

Chugai ESG Meeting

CHUGAI PHARMACEUTICAL CO., LTD.

16 November, 2021



Important Reminders



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Information regarding pharmaceuticals (including products under development) is included in this presentation, but is not intended as advertising or medical advice.

Chugai ESG Meeting

Agenda



Representative Director & Deputy Chairman **Sustainability Management** 01 Motoo Ueno Executive Vice President & CFO **Materiality and ESG Ratings** Toshiaki Itagaki **ESG** in the Context of Growth Strategy Vice President & Head of Clinical Development Div. **Drug Development in Pursuit of** 03 Tsukasa Kusano Sustainable Healthcare **ESG** in the Context of Growth Strategy Head of Sustainability Dept. **Global Environmental Initiatives** 04 Shigehiro Yamada, Ph.D. (Pharmaceutical Technology)



Sustainability Management



Representative Director & Deputy Chairman

Motoo Ueno

Chugai ESG Meetings



- Aiming to improve engagement and upgrade ESG initiatives through PDCA cycling -

2019 1st ESG Meeting

- ESG overview -

2020 2nd ESG Meeting

- ESG strategies/plans -

3rd ESG Meeting

- ESG as management strategy -

(Meeting topics)

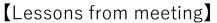
- · Value Creation by Chugai
- Material Issues
- IBI 21 and ESG Initiatives

(Lessons from meeting)

- ✓ Focus on stakeholder concerns
- ✓ Importance of strategy/planning

(Meeting topics)

- Progress toward sustainability
- Sustainability-related indicators
- Long-term plan (SCM/environment)
- Global health



- ✓ Explanation of ESG as management strategy
- ✓ Breadth of risk analysis

Relationship between growth strategy and material issues

Explanation of ESG carried out by business units as one component of management strategy

Outside Director's Message

- Significance of ESG meetings -



Outside Director Yoichiro Ichimaru

Your candid input makes Chugai stronger

Chugai has adopted a basic policy of creating shared value with society and designated ESG as a medium/long-term management strategy. As part of its vision of becoming a top innovator by 2030, Chugai is ramping up ESG activities in the aim of being a role model for the world. Even my colleagues and I on the Board of Directors have experienced increased opportunities in discussing sustainability issues.

For Chugai to realize the advanced and sustainable patient-centric healthcare to which it aspires, it is crucial for all employees to first and foremost take personal responsibility for business activities, including the ESG aspects thereof, and create shared value in their respective workplaces. I believe the pandemic has strongly reaffirmed that Chugai can alleviate burdens and contribute to quality of life for not only patients and their families but also the entire medical profession.

Again such a backdrop, I consider ongoing engagement around ESG, including this meeting, to be a meaningful driver of the cycle whereby we identify external stakeholders' expectations, needs and wishes and incorporate them into Chugai's management. I personally spent my career in the auto industry but much of my experience is transferable across sectors or industries. From the standpoint of creating new value by capitalizing on diversity, I look forward to earnestly engaging with Chugai employees and various external stakeholders.

Environmental Changes and Business Strategy



- We are implementing a new growth strategy formulated in light of changes in the environment and progress in activities -

Changes in external environment

(Society**)**

- COVID-19 resurgence
- Growing environmental risks besides climate change
- Escalation of geopolitical risks
- · Advancements in AI, IoT and other technologies

[Economy/corporate sector]

- · Adaptation to new-normal society
- Ongoing digital transformation
- Reconfiguration of work modalities and HR strategies
- New recommendations on various initiatives
- Revision of Japan's Corporate Governance Code

- External environment scenario analysis
- Risk analysis
- Reassessment of materiality



- Promotion/implementation of various activities
- Analysis of IBI 21 results/progress
- Identification of issues



Formulation/execution of New Growth Strategy

Business strategy integrating growth strategy and sustainability

Basic Policy (Envisioned Future)



- Emphasis on alignment among mission, growth strategy and material issues -



Envisioned Future for 2030

Top innovator in the healthcare industry



Material issues (25 issues across 8 categories)

Year in Review: Progress in ESG-related Activities



- We made steady progress while adapting to changes in the environment -

Sustainable Healthcare

- Made brisk progress in drug discovery/ development
- · Launched new products, additional indications
- Accelerated DX, most notably AI-based drug discovery
- Made progress in developing/supplying COVID-19 therapies

Global Environment

- Formulated Mid-Term Environmental Goals 2030
- Conducted scenario analysis based on TCFD recommendations
- Made progress toward environmental goals

Corporate Governance

- Board of Directors' effectiveness assessed by external third party
- Installed ERM system
- · Promoted engagement with stakeholders

Human Resources

- Implemented new HR system
- Strengthened talent management
- · Secured talent with high-level expertise
- Formulated/implemented new ways of working

Ethics and Compliance

- Monitored compliance
- Formulated purchasing policy and educated employees on it

Human Rights

- Conducted human-rights due diligence on contractors
- Implemented safeguards for clinical trial subjects

Supply Chain Management

- Made progress toward realizing digital plants
- Formulated Supplier Code of Conduct and shared it with suppliers
- Conducted supplier risk assessment

Social Contribution

- Codified social contribution activities, reset priorities
- Promoted global health activities

Example: Responsibility for COVID-19 Drug Access



- Initiatives to ensure stable supply of Actemra -

Actemra for COVID-19 pneumonia treatment

Overseas: recommended in WHO guidelines (July 2021)

US: emergency use authorization granted by FDA (June 2021)

Japan: filing scheduled in 2021

Stable supply initiatives

Built expandable production network across Roche Group before demand spiked

- Equipped Utsunomiya Plant with expandable production capacity
- Expanded outsourcing of formulation process to Genentech
- Maximized production by ramping up production network and transferring technology through contracts with large-scale manufacturers

More than doubled supply in 2021

Further initiatives in response to COVID-19

Supply shortages due to global demand spike in excess of doubled supply

- Production capacity limitations
- Raw material supply constraints
- Biologic production processes' complexity and labor-intensity
- Dynamic changes in COVID-19 pandemic



Roche Group-wide initiatives to improve drug access and combat COVID-19

- Strengthened distribution strategy in close coordination with global health authorities and partners
- Waived both Chugai and Roche's patent protection in low/middle-income countries
- Expedited development and mass marketing of therapies for mild/moderate cases (e.g., Ronapreve, AT-527) to prevent to develop severe symptoms

Example: Reprioritization of Social Contribution Activities (1)



Roche Roche Group

- Goals to Achieve Through Social Contribution Activities -

In our social contribution activities, we will support a foundation for advanced and sustainable patient-centric healthcare, and will work to advance initiatives for expanding a healthy society, centered on the following five areas.

- We have codified our approach to social contribution activities to realize our mission.
- We will focus on our five priority areas – healthcare, social welfare, inclusive society, next generation development, and local community – to respond to social needs.
- We define social contribution activities as activities that help to solve social issues and, in turn, realize our mission. They do not include business activities that directly lead to financial gain.

