.accessaccelerated.org/>

World Federation of Hemophilia Humanitarian Aid Program

The World Federation of Hemophilia (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. As the originator of Hemlibra, Chugai is participating in the program as a member of the Roche Group. Through this five-year program, the Roche Group will fund the establishment of infrastructure and conditions for the proper use of treatments by healthcare professionals and will provide prophylactic treatment by donating Hemlibra for about 1,000 people with hemophilia A.