Working with those involved in healthcare Area 1 Support the foundations of Healthcare advanced and sustainable patient-centric healthcare Area 2 Area 3 **Social Welfare Inclusive Society Expand healthy lives to Expand** a healthy society in people facing which diverse people can difficulties each shine in their own way Working with diverse Area 4 people **Next Generation** Development Expand a healthy society Working with the next generation **Expand the future of well-being** Work with local residents to expand sustainable communities Area 5 Local Community

Reference: social contribution activity policies

(https://www.chugai-pharm.co.jp/english/sustainability/community/)

Example: Reprioritization of Social Contribution Activities (2)





- Focusing on highly societally relevant initiatives in five priority areas -

Area 1 Healthcare

Support the foundations of advanced and sustainable patient-centric healthcare

- · Promoting research and education in medicine and pharmacology (support for, e.g., Tokyo Biochemical Research Foundation's activities)
- Supporting patient treatments and livelihoods (e.g., activities to raise awareness of diseases, collaboration with patient groups)
- · Improving access to health and medical care for the world's people (e.g., support for diagnosis/treatment of non-communicable diseases in low/middle-income countries)

Area 2 Social Welfare

Expand healthy lives to people facing difficulties

- Improving the lives of the elderly and those with disabilities (e.g., paratransit vehicle donation program)
- · Supporting children in developing countries and refugees (support activities through, e.g., Roche Children's Walk)

Area 3 Inclusive Society

Expand a healthy society in which diverse people can each shine in their own way

- Promoting inclusivity through sports (e.g., parasports promotion activities)
- Promoting inclusivity through cultural activities (support for, e.g., art/music/dance activities open to people with disabilities)
- · Promoting women's participation and advancement (e.g., sponsorship of women's empowerment events under the theme "living your authentic life")

Area 4 **Next Generation** Development

Working with the next generation Expand the future of wellbeing

- Cultivating interest in biotechnology/science (e.g., hosting of experimental biology seminars)
- · Advancing career education for students (e.g., hosting of company tours for schoolchildren, guestlecturing at schools)
- Expanding learning opportunities through website (e.g., publication of information on biotechnology and drugs)

Area 5 Local Community

Work with local residents to expand sustainable communities

- Preserving the natural environment (activities to, e.g., preserve watershed forests from which Chugai sites source water)
- Promoting local community activities (e.g., participation in community events local to Chugai sites)
 Restoring and reconstructing disaster-stricken areas (e.g., disaster relief activities)

Sustainability-related Governance



- Board of Directors and Executive Committee are increasingly devoting time to sustainability matters -

Board of Directors' main sustainability-related agenda items (Jan 2020 - Sep 2021)

Governance

- Convocation of and agenda-setting for General Meetings of Shareholders; approval of business reports, financial statements, etc.
- Nomination of director and Audit & Supervisory Board member candidates; appointment of Appointment Committee and Compensation Committee members
- Appointment/dismissal of <u>representative directors</u>, executive officers and advisors
- Directors' remuneration
- Implementation and reporting of evaluation of effectiveness of Board of Directors
- · Reporting on internal control, risk management, and IR activities
- Verification of cross shareholdings
- Approval and reporting of transactions in competition with the Company and other conflict-of-interest transactions
- · Review of revised version of Japan's Corporate Governance Code

Social and environmental

- Formulation of TOP I 2030 (matters related to foundation for growth and sustainability)
- · New production facility construction plans, R&D facility consolidation plans
- · Matters related to stable Actemra supplies
- HR-related reporting
- · Formulation of Mid-Term Environmental Goals 2030

Executive Committee's main sustainability-related agenda items (Jan 2020 – Oct 2021)

Environmental

- Mid-Term Environmental Goals' content/goal-setting (Jan., Jul., Sep. 2020, Jan. 2021)
- Measures implemented to achieve Mid-Term Environmental Goals and progress reporting (Jul. 2021 (twice), Oct. 2021)

HR

 Domestic group companies' HR management reforms, HR system changes (Nov. 2020, May 2021)

Other

 Chugai Pharmaceutical Corporate Pension Fund's endorsement of Japan's Stewardship Code (Oct. 2021)

Note: Underlining denotes agenda items for which advance briefings and/or Board deliberations were augmented in 2020

Example: Mid-Term Environmental Goals 2030's Formulation Process



- We set ambitious goals with external input -

Analyze/discuss

Review mid-term environmental plan 2020/

[Research/analyses]

- Gap analysis vs. external evaluations
- Scenario analysis based on TCFD recommendations
- Materiality reassessment
- Environmental technology survey

(Gathering of external input/discussion)

- Input from external experts
- External workshops
- · Discussions with outside directors

Identify environmental issues Formulate/set direction and rubrics

Set policies Assess goals

(Formulate policies)

- Divisional discussions of policies/goals
- Coordination with Roche's environmental compliance staff
- Commitment by senior management

(Approach to goals)

- · Longer-term timeline
- Focus on material items' comprehensiveness
- Goal-setting based on ambitions, not attainability

Finalize environmental goalsetting policy

Forward to EHS and Executive Committees for deliberations

(Bodies that deliberated on policies/plans)

- EHS Promotion Committee (4 times)
- Executive Committee (4 times)
- · Board of Directors (twice)
- Meetings with senior management (4 times)
- Sustainability Advisory Committee (twice)

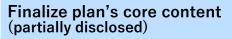
Disclose Mid-Term Environmental Goals 2030

[Disclosures]

- Financial results briefings
- News releases
- Annual Report 2020
- Website

[Feedback/recommendations]

- Need for disclosure of milestones
- Need for engagement on specific initiatives



Assess milestones

(this ESG Meeting)
Specifically explain milestones

Aiming to become Role Model for the World



- Grinding out PDCA cycle iterations based on creating shared value through innovation -

Envisioned Future for 2030

Top innovator in the healthcare industry



Expectation from patients all over the world



Attracting talent and players from around the world



Role model for – the world

Recognized for its ESG initiatives through its business activities, Chugai will become a global role model as a leader in resolving social issues.



Steps toward becoming role model for the world

External

Identify expectations/needs/wants and respond at high level

- Continuously keep abreast of changing expectations/needs/wants
- Earn top-level ESG ratings (e.g., DJSI inclusion, surveys)
- · Be a company indispensible to society



Internal

Create shared value through innovation

- Pursue innovation in both results and process
- Proactively adapt to changes in environment at individual workplace level
- Continuously progress in terms of communication and disclosure



Materiality and ESG Ratings



Executive Vice President & CFO

Toshiaki Itagaki

Materiality and Growth Strategy



- Promoting ESG through our TOP I 2030 growth strategy linked to materiality -



Medium/long-term targets/metrics toward realization of TOP I 2030 (medium-term milestones)

External

- Market changes
- Scientific/technological changes
- Customer changes



Internal

- · Advancement of R&D projects
- Promotion of leading-edge business models
- Rollout of key drivers

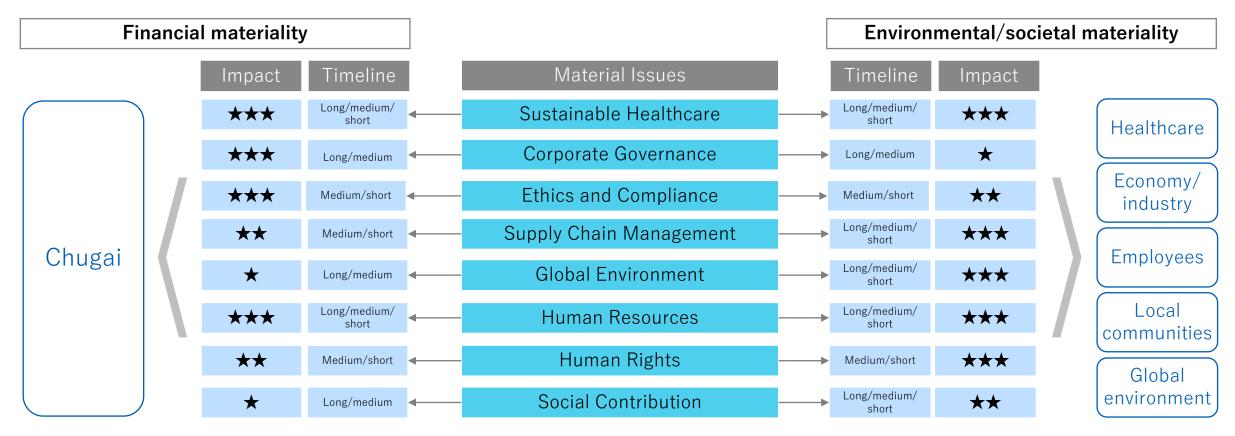


Creation of shared value through realization of top innovator vision

Management Strategy's Underlying Materiality Assessment



- We have reassessed impacts and timelines based on double materiality -
- We have clarified material issues' impacts and timelines based on a (strategic/operational) risk assessment (see page 54 of Annual Report 2020 for summary of risk assessment)
- We have assessed our material issues based on the double materiality concept in the European commission's Non-Financial Reporting Directive and proposed Corporate Sustainability Reporting Directive.



Reference: Existing Indicators for Materiality



- We set goals/indicators for individual material issues -

Category	Material Issue	2020-21 indicator(s)		
Sustainable Healthcare	Creation of innovative drugs and services	New products launched and new indications Number of projects and products based on PHC		
	Provision of solutions for patients	Market share in therapeutic area		
	Fair marketing	-		
	Fair pricing	-		
	Adverse event management	Customer satisfaction		
	Quality assurance and stable supply of products	-		
Corporate Governance	Corporate governance	· Review of Board of Directors effectiveness		
	Risk management	_		
	Disclosure and engagement	• ESG meeting for institutional investors and media		
Ethics and Compliance	Compliance	· Compliance monitoring		
	Code of conduct	· CCC and human rights training in Japan		
	Fair transactions	-		
Supply Chain Management	Supply chain management	· Risk assessment of major contract manufacturing organizations (CMOs)		
Global Environment	Climate change countermeasures (energy, etc.)	 Scope 1+2 CO₂ emissions Fuel consumption by MR vehicles Scope 1+2 energy consumption Halogenated hydrocarbons 		
	Use of renewable/recycled resources (water, waste, etc.)	· Industrial waste reduction · Plastic waste reduction · Water resource conservation (Water withdrawal)		
	Protection of biodiversity (environmental burden mitigation)	· Chemical substance management (SVHCs) · Hazardous waste reduction		
	Environmental management system	Expand verification items and scope		
	Employee job satisfaction	• Rate of paid leave taken • Work-from-home (WFH) participation rate • Employee awareness survey		
Human Resources	Development of employee potential	Number of next-generation leader candidates		
	Diversity and inclusion	· Ratio of female managers · Ratio of female managers (with subordinates)		
	Improvement of occupational health and safety	Prohibit smoking during work		
Human Rights	Human rights	Human rights due diligence on contractors		
	Safety of clinical trial subjects	_		
Social Contribution	Social contribution activities	· Set for each program		
	Improvement of access to healthcare	· Set for each program		

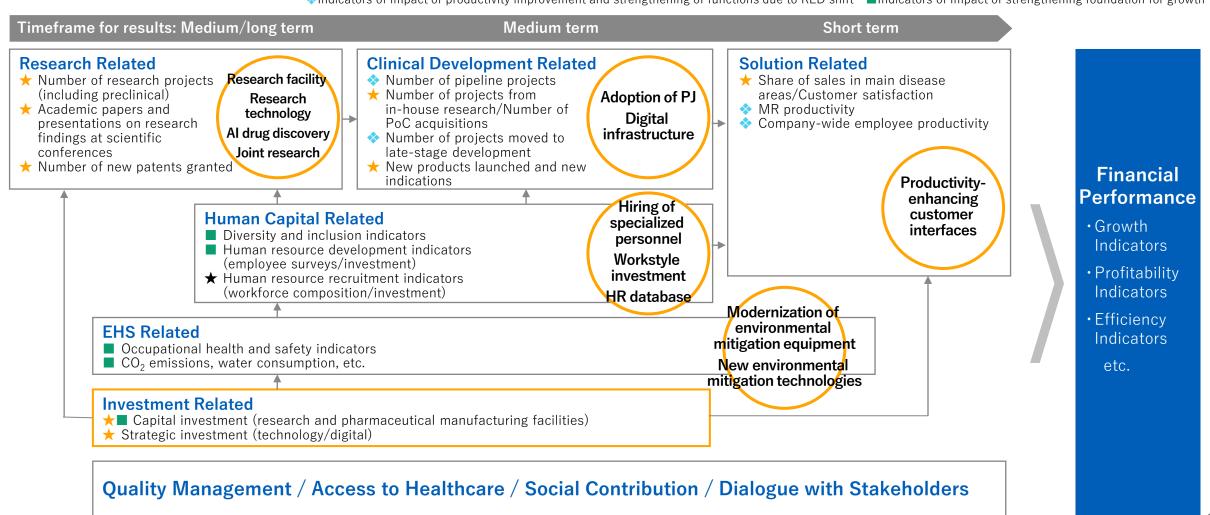
Nonfinancial Indicators in TOP I 2030



Roche Roche Group

- Resource allocation and nonfinancial indicator trends -

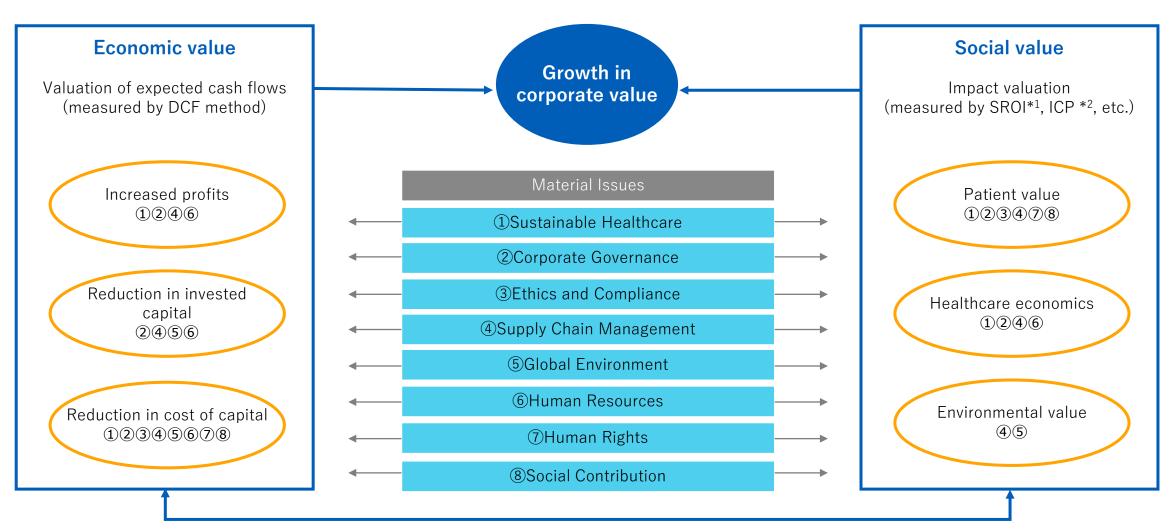
○ : TOP I 2030's main areas of investment ★: Indicators of RED shift's direct impact
Indicators of impact of productivity improvement and strengthening of functions due to RED shift
Indicators of impact of strengthening foundation for growth



ESG Initiatives and Corporate Value



- Corporate value = Economic value + Social value -



Example: HR-related Indicators (1)



- HR/organization strategies and indicators in TOP I 2030 (foundation for growth) -

Thoroughly implement new HR system

- Promote good fit between employees and their jobs to realize growth strategy
- Expedite development of next-generation leader candidates through strategic job rotations
- Foster an organizational culture that encourages bold challenges

(Indicators monitored)

- Number of next-generation leader candidates
- One-on-one check-in rate between superiors and subordinates

New ways of working

- Expand ranks of active employees through new ways of working
- Adopt telework model based on work from home and satellite offices
- Adopt highly flexible work modalities that boost productivity and job satisfaction

(Indicators monitored)

- Employee awareness survey (active employees)
- · Ratio of teleworkers to on-site staff

Acquire highly specialized talent

- Hire data scientists by developing new recruitment methods
- Strengthen internal identification and development of digerati
- Implement autonomous learning with i-Learning learning management system

(Indicators monitored)

- Job-fill rate for essential positions
- i-Learning utilization rate

Ongoing promotion of diversity and inclusion (D&I)

- Foster an innovation culture by promoting D&I
- Widely and persistently practice three behaviors conducive to inclusion
- Expedite promotion of female managers

(Indicators monitored)

- Ratio of female managers
- Employee awareness survey (D&I)

Example: HR-related Indicators (2)



- Trends driven by implementation of TOP I 2030 (RED shift and HR strategy) -

(Acquire highly specialized talent)

- Steadily recruit digerati and scientific personnel by manifesting TOP I 2030's HR vision and implementing its hiring strategies
- We are identifying digerati through internal surveys and internally developing over 100 digerati annually through the newly established Chugai Digital Academy

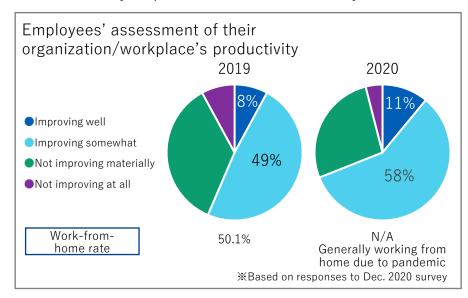
(New ways of working)

- Continue to maintain or increase productivity amid rapid shift to working from home in response to pandemic
- Optimally combine telework and on-site work to generate synergies in terms of productivity and job satisfaction

Digerati recruitment

Percentage attainment of 3-year digerati hiring target (cumulative) (mid-career hires) 74% 63 digerati 2019 2020 2021

Productivity improvement due to workstyle reforms







Improvement Through Issue Analysis Conducted So Far



- Using gap analysis to identify issues and drive PDCA cycle -



External evaluations

- Mid-level in Asia
- Issues: lagging behind in human rights, SCM, drug access

Strategic challenges

- Getting all organizational units involved
- Lack of clarity on companywide priorities

External evaluations

- Top level in Asia
- Rectified previous year's issues to global level

Strategic challenges

- Strengthening companywide commitment
- Lack of clarity on stakeholder engagement indicators

External evaluations

- Global level
- Included in DJSI World Index for first time
- Still below global average in some areas

Strategic challenges

- Implementing medium/ longterm initiatives
- Augmenting ESG information disclosure

External evaluations

- Global top level
- Ranked 2nd in DJSI World Index
- ESG gap analyses becoming less effective

Strategic challenges

 Launching original initiatives to become a role model for the world

(Actions taken in response)

- Clarified creation of shared value
- Specification of materiality

(Actions taken in response)

- Set target to be included in DJSI World Index in 2020
- Disclosed material issues and goals

(Actions taken in response)

- Set Mid-Term Environmental Goals 2030
- Set ESG survey response priorities and augmented information disclosure

Response to External ESG Ratings



Roche Roche Group

- Priorities identified based on results of analysis -

	\bigcirc Stable high ranking $\ riangle$ Stable low ranking $\ riangle$ Higher ratio	ng →Unchanged rat	ing \Lower rating
	Key 2020-21 initiatives	2020 rating	2021 rating
Materiality	· Augmented disclosure of material targets, etc.	1	0
Corporate governance	 Appointed female director Upgraded assessment of Board of Directors' effectiveness (third-party assessment) Disclosed how officers' performance-based remuneration is set, including indicators used in the process Disclosed Appointment and Compensation Committees' membership Upgraded information security/cybersecurity 		\rightarrow
Risk management	 Updated risk factors and augmented disclosure thereof Factored risk management indicators into executive remuneration 	1	0
Supply chain management (SCM)	 Made progress toward PSCI-compliant SCM and augmented disclosure of SCM initiatives Systematically disclosed SCM process Compiled labor safety indicators for outsourcing service providers 		0
Global environment	 Formulated medium/long-term environmental plans/targets Analyzed sensitivity to climate-change/water risks and disclosed financial impacts Expanded scope of both data from which indicators are compiled and third-party assurance 		0
Human resources	 Recruited and retained talent Commissioned third-party audit of occupational health and safety indicators 		0
Human rights	 Prepared human-rights risk map Systematically disclosed initiatives to address human rights issues 		1
Social contribution	· Disclosed program for carrying out social contribution activities	7	1
Healthcare access	 Expanded initiatives targeted at local healthcare needs/challenges Acted on strategy to improve drug access and addressed cost burden 	1	→
Tax strategy	Newly formulated and disclosed tax policies	7	0

Augmentation of ESG Information Disclosure



Roche Roche Group

- We are committed to increasing disclosure of idiosyncratic ESG information also -

- We are committed to ESG disclosure from the standpoint of both meeting growing societal expectations/needs and sharing strategic progress
- As a result, our external ESG ratings (e.g., DJSI, FTSE) have been improving
- We plan to expand thirdparty assurance audits and strive to improve
 Sustainalytics risk rating

Newly disclosed ESG information



Governancerelated

- Board of Directors and Executive Committee's main agenda items
- · Assessment of Board of Directors' effectiveness (results, progress)
- · Directors and Audit & Supervisory Board members' expertise and experience
- Performance-based remuneration-setting process, including performance indicators used
- Risks and risk management policies (risk scenarios, severity of impacts, risk appetite policies)

Social

- Supplier evaluations (targets, number of suppliers evaluated, evaluation results, improvements)
- · Improvement in access to healthcare (basic policies, progress)
- Basic approach to social contribution activities
- Product quality assurance (number of recalls)
- Employee remuneration (average pay disaggregated by position/gender)

Environmental

- · Addition of new mid-term environmental goals (previously 4 goals, now 10)
- · CO₂ emission reduction roadmap
- Sensitivity analysis and financial impacts of climate-change/water risks based on TCFD recommendations

HR-related

- Employee awareness survey results (engagement, workplace environment)
- · Hiring of digerati, percentage of job openings filled internally
- · HR development indicator (education/training expenses per employee)
- D&I indicators (e.g., female manager ratio, male employees' childcare leave usage rate)

Future Direction and Sustainable Growth Through ESG Analysis



- Evolving into a role model for the world -
- We have earned global-level ratings through gap analysis and, in the process, raised awareness and built out an ESG regime across organizational units.
- Going forward, we will pioneer original initiatives to become a role model for the world.

Current external ratings Dow Jones 2nd in world **Sustainability Indices** Powered by the S&P Global CSA Α-33rd **SUSTAINALYTICS** a Morningstar company out of 452 MSCI (1) AA 4.2 MSCI JAPAN 8.05 **EMPOWERING WOMEN INDEX (WIN)**

What we can gain through analysis of ESG issues

- Information useful for sustainability management
- Ascertained sustainability trends of importance to pharmaceutical industry
- Improve relative stature within pharmaceutical industry
- Obtain information useful for materiality analysis and KPI selection
- Upgrade internal ESG regime through responses to surveys
- Cascade ESG initiatives down to individual organizational units, improve cross-organizational coordination
- Build ESG reporting function
- Make progress in building sustainability strategy
- Objective evaluation as a sustainable company
 - Increase attractiveness to long-term investors
 - Enhance reputation in eyes of patients/healthcare providers
- Improve employee morale





Drug Development in Pursuit of Sustainable Healthcare



Vice President & Head of Clinical Development Div.

Tsukasa Kusano

Value Shared with Patients in Development Stage



Adding value with TOP I 2030 growth strategy's priority initiatives -

Address unmet medical needs

For patients

For Chugai

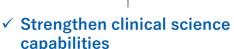
- Access to innovative new drugs
- Treatments for rare diseases
- Provision of innovative new drugs
- · Growth in corporate value
- ✓ Strengthen communication with regulatory authorities
- √ Identify clinical needs
- ✓ Strengthen medical/ safety science capabilities

Increase development success rate

- Smaller-scale clinical trials
- Reduced burden
- · Advancement of development technology
- Increased productivity & profitability
- √ Strengthen biology research
- ✓ Improve prediction accuracy
- ✓ Utilize M&S*2, human organoids, RWD*3



- Expedited access to new drugs
- · Competitive advantage in development
- · Growth in cash flow



- ✓ Reform development model
- ✓ Coordinate with early commercial production

Evaluate QOL*1, the true endpoint

- Objective proof of QOL
- Fulfillment of therapy and expansion of treatment options
- Maximization of product value
- · Advances in understanding patients



- ✓ Develop assessment
- ✓ Develop digital biomarkers

Core Value in Development Stage: Patient Centricity



- We will realize our 2030 vision by pursuing patient centricity -

FOSTER A SHARED COMMITMENT TO DEVELOPING NEW DRUGS AND BUILD RELATIONSHIPS OF TRUST AMONG PATIENTS, HEALTHCARE PROVIDERS AND CHUGAI EMPLOYEES

Patients feel more engaged in clinical trials and develop a collaborative mindset as they have access to extensive clinical trial information and are given more opportunities to express their views.

Chugai is able to develop new value-added drugs based on input from patients.

Sharing & Informing (Give)

Provide participants/patients with information

Cooperating & Participating (Take)

Listen to patients' voices & utilize them

Definition of Patient Centricity

Drug Development Together with Patients

Understand & consider patients, based on our core value, "Make each patient's wellbeing our highest priority."

Clinical Trials Harmonized with Patients



- Patients as Partners -

- We design protocols in collaboration with patients by involving patients in the clinical trial process
- In recent surveys of clinical trial subjects, positive to participate in clinical trials as "a good opportunity to let the company and others know about their illness"

Preparation



Patient Survey

- UMNs
- Preference
- Quantitative Endpoints
- Protocol/ICF

ICF: Informed Consent Form

eConsent: Electronic Informed Consent

pts: patients

PRO-CTCAE:

Patient Reported Outcome

Common Terminology Criteria for

Adverse Events

Clinical study ongoing



eConsent

- Multimedia incl. video
- Dictionary / Glossary
- Comprehension up
- E-signature



Digital Biomarker

- Object. Evaluation
- True Endpoints
- · Improve QOL
- Clinical settings

Termination



Layperson Summary

- Report for pts
- Plain words & expression



Thank you letter

- Appreciation
- Pts as a partner



Adoption of PRO-CTCAE

- Evaluation by pts
- · Understand symp.
- Pts adherence



Patient Survey

- Anxiety
- Motivation
- Requests

Case Study: Digital Solutions for Endometriosis



- Development of an objective, ongoing method of pain assessment, a key challenge in medical diagnosis/treatment -

Issues:

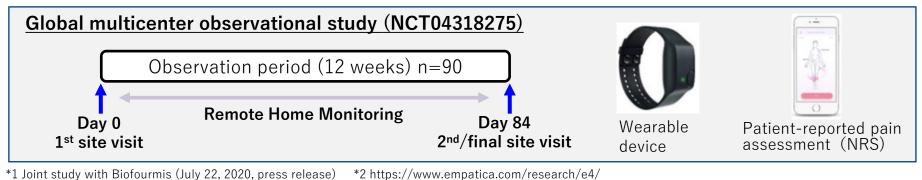
- Pain assessment is subjective
- Patients have difficulty accurately reporting their pain's severity, duration, etc.
- · Changes in pain over time cannot be adequately ascertained through outpatient visits

Solution:

- Identify objective and consecutive assessment of continuous pain
- · Promote understanding of endometriosis and alleviate patient burden (psychological, time-wise, cost-wise) by developing new biomarker

Protocol:

- · We are developing an objective pain assessment method through an observation study of endometriosis patients (conducted jointly with Biofourmis*1)
 - ✓ Collect vital sign data (pulse rate, blood volume, body temperature) via a wearable device (Empatica E4®*2)
 - ✓ Collect patient-reported pain assessments (on a numeric rating scale (NRS)) via a smartphone app
 - ✓ Construct a pain index through algorithmic analysis of the collected data
 - ✓ Validate pain index through comparison with patient-reported pain (NRS) assessments



Use of Decentralized Clinical Trials (DCTs)



- Clinical trial model not dependent on visits to trial site -

Patientcentric

- Reduction in burden of participation in trials
 DCTs alleviate psychological burden by offering more options (televisits/site visits)
- Increased access to trials
 DCTs reduce time demands imposed by site visits
- Increased engagement
 DCTs increase patients' engagement with clinical trials
 by incorporating new functions, programs and systems
 in addition to features such as home visits by nurses
 and online consultations

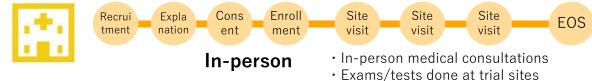
Improved clinical trial efficiency

Shorter trials

DCTs shorten the enrollment period and enable realtime data collection

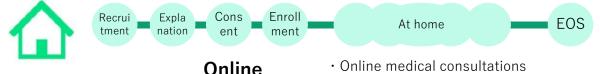
• Improved data quality/increased data quantity
DCTs reduce (1) the risk of data insufficiency by
collecting more direct and real-time data and boosting
patient retention and (2) the risk of having to reopen
enrollment due to greater patient attrition than
expected

Conventional clinical trials



 Drug administered and documents handed out at trial sites

Clinical trials not dependent on visits to trial site (DCT)

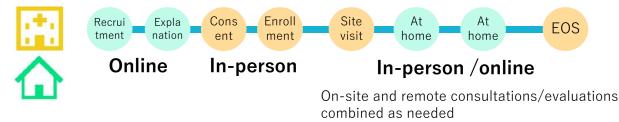


· Home visits by healthcare providers

Digital devices

Home delivery (drugs, materials)

Clinical trials not dependent on visits to trial site (hybrid DCT)



Source: Japan Pharmaceutical Manufacturers Association, *Iryou Kikan heno Raiin ni Izon shinai Rinshou Shiken Shuhou no Dounyuu Oyobi Katsuyou ni Muketa Kentou*

Hallmarks of Clinical Development Driven by Patient Value



Roche Roche Group

- Superior drug candidates lead to patient value -

Thought process behind development decision-making Unmet needs, clinical needs Medical Patients' true needs needs (OOL, burden reduction) • Drug discovery concept, modality, Drug's technology innovative-• First in class, best in class ness Potential to add patient value Probability of being allowed to charge Commercial an adequate price based on scientific evidence potential Marketability and cash flow outlook

Diverse clinical development program

We are building a diverse clinical development program backed by our innovative business model and development models

Approach to rare diseases

We are able to develop drugs that are not feasible for others to put through clinical trials, including drugs for rare diseases, based on a scientific rationale and our sense of responsibility

Diverse Clinical Development Programs



- Committed to flexible clinical development optimized for both patients and the medical profession -

Variety of Study style	Global/LocalDouble blind/OpenAdaptive Design	 Umbrella/Basket/Platform RWD*1 Clinical pharmacology 	tigator-initiated trials
Multiple Operation model	 Roche/Chugai model CCRC*²/CRO*³ Full outsource 	Co-developmentSimultaneous development for multi-indi	ication
A wide range of Modality	Small moleculeMid-size moleculeAntibody	Nucleic acidRegenerative medicineGene therapy (expected to enter clinical	trials)
Various Disease areas	 Oncology Immunology Infection Ophthalmology Alzheimer Neuroimmune/muscle/degeneration/Developmental disability 		HemophiliaMetabolismRare disease
Talented Members	Multinational workforceGender mix: roughly 50:50Personnel exchanges/join	• Mid-career hires: roughly 30% of workforms the HR development with Roche, Genentech, over	

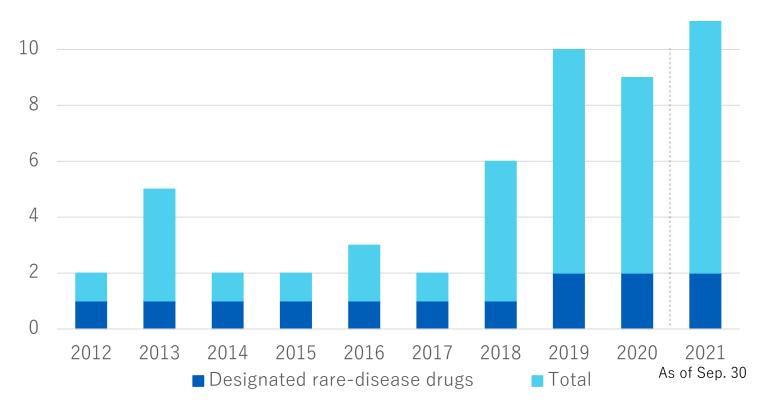
Approach to Rare Diseases



- Our technology/science-driven orientation impels us to address rare diseases -

• Our products were granted the rare disease designation 13 times over the past 10 years

New products launch and new indications*1 / Designated rare-disease drugs' share thereof*2



^{*1} Including both FoundationOne® CDx and FoundationOne® Liquid CDx Cancer Genomic Profile

Rare-disease drugs brought to market over past 10 years

Year approved/ marketed*3	Product name	Indication(s)
2012	Pulmozyme	Cystic fibrosis (improves lung function)
2013	Avastin	Malignant glioma
2014	Alecensa	Metastatic/unresectable <i>ALK</i> -positive NSC lung cancer
2015	Zelboraf	Malignant melanoma with <i>BRAF</i> V600 gene mutation
2016	Avastin	Cervical cancer
2017	Actemra	Large-vessel vasculitis
2018	Hemlibra	Suppression of bleeding in hemophiliacs without factor VIII inhibitors
2019	Tecentriq	Small-cell lung cancer
2019	Rozlytrek	Locally advanced or metastatic <i>NTRK</i> gene fusion-positive solid tumors
2020	Alecensa	ALK-positive anaplastic large-cell lymphoma
2020	Enspryng	Neuromyelitis optica and related diseases
2021	Evrysdi	Spinal muscular atrophy
2021	Polivy	Diffuse large B-cell lymphoma

^{*3} Year in which the drug was approved and first marketed with a rare disease designation. For products not yet on the market when approved, the year is the year the drug was first marketed.

^{*2} Rare-disease drug designation: A designation awarded by the Minister of Health, Labour and Welfare to drugs that meet certain criteria, including a Japanese patient population of less than 50,000 and a particularly acute medical need for the drug



Global Environmental Initiatives (Pharmaceutical Technology)



Head of Sustainability Dept.

Shigehiro Yamada, Ph.D.

Mid-Term Environmental Goals 2030



- Climate change countermeasures include long-term goal by 2050 -
- We set goals for three material issues: climate change countermeasures, use of renewable/recycled resources and protection of biodiversity.
- We replaced our four previous medium-term goals with 10 new medium-term goals to better address our three material issues from a medium/long-term perspective.
- As a climate change countermeasure, we have set a longer-term goal of reducing our CO₂ emissions to zero by 2050.

Material Issues	ltem	KPI (Base year 2019)
Climate change countermeasures (Prevention of global warming)	Scope 1+2*1 CO ₂ emissions	40% reduction by 2025 60–75% reduction by 2030 Zero emissions by 2050
	Scope 1+2*1 energy consumption	5% reduction*2 by 2025 15% reduction*2 by 2030
	Sustainable electricity ratio	100% by 2025
	Fuel consumption by MR vehicles	35% reduction by 2025 75% reduction by 2030
	Halogenated hydrocarbons (Base year 2020)	25% reduction by 2025 100% reduction by 2030
Use of renewable/ recycled resources (Resource conservation, waste management)	Industrial waste reduction	5% reduction*2 by 2025 10% reduction*2 by 2030
	Plastic waste reduction	5% reduction*2 by 2025 10% reduction*2 by 2030
	Water resource conservation (Water withdrawal)	15% reduction*2 by 2030
Protection of biodiversity (Reduction of environmental load)	Chemical substance management (SVHCs*3)	After 2021, manufacturing processes without using SVHC-listed chemicals are established for all Chugai original candidate molecules by commercial productions.
	Hazardous waste reduction	5% reduction*2 by 2025 10% reduction*2 by 2030

^{*1} Scope 1: Direct emissions, Scope 2: Indirect emissions from the generation of purchased energy *2 Per total floor area (Excluding leased properties) *3 Substances of Very High Concern

Material Issues Being Addressed in Pursuit of Mid-Term Environmental Goals



- Climate change countermeasures in particular involve technology, investment and operations -

Climate change countermeasures

Reduce CO₂ emissions and energy consumption

- Reducing CO₂ emissions from research/production facilities, which account for a vast majority of Chugai's emissions, is a priority (and also crucial to achieving Roche Group's targets)
- We must update facilities/equipment and improve energy efficiency
- We will source and secure stable supplies of sustainable electricity
- We will challenge to reduce Scope 1 emissions with technology (mitigate impacts on operations, investment, technology)

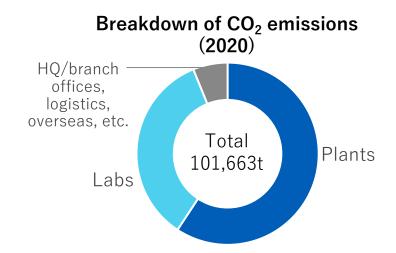
Discontinue use of halogenated hydrocarbons (HHCs)

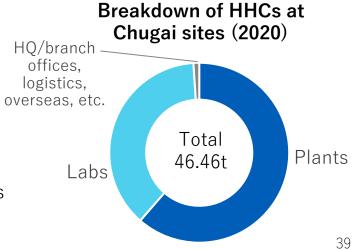
- Need to test/identify alternative technologies
- Impact of natural refrigerants' adoption on energy efficiency and water consumption
- Fixes for equipment for which no alternative technologies exist yet

Use of renewable/ recycled resources

Protection of biodiversity

- We will promote more agile and effective use of resources, placing priority on realizing a circular economy
- We will work on water management and water risk assessment in connection with business activities
- We must step up initiatives to reduce toxic chemical use on ongoing basis
- We must set plans in coordination with local communities

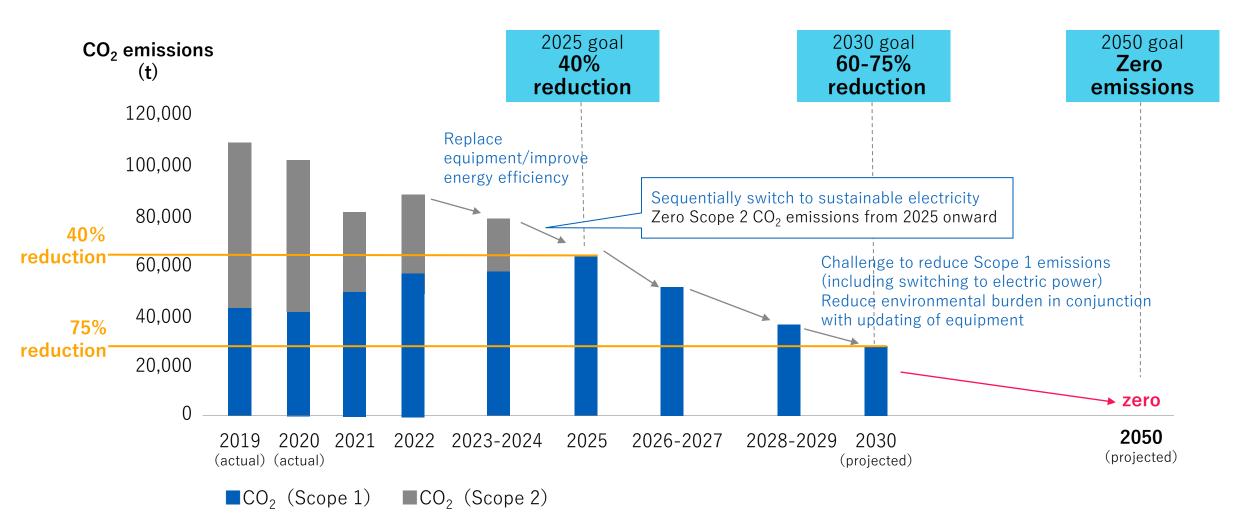




CO₂ Emission Reduction Roadmap (Company-wide)



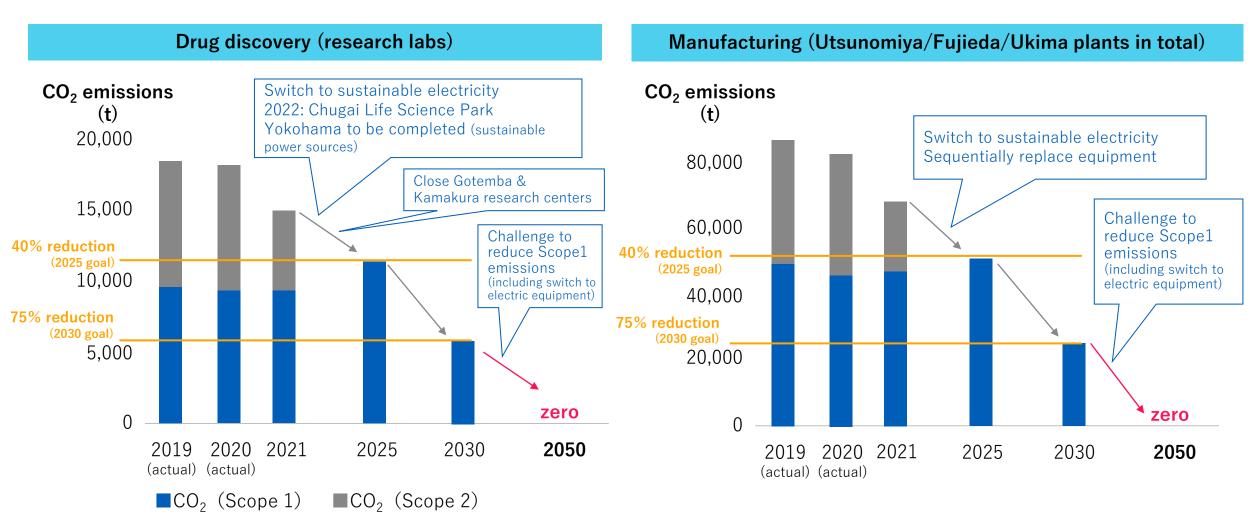
- Aiming to switch to 100% sustainable electricity by 2025 in process of achieving goals -



CO₂ Emission Reduction Roadmap (Drug Discovery/Manufacturing)



- Aiming to switch to 100% sustainable electricity by 2025 in process of achieving goals -



Manufacturing: Priority Climate Change Countermeasures



- Aiming to both upgrade drug manufacturing functions and achieve 2030 environmental goals -

Roche Roche Group

We must plan and take action to implement climate change countermeasures while also executing RED (research and early development) shift, ensuring supply stability and improving quality

Mid-Term Environmental Goals 2030 (climate change countermeasures)

Action steps

Scope 1+2 CO₂ emissions Scope 1+2 energy consumption

- Build new facilities, update equipment, improve processes
- Reduce energy consumption through drastic improvement in energy efficiency
- · Identify next-generation energy source(s) to replace natural gas

- · Reduce Scope 1 emissions
- Expand use of single-use plastic bioreactors
- Optimize HVAC/lighting through energy management

Sustainable electricity ratio

Stably source sustainable electricity

- · Sequentially switch to sustainable electricity
- Explore captive power generation (solar panels)

Halogenated hydrocarbon (HHC) usage

- Update production/HVAC equipment in conjunction with new construction/replacement of equipment
- Figure out what to do with machinery for which HHC-free technology has yet to be developed
- Install equipment that uses natural refrigerants
- Test new technologies

Manufacturing: Initiatives at Fujieda Plant



- New building will be equipped with advanced EHS technologies and produce APIs for small and mid-size molecule drugs that will drive future growth -

New building (FJ3) for manufacturing APIs for small/mid-size molecule drugs



· Completion of construction: Oct. 2024

• Start of operation: Mar. 2025

Total investment: ¥55.5 billion

We are building an integrated in-house supply chain in FJ3, a new building that will produce active pharmaceutical ingredients (APIs) from late-stage clinical development through initial commercial production. In addition to producing high potency compounds, FJ3 will be equipped with advanced environmental, health and safety (EHS) technologies.

Production functions

- FJ3 will be equipped with advanced containment technologies to enable production of high potency compounds
- Production lines will be largely automated to boost productivity and reduce manpower requirements

Environment

- HHC-free design by virtue of natural refrigerant use
- Will reduce energy consumption and CO₂ emissions through, e.g., waste heat recovery
- Will reduce waste through recycling of organic solvents/catalysts to help realize circular economy



- Safe design thoroughly prepared for explosion/fires
- Earthquake-resistant by virtue of seismic isolation structure



FJ2 is equipped with production lines and an HVAC system that use natural refrigerants, not HHCs (photo: refrigeration system that uses natural refrigerant)

Manufacturing: Initiatives at Ukima Plant



- Initiative to manufacture faster and more efficiently without using HHCs, burning natural gas or emitting CO₂ -

Roche Roche Group

Biologic API manufacturing building (UK4)

UK4, where biologic APIs for early-stage clinical trials will be produced, will pursue expeditious, flexible and sustainable manufacturing as an HHC-free, all-electric facility with no CO₂ emissions

HHC-free

• Will use natural refrigerants instead of HHCs

Gas-free

• Everything, including production processes, will be electric-powered (zero Scope 1 emissions) by virtue of UK4's energy efficiency

CO₂-free

- Single-use plastic bioreactors will be heavily used (expanded scope of application)
- Membrane water treatment system will contribute to energy efficiency
- HVAC/lighting will be optimized using HVAC mode-switching control, high-efficiency motors and motion sensors
- Non-GMP areas will be powered with on-site renewable energy



· Completion of construction: Sep. 2023

· Start of operation: Jan. 2024

· Total investment: ¥12.1 billion

How single-use plastic bioreactors reduce environmental burden

- · Single-use systems obviate the need for, e.g., tank cleaning and steam sterilization, thereby reducing water usage, power
 - consumption and, in turn, CO₂ emissions
- They therefore impose less overall environmental burden than conventional stainless-steel bioreactors
- Measurement instruments to be installed in UK4 will monitor and analyze environmental-burden data



[Issues to be addressed]

UK4 is expected to generate more plastic waste than other manufacturing sites. It will be important to figure out how to recycle waste such as used plastic bags and packaging materials.



Appendix

Advanced API Supply Capacity



- Building production capacity to stably supply APIs from early clinical development through commercial production -

Small/ mid-size molecule

Biologics

Phase 1~Phase 2



Scheduled to commence production in Dec. 2022

Phase 3∼ initial commercial production



Scheduled to commence production in Mar. 2025

Phase 1



Scheduled to commence production in Jan. 2024



Phase 1~Phase 2











Phase 3∼initial commercial production



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INNOVATION BEYOND IMAGINATION